

CODEX ALIMENTARIUS COMMISSION



**Food and Agriculture
Organization of
the United Nations**



**World Health
Organization**

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REP 12/FH

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

*Thirty-fifth Session
Rome, Italy, 2 - 7 July 2012*

REPORT OF THE FORTY-THIRD SESSION OF THE

CODEX COMMITTEE ON FOOD HYGIENE

Miami, USA, 5 - 9 December 2011

NOTE: *This report includes Codex Circular Letter CL 2011/26-FH*

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CX 4/20.2

CL 2011/26-FH

TO: Codex Contact Points
Interested International Organizations

FROM: The Secretariat
Codex Alimentarius Commission
Joint FAO/WHO Food Standards Programme
FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy

SUBJECT: Distribution of the report of the Forty-third Session of the Codex Committee on Food Hygiene (REP12/FH)

The report of the Forty-third Session of the Codex Committee on Food Hygiene (CCFH) is attached. It will be considered by the Thirty-fifth Session of the Codex Alimentarius Commission, (Rome, Italy, 2 - 7 July 2012).

MATTERS FOR ADOPTION BY THE CODEX ALIMENTARIUS COMMISSION:

Proposed Draft Standards and Related Texts at Steps 5/8 of the Procedure

1. Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food (REP12/FH para. 50 and Appendix III); and
2. Proposed Draft Annex on Melons to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003) (REP11/FH para. 118 and Appendix IV).

Other texts for adoption

3. Amendment to the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (REP12/FH, para. 14 and Appendix II); and
4. Proposed Revision of the *Risk Analysis Principles and Procedures Applied by the Codex Committee on Food Hygiene* (REP12/FH, para. 129 and Appendix V).

Governments and interested international organizations are invited to comment on the above texts and should do so in writing, preferably by e-mail to the Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy : codex@fao.org or fax: +39 06 570.54593), **before 31 March 2012.**

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SUMMARY AND CONCLUSIONS

The Forty-third Session of the Codex Committee on Food Hygiene reached the following conclusions:

MATTERS FOR ADOPTION BY THE 35TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION:

The Committee:

- agreed to forward the Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food; and the Proposed Draft Annex to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003) for adoption at Step 5/8 (REP12/FH para. 50 and Appendix III and para. 118 and Appendix IV, respectively); and
- the Proposed Amendment to the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/GL 30-1999) and the Revision to the *Risk Analysis Principles and Procedures Applied by the Codex Committee on Food Hygiene* for adoption (REP12/FH, paras. 14 and Appendix II and para. 129 and Appendix V, respectively).

MATTERS FOR ACTION BY THE COMMISSION

NEW WORK

agreed to propose to the Commission to approve new work on:

- Revision of the *Code of Hygienic Practice for Spices and Dried Aromatic Plants* (CAC/RCP 42-1995) (REP12/FH, paras 137 - 138 and Appendix VII); and
- Annex on berries to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003) (REP12/FH, paras 139 - 140 and Appendix VIII).

MATTERS OF INTEREST TO THE COMMISSION AND FAO/WHO

The Committee agreed to:

- return the Proposed Draft Revision of the *Principles for the Establishment and Application of Microbiological Criteria for Foods* and the Proposed Draft Guidelines for Control of Specific Zoonotic Parasites in Meat: *Trichinella spiralis* and *Cysticercus bovis* to Step 2 for redrafting, circulation for comments at Step 3 and consideration at its next session (REP 12/FH, para. 69 and para. 94, respectively); and
- agreed to request comments and proposals on the hygiene provisions in the draft Guidelines for Street-vended Foods (Near East) and further consideration at its next Session with the view to provide guidance to the CCNEA (REP12/FH, para. 12).

Request FAO/WHO

- develop risk-based examples for *Trichinella* spp. and *Cysticercus bovis* to illustrate the level of consumer protection likely to be achieved with different post-harvest risk management options (REP 12/FH, para. 92); and
- peer review the risk profiles contained in CX/11/43/6 in the context of the FAO/WHO Expert Consultation and to make these risk profiles available in the repository of risk profiles on the FAO and WHO websites (REP12/FH, para. 93).

MATTERS OF INTEREST TO OTHER COMMITTEES

Committee on General Principles

- The Committee revised the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/GL 30-1999) to simplify it in line with Activity 2.2 of the Strategic Plan (2008 – 2013) and taking into account the recommendations in CL 2010/1-GP for adoption by the 35th Session of the Commission (REP12/FH, para. 14 and Appendix II).

Committee on Fish and Fishery Products

- The Committee agreed to recommend to CCFFP to remove the criterion for *Salmonella* (section I-6.5) from the *Standard for Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008) and to include in the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003), Section 7.2.2.2, the following: “When appropriate, taking into account the epidemiological situation as indicated by the results of environmental monitoring and/or other surveillance, the competent authority may decide to implement a criterion for *Salmonella*.” (REP12/FH, para. 8); and
- The Committee endorsed the hygiene provisions in the Draft Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish as amended by CCFFP and noted that part of the rationale provided by CCFFP for the retention of the second paragraph of 6.5 *Clostridium botulinum* that no outbreaks had been reported from the consumption of uneviscerated fish was not accurate, since outbreaks had been reported from these products (REP12/FH, para. 10).

INTRODUCTION

1. The Codex Committee on Food Hygiene (CCFH) held its Forty-third Session in Miami, United States of America, from 5 to 9 December 2011, at the kind invitation of the Government of the United States of America. Dr Emilio Esteban, of the United States of America, chaired the Session. The Session was attended by 261 delegates representing 90 member countries, one member organization and 9 international organizations including FAO and WHO. A complete list of participants, including the Secretariats, is attached as Appendix I.

OPENING OF THE SESSION

2. The Session was opened by Ms Karen Stuck, US Codex Manager.

3. Dr Elisabeth Hagen, Under Secretary for Food Safety, the U.S. Department of Agriculture, addressed the Committee. In her keynote address, she stressed the high priority given to food safety by the U.S. Government and the three key policies taken to enhance food safety within the U.S.A, namely, the prevention of foodborne illnesses along the farm-to-fork continuum; the new Food Safety Modernization Act (FSMA) shifting the focus of federal regulations from responding to contamination to preventing it; and the food safety improvements in the pre-harvest as well as in-plant settings.

Division of Competence

4. The Committee noted the division of competence between the European Union and its Member States, according to paragraph 5, Rule II of the Procedure of the Codex Alimentarius Commission, as presented in CRD 1.

ADOPTION OF THE AGENDA (Agenda Item 1)¹

5. The Committee adopted the Provisional Agenda as its Agenda for the Session and agreed to:

- establish an in-session working group on the *Revision of the Principles for the Establishment and Application of Microbiological Criteria for Foods*, led by Japan and Finland and working in English, French and Spanish, with the terms of reference as outlined in CRD 10; and
- consider the Agenda Items in the following order: Items 2, 3, 8, 9, 7, 6, 4 and 5.

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES TO THE FOOD HYGIENE COMMITTEE (Agenda Item 2)²

6. The Committee noted the information presented in CX/FH 11/43/2 and CX/FH 11/43/2-Add.1 and made the following comments and/or decisions.

Criteria for *Salmonella* in the Codex Standard for Live and Raw Bivalve Molluscs (CODEX STAN 292-2008)

7. The Committee considered the report of the FAO/WHO Expert Meeting on *Salmonella* in bivalve molluscs (see Agenda Item 3) and discussed whether the criterion for *Salmonella* should be retained in the Standard. Some delegations were of the view that the criterion should be removed from the Standard as it was inconsistent with the *Principles for the Establishment and Application of Microbiological Criteria for Food* (CAC/GL 21-1997) and that the criterion provided little or no added protection for salmonellosis above that achieved by risk management strategies, such as sanitary surveys and faecal indicator monitoring. Some other delegations were of the opinion that the criterion should be retained as it was widely used in their territory, especially due to the high consumption of live and raw bivalve molluscs which were not submitted to any treatment to reduce the level of *Salmonella* contamination. The Committee agreed to a proposal, which provided a level of flexibility to the application of the criterion by indicating that it could be implemented by competent authorities taking into account the epidemiological situation and based on environmental monitoring as well as other surveillance.

¹ CX/FH 11/43/1; CRD 1 (Division of competence between the European Union and its Member States, prepared by the European Union); CRD 10 (comments of Finland and Japan).

² CX/FH 11/43/2; CX/FH 11/43/2-Add.1; CRD 11 (comments of European Union, India and Japan); CRD 14 (comments of Argentina).

Conclusion

8. Noting that this type of provision was more appropriate to a code of practice, the Committee agreed to recommend to the Committee on Fish and Fishery Products (CCFFP) to remove the criterion for *Salmonella* (Section I-6.5) from the *Standard for Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008) and to include in the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003), Section 7.2.2.2, the following: “When appropriate, taking into account the epidemiological situation as indicated by the results of environmental monitoring and/or other surveillance, the competent authority may decide to implement a criterion for *Salmonella*.”

Endorsement of hygiene provisions in Codex Standards/Related Texts

9. In accordance with its terms of reference, the CCFH considered the replies of the CCFFP to the proposals made at the 42nd Session and the hygiene provisions in the draft Guidelines for Street-Vended Foods, developed by the FAO/WHO Coordinating Committee for the Near East (CCNEA).

Draft Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish

10. The Committee endorsed the hygiene provisions as amended by the CCFFP. The Committee, however, noted that part of the rationale provided by the CCFFP for the retention of the second paragraph of Section 6.5 *Clostridium botulinum* that no outbreaks had been reported from the consumption of uneviscerated fish (REP11/FFP, para. 49) was not accurate since outbreaks had been reported from these products.

Draft Regional Guidelines for Street-vended Foods (Near East)

11. The Committee noted the concerns expressed on some of the hygiene provisions in the draft Guidelines and agreed that there was a need to provide guidance to the CCNEA in this regard.

Conclusion

12. The Committee agreed to request comments and proposals on the hygiene provisions in the draft Guidelines for further consideration at its next Session with the view to provide guidance to the CCNEA. The Committee agreed to inform the 35th Session of the Commission of this decision.

Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL 30-1999)

13. The Committee agreed to insert a footnote in the Scope section of the document to indicate that the risk assessment principles also applied to feed and feed ingredients for food-producing animals where it could impact on food safety rather than to refer to feed throughout the document, as proposed in Annex I of CX/FH 11/43/2-Add.1.

Conclusion

14. The Committee agreed to forward the amendment to the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* to the 35th Session of the Commission for adoption (see Appendix II).

MATTERS ARISING FROM THE WORK OF FAO, WHO AND OTHER INTERNATIONAL ORGANIZATIONS (Agenda Item 3)³

PROGRESS REPORT ON THE JOINT FAO/WHO EXPERT MEETINGS ON MICROBIOLOGICAL RISK ASSESSMENT (JEMRA) AND RELATED MATTERS (Agenda Item 3a)

15. The Representative of WHO, on behalf of FAO and WHO, presented this item and provided an overview of JEMRA and other FAO and WHO activities relevant to the work of the Committee.

16. Following the request of the 42nd Session of the Committee to review the current status of knowledge of parasites in food to address the foodborne parasites in a horizontal manner, a call for data and experts had been issued by FAO and WHO. It was indicated that, in early 2012, FAO and WHO were going to implement an expert review of the data and information submitted. Member countries were encouraged to respond to the call to further improve the database and facilitate the review to be done by FAO and WHO.

³ CX/FH 11/43/3; CX/FH 11/43/3-Add.1; CRD 12 (comments of European Union).

