CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Forty-sixth Session

27 November - 2 December 2023

REPORT OF THE FIFTY-THIRD SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE

San Diego, United States of America

29 November – 2 December 2022 and 8 December 2022 (report adoption)[1]

[1] Virtual only

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SUMMARY AND STATUS OF WORK

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Members, CCEXEC84 and CAC46	Adoption	Draft Guidelines for the Control of Shiga Toxin-Producing *Escherichia coli* (STEC) in Raw Beef, Fresh Leafy Vegetables, Raw Milk and Raw Milk Cheeses, and Sprouts (General Section, Annex I on raw beef and Annex III on raw milk and raw milk cheeses)	-	5/8	75 i., App. III
		Draft Guidelines for the Safe Use and Reuse of Water in Food Production and Processing (General Section and Annex I)	-	5/8	124 i., App. IV
Members, CCEXEC84 and CAC46	Approval	New work proposal on the development of Guidelines for food hygiene control measures in traditional markets for food			144, App. V
		Revision of the *Guidelines on the Application of the General Principles of food Hygiene to the control of Pathogenic Vibrio Species in Seafood* (CXG 73-2010)			147, App. VI
CCMAS	Action	Review of the methods of analysis for irradiated foods contained in the *General Methods for the Detection of Irradiated Foods* (CXS 231-2001) and incorporate them into the *Recommended Methods of Analysis and Sampling* (CXS 234-1999)			14, App. II
EWG (Chile, New Zealand, Kenya, the United States of America) CCFH54	Redrafting	Annex II on fresh leafy vegetables and IV on sprouts of the Proposed Draft Guidelines for the Control of Shiga Toxin-Producing *Escherichia coli* (STEC) in Raw Beef, Raw Milk and Raw Milk Cheeses, Fresh Leafy Vegetables, and Sprouts		2/3	75 ii, iii, iv.
PWG (Chile, New Zealand, Kenya, the United States of America) Members and Observers CCFH54	Revising			4	75 v
EWG (European Union, Chile, IDF) Members and Observers CCFH54	Revising and drafting	Annex II on fishery products) and III on dairy products) of the Proposed Draft Guidelines for the Safe Use and Reuse of Water in Food Production		2/3	124 ii, iii
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Responsible Party	Purpose	Text/Topic	Code	Step	Para.
PWG (the United States of America) CCFH54					
WG (United Kingdom) CCFH54	Alignment	To initiate work and consider the approach for the alignment of Codex texts developed by CCFH with the revised *General Principles of Food Hygiene* (CXC 1-1969)			149 - 150
EWG (Kenya Bolivia, and Nigeria) CCFH54	Drafting (subject to approval by CAC46)	Guidelines for food hygiene control measures in traditional markets for food			144 ii
EWG (Japan and Chile) CCFH54	Review / Drafting (subject to approval by CAC46)	Revision of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood* (CXG 73-2010)			147 ii
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Members and Observers	Action	Plan and implement activities to build awareness of Codex and to engage high level political support for Codex work on the occasion of the 60th anniversary of Codex in 2023; and actively engage in opportunities to contribute to the discussions on the future of Codex.			13 ii and iii

LIST OF ACRONYMS

CAC	Codex Alimentarius Commission
CCEXEC	Executive Committee of the Codex Alimentarius Commission
CCFH	Codex Committee on Food Hygiene
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
FERG	Foodborne Disease Burden Epidemiology Reference Group
GAP	Good Agricultural Practice
GHP	Good Hygienic Practice
HACCP	Hazard Analysis and Critical Control Point
HAV	Hepatitis A virus
IDF	International Dairy Federation
INFOSAN	International Food Safety Authorities Network
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
STEC	Shiga toxin-producing *Escherichia coli*
USA	United States of America
USDA	United States Department of Agriculture
WHO	World Health Organization
WOAH	World Organization for Animal Health

INTRODUCTION

1. The Codex Committee on Food Hygiene (CCFH) held its 53rd session in San Diego, United States of America, from 29 November to 2 December 2022 with virtual report adoption on 8 December 2022, at the kind invitation of the Government of the United States of America. Dr Jose Emilio Esteban, Chief Scientist, Food Safety and Inspection Service, Office of Public Health Science, United States Department of Agriculture (USDA) chaired the Session, which was attended by 51 Member countries, one Member Organization and 11 Observer Organizations. The list of participants is included in Appendix I.

OPENING[1]

2. Mr Steve Wearne, the Chairperson of the Codex Alimentarius Commission (CAC) delivered opening remarks via video message. He recognized the opportunity meeting physically provided to nurture, renew and grow the relationships core to the effectiveness of Codex. Mr Wearne acknowledged the appetite to progress work on the guidelines for the control of Shiga toxin-producing *Escherichia coli* (STEC) and on safe use and reuse of water, highlighting that discussions such as those on the safe use and reuse of water in food production exemplified our adaptation to the food safety challenges posed by changes in the world around us.

3. Dr Linda J Harris, Professor of Cooperative Extension in Microbial Food Safety, Food Science and Technology, University of California, Davis, delivered the keynote address. Recalling the importance of agriculture production in the state, Dr Harris highlighted some of the key challenges faced, from water availability to risk factors affecting the survival of foodborne pathogens in the fresh produce production environment. Dr Harris underlined the problems posed by STEC in the United States of America (USA) with reference to STEC outbreaks in various food commodities including leafy green vegetables, as well as foodborne illness outbreaks linked to unpasteurized milk. Dr Harris drew the attention of CCFH53 to the cycle of surveillance, epidemiological investigations, basic and applied research and prevention and control measures in containing foodborne pathogens and the constant need to evolve the approach to incorporate innovation and address new foods, pathogens or food/pathogen associations. Finally, Dr Harris commended CCFH's contribution to protecting consumers' health by establishing guidelines for the control of STEC and the safe use and reuse of water in food production.

4. CCFH53 expressed appreciation to Dr Harris for the timely presentation.

Division of competence[2]

5. CCFH53 noted the division of competence between the European Union (EU) and its Member States, in accordance with paragraph 5, Rule II, of the Rules of Procedure of the CAC.

ADOPTION OF THE AGENDA (Agenda Item 1)[3]

6. CCFH53 adopted the provisional agenda as its agenda for the Session.

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX SUBSIDIARY BODIES TO THE COMMITTEE (Agenda Item 2)[4]

<u>Matters for information</u>

7. The Codex Secretariat outlined the crosscutting activities taking place at CAC and the Executive Committee of the Codex Alimentarius Commission (CCEXEC), including a model for future Codex work, the 60th Anniversary of CAC, new food sources and production systems and monitoring the use and impact of Codex Standards. The Codex Secretariat presented a verbal update of the latest discussions on these matters from CAC45 and CCEXEC83, noting that this information had not been included in CX/FH 22/53/2 due to the short time period between CAC45/CCEXEC83 and CCFH53.

8. The Codex Secretariat confirmed that CAC45 had adopted the Guidelines for the Management of Biological Foodborne Outbreaks and the revision to the *General Principles of Food Hygiene* (CXC 1-1969). The Chairperson of CAC45 had noted that adoption of the revision to CXC 1-1969 had concluded an extensive revision of that text, foundational to many Codex food hygiene texts and extensively cross-referenced in other Codex texts. It was therefore necessary to ensure that Codex texts were fully aligned with the latest version of CXC 1-1969 and CAC45 requested that CCFH undertake work on the alignment of all food hygiene texts with CXC 1-1969, in line with its work management approach. It was noted that this item would be further considered under agenda item 9.

9. The Codex Secretariat also noted that the work on the future of Codex, which considered future working modalities, was relevant for all committees and Members and that consultations with chairpersons and host

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[1] CRD21 (Opening remarks)
[2] CRD1 (Division of competence and voting right between the European Union and its Member States)
[3] CX/FH 22/53/1
[4] CX/FH 22/53/2; CRD2 (Morocco and Thailand)

secretariats had been initiated while there would be an opportunity for Members and Observers to provide their input in March-April 2023. With regard to new food sources and production systems (NFPS), the Codex Secretariat noted the recommendation of CCEXEC83 to encourage Members to submit proposals related to NFPS using existing Codex mechanisms, and Codex subsidiary bodies to consider NFPS in their deliberations. Noting the ongoing work on monitoring of the use and impact of Codex standards, the Codex Secretariat highlighted that CXC 1-1969 was one of the texts included in the pilot survey on use and impact and that respondents indicated a high degree of familiarity and good level of satisfaction with it.

Matters for action

Review of the methods of analysis for irradiated foods contained in the General Methods for the Detection of Irradiated Foods (CXS 231-2001)

10. Brazil recalled that following CCFH51 (2019) they had reviewed the methods in the *General Methods for the Detection of Irradiated Foods* (CXS 231-2001) to determine their fitness for purpose and their possible conversion to performance-based criteria. Brazil stated that, after careful review, it was clarified that there was no possibility to convert the existing methods of analysis in CXS 231-2001 to performance-based criteria for the following reasons:

- The methods of analysis contained in CXS 231-2001 were used for labelling purposes and only provided an estimate of positive or negative results. As such, the necessary parameters to establish performance-based criteria such as accuracy, applicability, limit of detection, limit of quantification, precision, intra-laboratory repeatability and inter-laboratory reproducibility were not available.
- The maximum or minimum levels, which were needed to establish performance-based criteria, were not specified in the Codex Standards for the provisions analysed by the methods of analysis in CXS 231-2001.

11. Brazil noted the overall support from Members and Observers in response to CL 2020/55-FH to the proposal regarding performance criteria; the removal of the year of approval of the methods of analysis in order to be consistent with the Codex Committee on Methods of Analysis and Sampling's (CCMAS) decision on the *Recommended Methods of Analysis and Sampling* (CXS 234-1999); the change of the names of the commodities to provide further clarity; and that the methods of analysis in CXS 231-2001 were fit-for-purpose. In addition, Brazil drew the attention of CCFH53 to EN 13783 which, in their view, no longer be applied to "raw minced meat" due to the lack of detailed information on validation for this commodity.

12. CCFH53 noted the observation of one Member that the fitness-for-purpose of EN1785 to detect radiation-induced 2-alkylcyclobutanone in irradiated foods should be reviewed since 2-alkylcyclobutanone was reported to be present in some non-irradiated foods, such as nutmeg and cashew nuts, and thus, EN 1785 may be inappropriate to distinguish irradiated foods from non-irradiated foods in such cases. CCFH53 also took note of written comments on whether it was appropriate to modify the principle of EN 1785 to gas chromatographic/mass spectrometric analysis to align with the original document and whether to specify that EN 13751 was a screening method (CRD2). CCFH53 agreed to bring these issues to the attention of CCMAS.

Conclusion

13. CCFH53:

i. took note of the information provided in the working document and the additional information provided by the Codex Secretariat during the session;

ii. encouraged Members and Observers, on the occasion of the 60th anniversary of Codex in 2023, to plan and implement activities to build awareness of Codex and to engage high level political support for Codex work; and

iii. encouraged Members and Observers to actively engage in opportunities to contribute to the discussions on the future of Codex.

14. CCFH53 further agreed:

i. to inform CCMAS that it was not possible to establish performance criteria for the methods of analysis for irradiated foods contained in the *General Methods for the Detection of Irradiated Foods* (CXS 231-2001) as they were detection methods recommended solely for the purposes of food labelling and the necessary parameters (e.g. accuracy; applicability; limit of detection; limit of quantification; precision) that enable establishment of performance criteria were not available;

ii. to recommend to CCMAS that the methods of analysis for irradiated foods listed in CXS 231-2001 were still fit-for-purpose. CCFH53 also proposed that CCMAS consider: whether EN 13751 should be specified as a screening method; and the applicability of EN 13783 to raw minced meat since no information was found on validation for this commodity; and to note the report of one Member that 2-

alkylcyclobutanone was also present in some non-irradiated foods and hence EN 1785 may need further consideration as a method for detection of irradiated foods.

iii. to recommend that the methods in CXS 231-2001 should be included in CXS 234-1999 with the changes as proposed in Table 1 (see Appendix II), subject to confirmation of the assigned method type by CCMAS and resolution of the issues identified in point ii; and

iv. following the inclusion of the methods of analysis for irradiated foods in CXS 234-1999, to recommend that CAC revoke the *General Methods for the Detection of Irradiated Foods* (CXS 231-2001).

MATTERS ARISING FROM THE WORK OF FAO AND WHO (INCLUDING JEMRA) (Agenda Item 3)[5]

15. The FAO Representative, on behalf of both FAO and WHO, expressed appreciation to all the Members who supported the work of the Joint FAO/WHO Scientific Advice Programme, notably the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA).

16. The Representative provided a summary of work undertaken since CCFH52, as well as the planned future work related to CCFH and highlighted the following:

- JEMRA published, since CCFH52, five full reports on: i) Ranking of low moisture foods in support of microbiological risk management: meeting report and systematic review[6]; ii) Microbiological hazards in spices and dried aromatic herbs: meeting report[7]; iii) Risk assessment of food allergens, part 1: review and validation of Codex Alimentarius priority allergen list through risk assessment: meeting report[8]; iv) *Listeria monocytogenes* in ready-to-eat (RTE) foods: attribution, characterization and monitoring[9]; and v) Control measures for STEC associated with meat and dairy products[10].
- Three JEMRA meetings had been held since March 2022 on the following topics: i) Prevention and control of microbiological hazards in fresh fruits and vegetables (part 4)[11]; ii) Pre-and post-harvest control of nontyphoidal *Salmonella* spp. in poultry meat[12]; and iii) Microbiological risk assessment of *Listeria monocytogenes* in foods[13] and one ad hoc expert consultation on risk assessment of food allergens (evaluation of exemptions for derivatives of priority food allergens). Four summary reports related to these meetings, including an update on recommended allergen threshold levels for milk and sesame[14], were published since March 2022.
- One JEMRA workshop on the safety and quality of water used with fresh fruits and vegetables was conducted in Honduras with participation from ten Latin American countries.

17. The Representative informed CCFH53 that meeting planning for 2023 was already underway and JEMRA had scheduled a meeting on pre- and post-harvest control of *Campylobacter* spp. in poultry meat. The Representative further noted that JEMRA would also be convening meetings on a farm-to-table risk assessment of *Listeria monocytogenes* (part II); viruses in foods; and risk assessment of *Salmonella* and *Campylobacter* in poultry meat.

18. The Representative of WHO brought the attention of CCFH53 to the work of the Foodborne Disease Burden Epidemiology Reference Group (FERG), explaining its three-year strategic framework and its main activities. The Representative also highlighted the recent activities of the joint FAO/WHO International Food Safety Authorities Network (INFOSAN) including the launch of the new INFOSAN Community Website noting that INFOSAN continued to develop and strengthen the Network as well as capacities for preparedness and response to food safety incidents.

19. Specific scientific and microbiological risk assessment information was provided under the relevant agenda items. The JEMRA Secretariat also indicated their availability for ongoing dialogue and exchange with CCFH and in particular chairs and co-chairs of electronic working groups (EWG). To facilitate such ongoing dialogue,

[5] CX/FH 22/53/3
[6] https://www.fao.org/3/cc0763en/cc0763en.pdf and https://www.who.int/publications/i/item/9789240044036
[7] https://www.fao.org/3/cb8686en/cb8686en.pdf and https://www.who.int/publications/i/item/9789240045187
[8] https://www.fao.org/3/cb9070en/cb9070en.pdf and https://www.who.int/publications/i/item/9789240042391
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[12] https://www.fao.org/3/cc2579en/cc2579en.pdf and https://cdn.who.int/media/docs/default-source/food-safety/jemra/jemra-meeting-salmonella-poulty-meat-summary-and-conclusions-oct2022.pdf?sfvrsn=85adc558_3
[13] https://www.fao.org/3/cc2966en/cc2966en.pdf and https://cdn.who.int/media/docs/default-source/food-safety/jemra/jemra-listeria-meeting-summary-and-conclusion.pdf?sfvrsn=3f502119_3
[14] https://www.fao.org/3/cb9312en/cb9312en.pdf and https://cdn.who.int/media/docs/default-source/food-safety/jemra/2nd-allergen-summary-report-milk-and-sesame-apr2022.pdf?sfvrsn=35130ec2_7

JEMRA has set time aside on the last Tuesday of every month from 16:00 to 17:00h CET (referred to as JEMRA office hours), but could also be available at another mutually agreed upon time. To make the best use of this time, the JEMRA Secretariat requested one-week advance notification to jemra@fao.org or jemra@who.int, indicating the topic for discussion, to facilitate preparation for the meeting.

Conclusion

20. CCFH53:

i. noted the information provided by FAO and WHO and expressed appreciation for the valuable work that had been undertaken over the past eight months;

ii. encouraged delegations to utilize the JEMRA office hours to discuss ongoing work and requests for scientific advice; and

iii. acknowledged that the future work plan of JEMRA would be demanding and stressed the importance of prioritizing any new work.

INFORMATION FROM THE WORLD ORGANISATION FOR ANIMAL HEALTH (Agenda Item 4)[15]

21. 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 to ensure engagement, as relevant, or to align relevant WOAH standards. In particular the willingness to engage in any revision of the *Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat* (CXG 78-2011), was noted. The Representative also highlighted ongoing updates to Chapter 6.10. Responsible and prudent use of antimicrobial agents in veterinary medicine, of the *Terrestrial Code* indicating that it considered the outputs of the Codex Task Force on Antimicrobial Resistance to ensure alignment and that work to revise Chapter 5.2 was forthcoming. The relevant WOAH Specialist Commissions had, in September 2022, agreed to prioritise work to revise the certification procedures of both the *Aquatic Code* and *Terrestrial Code*, to include more information on electronic veterinary certification and to align them with the recently updated *Codex Guidelines for design, production, issuance and use of generic official certificates* (CXG 38-2001). Finally, the Representative highlighted the rebranding of WOAH noting that it aimed to promote the overarching purpose and main activities of the organization in a concise and dynamic way.

Conclusion

22. CCFH53 noted the ongoing commitment of WOAH to work with CCFH on relevant areas and the importance of ongoing collaboration in order to continue to be effective in the future.

PROPOSED DRAFT GUIDELINES FOR THE CONTROL OF SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* (STEC) IN RAW BEEF, FRESH LEAFY VEGETABLES, RAW MILK AND RAW MILK CHEESES, AND SPROUTS (Agenda Item 5)[16]

23. Chile, speaking also on behalf of France, New Zealand and the USA introduced the item and recalled the efforts that had been made since CCFH52 to progress the text including in the EWG, through a virtual meeting of the working group open to all Members, and a physical working group (PWG) immediately prior to the Session. Chile further noted that the co-chairs had revised the general section and the annexes (except sprouts) based on the written comments received and the discussions in the PWG on the general section and part of the annex on raw beef, which were available as CRD13, and proposed that this document be considered for further discussion.

Discussion

24. CCFH53 considered the revised proposed draft guidelines including the annexes on raw beef and raw milk and raw milk cheeses contained in CRD13 section by section. Unless otherwise stated below CCFH53 agreed with the revisions in CRD13 and in addition to the changes outlined below made editorial corrections, and amendments to improve accuracy, clarity and consistency within the proposed draft guidelines.

General section

Objective

25. In response to concerns raised in the PWG regarding the need to qualify that raw milk as indicated in the

[15] CX/FH 22/53/4

[16] CX/FH 22/53/5; CX/FH 22/53/5 Add.1 (Argentina, Australia, Canada, Colombia, Costa Rica, Cuba, Egypt, India, Japan, Kenya, Malaysia, Morocco, Peru, Republic of Korea, Saudi Arabia, Singapore, Thailand, United Kingdom, USA and IDF/FIL); CRD3 (Brazil, European Union, India, Indonesia, Morocco, Philippines and Uruguay); CRD9 (Dominican Republic); CRD13 (Report of the PWG on the Proposed Draft Guidelines for the Control of Shiga Toxin-Producing *Escherichia coli* (STEC) in Raw Beef, Fresh Leafy Vegetables, Raw Milk and Raw Milk Cheeses, and Sprouts); CRD17 (Nigeria); CRD18 (Thailand)

guidelines was intended for drinking and not for further processing, the Chairperson of the Working group recalled the history of discussions that had led to the current title of raw milk and raw milk cheeses. Noting that the annex on this topic explained this issue, for clarity and consistency CCFH53 agreed to also include "intended for drinking" after raw milk in the objective.

Scope and Use

26. As further clarification with regard to raw milk, a footnote was added to the reference to raw milk in the scope to indicate that these guidelines present specific guidance for control of STEC related to raw milk intended for drinking and for production of raw milk cheeses.

Definitions

27. CCFH53 confirmed their agreement with the revised definitions for; i) fresh leafy vegetables with an editorial change to put a slash between coriander and cilantro in recognition that in some countries these were considered to be the same product; and ii) sprouts, confirming that it should include reference to both seeds and beans in line with the JEMRA report; and with the added definition for control measures as proposed by the PWG.

28. The footnote to the definition of raw milk, referring to the impact of temperatures between 40ºC and pasteurization temperatures, was revised with the first sentence moved to become the second sentence for ease of understanding.

29. There was extensive discussion on the proposed footnote 9 in CRD13 to the definition of STEC, which indicated that generally production of the Shiga toxin alone was not sufficient to cause severe illness without adherence of bacterial cells to gut epithelial cells. Some Members were of the view that this footnote was potentially misleading and could be interpreted that the guidelines were only focused on controlling STEC that had both *stx* and adherence genes, which in their view was not the case. They further noted that the differences in risk associated with the different virulence genes were adequately described in the section on "Laboratory analysis criteria for detection" of STEC and Table 1 in the guidelines. Others were of the view that it was useful to indicate early in the document that there were differences in risk between STEC with different virulence genes to enhance understanding of the risk-based approach presented in these guidelines. JEMRA indicated that STEC with the stx_{2d} gene alone had caused severe illness. Based on this CCFH53 agreed to delete the footnote.

Primary production to consumption approach to control measures

30. Responding to a concern in the second paragraph that Good Hygiene Practices (GHPs) were not sufficiently broad to cover the foundation of most food safety control systems, it was agreed to also include "prerequisite programmes" which addressed the concern and also ensured consistency with both the *Guidelines for the Control of Nontyphoidal Salmonella spp. in Beef and Pork Meat* (CXG 87-2016) and the *General Principles of Food Hygiene* (CXC 1-1969). In the same paragraph, "food safety control system" was replaced with "food hygiene system", which was defined in the CXC 1-1969 to avoid introduction of a new term.

Primary production control measures

31. In order to provide clarification of the term "plants" in this section, additional text was added to indicate these were vegetation (crops) rather than physical processing facilities.

32. In response to a proposal that this and the two subsequent sections should be sub-sections under primary production, it was clarified that the structure followed that of the *Guidelines for the Control of Nontyphoidal Salmonella spp. in Beef and Pork Meat* (CXG 87-2016) and for consistency it should remain the same.

Implementation of control measures

33. The title of this section was changed to "Validation, implementation and verification of control measures" to better reflect the content of the section.

34. As some delegations noted that the meaning of "food safety outcome" in the second paragraph of this section was not clear, it was agreed to change this to "food safety objective" which was defined in Codex.

Validation

35. Concerns were expressed on the second sentence in this section in square brackets noting that it was proposing that validation demonstrate that control measures reduce the risk to public health, which was not possible to achieve and revised text based on the *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008) was proposed. However, as that proposal was very similar to the text in the subsequent paragraph, and thus already covered, it was agreed to delete the text in square brackets.

<u>Regulatory system</u>

36. There was extensive discussion on the second paragraph of this section and whether competent authorities “should” or “may” assess the documented process control systems of a food business operator (FBO). Some were of the view that this was too big a burden to place on the competent authorities while others expressed the view that if competent authorities choose to provide guidance on the development of food hygiene systems, as indicated as an option in the previous paragraph, then they should follow up by assessing such systems. It was agreed to use “should” in this paragraph, noting that the flexibility was provided in the previous paragraph.

37. Responding to a request for clarification between “food hygiene system” in the first paragraph of this section and “process control systems” in the second paragraph, it was noted that the first referred to food hygiene systems broadly while the second was specifically addressing process control for STEC.

38. There was also a proposal to change the title to “Competent authority responsibility” but in order to retain consistency with CXG 87-2016 the existing title was maintained.

<u>Food business operators</u>

39. In the second paragraph (second to last sentence) it was proposed to replace “where appropriate” with “in particular for those processes for which correlation may be less evident (e g water, milk and dairy)” since the term “where appropriate” was very vague and should be replaced by guidance specifying where additional STEC testing was relevant. In the debate that followed, it was noted that there was no correlation between indicator organisms and STEC, and also that “where appropriate” gave flexibility to introduce periodic testing, if needed, for example after a potential contamination event such as after heavy rains or flooding. JEMRA confirmed that there were limitations to testing but there were times when periodic testing was appropriate such as to establish a baseline, or after specific events such as heavy rainfall or an animal/wildlife incursion. It was agreed to retain the original text.

40. The last sentence of the paragraph was revised to clarify the link between testing and corrective actions, as such actions enabled testing to contribute to reducing prevalence.

<u>Laboratory analysis criteria for detection of STEC</u>

41. In the second to last paragraph of this section, the words “and a better estimation of food safety risk” were added to clarify that having an isolate in addition to molecular data would facilitate further epidemiological investigation and therefore contribute to the estimation of risk. In response to a concern as to whether this paragraph adequately addressed the need for data on other relevant traits such as antimicrobial resistance it was noted that the reference to characterization of STEC adequately covered any other traits that one may want to look for.

JEMRA scientific advice

42. Before consideration of the annexes, the FAO Representative provided an overview of JEMRA's work related to STEC in beef, dairy and fresh leafy vegetables, addressing aspects such as interventions and challenges with testing of irrigation water or product for monitoring for STEC. The Representative presented the effectiveness of specific interventions for control of STEC in beef, raw milk, raw milk cheese and fresh leafy vegetables and addressed questions posed by the PWG regarding recommendations for growing of leafy greens in proximity to animal rearing, harvest buffer zones following in-field contamination and the storage temperature of fresh leafy vegetables. In conclusion, the Representative highlighted that there were no single and highly effective interventions for removing STEC once a raw product had been contaminated. For the control of STEC, prevention was the key and multi hurdle strategies were needed. He further noted that interventions did not need to be STEC specific to be effective, and good agricultural and good hygiene practices were beneficial for the control of STEC. However, vigilance was required throughout the food chain as the loss of control downstream would negate any interventions taken upstream.

Annex 1: Raw beef

43. CCFH53 agreed some changes throughout the document to ensure that serogroup and serotype were used appropriately and in the correct location e.g. STEC serotype O157:H7. In addition, references to specific STEC prevalence and concentrations were removed and replaced with more descriptive language in recognition that such numbers were usually context specific and so could vary.

Introduction

44. In the second-to-last paragraph, the second sentence was revised to indicate that the practices listed were examples and that it was not necessarily an exclusive list and “knife scoring” was removed as the context in which it would be used (e.g. marinating of meat) had been removed from the annex so it was no longer relevant.

45. In the last paragraph, the footnote to non-intact beef products was moved to the definition of non-intact beef products in the definitions section and an additional sentence was added at the beginning to clarify that mixing of tissues from one or multiple animals/herds can increase the likelihood of spreading and diluting STEC contamination of ground/minced raw beef.

Figure 1 – Process Flow Diagram

46. The words "Primary production" were deleted from the top of the process-flow diagram and "post-mortem inspection" was inserted as a step between "splitting" and "carcass-washing" and “trimming” was added as part of “carcass-washing”. While other proposals were made for the order of the steps it was recalled that the guidelines indicated that the steps were generic and that not all steps may occur or be in the order shown at any particular establishment. Therefore, it was agreed that no further changes would be made.

Vaccination

47. Recalling the extensive discussions on vaccination in the PWG, the EWG Chair proposed a revised paragraph which rather than refer to commercial aspects tried to focus more on aspects related to administration regime among others to better reflect the available data on efficacy and variations in efficacy. The new text was agreed with some editorial amendments to enhance clarity.

Good management practices at primary production

48. One Member questioned the inclusion of guidance on slatted housing as it had not been considered by JEMRA in their assessment of control measures. It was clarified that this was based on practice, noting that a balance between overcrowding and understocking was needed to ensure animals did not contaminate each other with faecal material and that faeces were pushed through the slatted floor system.

Slaughter and dressing

49. Concern was expressed at the complexity of the guidance given in the third paragraph on how the impact of interventions might be quantified and it was suggested that the text be simplified to read “The impact of interventions should be validated” and the rest of the text deleted. While there was general support for the introduction of validation, some Members felt it was still useful to have the remaining text to give some guidance on how such validation could be undertaken. It was agreed to retain these, indicating they were just examples in recognition that there may also be other ways to undertake validation.

Specific control measures at lairage and antemortem inspection

50. There was a proposal to delete reference to straw bedding in lairage in the third paragraph as this had not been covered in the JEMRA work. However, some Members expressed the view that it was useful to give guidance on how a dry bedding area might be achieved and so it was retained as an example. Concern was also expressed about limiting time in lairage, as it seemed counter to guidance that animals should be rested before slaughter and it was noted that it might not always be possible to limit time in lairage. JEMRA noted that their findings indicated that time should be minimized, as extending the time may lead to an increase in shedding of STEC. In order to find a balance between what was practical and what was optimal for STEC control “whenever possible” was added.

51. In the subsequent paragraph "clean water" was replaced with "fit-for-purpose water" as being more appropriate to the context. In the last paragraph, reference to social stress was removed, as no reference to this had been included in the JEMRA assessment.

Specific control measures at stunning, sticking and bleeding

52. In the third paragraph, "skull" was replaced with "head meat" in recognition that contamination of the meat was the concern.

Specific control measures at bunging

53. A description on bunging was added as a first sentence to align with other sections where a description of the step had been provided.

Specific control measures at post-mortem inspection

54. Examples of physical contaminants were added to the second bullet for clarity, given the focus of the guideline was a microbiological hazard.

Specific control measures at carcass washing

55. At the end of the first paragraph, “of contamination” was added for clarity. One Member expressed concerns about washing with water under pressure and suggested that specific guidance on the topic may be useful. However, it was agreed that the current text, which indicated "care should be taken", was adequate to convey that message. “Such” biocidal treatments was replaced with “some” since not all may be applied with hot water.

Carcass washing with biocides

56. The penultimate sentence referring to factors affecting the effectiveness of biocidal treatments was removed as it was covered in a previous paragraph.