17. The Committee was informed that, in response to a request made by its 42nd Session, a call for data requesting the information on the identification and control of microbial hazards associated with melons was issued. The information was reviewed and summarized by FAO/WHO and an expert, and provided to the members of the physical working group (June 2011) to develop an annex on melons to the *Code of Hygienic Practice for Fresh Fruits and Vegetables*. This report would undergo a peer-review process and be made available to the public.

18. The Representative announced that the “web-based tool for the Control of *Salmonella* and *Campylobacter* in Chicken Meat” was finalized and uploaded on the website (www.mramodels.org/poultryrmttool). The Representative expressed the appreciation of FAO and WHO to all who had reviewed the tool on several occasions and had conducted pilot studies utilizing the tool and provided their feedback. The Representative indicated that the continuous feedback from the users would be appreciated to further improve the tool.

19. The Committee also noted that another web-based tool to assess the impact of sampling plans was close to completion and the case studies to show how to apply this tool were under development. FAO and WHO would continue to develop the supporting materials to facilitate the application of this tool in 2012.

20. With regard to the follow-up work on *Vibrio* spp. in seafood, it was reported that an FAO/WHO Expert Meeting was convened in October 2011 to address the first part of the four steps suggested by the 42nd Session of the Committee⁴. The Expert Meeting discussed the performance criteria of analytical methods that would be required for users at the different points in the food chain. The Expert Meeting also proposed the strategy and provided concrete advice to enhance the data collection of *Vibrio* spp. in member countries. The final report of this Expert Meeting would be made available on the FAO and WHO websites in due course.

21. Finally, the Representative noted that the results of the survey conducted at the last Session to ask the views of the Committee on the current JEMRA activities and how it could be further improved was now summarized and would be used as a baseline against which future improvements could be measured and the comments from the survey would be taken into consideration in the work planning of JEMRA for the biennium 2012/2013.

22. The Representative of FAO, on behalf of FAO and WHO, explained the conclusions of the FAO/WHO Expert Meeting on *Salmonella* in bivalve molluscs (20-21 October 2011) which addressed the questions from CCFFP on whether there is significant public health risk associated with *Salmonella* in live and raw bivalves and whether the criterion and the accompanying sampling plan in the *Standard for Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008) would be meaningful for public health protection. The Expert Meeting noted that in parts of the world, where bivalve harvesting for direct human consumption (HDHC) was controlled through sanitary surveys using faecal coliforms or *Escherichia coli*, 0.5-2% samples could be positive for *Salmonella*, but epidemiological evidence from these regions indicated that there had been very few outbreaks (in the order of one every few years) and usually involving a relatively small number (<10) of consumers. Thus, the Expert Meeting concluded that bivalves harvested from HDHC areas do not cause frequent outbreaks of salmonellosis.

23. The Expert Meeting used two approaches to address the question on the usefulness of the criterion. The first, based on available data, looked at the incremental value of the *Salmonella* test over the faecal indicator (faecal coliform/*E. coli*) test. This indicated that performing *Salmonella* tests in addition to the *E. coli* test would increase the number of unacceptable lots detected from 9.0 to 9.5%. The second theoretical approach was based on the performance of the $n=5, c=0, m=0/25g$, which cannot reliably detect contamination levels of less than 2-5 cells of *Salmonella*/200g serving (which translates to an estimated risk of 1 in 200 servings). Thus, the assurance provided is that the risk was less than 1 in 200 and epidemiological data indicated that it is much lower than that. Therefore, the conclusion of the Expert Meeting was that the *Salmonella* criterion provided little or no additional protection above that achieved by the current risk management strategy using faecal indicators.

⁴ REP 11/FH, para. 20.

24. Several Delegations expressed appreciation for the work undertaken by JEMRA, specifically on the development of the web-based tool for the control of *Salmonella* and *Campylobacter* in chicken meat noting that the tool would facilitate the implementation of the recently adopted *Guidelines for the Control of Campylobacter and Salmonella spp. in Chicken Meat* (CAC/GL 78-2011) and would enable members to take a more risk-based approach to the management of *Campylobacter* and *Salmonella* in chicken meat. In addition, the finalization of the sampling plan tool was encouraged to facilitate and complement the ongoing work on the revision of the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (see Agenda Item 5).

INFORMATION FROM THE WORLD ORGANIZATION FOR ANIMAL HEALTH (OIE) (Agenda Item 3b)

25. The Observer from OIE informed the Committee that the OIE considered highly important that OIE and Codex have a joint approach to standard-setting on certain key topics, including trichinellosis and other zoonotic parasitic diseases, in order to ensure appropriate harmonisation of standards and recommendations while avoiding duplication of effort, overlap and gaps in the setting of international health standards.

26. The Observer informed the Committee that the OIE was reviewing scientific literature on *Salmonella* spp. in food-producing animals other than poultry and on verotoxigenic *E. coli* (VTEC) in food-producing animals with the view to determine the usefulness and feasibility of developing OIE advice on the control of these pathogens in the production phase to reduce foodborne illness.

27. The Observer also informed the Committee of the work of the OIE expert *ad hoc* Group on Zoonotic Parasites, which included participation of FAO, WHO and the Codex Secretariat, on the revision of the *Terrestrial Code* Chapter 8.13 on Trichinellosis with the goal of putting more emphasis on control measures at the on-farm level to help prevent foodborne illness in humans. The revised Chapter included recommendations for the safe importation of fresh meat or meat products of domestic and wild pigs, domestic and wild equines. Further work on the revision of the chapters on Trichinellosis and porcine cysticercus will take into account the country, zone, establishment, compartment and free trade commodity approach.

28. The Committee thanked the Observer from the OIE for the useful information and their participation in CCFH work and highlighted the importance for continued strengthening of the collaboration between Codex and OIE.

PROPOSED DRAFT GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF VIRUSES IN FOOD (Agenda Item 4)⁵

29. The Committee recalled that at its 42nd Session it had agreed to circulate the proposed draft Guidelines, as amended, for comments at Step 3 and to establish an electronic working group, led by The Netherlands, to prepare a revised proposed draft Guidelines on the basis of the written comments at Step 3 and the recommendations and discussions at the Session. It was further agreed that a physical working group, led by The Netherlands, would meet immediately prior to the current Session to consider comments submitted and to prepare a proposal for consideration to facilitate the finalization of the proposed draft Guidelines.

30. The Delegation of The Netherlands introduced the report of the physical working group, as presented in CRD 3, and explained that the physical working group had prepared revised draft Guidelines on the basis of the comments submitted and made during the physical working group's meeting. The working group made several changes, additions and rearrangements of the text to improve clarity and to give better guidance on some control measures. Other changes included, amongst others: the deletion of: "gamma irradiation" in Section 5.2.2 "Specific process procedures"; and the example of the length of time that a person, who had gastroenteritis, could return to work post-symptomatic.

⁵ CX/FH 11/43/4; CX/FH 11/43/4-Add.1 (comments of Argentina, Australia, Brazil, Colombia, Costa Rica, Egypt, Jamaica, Japan, Kenya, Mexico, New Zealand, Nicaragua, Peru, Senegal, Thailand, United States of America and IIR); CRD 3 (Report of the physical working group on the proposed draft Guidelines on the application of general principles of food hygiene to the control of viruses in food); CRD 4 (comments of Bolivia, European Union, Ghana, Guatemala, Honduras, India, Indonesia, Malaysia, Mali, Mexico, Nigeria, Norway, Viet Nam and IACFO).

31. The Delegation further noted that the working group had only partly discussed the two Annexes, due to time constraints. The working group had also suggested that the Committee could consider to forward Annex 1 “Control of Hepatitis A Virus (HAV) and Norovirus (NoV) in bivalve molluscs to the Codex Committee on Fish and Fishery Products (CCFFP) to verify consistency with the provisions in the *Standard for Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008) and the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

32. The Committee considered the proposed draft Guidelines, as revised by the working group, paragraph by paragraph and generally supported the revised text. In addition to minor editorial amendments and revisions to the French and Spanish version, the Committee made the following comments and changes.

Guidelines on the application of general principles of food hygiene to the control of viruses in foods (main text)

33. In the Introduction (paragraph 9), the Committee agreed to refer to both viral RNA and DNA detection, as more accurate and because the paragraph was part of the general introduction and not specific to Norovirus (NoV) and Hepatitis A Virus (HAV).

34. In Section 5.1 “Control of food hazards in relation to viral contamination”, the Committee noted that Sanitation Standard Operating Procedures (SSOPs) were very specific prerequisite programmes; however, it retained them as they were listed as an example in the document.

35. The new paragraph on clothes of food handlers, after paragraph 34 of Section 6.1.2 “Cleaning procedures and methods”, was moved to Section 7.3 “Personal cleanliness” (after paragraph 53) as more appropriate.

36. In Section 7.2 “Illness and injuries”, the Committee discussed the example of shedding of NoV and agreed to modify the period to “two or more weeks” on the basis of the information available.

37. The Committee accepted the proposal of the working group that “to the extent possible” children should not be present in food handling areas, where food is grown, harvested, stored or prepared.

38. The Committee amended: the new paragraph in Section 9.4 “Consumer education” to emphasize that countries should develop educational programmes to alert consumers of the risks of viruses in ready-to-eat foods; and the first paragraph of Section 10.1 “Awareness and responsibilities” by adding a sentence to strengthen the need to increase stakeholders’ awareness on viral foodborne outbreaks. The Committee also deleted the last bullet point in Section 10.2 “Training programmes” as it was not relevant to the section.

Annex I - Control of Hepatitis A virus (HAV) and Norovirus (NoV) in bivalve molluscs

39. The Delegation of Norway recommended to send Annex I to the CCFFP to align it with Section 7 on live and raw bivalve molluscs of the *Code of Practice on Fish and Fishery Products* (CAC/RCP 52-2003) and the *Standard on Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008). The Codex Secretariat noted that there was no obligation for the CCFH to forward the text to the CCFFP and that the responsibility of ensuring consistency of the text with other Codex texts was part of the task of the Committee and its working groups. It was further noted that it was the responsibility of the commodity committees to send their documents to the CCFH and other horizontal committees for endorsement and that the CCFFP would be informed of relevant CCFH work through the document on matters referred from the Commission and other Codex Committees and Task Forces.

40. In this regard the Delegation of Norway expressed concern that the CCFFP had not been informed earlier of this work and did not have the opportunity to provide their comments on the consistency of the Annex with relevant CCFFP texts.

41. The Committee revised the Annex and, in addition to some editorial changes, deletion of some repetitions and redundancies to improve the readability and use of the Annex, made the following comments and changes.

42. In the Section 2.3 “Definitions”, the Committee: replaced the definition for “Clean water” with a reference to the relevant section of CAC/RCP 52-2003 for consistency; and added the definitions for “Depuration”, “Relaying”, “Relaying areas” and “Growing areas” with a reference to the relevant section of CAC/RCP 52-2003.

43. The Committee amended paragraph 6 of Section 3 “Primary production”, to refer to sanitary survey of growing areas and to clarify that the time of conducting sanitary surveys depended also on climatic conditions, such as heavy rainfall.

44. The paragraphs on relaying (paragraph 7 and the new preceding paragraph) were moved to Section 3.2 “Hygienic production of food sources” as more appropriate.

45. The Committee noted that testing for NoV or HAV was an option and that testing for indicators of faecal contamination was more practical; that viral testing was expensive, complex and difficult and did not provide information about the infectious nature of the virus; and that testing of areas or other equivalent measures should be undertaken when there was evidence that the areas had been impacted by human sewage and not only on the basis of presumption. Therefore, the Committee amended the last sentence of paragraph 12 to specify that testing for the presence of indicators of faecal contamination and/or NoV or HAV should be conducted when there is evidence of human sewage contamination.

46. Section 9.3 “Labelling” was amended to also refer to the labelling provisions of the *Standard on Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008). The second paragraph of the Section was replaced with a new paragraph which addressed the labelling of unpackaged live and raw bivalve molluscs, consistent with the text of Section 9.3 “Labelling” of the *Guidelines on the Application of the General Principles of Food Hygiene to the Control of Pathogenic Vibrio species in Seafood* (CAC/GL 73-2010).

Annex II - Control of Hepatitis A Virus (HAV) and Norovirus (NoV) in fresh produce

47. The Committee amended the first sentence of paragraph 7 to improve its readability and in Section 2.3 “Definitions” replaced the definition for “Clean water” with a reference to the relevant section of CAC/RCP 53-2003.

48. The Committee moved the text under Section 4.4.4 to a new Section 3.2.3.1 “Personnel hygiene and sanitary facilities” as more appropriate.

Conclusion

49. In the light of the discussion and considerable progress made, the Committee agreed that the proposed draft Guidelines should be advanced to Step 5/8. The members of the FAO/WHO Coordinating Committee for Latin America and the Caribbean (CCLAC), present at the Session, were of the opinion that there is a wide technological disparity among countries regarding testing for viruses. These countries further expressed the view that the issue of food viruses was under development and much information was currently being generated. Thus this new information would not be in the document and its inclusion would be important in the short term. The countries of the region also noted that the short time between the conclusion of the physical working group, held immediately prior to the session, left little time for analysis by their technicians of the different modifications to the document and their implications. Given the importance of the issue of viruses in food, it was understood that the speed of the process might lead to future difficulties in the implementation of the Guidelines, and consequently cause a negative impact on their economies. Despite these concerns and in a spirit of compromise, these members accepted to advance the Guidelines to Step 5/8.

Status of the Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food

50. The Committee agreed to forward the Proposed draft Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food to the Commission for adoption at Step 5/8 with the recommendation to omit Steps 6 and 7 (*see* Appendix III).

PROPOSED DRAFT REVISION OF THE PRINCIPLES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA FOR FOODS (Agenda Item 5)⁶

51. The Committee recalled the decision of the 42nd Session to return the proposed draft revision of the Principles to Step 2 for revision by a physical working group, led by Finland and co-chaired by Japan, which was tasked to: (i) further consider the main document taking into account the comments received before and during the 42nd Session; (ii) elaborate an Annex with practical examples on the establishment and application of microbiological criteria; and (iii) initiate development of an Annex to address the statistical and mathematical aspects of establishing microbiological criteria including the elaboration of a sampling plan. The Committee further recalled that it had established an in-session working group to consider this Item (*see* Agenda Item 1).

52. The Delegation of Japan, introduced the reports of both the physical working group, held in Grange (Ireland) in July 2011 (CX/FH 11/43/5) and the in-session working group (CRD 19). The Co-chair of the working group highlighted the recommendation of the physical working group that the CCFH request FAO/WHO to provide technical support on the development of the Annex on the statistical and mathematical aspects, and in particular:

- prepare a Call for Data and collect from appropriate sources any relevant guidance regarding sampling plans, approaches and paradigms that could be applicable for the Annex on statistical and mathematical considerations;
- convene an expert meeting to peer review the collected materials for the suitability of developing the Annex on statistical and mathematical considerations for elaborating microbiological criteria; and
- prepare a report to be considered by CCFH for the elaboration of the Annex on statistical and mathematical considerations for elaborating microbiological criteria.

53. The main conclusions of the in-session working group were:

- to restructure the main document, as proposed by Australia with modifications;
- to retain the three categories of microbiological criteria, as the concepts could be useful; and
- to focus on food safety criteria and process hygiene criteria and not to address food processing environment criteria at this time.

54. With regard to the use of microbiological criteria in validation, the in-session working group had concluded that: (i) the maximum limit of microbiological criteria could be used as a target for validation; and (ii) all the components of microbiological criteria could be used in verification.

55. With regard to attributes versus variable sampling plans, the working group had concluded that these concepts should be rewritten in a more user-friendly manner and that, since these were more theoretical issues, they should not be central to the document.

56. The in-session working group proposed that the CCFH establish a physical working group with the following terms of reference:

- elaborate an Annex with practical examples on the establishment and application of microbiological criteria for different purposes through electronic means by teams of two or more countries;
- finalize these practical examples; and
- review and complete the main document based on the examples and the comments received before and during the current session.

57. The Committee discussed the proposals of the working groups as follows.

⁶ CX/FH 11/43/5; CX/FH 11/43/5-Add.1 (comments of Argentina, Australia, Brazil, Colombia, Costa Rica, Egypt, Jamaica, Japan, Kenya, Mexico, New Zealand, Peru, Philippines, Senegal, United States of America, Uruguay, ALA, ICMSF, IDF and IPC); CRD 5 (comments of Bolivia, European Union, Ghana, Honduras, India, Indonesia, Malaysia, Mali, Nicaragua, Switzerland and Viet Nam); CRD 10 (comments of Finland and Japan); CRD 14 (comments of Argentina); CRD 19 (Report of the in-session working group on Microbiological Criteria in Foods).

Request to FAO/WHO

58. The Committee agreed with the recommendation of the working group but noted that this request was not a high priority at this moment and could be considered in the future.

Structure of the documents and main elements thereof

59. The Committee agreed with the proposed structure and focus of the document.

New physical working group

60. The Committee agreed to establish a physical working group, led by Finland and co-chaired by Japan, as proposed. It noted the offer of Japan to host the meeting in English only and that in order to provide broad coverage in all three languages consideration would be given to other solutions. In this regard the European Union offered to host the physical working group with with interpretation in all three languages. The Committee welcomed this offer and noted that the meeting of the physical working group was tentatively planned in May/June 2012.

61. The Committee agreed to the proposal to elaborate practical examples, through electronic means by teams of two or more countries (lead country and two or more collaborating countries). The Committee also noted that support from the Codex Trust Fund could be explored to facilitate the active participation of developing countries in the elaboration of these examples.

62. The Representative of WHO informed that the Codex Trust Fund welcomed the initiative of the Committee as this could be a good example of shifting the emphasis of the Codex Trust Fund from Objective 1 “Widen participation” to Objective 2 “Strengthen overall participation”, and would be willing to provide their support only on the condition of strong commitment from leading countries and collaborating countries towards the successful completion of the development of the examples. The Representative also informed that any country that had ever been eligible for Codex Trust Fund support could be considered a candidate for this initiative.

63. The Committee noted that FAO and WHO would follow up on this pilot initiative to design an appropriate framework for the project and communicate with the participating countries in due course.

64. The Committee decided on the following examples to be developed and confirmed the drafting teams as follows:

Example 1: A GHP-based approach.

Drafting team: European Union (lead), Benin, Cameroon, Ghana and Panama.

Example 2: Microbiological Criterion is established for food to assess the acceptability of a food lot.

Drafting team: United States of America (lead), Argentina, Thailand and Uruguay.

Example 3a: Microbiological Criterion is established for the food to verify the performance of a HACCP System

Drafting team: IDF (lead), Bolivia, Gambia, and Nigeria.

Example 3b: Microbiological Criterion is established for the food to verify the performance of a Food Safety Control System.

Drafting team: New Zealand (lead), Costa Rica, Kenya, Kiribati and Samoa.

Example 4: Microbiological Criterion is established for a high prevalence foodborne pathogen for a risk-based approach.

Drafting team: Denmark (lead), Brazil, Colombia, Costa Rica, Senegal and ALA.

Example 5a: Operationalising a Performance Objective with a Microbiological Criterion for a risk-based approach.

Drafting team: Canada (lead), Brazil, France and India.

Example 5b: Operationalising a Performance Objective with a Microbiological Criterion for a risk-based approach.

Drafting team: United States of America (lead) and Brazil.

65. The Committee noted that the work on the development of these examples would start immediately after the current Session and that it was the responsibility of the leader of each team to make contact with the team members through their national Codex Contact Points.

66. The Committee also agreed to the proposal of the working group that the examples be developed according to the structure, presented in Annex 1 of CX/FH 11/43/5.

67. The Committee further agreed to convene a physical working group, led by Finland and co-chaired by Japan and working in English, French and Spanish, to meet immediately prior to its next Session to review comments received at Step 3 and facilitate the discussion at the Plenary.

68. The Committee agreed that the physical working group would include a presentation on microbiological criteria to help understanding of microbiological criteria and their application.

Status of the Proposed Draft Revision of the Principles for the Establishment and Application of Microbiological Criteria for Foods

69. The Committee agreed to return the proposed draft revision of the *Principles for the Establishment and Application of Microbiological Criteria for Foods* to Step 2 for redrafting by the aforementioned physical working group, for comments at Step 3 and consideration at the next Session.

PROPOSED DRAFT GUIDELINES FOR CONTROL OF SPECIFIC ZOOONOTIC PARASITES IN MEAT: *TRICHINELLA SPIRALIS* AND *CYSTICERCUS BOVIS* (Agenda Item 6)⁷

70. The Committee recalled the decision of the 42nd Session to request the 34th Session of the Commission to approve new work on Guidelines for Control of Specific Zoonotic Parasites in meat: *Trichinella spiralis* and *Cysticercus bovis* and to establish a physical working group, co-chaired by the European Union and New Zealand, to develop proposed draft Guidelines for Control of Specific Zoonotic Parasites in meat: *Trichinella spiralis* and *Cysticercus bovis* for circulation for comments at Step 3 and consideration by the current Session.

71. The Delegations of the European Union and New Zealand provided a presentation on the approach to developing the proposed draft guidelines, as summarised in CRD 18. The new approach replied to the need to establish a risk-based approach to the different ranges and intensities of inspection procedures used for *Trichinella* and *Cysticercus bovis* proportional to the epidemiological situation of a country or region. It was noted that such an approach was consistent with the provisions of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), which required that the selection of risk management options be based on the proportionality of risk and that the development of this new approach called for strong cooperation with OIE so as to facilitate a whole food chain approach to risk reduction measures.

72. The Delegations of the European Union and New Zealand summarised the recommendations of the physical working group, as presented in CX/FH 11/43/6, and proposed to:

- (i) establish an electronic working group to revise the proposed draft guidelines (Appendices I and II to CX/FH 11/43/6) on the basis of the written comments submitted at the present Session;
- (ii) discuss a proper location of the risk profiles on *Trichinella* and *Cysticercus bovis* (Appendices III and IV to CX/FH 11/43/6);
- (iii) consider extending the scope of the work on *Trichinella spiralis* to *Trichinella* spp; and
- (iv) discuss the status of the general document on parasites and the collaboration with OIE.

⁷ CX/FH 11/43/6; CX/FH 11/43/6-Add.1 (comments of Brazil, Colombia, Costa Rica, Egypt, Jamaica, Japan, Kenya, Mexico, Norway, Peru, Senegal, Uruguay, United States of America and OIE); CRD 6 (comments of European Union, Ghana, Guatemala, Honduras, Indonesia, Malaysia, Mali, Viet Nam and CLITRAVI); CRD 14 (comments of Argentina); CRD 18 (approach to developing the proposed draft standards on specific parasites in meat: *Trichinella* spp. and *Cysticercus bovis*, prepared by the European Union and New Zealand).