Specific control measures at carcass fabrication (mechanical tenderization, grinding/mincing)

57. There was a proposal to refer to when biocides were approved by competent authorities in the third paragraph. However, it was noted that this paragraph was more focused on the scientific facts and that a statement on approval by competent authorities had been included in the general section to avoid the need to repeat this concept throughout the text. To add further clarity the paragraph, which had two concepts, was split into two sentences and the word "precursor" was added before the word "materials" as the term "precursor materials" in the industry was considered to cover both meat and fat.

58. In the fourth paragraph of this section, in the chapeau, "i.e." was replaced with "e.g." to better reflect that the text in parenthesis was only intended as examples. In bullet 4 “as approved” was deleted as the aspect of approval by the competent authority was addressed in an overarching manner in the general part of the guidelines.

59. A range of views were expressed in the original third bullet of this paragraph, which addressed testing, with some Members proposing deletion due to the limitations of testing, and that it could be interpreted as supporting routine monitoring. In contrast, some other Members supported its retention, as the bullets in this paragraph just presented options to be used as appropriate and this particular one on testing may also be useful in some scenarios. If bullet 3 was to be retained, it was proposed that there needed to be further clarity of the text and indications of possible scenarios when testing could be useful. Following a comment that bullet 3 was different in nature from the other examples given, it was agreed to remove the bullet on testing from the list and address it in a separate paragraph. CCFH53 agreed to a revised paragraph which indicated some of the specific conditions in which testing might be appropriate and clarified that for the purpose of these guidelines, the words "a negative result" and "non-detected" had the same meaning.

Annex 3: Raw milk and raw milk cheeses

Introduction

60. There was extensive discussion on the footnote for thermization and concerns that users of the guidelines might misunderstand its efficacy in terms of pathogen reduction. The co-chairs of the EWG clarified that the footnote was added as “thermization” may not be a well-known term and it was only included in the text to indicate that consuming raw drinking milk or raw milk cheeses without any control measures was associated with a higher risk of illness than drinking pasteurized milk or eating cheeses made from milk subject to heating such as thermization. Thermization had already been defined in *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004), therefore the footnote was revised to incorporate the key concepts of that definition for clarity. Upon agreement on the footnote, the square brackets were removed from the related sentence in paragraph 2.

61. Paragraph six was revised to incorporate prerequisite programmes including GHP, rather than referring to surveillance and monitoring since "prerequisite programmes" as defined in CXC 1-1969 covered a broad range of practices and procedures. A proposal to include reference to the Hazard Analysis and Critical Control Point System (HACCP) was rejected, as there were no critical control points (CCPs) identified in the case of raw milk and raw milk cheese production.

Control measures for STEC for dairy herds at the dairy farm

62. There was a proposal to replace "cows" with "animals" in the first paragraph to be more inclusive; however as available data related mainly to cows, it was agreed to retain as written. An addition was made to the end of the first bullet to provide more clarity on the meaning of the term "excess manure".

63. It was agreed to remove the square brackets in the second paragraph with some editorial amendments to enhance clarity, including the insertion of the word "manage" as an overarching term to cover any actions that may be taken to reduce or minimize the risk of transmission from the indicated sources.

64. In the third paragraph, the first bullet was simplified for clarity, noting that the intent was that newborn and young animals should be segregated from each other, as well as from mature animals; and in the second bullet, it was proposed to change cattle to animals. Following consultation with the JEMRA Secretariat, CCFH53 determined that doing so was not an over extrapolation of the available data, and the change was agreed.

65. The last sentence of the fourth paragraph was revised to provide greater clarity and since it related to on-farm activities, GHPs were replaced with “good agricultural practices” (GAPs). In the fifth paragraph, the term "validated" was added before "control measures" so as to indicate that unless validated for the specific context, they may not be very effective.

Control during processing

66. As was the case in the annex on raw beef, specific concentrations of microorganisms were removed from the second paragraph. The text in parentheses in the first line of the third paragraph was revised to clarify that heating increased separation of the whey from the curd.

67. One Member proposed that more specific guidance, particularly in relation to GHPs, should be provided in this section. It was recalled that this annex should be read in conjunction with the general section of the guidelines which addressed GHPs.

Validation and monitoring of control measures

68. There was a proposal to add HACCP to the first paragraph in addition to GHPs since this section related to validation, which was essential in case HACCP was applied. Some concerns were expressed with this proposal as it had been agreed that HACCP was not relevant in these guidelines as CCPs had not been identified. It was suggested that rapid acidification or the ripening period might be CCPs and so it was agreed to include reference to HACCP with these examples.

Verification of control measures – At the dairy farm

69. In the third paragraph it was proposed to replace GHPs with GAPs as this paragraph related to activities on the farm. However, since this paragraph also covered the hygiene and sanitation of milking equipment and milk tanks, GHPs were still relevant and therefore both GHPs and GAPs were included.

Verification of control measures – Milk collection at the dairy establishment

70. It was agreed to change “surveillance” to “monitoring” in this and subsequent steps to better reflect the nature of the activity undertaken.

Verification of control measures – During processing

71. In the first paragraph, “milk quality” was changed to “milk safety” since this related to STEC control rather than the quality of the milk. In the third paragraph a reference to the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Food* (CXG 21-1997) was included as it also made reference to sampling plans.

Figure 2

72. It was agreed to add “brining” as an additional step between “form/press/drain” and “aging”.

Annex 2: Fresh leafy vegetables and Annex 4: Sprouts

73. CCFH53 did not have time to discuss these annexes. However, it was noted that the definitions of fresh leafy vegetables and sprouts were agreed upon in the general section and should now be considered in these annexes. In addition, further work should take into account the report of the PWG that indicated agreement that microgreens be considered as part of the fresh leafy vegetables annex.

74. CCFH53 expressed appreciation to the chair and co-chairs of the EWG for the great work done and agreed that there were no outstanding issues in the general section and annexes 1 and 3 of the proposed draft guidelines, and that the work on the outstanding annexes should continue between this session and CCFH54.

Conclusion

75. CCFH53

i. noting that there were no outstanding issues to be addressed in the general section and the annexes on raw beef and raw milk and raw milk cheeses, agreed to forward the proposed draft Guidelines and these two annexes for adoption at Step 5/8 by CAC46 (Appendix III);

ii. agreed to return the annexes on fresh leafy vegetables and sprouts to Step 2/3 for redrafting and circulation for comments;

iii. agreed to establish an EWG, chaired by Chile and co-chaired by New Zealand, Kenya, and USA, and working in English (noting that comments would also be accepted in Spanish), to:

a. further develop the annex on fresh leafy vegetables using CRD13 as a basis and taking into consideration the general section of the guidance as agreed at CCFH53 and the CRDs submitted at CCFH53;

b. continue the development of the annex on sprouts describing interventions relevant to control STEC, taking into consideration the written comments that were submitted through the Online Commenting System (OCS) in response to the CL 2022/56-FH, and CRDs submitted at CCFH53, as well as the general section of the guidance as agreed at CCFH53; and

c. prepare a report and revised text to be submitted to the Codex Secretarial three months before CCFH54 for circulation for comments at Step 3;

iv. requested that efforts be made to convene a virtual meeting of the EWG working in English, French and Spanish between CCFH53 and CCFH54 to facilitate progression of the work; and

v. agreed to establish a PWG, chaired by Chile and co-chaired by New Zealand, Kenya and the USA, working in English, French and Spanish to be held in conjunction with CCFH54 to consider all comments received and to prepare a revised proposal for consideration by the plenary.

PROPOSED DRAFT GUIDELINES FOR THE SAFE USE AND REUSE OF WATER IN FOOD PRODUCTION (Agenda Item 6)[17]

JEMRA scientific advice

76. Before embarking on discussions on the proposed draft guidelines, the FAO Representative provided an overview of JEMRA's work related to water since 2016. This work had been undertaken in response to a request by CCFH for advice on how to address clean and potable water in texts under development in CCFH. In response, JEMRA recommended the fit-for-purpose concept to address the various issues the committee faced, noting that fit-for-purpose water required a risk-based approach and application of appropriate risk mitigation measures.

77. JEMRA had also addressed the application of fit-for-purpose water in specific commodity areas. Two decision tree tools and microbiological criteria had been developed for fresh produce, where the first decision tool the main considerations were whether or not the product would be eaten raw and the water would come in contact with the food. The second decision tree was based on a qualitative risk assessment, and enabled determination of risk management options to mitigate risk. Field testing of the re-use water decision trees had indicated ease of use by FBOs.

78. For fishery products, the decision tree developed differentiated between fish harvested from fresh or sea water and was applicable from processing on fishing vessel onwards.

79. JEMRA had also provided clarification on the use of microbiological criteria and indicator organisms. For fresh fruit and vegetables, it was noted that there was no direct correlation between indicator organisms and the presence of pathogens. However, case studies for fishery and dairy products demonstrated that indicator organisms could be considered as predictors of pathogens, such as *Listeria monocytogenes*. The FAO Representative noted that JEMRA had indicated that microbiological criteria may be useful for verification of operational control but should be established on a case-by-case basis; noting that microbiological criteria for characterizing water quality and safety in production and processing should be science-based. However, improvements in the available analytical methodologies for verifying water quality were also needed.

80. A summary of technologies that could be used to mitigate risks associated with the use of fit-for-purpose water was also provided.

Report of the EWG

81. Honduras, speaking on behalf of Chile and the EU, introduced the item and recalled the efforts that had been made since CCFH52 to progress the text including in the EWG, through incorporation of the scientific advice provided by JEMRA, and a PWG immediately in advance of the session. A summary of the discussions and progress made in the PWG was provided and it was noted that a revised version of the proposed draft

[17] CX/FH 22/53/6 Rev., CX/FH 22/53/6 Add.1 (Argentina, Australia, Canada, Colombia, Costa Rica, Cuba, Egypt, India, Iraq, Japan, Kenya, Malaysia, Morocco, Peru, Republic of Korea, Singapore, Thailand, United Kingdom, Uruguay, USA and Consumer Goods Forum, FAO, Food Industry Asia, ICBA, IDF/FIL), CRD4 (Brazil, EU, India, Morocco, Norway and the Philippines); CRD 9 (Dominican Republic); CRD11 (Syrian Arab Republic); CRD16 (Republic of Korea); CRD17 (Nigeria); CRD18 (Thailand); CRD20 (Report of the PWG on the Proposed Draft Guidelines for the Safe Use and Reuse of Water in Food Production and Processing)

guidelines and annex 1 on fresh produce, based on the written comments received and the discussions in the PWG had been presented in CRD20. It was proposed that this document be considered for further discussion.

Discussions

82. CCFH53 considered the revised proposed draft guidelines including the annex on fresh produce contained in CRD20 section by section. Unless otherwise stated below, CCFH53 agreed with the revisions in CRD20 and in addition to the changes outlined below made editorial corrections, and amendments to improve accuracy, clarity and consistency within the proposed draft guidelines.

Introduction

83. As the scope of the guidelines was not specific to drinking water it was agreed to delete reference to safe drinking water at the beginning of paragraph two and just refer to water.

84. A proposal was made to change “water safety” to “food safety” in the fourth paragraph, since water was part of food. This was rejected as the focus of this document was water safety and it was considered that changing to “food safety” changed the sense of the text and reduced clarity.

85. The last sentence of paragraph five was revised to refer to the “right type of water” rather than the “right water safety” for clarity.

86. Clarification was sought on whether “hazard analysis” was the appropriate term to use in paragraph six and it was suggested that a broader term like “risk evaluation” may be more appropriate. The co-chairs of the EWG noted that a “hazard analysis”, as described in CXC 1-1969 contained two elements, an analysis of the risk factors and consideration of the management options, which was in line with the intent of this paragraph. It was therefore agreed to retain the original text.

87. It was noted that there was some overlap between the seventh paragraph and the purpose and scope of the document and it was suggested that this paragraph might not be needed. However, the Chair of the EWG highlighted that each paragraph had a different purpose with this paragraph highlighting the need for this work. To avoid possible confusion, it was agreed to delete Codex from paragraph seven so that the text reflected a more general need.

88. In paragraph eight, the word “safe” was deleted before “sourcing” as it was proposed that this could be interpreted as all water having to be safe at the source, which seemed to contradict the purpose of these guidelines. As some concerns were expressed at the deletion, as this term was used widely in the guidelines and often incorporated the broader concept of sourcing, it was agreed that any further deletions of “safe sourcing” would be considered on a case-by-case basis.

Purpose and Scope

89. There was extensive discussion on the purpose and scope with the following views expressed:

- Potential physical and chemical hazards should be listed so that even though these were not addressed explicitly in these guidelines, it was clear that these also needed to be managed
- Storage should be included in addition to production and processing
- Potential allergens due to water treatment should be considered
- Rather than referring to primary production and processing the scope should cover the food chain
- Clarification was needed that the scope included those steps between primary production and processing such as those at the post-harvest stage
- The exceptions such as “household use” were not very clear
- Clarity was needed on whether retailers and food services should be included or excluded as depending on the nature of their activities the guidance may not be so relevant, although it was recognized that processing was part of some retail operations

90. In responding to the comments, the Chair of the EWG recalled that the scope of the document was microbiological hazards, but that the need to also consider physical and chemical hazards was included in the General Principles; the exemptions could be deleted noting that such a list could never be fully comprehensive and it would be more appropriate to ensure the scope was clear to the extent that whatever was not mentioned would be understood as excluded; and that expanding the scope to the food chain may be too broad considering the content of the draft guidelines.

91. In the ongoing discussion, it was further noted that as allergens were chemical hazards, they would, therefore be excluded from the scope; as FBOs had been defined in CXC 1-1969, it may be more appropriate to use that term in the scope noting that more information on the FBOs primarily targeted by this text were included

under the subsequent section on use; and that it was useful to clarify what microbiological hazards included. Taking the various views expressed into account a revised purpose and scope was proposed and with some edits was agreed as follows: “These guidelines provide a framework of general principles and examples for applying a risk-based approach to determine if the water to be sourced, used, and reused by FBOs involved in production and processing of relevant commodities is fit for purpose by addressing microbiological hazards, such as bacteria, parasites, and viruses.”

Use

92. In the first paragraph, food service operators, retailers, and traders were removed, as these were not considered the primary target for these guidelines, although it was noted that some retailers undertake in-house processing. The text after "competent authorities" was removed as this term was defined in CXC 1-1969.

93. It was agreed to include the *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020) and the *Code of Hygienic Practice for Meat* (CXC 58-2005) in the second paragraph, noting that these were relevant to either the general guidance or one or more of the annexes. As a means of future proofing, an addition was made to the first sentence to refer to “all relevant Codex texts, including but not limited to”.

General Principles

94. There was agreement with the first principle after removing a reference to “safe” as this was considered unnecessary since the definition of fit-for-purpose included the reference to “safe water”.

95. It was noted that the second principle contained two concepts, that of encouraging water reuse and that of ensuring reuse water was treated or reconditioned so that it was fit-for purpose. Some Members disagreed with the statement that water reuse be encouraged and noted that they did not think it was the role of Codex to encourage such use but only to indicate how water could be safely reused and as such the statement did not have a place in the general principles. It was agreed to remove this concept from the principles, although some Members expressed their disappointment at this, as given dwindling water resources, they considered Codex had a role to play in promoting its sustainable use.

96. Reference to a “HACCP system” was removed from the end of principle three as this was already captured in “food hygiene system”, which as defined in CXC 1- 1969 captured prerequisite programmes and HACCP. The same change was made in subsequent sections of the guidelines as appropriate.

97. An Observer highlighted that the fourth principle contradicted the fit-for-purpose approach by indicating that water used as a food ingredient had to be potable in line with the WHO drinking water guidelines noting that in certain sectors such as the dairy sector, water recovered from foods such as milk was safely used as a food ingredient. The JEMRA secretariat indicated that this principle was a paraphrase from the JEMRA report, where the term “whenever necessary” was also used[18]. Reflecting on a proposal to also add “whenever necessary“ to the principle, many Members expressed concerns on such an addition, and they considered it opened the door to bad practice and noted that a principle should not give such flexibility. Some also considered that in the example provided by an Observer, water recovered from a food and reused as an ingredient would not be considered water. In trying to find a way forward the Chair of the EWG recalled that there was a definition for potable water in the guidelines and proposed to simplify the principle by indicating that when used as an ingredient, water should be potable and to remove reference to other guidelines. CCFH53 agreed with this proposal.

Definitions

98. CCFH53 agreed with the proposed definition of “water fit-for-purpose” with the change of “risk factors” to “relevant factors”, as the examples given were broader than risk factors, and deletion of “in the water sources” from the end of the definition as it was not needed.

99. The definition for “first-use water” was deleted as this term had been removed from the text and was therefore no longer needed.

100. The definitions for “risk assessment”, “food hygiene system”, and “HACCP system” were also deleted as they were defined in the Codex Procedural Manual or the *General Principles of Food Hygiene* (CXG 1- 1969).

[18] FAO and WHO. 2019. Safety and Quality of Water Used in Food Production and Processing – Meeting report. Microbiological Risk Assessment Series no. 33. Rome.

101. A definition of “wastewater” as “used water that has been contaminated because of human activities”, which had been agreed by the PWG but erroneously omitted from the revised text presented in CRD20 was reinserted and agreed by CCFH53.

102. The reference to “other than first-use and reclaimed water” were deleted from the definition of “recycled water” as “first-use water” no longer appeared in the document and “reclaimed water” had been defined separately and was distinguished from “recycled water”.

<u>Section 1: Water fit-for-purpose assessment</u>

103. In the fifth paragraph, the concept of storage was added to the chapeau. In the first bullet on descriptive assessments, it was clarified that the focus was on a review of documentation as well as an onsite visits rather than documentation of the evaluation and the word “written” was deleted to help avoid misunderstanding. It was noted that this concept needed to be clarified in the other language versions. The example in the last bullet was simplified to “wastewater in agriculture” for clarity and “in water” was deleted after “pathogens” as this may also refer to pathogens in the food.

<u>Section 2: Water safety management</u>

104. In the first paragraph “water quality values” was deleted as it was not clear what they were, and to avoid any misunderstanding that it was necessary to consider all the risk management decisions listed, “as appropriate” was added to the end of the sentence.

<u>Figure 1</u>

105. All references to active and passive management were replaced with a description of what they were intended to mean; “reused water” was replaced with “reuse water” for consistency with the text and in the second bullet of Purpose “food” was added before “safety”. As a consequence, “active management” and “passive management” were deleted from the definitions section.

Annex I – Fresh produce

<u>Purpose and scope</u>

106. Microbiological quality was deleted before “sourcing” to avoid introduction of another term that was unclear and to be consistent with the use of “safe sourcing” in the general section.

<u>Use</u>

107. *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997) was added since microbiological criteria were mentioned in the purpose and scope.

<u>Definitions –Fresh produce</u>

108. “Nuts” were retained and “herbs” were added to the definition. While a concern was expressed at including mushrooms due to different growing methods and water use, Members generally indicated that in their jurisdictions mushrooms were considered part of fresh produce so they were retained, but “edible” was deleted as these guidelines related to food, hence it was not needed. The co-chair of the EWG indicated that the definition should refer to produce being presented to the consumer in a raw state instead of only produce consumed by the consumer in a raw state to better represent the scope of the guidelines as well as the scope of the work undertaken by JEMRA.

<u>Water Sources</u>

109. In the first paragraph ‘reclaimed’ was changed to ‘reconditioned’ for greater clarity. In addressing a query on “hygienically collected rainwater” (bullet 3) it was noted that the risk associated with use of rain water could vary according to how it was collected and stored, therefore it was important to clarify that for rainwater to be considered low risk, collection systems and storage tanks must be hygienically maintained.

110. In the third bullet of the second paragraph, the example of the distance of what “far enough away” might be was deleted as this was very context specific and depended on aspects like slope, soil type etc. and therefore a numerical example was not appropriate or helpful.

111. In the third paragraph (bullet 1), “reclaimed water” was removed as based on its definition it could not be considered to be of higher risk.

<u>Figure 1</u>

112. The title was changed to refer to “fit-for-purpose assessment” rather than “risk assessment” and the same change was reflected in the decision tree. Two of the questions were revised for clarity based on comments and practical application of the tool; references to WHO were removed; and “waste” was changed to “water” in the last question box.

Water for irrigation (including greenhouses)

113. In the second paragraph, "suitable quality" was changed to "fit-for-purpose" for improved clarity. In the third paragraph, bullet 7, "Where possible" was added to give flexibility.

Water for indoor storage and distribution facilities

114. In the second paragraph, bullet 1, reference to fertilizers and pesticides was removed since chemicals were outside the scope but the concept that agriculture inputs may introduce microbiological hazards and hence care was needed, was retained.

Harvest and post-harvest use of water - General

115. In the sixth paragraph, the text in parentheses was deleted as it was subjective, processing aids were deleted as these may be defined differently in different countries and were not needed for clarity and it was indicated that in order for biocides to maintain the microbiological quality of process water, the residual concentration levels should be maintained.

Documentation

116. "If necessary" was added to the third bullet of the first paragraph to provide flexibility as monitoring water temperature was not always possible.

Water fit for purpose assessment

117. "Labelling with instructions for the intended use" of the food was added to the list of bullets in the first paragraph as a factor to be considered in the assessment.

Table 1

118. In the column header text that read "reused water untreated/wastewater", the text "reused water untreated" was deleted and in the column header text that read "cooked or processed by consumer or a food business operator", the text "or processed by consumer or a food business operator" was deleted as Members were not convinced of its added value and some also preferred that this table be fully aligned with the table produced by JEMRA. It was agreed to maintain the new footnote to the table to indicate that cooking as a step could be variable and that needed to be considered in assigning risk levels.

Indicator organism for monitoring hazards in water used in fresh produce production

119. "Bacterial" was added to clarify the type of faecal indicators bacteriophage were being compared to and "coliphage" was removed to avoid any confusion with bacteriophage.

Examples for determining water fit-for-purpose sampling frequency and microbiological criteria

120. Two new paragraphs were proposed to replace the existing second paragraph, which was considered unclear and did not give sufficient guidance between level of risk and frequency of testing. The addition was agreed and a reference to Figure 3 was also added.

Figure 3

121. There were mixed views on whether or not to retain this figure noting it was from a source other than JEMRA, it did not make the linkage to risk, there was some overlap with Figure 1 and Table 1 and it was not consistent with the revised paragraph immediately preceding it. Others were of the view that it was relevant as it did make the linkage to frequency of testing and provided more details than Figure 1 in that regard. It was agreed to retain the figure as an example but to make some revisions to ensure it was aligned with the preceding text and adequately linked to the different risk levels.

Examples of decision support system tools

122. It was noted that using paragraph numbers for cross referencing was not workable in the final version of the standard and CCFH53 asked the Codex Secretariat to address this in the text, as well as ensure consistent use of fit-for-purpose and that references to JEMRA were correct.

123. CCFH53 expressed appreciation to the chair and co-chairs of the EWG for the great work done and agreed that there were no outstanding issues in the general section and annex 1 of the proposed draft guidelines. It was noted that CCFH53 did not have time to discuss the two remaining annexes and that the work on those should continue between this session and CCFH54.

Conclusion

124. CCFH53

i. noting that there were no outstanding issues to be addressed in the general section and the annex on fresh produce, agreed to forward the proposed draft Guidelines and Annex 1 for adoption at Step 5/8 by CAC46 (Appendix IV);

ii. agreed to return the annex on fishery products to Step 2/3 for redrafting and circulation for comments;

iii. agreed to establish an EWG, chaired by the EU and co-chaired by Chile and the International Dairy Federation (IDF) (on an exceptional basis, due to the need for their specific expertise in developing the annex on dairy products) and working in English (noting that comments would also be accepted in French and Spanish), to:

   a. further develop the annex on fishery products taking into consideration the written comments that were submitted through the OCS in response to the CL 2022/49-FH, and CRDs submitted at CCFH53, as well as the general section of the guidance as agreed at CCFH53;

   b. initiate the development of the annex on dairy products, taking into consideration the general section of the guidance as agreed at CCFH53; and

   c. prepare a report and revised text to be submitted to the Codex Secretarial three months before CCFH54 for circulation for comments at Step 3; and

vi. agreed that a PWG, chaired by the EU and co-chaired by Chile and IDF, working in English, French and Spanish may be established and held in conjunction with CCFH54 to consider all comments received and to prepare a revised proposal for consideration by the plenary.

DISCUSSION PAPER ON REVISION OF THE *GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF PATHOGENIC VIBRIO SPECIES IN SEAFOOD* (CXG 73-2010) (Agenda Item 7)[19]

125. Japan introduced this item with the updated project document taking into account the comments received in advance of CCFH53 (CRD10). Japan recalled that CAC33 (2010) adopted the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood* (CXG 73-2010) which had general guidance and an annex that provided detailed information on control measures for *Vibrio parahaemolyticus* and *Vibrio vulnificus* in bivalve molluscs. Japan noted that, based on the latest scientific information from the JEMRA meeting on *V. parahaemolyticus* and *V. vulnificus* in 2019, where updated risk assessment models/tools were applied, that there were advancements since CXG 73-2010 had been adopted. Japan drew the attention of CCFH53 to the factors that needed consideration including the emergence of highly pathogenic strains, in particular the Pacific Northwest (PNW) *V. parahaemolyticus* strain (ST36), significant geographical spread of infections of *Vibrio* spp. in association with climate change, and potential demographic effects on increased risk in densely populated coastal regions. Japan outlined key issues relevant to the control of *V. parahaemolyticus* and *V. vulnificus* which could be taken into consideration in the new work as follows:

- updated microbiological monitoring methods including molecular-based approaches;
- latest data on new pathogenic strains, their geographical spread and clinical incidence;
- detection and characterization of *Vibrio* species;
- novel methods including remote sensing-based techniques, satellite imagery and whole genome sequencing which would facilitate predicting periods of elevated risk and better control the viruses; and
- practical interventions, including pre-harvest interventions (e.g. relaying at harvest such as reduced cooling times), and post-harvest treatments (e.g. high-pressure processing, freezing and pasteurization), contributing to the reduction of risks of vibriosis associated with the consumption of seafood.

126. Japan further stressed that this work would include alignment of CXG 73-2010 with the *General Principles of Food* Hygiene (CXC 1-1969).

[19] CX/FH 22/53/7; CX/FH 22/53/7 Add.1 (Australia, Brazil, Canada, Chile, Colombia, Costa Rica, Cuba, Egypt, India, Kenya, Norway, Peru, Saudi Arabia, Singapore, Uruguay and USA); CRD5 (European Union, Indonesia, Morocco and Philippines); CRD8 (United Kingdom); CRD9 (Dominican Republic); CRD10 (Revised project document for the revision of *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood* (CXG 73-2010)); CRD11 (Syrian Arab Republic); CRD12 (ISO); CRD17 (Nigeria)

Discussion

127. CCFH53 noted general support for the proposed revision of CXG 73-2010.

128. Responding to a question on the availability of data on the prevalence of pathogenic *Vibrio* spp. and related foodborne illness in the Caribbean region, the JEMRA Secretariat stated that data collected from the Latin American and Caribbean region from 2010 to 2019 had been compiled in MRA35 and would be available in the process of revising CXG 73-2010, but acknowledged the difficulty in having data from all geographic regions.

129. Several delegations proposed expanding the scope of the work to include other *Vibrio* spp. such as *V. alginolyticus* and *V. cholerae* as well as seafood other than bivalve molluscs. The Chairperson reminded CCFH53 that the general section of CXG 73-2010 included all pathogenic *Vibrio* spp. and all seafood, with the Annexes focusing only on *V. parahaemolyticus* and *V. vulnificus* in bivalves based on evidence of their impact on public health. The JEMRA Secretariat stated that, based on currently available data, *Vibrio*-related outbreaks associated with seafood were most commonly caused by *V. parahaemolyticus* and *V. vulnificus*. They further stated that the hazard characteristics of *V. alginolyticus* were similar to *V. parahaemolyticus,* indicating that similar interventions would be effective in controlling *V. alginolyticus*.

130. Some Members noted that the revision should include all seafood products along with bivalve molluscs, and a request to JEMRA to review available scientific literature on *Vibrio* spp. in fishery products other than bivalve molluscs.

131. Japan, while acknowledging that *V. parahaemolyticus* and *V. vulnificus* were major contributors to vibriosis outbreaks, agreed to consider if any updates were needed to the project document to accommodate those comments.

Conclusion

132. CCFH53 supported the new work proposal and agreed that the project document to include all seafood along with bivalve molluscs, would be considered further in conjunction with forward work plan under Agenda Item 9.

DISCUSSION PAPER ON REVISION OF THE *GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF VIRUSES IN FOOD* (CXG 79-2012) (Agenda Item 8)[20]

133. Canada introduced this item, recalling that Canada, with support from the Netherlands, reviewed the *Guidelines on the* Application *of General Principles of Food Hygiene to The Control of Viruses in Food* (CXG 79-2012) following the inclusion of the possible revision of CXG 79-2012 in the forward work plan at CCFH51 (2019). Canada summarised the main aspects to be considered for a possible inclusion in a revision of CXG 79-2012 as follows:

- expansion of the scope to address viruses other than hepatitis A virus (HAV) and norovirus (NoV) and emerging vehicles of foodborne illnesses such as frozen fruits;
- 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 commodities and in assessing potential infectivity of viruses; and
- consideration of new scientific findings to control HAV and NoV in bivalve molluscs and in fresh produce made available since the publication of CXG 79-2012 including indicators to monitor seawater quality of molluscs growing areas and risk assessment models.

134. Based on the proposal in the discussion paper and taking into account comments from Members and Observers in response to CL 2022/50/OCS-FH, Canada identified five areas in which scientific advice from JEMRA would be required as follows:

i. An up-to-date review of the foodborne viruses and relevant food commodities of highest public health concern

[20] CX/FH 22/53/8; CX/FH 22/53/8 Add.1 (Australia, Brazil, Canada, Chile, Colombia, Costa Rica, Cuba, Ecuador, Egypt, European Union, India, Iran, Kenya, Mauritius, Peru, Philippines, Saudi Arabia, Singapore, Uruguay, USA and IFT, International Frozen Food Association); CRD6 (Indonesia and Thailand); CRD8 (United Kingdom); CRD9 (Dominican Republic); CRD12 (ISO); CRD17 (Nigeria)

ii. A review of the scientific evidence on prevention and intervention measures and the efficacy of interventions in the food continuum

iii. A review of the analytical methods for relevant enteric viruses in food commodities

iv. A review of scientific evidence on the potential utility of viral indicators or other indicators of contamination

v. 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

Discussion

135. CCFH53 expressed appreciation for the discussion paper and were generally in agreement with the conclusion and the identified areas on which to request scientific advice from JEMRA.