73. The Observer from OIE summarised the status of OIE work on the revision of Chapter 8.13 “Infection with *Trichinella* spp.” of the *Terrestrial Animal Health Code* and noted that the revised chapter, prepared by the *ad hoc* Expert Group on zoonotic parasites and revised by the OIE Code Commission in September 2011 had been circulated for comments to OIE Members. The Observer noted that the meeting of the OIE Code Commission (February 2012) would decide on the basis of the comments submitted whether to forward the revised chapter to the OIE General Assembly for adoption in May 2012 or to have another round of comments. The Observer stressed the need for a coordinated approach between OIE and Codex to the development of the guidelines on *Trichinella* at both global and national level. The Committee also noted that the OIE *ad hoc* Expert Group would consider work on porcine cysticercus at its next meeting.

74. The Representative of WHO, restated that FAO and WHO would continue to receive additional inputs from member countries and any interested parties on parasites in food and their public health and trade implications and, assuming that sufficient data and information would be made available, FAO and WHO would implement an expert review in early 2012 to identify: the parasite-commodity combinations of particular concern; the issues that need to be addressed by risk managers; and the options available to them.

75. The Committee considered the proposals presented by the Delegations of the European Union and New Zealand, as follows.

Electronic working group to revise the proposed draft guidelines

76. The Committee expressed general support for the establishment of an electronic working group to prepare revised proposed guidelines. However, some delegations were of the view that this work should wait until OIE had finalised its work on the revision of Chapter 8.13 of the *Terrestrial Animal Health Code*, while others were of the view that the Codex and OIE work could progress in parallel.

77. Other delegations, expressed concern as to the continuation of this work, which, in their view, should wait for the outcome of the FAO/WHO Expert Consultation on parasites, requested at the 42nd Session of the Committee⁸ and the development of a general guidance document on parasites that would provide the framework in which annexes on specific parasite/commodity combinations could be addressed. In this regard, the Codex Secretariat clarified that the guidelines on specific parasites could be either part of a general document on parasites or appended to another appropriate Codex document, such as the *Code of Hygienic Practice for Meat* (CAC/RCP 58-2005).

78. Some delegations also questioned whether the work on these two low-risk parasites was justified from a public health point of view. In this regard, other delegations noted that the main outcome of this work (i.e., the development of risk-based control measures for the control of *Trichinella* and *Cysticercus bovis*) would allow countries to better allocate resources currently used for the control of these two parasites, to other high-risk pathogens.

79. One delegation also noted that the proposed draft guidelines had some limitations as they were focusing on the effects of the control measures on the specific parasites and did not consider effects of these measures on other parasites/pathogens.

Consideration of risk profiles

80. On the question regarding the future of the risk profiles for *Trichinella* and *Cysticercus bovis*, the Committee noted that appending the profiles to the end of the documents was not appropriate as risk profiles were usually developed as preliminary risk assessment activities and provided information on the need to produce a risk assessment, code of practice or other related efforts / texts. Since the Committee had already initiated the work on the two parasites, the risk profiles were no longer needed.

81. However, the Committee noted that the risk profiles contained valuable information that could be considered by the FAO/WHO Expert Consultation on parasites. The Committee noted that the example of “sub-Saharan Africa” in Section 2 “Description of the public health concern” of the risk profile for *Cysticercus bovis* was not necessary, as the same risk existed in other areas with similar conditions.

82. The Representative of WHO suggested that the risk profiles be peer-reviewed by FAO/WHO experts, in the context of the FAO/WHO Expert Consultation and made available in the repository of risk profiles on the FAO and WHO websites.

⁸ REP11/FH, para.144.

Extending the scope of the work on *Trichinella*

83. Some delegations were of the opinion that it was premature to consider extending the scope of the Guidelines to *Trichinella* spp. and that this decision should wait for the outcome of the FAO/WHO Expert Consultation on parasites. Other delegations noted that the extension of the scope of the work to all *Trichinella* species was consistent with the OIE Chapter on *Trichinella* infections and that control measures did not differentiate among the various *Trichinella* species.

General document on parasites and the collaboration with OIE

84. The Committee noted that decision regarding work on a general document on parasites should wait for the outcome of the FAO/WHO Expert Consultation.

85. With regard to the collaboration with OIE, the Committee noted that collaboration with OIE was necessary to ensure that OIE and Codex cover, in an integrated way, the risk reduction measures along the food chain (i.e. pre- and post-harvest). The Committee noted that mechanisms were in place to allow coordination of OIE and Codex work, such as participation of OIE in the meetings of the Committee and in electronic / physical working groups and that the Codex Secretariat, FAO and WHO had been invited by OIE to participate in the *ad hoc* Expert Group on zoonotic parasites. The Committee also noted that coordination of provision of inputs to Codex and OIE work at national level was necessary to ensure an integrated approach to this work.

Conclusion

86. In light of the above discussion, the Committee agreed that the proposed draft Guidelines be returned to Step 2 for further elaboration and to expand the scope of the Guidelines on *Trichinella spiralis* to all *Trichinella* species.

87. The Committee agreed to establish an electronic working group, led by the European Union and New Zealand, open to all interested parties, and working in English only, to redraft the proposed draft guidelines for control of specific zoonotic parasites in meat, taking into account:

- the discussion at this Session;
- written comments provided at this Session;
- the development of the OIE work on the revision of Chapter 8.13 “Infection with *Trichinella* spp.” of the OIE *Terrestrial Animal Health Code*; and
- the outcome of the FAO/WHO expert consultation on parasites to be held in 2012.

88. The Committee further noted that:

- progress on the development of risk-based selection of post-harvest measures for *Trichinella* were tightly linked to the OIE progress on the revision of Chapter 8.13 of the OIE *Terrestrial Animal Health Code*; and
- the development of risk-based post-harvest measures for *Cysticercus bovis* were not dependent on OIE pre-harvest guidelines.

89. Therefore, the Committee agreed that, in the case of delayed progress in OIE work on the revision of Chapter 8.13, the electronic working group would focus its work on the guidelines for *Trichinella* spp. on the general aspects of post-harvest options.

90. The Committee noted that active participation of the OIE in the electronic working group was necessary to ensure that OIE and Codex cover, in an integrated way, the risk reduction measures along the food chain (i.e., pre- and post-harvest) and encouraged OIE participation.

91. In order to ensure full coordination of Codex and OIE in work on food-borne parasites, the Committee encouraged the Codex Secretariat to explore the possibility that OIE involves representatives of the CCFH electronic working group in its work on food-borne parasites.

92. The Committee agreed to request FAO/WHO to develop risk-based examples for *Trichinella* spp. and *Cysticercus bovis* to illustrate the level of consumer protection likely to be achieved with different post-harvest risk management options. Development of these options should be based on the slaughterhouse information (e.g., intensities of slaughter inspection or types of post-harvest control measures) and other data sources such as human illness. The Committee noted that the time and extent of the provision of FAO/WHO scientific advice would depend on the availability of data and information as well as the availability of adequate financial resources.

93. The Committee further agreed to send the risk profiles, attached to CX/FH 11/43/6, to FAO/WHO for peer review and inclusion in the repository of risk profiles on the FAO and WHO websites, with the understanding that all relevant information would be taken into account by the FAO/WHO Expert Consultation on parasites.

Status of the Proposed Draft Guidelines for Control of Specific Zoonotic Parasites in Meat: *Trichinella spiralis* and *Cysticercus bovis*

94. The Committee agreed to return the proposed draft Guidelines for the Control of Specific Zoonotic Parasites in meat to Step 2 for revision by the above working group, circulation for comments at Step 3 and consideration by the next Session of the Committee.

PROPOSED DRAFT ANNEX ON MELONS TO THE CODE OF HYGIENIC PRACTICE FOR FRESH FRUITS AND VEGETABLES (CAC/RCP 53-2003) (Agenda Item 7)⁹

95. The Committee recalled the decision of the 42nd Session to request the 34th Session of the Commission to approve new work on the Annex on Melons to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003) and to establish a physical working group, led by the Canada and co-chaired by the United States of America, to develop the proposed Annex for circulation for comments at Step 3 and consideration by the current Session of the Committee, pending approval of the Commission.

96. The Delegation of Canada introduced the report of the physical working group, as presented in CX/FH 11/43/7, and highlighted some of the key aspects on which considerable discussion had been held namely, the type of water to be used at the various processing stages; the presence of children and non-essential people in the field; and the use of hand wipes in combination with hand sanitizers, where no clean running water was available.

97. The Committee considered the proposed draft annex section by section and in addition to editorial changes and amendments to the French and Spanish versions, made the following comments and/or changes:

Introduction

98. The Committee amended the second paragraph to more accurately reflect that pathogens other than *Salmonella*, such as *Listeria monocytogenes*, were also implicated in foodborne outbreaks from melons; and to further clarify the potential for introduction, growth and survival of pathogens could be due to cross-contamination.

Section 2 – Scope, use and definitions

99. The Committee amended the scope to make it more generic and amended the definition for melons to more clearly indicate that melons included several varieties other than those mentioned by name.

Section 3 – Primary Production

100. The second paragraph of Section 3.1.1 was amended to indicate that, in addition to production sites, water sources used during production could determine the risk of microbiological contamination at the start of and during the growing season. The Committee further agreed to indicate that production sites should not be used for melon production when risks were serious.

101. The second bullet point of Section 3.1.2 was amended to clarify that, for public irrigation systems, local ordinances might be required to keep animals away from the melon area.

⁹ CX/FH 11/43/7; CX/FH 11/43/7-Add.1 (comments of Australia, Brazil, Colombia, Guatemala, Honduras, Mexico, New Zealand, United States of America and Uruguay); CX/FH 11/43/7-Add.2 (comments of Argentina, Ghana, Jamaica, Kenya, Philippines and Senegal); CRD 7 (comments of Brazil, Egypt, European Union, Honduras, India, Malaysia, Mali, Nigeria and IACFO); CRD 13 (comments of Republic of Korea); CRD 17 (comments of Dominican Republic, Guatemala and Honduras).

102. The second paragraph of Section 3.2 was amended to take into account the various production practices in use, such as the use of mulch covered beds on which to place melons; the use of rice straw to prevent sunburn; and use of biodegradable materials. In addition, reference to hand washing and use of gloves in the third bullet point was deleted as adequately dealt with in Section 3.2.3 and a new fourth bullet point was inserted to indicate that the biodegradable materials should be used only once in order to prevent cross-contamination.

103. The first bullet point of Section 3.2.1.1.1 was amended to indicate that overhead irrigation, which was not generally used, could enhance downy mildew infection in melons.

104. For purposes of flexibility, the first bullet point of Section 3.2.3. was amended to allow businesses to have written Standard Operating Procedures (SOPs) only where appropriate; and in the last bullet point, to indicate that, to the extent possible, children should not be allowed in the harvest area. The latter amendment was also consistent with an earlier decision on access of children in harvest areas (*see* Agenda Item 4).

105. Section 3.2.3.1 was amended by:

- moving the second bullet point to Section 10 since the content dealt with training and to make the training examples more flexible by replacing “should” with “could”;
- making the third bullet point more flexible by indicating that facilities should be sufficient for all personnel and not to cite examples stipulating the number of facilities per number of persons and reference to the need for separate facilities for both genders; and
- indicating that in instances where no running water was available, an acceptable alternative hand washing method should be recommended by the relevant authority and not to refer specifically to hand wipes in the final bullet point.

106. In Section 3.2.3.2, first bullet point, the need for record keeping was deleted as not practical and the second bullet point was amended to indicate that incentives should be considered for agricultural workers who report illnesses in order to ensure that such workers would report illnesses without fear of loss of wages or benefits.

107. In Section 3.3, the second to last sentence was amended in line with an earlier decision regarding flexibility for written SOPs. To provide more general guidance on storage, a new sentence was inserted at the end of this section to indicate that the length of storage for melons at a recommended temperature would depend on the stage of maturity of melons when harvested.

108. In the second bullet point of Section 3.3.1, reference to field packing operations was included to emphasize the need for good personal hygiene in field packing operations; and the eighth bullet point was amended by removing reference to mechanical damage and to refer to damaged melons.

109. The second bullet point in Section 3.3.2, pesticides was added as another example.

Section 4 Establishment: Design and Facilities

110. Section 4.2.1 was amended to more clearly indicate that facilities and their equipment should be designed in such a way to allow cleaning and disinfection.

Section 5 – Control of Operation

111. Section 5.1 was amended to emphasize that prevention was important with respect to control of operations and to indicate that where brushes were used, they should be routinely inspected, cleaned and adjusted as brushes could be a source of cross-contamination or damage to melons.

112. The first bullet points in Sections 5.2.2.1 and 5.2.2.2 were deleted as already more appropriately covered in Section 4.4.2.

113. Section 5.2.2.2 was amended to indicate that although clean water should be used in water-based chemical treatments that use of potable water was preferable.

114. Section 5.5.3 was deleted as it was not general practice to transport and distribute melons on ice.

Section 6 – Establishment, maintenance and sanitation

115. A new Section 6.1.1 “General” was added to clarify that food contact surfaces should be cleaned and disinfected before the start of the melon season and throughout the season to prevent build-up of pathogens on equipment which could result in contamination and lead to illness.

Section 9 – Product information and consumer awareness

116. A footnote was added to Section 9.4 to reference the WHO “Five Keys to Safer Food” as useful additional guidance for use in consumer education. The fifth bullet point was amended to indicate that consumers should also be informed on the use of disinfectant solutions for the washing of melons, where appropriate.

Conclusion

117. In light of the above discussion and considerable progress made, the Committee agreed to advance the proposed Draft Annex on melons to Step 5/8.

Status of the Proposed Draft Annex on Melons to the Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003)

118. The Committee agreed to forward the proposed Draft Annex on Melons to the Commission for adoption at Step 5/8 with the recommendation to omit Steps 6 and 7 (*see* Appendix IV).

DISCUSSION PAPER ON THE REVIEW OF THE RISK ANALYSIS PRINCIPLES AND PROCEDURES APPLIED BY THE CODEX COMMITTEE ON FOOD HYGIENE (Agenda Item 8)¹⁰

119. The Delegation of the European Union, in introducing the discussion paper, recalled that at its 41st Session the Committee had agreed to forward the *Risk Analysis Principles and Procedures Applied by the CCFH* to the 33rd Session of the Commission for adoption and subsequent inclusion in the Codex Procedural Manual and to request the Committee on General Principles (CCGP) to take care of some inconsistencies that existed between the main document and the Annex on the process by which the CCFH undertakes its work. The Committee also recalled that its 42nd Session had agreed to review the *Risk Analysis Principles and Procedures* with a view to its simplification in line with Activity 2.2 of the Strategic Plan (2008-2013) and taking into account the recommendations in CL 2010/1-GP.

120. The Delegation of the European Union noted that the main part of the document described the risk analysis principles and procedures applied by the CCFH following the classical sequence of steps and that the content of the Annex was not always related to risk analysis and was more on the process of work management of the CCFH.

121. The Delegation explained that the proposal for simplification of the *Risk Analysis Principles and Procedures* mainly consisted in deletion of the Annex and the transfer of relevant information from the Annex (i.e., related to prioritization of proposals for new work; and on obtaining scientific advice) to the main document.

122. The Committee noted that the discussion paper only focused on the simplification of the Risk Analysis Principles and Procedures and did not include any recommendations regarding the Annex on the process by which the CCFH undertakes its work. The Committee noted that the Annex, in order not to be lost, could either be included in another section of the Procedural Manual or in an Appendix to its report. It further noted that a better location of the Annex and other similar documents, which would ensure their easy accessibility and visibility, could be explored in future, including their posting on the new Codex website (www.codexalimentarius.org), which offered improved features for presenting the work of the Commission and its subsidiary bodies. One Delegation was of the opinion that removing the Annex and creating an independent internal process of this Committee was sufficient to address the CCGP concern.

123. The Committee considered the proposed revised text, as presented in the Appendix to CX/FH 11/43/8, and, in addition to the revisions proposed in the discussion paper and minor editorial changes, made the following comments and decisions.

124. The Committee noted a proposal to revise the title of the document to make it more consistent with its content that described the procedures followed by the CCFH in applying risk analysis principles. However, in view of the need to ensure consistency with titles of corresponding documents, it was agreed to retain the title unchanged.

125. The Committee agreed to insert in paragraph 4 the second sentence of paragraph 5 of the Annex “*The proposal for new work should indicate the specific nature or outcome of the new work being proposed (e.g., new or revised code of hygienic practice, risk management guidance document)*”, which provided Codex members with useful information concerning the submission of proposals for new work.

¹⁰ CX/FH 11/43/8; CRD 8 (comments of European Union, India, Japan, Mali and Philippines).

126. The Committee agreed to delete the second sentence of paragraph 8 “*This advice will be typically sought through FAO/WHO (e.g., through JEMRA, ad hoc expert consultation). Though in certain instances such advice may be requested from other international scientific bodies (e.g. ICMSF).*” as it repeated information included in paragraph 7.

127. The Committee agreed to add a new paragraph at the beginning of Section V “Risk Management” to clarify the types of risk management options recommended by the CCFH to the Commission.

128. In addition, the Committee agreed to change as more appropriate:

- “undertaking” to “commissioning” in paragraph 8;
- “decisions” to “recommendations” in bullet (ii) of paragraph 9; and
- “deciding” to “recommending” in paragraph 18.

Conclusion

129. The Committee agreed to forward the revised *Risk Analysis Principles and Procedures Applied by the Codex Committee on Food Hygiene* (see Appendix V) to the 35th Session of the Commission for adoption, through the Codex Committee on General Principles. The Committee further agreed to attach the Annex on the process by which the CCFH undertakes its work to this report (see Appendix VI) and to decide on a more appropriate location in the future.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 9)

DISCUSSION OF THE REPORT OF THE WORKING GROUP FOR ESTABLISHMENT OF CCFH WORK PRIORITIES¹¹

130. The Delegation of Thailand, the chair of the working group for establishment of CCFH work priorities, held immediately before the present Session, introduced this Item and provided an overview of discussions and outcomes of the working group as presented in CRD 2.

131. The working group had recommended the Committee consider two new work proposals as follows:

- Revision of the *Code of Hygienic Practice for Spice and Dried Aromatic Plants* (CAC/RCP 42-1995); and
- Annex on berries to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003).

132. The working group also recommended the development of two discussion papers on:

- the development of a code of hygienic practice for low-moisture foods; and
- new work and periodic review/revision of codes of hygienic practice that would:
 - provide a process for ensuring that prior decisions relating to new work were not lost, including the handling of project documents for work that were not initially considered a priority by the Committee;
 - ensure that any list developed by CCFH related to new work including the current list of existing codes that needed to be revised, would be retained, reviewed and updated on a regular basis; and
 - develop criteria to be used in assessing the priorities for moving work in the agenda of CCFH.

New Work Proposals

133. The Committee noted that in view of the finalization of work on Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food (Agenda Item 4) and the Annex on Melons to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (Agenda Item 7), it could accommodate both new work items in its work plan.

¹¹ CX/FH 11/43/9; CRD 2 (Report of the CCFH working group for the establishment of CCFH work priorities); CRD 9 (comments of Ghana, Nigeria and Norway); CRD 15Rev (Project Document prepared by Brazil); CRD 16 (Discussion paper on *Code of Hygienic Practice for Low-Moisture Foods*, prepared by USA, with input from Australia, Canada and the United Kingdom).

134. The Committee considered the two proposals as follows.

Revision of the *Code of Hygienic Practice for Spices and Dried Aromatic Plants* (CAC/RCP 42-1995)

135. The Committee generally supported this new work. The Delegation of Brazil was of the view that the Committee needed to follow a more horizontal approach to development of Codex texts in line with Goal I “Promoting Sound Regulatory Frameworks” of the Codex Alimentarius Commission Strategic Plan 2008 – 2013 and therefore did not support this new work. The Delegation pointed out that it would be more appropriate to deal with a hygienic practice for spices in the context of a more general Code of Hygienic Practice for Low-Moisture Foods (as outlined in CRD 16).

136. The Chairperson clarified that it was the intention of the Committee to follow a more horizontal approach to its work, such as the development of a code of hygienic practice for low-moisture foods, and that the work on the revision of the *Code of Hygienic Practice for Spices and Dried Aromatic Plants* could be started in the interim and be incorporated as an annex to a general code at a later stage .

Conclusion

137. Based on the recommendation of the working group, the Committee agreed to the proposal for new work on revision of the *Code of Hygienic Practice for Spices and Dried Aromatic Plants* (CAC/RCP 42-1995) and to submit the project document (*see* Appendix VII) to the 35th Session of the Commission for approval. The Delegation of Brazil expressed its reservation to this decision.

138. The Committee agreed to establish an electronic working group, led by the United States of America, open to all interested parties and working in English only, to develop the proposed draft revision of the *Code of Hygienic Practice for Spices and Dried Aromatic Plants* for comments at Step 3 and consideration by the next Session of the Committee, pending approval by the Commission.

Annex to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003)

139. The Committee agreed to the proposal of the working group for new work on an Annex on berries to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* noting an earlier decision for development of commodity specific annexes based on a ranking of fruits and vegetables by the FAO/WHO Expert Consultation on Microbiological Hazards in Fresh Fruits and Vegetables.

140. The Committee noted that *Code of Practice for the Processing and Handling of Quick Frozen Foods* (CAC/RCP 8-1976) applied to all quick frozen foods, including fruits and vegetables and could be referenced in this work.

Conclusion

141. The Committee agreed to submit the revised project document to the 35th Session of the Commission for approval (*see* Appendix VIII). The Committee also agreed to establish an electronic working group, led by Brazil, open to all interested parties and working in English only, to develop the proposed draft annex on berries for comments at Step 3 and consideration by the next Session of the Committee, pending approval by the Commission.

142. A delegation proposed that in the future the entire structure of the *Code of Practice for Fresh Fruits and Vegetables* and its annexes be reviewed to ensure consistency across the document and to reduce duplication in the annexes. It was agreed that this matter could also be addressed in the discussion paper on new priorities (*see* paragraph 144).

Other matters

143. The Committee agreed to the recommendations of the working group for the development of two discussion papers on low moisture foods and new work periodic review and revision of codes of hygienic practice, respectively.

144. The United States of America would further develop the discussion paper for a code of hygienic practice for low moisture foods as outlined in CRD 16, while Australia would prepare the discussion paper on new work and periodic review/revision of codes of hygienic practice as outlined in CRD 2 and taking into account the proposal for review of the structure of the *Code of Hygienic Practice for Fresh Fruits and Vegetables*, for consideration at the next Session.

145. The Committee thanked the Delegation of Thailand for their excellent work in chairing the working group and agreed to re-establish the working group on CCFH work priorities which will meet the day before the next Session of the Committee and accepted the offer of the Delegation of the United States of America to chair this working group.