136. Delegations acknowledged the importance of the five areas identified for scientific advice, and expressed views on their prioritization, with many stressing the importance of items 1, 3 and 4, noting that the review (item 1) would be important to inform any consideration of analytical methods. Several delegations also noted the importance of item 2 but there was general agreement that item 5 could only be addressed following the collection of data through work in the other areas. One delegation stressed the importance of including in the review statistical data on the incidence of foodborne disease including mortality, morbidity and the potential for transmission via foods and prevalence in foods.

137. The JEMRA Secretariat stated that, despite the amount of work required, they would aim to address these areas in two JEMRA meetings. The JEMRA Secretariat further noted that the WHO FERG had included foodborne viruses in their work plan and outputs from that work may support the JEMRA work.

138. One delegation questioned whether the FERG could prioritize viruses as part of their work. The delegate further drew attention of the need to establish a dose-response model for viruses. WHO confirmed that FERG could prioritize viruses and that development of a dose-response model would be a part of the JEMRA risk assessment.

139. In terms of the time-frame for the work, it was noted that the up-to-date review in particular would be needed in the development of a new work proposal on the revision of the *Guidelines on the Application of General Principles of Food Hygiene to The Control of Viruses in Food* (CXG 79-2012) for CCFH54. Canada and the Netherlands confirmed their willingness to prepare such a proposal based on the scientific advice provided.

Conclusion

140. CCFH53 agreed to request JEMRA to provide scientific advice on the areas identified in paragraph 134, with priority given to items 1, 3 and 4, and noted that Canada together with the Netherlands would provide a project document taking into account the scientific advice from JEMRA for consideration by CCFH54.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 9)[21]

141. The USA, as the Chair of the PWG, outlined the recommendations of the PWG to CCFH53 (CRD15) to support new work proposals, namely the project document on guidelines (or a code of practice) for food hygiene control measures in traditional food markets, which was presented by Bolivia and revised as contained in CRD19; and the project document on revision of *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood* (CXG 73-2010), including alignment with the revised *General Principles of Food Hygiene* (CXC 1-1969) prepared by Japan and discussed under agenda item 7. The USA further introduced the discussion paper on the revision of the *Guidelines on the Application of the General Principles of Food Hygiene to the Control of Viruses in Food* (CXG 79-2012) prepared by Canada discussed under agenda item 8 where CCFH53 agreed to request scientific advice from JEMRA on prioritized elements (para 134). The USA also highlighted projects prioritized by assigning rankings in the forward work plan.

142. The Chairperson indicated that due to the progress made at CCFH53 it would be possible to take on new work and that it was also important to bear in mind the longer-term planning of the committee.

<u>Guidelines for food hygiene control measures in traditional markets for food</u>

143. One delegation expressed concern about the use of “traditional market” in the title of the project document, and proposed making the title more general by replacing “traditional market” with “food market” and including traditional markets in the scope of the guidelines. The Chairperson proposed retaining the title for now, expecting that the title would be refined if needed as the work progressed.

[21] CX/FH 22/53/9; CRD7 (Indonesia and Thailand); CRD9 (Dominican Republic); CRD12 (ISO); CRD14 (Mexico); CRD15 (Report of the PWG on new work proposals/forward work plan); CRD16 (Republic of Korea); CRD18 (Thailand); CRD19 (Revised proposal for new work on guidelines for food hygiene control measures in traditional markets for food)

Conclusion

144. CCFH53 agreed to:

i. forward the project document to CAC46 for approval as new work (Appendix V); and

ii. establish an EWG, chaired by Kenya and co-chaired by Bolivia, and Nigeria, working in English, to prepare, subject to approval of the Commission, the proposed draft guidelines for circulation for comments at Step 3 and consideration at CCFH54.

145. The report of the EWG should be made available to the Codex Secretariat at least three months before CCFH54 for circulation for comments at Step 3;

Revision of *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood* (CXG 73-2010)

146. In response to a question raised by the JEMRA secretariat that the project document in CRD10 did not specifically address the need to request scientific information from JEMRA with regard to other *Vibrio* spp. such as *V. alginolyticus* and *V. cholerae* as well as seafood other than bivalve molluscs, Japan stated that such *Vibrio* spp. were covered in the main body text of current CXG 73-2010, and the JEMRA reports published since 2010 covered seafood other than bivalve molluscs. Hence, Japan indicated that it was not necessary to request any scientific advice from JEMRA at this moment, but did not preclude the possibility that a need for scientific advice might be identified as the work progressed.

Conclusion

147. CCFH53 agreed:

i. to forward the project document to CAC46 for approval as new work (Appendix VI);

ii. to establish an EWG and hold a potential virtual meeting of the EWG, chaired by Japan and co-chaired by Chile, working in English, to prepare, subject to approval of the Commission, the proposed draft revised guidelines for circulation for comments at Step 3 and consideration at CCFH54; and

iii. that a PWG may be held in conjunction with CCFH54, working in English, French and Spanish

148. The report of the EWG should be made available to the Codex Secretariat at least three months before CCFH54 for circulation for comments at Step 3.

Alignment of CCFH documents with the revised *General Principles of Food Hygiene* (CXC 1-1969)

149. The United Kingdom agreed to lead an alignment working group (in English) to initiate the work on alignment, consider the optimal approach to be taken, and to update CCFH54 on progress made. The Chairperson encouraged other Members to support this effort noting the extent of work to be undertaken.

150. In response to a question by Japan whether a guideline for the alignment with CXC 1-1969 would be made available shortly after CCFH53 in order to revise CXG 73-2010 to match with the alignment with CXC 1-1969, the Chairperson clarified that the report by the United Kingdom would be made available for the consideration at CCFH54, and thus Members were invited to coordinate with the United Kingdom for their work if they would need assistance for the alignment before CCFH54.

Forward work plan

151. CCFH53 reviewed the work plan and noted the intent of:

- Canada and the Netherlands, to prepare a project document on the revision of *Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food* (CXG 79-2012) for consideration at CCFH54, taking into account discussions at CCFH53 under item 8;
- USA, Honduras, Brazil and the EU to prepare a discussion paper on the possible revision of *Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat* (CXG 78-2011) for consideration at CCFH54; and
- France, USA and Canada to prepare a discussion paper on the possible revision of *Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Foods* (CXG 61-2007) for consideration at CCFH54.

152. The Chairperson reminded CCFH53 the deadline of the submission of new work proposals would be 1st September 2023 as per normal practice.

Conclusion

153. CCFH53 agreed to:

i. endorse the revised forward work plan (Appendix VII); and

ii. establish a PWG on CCFH Work Priorities, chaired by the United States of America, to be held in conjunction with CCFH54, working in English, French and Spanish.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 10)

154. CCFH53 was informed that CCFH54 would be held from 11 to 15 March 2024 with the final arrangements subject to confirmation by the host Government in consultation with the Codex Secretariat.

Appendix I

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Appendix II

General methods for the detection of irradiated foods

(For recommendation to CCMAS to transfer the methods of analysis to the *Recommended Methods of Analysis and Sampling* (CXS 234-1999))

New texts added are shown in **bold/underlined** font. Texts proposed for deletion are shown in ~~strikethrough~~.

Commodity	Provision	Method	Principle	Type
Food containing fat **(e.g. raw meat and chicken, cheese, fruits)**	Detection of irradiated food **- Detection of radiation-induced hydrocarbons**	EN 1784 ~~: 1996~~	Gas chromatographic analysis of hydrocarbons	Type II
Food containing fat **(e.g. raw meat and chicken, liquid whole egg)**	Detection of irradiated food **- Detection of radiation-induced 2-alkylcyclobutanones**	EN 1785[1]~~: 1996~~	Gas chromatographic/ mass spectrometric analysis of 2-alkylcyclobutanones	Type III
Food containing bone	Detection of irradiated food - **Radiation induced Electron Spin Resonance (ESR) signal attributed to hydroxyapatite (principal component of bones)**	EN 1786~~: 1996~~	ESR spectroscopy	Type II
Food containing cellulose **(e.g., nuts and spices)**	Detection of irradiated food **- Radiation induced Electron Spin Resonance (ESR) signal attributed to crystalline cellulose**	EN 1787~~: 2000~~	ESR spectroscopy	Type II
Food containing silicate minerals **(e.g. herbs, spices, their mixtures and shrimps)**	Detection of irradiated food - **Thermoluminescence glow ratio used to indicate the irradiation treatment of the food**	EN 1788~~: 2001~~	Thermoluminescence	Type II
Food containing silicate minerals **(e.g. shellfish, herbs, spices, seasonings)**	Detection of irradiated food **- Measurement of photostimulated luminescence intensity**	EN 13751[2] ~~: 2002~~	Photostimulated luminescence	Type III
Food containing crystalline sugar **(e.g. dried fruits and raisins)**	Detection of irradiated food **- Radiation induced Electron Spin Resonance (ESR) signal attributed to crystalline sugar**	EN 13708~~: 2001~~	ESR spectroscopy	Type II

Herb**s and** spices ~~and raw minced meat~~ [3]	Detection of irradiated food **- Difference between total microorganism count and viable microorganism count**	EN 13783~~: 2001~~ NMKL 231 ~~(2002)~~	Direct Epifluorescent Filter Technique/Aerobic Plate Count (DEFT/APC) (screening method)	Type III
Food containing DNA **(e.g. food products, both of animal and plant origin such as various meats, seeds, dried fruits and spices)**	Detection of irradiated food **- Detection of DNA fragmentation presumptive to irradiation treatment**.	EN 13784~~:2001~~	DNA comet assay (screening method)	Type III

Notes

[1] One Member noted that 2-alkylcyclobutanone was also present in some non-irradiated foods and hence EN1785 may need further consideration as a method for detection of irradiated foods.

[2] Consideration should be given to whether EN13751 should be specified as a screening method.

[3] No information was found on validation of the method for this commodity.

Appendix III

GUIDELINES FOR THE CONTROL OF SHIGA TOXIN-PRODUCING *E. 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)

(at Step 5/8)

INTRODUCTION

1. Shiga toxin-producing *Escherichia coli* (STEC) are recognized as foodborne pathogens causing human illnesses, with a wide range of mild to severe gastrointestinal presentations from asymptomatic to diarrhoea to bloody diarrhoea, occasionally leading to severe haemolytic uremic syndrome (HUS) with kidney failure and death. STEC have occasionally been linked with neurological symptoms, including epileptic seizures and cognitive dysfunction. Strains of *E. coli* that are pathogenic to humans have been classified into several groups, and STEC are defined by the potential to produce one or more Shiga toxins. STEC strains are a diverse group which can cause disease in humans. STEC strains that can cause haemorrhagic colitis may be referred to as enterohaemorrhagic *E. coli* (EHEC). The most well-studied and documented STEC serotype is *E. coli* O157:H7. The burden of the disease is significant, with substantial outbreaks associated with diverse food commodities. Thus, STEC have a serious impact on public health.

2. Clinical symptoms of the disease in humans arise as a consequence of consuming food contaminated with *E. coli* that produces Shiga toxin type 1 (Stx1) (encoded by the gene *stx1*) and/or Shiga toxin type 2 (Stx2, encoded by the gene *stx2*). Historically, the term verotoxin has also been used for the Shiga toxins of *E. coli* and the term verotoxigenic *E. coli* (VTEC) used synonymously with STEC. In this document, the term "Shiga toxin" (Stx) is used to indicate the protein toxin "*stx"* to indicate the toxin gene, and "STEC" to indicate the *E. coli* strains demonstrated to carry *stx* and produce Stx. STEC are pathogenic to humans after ingestion and attachment to the intestinal epithelial cells where production of Stx occurs. Attachment to intestinal epithelial cells is the result of other proteins, including the principal adherence protein intimin, encoded by *eae.* The aggregative adherence fimbrial adhesins commonly associated with enteroaggregative *E. coli*, regulated by the *aggR* gene, when found in isolated strains with *stx,* have also been linked to severe illness and have been used as predictors of pathogenicity. Combinations of virulence genes and their association with disease severity that can be used for risk management purposes are described in these guidelines. There may be additional genes involved in pathogenicity that have not yet been identified. Some of these virulence genes are located on mobile genetic elements (e.g. plasmids, bacteriophages, pathogenicity islands) and can be horizontally transmitted to related microorganisms or be lost. Symptoms and their severity are determined by the variability in the virulence genes, among other factors such as gene expression, dose, host susceptibility, and age. Because STEC are primarily a genotype-based hazard, this has implications for hazard identification and characterization, which will be discussed in these guidelines.

3. Direct contact with animals and person-to-person transmission have been identified as important routes of transmission. Historically, foodborne illnesses caused by STEC have been linked to the consumption of raw or undercooked ground/minced or tenderized (i.e. non-intact) beef; however, fresh leafy vegetables, sprouts, and dairy products (raw milk and raw milk cheeses) have been increasingly recognized as commodities that pose a risk of illness from STEC. Sources of STEC in these foods can vary, as does the ability of the organism to survive and multiply within them. The association of specific food categories with STEC illness reflects the historical and current practices of food production, distribution, and consumption. Changes in food production, distribution and consumption can cause changes in STEC exposure. Consequently, microbial risk management should be informed by an awareness of current local sources of STEC exposure. This guidance document will identify commodity-specific intervention practices based on known source attribution in these different foods, and practices for monitoring STEC in food products, including the utility of indicator microorganisms.

4. It is generally accepted that animals, in particular ruminants, are the primary reservoir/source of STEC. STEC-positive ruminants are typically asymptomatic. Contamination with intestinal content or faeces is the most likely initial source of STEC in most foods. For example, STEC outbreaks have been associated with raw beef contaminated with STEC during the slaughtering process, field-grown fresh leafy vegetables have been linked to STEC-contaminated irrigation water, and STEC illnesses from sprouts have resulted from contamination during seed production enhanced during sprouting. Raw milk is most commonly contaminated as a result of soiled udders and teats, as well as poor hygiene during milking.

5. The large degree of variation exhibited by STEC in their biological properties, host preferences, and environmental survival presents a challenge for managing the presence of STEC in animal and plant production. In practice, this means that there is no "one size fits all" solution, and different production systems may require

different approaches to control STEC (such as approaches based on pathogenicity and ability to cause severe illness). In most instances, control measures will reduce STEC but not eliminate them.

6. These guidelines build on general food hygiene provisions already established in the Codex system and propose potential control measures specific for STEC strains in raw beef, fresh leafy vegetables, raw milk and raw milk cheeses, and sprouts.

7. Examples of control measures in each commodity-specific annex have been subjected to a scientific evaluation by the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA) in development of the guidelines. Such examples are illustrative only; their use and approval may vary among member countries.

8. The format of this document:

- provides an opening general section with STEC guidance applicable to all commodities;
- demonstrates the range of the approaches of control measures for STEC;
- facilitates development of hazard analysis and critical control points (HACCP) plans at individual establishments and at national levels; and
- assists in assessing the equivalence[1] of control measures for raw beef, fresh leafy vegetables, raw milk and raw milk cheeses, and sprouts applied in different countries.

9. The guidelines provide flexibility for use at the national (and individual processing) level.

OBJECTIVES

10. These guidelines provide information to governments and food business operators (FBOs) on the control of STEC that aims to reduce foodborne disease from raw beef, fresh leafy vegetables, raw milk and raw milk cheeses, and sprouts. They provide a science-based and practical tool for the effective control of STEC in raw beef, fresh leafy vegetables, raw milk intended for drinking and raw milk cheeses, and sprouts, according to national risk management decisions. The control measures that are selected can vary among countries and production systems.

11. These guidelines do not set quantitative limits as described in the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997)[2] for STEC in raw beef, fresh leafy vegetables, raw milk and raw milk cheeses, and sprouts. Rather, the guidelines describe control measures that countries can establish as appropriate to their national situation as described in the *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CXG 63-2007).[3]

SCOPE AND USE OF THE GUIDELINES

Scope

12. These guidelines are applicable to STEC that may contaminate raw beef, fresh leafy vegetables, raw milk[i] and raw milk cheeses, and sprouts and cause foodborne disease. The primary focus is to provide information on scientifically-validated practices that may be used to prevent, reduce, or eliminate STEC contamination of raw beef, fresh leafy vegetables, raw milk and raw milk cheeses, and sprouts.

Use

13. The guidelines provide specific control measures for STEC in raw beef, fresh leafy vegetables, raw milk and raw milk cheeses, and sprouts according to a primary production-to-consumption food chain approach, with potential control measures being identified at applicable steps in the process flow. The guidelines are supplementary to, and should be used in conjunction with, the *General Principles of Food Hygiene* (CXC 1-1969),[4] the *Code of Hygienic Practice for Meat* (CXC 58-2005),[5] the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003),[6] the *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004),[7] the *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008),[8] *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CXG 63-2007)[3] and *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997).[2] These general and overarching provisions are mentioned as appropriate, and their content is not duplicated in these guidelines.

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[i] These guidelines present specific guidance for control of STEC related to raw milk intended for drinking and for production of raw milk cheeses.

14. The guidelines present a number of control measures. These control measures will likely vary at the national level and therefore these guidelines only provide examples of them. Examples of control measures are limited to those that have been scientifically demonstrated as effective in a commercial setting. Countries should note that these control measures are indicative only. The quantifiable outcomes reported for control measures are specific to the conditions of particular studies, and the control measures would need to be validated under local commercial conditions to provide an estimate of hazard reduction. Government and FBOs can choose hazard-based control measures to inform decisions on critical control points (CCPs) when applying HACCP principles to a particular food process.

15. Several control measures as presented in these guidelines are based on the use of physical, chemical and biological decontamination processes to reduce the prevalence and/or concentration of STEC-positive commodities, for example decontamination of beef carcasses from slaughtered cattle (i.e. beef from animals of the species of *Bos indicus*, *Bos taurus*, and *Bubalus bubalis*). The use of these control measures is subject to approval by the competent authority, where appropriate, and varies based upon the type of product being produced. Also, these guidelines do not preclude the choice of any other control measure that is not included in the examples provided herein, and that may have been scientifically validated as being effective in a commercial setting.

16. The provision of flexibility in the application of the guidelines is an important attribute. They are primarily intended for use by government risk managers and FBOs in the design and implementation of food hygiene systems.

17. The guidelines should be useful when assessing whether different food safety measures for raw beef, fresh leafy vegetables, raw milk and raw milk cheeses, and sprouts in different countries are appropriate.

DEFINITIONS

18. For the purposes of these guidelines, the following terms are defined as below:

Control measure: Any action or activity that can be used to prevent or eliminate a hazard or reduce it to an acceptable level.[4]

Fresh leafy vegetables: Vegetables of a leafy nature where the leaf is intended for raw consumption**,** 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.

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

Monitor: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control.[4]

Raw beef: Skeletal muscle meat from slaughtered cattle, including primal cuts,[ii] sub-primal cuts, and trimmings.

Raw milk: Milk (as defined in the *General Standard for the Use of Dairy Terms* (CXS 206-1999))[9] which has not been heated beyond 40 ºC or undergone any treatment that has an equivalent effect.[iii, iv, 7]

Raw Milk Cheeses: Cheeses made from raw milk.

Shiga toxin-producing *E. coli* (STEC): A diverse group of pathogenic bacterial strains of *Escherichia coli* that are demonstrated to carry Shiga toxin genes (*stx*) and produce Shiga toxin protein (Stx).

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).[10]

[ii] A primal cut is a piece of meat on the bone initially separated from the carcass of an animal during butchering. Primal cuts are then divided into sub-primal cuts. These are basic sections from which steaks and other subdivisions are made.

[iii] Temperatures between 40 ºC and pasteurization temperatures are generally considered to be insufficient to consistently kill STEC in raw milk. Heat treatment beyond 40 ºC results in changes such that the structure of the resultant product is no longer the same as that of raw milk.

[iv] Milk that has been subject to processing techniques such as microfiltration and/or bactofugation is no longer considered raw milk because these processes require milk to be heated above 40 °C.

Validation of control measures: Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.[4]

Verification: The application of methods, procedures, tests, and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended.[4]

PRINCIPLES APPLYING TO CONTROL OF STEC IN RAW BEEF, FRESH LEAFY VEGETABLES, RAW MILK AND RAW MILK CHEESES, AND SPROUTS

19. Overarching principles for good hygienic practice for meat production are presented in the *Code of Hygienic Practice for Meat* (CXC 58-2005),[5] Section 4: General principles of meat hygiene. For fresh leafy vegetables and sprouts, overarching principles for good hygienic practice are presented in the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003),[6] Annex I on Ready-to-eat fresh pre-cut fruits and vegetables, Annex II on Sprouts and Annex III on Fresh leafy vegetables. Additionally, see the *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004)[7] for dairy products. Two overarching food safety principles that have particularly been taken into account in these guidelines are:

> a) The principles of food safety risk analysis[11] should be incorporated wherever possible and appropriate in the control of STEC in raw beef, fresh leafy vegetables, raw milk and raw milk cheeses, and sprouts from primary production to consumption.
>
> b) Wherever possible and practical, competent authorities should formulate risk management metrics[3] so as to objectively express the level of control of STEC in raw beef, fresh leafy vegetables, raw milk and raw milk cheeses, and sprouts that is required to meet public health goals (including focusing on subtypes of particular concern where appropriate).

PRIMARY PRODUCTION-TO-CONSUMPTION APPROACH TO CONTROL MEASURES

20. These guidelines incorporate a "primary production-to-consumption" flow approach that identifies the main steps in the food chain where control measures for STEC can potentially be applied in the production of each commodity. The systematic approach to the identification and evaluation of potential control measures allows consideration of the use of controls in the food chain and allows different combinations of control measures to be developed and implemented. This is particularly important where differences occur in primary production and processing systems among countries. Risk managers need the flexibility to choose risk management options that are appropriate to their national context.

21. Good hygiene practices (GHPs) and other prerequisite programmes provide the foundation for most food hygiene systems. Where possible and practicable, food safety control measures for STEC should incorporate hazard analysis activities and appropriate control measures. Identification and implementation of risk-based control measures based on risk assessment can be elaborated by application of a risk management framework process as advocated in the *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CXC 63-2007).[3] While these guidelines provide generic guidance on development of control measures for STEC, development of risk-based control measures for application at a single step or at multiple steps in the food chain are primarily the domain of competent authorities at the national level. FBOs can select the risk-based measures to facilitate the effective application of process control systems and comply with the requirements of the competent authority. When no microbiological criteria or food safety objectives have been established by competent authorities, FBOs are also able to propose control measures based on risk assessment. These control measures need to be validated.

22. Specific control measures for STEC are described in each commodity-specific annex, where appropriate: Annex I – Raw beef; Annex II – Fresh leafy vegetables; Annex III – Raw milk and raw milk cheeses; Annex IV – Sprouts.

Development of risk-based control measures

23. Competent authorities operating at the national level should, working with the relevant food sector, develop risk-based control measures for STEC where possible and practical.

24. Risk-modelling tools can be developed[12] to assess the impact of control measures on the prevention, reduction, or elimination of the hazard. The capability and limitations, including the need for quantitative data, of the tools should be clearly specified and understood by the risk manager.

25. Competent authorities formulating risk management metrics[3] as regulatory control measures should apply a methodology that is scientifically robust and transparent.

PRIMARY PRODUCTION CONTROL MEASURES

26. Controls in the primary production phase of the process flow are focused on decreasing the number of animals that are carrying STEC, and the degree of shedding by those that are, as well as preventing or reducing contamination of crops/plants with STEC on the farm. In addition, good agricultural practices (GAPs) and animal husbandry practices related to water, worker hygiene, appropriate use of fertilizers and biosolids, appropriate handling during transport, temperature control, and cleanliness of contact surfaces can reduce the incidence of STEC at primary production.

PROCESSING CONTROL MEASURES

27. Appropriate controls to prevent and/or reduce the contamination and cross-contamination by STEC of commodities during processing are important. Control measures during post-processing handling and storage are also important to prevent growth of and cross-contamination with STEC.

FOOD DISTRIBUTION CONTROL MEASURES

28. Control measures during distribution to ensure product is stored at an appropriate temperature to prevent growth of STEC, when present, to higher levels and to minimize cross-contamination by STEC are important.

VALIDATION, IMPLEMENTATION, AND VERIFICATION OF CONTROL MEASURES

29. Implementation[v] involves giving effect to the selected control measure(s), development of an implementation plan, communication of the decision on control measure(s), ensuring a regulatory framework and infrastructure for implementation exists, and a monitoring and evaluation process to assess whether the control measure(s) have been properly implemented.

Prior to validation

30. Prior to validation of the control measures for STEC, the following tasks should be completed:

a) Identification of the specific measure or measures to be validated. This would include analysis of any measures agreed to by the competent authority and whether any measure has already been validated in a way that is applicable and appropriate to specific commercial use, such that further validation is not necessary.

b) Identification of any existing food safety objective or target established by the competent authority or FBOs. In order to comply with the target set by the competent authority, FBOs may set stricter targets than those set by the competent authority.

Validation

31. Validation of control measures may be carried out by FBOs and/or the competent authority.

32. Where validation is undertaken for a measure to control STEC, evidence will need to be obtained to show that the measure is capable of controlling STEC to a specified target or outcome. This may be achieved by use of a single measure or a combination of control measures. The *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008)[8] (Section VI) provides detailed advice on the validation process.

Implementation of validated control measures

33. Refer to Section 9.2 of the *Code of Hygienic Practice for Meat* (CXC 58-2005),[5] the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003),[6] and the *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004).[7]

FBO responsibility

34. FBOs have the primary responsibility for implementing, documenting, validating, verifying, and supervising process control systems to ensure the safety and suitability of raw beef, fresh leafy vegetables, raw milk and raw milk cheeses, and sprouts. These should incorporate measures for control of STEC as appropriate to national government requirements and the FBO's specific circumstances, and where applicable, the measures should be applied in accordance with manufacturer's instructions.

[v] See Section 7 of the *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CXG 63-2007).

35. The documented control measures should describe the activities applied, including any sampling procedures, specified targets (e.g. performance objectives or performance criteria) set for STEC, FBO verification activities, and corrective actions.

Regulatory systems

36. The competent authority, working with the relevant food sector, may provide guidelines and other implementation tools to FBOs, as appropriate, for the development of the food hygiene systems.

37. The competent authority should assess the documented process control systems to ensure they are science based and establish verification frequencies. Microbiological testing programmes, or molecular testing programmes, should be established to verify the effectiveness of control measures for STEC.

Verification of control measures

38. Refer to Section 9.2 of the *Code of Hygienic Practice for Meat* (CXC 58-2005),[5] the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003),[6] the *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004),[7] and Section IV of the *Guidelines for the Validation of Food Safety Control Measures* (CXC 69-2008).[8]

Food business operators

39. FBOs may use testing information on indicator microorganisms for verification of STEC control measures due to the high cost of testing for detection of STEC and its low prevalence in food. FBO verification activities should verify that all control measures for STEC have been implemented as intended. Verification should include observation of monitoring activities (such as having an employee with overall responsibility for monitoring activities observe the person conducting a monitoring activity at a specified frequency), reviewing monitoring, corrective action and verification records, and sampling and testing for indicator microorganisms and STEC where appropriate.

40. Due to typically low numbers and low prevalence of STEC in food, quantitative monitoring of STEC is impractical and the utility of presence/absence testing in monitoring process performance is also limited.[13] Process performance monitoring may be accomplished more effectively and efficiently by quantitatively monitoring sanitary and hygiene indicator microorganisms. These indicator microorganisms do not indicate pathogen presence or absence; instead, they provide a quantitative measure of the control of general microbial contamination in the product and processing or growing environment. The hygiene indicator microorganisms used should be those that are the most informative for the specific processing or growing environment. An increase in the number of the indicator microorganisms above established control values indicates a loss of control and the need for corrective action. Additionally, with the increase in the frequency of verification, there is also an increase in the speed of detecting a loss of control of manufacturing hygiene. Verification at multiple points in the processing chain can assist in rapid identification of the specific process step where corrective action should be taken. Monitoring of hygiene indicator microorganisms can be supplemented by periodic testing for STEC, where appropriate and as needed, to make risk-based decisions. If testing results are linked to requirements for corrective action, then STEC testing can contribute to reducing contamination rates, improving food safety, and promoting continuous process improvement.

41. Verification frequency could vary according to the operational aspects of process control, the historical performance of the establishment, and the results of verification activity itself.

42. Record-keeping is important to facilitate verification and for traceability purposes.

Regulatory systems

43. The competent authority should verify that all regulatory control measures implemented by FBOs comply with regulatory requirements, as appropriate, for control of STEC.

MONITORING AND REVIEW

44. Monitoring and review of food hygiene systems is an essential component of the application of a risk management framework.[vi] It contributes to verification of process control and demonstrating progress towards achievement of public health goals. Effective monitoring programmes are essential to verify the effectiveness of STEC control processes throughout the food chain.

[vi] See Section 8 of the *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CXG 63-2007).

45. Information on the level of control of STEC at appropriate points in the food chain can be used for several purposes, e.g. to validate and/or verify outcomes of food control measures, to monitor compliance with regulatory goals for STEC control, and to help prioritize regulatory efforts to reduce foodborne illness. Systematic review of monitoring information allows the competent authority and relevant stakeholders to make decisions in terms of the overall effectiveness of the food hygiene systems and make improvements where necessary.

Monitoring

46. Monitoring via sampling and testing should be carried out at appropriate steps throughout the food chain using a validated diagnostic test and randomized or targeted sampling as appropriate.

47. For instance, the monitoring programmes for STEC and/or indicator microorganisms, when appropriate, in raw beef, fresh leafy vegetables, raw milk and raw milk cheeses, and sprouts may include testing at the farm (e.g. for fresh leafy vegetables), in the slaughter and processing establishments, and retail distribution chains where appropriate and according to the monitoring objective.

48. Competent authority regulatory monitoring programmes should be designed in consultation with relevant stakeholders, where appropriate, and should consider the sampling plan, including the number, location, collection and testing of samples and resource constraints. Given the importance of monitoring data for risk management activities, sampling and testing components of regulatory monitoring programmes should be standardized on a national basis and be subject to quality assurance.

49. The type of samples and data collected in monitoring systems should be appropriate for the outcomes sought. Enumeration and further characterization of microorganisms generally provide more information for risk assessment and risk management purposes than presence/absence testing. Where the regulatory monitoring programme is to be carried out by FBOs, there should be flexibility with respect to the procedures used, as long as the FBO procedures provide equivalent performance to regulatory procedures.

50. Monitoring information should be made available to relevant stakeholders in a timely manner (e.g. where appropriate, to producers, FBOs, competent authorities, the public health sector, and consumers).

51. Monitoring information collected from throughout the food chain should be used to affirm achievement of risk management goals. Wherever possible, such information should be combined with human health surveillance data and foodborne illness source attribution data to validate risk-based control measures and verify progress towards risk-reduction goals.

Laboratory analysis criteria for detection of STEC

52. The choice of analytical method should reflect both the type of sample to be tested and the purpose for which the data collected will be used. The purpose of analysis for bacterial foodborne pathogens, including STEC, can be divided into the following categories:

- product batch or lot acceptance;
- process performance control to meet domestic food regulation;
- to verify controls to meet market access requirements (e.g. to meet microbiological criteria of another country); and
- public health investigations.

53. The number of foods identified as a vehicle for STEC transmission has increased over time. Baseline studies and targeted surveys are conducted to provide prevalence data and identify risk factors along the food chain. These data, together with public health surveillance data, are used in risk assessments and risk profiles of STEC/ food combinations to prioritize foods and 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). Analytical methods that are fit for purpose, that will provide answers to risk management questions, and that are within the resources of governments and FBOs should be chosen.[13] In the event that a laboratory does not have the resources and technology to characterize the isolate, it could be sent to a reference centre/laboratory.

54. The risk of severe illness due to STEC infection can be predicted to a large extent according to virulence factors (encoded by genes) present in an STEC strain, and testing for such factors should be used as complementary data to assess and predict the virulence potential of STEC strains recovered from food samples. Based on current scientific knowledge, all STEC strains are pathogenic for humans and capable of causing illness. However, STEC strains with *stx2a* and adherence genes, *eae* or *aggR,* have the greatest association with severe

illness such as bloody diarrhoea (BD), HUS and hospitalizations. Thus, to appropriately manage the risk of STEC in commodities discussed in this guidance document, tests that detect virulence factors such as these should be used. The risk of severe illness may also depend on virulence gene combinations and gene expression, the dose ingested, and the susceptibility of the human host, so a risk management framework should also be applied when laboratory methodologies for STEC detection are selected by countries.

55. The severity of STEC illness and the potential to cause diarrhoea, BD and HUS, hence the degree of public health relevance, can be defined to a large extent by the combination of virulence genes within an isolated strain of STEC. These combinations can be ranked from the most severe (1) to least severe (5), and are recommended by JEMRA[13] as criteria (Table 1) for developing risk management goals that prioritize:

- the STECs of greatest public health relevance;
- the design of monitoring and surveillance programmes by competent authorities; and
- resourcing public health investigations and recalls in response to a positive test.

56. The JEMRA report notes that the association of Stx subtypes other than Stx2 with HUS is less conclusive and varies depending on other factors, for example host susceptibility, pathogen load, and antibiotic treatment. Knowledge on virulence factors and their combination and their public health importance is evolving rapidly, and it is therefore important to continually monitor new scientific evidence.

Table 1. STEC virulence genes in isolated strains and the potential to cause diarrhoea (D), bloody diarrhoea (BD) and haemolytic uremic syndrome (HUS) (where 1 is the highest risk level). *

LEVEL	TRAIT (GENE)	POTENTIAL FOR
1	stx_{2a} + *eae* or *aggR*	D/BD/HUS
2	stx_{2d}	D/BD/HUS**
3	stx_{2c} + *eae*	D/BD^
4	stx_{1a} + *eae*	D/BD^
5	Other *stx* subtypes	D^

* depending on host susceptibility or other factors; e.g. antibiotic treatment
**association with HUS dependent on stx_{2d} variant and strain background
^ some subtypes have been reported to cause BD, and on rare occasions HUS

57. The determination of virulence and other salient marker genes for testing purposes may be achieved by using, for example, polymerase chain reaction (PCR) methods or whole genome sequencing (WGS) analysis on isolated strains. Special consideration should be given to the efficacy of sample collection techniques to maximize portions of product most likely to be contaminated. The choice of enrichment culture techniques used to recover STEC from foods is also important, as STEC strains are physiologically diverse, with variable growth characteristics. Selective conditions which are permissive to specific sub-populations of STEC, such as *E. coli* serotype O157:H7, can be used, but this poses the risk of inhibiting the multiplication of other STEC strains, preventing their detection.

58. In addition, bacteria other than STEC may contain the same virulence genes and the detection of these genes alone may not fully reflect health risks due to differential or lack of gene expression. It is therefore important to confirm that the defining genes are within a single STEC isolate, following isolation by traditional culture, with or without immunomagnetic separation (IMS), or other validated methods (e.g. molecular techniques). An isolate may also be required for characterization of STEC (e.g. molecular sequencing for epidemiological investigation) and a better estimation of food safety risk.

59. The virulence genes carried by STEC isolates should be considered when deciding how STEC will be managed in food commodities, including the actions to be taken when STEC is detected in the food. As shown in Table 1, different combinations of virulence genes differ in the risk for severe illness, but other factors also play a role. Both strains carrying particular virulence genes and other factors associated with a greater risk of severe illness, or number of illnesses, may vary regionally. Countries may identify factors to differentiate STEC that are considered to be a higher priority (e.g. those strains with virulence factors capable of causing severe illness or considered to cause significant numbers of illness in that country) from those that are a lower priority. In general, more stringent corrective actions would be applied in response to the presence of high priority STEC strains.

Review

60. Periodic review of monitoring data for STEC at relevant process steps should be used to inform the effectiveness of risk management decisions and actions, as well as future decisions on the selection of specific control measures for STEC and provide a basis for their validation and verification.

61. Information gained from monitoring for STEC in the food chain should be integrated with human foodborne disease surveillance, food source attribution data, and withdrawal and recall data, where available, to evaluate and review the effectiveness of STEC control measures from primary production to consumption.

62. Where monitoring of hazards or risks indicates that regulatory performance goals are not being met, risk management strategies and/or control measures should be reviewed.

Public health goals

63. Competent authorities should consider the results of monitoring and review when re-evaluating and updating public health goals for control of STEC in foods, and when evaluating progress. Monitoring of food chain information in combination with data on food source attribution and human health surveillance is an important component. The surveillance and application of controls for the proper functioning of the STEC control systems need to ensure that the food chain is sufficiently safe for human health.

NOTES

[1] FAO and WHO. 2003. *Guidelines on the Judgement of Equivalence of sanitary Measures Associated with Food Inspection and Certification Systems.* Codex Guideline, No. CXG 53-2003. Codex Alimentarius Commission. Rome.
[2] FAO and WHO. 1997. *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods*. Codex Guideline, No. CXG 21-1997. Codex Alimentarius Commission. Rome.
[3] FAO and WHO. 2007. *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM).* Codex Guideline, No. CXG 63-2007. Codex Alimentarius Commission. Rome.
[4] FAO and WHO. 1969. *General Principles of Food Hygiene.* Codex Code of Practice, No. CXC 1-1969. Codex Alimentarius Commission. Rome.
[5] FAO and WHO. 2005. *Code of Hygienic Practice for Meat.* Codex Code of Practice, No. CXC 58-2005. Codex Alimentarius Commission. Rome.
[6] FAO and WHO. 2003. *Code of Hygienic Practice for Fresh Fruits and Vegetables.* Codex Code of Practice, No. CXC 53-2003. Codex Alimentarius Commission. Rome.
[7] FAO and WHO. 2004. *Code of Hygienic Practice for Milk and Milk Products.* Codex Code of Practice, No. CXC 57-2004. Codex Alimentarius Commission. Rome.
[8] FAO and WHO. 2008. *Guidelines for the Validation of Food Safety Control Measures.* Codex Guideline, No. CXG 69-2008. Codex Alimentarius Commission. Rome.
[9] FAO and WHO. 1999. *General Standard for the Use of Dairy Terms.* Codex Standard, No. CXS 206-1999. Codex Alimentarius Commission. Rome.
[10] FAO and WHO. 2022. *Prevention and control of microbiological hazards in fresh fruits and vegetables – sprouts.* Microbiological Risk Assessment Series No. 43. Rome.
[11] FAO and WHO. 2007. *Working Principles for Risk Analysis for Food Safety for Application by Governments.* Codex Guideline, No. CXG 62-2007. Codex Alimentarius Commission. Rome.
[12] FAO and WHO. 1999. *Principles and Guidelines for the Conduct of Microbiological Risk Assessment.* Codex Guideline, No. CXG 30-1999. Codex Alimentarius Commission. Rome.
[13] FAO and WHO. 2018. *Shiga toxin-producing Escherichia coli (STEC) and food: attribution, characterization, and monitoring.* Microbiological Risk Assessment Series No. 31. Rome. Available at http://www.fao.org/3/ca0032en/ca0032en.pdf.

ANNEX I

RAW BEEF

INTRODUCTION

1. Foodborne outbreaks of Shiga toxin-producing *Escherichia coli* (STEC) have been linked to a wide variety of foods, including meat products. Beef is one of the most significant sources of foodborne STEC outbreaks, with raw or undercooked non-intact raw beef products (e.g. ground/minced or tenderized beef) recognized as posing an elevated risk to consumers.

2. STEC can be part of the normal intestinal microbiota of cattle, with the reported prevalence in cattle faeces varying greatly, depending on factors such as animal age, herd type, season, geographic location, and production type. STEC shedding by individual cattle is transient and episodic. In addition, STEC can be found within the farm environment, and it is therefore likely that cattle arriving for slaughter have STEC on their hides. Individual feedlot cattle studies have reported high prevalence of STEC on cattle hides presenting for slaughter.

3. The sporadic nature of STEC and common movement and comingling of cattle through means such as feedlots, lairage, and livestock markets allows STEC to spread between animals and herds. The transient nature of STEC in cattle and the impracticality of testing all cattle for STEC prior to slaughter demonstrates the need for slaughter operations to treat all incoming cattle as if they could have STEC on the hide or could be shedding STEC in their faeces.

4. STEC carried by cattle could be spread to carcasses during slaughter. Prior to slaughter, the muscle tissue of healthy cattle is free of STEC. STEC can be transferred to carcass surfaces from the contents of the gastrointestinal tract or hide during the operations of de-hiding, head removal, bunging and evisceration. Generally, contamination is confined to the carcass surface and is not found in deep muscle tissues of intact raw beef.

5. STEC contamination has historically been detected in non-intact raw beef products. Practices including grinding/mincing, and mechanical tenderization in which blades or needles penetrate the muscle surface, create a potential for increased food safety risks due to the transfer of pathogens from the surface to the interior, resulting in internalization of STEC into previously intact raw beef.

6. Mixing of tissues from one or multiple animals/herds can increase the likelihood of spreading and diluting STEC contamination of ground/minced raw beef. Distribution and level of STEC in non-intact raw beef, such as ground/minced products, are often higher than in intact beef because ground or disrupted tissue presents an environment that is more conducive for bacterial growth. In addition, many of the processing and post-processing interventions are more efficacious if the targeted pathogen is exposed on the surface of the meat as opposed to embedded within a tissue matrix.

SCOPE

7. This guidance applies to control of STEC in raw beef, including non-intact products such as raw ground/minced or tenderized beef.

8. This guidance does not apply to raw beef meat preparations (raw beef meat which has had foodstuffs, seasonings or additives added to it).

DEFINITIONS

9. For the purpose of this guideline, the following definitions apply:

Non-intact raw beef:[i] Comminuted beef products such as those that are ground or minced, as well as those that have been mechanically tenderized.

Raw beef: Skeletal muscle meat from slaughtered cattle, including primal cuts,[ii] sub-primal cuts, and trimmings.

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[i] Non-intact raw beef products can also include raw beef that has been injected/enhanced with solutions or reconstructed into formed entrees (e.g. beef that has been scored to incorporate a marinade, beef that has a solution of proteolytic enzymes applied to or injected into the cut of meat, or a formed and shaped product such as beef gyros), but these non-intact beef products are out of scope for this document.

[ii] A primal cut is a piece of meat on the bone initially separated from the carcass of an animal during butchering. Primal cuts are then divided into sub-primal cuts. These are basic sections from which steaks and other subdivisions are made.

Minced beef: Boneless beef which has been comminuted, i.e. reduced into fragments.[iii]

Tenderized raw beef:[iv] Cuts of beef that have gone through a technological process for the rupture of muscle fibres by mechanical action with small blades or needles which penetrate the muscle surface thereby resulting in tenderizing.

PRIMARY PRODUCTION TO CONSUMPTION APPROACH TO CONTROL MEASURES

10. These guidelines incorporate a "primary production to consumption" flow diagram that identifies the main steps in the food chain and identifies where control measures for STEC may potentially be applied in the production of raw beef. Some of the control measures of this document may be subject to approval by competent authorities.

11. While control in the primary production phase can decrease the number of animals carrying and/or shedding STEC, controls after primary production are important to prevent the contamination and cross-contamination of carcasses and, in particular, raw ground/minced beef. The systematic approach to the identification and evaluation of potential control measures allows consideration of the use of controls in the food chain and allows the application of control measures individually or in combination. This is particularly important as individual countries use different primary production and processing systems. Risk managers need the flexibility to choose risk management options that are appropriate to their national context.

12. STEC have a wide range of potential hosts, and STEC cells can potentially persist for over a year in the natural environment; therefore, effective control strategies based on preventing STEC infection of cattle or contamination of their environment can be difficult to implement.

13. Interventions to control enteric pathogens should always be part of an integrated food safety system that includes all the stages from primary production to consumption. Measures to reduce STEC shedding or hide contamination prior to slaughter have the potential to reduce environmental exposure to STEC and may improve raw beef safety, but they cannot prevent STEC contamination or compensate for poor hygienic practices during slaughter, processing, and distribution. Conversely, there is evidence that the adoption of good hygienic practices during slaughter and processing can minimize carcass contamination with STEC. Consequently, the adoption of best practices for preharvest management of cattle can support hygienic slaughter and processing.

14. Operations to decontaminate carcasses or raw beef cuts will be of limited effectiveness if poor hygienic practices during subsequent processing and distribution permit recontamination or if the initial contamination load is high. Decontamination only reduces STEC by a certain amount, which can be quite variable depending on the type of treatment, duration, method of application, operator training, temperature, etc.

GENERIC FLOW DIAGRAM FOR APPLICATION OF CONTROL MEASURES

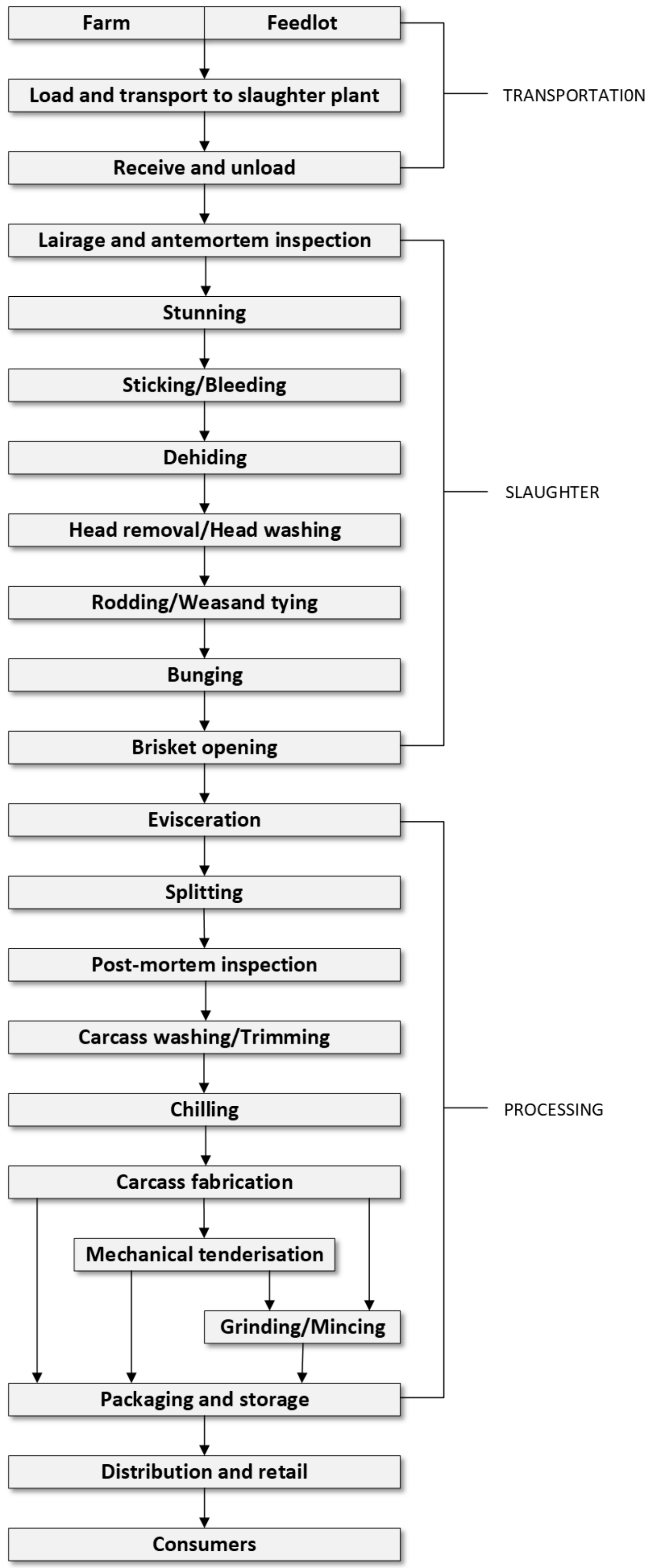
15. Figure 1 provides an example of a process flow diagram for primary production to consumption of beef.

16. These process steps are generic, and not all the steps may occur during processing, in the order shown, or at the same establishment. Grinding/mincing, for example, can be done at sites other than the slaughter or fabrication site, and carcass washing with or without biocides is not performed in all countries or slaughterhouses. This flow diagram is for illustrative purposes only. For application of control measures in a specific country or an establishment, a complete and comprehensive flow diagram should be drawn up for each situation.

[iii] Adapted from the *Code of Hygienic Practice for Meat* (CXC 58-2005).

[iv] Tenderizing processes that include the injection of solutions with or without a vacuum are out of scope.

Figure1: Example flow diagram of raw beef primary production and processing



PRIMARY PRODUCTION

17. Control measures to reduce the carriage of STEC in cattle prior to slaughter and that have the potential to reduce the prevalence of STEC are described in this section.

Specific Control Measures for Primary Production

18. The prevalence of STEC shedding in a herd and the individual animal shedding status for STEC is generally unpredictable, although factors have been identified that may influence STEC shedding. Interventions proposed to reduce the prevalence of STEC shedding or numbers of STEC shed by cattle include animal vaccination, dietary additives used in water and feeds, manipulation of animal feeds, and primary production management practices, as explained below.

19. Many of these proposed pre-slaughter control methods have not been demonstrated to effectively reduce the prevalence or the level of STEC shedding from cattle in a commercial setting. Research into pre-harvest control of STEC in cattle has focused on the serotypes O157:H7 and O157: NM and so there is often limited data available on the impact on other STEC serotypes. Additionally, some of the proposed methods are focused on specific subpopulations of STEC (e.g. vaccines).

Diet components

20. A wide variety of cattle diets have been investigated for their impact on STEC serotype O157:H7 prevalence and/or level of shedding, including hay, barley, distillers and brewers' grains, sage brush, millet, alfalfa. Both STEC serotype O157:H7 and generic *E. coli* populations have been demonstrated to respond to changes in diet, but replication of results indicating STEC serotype O157:H7 reduction has been poor, and no dietary composition has been identified that reliably reduces STEC serotype O157:H7. Some diets that have been proposed increase STEC serotype O157:H7 shedding.

21. In general, research supports that cattle on grain-based diets appear to shed higher levels of generic *E. coli* in their faeces than cattle on forage diets, but the effect of forage diets on faecal shedding of STEC serotype O157:H7 is inconclusive.

Use of direct-fed microbials

22. Faecal shedding of STEC serotype O157:H7 by cattle can be reduced using direct-fed microbials (DFM) such as *Lactobacillus acidophilus* and *Propionibacterium freudenreichii*. The impact of DFM against STEC is highly specific, thus STEC reduction with one probiotic product cannot necessarily be extrapolated to another product. To be effective, the component strains in the product should be consistent and the products should be administered at the recommended CFU/g doses in feed.

Vaccination

23. Some vaccines have been shown to reduce faecal shedding of STEC serotype O157:H7 but their efficacy at individual level is dependent on type of vaccine and the number of doses administered; most vaccines will need more than one application in order to be effective. The impact of reducing STEC serotype O157:H7 in raw beef is dependent on the extent of adoption of vaccination. The use of vaccines should consider feasibility of application regimes to ensure their efficacy at individual and herd level.

Good management practices at primary production

24. The following good management practices for cattle are recommended for minimizing STEC shedding and hide contamination on animals presented for slaughter. Of particular concern is preventing the formation of faecal accumulation on animal hides, as this can interfere with hygienic dehiding and evisceration.

- Stressful situations should be minimized wherever possible, because increased stress increases shedding of pathogens (e.g. poor animal husbandry, rough handling, dietary stress (including sudden changes to diet) and feed deprivation).
- Minimize exposure between herds to avoid or reduce horizontal transmission of STEC across herds.
- Reducing animal density to reduce direct animal-to-animal transmission (e.g. maintain ample space for animals to move to reduce defecation directly onto one another).

- To the extent of possible, maintain clean living conditions (e.g. clean holding areas, remove gross contamination, and maintain clean and dry bedding) to prevent potential transmission from the living environment (e.g. animals resting in STEC-contaminated materials). Use of slatted housing requires careful attention to stocking density to avoid hide soiling.
- Reduce the potential for STEC transmission through consumption of contaminated feed and water by the following:
  - Design feed and water delivery systems (tanks, trough, bins, etc.) in a way to reduce the potential for animal entrance and defecation.
  - Ensure water is fit for purpose and of a microbiological quality that minimizes animal contamination. If there is doubt, treat the water to render it both microbiologically and chemically safe.
  - Clean water troughs and, when possible, use materials in water troughs that facilitate the cleaning process.

TRANSPORTATION

Specific control measures for transport to slaughterhouse

25. Transportation can be a major contributor to the increasing occurrence of pathogens in cattle and a source of hide contamination. Contributing factors include mixing of animals of different origin, increased stress, increased exposure to STEC during extended duration of transportation, and cleanliness of transport vehicles.

26. Transportation practices should minimize any condition that could affect contamination of the meat. Control measures implemented prior to transportation may include:

- Handle animals so that they are not unduly stressed.
- As much as practical, minimize the distance over which cattle are transported to slaughter; longer transportation distances have been shown to increase the risk of having STEC-positive hides at slaughter compared to cattle that travel a shorter distance.
- Ensure animals are as clean as possible to reduce the risk for pathogen cross-contamination from hides onto carcasses during the slaughter and dressing processes. The likelihood of STEC contaminating the meat increases where levels of faecal contamination on the hide are high.
- Load the animals onto clean vehicles, prevent faecal transfer from the top level to bottom level in multi-level trailers to the extent possible, and do not overcrowd the vehicle.

27. Cross-contamination among animals from different farms during transportation to the slaughter facility and at lairage (holding pens) can be an important source of hide contamination. Therefore, appropriate controls should be in place to minimize hide contamination. Controls may include:

- When possible, separate lots of animals from different farms, use holding pens of an appropriate size for the number of animals, avoid overpopulation and stress of the animals.
- Appropriately clean holding pens between lots of cattle.
- Implement visual inspection and controls, when needed, for soiled animals, transportation vehicles and lairage pens for visible faecal contamination.

Specific control measures at receive and unload

28. Maintain herd integrity during load assembly and transport through unloading and placing in holding pens. To minimize STEC shedding, stress levels should be minimized using good animal handling practices; minimize or eliminate the use of electric prods and avoid overcrowding.

29. Adequate training of the operators on procedures that can minimize stress at this step (which could increase shedding of STEC) is recommended.

SLAUGHTER AND DRESSING

30. Good hygiene practices (GHP) and emphasis on good manufacturing practices (GMP) at slaughter are necessary to prevent transfer of STEC from the hide and digestive tract to the carcass. Particular focus should be given to ensuring best practice in the operations of dehiding, head removal, clipping the weasand, bunging and

evisceration, as these operations are the initial sources of microbiota that contaminate meat surfaces. Other measures may include physical chemical, or biological interventions that can be applied alone or in combination; these are likely to reduce the number of STEC microorganisms but should not be considered to eliminate STEC on every carcass.

31. The specific control measures during this stage are intervention techniques aimed at preventing transfer of contamination to the carcass, as well as cross-contamination to other carcasses. Interventions selected should be validated for their effectiveness.

32. Interventions aimed at removing STEC from the surface of beef carcasses should consider that tolerance to salt and acid has been observed in some STEC strains. Determining the effectiveness of interventions to reduce microbial pathogens is complex, particularly as multiple interventions may be applied simultaneously or in sequence. The impact of interventions should be validated (e.g. by conducting experimental trials with surrogate microorganisms that have similar or greater resistance to individual treatments than STEC. Careful consideration is needed when determining suitable strains for validation of interventions, since surrogates may not necessarily be equivalent to wild-type strains isolated from raw beef).

33. Interventions should be safe and application feasible along the production process and should not change the organoleptic properties of beef.

34. The interventions described for the following steps may reduce the level of microbiota, including STEC, on raw beef. Many operations can be performed manually or with automated equipment. Automation of interventions offers the advantage of greater consistency of application but needs proper adjustment and supervision.

35. Operators should be effectively and appropriately trained to perform their operation in the slaughter process in order to minimize the potential for STEC contamination.

Specific control measures at lairage and antemortem inspection

36. In this stage, the condition of the animals should be evaluated; animals should be as clean and dry as possible to minimize the initial load of microorganisms, which potentially includes STEC, on their hide. STEC is harboured on the hide, not only in faecal material, but also in dried-on dust. The level of both on the hide should therefore be minimized. Where practical, dirty, or wet animals should be segregated to prevent cross-contamination.

37. The lairage area should be cleaned to the extent possible for each lot of animals using fit-for-purpose water under appropriate pressure to remove gross contamination on the floor. Cleaning and disinfection should be applied according to GHP and manufacturer’s instructions. The lairage area should be designed to be well-drained in order to facilitate drying. A dry bedding area is preferable where possible (e.g. the use of straw-bedded pens may be considered). Whenever possible, waiting time at the lairage should be minimized.

38. GHP such as washing dirty live animals (e.g. spray, mist, rinse, or wash), specifically the animal´s hide, with different substances (e.g. fit-for-purpose water, bacteriophage) to reduce contamination has been investigated. However, in general, the evidence for washing in reducing the transfer of STEC from hide to carcass is low.

39. When feasible, at lairage cattle should not be comingled with other herds/lots to prevent cross-contamination between herds/lots.

Specific control measures at stunning, sticking and bleeding

40. Prior to stunning, animals may be sprayed in the accessway using low volume water jets at appropriate pressure. Similarly, the perianal region may be washed, but sparingly and only to remove faeces (the source of STEC) released during the stunning process. Washes should be designed to reduce faecal and STEC contamination and not stress the animal or inhibit the stunning, sticking or bleeding effectiveness. Where water is applied, consideration should be given to removal of excess water prior to hanging of the carcass.

41. The stunning box and sticking table should be kept as clean as possible with frequent removal of faeces and ingesta to avoid contamination of animal hides in the fall after the stunning process.

42. Any stunning method (e.g. self-contained bolt, firearm, electrical stunning) should be evaluated and used in a manner that minimizes STEC transfer into the head meat.

43. Sticking and bleeding should be done in a manner to reduce transfer of hide contamination to the carcass. This includes cleaning and disinfection of knives. Preparing the penetration or cut sites (e.g. with steam/vacuum treatment or a mechanical process like scraping the hide surface) can reduce the likelihood of contamination.

44. Allow an adequate distance between carcasses (i.e. avoid carcass-to-carcass contact), walls and equipment to minimize cross-contamination during processing.

Specific control measures at dehiding

45. Dehiding is the systematic process for separating the hide from the carcass and is perhaps one of the most critical operations in determining the level of STEC transferred to the carcass. To prevent transfer of contamination from the hide to the freshly exposed carcass, operators working at this stage should be appropriately trained to perform this operation to maximize hygienic dressing.

46. To prevent transfer of contamination from the hide to the carcass during hide opening (opening cuts), techniques can include:

- Using clean and disinfected knives to cut through the hide.
- Cleaning and disinfecting the knife (or tool) each instance the hide is penetrated, or using different knives, one to cut through the hide and the other to remove the hide.
- Using a systematic trimming pattern, to work outward from a single hide opening site.
- Using one hand to hold, pull and control the hide while separating/cutting the hide away from the carcass using the other hand.
- Washing hands and aprons as often as needed to prevent cross-contamination of carcasses.

47. The number of workers, their training requirements, and the role of their rotation in cross-contamination during the dehiding process, needs to be considered.

48. The dehiding operation should be performed in a manner to avoid contact of the hide with the already exposed parts of carcass (i.e. dehiding the entire peri-anal region and bending the hide, making it stay above the tail). Using non-absorbent paper to protect specific areas of the carcass such as the brisket and bagging of the tail may also be useful practices for reduction of STEC contamination due to contact with hide during dehiding. Remove the hide from the top down rather from the bottom up to prevent contaminating the carcass with dust and hair that may be contaminated with STEC. Care should also be taken to avoid cross-contamination in other operations carried out simultaneously with dehiding, such as the removal of the pizzle, the skinning of the shank tendons, the removal of the udder or scrotum, and transfers by overhead rail.

49. Measures should be taken to prevent tail flapping and its contact to the carcass when hide pullers are used.

Specific control measures at rodding

50. The rodding operation consists of using a metal rod to free the oesophagus (weasand) from the trachea and surrounding tissues. In some countries, weasand meat may be recovered from the gastrointestinal tract for use in raw ground/minced beef production. The rodding operations should be performed in a manner to avoid contamination of the weasand and of the carcass interior from the exterior. If, during the rodding operation the gastrointestinal tract is punctured, it can cause contamination of the carcass interior and exterior with ingesta.

51. To prevent cross-contamination of the carcass from the weasand/oesophagus during the rodding operation, procedures can include:

- Avoid a delay in tying the weasand to minimize contamination of neck meat with STEC.
- Hanging the carcass vertically, to cut the muscle and tissue to expose the oesophagus.
- Using ties, clips, or bungs to close the weasand hygienically to prevent rumen spillage.
- “Dropping” heads by cutting the oesophagus below the tie or clip.
- Changing or cleaning and disinfecting the weasand rod between each carcass.