146. The Committee was reminded that all items previously submitted as proposals for new work that were not accepted or given low priority should be re-submitted in response to a circular letter to request comments on new work and/or revision of existing standards for consideration by the working group on CCFH Work Priorities.

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

147. The Committee was informed that the 44th Session of the CCFH was tentatively scheduled to be held in New Orleans, the United States of America from 12 to 16 November 2012. The exact time and venue would be determined by the host Government in consultation with the Codex Secretariat.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by:	Reference in REP12/FH
Proposed Amendment to the <i>Principles and Guidelines for the Conduct of Microbiological Risk Assessment</i> (CAC/GL 30-1999)	-	Governments 35 th CAC	Para. 14 and Appendix II
Proposed Revision to the <i>Risk Analysis Principles and Procedures Applied by the Codex Committee on Food Hygiene</i>	-	Governments 35 th CAC	Para. 129 and Appendix V
Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food	5/8	Governments 35 th CAC	Para. 50 and Appendix III
Proposed Draft Annex on Melons to the <i>Code of Hygienic Practice for Fresh Fruits and Vegetables</i> (CAC/RCP 53-2003)	5/8	Governments 35 th CAC	Para. 118 and Appendix IV
Proposed Revision of <i>Principles for the Establishment and Application of Microbiological Criteria for Foods</i> (CAC/GL 21-1997)	2/3	Physical Working Group (Finland / Japan) Governments 44 th CCFH	Para. 69
Proposed Draft Guidelines for Control of Specific Zoonotic Parasites in Meat: <i>Trichinella spiralis</i> and <i>Cysticercus bovis</i>	2/3	Electronic Working Group (EU / NZ) Governments 43 rd CCFH	Para. 94
New Work			
Revision of the <i>Code of Hygienic Practice for Spices and Dried Aromatic Plants</i> (CAC/RCP 42-1995)	1/2/3	35 th CAC Electronic Working Group (USA) 44 th CCFH	Paras 137-138 and Appendix VII
Annex on Berries to the <i>Code of Hygienic Practice for Fresh Fruits and Vegetables</i> (CAC/RCP 53-2003)	1/2/3	35 th CAC Electronic Working Group (Brazil) 44 th CCFH	Para. 139 and Appendix VIII
Discussion papers			
Discussion paper on a code of hygienic practice for low-moisture food	-	USA	Para. 144
Discussion paper on new work and periodic review/revision of codes of hygienic practice	-	Australia	Para. 144

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Appendix II**PROPOSED AMENDMENT TO THE *PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK ASSESSMENT*****CAC/GL-30 (1999)*****1. SCOPE***

The scope of this document applies to Risk Assessment of microbiological hazards in food¹

¹ These principles for risk assessment should also apply to feed and feed ingredients for food producing animals where it could impact food safety.

Appendix III**PROPOSED DRAFT GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF VIRUSES IN FOOD****(At Step 5/8 of the Procedure)****INTRODUCTION**

1. In recent years, viruses have been increasingly recognized as important causes of foodborne diseases. Viruses are micro-organisms that differ in size, structure and biological characteristics from bacteria. Viruses are strictly host-dependent for their replication and have their own typical host range and cell preference (tropism). Viruses can be transmitted in different ways, e.g., via the respiratory or faecal-oral routes. Human viruses can be transmitted directly from person-to person, but also indirectly via virus-contaminated water, air, soil, surfaces or food. Some viruses (zoonotic viruses) are transmitted from animals to humans. Data from recent studies have shown that foodborne viral infections are very common in many parts of the world, despite the measures already in place mainly targeted at reducing bacterial contamination.

2. The human enteric viruses most frequently reported as involved in foodborne outbreaks are norovirus (NoV) and hepatitis A virus (HAV). Other viruses such as rotavirus, hepatitis E virus (HEV), astrovirus, Aichi virus, sapovirus, enterovirus, coronavirus, parvovirus and adenovirus can also be transmitted by food, and anecdotal evidence suggests the list of foodborne viruses may be even longer. Based on the symptoms of disease, these viruses can be grouped into those that cause gastroenteritis (e.g. NoV), enterically transmitted hepatitis (e.g. HAV, that replicates in the liver), and a third group which replicates in the human intestine, but only causes illness after they migrate to other organs such as the central nervous system (e.g., enterovirus). The major foodborne viruses are those that infect via the gastrointestinal tract and are excreted in faeces and/or vomit, and are infectious for humans when ingested via the oral route. Asymptomatic infections and shedding are common and have to be considered in food production.

3. Noteworthy aspects of foodborne viruses and the associated infections/illnesses that determine management strategies to be different from management strategies for bacterial pathogens:

- Viruses need to enter living host cells in order to be able to multiply (replicate). Unlike bacteria, they do not replicate in food. Consequently, viruses do not cause deterioration of the product and the organoleptic properties of the food are not affected due to viral contamination.
- Even though high numbers of viral particles are shed in the stools of symptomatic or asymptomatic infected persons (e.g., exceeding 10^6 particles per gram of stool) or in vomit, only a few viral/infectious particles (less than 100) are needed to cause infection that may lead to illness.
- Human enteric viruses, such as NoV and HAV, are very infectious and person-to-person spread is the most common transmission route. Secondary spread of these viruses after primary introduction by, for example, food-related contamination, is common and often results in larger, prolonged outbreaks.
- Non-enveloped viruses, such as NoV and HAV, are covered in a protein-based structure called a capsid. Enveloped viruses, such as influenza, have a capsid and are further coated in a biological membrane derived from the host cell. Both the capsid and envelope structures influence environmental persistence and resistance to cleaning and disinfection and interventions. However, the non-enveloped viruses tend to be more resistant to inactivation from solvents (e.g., chloroform) and desiccation.
- Viruses transmitted by the faecal-oral route can persist for months in foodstuffs or in the environment (e.g. in soil, water, sediments, bivalve molluscs or on various inanimate surfaces). Most foodborne viruses are more resistant than bacteria to commonly used control measures, (e.g., refrigeration, freezing, pH, drying, UV radiation, heat and pressure, disinfection, etc).
- Freezing and refrigeration temperatures preserve viruses and are believed to be important factors that increase the persistence of foodborne viruses in the environment. Heat and drying can be used to inactivate viruses, but there are virus-to-virus differences in resistance to these processes. The presence of organic matter, such as faecal material and the food matrix can influence relative resistance to heat and drying.

- Traditional hand washing practices may be more effective for infectious virus reduction as compared to the use of hand sanitizing-agents. The majority of chemical disinfectants used in food establishments do not effectively inactivate non-enveloped viruses, such as NoV or HAV.
- Zoonotic foodborne transmission of viruses is not commonly reported as is the case for many bacterial pathogens, such as *Salmonella* and *Campylobacter*, however, it does occur, e.g., for HEV.
- In general, testing of foods for foodborne viruses is challenging and requires matrix-dependent extraction and concentration techniques and is based on detection of viral nucleic acids.
- There is a current lack of methods for assessing the level of inactivation of foodborne viruses in food. This has led to the use of surrogate viruses, e.g. the use of feline calicivirus and murine norovirus in place of NoV. When evaluating risk management options, the use of a surrogate will not always mimic the resistance of the intended foodborne viruses.

4. During the FAO/WHO Expert meeting on “Viruses in Food”¹, NoV and HAV were determined to be the viruses of greatest concern from a food safety perspective based on the incidence of reported foodborne disease, the severity of disease, including mortality, and their potential for transmission via foods. Estimates of the proportion of viral illness attributed to food are in the range of around 5% for HAV and 12-47% for NoV¹. Data from at least 4 continents show that this is a major public health issue worldwide, although data from many countries are sparse. HAV and rotavirus were identified as the major foodborne viruses that cause severe disease and significant mortality. The primary mode of transmission for rotavirus is person-to-person spread, but in areas with poor hygienic situations waterborne and foodborne spread may play a role. Like HAV and NoV, HEV is transmitted by the faecal-oral route. HEV has been found to be responsible for sporadic and epidemic acute hepatitis, especially in some areas. HEV infection is usually associated with contaminated drinking water, but has also been linked to eating raw deer meat, undercooked pork liver or wild boar meat.

5. NoV: Norovirus, formerly Norwalk-like virus, infections occur year-round, and cause gastro-enteritis in people of all ages. Overall, illness is relatively mild, but can be more severe and may result in death in high-risk groups such as the elderly or people with underlying disease. The greatest public health impact from NoV outbreaks has been reported in institutions such as hospitals and nursing homes, where NoV outbreaks commonly occur due to the close proximity of patients in an enclosed environment. Clear wintertime peaks in incidence have been observed when looking at reported outbreaks, but other than in the case of bivalve molluscs these are particularly associated with infections spread through person-to person contact or contaminated environmental surfaces (e.g., outbreaks in healthcare facilities) rather than foodborne infections. The incubation period is 12-72 hours; in most cases symptoms appear between 24-30 hours. The onset of symptoms after NoV infection is often characterised by sudden onset of one or several episodes of projectile vomiting and/or by one to several days with diarrhoea. NoV-infected persons shed large amounts of infectious virus particles (10^6 - 10^{10} particles/g) in their stool while having symptoms, but this may also occur before the onset of symptoms, and shedding may continue up to 8 weeks after resolution of symptoms even in immuno-competent persons. The disease and shedding period may be longer in the case of immuno-suppressed individuals. Some NoV infections occur without resulting in apparent symptoms. A vaccine against NoV is not available at present.

6. HAV: Hepatitis A virus is a cause of acute viral hepatitis. The incidence of HAV infection varies considerably among and within countries. In countries where HAV infection is highly endemic, the majority of people are infected in early childhood, when the infection is asymptomatic in over 90% of children under 5 years of age. Virtually all adults in these areas are immune. In countries, where HAV infections are less common as a result of increased standards of public health such as access to safe drinking water, sanitation and hygiene, very few persons are infected in early childhood, and the majority of adults remain susceptible to infection by HAV. Later in life (persons over 40 years), HAV infection is symptomatic in over 80% of the infected persons and may result in a more severe disease outcome. As a result, the potential risk of outbreaks of hepatitis A is increased in these regions. The incubation period for HAV is at least 2 weeks, to a maximum of 6 weeks, with an average of 28 days. The peak infectivity occurs in the 2 weeks preceding the onset of jaundice, i.e. the presence of yellow colouring of the skin and/or mucous membranes. The virus is shed in large numbers (10^6 - 10^8 particles/g) in faeces from the final 2 weeks of the incubation period up to 5 weeks into the

¹ FAO/WHO [Food and Agriculture Organization of the United Nations/World Health Organization]. 2008. Viruses in Food: Scientific advice to support risk management activities: meeting report. Microbiological Risk Assessment Series. No. 13.

symptomatic phase. In HAV endemic areas, children may be an important risk factor in the spread of HAV during primary production or food preparation activities. Some HAV infections occur without symptoms. Vaccines against HAV are available.

7. During the FAO/WHO Expert meeting on “Viruses in Food”¹, three major sources of viral contamination of foods were identified: 1) human sewage/faeces, 2) infected food handlers and 3) animals harbouring zoonotic viruses, although combinations of these have also been described. The virus-commodity combinations of greatest public health concern selected were NoV and HAV in prepared (ready-to-eat) foods, bivalve molluscs, and fresh produce.