52. If the gastrointestinal tract has been punctured, causing a major contamination, the carcass should be identified and additional procedures to avoid cross-contamination of other carcasses should be performed, such as separating the carcass immediately from the others.

53. When appropriately applied, these procedures will reduce contamination with gut microorganisms, but their specific effect on contamination by STEC remains unknown. Nevertheless, procedures that reduce faecal contamination are most likely to have an impact on STEC contamination.

Specific control measures at bunging

54. Bunging is the point in the slaughter process where a cut is made around the rectum to free it from the carcass. Then it is tied off and bagged to prevent spillage of faecal material.

55. Rectum occlusion should be performed hygienically, in order to avoid contamination of the carcass and tools with the gastrointestinal contents or the hide, if the dehiding was not already done.

56. The use of separate clean knives for dehiding and rectum removal is recommended to avoid cross-contamination of the rest of the carcass.

57. To prevent transfer of contamination from the bung to the carcass, techniques can include:

- Stuffing the bung with physical materials (e.g. paper towels) to push faecal material into the bung and reduce faecal movement out of the bung.
- Bag the bung by wrapping the bung in a bag and fastening it, i.e. with a rubber band, to contain any leakage that may occur during the evisceration process.

Specific control measures at brisket opening

58. Brisket opening should be performed hygienically to avoid contamination of the carcass and tools, especially if dehiding has not been done.

59. To prevent introduction of contamination into the carcass during brisket opening, procedures can include:

- Cleaning and disinfecting the brisket saw and knife between each carcass and ensuring that the gastrointestinal tract is not punctured.
- If the gastrointestinal tract has been punctured causing a major contamination, the carcass should be identified and additional procedures to avoid cross-contamination of other carcasses should be performed, such as separating the carcass immediately from the others.

PROCESSING

60. STEC on the carcass can remain on meat cuts or be transferred to previously uncontaminated meat cuts as the carcass is further processed, especially via hands and meat processing equipment.

Specific control measures at evisceration

61. Evisceration includes procedures to remove the digestive track and organs from the carcass. The evisceration should be done avoiding contamination with gastrointestinal contents due to a cut in the gastrointestinal tract.

62. To prevent contamination of the carcass by the viscera during removal, techniques can include the following:

- Removing visible contamination from the area to be cut (e.g. by trimming, by using air knives, or by steam vacuuming) before the cut is made. This should be done in a timely manner and in accordance with commonly accepted reconditioning procedures.
- Use belly spreaders, when possible.

63. To prevent contamination of the carcass by employees during evisceration, techniques can include:

- The appropriate use of knives and equipment to prevent damage (i.e. puncturing) to the rumen and intestines.
- Using footbaths or separate footwear by employees on moving from evisceration lines to prevent contaminating other parts of the operation.
- Using trained and experienced individuals to perform the evisceration; this is particularly important at higher line speeds.

64. If the gastrointestinal tract has been punctured causing a major contamination, no further work should be carried out on the carcass until it has been removed from the slaughter line. Cleaning of the environment as well

as operator protective equipment and tools being used at the time of the contamination event should be undertaken as needed, to prevent cross-contamination of leading and trailing carcasses.

Specific control measures at carcass splitting and trimming

65. Carcass splitting is the point in the process where carcasses are split vertically into two halves.

66. To prevent the split carcass from becoming contaminated, techniques can include:

- Removing visible carcass defects that may contaminate the saw or cleaver (e.g. faeces, milk, ingesta, abscesses) in a sanitary manner before splitting the carcass.
- Cleaning to remove organic material and disinfecting the saws and knives between each carcass.
- Allowing adequate distance between split half carcasses and between different carcasses (i.e. avoid carcass-to-carcass contact), walls and equipment.

67. Targeted removal of visible contamination on carcasses by trimming may be applied, but trimming may also contribute to possible redistribution of contamination on the carcass or cross-contamination of other carcasses from knives (if not using a knife-switching disinfection protocol in-between cuts) and personnel hands/gloves. Removal of visible faecal material from carcasses is a GHP; there is published evidence of efficacy for reducing STEC in raw beef, although the efficacy of this intervention is dependent on the workers' skill level.

68. Carcass trimming should be done in an area designated for that purpose and should result in trimmed carcasses that are free of visible contaminants.

Specific control measures at post-mortem inspection

69. Post-mortem inspection is useful to detect faecal contamination and some GHP-based measures at this step that could prevent contamination with STEC are:

- Ensuring the line speed and the amount of light are appropriate for effective post-mortem inspection of carcasses and visualization of physical contaminants (e.g. faecal material, bone dust, and hair).
- Minimizing touching the carcasses with hands, tools or garments during post-mortem inspection palpation and incision to reduce cross-contamination. Hands-free inspection should be encouraged, where possible.

Specific control measures at carcass washing

70. Carcass washing with potable water alone may remove visible soiling and reduce overall bacterial counts on beef carcasses. However, care must be taken when washing carcasses to prevent splashing and spread of contamination.

71. The effectiveness of validated biocidal carcass washing depends on factors such as concentration, temperature, method of application, operator competency and the initial load of STEC on the carcass.

Carcass washing with biocides

72. Carcass washing with biocides, such as organic acids (e.g. citric acid, lactic acid, acetic acid), oxidising agents (e.g. chlorine, peroxides, ozone) or other agents, in accordance with label directions, may be effective in reducing STEC. Some biocidal treatments may be applied with hot water to have a combined thermal impact. Individual STEC strains may vary in their sensitivity to such treatments. Organic acids alone can reduce but not completely eliminate STEC serotype O157:H7.

Carcass surface pasteurization

73. This form of treatment is most commonly applied to carcass sides at the end of dressing. Water at ≥85 °C may be applied as a spray, a sheet or as steam. Treatment is most effective when applied to clean, dry carcass sides as large drops or sheets of water; when applied under such conditions the treatment can achieve reductions in total *E. coli* in commercial slaughter operations.

Steam and vacuum

74. The carcasses are sprayed with steam and then an aspiration is performed, which fulfils a double function of eliminating and/or inactivating surface contamination. The manual device includes a vacuum tube with a hot water spray nozzle, which delivers water at approximately 82–95 °C on the surface of the carcass. The process is effective at removing visible contamination on the carcasses.

Specific control measures at chilling

75. Rapid chilling minimizes the potential for bacterial growth; STEC can only replicate at temperatures of 7 °C and above. The potential for bacterial growth is also dependent upon the water activity at the carcass surface, and if water activity is low enough (less than a_w 0.95), a decline in bacterial numbers will occur. Thus, controlling the humidity of the chilling process can impact STEC levels on the carcass.

Specific control measures at carcass fabrication (mechanical tenderization, grinding/mincing)

76. Mechanical tenderizers and associated processing equipment should be cleaned and disinfected on a regular basis to minimize the potential for translocating STEC from the exterior surface of the product to the interior and to minimize the potential for cross-contamination among lots of production.

77. Manufacturers of tenderized beef should consider supplier assurances that require the incoming meat to be produced in accordance with good agricultural practices (GAPs) and GHPs to reduce STEC or, in the absence of these assurances, treat the beef prior to mechanical tenderization.

78. Biocidal washes, such as lactic acid, peroxyacetic acid and acidified sodium chlorite have been shown to reduce the concentration of *E. coli* serotype O157:H7 and other STEC on beef (i.e. carcasses, primal cuts, or other cuts). Biocidals could be used to minimize contamination of precursor materials used to manufacture ground/minced beef.

79. To minimize STEC contamination of, and/or the spread of contamination throughout ground/minced beef, measures may include, where appropriate (e.g. supported by a risk assessment and context in the country of production or end use):

- Storing products to prevent the growth of STEC. Multiplication of STEC is inhibited below 7 °C, but low temperatures do not significantly reduce STEC. Establishments need to control STEC, using adequate time/temperature combinations.
- Cleaning/disinfection of equipment and the environment on a regular basis and ensuring employees follow GHPs to avoid cross-contamination.
- Treating the outer surfaces of the beef with organic acid sprays or other validated treatments.
- Appropriately chilling raw meat during production to reduce possible multiplication of STEC if they are present.

80. When appropriate and indicated by conditions (e.g. to validate a process or intervention, or monitor effectiveness of a control system or process; when a deviation, disruption or change to a process, has been identified or suspected), manufacturers could specify that beef that will be used for grinding or already minced beef should be pretested according to a defined sampling plan and samples found negative (i.e. not detected) for specific strains of STEC, e.g. *E. coli* serotype O157:H7.

81. Since processes such as grinding/mincing may potentially spread contamination in the meat, there should be increased awareness when handling ground/minced beef products throughout the rest of the food chain.

Specific control measures at packaging and storage

82. A range of non-thermal preservation technologies (e.g. pulsed light, natural bio-preservatives, high hydrostatic pressure, ionizing radiation) and thermal preservation technologies (e.g. microwave and radiofrequency tunnels, Ohmic heating or steam pasteurization) have been investigated for meat decontamination either during processing or after final packaging. The practical use of these methods is dependent upon the impact on the organoleptic properties of the meat and its final use. Factors determining the effectiveness of such treatments include the sensitivity of the microorganism, the temperature of the environment, the intrinsic characteristics of the food (e.g. fat content, salt, additives, pH) and the level of initial contamination.

83. During packaging and storage, temperature control should minimize the potential for bacterial growth; STEC can only replicate at temperatures of 7 °C and above.

DISTRIBUTION/RETAIL

Specific control measures at distribution and retail

84. Control of refrigeration temperatures should be maintained during transport and storage of the carcasses, beef cuts, or minced/ground beef along the distribution chain until the product reaches the consumer.

85. Raw beef should be stored and prepared separately from cooked or ready to eat food to prevent cross-contamination. If product is removed from the original package for further processing or re-portioning, appropriate good hygienic practices should be observed to avoid recontamination with STEC.

Packaging conditions

86. Ground/minced products should have sufficient information so that the recipient can safely handle and prepare the product, e.g. use-by dates and the need for thorough cooking on the label.

87. Since not all tenderized products are readily distinguishable from non-tenderized products, labelling to state that the product is tenderized, along with validated cooking instructions, should be included to provide consumers and food service workers the essential information to safely prepare the product.

CONSUMERS

88. The consumer has an important role in the prevention of foodborne illness from STEC during the manipulation of raw beef at home and should be made aware of the proper cooking and handling of raw beef.

89. Since non-intact raw beef products may pose an increased risk for consumers, appropriate consumer guidance on safe handling, including cooking temperatures, may be needed.

90. Consumers should apply the general principles for safer food to ensure safety of raw beef when handling, preparing and consuming beef. These are:

- Keep the food preparation and consuming sites clean.
- Separate raw and cooked food to avoid/prevent cross-contamination.
- Cook appropriately.
- Keep food at safe temperatures.
- Use safe water and raw materials for food preparations.

VALIDATION OF CONTROL MEASURES

91. Refer to the general section of this guidance.

MONITORING OF CONTROL MEASURES

92. Monitoring data are used to measure the effectiveness of any control measure put in place, to establish alternative or improved measures, and to identify trends and emerging STEC hazards, food vehicles, and food chain practices.

93. Process performance monitoring may be accomplished more effectively and efficiently by quantitatively monitoring indicator microorganisms. These indicator microorganisms do not indicate pathogen presence; instead, they provide a quantitative measure of the control of microbial contamination in the product and processing environment. Periodic testing for the 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 country) may also be conducted for verification of process performance.

94. Some raw beef will need more control measures and monitoring than others (e.g. non-intact raw beef).

VERIFICATION OF CONTROL MEASURES AND REVIEW OF CONTROL MEASURES

95. STEC testing may be an important part of verification of process performance. However, STEC are generally present at very low levels and are characterized by heterogeneous distribution (including in ground/minced products), making STEC detection challenging. This means that there may be a significant delay in identifying loss of process control based on STEC detection. Consequently, verification programmes should focus on quantitative monitoring of indicator microorganisms. Hygiene indicators used should be those that are the most informative for the specific processing environment. An increase in the numbers of the selected indicator microorganisms indicates decreasing process control and corrective action should be taken. The speed in detecting a loss of control increases with the verification frequency. Verification at multiple points in the processing chain can assist in rapid identification of the specific process where corrective action should be taken.

96. Regular 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 demonstrated to cause significant illness in that country) can also be conducted for verification of process performance. Lot testing may be of significant utility, particularly in

raw beef that is intended for further processing into ground/minced beef and contributes to directly reducing contamination rates in retail ground/minced beef and promoting continuous process improvement.

97. Verification of other control measures, (e.g. concentration of organic acid, temperature of a steam/vacuum or hot water treatment, etc.), should be routinely conducted in addition to appropriate microbiological testing.

CONSIDERATIONS FOR LABORATORY TESTING FOR DETECTION OF STEC IN RAW BEEF

98. Intact raw beef cuts used for purposes other than the manufacture of finished ground or blade tenderized raw beef products do not present the same level of risk, since STEC will be on the external surfaces that will receive the most heat in cooking; testing for STEC therefore offers limited value. However, when the final intended use of raw beef cuts is not known, sampling could be implemented for STEC strains demonstrated to be a country's highest priority for verification and if supported by in-country risk assessment. In general, the occurrence of STEC in meat products is lower for intact meat products than in trim or ground/minced beef. However, the overall occurrence of STEC in these products can vary considerably due to differences in primary processing and post-processing conditions and interventions.

ANNEX II

FRESH LEAFY VEGETABLES (under development)

ANNEX III

RAW MILK AND RAW MILK CHEESES

INTRODUCTION

1. Although most milk for drinking is either pasteurized or sterilized by ultra-high temperature (UHT) processing, raw drinking milk is consumed in many countries. Raw milk cheeses are fermented products made from raw milk that are consumed in a variety of countries around the world. Cheeses are produced by both large manufacturers and small factories such as farm cheese producers, artisanal cheese producers or large-scale industry and cheese makers. Specific combinations of ingredients and cheese-making processes are used by manufacturers to obtain a wide variety of cheeses with desired characteristics that meet consumer expectations.

2. Raw milk and raw milk cheeses have been associated with foodborne infections in humans from different countries caused by Shiga toxin-producing *Escherichia coli* (STEC). Consuming raw drinking milk or raw milk cheeses without any control measures is associated with a higher risk of illness than drinking pasteurized milk or eating cheeses made from milk subject to heating such as thermization[i] in conjunction with other control measures or pasteurization to reduce the risk from foodborne pathogens. The infectious dose for STEC in raw milk or raw milk cheese is low. A comprehensive approach, considering all the aspects of raw milk and raw milk cheeses from production to consumption, is necessary to reduce the presence of STEC in these products.

3. Cattle are a main source of STEC. Infected cattle can carry the bacteria in their gastrointestinal tract without any symptoms of disease and shed them in their faeces. STEC have also been isolated from the faeces of other species of animals, including buffalo, goat, camel, yak and sheep, which are commonly milked for human consumption. Detailed investigations have shown that without observance of appropriate cleaning and disinfecting steps and udder good hygiene practices, faecal matter can contaminate the cow's teats and udders, which can increase the risk of microbial contamination of the milk during the milking process. For this reason, STEC can potentially be found in raw milk. When STEC-contaminated milk is used to produce raw milk cheeses, STEC may survive in the resulting cheeses.

4. Raw milk cheeses are made from raw milk coagulated through the action of rennet, selected microbiological organisms or other suitable coagulating agents, and then partially or completely draining the whey resulting from the coagulation. This process results in a concentration of milk protein and milk fat. Following this step, various processing techniques are applied to produce the end-products. Different microbiota and very diverse enzymatic reactions play a complex role during processing and maturation. This results in very different cheese types, including fresh, blue, semi-soft, semi-hard, hard, or extra-hard product, which may be ripened, coated, cooked or pressed. The different processing steps applied, and the raw milks used from different species (e.g. cow, buffalo, goat, sheep, yak) can influence the behaviour (survival, growth or inactivation) of STEC strains.

5. This document is intended for use by a variety of food business operators (FBOs) using diverse milk production systems and cheese-making processes. Therefore, flexibility has been included throughout it to allow different systems of control and prevention of contamination considering cultural matters and different processing practices and conditions.

6. This guidance describes prerequisite programmes, including good hygiene practices, that can contribute to control STEC in raw milk and raw milk cheeses at different steps in the production chain and, when implemented correctly, can help reduce the risk of contamination and resulting illness. Effectiveness of interventions of different production practices to control STEC based on published data is variable. This is due to the significant differences in experimental design and manufacturing practice among studies. In particular, the efficacy of control measures at multiple steps in the food chain on the overall reduction of concentration of STEC in raw milk and raw milk cheeses has not been quantified. Consequently, it will be up to competent authorities and each operator (farmer, dairy, or FBO) to define and implement appropriate risk-based monitoring and control measures, considering relevant scientific and technical information.

[i] Thermization: the application to milk of a heat treatment of a lower intensity than pasteurization that aims at reducing the number of microorganisms.

OBJECTIVE

7. The objective of this annex is to provide science-based guidance for the control of STEC related to raw drinking milk and raw milk cheeses. This guidance focuses on control of STEC during raw milk production (cow, buffalo, goat, camel, yak and sheep), raw milk cheese making, storage, and distribution to consumers.

SCOPE AND DEFINITIONS

Scope

8. This annex presents specific guidance for control of STEC related to raw milk intended for drinking and for raw milk cheeses.

Definitions

- Refer to the *General Standard for the Use of Dairy Terms* (CXS 206-1999),[1] and the *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004)[2] Annex I (Guidelines for the primary production of milk) and Annex II (Guidelines for the management of control measures during and after processing). Also refer to the *General Principles of Food Hygiene* (CXC 1-1969)[3] and the *General Standard for Cheese* (CXS 283-1978).[4]
- **Milk:** Milk is the normal mammary secretion of milking animals obtained from one or more milkings without either addition to it or extraction from it, intended for consumption as liquid milk or for further processing.[1]
- **Raw milk:** Milk (as defined in the *General Standard for the Use of Dairy Terms* (CXS 206-1999))[1] which has not been heated beyond 40 ºC or undergone any treatment that has an equivalent effect.[ii, iii,2]
- **Raw milk cheeses:** Cheeses made from raw milk.

PRIMARY PRODUCTION-TO-CONSUMPTION APPROACH TO CONTROL MEASURES

9. Figures 1 and 2 provide flow diagrams describing key steps of raw milk and raw milk cheeses production. Not all steps occur in all operations, there may be other steps, and steps may occur in a different order than shown in the figures.

10. Raw milk should come from healthy animals, be obtained by hygienic milking practices and be free of colostrum. Raw milk can be a potential source of microbial pathogens, including STEC. It is of major importance to ensure the sanitary quality of the raw milk, as it does not undergo a microbial reduction treatment prior to packaging for drinking milk or before making raw milk cheeses.

11. The application of combined control measures throughout the food chain particularly at the farm, transport and processing is necessary for the control of STEC in the end-products. However, these measures and flow diagrams can vary according to different dairy farming practices and cheese-making processes.

PRIMARY PRODUCTION – MILK PRODUCTION AT DAIRY FARM

Control measures for STEC for dairy herds at the dairy farm

12. STEC are commonly present in the microbiota of milk-producing animals, and it is not possible to eradicate them. The excretion of STEC by ruminants seems to be sporadic but may also be persistent over several months. Studies have shown that excretion varies according to the season, peaking in warmer months. Excretion also varies among individual cows, with some individuals considered to be “high shedders” (a high-level excretion of STEC), and excretion levels may even differ between cow droppings of the same animal. Other factors proposed to contribute to changes in STEC excretion include age, diet, housing, stress, herd size, animal health, geographical area, and previous contamination with STEC strains. Faecal contamination of milk from sheep and goats occurs but is less likely than from cows, because of anatomical differences as their faeces tend to be more solid and thus are less likely to cross-contaminate. There are no established methods to prevent STEC carriage or ensure reduced shedding by ruminants. In addition, no interventions specific for small ruminants are suggested. Control measures should be implemented to minimize spread between animals and their environments. The following are examples of measures that may be useful:

[ii] Temperatures between 40 ºC and pasteurization temperatures, are generally considered to be insufficient to consistently kill STEC in raw milk. Heat treatment beyond 40 ºC results in changes such that the structure of the resultant product is no longer the same as that of raw milk.

[iii] Milk that has been subject to processing techniques such as microfiltration and/or bactofugation is no longer considered raw milk because these processes require milk to be heated above 40 °C.

- Maintain animal health and minimize animal stress.
- Maintain the hygienic condition of bedding and remove it when it becomes soiled with manure in a manner that increases the likelihood of contamination of the milk.

13. Other wildlife or livestock, pests, and birds can also carry STEC and thus contribute to their circulation in milking herds. It may be useful to manage each of these potential sources, using scientifically validated methods, and thus reduce or minimize the risk of transmission from these sources.

14. Animal-to-animal transmission via faecal-oral transmission is a likely contamination route of STEC within the herd. In addition, the introduction of new animals to a herd may introduce STEC. The following are examples of measures that may be useful:

- Segregate and limit faecal cross-contamination between newborn or young animals and mature animals.
- Keep young animals in the same groups throughout rearing without introducing new animals.

15. Environmental transmission has also been demonstrated due to poor housing conditions or to the survival of STEC (potentially more than a year) in effluent and the environment (soil, plants, crops, grain and water). Pastures can also maintain bacterial circulation by faeces deposited onto the ground and/or spreading of effluent. Good agricultural practices for managing manure and slurry include frequent removal from the milking herd environment, maintaining necessary intervals between spreading on pasture and the reintroduction of animals for grazing.

16. When appropriate, other validated control measures at primary production, such as diet, vaccination, administration of probiotics and additional good management practices (as described in the raw beef Annex) may be helpful in minimizing the shedding of STEC and, thus, contamination of raw milk.

17. Contaminated feed and water (surface water, roofing water, contaminated drinking water) can contribute to the introduction or circulation of STEC, following direct or indirect contamination. The presence of STEC in feed can be minimized by application of good manufacturing practices and appropriate manure and slurry management when the feed is produced on the farm (*Code of Practice on Good Animal Feeding* (CXC 54-2004)).[5] Secure storage of feed is important to prevent STEC contamination from runoff water, pests, and birds. In addition, it is important to limit water contamination for watering animals by adequate maintenance of water troughs.

Control measures for STEC during preparation of animals for milking, milking, and then transfer of milk to bulk containers/tanks

18. The major route of raw milk contamination is from faecal sources (directly or indirectly). Faeces can soil the teats, and the milk can subsequently become contaminated during the milking process. Therefore, limiting faecal contamination during milking is of key importance to manage STEC on the farm. For this, it is important to apply good hygiene practices during milking, to keep animals clean, and most importantly to prevent contamination with faeces.

Minimizing faecal contamination before and during milking:

- Ensure a clean and hygienic environment for the milking animals to reduce faecal contamination. For example, the area where milking will be performed should be cleaned after each milking and allowed to dry when possible.
- Clean and disinfect all milking materials, utensils, and equipment.
- Udders and teats should be properly cleaned before the milking process to minimize the risk of contamination of milk with STEC.
- In the case of manual milking, in addition to udder and teats, the operator's hands need to be properly cleaned.

19. STEC can also potentially persist on milking equipment and pipelines if these are not adequately cleaned and disinfected (Annex I Guidelines for the primary production of milk from the *Code of Hygienic Practice for Milk and Milk Products* CXC 57-2004).[2] Cleaning and disinfecting are more challenging if equipment is not well designed for cleaning, and/or not well maintained. STEC can form biofilms in milking machines if they are improperly designed, poorly maintained and/or poorly cleaned. Studies have shown biofilm formation by STEC serotypes O157:H7 and non-O157 STEC with increased tolerance to sanitizers commonly used in the food processing environment, particularly if cleaning is not done effectively (resulting in biofilm formation in which the sanitizer cannot reach microorganisms) or the unintended application of a sanitizer at sublethal concentrations. All equipment that may come in contact with milking animal teats and milk as it is collected, such as milk collecting buckets, should be thoroughly cleaned and disinfected before every use. The hygienic quality of the water used for the last rinse is very important to prevent contamination of the milking machine (*Code of Hygienic Practice for Milk and Milk Products* CXC 57-2004).[2] In line with the *General Principles of Food Hygiene* (CXC 1-1969),[3] only water fit for purpose (i.e. it does not cause contamination of the milk) should be used. If recycled water is used, it should be treated and maintained under conditions ensuring that its use does not impact the safety of the milk (CXC 57-2004).[2]

CONTROLS DURING MILK COLLECTION, STORAGE AND TRANSPORTATION

20. If milk is processed immediately after milking, cooling is not necessary.

21. All equipment that may come in contact with milk, such as tubes and pipes used for transferring milk to larger containers, pumps, valves, storage containers and tanks, etc., should be thoroughly cleaned and disinfected before every use. Although not a standard practice, a full cleaning, once per 24 h, tanker cleaning approach, with the use of a between-load water rinse with or without a disinfecting treatment has been shown to reduce the presence of surface bacteria in the tanker, and thus may provide some risk reduction.

22. STEC can rapidly replicate in raw milk if the milk is at the temperature of STEC growth. Therefore temperature control of the milk post-harvest is crucial, including during its storage at the farm and throughout the collection route to prevent microbial growth (see the Code of Hygienic Practice for Milk and Milk Products (CXC 57-2004),[2] Annex I Guidelines for Primary Milk Production). Temperatures ≥ 6 °C, extended storage of raw milk, and high initial bacterial counts in raw milk during collection, storage and transportation have been associated with increased counts of *E. coli* in raw milk. Milk temperature should be monitored during storage and checked before it is unloaded, when possible.

23. Transport has not been identified as a step likely to contaminate the milk with STEC, if good hygiene practices are followed. However, transport is identified as a stage where growth of STEC may occur if the temperature of the milk is not properly maintained.

CONTROL DURING PROCESSING

24. The contamination of dairy products with STEC during processing in the manufacturing plants is rare if appropriate hygiene practices are followed. It is recommended that the products should be prepared and handled in accordance with the appropriate sections of the *General Principles of Food Hygiene* (CXC 1-1969),[3] the *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004)[2] and other relevant Codex texts such as codes of hygienic practice and codes of practice.

25. At the initial stages of cheese-making, the temperature (ranging from 27°C–35°C), a_w value and nutrients in milk provide favourable conditions for the growth of STEC. During the first hours of cheese-making (transition from milk to curd), an increase in STEC level can be observed in some cheese-making processes. This increase in number is due to the multiplication of the cells in the liquid milk and then in the curd where cells are entrapped. However, “cooking” of cheese curd, as well as rapid acidification (when pH decreases to under 4.3), coupled with the increase of non-dissociated lactic acid, have been associated with STEC or *E. coli* log reductions. During the ripening step, the microbial stability of cheeses is determined by the combined application of different hurdle factors (pH, a_w, titratable acidity, sodium chloride, non-dissociated lactic acid, amount of starter cultures (such as lactic acid bacteria)) still active in the cheese, brining of the cheese, as well as the temperature and length of time for ripening. These hurdles create an increasingly challenging environment for STEC during the manufacturing process and ripening. The food business operator (FBO) should analyse the risks associated with its manufacturing process with respect to the potential for growth or decline of STEC. Based on this assessment, the FBO should adapt the process and/or implement controls to reduce any identified risks for STEC contamination and growth.

26. “Cooking” of cheese curd (heating to increase separation of whey from the curd), rapid acidification or long ripening may not be compatible with some traditional production practices, as they may impact the sensory

characteristics of the cheese. In such cases appropriate control measures should be identified and applied. For example, testing raw milk for the presence of STEC can be established, as well as an audit programme of milk suppliers to assess their hygienic practices.

27. Nevertheless, these procedures have the potential to reduce STEC, but they cannot ensure the safety of the product if the raw milk is contaminated with STEC. Consequently, the microbiological quality of raw milk used in cheese making is crucial for reduction of the risk associated with the end products.

PRODUCT INFORMATION FOR CONSUMERS

28. In line with the *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004,[2] Section 9.1), raw milk products should be labelled to indicate they are made from raw milk according to national requirements in the country of retail sale.

VALIDATION, MONITORING AND VERIFICATION OF CONTROL MEASURES

E. coli enumeration and STEC testing

29. Although STEC can be isolated from raw milk and raw milk cheeses, STEC testing is uncommon and most sampling and testing protocols target indicator microorganisms such as *E. coli*, whose level can be used as an indicator of raw milk sanitary quality prior to raw milk cheeses production. Microbiological criteria (refer to the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Relating to Foods* (CXG 21-1997))[6] based on process and hygiene indicator microorganisms (e.g. *E. coli* / Enterobacteriaceae) may also prove a useful tool for validation, monitoring and verification of control measures.

30. Even if they are useful hygienic markers of the quality of raw milk, the presence or concentration of generic *E. coli* or other indicator microorganisms in raw milk does not necessarily indicate the presence of STEC. More specific analyses are needed to detect and confirm by strain isolation the presence of STEC. Periodic 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) may also be conducted for verification of hygienic practices.

31. Testing raw milk for the presence of STEC strains considered to be a country's highest priority can be established, but testing may not be effective on its own: because of the low prevalence of STEC, samples tested may not contain STEC despite their presence in the food. Thus, such testing should be used in combination with other control measures, including an audit programme of milk suppliers to assess hygienic practices on the farm.

Validation and monitoring of control measures

32. Control measures should be validated before being implemented. To limit the cost of this important step, it can be shared by several FBOs and a professional organization which may gather, analyse, and interpret data in order to establish alternative or improved measures, for example by writing GHP and/or HACCP (e.g. fast acidification or long ripening) guidelines adapted to the local context or to the traditional steps of raw milk harvesting and processing.

33. The description of control measures may also include the procedures for monitoring their implementation to ensure the control measures are carried out as intended.

Verification of control measures

34**. At the dairy farm:** Testing milk periodically for microorganisms that are indicators of faecal contamination or hygiene can be implemented. For example, routine analysis of milk at the point of production for microbial quality indicator microorganisms (*E. coli*, coliform levels, or total aerobic plate counts) can provide information on the hygiene of the operation. Nevertheless, low levels of indicator microorganisms do not confirm the absence of STEC nor other pathogens.

35. Enhanced monitoring should be implemented when STEC strains have been detected in raw milk; and production and sale of the product that have not undergone effective treatment should be ceased until the contamination issue has been resolved. In such situations, input from technical experts or professional association guidance, as well as guidance from competent authorities, can help to identify the risk factors for milk contamination. Finally, a criterion should be defined for when to return to routine monitoring. This criterion should be based on experience and statistical evaluation of the history of microbiological analyses results.