8. There are currently no effective, realistic and validated risk management options to eliminate viral contamination of both bivalve molluscs and fresh produce prior to consumption without changing the normally desired characteristics of the food. Because of concerns about virus persistence during food processing, effective control strategies need to focus on prevention of contamination. Such prevention will have to occur primarily at the pre-harvest level for some products (bivalve molluscs, fresh produce for raw consumption), at the harvest level (fresh fruits and vegetables) and at the post-harvest phase for others (prepared, ready-to-eat foods).

9. Evidence of viral contamination is primarily based on the detection of viral RNA/DNA since many foodborne viruses cannot be reliably cultured *in vitro*. Quantitative and semi-quantitative real time reverse transcription polymerase chain reaction (real time RT-PCR) methods have been developed for various food/virus combinations that are sensitive and specific. Detection of viral RNA/DNA does not discriminate between infectious and non-infectious virus particles and test results are subject to variability depending on the food product, the distribution of virus within the food matrix and the presence of PCR inhibitors. Importantly, there is a degree of uncertainty as to how the lower limits of detection relate to product safety. Molecular technologies should be fully validated and the intended use and interpretation clearly defined. Ideally, the testing laboratory should be accredited.

SECTION 1 - OBJECTIVES

10. The primary purpose of these guidelines is to give guidance on how to prevent or minimize the presence of human enteric viruses in foods, and more specifically of NoV and HAV in foods. The guidelines provide advice to governments on a framework for the control of human enteric viruses in food, especially NoV and HAV, with a view towards protecting the health of consumers and ensuring fair practices in food trade. The guidelines also provide information that will be of interest to the food industry, consumers and other interested parties. Information provided in these guidelines may also assist in minimizing the risks of foodborne illness from new and emerging viruses in foods.

SECTION 2 - SCOPE, USE AND DEFINITION

2.1 SCOPE

2.1.1 Food chain

11. These guidelines are applicable to all foods, with a focus on ready-to-eat food, from primary production through consumption, for the control of human enteric viruses, in particular NoV and HAV, in foods. They should complement controls in place for any other pathogens.

2.2 USE

12. These guidelines follow the format of the *General Principles of Food Hygiene* (CAC/RCP 1-1969) and should be used in conjunction with it and other relevant Codes of Practice, such as the *Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering* (CAC/RCP 39-1993), the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003). The annex on the *Control of Hepatitis A Virus (HAV) and Norovirus (NoV) in Bivalve Molluscs* (Annex I) and the annex on the *Control of Hepatitis A Virus (HAV) and Norovirus (NoV) in Fresh Produce* (Annex II) are supplements to these guidelines and provide additional recommendations for these specific virus-commodity combinations.

2.3 DEFINITIONS

Human enteric virus – a virus that replicates in the gastro-intestinal tract or in the liver and is excreted in faeces and/or vomitus from humans. It is transmitted mainly by the faecal-oral route and is infectious to humans.

Fresh produce – fresh fruit and vegetables grown in the field (with or without cover) or in protected facilities (hydroponic systems or greenhouses).

Ready-to-eat food (RTE-food) - any food that is normally eaten in its raw state or any food handled, processed, mixed, cooked, or otherwise prepared into a form, that is normally eaten without further steps, which could remove viruses or eliminate their infectivity.

Clean water - water that does not compromise food safety in the circumstances of its use.

SECTION 3 - PRIMARY PRODUCTION/HARVESTING AREA

OBJECTIVES: To describe the setting in which the primary production occurs and to identify different aspects of production processes that should be controlled to reduce the chance of viral contamination of food.

RATIONALE: Food may become contaminated at the primary production area by water, soil, harvesting containers or utensils contaminated by faeces or vomit or by food handlers.

3.1 ENVIRONMENTAL HYGIENE

13. Potential sources of viral contamination of the environment should be identified prior to production activities. Sources of viral contamination of food at the primary production site include water, soil, manures (not properly treated), sludge or fertilizers contaminated by faeces of human origin or proximity to other production activities which could result in run-off or flooding with virus-contaminated waters. Primary food production should not be carried out in areas where the presence of viruses may lead to the viral contamination of food. Assessment of environmental conditions is particularly important because subsequent control steps during production may not be adequate to remove contamination.

3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

14. Food sources should be protected from faecal contamination and vomit or vomit-derived aerosols.

15. The source of water used for primary production and the method of delivery of the water can affect the risk of contamination of food during production. Growers should seek appropriate guidance on water quality and delivery methods to minimize the potential for contamination by viruses. Water for primary production of fresh produce should be suitable for its intended use and not compromise food safety and should be applied using an appropriate method. Also during harvesting of foods, clean water, such as for washing, should be used. (Refer to *WHO Guidelines for the safe use of wastewater, excreta and grey water. Volume 2: Wastewater use in agriculture* (World Health Organization 2006 ISBN 92 4 154683 2, v.2; www.who.int/water_sanitation_health/wastewater/gsuweg2/en/index.html) and *WHO Guidelines for the safe use of wastewater, excreta and grey water. Volume 3 Waste water and excreta use in aquaculture* (http://whqlibdoc.who.int/publications/2006/9241546840_eng.pdf).

16. Natural fertilizers may contain human pathogenic viruses that persist for weeks or months. Proper treatment such as application of heat, chemical or biological treatments of biosolids, manures and waste by-products will reduce the risk of potential human virus survival. Growers should seek appropriate guidance on the use and treatment of biosolids, manures and waste by-products.

17. Aquaculture operations should not be established in areas susceptible to sewage contamination, in particular those for production of products intended for consumption without further treatment.

3.3 HANDLING, STORAGE AND TRANSPORT

18. Harvesting methods vary depending on the characteristics of the product. Specific control measures should be implemented to minimize the risk of contamination from viruses associated with the method.

19. Harvesting equipment, utensils and containers should be in a clean condition and in good working order.

3.4 CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION

20. Refer to Section 7 of this document for aspects of personnel hygiene in primary production

SECTION 4 - ESTABLISHMENT: DESIGN AND FACILITIES

OBJECTIVES: Equipment and facilities should be designed, constructed and laid out to ensure that surfaces can be cleaned and disinfected if needed.

RATIONALE: Inability to properly clean and disinfect may result in persistence of the virus leading to potential contamination of food.

4.4 FACILITIES

4.4.4 Personnel hygiene facilities and toilets

4.4.4.1 Changing facilities and toilets

21. Hygienic and sanitary facilities should be available to ensure that an appropriate and acceptable degree of personal hygiene can be maintained.

22. Harvest and production may be subject to seasonal influx of workers to meet the needs of producers and may vary for different products. An inherent danger at the farm and production level is an under-supply of suitable toilet and hand washing facilities to meet this influx. Food business operators should ensure that suitable facilities are provided, are readily accessible and meet appropriate hygiene standards.

23. Hygienic and sanitary facilities should:

- be located in proximity to the production area;
- be located in areas adjacent to the processing area, but without direct access to it;
- be in sufficient numbers to accommodate personnel;
- be of appropriate design to ensure hygienic removal of wastes;
- be designed so that there is no seepage into underground water or enter the agricultural field;
- have adequate means for washing and drying hands;
- be maintained under sanitary conditions and good repair;
- be appropriately cleaned and disinfected (see 6.2 cleaning programmes); and
- be separate for guests and personnel of the establishment, when feasible.

4.4.4.2 Hand washing facilities

24. Hand washing facilities should be supplied with hand cleanser (soap). Where possible, hand washing facilities should have non-hand operable taps and single-use towels to help prevent the re-contamination of clean hands. Hand washing and drying instructions should be visibly present for all users of these facilities.

25. Hand washing and drying facilities should be suitably located in food preparation or production areas to ensure food handlers have ready access to them. There should be hand washing facilities within close proximity to the toilets and positioned so that the personnel must pass by them before returning to the food handling area.

SECTION 5 - CONTROL OF OPERATION

OBJECTIVES: Processing operations should be controlled to prevent contamination of food with viruses.

RATIONALE: Preventive measures against the identified hazards or risks may help to reduce virus contamination.

5.1 CONTROL OF FOOD HAZARDS

26. Control of human enteric viruses such as NoV and HAV in food will typically require a stringent application of hygiene control systems, which could be referred to as, e.g., Good Hygienic Practices (GHPs) and sanitation standard operation procedures (SSOPs). These prerequisite programs, together with validated interventions, e.g., as part of a HACCP-based system, provide a framework for the control of enteric viruses.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.1. General Control Programs

27. Any food possibly contaminated by vomit particles or by aerosols containing vomit particles should be disposed of. Any food handled by an ill person should be evaluated to determine the need to dispose of it. Food handled by someone with NoV during that day (or the day before) should be considered a risk and disposal of implicated products should be considered. For foods handled by someone with HAV, consider what other foods were handled at least two weeks before the illness occurred, because HAV viruses may be shed at peak levels at least two weeks before symptoms appear. In this situation, disposal of the implicated food also should be considered.

28. If an outbreak has been traced back to an establishment, the necessary steps should be taken to find the source, to eliminate the virus, and to avoid future outbreaks.

5.2.2 Process-Specific Control Systems

5.2.2.1 Time and temperature control

- **Cooling and freezing:** Cooling and freezing processes should not be considered suitable for the control of foodborne viruses as they do not reduce virus infectivity to levels considered safe.
- **Heat treatment:** The effects of heat treatment on virus infectivity in foods are highly dependent on virus (sub)-type, food matrix and the initial level of viral contaminants. Cooking procedures in which an internal temperature of the food reaches at least 90 °C for 90 seconds are considered adequate treatments to destroy viral infectivity in most foods. However, light cooking, e.g., steaming, searing, may not be adequate to inactivate viral infectivity leading to unsafe foods. Conventional pasteurization (e.g. 63 °C for 30 min or 70 °C for 2 min) is more effective than High Temperature Short Time (HTST; 72 °C for 15–20 seconds) pasteurization, and likely yields at least a 3 log₁₀ inactivation of NoV. However, given the potential for contamination with millions of viral particles and an infectious dose as low as a few viral particles, even conventional pasteurization may not adequately inactivate NoV in a contaminated food. Commercial canning is considered an adequate treatment to destroy viral infectivity in foods.

5.2.2.2 Specific process steps

29. Various processes have been shown to reduce virus load in selected food items but are subject to substantial variability depending on virus type and subtype, food matrix and location of virus on food matrix. As such, these processes by themselves will be inadequate to protect the consumer, but when the processes are combined, the additive effect of the processes may enhance the level of inactivation of viruses present. Processing combination should be subject to rigorous validation to ensure consumer protection.

- **Washing:** The washing of food ingredients or products in water, either treated (UV, ozone, chlorine, etc) or untreated, may not be effective if the food surface is rough, broken or pitted or when viruses are internalized.
- **Reduce pH:** Human enteric viruses are very stable at low pH levels. More than 3 log₁₀ inactivation of HAV may occur only at pH < 3, a pH that is not always acceptable for the sensorial quality of foods.
- **Reducing water activity (RA_w):** RA_w may accelerate degradation or inactivation rates of viruses, but its effect on virus infectivity in foods (or on fomites) is highly dependent on virus (sub)type and food matrix and thus RA_w cannot be considered an effective generic measure to reduce viral loads at present. The drying/desiccation of human enteric viruses on processing equipment surfaces may reduce virus titers.
- **High hydrostatic pressure (HHP):** The effects of HHP on virus infectivity in foods are highly dependent on virus (sub)type and food matrix, but may be considered a measure to reduce viral loads for some virus(types) present in specified matrices.
- **Ultraviolet (UV) Irradiation:** UV-irradiation does reduce virus infectivity but its effectiveness is highly dependent on the presence of the virus on the surface of the food, the virus (sub)-type and the food matrix. It cannot be considered an effective generic measure to reduce viral loads on or in food. UV irradiation can be effective for the inactivation of viruses on surfaces for food preparation and for the inactivation of viruses in water and aerosols.