36. General hygiene audits can be useful to check periodically that the GHPs and GAPs are effectively implemented at each farm where the milk is collected. They might be conducted by the dairy establishment, competent authority or by a local professional association.

37. **Milk collection at the dairy establishment:** Routine monitoring of the quality of the raw milk received by the dairy establishment (indicator microorganisms or/and STEC) conducted by the dairy establishment can be based on samples collected periodically or even for each load. Sampling milk filters may be a more suitable monitoring point for STEC than sampling raw milk from the bulk tank, considering dilution due to pooling and sporadic contamination issues. Milk filter sample analysis can also be useful in investigating the source of contaminated cheese.

38. Enhanced monitoring of all the suppliers can be set up when STEC strains have been detected in mixed milk unloaded at the processing plant. In such a situation, another measure could be to increase the frequency of sampling and STEC analysis in order to assess the milk origin of the strain, the magnitude of contamination and the persistence of the strains in the processing plant. Then, criteria to return to routine monitoring should be defined.

39. **During processing,** the FBO or industry association generally defines its sampling plan in line with an acceptable hygiene level. A milk safety check based on STEC detection is an option that some FBOs may consider for raw milk (STEC negative milks). This approach can nevertheless be difficult because of the complexity, the time taken and the cost to analyse for STECs in milk. Alternatively, milk safety checks can be performed based on *E. coli*, to verify the application of GHPs.

40. Sampling and testing of raw milk cheeses are an important part of verification plans, to confirm that practices and procedures described in the food safety programme are successful. Accurate safety and quality test results are crucial and depend on appropriate sampling and sample handling, the type of representative samples, and proper analytical methods. For routine monitoring, FBOs should consider analysing cheese during the early stages of manufacturing (e.g. after coagulation), when the peak of STEC growth is likely to take place. Testing at this time would have a greater sensitivity than end-product testing and would save producers the expense of ageing and storing contaminated products. Analysis could also be done during ripening and/or before placing the cheese on the market.

41. When STEC is detected in raw milk, it has been found at very low levels in cheeses. This contamination is characterized by heterogeneous distribution, making STEC difficult to detect. Sampling plans should therefore be designed according to the *General Guidelines on Sampling* (CXG 50-2004)[7] and the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997).[6] In addition, sampling plans should be adapted over the entire production chain (number of samples, nature of the samples (i.e. milk, cheese at the start of coagulation, during ripening, etc.), quantity analysed, frequency of analysis, etc.).

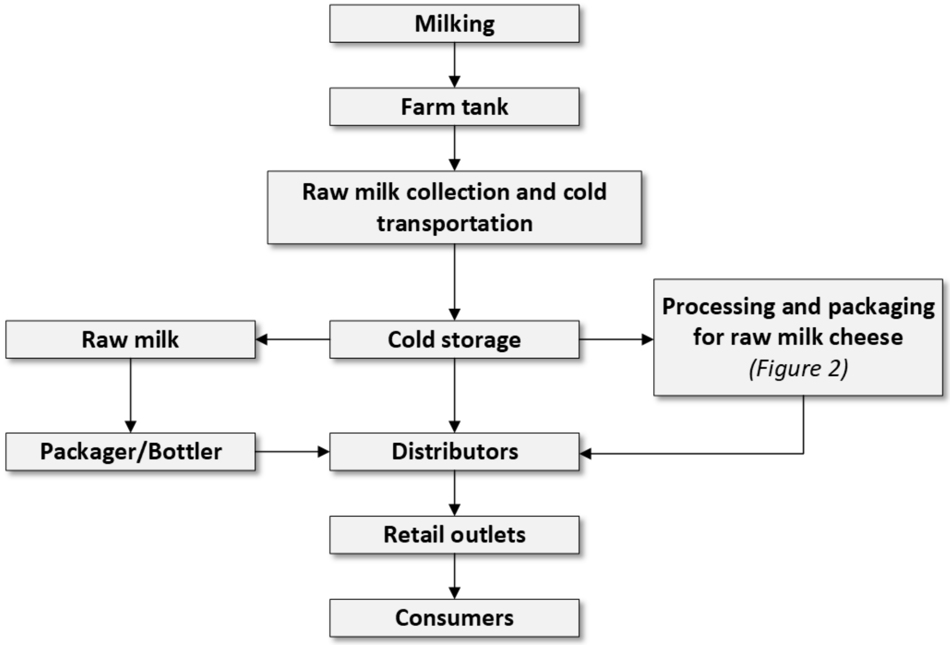
43. Enhanced monitoring can be put in place when STEC are detected in curds or in cheeses or in the case of a public health risk. For example, other batches of cheeses can be screened in greater detail for STEC to assess the magnitude of contamination. In addition, it is important to identify the remaining contaminated milk, if any, and stop using it for production of raw milk cheese.

44. **Quantitative risk assessment:** Several sampling plans may be applied at different steps (milk harvested at the farm, milk delivered at the dairy establishment, curds, final products). Their combination in a quantitative risk assessment (QRA) model can help assess the efficacy of this sampling plan, using simulation, in terms of risk reduction of illness and percentage of batches rejected. Specific QRA models for STEC in several raw milk cheeses matrices have been developed. QRA models can also be built based on databases obtained when combining results of microbiological analyses performed regularly on the milk at different levels (farm and tank) and on cheeses (during the process and on the final product), values on technological process parameters and physico-chemical values (e.g. pH, a_w) on the capacity for growth or survival of the microorganisms considered.

45. QRA models can help compare sampling plans to determine which one provides better protection.

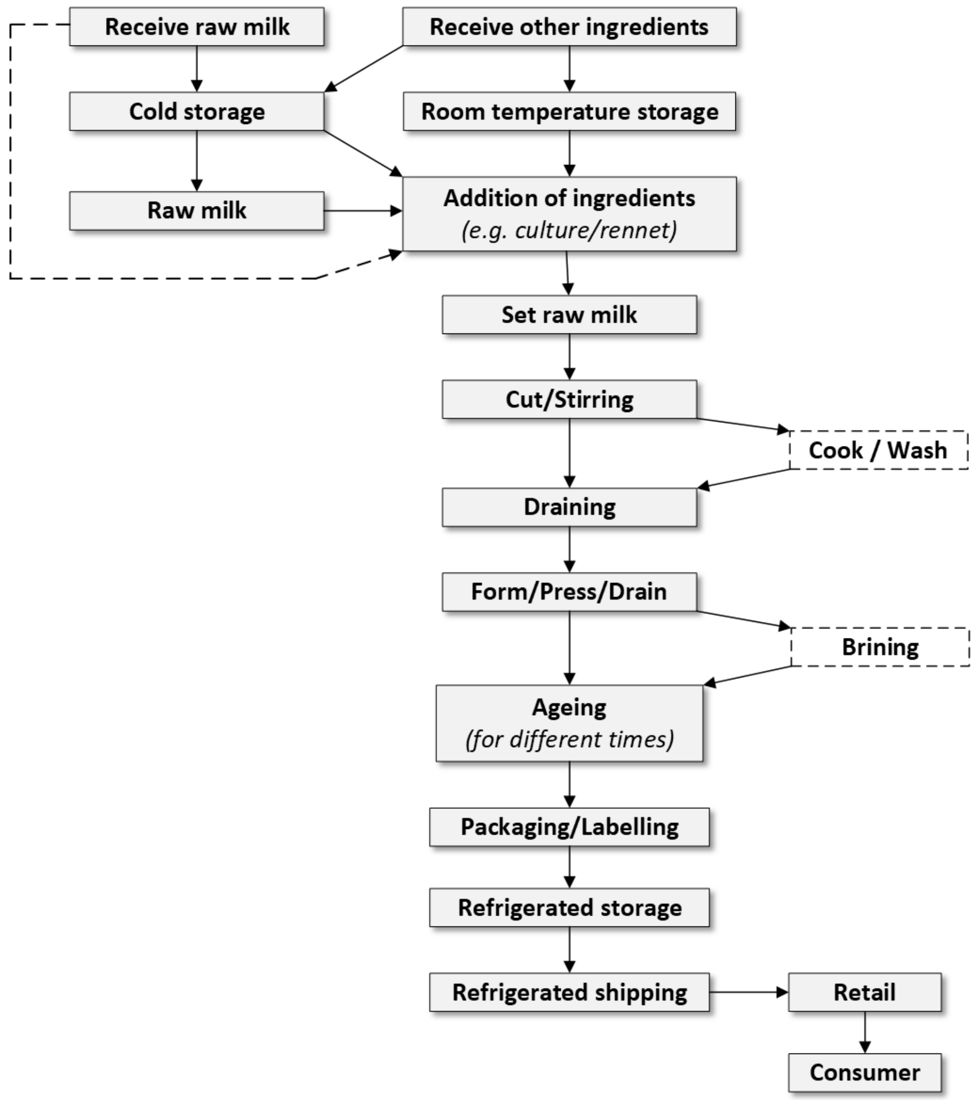
46. **Application of prerequisite programmes, including good hygiene practices, and HACCP principles**: Given the low frequency and low level of contamination by STEC strains and the limits of the sampling plans, it is the combination of control measures (including GHPs and HACCP, when applicable) throughout the dairy chain that will reduce the risk of STEC contamination of the products put on the market.

Figure 1. Process flow diagram for raw milk production, distribution and sale



The diagram illustrates a generalized process flow for raw milk for illustrative purposes only. Steps may not occur in all operations and may not occur in the order presented in the flow diagram.

Figure 2: Making cheese from raw milk



The diagram illustrates a generalized process flow for raw milk cheese for illustrative purposes only. Steps may not occur in all operations and may not occur in the order presented in the flow diagram.

NOTES

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[1] FAO and WHO. 1999. Codex *General Standard for the Use of Dairy Terms.* Codex Standard, No. CXS 206-1999. Codex Alimentarius Commission. Rome.
[2] FAO and WHO. 2004. *Code of Hygienic Practice for Milk and Milk Products.* Codex Code of Practice, No. CXC 57-2004. Codex Alimentarius Commission. Rome.
[3] FAO and WHO. 1969. *General Principles of Food Hygiene.* Codex Code of Practice, No. CXC 1-1969. Codex Alimentarius Commission. Rome.
[4] FAO and WHO. 1978. *General Standard for Cheese.* Codex Standard, No. CXS 283-1978. Codex Alimentarius Commission. Rome.
[5]FAO and WHO. 2004*. Code of Practice on Good Animal Feeding.* Codex Code of Practice, No*.* CXC 54-2004. Codex Alimentarius Commission. Rome.
[6] FAO and WHO. 1997. *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Relating to Foods.* Codex Guideline, No. CXG 21-1997. Codex Alimentarius Commission. Rome.
[7] FAO and WHO. 2004. *General Guidelines on Sampling.* Codex Guideline, No. CXG 50-2004. Codex Alimentarius Commission. Rome.

ANNEX IV

SPROUTS (under development)

Appendix IV

GUIDELINES FOR THE SAFE USE AND REUSE OF WATER IN FOOD PRODUCTION AND PROCESSING

(General Section and Annex I on Fresh Produce)

(At Step 5/8)

INTRODUCTION

1. Water has an important role in all stages of the food chain from initial sourcing, storage, treatment, distribution, use in irrigation of food crops and forage for animals, primary production, and food processing through to consumption of the final food. It is used as an ingredient, in direct and indirect contact (e.g. washing, cooling the product, or cleaning of equipment surfaces in contact) with food, food packaging, and for hygiene sanitation in food processing. The important role of water in food production has led to the need to ensure its safety and quality since it can be a carrier for the transmission of diseases, contamination, or unwanted sensory attributes.
2. Water is a dwindling resource worldwide and not all food producers and processors have access to safe water sources, or this access may be limited. Noting that the availability and microbiological quality of water are different in each country, region, context, setting, and food establishment, water should always be fit for use for each specific purpose, and it should be managed in a way that the safety of food is ensured, while simultaneously avoiding unnecessary consumption and waste.
3. Water used along the food production and processing chain can have different microbiological quality requirements, and types of water other than potable water may be suitable for certain purposes, provided that they do not compromise the safety of the final product for the consumer.
4. Requirements for water safety should therefore be considered in context, considering the purpose of the water use, the potential hazards associated with the water use, and whether there is any subsequent measure to decrease the potential for contamination along the food chain.
5. A risk-based approach to water sourcing, treatment, handling, storage, and use can help in identifying the hazards associated with the water and its use and determine treatments, if applicable, that water needs to undergo to meet the safety parameters specific to each intended use. This approach can also provide a means to address many of the water access and safety challenges associated with reuse based on the principle of using the right type of water for the intended purpose/need.
6. Deciding whether water is fit for purpose should be based on a hazard analysis that considers risk factors such as those associated with the source water, the end use of the food product (e.g. whether the food is eaten raw – without steps that would mitigate potential hazards introduced by the water source), and management options such as treatment options and their efficacy and the application of multiple barrier processes for risk mitigation.
7. These guidelines respond to the need for a document outlining a risk-based approach to safe sourcing, use, and reuse of water fit for purpose, rather than focusing on the use of potable water or water of other quality types (e.g. clean water). Using the risk-based approach outlined in these guidelines will allow for a specific assessment of the fitness of the water for the intended purpose.
8. Associated annexes provide product-specific guidelines for the sourcing, collection, storage, treatment, handling, distribution, use, and reuse of water in both direct and indirect contact with food throughout the food chain. The annexes also provide examples such as decision tree tools (DTTs) that can help to determine if water is fit for purpose.

OBJECTIVES

9. The *Guidelines for the safe use and reuse of water in food production and processing* aim to:
    - Provide guidance for food business operators (FBOs) and competent authorities on the application of a risk-based approach for the use and reuse of water that is fit for purpose.
    - Provide practical guidance and tools (e.g. DTTs) and risk-based microbiological criteria as examples to help FBOs evaluate risks and potential interventions of water as part of their food hygiene system.

PURPOSE AND SCOPE

10. These guidelines provide a framework of general principles and examples for applying a risk-based approach to determine if the water to be sourced, used, and reused by FBOs involved in production and processing of

relevant commodities is fit for purpose by addressing microbiological hazards, such as parasites, bacteria, and viruses.

USE

11. The document is intended for use by FBOs (primary producers, packing houses, manufacturers, processors) and competent authorities as appropriate.

12. These guidelines are complementary to and should be used in conjunction with all relevant Codex texts, including but not limited to: the *General Principles of Food Hygiene* (CXC 1-1969),[1] the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003),[2] the *Code of Practice for Fish and Fishery Products* (CXC 52-2003),[3] the *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004),[4] *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CXG 63-2007),[5] *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997),[6] *Code of Practice on Food Allergen Management for Food Business Operators (CXC 80-2020)*,[7] *Code of Hygienic Practice for Meat* (CXC 58-2005),[8] and *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CXG 30-1999).[9]

GENERAL PRINCIPLES

a) Water, as well as ice and steam made from water, used at any stage of the food chain, should be fit for its intended purpose, as determined by a risk-based approach comprising the evaluation of microbiological, chemical, and physical hazards and should not compromise the safety of finished foods for consumers.

b) When re-using, water should be treated or reconditioned, effectively monitored and the treatment should be validated to eliminate or reduce hazards to an acceptable level according to its intended use.

c) In all situations, water sourcing, use, and reuse should be part of an FBO´s food hygiene system.

d) When using water as an ingredient in food, it should be potable.

DEFINITIONS

13. For the purposes of this document the following definitions apply:

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.

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.

Potable water: Water fit for human consumption.

Reuse water: Water that has been recovered from a processing step within the food operation, including from the food components and/or water that, after reconditioning treatment(s) as necessary, is intended to be reused in the same, prior or a subsequent step of the food processing operation. Types of reuse water can include reclaimed water from food, recycled water from food operations, or recirculated water in a closed loop system.

Reclaimed water: Water that was originally a constituent of a food material, which has been removed from the food material by a process step and is intended to be subsequently reused in a food processing operation.

Recycled water: Water which has been obtained from a step in the food production or food processing operation to be reused in the same, prior or a subsequent step of the operation, after reconditioning, when necessary.

Recirculated water: Water reused in a closed loop for the same processing operation without replenishment.

Reconditioning: The treatment of water intended for reuse by means designed to eliminate or reduce microbiological contaminants to an acceptable level according to its intended use.

Water sourcing: The act of identifying and obtaining water for food production from a particular water source (e.g. groundwater, surface water, captured water).

Wastewater: Used water that has been contaminated because of human activities.

SECTION 1: WATER FIT-FOR-PURPOSE ASSESSMENT

14. Assessing if water is fit for purpose is required for all sectors and steps in the food chain. Risk principles (i.e. a risk-based approach) should be applied in evaluating if the water is fit-for-purpose during sourcing, collection, storage, treatment, handling, use, and reuse.

15. Conducting such an assessment requires complete knowledge of the water system, the diversity and magnitude of the hazards that may exist, and the capacity of existing processes and infrastructure to address and control risks.

16. Water fit-for-purpose assessments also require the identification of potential microbiological hazards with the capacity to cause damage to water safety and their sources and should also address safe water sourcing, use, or reuse, when developing and implementing the plan. Additional factors to be considered could include water storage and distribution, including the hygienic design, and the need for special expertise.

17. Water use and reuse systems should be subjected to routine, risk-based monitoring and verification of appropriate parameters. The frequency of monitoring and verification can be dictated by different factors such as the source of the water or its prior condition, the efficacy of any treatments, and the intended use and reuse of the water. Relevant routine monitoring data by environmental agencies and public health organizations could be also useful in determining the frequency of monitoring and verification activities.

18. In the context of safe water sourcing, collection, treatment, handling, storage, use, and reuse, water fit-for-purpose assessments can include the following risk-based approaches:

    - Descriptive assessment (least comprehensive) – an onsite as well as a document-based evaluation from which a written descriptive assessment is generated. Examples include a sanitary inspection used in evaluating and managing risks from irrigation water and rapid assessment of water safety.
    - Semi-quantitative water assessment – the development and use of risk matrices that establish categories of risks from high to low, including consideration of sanitary conditions and their likelihood and estimated frequencies of unacceptable sanitary conditions. These are normally used for planning, prioritization, and a rapid assessment of the safety and quality of water sources collection, storage, treatment, and handling.
    - Quantitative microbial water assessment (QMWA) (most comprehensive) – a mathematical modelling approach that can be used for estimating risks related to water use with a health outcome target. QMWA helps identify how much of an impact a pathogenic microorganism will have on the health of the population, e.g. guiding wastewater use in agriculture.

SECTION 2: WATER SAFETY MANAGEMENT

19. Water fit-for-purpose assessments can be used for management decisions in setting target objectives for water sources and treatments for achieving public health outcomes, performance targets (e.g. food safety objectives, performance objectives), acceptable levels of risk, and treatment process efficacies as appropriate.

20. Risks associated with the use of water should be managed with measures implemented within the framework of a structured food hygiene system with monitoring and verification activities in place to ensure that the system is operating as expected.

21. As part of the food hygiene system, where appropriate, all water systems should be mapped in a process flow diagram and evaluated in the hazard analysis.

22. Once potential hazards and their sources have been identified, the risks associated with each hazard or hazardous event should be compared so that priorities for risk management can be established and documented. A semi-quantitative matrix might be useful to identify hazards and prioritize control measures for risk management purposes.

23. Treatment or reconditioning of water intended for fit-for-purpose use and reuse should be based on hazard analysis of the sourced water and, where deemed necessary, treatments should ensure that hazards are eliminated, controlled, or reduced to an acceptable level.

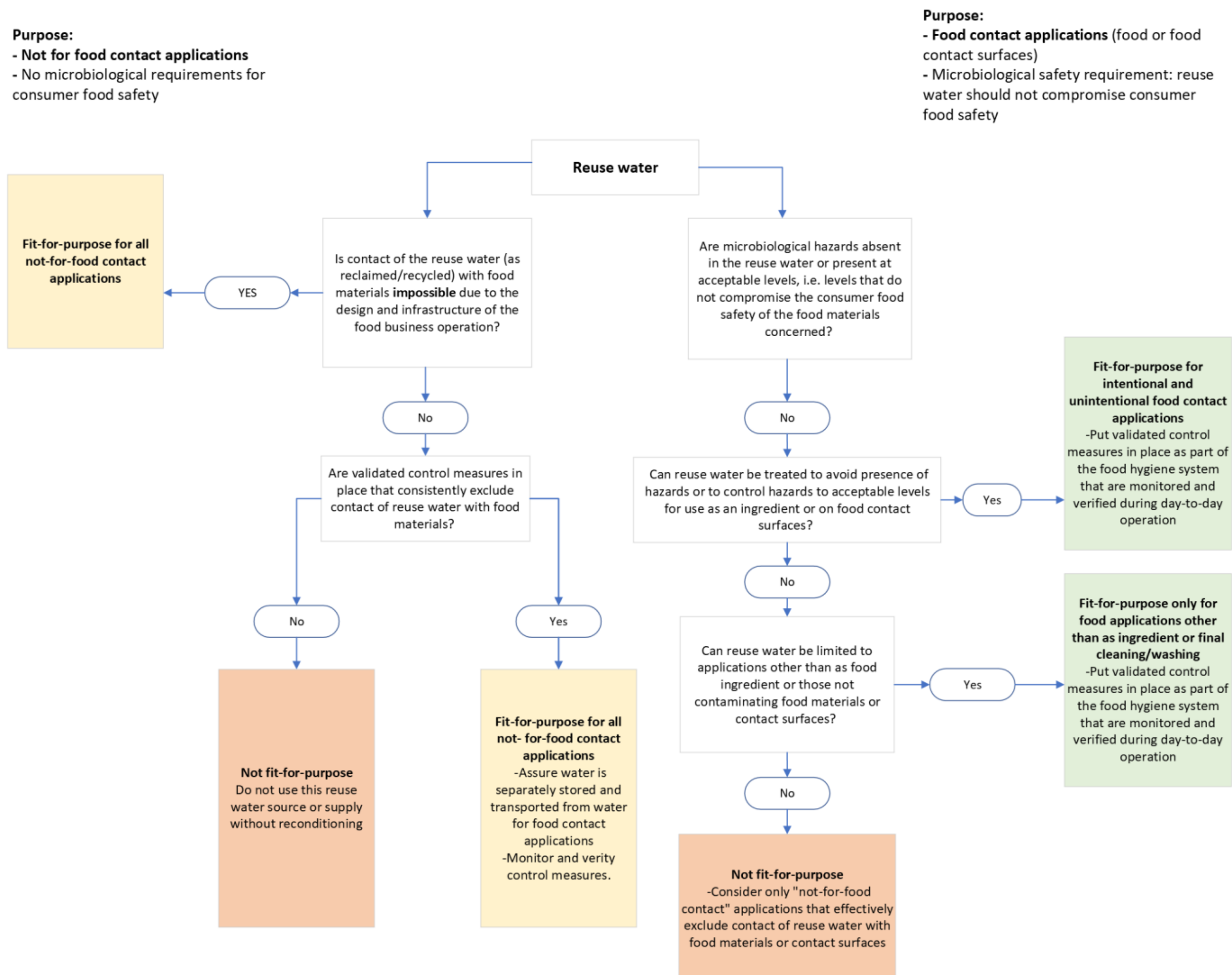
SECTION 3: DECISION SUPPORT SYSTEMS

24. Decision support systems (DSS) tools, such as decision trees (DTs) or matrices, are considered to be useful risk management tools to assist stakeholders in making decisions to determine if water is fit for purpose and the required quality for use or reuse at a given step in the supply chain.
25. DSS should allow for the diversity in food production, resulting in different types of risks and risk management steps necessary to ensure the water's fitness for purpose in food production. Examples include the food types

involved and their intended use; the food-water interactions; the specific waterborne food safety hazards; and their likelihood and magnitude of transmission to the consumer when present in different foods.

26. An example of a risk-based DSS tool with further guidance is provided in Figure 1.

Figure 1. Example of a risk-based decision support system (DSS) framework tool for the purpose of deciding if reused water can be used in either a food contact application or a not-for-food-contact application for microbiological hazards.



NOTES

[1] FAO and WHO. 1969. *General Principles of Food Hygiene.* Codex Code of Practice, No. CXC 1-1969. Codex Alimentarius Commission. Rome.
[2] FAO and WHO. 2003. *Code of Hygienic Practice for Fresh Fruits and Vegetables.* Codex Code of Practice, No. CXC 53-2003. Codex Alimentarius Commission. Rome.
[3] FAO and WHO. 2003. *Code of Practice for Fish and Fishery Products.* Codex Code of Practice, No. CXC 52-2003. Codex Alimentarius Commission. Rome.
[4] FAO and WHO. 2004. *Code of Hygienic Practice for Milk and Milk Products.* Codex Code of Practice, No. CXC 57-2004. Codex Alimentarius Commission. Rome.
[5] FAO and WHO. 2007. *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM).* Codex Guideline, No. CXG 63-2007. Codex Alimentarius Commission. Rome.
[6] FAO and WHO. 1997. *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods*. Codex Guideline, No. CXG 21-1997. Codex Alimentarius Commission. Rome.
[7] FAO and WHO. 2020. *Code of Practice on Food Allergen Management for Food Business Operators.* Codex Code of Practice, No. CXC 80-2020*.* Codex Alimentarius Commission. Rome.
[8] FAO and WHO. 2005. *Code of Hygienic Practice for Meat.* Codex Code of Practice, No. CXC 58-2005. Codex Alimentarius Commission. Rome.
[9] FAO and WHO. 1999. *Principles and Guidelines for the Conduct of Microbiological Risk Assessment.* Codex Guideline, No. CXG 30-1999. Codex Alimentarius Commission. Rome.

Annex I

FRESH PRODUCE

INTRODUCTION

1. Water can be a source of contamination of all microbiological pathogens associated with the consumption of fresh produce. These pathogens include bacteria such as, but are not limited to, *Salmonella* spp., *Shigella* spp, *Campylobacter* spp., *Listeria monocytogenes* and pathogenic strains of *Escherichia coli* spp., and also viruses such as hepatitis A and norovirus, and parasites such as *Cyclospora* spp*., Giardia* spp. and *Cryptosporidium* spp.

2. Water is used at all steps in the production chain of fresh produce, from irrigation and other pre-harvest practices, such as fertilization and pesticide application, during harvesting, such as washing in the field, and post-harvest practices, such as cooling, transporting, washing and rinsing, until final washing steps by the consumer. Control measures to prevent water from becoming a source of microbiological contamination of the fresh produce, should be considered at all stages, and an overall management strategy should be developed, taking into account risk factors and control measures applicable at each step.

PURPOSE AND SCOPE

3. The purpose and scope of this annex are to elaborate guidelines for the safe sourcing, use and reuse of water in direct and indirect contact with fresh produce (for primary production and processing) by applying the principle of ‘fit for purpose’ using a risk-based approach. The annex recommends good hygiene practices (GHP) and risk-based, sector-specific potential prevention and intervention strategies. It provides examples and/or practical case studies for determining appropriate fit-for-purpose microbiological criteria, (i.e. criteria for bacteria, viruses, parasites), as well as examples of the DSS tools such as DTs to determine the water quality needed for the specific intended purpose in the fresh produce supply chain.

USE

4. This annex is complementary to and should be used in conjunction with the main document, the *General Principles of Food Hygiene* (CXC 1-1969),[1] the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003),[2] *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CXG 63-2007),[3] *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997),[4] and *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CXG 30-1999).[5]

DEFINITIONS

Fresh produce: Any fresh fruit, nuts, mushrooms, herbs, and vegetables that are likely to be presented to consumers in a raw form, either unprocessed or physically altered from its original form but remaining in the fresh state (e.g. washed, peeled, cut), and that are generally considered as perishable regardless of it being intact or cut from root/stem at harvest.

Biocide: A chemical substance or microorganism intended to destroy, deter, render harmless or exert a controlling effect on any harmful organism by chemical or biological means.

PRE-HARVEST USE OF WATER

5. An adequate supply of water of a suitable quality (fit for purpose) should be available for use in the various operations in the primary production of fresh produce.

6. Water has several uses in primary production, e.g. irrigation, application of pesticides and fertilizer, protection against frost/freezing and prevention of sunscald. The quality of water used in primary production is usually very variable. Several parameters may influence the risk of microbiological contamination of fresh produce via water: the source of water, water storage and delivery infrastructures, the type of irrigation system (e.g. drip, furrow, sprinkler/overhead) influencing whether the water has direct contact with the edible portion of the fresh produce, the timing of irrigation in relation to harvesting and exposure of plants to sunlight that can reduce contamination that occurs from water (e.g. microbial die-off). Water used for primary production, including for frost protection and protection against sunscald, which has contact with the edible portion of fresh produce, should not compromise produce safety.

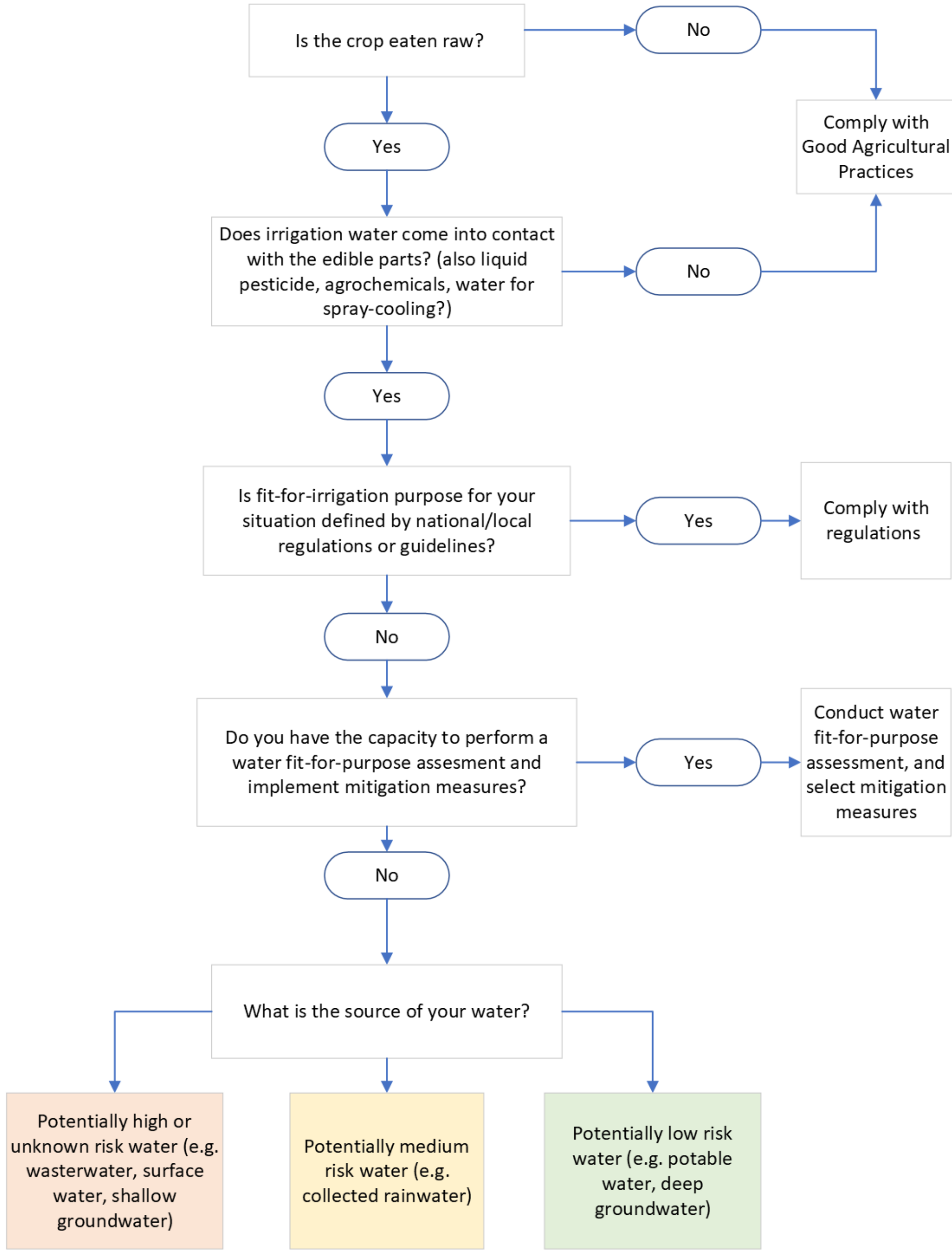
Water sources

7. Growers should identify the sources of water used during primary production (e.g. municipality, groundwater including well water, surface water (e.g. open canal, reservoir, river, lake, farm pond), reused irrigation water, rainwater, reconditioned wastewater or discharge water from aquaculture). Apart from municipality (potable) water, examples of water sources that present the lowest risk of contamination (provided these sources and storage and distribution facilities are properly constructed, maintained, monitored and capped, as appropriate) are:
    - water in deep wells or boreholes;
    - water in shallow wells, provided they are not influenced by surface waters; and
    - hygienically collected rainwater.
8. A number of preventative measures can be implemented to protect a water source if determined to be vulnerable:
    - If using more than one water source, ensure all sources are clearly identified to prevent inappropriate use, e.g. provide separate systems for wastewater, potable water supplies, etc.
    - Ensure water sources are protected (as much as possible) from contamination by wild and domestic animals, e.g. fencing or netting.
    - If storing manure, slurry, composts and other soil amendments, ensure there are no leaks or spillage and they are positioned downhill from the water source, and far enough away to minimize contamination.
    - Ensure the catchments and gutters of the water harvesting, distribution and delivery system are regularly cleaned and maintained.
    - Ensure that all water storage tanks or water reservoirs are covered, i.e. protected, to prevent contamination.
    - If using a private well, ensure it is located away from contamination sources, and constructed appropriately to prevent contamination, e.g. sealed on top.
    - Regularly check irrigation systems for damage or leaks and flush lines to remove accumulated organic debris/biofilms. If there has been a period of wet weather, it is recommended to flush the system prior to use.
9. Water sources that pose a higher risk of contamination may need treatment, for example:
    - Wastewater: before using wastewater for crop irrigation, an expert should be consulted to assess the relative risk and determine the suitability of the water source. Measures to ensure the safe use may include wastewater treatment, application techniques that minimize contamination, die-off periods before harvesting, produce washing, disinfection and cooking.
    - Surface water (e.g. rivers, lakes, canals, lagoons, ponds, reservoirs): when contaminated, options such as application of chemical treatment, sand filtration (combined with other treatment such as application of UV-C), microfiltration or storage in catchments or reservoirs to achieve partial microbiological treatment should be considered. The efficacy of these treatments should be evaluated and monitored.

Assessing and testing of water

10. Growers or associated operators should assess the microbiological quality of water, as prescribed by the competent authority, and its suitability for the intended use, and identify corrective actions in case of unacceptable results, to prevent or minimize contamination (e.g. from livestock, wildlife, sewage treatment, human habitation, manure and composting operations or intermittent or temporary environmental contamination, such as heavy rain or flooding). A decision tree on the possible need for a fit-for-purpose assessment on the water is proposed in Figure 1.

Figure 1: Decision tree on the possible need for a fit-for-purpose assessment on the water.



11. When water is tested for microbiological hazards, the results should be used by growers and associated operators to inform on the use of water according to the risk associated with the production. The frequency of testing will depend on the water source (i.e. lower for adequately maintained deep wells, higher for surface waters), observed quality based on preceding testing, the risks of environmental contamination, including intermittent or temporary contamination, and factors such as the implementation of another water treatment process by growers.

12. If water testing is limited to indicator organisms, frequent water tests may be useful to establish the baseline water quality so that subsequent changes in the levels of contamination can be identified. Water testing should

be more frequent when establishing the baseline, but the frequency can be lowered once there is a better understanding of the patterns (e.g. seasonality) for microorganisms in the water source. Then, if there are results outside of the range, testing frequency can be increased again at that point.

13. Growers and associated operators should reassess the potential for microbiological contamination and the need for additional testing if events, environmental conditions (e.g. temperature fluctuations due to change in season, heavy rainfall) or other conditions indicate that water quality may have changed.

14. When testing, growers may consult, if necessary, the competent authority or experts, or refer to regulations, in order to determine and document the following:

    - where to sample (e.g. surface of the water or deeper, close to the edge of surface water or farther back from the bank) and how much to sample;
    - Which validated test methods should be conducted (e.g. for which pathogens and/or indicator organisms);
    - which parameters should be recorded (e.g. temperature of water sample, water source location, weather description and/or time and temperature between sampling and analysis);
    - how often tests should be conducted;
    - how test results should be analysed and interpreted over time, for example, to calculate the rolling geometric mean; and
    - how test results will be used to define corrective actions including use of an alternative source of water.

15. If the water source is found to have unacceptable levels of indicator organisms or is contaminated with waterborne pathogens, corrective actions should be taken to ensure that the water is suitable for its intended use. Possible corrective actions to prevent contamination of water and fresh produce at primary production may include:

    - the installation of fencing to prevent large animal contact;
    - improvement of good agricultural practices (GAPs) to prevent contamination from animal waste and fertilizer;
    - the proper maintenance of wells;
    - the prevention of the stirring of the sediment when drawing water;
    - the proper maintenance of distribution and storage systems;
    - changing the water application method to avoid direct contact of the water with the edible portion of the crop; and
    - maximizing the interval between application of irrigation water and crop harvest, as time-to-harvest intervals will impact the die-off rate of microorganisms which is affected by different weather conditions, produce types, and type of bacteria.

Possible corrective action to reduce contamination at primary production may include:

- water filtering by a system that allows capturing particles on which microbiological contaminants may be attached;
- chemical water treatment; and,
- the construction of settling or holding ponds or water treatment facilities;

16. The effectiveness of corrective actions should be verified by regular testing. Where possible, growers should have a contingency plan in place that identifies an alternative source of water.

Water for irrigation (including greenhouses)

17. The irrigation system or application method affects the risk of contamination. The timing, the quality of water used, and whether the water has direct contact with the edible portion of the plant should all be considered when selecting the irrigation system or application method to use. Overhead irrigation presents the highest risk of contamination where it wets the edible portion of the crop. The duration of wetting can be several hours,

and the physical force of water-droplet impact and the splashing of the soil to the edible part of the product may drive contamination into protected sites on the leaf/produce. If overhead irrigation cannot be avoided, the use of low volume sprays can reduce the risk. Subsurface or drip irrigation that results in no wetting of the plant is the irrigation method with the least risk of contamination, although localized problems may still arise, e.g. when using drip irrigation, care should be taken to avoid creating pools of water on the soil surface or in furrows that may come into contact with the edible portion of the crop.

18. Water for irrigation should be fit for purpose. Special attention should be given to water quality in the following situations:

    - irrigation by water-delivery techniques that expose the edible portion of fresh produce directly to water (e.g. sprayers), especially close to harvest time;
    - irrigation of fresh produce that have physical characteristics such as leaves and rough surfaces that can trap water; and
    - irrigation of fresh produce that will receive little or no post-harvest wash treatments prior to packing, such as field-packed produce.

19. A number of GAPs for irrigation might be considered:

    - Establish no-harvest zones if the irrigation source water is known or likely to contain human pathogens, and where failure at connections results in overspray of plants or localized flooding;
    - Record the crop, date and time of irrigation, water source and any pesticides or fertilizers applied using water.
    - Maintain and protect the source of the water used/stored and verify its quality.
    - Where possible, avoid the use of high-risk water sources such as poorly stored rainwater, untreated wastewaters and surface waters from rivers, lakes and ponds.
    - Growers should focus on the adoption of GAPs to minimize and control the risk of contaminated water and not use testing as the sole method for ensuring control of microbial pathogens in water.
    - The type of crop (i.e. ready-to-eat or requiring cooking), timing, irrigation system, soil type and whether the irrigation water has direct contact with the edible portion of the plant should be considered by growers. If contaminated water is in contact with the edible portion of plants, the risk of contamination increases, especially if close to harvesting.
    - Where possible, avoid water spraying immediately prior to harvest. Water spraying, i.e. misting, immediately prior to harvest, presents an increased microbiological risk. If the soil is heavy and non-free draining, contaminated water can accumulate on the soil surface, increasing the risk of crop contamination.
    - Minimize soil splashing from irrigation by choosing a system that delivers small water droplets. For low-growing crops, it may not be possible to minimize water contact in this way. The risk of contamination increases if large irrigation droplets are used or heavy rain occurs. It should also be noted that if the soil has been contaminated by irrigation water, soil splash can transfer contamination to crops.
    - Inspect the complete irrigation system under the farmer's control at the beginning of each growing season and repair the system or apply corrective measures if necessary.
    - Properly store organic fertilizers and manure in areas away from water sources, with no possibility of being washed away by runoff.

20. Those responsible for the water-distribution system, where appropriate, should regularly carry out an evaluation to determine if a contamination source exists and can be eliminated. Water testing records should be kept.

Water for fertilizers, pest control and other agricultural chemicals

21. Water used for the application of water-soluble fertilizers, pesticides and other agricultural chemicals that come in direct contact with products should be of the same quality as water used for direct contact irrigation and should not compromise produce safety, especially if they are applied directly on edible portions of the fresh

produce close to harvest. Human pathogens can survive and multiply in many agrichemicals, including pesticides.

Hydroponic water

22. Microbiological risks of water used in growing fruits and vegetables hydroponically may differ from the microbiological risks of water used to irrigate fruits and vegetables in soil because the nutrient solution used may enhance the survival or growth of pathogens. It is especially critical in hydroponic operations to maintain the water quality to reduce the risk of contamination and survival/growth of pathogens.

23. The following should be taken into consideration:
    - Water used in hydroponic culture should be changed frequently or, if recycled, treated to minimize microbiological contamination.
    - Water-delivery systems should be maintained and cleaned, as appropriate, to prevent microbiological contamination of water.
    - In the case of a combination of aquaculture and hydroponics (i.e. aquaponics), effluent from fish tanks should be treated to minimize microbiological contamination.

Water for other agricultural uses

24. Clean water should be used for other agricultural purposes, such as dust abatement and the maintenance of roads, yards and parking lots, in areas where fresh produce is grown. This includes water used to minimize dust on dirt roads within or near primary production sites. This provision may not be necessary when water used for this purpose cannot reach the fruits and vegetables (e.g. in the cases of tall fruit trees, live tree fences or indoor cultivation).

Water for indoor storage and distribution facilities

25. Where appropriate, an adequate supply of clean water with appropriate facilities for its storage and distribution should be available in indoor primary production facilities. Non-potable water should have a separate storage and distribution system.

26. Non-potable water systems should be identified (for example with labels or colour codes) and should not connect with or allow reflux into potable water systems. Water for indoor storage and distribution facilities should:
    - avoid contaminating water supplies by exposure to agricultural inputs that may contain microbial hazards;
    - clean and disinfect water storage facilities on a regular basis; and
    - control the quality of the water supply.

HARVEST and POST-HARVEST USE OF WATER

General

27. Water used during harvesting and post-harvest practices includes any water that contacts fresh produce during or after harvest including water used for rinsing, washing, transporting or fluming, cooling, waxing or icing. The microbiological quality of post-harvest water is critical because microbial die-off on the fresh produce before consumption is minimal, in particular in case of ready-to-eat produce.

28. Water-quality management varies throughout the operations. Packers should follow GHPs to prevent or minimize the potential for the introduction or spread of pathogens in processing water. The quality of water used should depend on the stage of the operation: for example, clean water could be used for initial washing stages, whereas water used for final rinses should be of potable quality.

29. Clean, or preferably potable water, should be used when water is applied under pressure or vacuum during washing, as these processes may damage the structure of and force pathogens into plant cells.

30. It is recommended that the quality of the water used in packing establishments be controlled, monitored and recorded by testing for indicator organisms and/or foodborne pathogens. When the results of such (verification) testing are not available right away, or when the frequency of verification testing is low, it is recommended to carry out other complementary operational monitoring such as rapid water-quality testing by testing of turbidity, chlorine residuals or visual observation.

31. If water is used in pre-washing and washing tanks, additional controls (e.g. changing water whenever necessary and controlling product throughput capacity) should be adopted.

32. If large quantities of fresh produce are washed in the same volume of water, accumulation of microorganisms occurs which favours cross-contamination between different product batches. Residual concentration of biocides in the process water can be used to maintain the microbiological quality of process water to avoid accumulation of microorganisms in the water tank and reduce cross-contamination in the washing tank.

33. Post-harvest operations/systems that use water should be designed in such a manner as to minimize places where the product may lodge, or cause dirt buildup.

34. The use of biocides to maintain the microbiological quality of process water should comply with the requirements established by the competent authority and should be validated for efficacy. Biocides should never replace GHPs but be used in addition to GHPs, and where necessary to minimize post-harvest cross-contamination with biocide levels, monitored, controlled and recorded to ensure the maintenance of effective concentrations. The application of biocides should be followed by rinsing of the fresh produce as necessary to ensure that chemical residues do not exceed levels established by the competent authority, using overhead spray, not by an immersion tank without cross-contamination attention.

35. Where appropriate, 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.

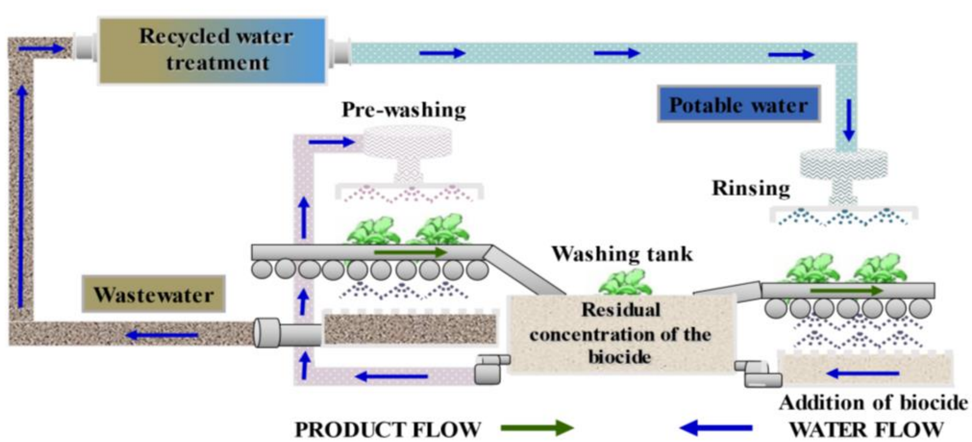
36. Ice that may come in contact with fresh produce should be made from potable water and produced, handled, transported, and stored in such a manner as to protect it from contamination.

37. Immersion of warm, whole or fresh-cut produce in cool water may induce water into the internal parts of the fresh produce and some fresh produce with high water contents, e.g. apples, celery, melons and tomatoes, are more susceptible to internalization through openings in the peel such as stem-end vascular tissue, stomata or puncture wounds. If the temperature of the wash water is less than the temperature of the produce, the temperature differential can force water into the produce contaminating it on the inside. It is recommended that in these cases, the temperature of the initial wash water is 10 °C higher than the fresh produce, if possible.

Reuse of water

38. Water reuse is also possible in the fresh produce industry. As a principle, water reuse should move backwards through the system from clean to less clean steps in the process. Figure 2 shows how water from the rinsing step can be used for the washing tank and how the water in the washing tank can be used as a pre-washing step.

Figure 2. Example of a potential option for water reuse in the fresh produce industry.



39. The water used in the final rinsing step should be potable water. After rinsing, this water should be treated with a biocide to have a residual concentration of the biocide able to minimize cross-contamination in the

washing tank. By doing this, the water in the washing tank will have an "antimicrobial" activity to inactivate any potential pathogens that might be present in the washing tank coming from the produce.

40. The water from the washing tank can be also used as a pre-washing step. The pre-washing step should remove most of the organic matter and reduce the bacterial load that comes with the produce. This step will help maintain a residual concentration of biocides in the wash water tank, as some biocides are inactivated by organic matter. Reducing the soil and the dust that comes from the field in the pre-washing step will reduce the amount of organic matter and microorganisms introduced into the washing tank, increase the microbial quality of the water in the tank, and help maintain a residual concentration of biocides that are inactivated by organic matter.

41. The final rinsing step should also minimize the residues of the biocides (e.g. disinfection-by-products) in the fresh produce coming from the washing tank.

42. In order to have a more sustainable industry, which avoids the use of excessive amounts of water, the water used by the industry can be recycled using reconditioning treatments similar to those that are implemented in wastewater treatment plants to have water of a quality similar to that of potable water.

43. Recycled water should be treated and maintained in conditions that do not constitute a risk to the safety of fresh produce. The treatment process should be effectively monitored, controlled, and recorded. For example, a treatment process that includes primary screening, secondary filtration and a biocidal treatment could be used to maintain the suitability of recycled water.

44. Recycled water may be used with no further treatment, provided its use does not constitute a risk to the safety of fresh produce (e.g. use of water recovered from the final rinsing for the washing step).

45. If treating water for use in washing and rinsing, it is recommended to seek professional advice from experts on the safe (re-)use of water in fresh produce before purchasing, installing, and using any water treatment system, e.g. water chlorination system.

Documentation

46. Documented procedures should be developed for the washing and rinsing of fresh produce, including on:

    - the use of vigorous washing to increase the chances of removing contamination if the fresh produce is not subject to bruising;
    - the frequency of water replenishment for washing and rinsing considered suitable to minimize risks of fresh produce contamination;
    - the monitoring of the water temperature during washing and rinsing, if necessary;
    - the use of a de-watering step, where possible, to remove excess water from the fresh produce, as dry produce is less likely to become re-contaminated; in such case, water should be removed gently to prevent damage to produce.

47. Develop documented procedures for cleaning and sanitizing of surfaces coming into contact with the fresh produce and used in washing and rinsing of fresh produce which includes:

    - All washing and rinsing equipment should be hygienically designed to help ensure adequate cleaning and sanitizing.
    - All equipment should be cleaned after use. Mud, soil and fresh produce debris should be removed from equipment, then it should be washed with a detergent and rinsed before a final wash with a chemical disinfectant and, where necessary, a thorough rinse with potable water.
    - Ancillary equipment such as knives and blades, and boots and protective clothing should be cleaned and disinfected at the end of each day.
    - Maximum run time, between cleaning and sanitation cycles, should be determined for each process line.

WATER FIT-FOR-PURPOSE ASSESSMENT

48. The development of a risk-based strategy for water sourcing, use and reuse should take into account:

    - identification of water-related microbiological hazards and source of those hazards, relevant for the area of production;

- sources of water available;
- the description of the water supply system (e.g. delivery and storage system)
- uses of water considered such as irrigation, washing (fresh produce, containers and surfaces), storage on ice, etc.;
- type of irrigation, in particular, if the water is in direct contact with the produce;
- type of crop (e.g. leafy greens versus fruit trees);
- physiological characteristics of the fresh produce (such as the peel and whether the produce would be subject to infiltration of water in the produce);
- water treatment and water disinfection techniques available such as heating, microfiltration and treatment with chlorine, chlorine dioxide, chloramine, ozone, UV-C;
- application after use of water (e.g. irrigation cessation, washing, peeling);
- consumers' habits such as eating raw, cooking, fermenting, etc.; and
- labelling with instructions for the intended use of the food.

49. If the fresh produce is consumed raw, the source of water should be identified, and the related risk should be assessed in view of determining the level of control measures.

    - Potentially high or unknown risk if for example untreated wastewater, surface water or shallow groundwater.
    - Potentially medium risk if for example collected rainwater.
    - Potentially low risk if treated (waste) water, potable water or deep groundwater.

50. The matrix in Table 1 is an example that can be used as a simple approach to the potential level of risk posed by the use or reuse of various water sources during pre-harvest stages of fresh produce and their intended use.

Table 1[6] Example to estimate the potential level of risk posed by the use or reuse of various water sources during pre-harvest stages of fresh produce according to their intended use.

Intended use of fresh produce	Contact of the water with edible portion?	Water source				
		Wastewater	Surface and groundwater of unknown quality	Groundwater collected from protected wells	Hygienically collected rainwater	Potable water, deep groundwater, or other water, including treated reused water, which complies with the microbiological criteria applicable to potable water.
Ready-to-eat	YES	High risk	High risk	Medium risk	Medium risk	Low risk
	NO	High risk	High risk	Low risk	Low risk	Low risk
Cooked	YES	Low risk[i]	Low risk[i]	Low risk	Low risk	Low risk
	NO	Low risk[i]	Low risk[i]	Low risk	Low risk	Low risk

[i] Instead of low-risk ranking in the JEMRA report, No. 33,[10] medium-risk ranking may be considered because the microbial reduction of cooking procedures can be highly variable, depending on the type of produce, the cooking time and temperature applied and the level of contamination of the water. Contact of water with the edible part may also enhance the risk.

51. When data (e.g. on microbial quality of the water sources, and on relevant health data from exposed populations) and resources allow the conduct of a quantitative or semi-quantitative risk assessment can be considered. This may allow risk mitigation measures to be more cost-effective and tailored to the specific needs.

RISK MITIGATION/RISK MANAGEMENT STRATEGIES

Indicator organism for monitoring hazards in water used in fresh produce production

52. Indicator organisms should be used as indicators of faecal contamination rather than presence or concentration level of any specific pathogen. The major indicator organisms are *E. coli* and enterococci.

53. Such faecal indicators can be used as process indicators or to validate the efficacy of water treatments if they respond to treatment processes in a similar manner to pathogens of concern.

54. It should be taken into account that, in general, faecal indicators reasonably predict the probable presence of faecal pathogens in water, but they cannot precisely predict the concentrations present, with the possible exception of heavily polluted waters. The correlation becomes erratic and biologically improbable as dilution occurs.

55. Bacteriophages are better indicators of enteric viruses than bacterial faecal indicators, although they cannot be absolutely relied upon as indicators for enteric viruses. A combination of two or more bacteriophages can be considered. Bacteriophages can be used as good process indicators to determine the efficacy of water treatments against enteric viruses.

56. Protozoa and helminths cysts/eggs survive more easily than bacteria and viruses and there is no suitable indicator of their presence/absence in irrigation water. Specific tests should be performed if the presence of these parasites is suspected.

Examples for determining water fit-for-purpose sampling frequency and microbiological criteria

57. The determination of a fit-for-purpose sampling frequency can contain the following steps:
    - Identify the activities at the farm in which water is applied.
    - Identify the sources of water available for the farm.
    - Evaluate the use of water in relation to the potential contamination to edible parts of the fresh produce.
    - Check the quality of the water before its use (before the start of the growth season).
    - Monitor the quality of water regularly during the growing period.[ii]

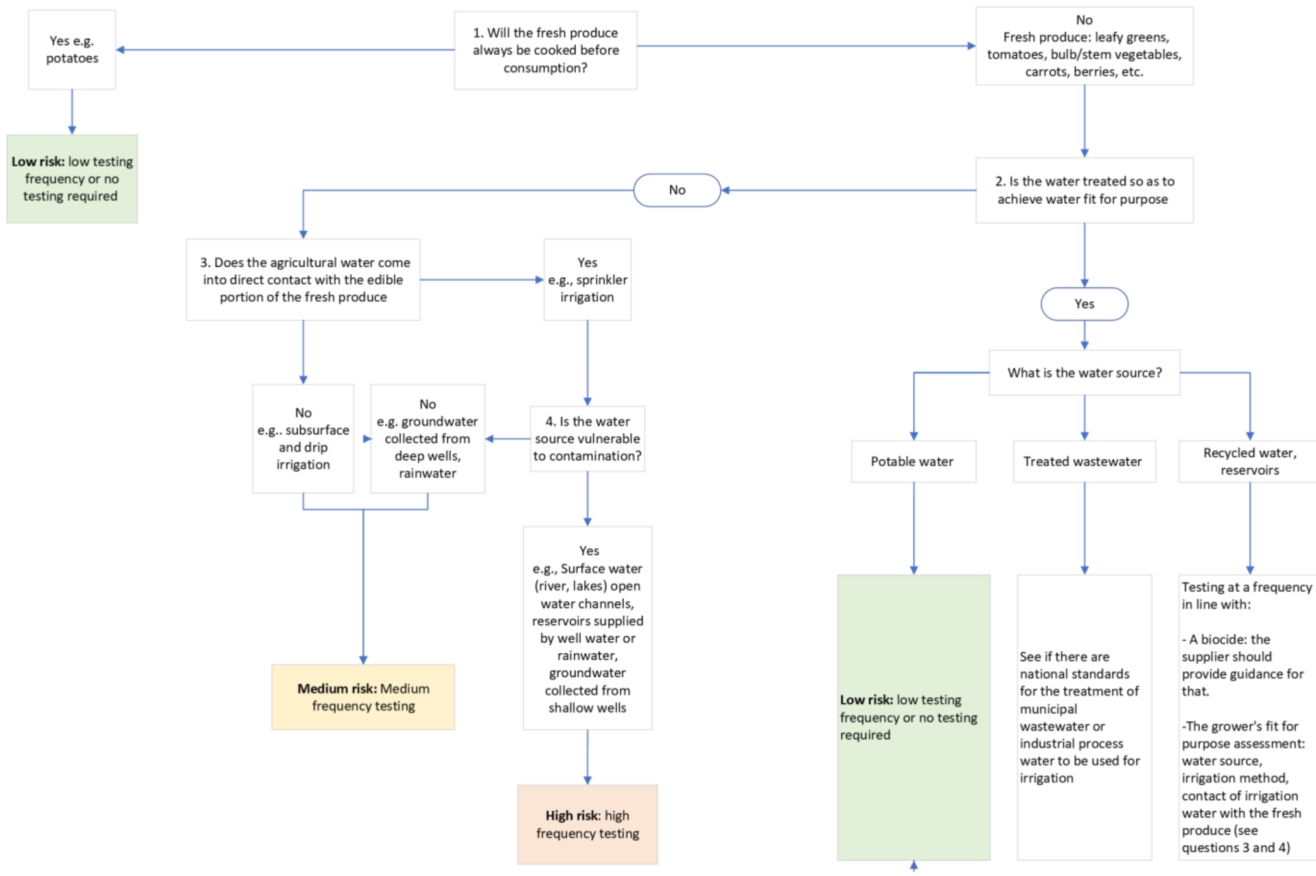
58. A risk-based approach can be used for determining testing frequency. For example, the use of potentially high or unknown risk water (see Figure 1 and Table 1) should result in a high frequency of testing, potentially medium-risk water should result in a medium frequency of testing, and potentially low-risk water should result in a low frequency of testing or no testing.

59. A decision tree approach (for example Figure 3)[iii] could also be used to determine the frequency of testing.

[ii] Examples of monitoring strategies have been provided in Annex 4 of the JEMRA report (FAO and WHO. 2021. *Safety and quality of water used with fresh fruits and vegetables*. Microbiological Risk Assessment Series No. 37. Rome. https://doi.org/10.4060/cb7678en).

[iii] Adapted from European Commission Notice No. 2017/C 163/01 Guidance document on addressing microbiological risks in fresh fruit and vegetables at primary production through good hygiene. (https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52017XC0523(03)&from=LV). Accessed by JEMRA as resource for Figure 3 in MRA 33, Safety and Quality of Water Used in Food Production and Processing.

Figure 3: Example of a decision tree for water testing frequency.



Examples of decision support system (DSS) tools

60. There is no single DSS tool that applies/fits in all situations. The DTs and examples in Figures 1 and 3, therefore should rather be considered as an approach to evaluate a situation instead of as a tool fixed for all purposes.

61. Based on Table 1 and Figure 3 of the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA) report No. 33 (FAO and WHO, 2019),[6] a DSS can be developed, using scores to assess the risk or the effectiveness of control measures related to the risk derived from the use of water. The scores below are examples for illustration only. There may be other considerations that could result in a different score.

62. Scores in the decision tool are:

- Related to the irrigation systems/direct or indirect contact with fresh produce:
  - No direct or indirect contact between irrigation water and produce: 3
  - Drip irrigation: 3
  - Furrow irrigation: 1
  - Overhead irrigation: 0
- Related to the application of mitigation options on water before irrigation:
  - On-farm water treatment ponds with 18+ hrs sedimentation period; water fetching without disturbing pond sediment: 1
  - Filtering water before irrigation: 1
  - None: 0

- Related to the application of one or more of the following mitigation options at or post-harvesting
  - Irrigation cessation (3 days): 2
  - Washing with running potable water: 1
  - Washing with running potable water + added biocide: 2
  - Peeling: 2
  - None: 0

63. The sum of scores is used to determine whether the water is safe to use for its intended purpose. The higher the sum of the scores the lower the associated risk. If the score is too low, the above scores can be used to select additional mitigation options or have an indication to which extent the microbiological quality of the water should be improved.

- When low-risk water (potable water, deep groundwater, other water showing compliance with microbiological criteria of potable water) is used and without the use of fresh manure, excreta, or sludge as fertilizer, the risk at primary production can be considered as low.
- When medium-risk water (e.g. collected rainwater or other water showing low microbiological contamination (e.g. *E. coli* 10 to 100 CFU/100ml)) is used, and without the use of fresh manure, excreta, or sludge as fertilizer, the risk at primary production can be considered as low, if a score of 4 is reached, by applying the irrigation system or mitigation options in the previous paragraph.
- When high or unknown risk water (wastewater, surface water, shallow groundwater, other water showing high microbiological contamination (e.g. *E. coli* 1000 CFU/100ml or more)) and without the use of fresh manure, excreta, or sludge as fertilizer, the risk at primary production can be considered as low, if a score of 6 and more is reached by applying the irrigation system or mitigation options in the previous paragraph.

64. An example of a DSS tool[iv] is provided in the appendix, based on the decision tool described in this section.

[iv] Other region/country specific examples can be found as « Sources for Figure 3 » in the 2019 FAO/WHO meeting report on Safety and Quality of Water Used in Food Production and Processing (MRA 33).[6]

Appendix 1: Examples of decisions based on support systems tool

The scores below are examples for illustration only. They are based on the DSS described in the last section of the annex on fresh produce. There can be other considerations that would result in a different score.

- Medium risk water, irrigation water not in contact with the edible portion of the fresh produce (3), no other treatment => total of 3: better to use other source or add mitigation option(s)
- Unknown risk water, irrigation water not in contact with the edible portion of the fresh produce (3), filtering before irrigation (1) and irrigation cessation (2) => total of 6: acceptable
- Medium risk water, irrigation water in contact with the edible portion of the fresh produce (0), irrigation cessation (2) + washing with potable water and biocide (2) => total of 4: acceptable.
- Unknown risk water, irrigation water in contact with the edible portion of the fresh produce (0), but filtering before irrigation (1) and irrigation cessation (2) + washing with potable water and biocide (2) + peeling (1) => total of 6: acceptable
- Medium risk water, irrigation water in contact with the edible portion of the fresh produce (0) + washing with running potable water and added biocide (2) + peeling (2) => total of 4: acceptable.

Scoring:

- 1–3 unacceptable (use other source or add mitigation options),
- 4–6 acceptable without further mitigation options.

NOTES

[1] FAO and WHO. 1969. *General Principles of Food Hygiene.* Codex Code of Practice, No. CXC 1-1969. Codex Alimentarius Commission. Rome.
[2] FAO and WHO. 2003. *Code of Hygienic Practice for Fresh Fruits and Vegetables.* Codex Code of Practice, No. CXC 53-2003. Codex Alimentarius Commission. Rome.
[3] FAO and WHO. 2007. *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM).* Codex Guideline, No. CXG 63-2007. Codex Alimentarius Commission. Rome.
[4] FAO and WHO. 1997. *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods*. Codex Guideline, No. CXG 21-1997. Codex Alimentarius Commission. Rome.
[5] FAO and WHO. 1999. *Principles and Guidelines for the Conduct of Microbiological Risk Assessment.* Codex Guideline, No. CXG 30-1999. Codex Alimentarius Commission. Rome.
[6] FAO and WHO. 2019. *Safety and Quality of Water Used in Food Production and Processing – Meeting report.* Microbiological Risk Assessment Series, No. 33. Rome. https://www.fao.org/3/ca6062en/CA6062EN.pdf

Annexes II Fishery Products and III Dairy Products (Under development)

Annex II

FISHERY PRODUCTS (Under development)

Annex III

DAIRY PRODUCTS (Under development)

Appendix V

PROJECT DOCUMENT

Development of Guidelines for Food Hygiene Control Measures in Traditional Markets for Food

(For approval)

1. Purpose and Scope of the Standard

Proposed new work to develop Guidelines for Food Hygiene Control Measures in Traditional Markets for Food would provide national and local governments worldwide with relevant advice to ensure that traditional markets for food are designed and managed effectively to promote food safety for the food sold in the markets. The proposed global guidelines would be informed by four regional guidance for street-vended food that have content on the management of markets and could also provide food business operators with advice on food handling, health and hygiene relevant to ensuring the safety of food sold in the markets.

Traditional markets for food have many names around the globe. In some areas they are called street food markets, local markets, public markets, municipal markets, open air markets and farmers' markets. Traditional markets for food are dedicated spaces for consumers, food retailers and wholesalers to purchase food for home preparation, and other food processing. Markets frequently also have street-vended food available for sale and consumption.

Traditional markets for food need focused attention and support if they are to improve food safety. In addition to being an important food source, markets are community gathering areas and an ideal place for sharing food safety, nutrition and community health information. Having a normative global exercise to update and harmonize guidelines will equip stakeholders (regulators, vendors, FBOs, consumers) to strengthen capacities in those markets so they can provide safer food, market access, and help in delivering the 2030 Sustainable Development Goals. This was recognized by the World Health Organization in its Global Strategy for Food Safety 2022-2030, which says, "Developing guidance and scale-up plans to improve the safety of food traded in traditional food markets is a priority."[1]

2. Relevance and Timeliness

Street-vended foods are defined by Codex as "ready-to-eat foods and beverages prepared and/or sold by vendors in streets and other public places for immediate consumption or consumption at a later time" (see Guidelines and Codes of Practice described in section 6). Codex Guidelines and Codes of Practice also provides definitions for "Street Food Centers" and "Street Food Stalls" as the places where street foods are prepared, displayed, served and sold to the public. The term "Traditional markets," is broader, and used to describe dedicated spaces where consumers, food wholesalers and retailers can purchase fresh food for home preparation. They also frequently allow vendors to sell street-vended prepared food.[2]

Traditional markets for food in low- and middle-income countries (LMICs) play a critical role in food security and nutrition. In some regions, researchers estimate that up to 85% of food is purchased in those markets.[3] They are a particularly important source for lower-income and food insecure populations to access fresh, highly nutritious foods such as fresh fruits and vegetables. They also provide hotels, local and international food companies with ingredients for the food they produce. Most of the small exporters source their products from the traditional markets and they find their way to international trade.

However, these markets frequently lack the infrastructure and hygienic conditions needed to ensure food safety. These markets can be especially risky for foodborne hazards. This is due to poor market infrastructure, including limited access to potable water, poor hygienic conditions, and poor storage practices, among others.[4]

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[1] WHO global strategy for food safety 2022–2030: towards stronger food safety systems and global cooperation. Geneva: World Health Organization; 2022.

[2] DeWaal et al; *Regional Codex Guidelines and Their Potential to Impact Food Safety in Traditional Food Markets*; J Food Prot (2022); https://doi.org/10.4315/JFP-22-052.

[3] Anenu, Kebede, Researcher, ILRI/Addis Ababa University, oral remarks at the International Association of Food Protection, August 2022. See also Tschirley, D., Reardon, T., Dolislager, M., & Snyder, J. (2015). The Rise of a Middle Class in East and Southern Africa: Implications for Food System Transformation: The Middle Class and Food System Transformation in ESA. Journal of International Development, 27(5), 628–646. https://doi.org/10.1002/jid.3107.

[4] Alves da Silva, S., Cardoso, R. de C. V., Góes, J. Â. W., Santos, J. N., Ramos, F. P., Bispo de Jesus, R., Sabá do Vale, R., & Teles da Silva, P. S. (2014). Street food on the coast of Salvador, Bahia, Brazil: A study from the socioeconomic and food safety perspectives. Food Control, 40, 78–84. https://doi.org/10.1016/j.foodcont.2013.11.022

Cortese, R. D. M., Veiros, M. B., Feldman, C., & Cavalli, S. B. (2016). Food safety and hygiene practices of vendors during the chain of street food production in Florianopolis, Brazil: A cross-sectional study. Food Control, 62, 178–186. https://doi.org/10.1016/j.foodcont.2015.10.027

While four regional committees considered the food safety issues of street-vended foods, their scope has not addressed the hygienic conditions of traditional markets generally. While the content of the regional guidance is useful, it does not cover all aspects of market operations, with variability in coverage from region to region. Given the global burden of disease estimates of 600 million consumers a year, the need to improve conditions in traditional markets is acute. Given the importance of traditional markets for food in many areas of the world, global guidance would be very timely, and provide important health protection to consumers. As food security is of paramount importance for countries, updated and harmonized guidance to address food hazards will provide incentives for governments to address conditions in and modernize existing traditional markets.

3. Main aspects to be covered

Appropriate food safety regulation, inspection and enforcement in traditional markets for food have an important role in preventing and controlling foodborne and zoonotic diseases, improving health, enhancing food security and strengthening the economy. The proposed Guidelines for Food Hygiene Control Measures in Traditional Markets for Food would be developed by the Committee, using a process to identify the relevant food safety topics from the existing Codex guidelines and codes of practice for street-vended foods. A 2021 comparative review of the regional guidance found there are many common food safety content areas and also gaps in the existing regional guidelines.[5] The common areas relevant and important to harmonized global guidelines for traditional markets for food include:

- **Policy and regulation** Common topics include the roles of stakeholders and authorities; regulation and monitoring of markets; and registration of vendors.
- **Market infrastructure** Common topics include design and infrastructure of markets; and maintenance and sanitation in markets.
- **Food handling** Common topics include food sourcing and handling in markets; requirements for food preparation; and protection and sale of ready-to-eat food.
- **Personal health and hygiene of market participants.**
- **Training and education**.

In addition to this relevant content, WHO and FAO have published recommendations for governments on their oversight of traditional markets. This advice could also inform harmonized global guidelines for traditional markets for food.

4. Assessment against the Criteria for the establishment of work priorities

4.1 The text needs to be revised in order to meet the General criterion: Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and considering the identified needs of developing countries.

Traditional markets for food provide consumers with both the ingredients for preparing meals at home and also fully prepared and ready-to-eat foods. The conditions at the markets, including access to clean water, waste management and proximity to live animals, can lead to the spread of food pathogens and unsafe food handling. Conditions and practices that promote food safety are vital for both raw ingredients and prepared foods.

Traditional markets for food are an important source of nutritious and culturally appropriate food contributing to food security for billions of people all over the world. The markets also have a critical social function as settings where people purchase their food and meet with others. They provide a source of income for the community and attract tourists.[6] Considering street food alone, an estimated 2.5 billion people eat street food worldwide every day. It is a source of income for a vast number of people, particularly women.[7]

In addition to providing guidance for governments, some of the regional codes of practice have useful advice for small and/or less-developed food businesses in both developed and developing countries. This objective should be retained in the new work.

Gadaga, T. H., Samende, B. K., Musuna, C., & Chibanda, D. (2008). The microbiological quality of informally vended foods in Harare, Zimbabwe. Food Control, 19(8), 829–832. https://doi.org/10.1016/j.foodcont.2007.07.016
Muyanja, C., Nayiga, L., Brenda, N., & Nasinyama, G. (2011). Practices, knowledge and risk factors of street food vendors in Uganda. Food Control, 22(10), 1551–1558. https://doi.org/10.1016/j.foodcont.2011.01.016

[5] DeWaal et al; *Regional Codex Guidelines and Their Potential to Impact Food Safety in Traditional Food Markets*; J Food Prot (2022); https://doi.org/10.4315/JFP-22-052.

[6] FAO and WHO World Food Safety Day Poster on traditional markets for food

[7] FAO and WHO World Food Safety Day 2022 Poster on street food vending

4.2 Diversification of national legislation and apparent resultant or potential impediments to international trade

While there is not a survey of national legislation on traditional markets, the gaps evident in the regional guidelines for street-vended foods are indicative of gaps that may exist in national legislation. For example, the Latin America Code of Practice has specific details on food handling relevant to street-food vendors but lacks infrastructure requirements for the markets.

4.3 Work already undertaken by other international organizations in this field

The World Health Organization published its Global Strategy for Food Safety 2022- 2030 and identified traditional markets for food as an important area of focus. It says, 'Developing guidance and scale-up plans to improve the safety of food traded in traditional food markets is a priority." In addition, the Global Strategy recognizes the role that Codex standards play in helping national governments develop effective food safety programs: "Member States should promote the uptake of Codex standards within domestic legislation, setting public health goals that the food industry can use as a benchmark when bringing innovation and economic change to sustainable national food systems. Member States should also consult the guidance from Codex standards to improve food safety by implementing measures to improve food hygiene and food handling,

The Global Alliance for Improved Nutrition has undertaken research on the normative standards that apply to traditional markets for food, including a comparative review of the four regional texts on street-vended food. It also examined WHO and FAO documents that can inform the Committee's work on traditional markets, including those developed during COVID to address conditions in markets that handle live animals.[8]

4.4 Amenability of the subject of the proposal to standardization

The four regional guidance for street-vended food provide many areas of overlap that indicate that global standardization would be achievable.

4.5 Consideration of the global magnitude of the problem or issue

Traditional markets for food exist all over the world and provide affordable fresh food for millions of consumers globally. In low- and middle-income countries, traditional markets for food can be the primary source of household foods, and they provide employment for many in the community. For consumers living in low- and middle-income countries, traditional markets are frequently their primary source of fresh foods, like meat, fish, fruits, and vegetables.

Markets that sit near country borders often sell foods to consumers, retailers and wholesalers on both sides of the border, so they are a source of food in regional trade. In addition, many fruits, spices, nuts and grains can enter international trade, as the markets are a source of products for commercial food processors and distributors. Examples of foods that might be sourced from traditional markets for food that enter international trade include frozen and dried fruits, vegetables, nuts, spices and grains. Lack of hygienic conditions in the market can impact the safety of all those foods.

The proposed Guidelines for Food Hygiene Control Measures in Traditional Markets for Food, as a harmonized global standard, could give governments relevant guidance on the market conditions and practices that can improve food safety and provide more efficient food control.

5. Relevance to the Codex strategic objectives

The proposed work directly relates to the following Codex Strategic Goals from the 2020-2025 Strategic Plan.

Goal 1 Address current, emerging and critical issues in a timely manner

COVID 19 illustrated the importance of addressing conditions in traditional markets for food, where food, people and animals all come together. Codex, through its regional Committees, has never directly addressed food safety issues in traditional markets, though its work on street-vended foods does indirectly provide some guidance in this area.

Goal 2 Develop standards based on science and Codex risk-analysis principles

Risk analysis as it applies to food safety across the food chain is an internationally accepted discipline and forms an integral part of any well-designed food safety control system. Through an active involvement of scientific and technical experts from many Codex members and observers we aim for a harmonized global standard addressing developments in the field of food safety risk management as they apply to traditional markets.

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[8] See https://www.gainhealth.org/resources/reports-and-publications/regional-codex-guidelines-and-their-potential-impact-food-safety. This research was also adapted for the Journal of Food Protection, previously cited.

Goal 3 Increase impact through the recognition and use of Codex standards

By creating standards of importance for many countries in managing domestic food trade, Codex will increase its relevance to low- and middle-income countries where traditional markets for food play a vital role in food distribution.

Goal 4 Facilitate the participation of all Codex Members throughout the standard setting process

Development of harmonized guidance for traditional markets has already generated support from countries in three Codex regions. The new work should generate great interest and broad participation from all members, with the objective to produce a user-friendly document that could be adopted and enforced as widely as possible. It provides specific attention to the food safety activities of small enterprises and to developing countries.

Goal 5 Enhance work management systems and practices that support the efficient and effective achievement of all strategic plan goals

More expeditious and efficient work by Codex is necessary to provide members and international organizations with the standards, guidelines, and recommendations that they need. During the development of this harmonized guideline, all working documents and electronic discussions will be distributed in a timely and transparent manner, using web-based technologies available freely to all.

This strategic goal is one of the core objectives of the Committee for Food Hygiene, as it will provide a solid ground for all Codex works related to food hygiene in traditional markets.

6. Information on the relation between the proposal and other existing Codex documents

While there are four separate Codex regional guidance on the regulation of street-vended foods, there is no guidance specific to traditional markets for food where both raw and prepared foods are often sold at the same location. Taken as a group, the regional guidance on street-vended foods has significant information relevant to the regulation of traditional markets for food. However, taken individually, gaps in each of the Codex documents show that global guidance is needed.

The regional guidance is listed below:

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

Many of the topics covered in the four regional guidance for street-vended foods are relevant to traditional markets for food, and many food safety topics overlap. But the approach varies widely between the regional guidance. For example, the African Guidelines contains specific advice on market infrastructure and cleaning practices; whereas the Latin American Code of Practice contains minimal content in those areas but has the most comprehensive information on the handling of raw foods in the market. Each of the regional guidance has content that should be considered in developing a uniform Codex text to cover the broader topic of traditional markets for food.

The proposed Guidelines for Food Hygiene Control Measures in Traditional Markets for Food will provide advice on food safety regulation and oversight activities relevant to traditional markets for food where both raw and prepared foods are often sold. It would be informed by the existing regional guidelines described above that cover street-vended foods and can co-exist with that guidance if the Committee chooses.[9]

7. Identification of any requirement for and availability of expert scientific advice

The FAO and WHO could facilitate this effort by reviewing their recommendations related to traditional markets for food and determining if there is useful information to address food safety that should be considered by the Committee. Also, a number of Codex observer organizations are willing to provide their expertise to aid in improving the content of the document or to make it easier to use.

[9] We note some of the regional guidance have not been updated recently (e.g., the Africa Guideline was last updated in 1997; the Latin American Code of Practice was updated in 2001).

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for

Technical input is expected from Codex observer organizations, including the Global Alliance for Improved Nutrition and the Consumer Foods Goods Forum. Such input is important as these organizations would be among the organizations that would be advocating for and applying harmonized guidance.

9. The 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

Subject to the approval of the 46th session of the Codex Alimentarius Commission in 2023, the aim will be to complete the work within three sessions of CCFH, i.e., by CCFH56 for submission for final adoption to CAC.

Appendix VI

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

(For approval)

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 Vibrio species in seafood* (CXG 73-2010) to provide risk management options based on the latest scientific advice from FAO/WHO and to incorporate some relevant aspects of the revision of the *General Principles of Food Hygiene* (CXC 1-1969).

The intended scope of the guidelines will not be changed from the original guidelines.

2. Relevance and Timeliness

An FAO/WHO expert working meeting[1] held in 2019 noted several critical developments in the last decade: 1) The emergence of highly pathogenic strains, in particular the Pacific Northwest (PNW) *V. parahaemolyticus* strain (ST36), which have spread to the East coast of the United States of America, Europe, South America, and New Zealand. The pandemic spread of these highly pathogenic strains is of global concern for seafood safety. 2) In response to climate change, there has been a significant geographical spread regarding where seafood-associated vibrio infections have been reported, with a general trend in the poleward spread of *V. parahaemolyticus* and *V. vulnificus* cases. Over the last decade in particular, there has been an increase in reported illnesses as well as the geographical spread of foodborne infections associated with these bacteria into regions where reported infections were previously absent. 3) Globally, an increased at-risk population, increased population densities in coastal regions and improvements in diagnosis of infections may also have played a role in accentuating reported cases. 4) A range of new approaches for best practice, such as high-pressure treatment, harvesting curfews, relaying and temperature controls appear to offer effective and cost-effective approaches for reducing human health risks postharvest associated with these pathogens. Finally, 5) a range of new methods, such as those utilizing genomics and satellite imagery, provide novel means of complementing approaches outlined in previous risk assessment exercises for these globally important foodborne pathogens. New scientific information provided by FAO/WHO justify the need and timeliness of the revision of the Guideline.

New information provided by FAO/WHO can offer significant benefits to competent authorities and food businesses to minimize the risk associated with pathogenic vibrios.

While the fundamental principles in the original document (CXG 73-2010) are likely to largely remain the same, practical guidance covering the specific implementation of control measures will help national competent authorities to reduce the burden of food-borne vibriosis and to ensure fair practice in the international seafood trade.

3. Main aspects to be covered

The new work is intended to update Guidelines on the application of the *General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood* based on the latest scientific information, and to incorporate some relevant aspects of the revised *General Principles and Food Hygiene (CXC 1-1969)*. 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 *V. parahaemolyticus* and *V. vulnificus;* including:

- microbiological monitoring methods, particularly molecular-based 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 vibrio's,
- remote sensing-based techniques to measure variables such as temperature and salinity, climate change,
- practical interventions that can be used to reduce vibriosis risks associated with the consumption of seafood, include preharvest intervention e.g., relaying, at harvest (such as reduced cooling

[1] FAO and WHO. 2021. Advances in science and risk assessment tools for *Vibrio parahaemolyticus* and *V. vulnificus* associated with seafood. Meeting report. Microbiological Risk Assessment Series No. 35. Rome. https://doi.org/10.4060/cb5834en

times), and post-harvest treatments, e.g., high pressure processing, freezing and pasteurization etc.

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 the risk of vibriosis.

Criteria applicable to general subjects

(a) Diversification of national legislation and apparent resultant or potential impediments to international trade.

Additional guidance by Codex might assist countries in amending their legislation to reduce the risk of vibriosis and support fair practice in international seafood trade.

(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 *Vibrio* spp. in seafood.

(e) Consideration of the global magnitude of the problem or issue.

There is some evidence for the global spread of pathogenic *Vibrio* strains. Codex guidance is an essential contribution to reducing the global public health burden of vibriosis.

5. Relevance to the Codex strategic objectives

The proposed work is directly related to the purposes of the Codex Alimentarius Commission. Namely, goals one and five of the Codex Strategic Plan 2020-2025, to “Address current, emerging and critical issues in a timely manner” and to “Enhance work management systems and practices that support the efficient and effective achievement of all strategic plan goals”. 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 new information provided by FAO/WHO.

6. Information on the relation between the proposal and other existing Codex documents as well as other ongoing work

The amendment of specific guidance on pathogenic vibrio 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

Not required at this moment, but during the course of the revision, the Codex Committee on Food Hygiene (CCFH) may need additional scientific advice.

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 developing a standard should not normally exceed five years.

Subject to the Codex Alimentarius Commission approval at its 46th Session in 2023, it is hoped that the new work can be expedited (i.e., within two sessions of CCFH).

Appendix VII

CCFH FORWARD WORKPLAN

Title of Work	Last Revision	Information to Update (Yes/No)[1]	Impact to Public Health (High= 20/ Medium = 14/ Low = 8)	Trade Impact (10/5/4/2/0)[2]	Project document/ discussion paper (Yes/No)	FAO/WHO assistance needed? (Yes/No)	Comments	Total
Guidelines for Food Hygiene Control Measures in Traditional Food Markets (or a Code of Practice)	N/A	Yes	20	5	Yes Discussion paper (CRD26) CCFH52; Project document CCFH53	Not at this time		25
Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood (CXG 73-2010)	2010	Yes	20	10	Yes Project document CCFH53	Not at this time	Structure based on old GPFH sections will need revision to align with revised GPFH. Editorial: Water should reference revised GPFH section 7.3 and the MRA series 33 for guidance (ultimately the Guidelines for the safe use and re-use of water in food production)	30

[1] Information to Update (Currency of information): 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.

[2] 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

Title of Work	Last Revision	Information to Update (Yes/No)[1]	Impact to Public Health (High= 20/ Medium = 14/ Low = 8)	Trade Impact (10/5/4/2/0)[2]	Project document/ discussion paper (Yes/No)	FAO/WHO assistance needed? (Yes/No)	Comments	Total
Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat (CXG 78-2011)	2011	Yes (*Salmonella*)/ No (*Campylobacter*)	20	10	No	Yes CCFH has requested JEMRA to collate the relevant scientific information on *Salmonella* and *Campylobacter* in chicken meat in preparation for an update		30
Code of Practice on Food Allergen Management for Food Business Operators (CXC 80-2020)	2019	Yes (FAO/WHO Expert consultations) /No (CCFL input)	20	10	No		CCFL meets in May 2023 and will address the input from the FAO/WHO Expert Consultation on Allergens, including priority allergens, thresholds and allergen advisory labelling. CCFH should anticipate the need for revisions to this document in the near future.	30
Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food (CXG 79-2012)	2012	Yes	20	10	Discussion paper – CCFH53 Agenda item 8 CX/FH 22/53/8	Yes Discussion Paper identifies 5 elements where JEMRA input is needed	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[3]			13

[3] 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

Title of Work	Last Revision	Information to Update (Yes/No)[1]	Impact to Public Health (High= 20/ Medium = 14/ Low = 8)	Trade Impact (10/5/4/2/0)[2]	Project document/ discussion paper (Yes/No)	FAO/WHO assistance needed? (Yes/No)	Comments	Total
Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Foods (CXG 61-2007)	2009	Yes	20	10	No	Yes	JEMRA report *Listeria monocytogenes* in ready-to-eat (RTE) food: attribution, characterization and monitoring; FAO/WHO to conduct a full farm to table risk assessment for *Listeria monocytogenes* in foods Text should be aligned to revised sections of GPFH and new wording for headings	30
Texts below are ordered most recent to oldest. There is no new information for an update, however, revisions may be needed for alignment with other documents.								
Guidelines for Developing Performance Based Criteria for Microbiological Methods[4]	N/A	No[5]						
Code of Hygienic Practice for Low-Moisture Foods (CXC 75-2015)	2018	No					Sections should be re-aligned with revised GPFH sections.	
Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003)	2017	No					GPFH definitions - types of water should reference updated text of GPFH/ expert information	

[4] Review of methods in the *General Methods for the Detection of Irradiated Foods* (CXS 231 - 2001) to determine their fitness for purpose and their possible conversion to performance-based criteria. (See CCFH51 CRD3 where this was added to the Forward Workplan.)
[5] Changed from "yes". See CX/FH 22/53/2 Appendix 1 for information on why it is not possible to establish performance-based criteria for these methods for detection of irradiated foods.

Title of Work	Last Revision	Information to Update (Yes/No)[1]	Impact to Public Health (High= 20/ Medium = 14/ Low = 8)	Trade Impact (10/5/4/2/0)[2]	Project document/ discussion paper (Yes/No)	FAO/WHO assistance needed? (Yes/No)	Comments	Total
Guidelines on the Application of General Principles of Food Hygiene to the Control of Foodborne Parasites (CXG 88-2016)	2016	No					Section 3.1 - should update reference to align with revised GPFH to 'section 2.1'.	
Guidelines for the control of non-typhoidal Salmonella in Beef and Pork (CXG 87-2016)	2016	No					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.	
Guidelines for the Control of Trichinella spp. in Meat of Suidae (CXG 86-2015)	2015	No						
Guidelines for the Control of Taenia saginata in Meat of Domestic Cattle (CXG 85-2014)	2014	No						
Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CXG 30-1999)	2014	No					Hazard definition should be updated. Hazard identification should reference GPFH as a starting point.	

Title of Work	Last Revision	Information to Update (Yes/No)[1]	Impact to Public Health (High= 20/ Medium = 14/ Low = 8)	Trade Impact (10/5/4/2/0)[2]	Project document/ discussion paper (Yes/No)	FAO/WHO assistance needed? (Yes/No)	Comments	Total
Principles and Guidelines for the Establishment and Application of Microbiological Criteria related to Foods (CXG 21-1997)	2013	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.	
Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters (CXC 33-1985)	2011	No					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.	
Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CXC 66-2008)	2009	No					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.	

Title of Work	Last Revision	Information to Update (Yes/No)[1]	Impact to Public Health (High= 20/ Medium = 14/ Low = 8)	Trade Impact (10/5/4/2/0)[2]	Project document/ discussion paper (Yes/No)	FAO/WHO assistance needed? (Yes/No)	Comments	Total
Code of Hygienic Practice for Milk and Milk Products (CXC 57-2004)	2009	No					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.	

Title of Work	Last Revision	Information to Update (Yes/No)[1]	Impact to Public Health (High= 20/ Medium = 14/ Low = 8)	Trade Impact (10/5/4/2/0)[2]	Project document/ discussion paper (Yes/No)	FAO/WHO assistance needed? (Yes/No)	Comments	Total
Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM) (CXG 63-2007)	2008	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.	
Code of Hygienic Practice for Eggs and Egg Products (CXC 15-1976)	2007	No					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.	

Title of Work	Last Revision	Information to Update (Yes/No)[1]	Impact to Public Health (High= 20/ Medium = 14/ Low = 8)	Trade Impact (10/5/4/2/0)[2]	Project document/ discussion paper (Yes/No)	FAO/WHO assistance needed? (Yes/No)	Comments	Total
Code of Hygienic Practice for Meat (CXC 58-2005)[6]	2005	No					Should be updated for sections referenced to GPFH to align with revised GPFH sections.	
General Standard for Irradiated Food (CXS 106-1983)	2003	No					remove reference to Rev 3 and wording on HACCP as HACCP covered within GPFH text	
Code of Practice for Radiation Processing of Food (CXC 19-1979)	2003	No					Introduction – last paragraph should be updated to reflect HACCP application as in revised GPFH. Sections should be updated to align with revised GPFH.	
Code of Hygienic Practice for Bottled/Packaged Drinking Waters (other than natural mineral waters) (CXC 48-2001)	2001	No					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.	

[6] Code developed by the Codex Committee on Meat Hygiene

Title of Work	Last Revision	Information to Update (Yes/No)[1]	Impact to Public Health (High= 20/ Medium = 14/ Low = 8)	Trade Impact (10/5/4/2/0)[2]	Project document/ discussion paper (Yes/No)	FAO/WHO assistance needed? (Yes/No)	Comments	Total
Code of Hygienic Practice for the Transport of Food in Bulk and Semi-packed Food (CXC 47-2001)	2001	No					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	
Code of Hygienic Practice for Refrigerated Packaged Foods with Extended Shelf-life (CXC 46-1999)	1999	No					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	

Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering (CXC 39-1993)	1993	No					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.	
Code of Hygienic Practice for Low-acid and Acidified Low-acid Canned Foods (CXC 23-1979)	1993 1993	No					(CXC 23-1979): Definitions - cleaning, disinfection, and potable water should be updated to align with revised GPFH. Sections should be	

Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods (CXC 40-1993) *Guideline Procedures for the Visual Inspection of Lots of Canned Foods for Unacceptable Defects* (CXG 17-1993)[7] *Code of Hygienic Practice for Canned Fruit and Vegetable Products* (CXC 2-1969)[15]	1993 1969						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). (CXC 40-1993): 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. (CXC 2-1969): 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.	

[7] Documents developed by the Codex Committee on Processed Fruits and Vegetables.

Title of Work	Last Revision	Information to Update (Yes/No)[1]	Impact to Public Health (High= 20/ Medium = 14/ Low = 8)	Trade Impact (10/5/4/2/0)[2]	Project document/ discussion paper (Yes/No)	FAO/WHO assistance needed? (Yes/No)	Comments	Total
Code of Hygienic Practice for the Processing of Frog Legs (CXC 30-1983)	1983	No					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	