30. When new virucidal technologies or treatment combinations are being developed, they should be validated with the appropriate hazard/food combination prior to their implementation in the food production

chain. Their effectiveness should be evaluated using virus infectivity assays where possible. When such assays do not exist for the specific virus, use of suitable surrogate viruses, or molecular assays, which can evaluate decline in virus genome copies, should be considered. The results should be evaluated with caution as the surrogates will not always mimic the resistance of the intended foodborne viruses. Some treatments might be subject to prior approval by the competent authority.

5.3 INCOMING MATERIAL REQUIREMENTS

31. Raw ingredients contaminated with viruses may lead to contamination of food handlers' hands, other foods, or food contact surfaces. Preferably, use raw ingredients from suppliers or production plants with an adequate food safety management system.

5.4 PACKAGING

32. Various types of packaging that are aimed at inhibiting bacterial or fungal growth are not effective against human viruses because human viruses do not grow in foods.

5.6 MANAGEMENT AND SUPERVISION

33. Managers and supervisors should understand the importance of applying good hygiene practices and personnel health and hygiene, in aspects such as:

- the availability of adequate hygiene facilities;
- compliance with hand washing instructions;
- exclusion from the premises of food handlers or any persons, including children, with symptoms of gastroenteritis or acute hepatitis or those recovering from these infections (see section 7.2);
- how to clean and disinfect surfaces when contaminated.

5.7 DOCUMENTATION AND RECORDS

34. It is recommended that control procedures used for viruses be monitored to ensure their continuing effectiveness.

5.8 RECALL PROCEDURES

35. Based on the determined level of risk associated with the presence of viruses in a given food product, a decision may be taken to recall the contaminated product from the market. The need for public information and communicated warnings should be considered.

SECTION 6 – ESTABLISHMENT: MAINTENANCE AND SANITATION

OBJECTIVES: To provide specific guidance on preventive maintenance and especially sanitation procedures after an event of vomiting, diarrhoea and/or notification of hepatitis.

RATIONALE: Vomiting/diarrhoea events and persons shedding viruses are likely to cause widespread contamination of food production premises, and measures to eliminate this contamination should be taken.

6.1 MAINTENANCE AND CLEANING

6.1.1 General

36. A food establishment shall have a set of procedures to be followed by employees when responding to vomiting or diarrhoea events that involve the discharge of vomitus or faecal matter onto surfaces and that address the specific actions employees must take to minimize the potential for the spreading of contamination and for increasing exposure of employees, food, and surfaces to vomitus or faecal matter.

6.1.2 Cleaning procedures and methods

Cleaning and disinfection:

37. Each establishment should have documented regular cleaning and disinfection procedures. Disinfection should always be preceded by cleaning. It is also recommended that establishments have a procedure for the disinfection of surfaces possibly contaminated with enteric viruses, such as NoV or HAV. Cleaning and disinfection should take place immediately after each vomiting event in premises or rooms, after reported symptoms of gastroenteritis or symptoms indicative of hepatitis of any personnel. Cleaning and disinfection

should include all surfaces suspected to be contaminated with viruses, both in the hygiene facilities and toilets and (as a preventive measure) in food production areas (e.g., equipment, utensils, telephones, keyboards, door handles, etc.), as viruses in vomit, aerosols and faecal matter are persistent and can stay infectious for a long period.

38. Ideally, because of the exposure to highly infectious substances, disposable materials such as gloves, facemasks and aprons or smocks should be worn during cleaning and disinfection by a person trained in cleaning-up infectious material. Any spillage or contamination with faeces or vomit should be dealt with immediately, and food handling in the same area(s) should be stopped. Absorbent material such as paper towels and tissues may be used to limit the spread of contaminated fluids but should then be properly disposed of, e.g., in closed plastic bags, so as not to be a vehicle for further contaminating foods, surfaces or personnel.

Surface disinfection:

39. Surfaces should always be cleaned prior to disinfection to ensure effective disinfection. For surface disinfection, solutions of ≥ 1000 ppm free chlorine applied for 5 to 10 min at room temperature consistently show $> 3 \log_{10}$ reduction in viral infectivity. Freshly constituted hypochlorite solutions are preferable. Alternatively, chlorine dioxide solutions at concentrations of 200 ppm may be used. The solutions are corrosive, and need to be thoroughly rinsed from food contact surfaces afterwards, e.g., by washing with clean water. Adequate precautions should be taken during cleaning or disinfection of rooms, equipment or utensils to prevent food being contaminated by wash water, detergents and disinfectants. Food preparation should only begin after thorough disinfection has taken place.

40. Experiments have demonstrated that a vaporized hydrogen peroxide (VHP) treatment at >100 ppm for 1 h is effective against bacteria, bacterial spores and a range of viruses including poliovirus, rotavirus, adenovirus, and murine norovirus. This treatment can be applied to whole rooms, including kitchens, and results in disinfection of various surfaces such as stainless steel and framing panel and is a less labour-consuming alternative to manual disinfection using chlorine solutions.

41. UV irradiation at $> 40 \text{ mWs/cm}^2$ ($=\text{mJ/cm}^2$) causes $> 3 \log_{10}$ reduction of feline calicivirus (FCV) and murine norovirus (MNV), which have been used as models for human NoV, and this treatment can be considered for reducing viral infectivity on surfaces, in aerosols and in water.

42. Most other surface disinfectants lack efficacy (i.e., consistently cause less than a $3 \log_{10}$ reduction in infectivity) against enteric viruses at manufacturer's recommended concentrations and exposure times. It is well recognized that the majority of chemical disinfectants currently used in institutional and domestic environments and in the food industry do not effectively inactivate NoV and HAV. New compounds and/or methods can be considered if they show virucidal activity of $> 3 \log_{10}$ for non-enveloped viruses in standardized carrier tests and are approved for use on food contact surfaces. Interpretation of results from the use of human NoV surrogates, specifically feline calicivirus and murine NoV, in the evaluation of disinfectants should be made with caution as these surrogates exhibit different physiochemical properties as compared to NoV.

6.2 CLEANING PROGRAMMES

43. Cleaning and disinfection programs should include disinfectant agents and specific cleaning (including manual and automatic dishwashing) and disinfection procedures that are able to inactivate enteric viruses and include a checklist of which surfaces should be disinfected (see section 6.1.2). These programmes should be in place (including the name, volume and concentration of disinfectants, time, temperature and/or pH to be applied and equipment to be used). When cleaning and disinfection is needed for potential virus contamination, accurate documentation and monitoring of the cleaning and disinfection are recommended.

6.4 WASTE MANAGEMENT

44. Food possibly contaminated with virus particles should be discarded in a manner such that contact between this food and any person, food or food contact surfaces is prevented.

SECTION 7 – ESTABLISHMENT: PERSONAL HYGIENE

OBJECTIVES: To prevent food handlers from contaminating food with viruses, in particular NoV and/or HAV due to poor personal hygiene.

RATIONALE: Food handlers may shed virus and the infectious dose is very low. There is a need for strict personal hygiene of food handlers, particularly in relation to the prevention of NoV and/or HAV, contamination.

7.1 HEALTH STATUS

45. Diarrhoea and vomiting may be caused by infectious (e.g., NoV, *Salmonella*) or non-infectious (e.g., toxins) agents. All cases of gastroenteritis should, however, be regarded as infectious unless good evidence suggests otherwise. Fever, headache, fatigue combined with dark urine and light stools, or jaundice, are indicative of hepatitis, which should also be regarded as an infectious condition. Persons with the above symptoms should therefore be excluded from handling food or from being present in the premises, to reduce the likelihood of transmission of any infectious agents via food.

46. Refer to the Introduction Section of these guidelines for the incubation and contagious periods of NoV and HAV viruses.

7.2 ILLNESS AND INJURIES

47. Food handlers with clinical symptoms of gastroenteritis or with symptoms of acute hepatitis should be excluded from the handling of food, food contact surfaces and food equipment and should not be present in the area where food is exposed, so as to reduce the likelihood of transmission of the human enteric viruses, NoV and HAV. Worker(s) should leave the food handling area, if possible, before the onset of vomiting or any diarrhoea event and in any case directly after these events. Any person with symptoms of acute hepatitis should seek medical advice.

48. Persons who have had gastroenteritis should only be allowed to return to work after a period without symptoms of diarrhoea and vomiting. Persons, who have had hepatitis, should only be allowed to return to work after disappearance of jaundice.

49. As shedding of viruses, such as NoV or HAV, may continue for several weeks after symptoms have subsided (e.g., NoV may be post-symptomatically present on average for 2 or more weeks in the stools of recently infected persons), training and instructions should be given to all personnel on the infectivity, transmission and disinfection of foodborne viruses, and the importance of following strict hand hygiene instructions at all times.

50. When one of the staff members has symptoms of gastroenteritis or hepatitis, other staff members may be or become (asymptomatically) infected at that point. Similarly, when a family/house member of a staff member has symptoms of gastroenteritis or hepatitis, the staff member may be (asymptomatically) infected, and/or serve as a vector carrying infectious virus on their person. In these specific situations, in particular, compliance with strict hand hygiene measures is important to reduce the risk of further spread of the illness.

51. Vaccination of food handlers against hepatitis A should be recommended where necessary to reduce the risk of viral contamination of the food, taking into account the epidemiological situation and/or immune status of the local population, e.g., where HAV is endemic or the population has low immunity. Where feasible and appropriate, checking for HAV immune status of food handlers could be useful.

7.3 PERSONAL CLEANLINESS

52. Personal hygiene of food handlers is critical. Food handlers should be aware of the infectious nature and transmission routes of enteric viruses, such as NoV and HAV. As asymptomatic shedding can occur, food handlers should adhere to hand washing instructions at all times. Training should be provided for food handlers, managers and other company personnel (see Section 10).

53. Hands should be washed and dried before handling of food. The most effective way of preventing spread of viruses is thorough hand washing. Hands should be lathered with soap and then washed with clean running water². The use of disposable hand towels and non-hand operable taps should be encouraged wherever possible.

² WHO Guideline on hand hygiene in health care. WHO/EIP/SPO/QPS/05.2.
http://whqlibdoc.who.int/hq/2005/WHO_EIP_SPO_QPS_05.2.pdf

Hands should be washed in sinks dedicated to such a purpose and not washed in dishwashing sinks or food preparation sinks, to the extent possible.

54. Everyone should always wash his or her hands especially before handling food, after using the toilet or after being in contact with faecal matter (also after changing diapers/nappies, cleaning toilets), or after being in contact with vomit.

55. If gloves are used, a procedure for glove use should be developed and followed. If gloves are used in the handling of food products, they should be in a sound, clean and sanitary condition. If disposable gloves are used, they should be discarded when they become torn, soiled, or otherwise contaminated and replaced. When gloved hands have been in contact with potentially contaminated items, new gloves should be put on before preparing food. The wearing of gloves or the use of hand sanitizers does not exempt the person from having thoroughly washed hands before putting on gloves.

56. Clothes of food handlers who have been infected, or suspected to have been infected, should be washed. It has been shown that conventional household washing detergents have a good virucidal efficiency at 40 °C.

7.4 PERSONAL BEHAVIOUR

57. Items such as money, tickets, etc., should not be handled at the same time as food. After any contact with potentially virus-contaminated material, hands should be thoroughly washed. If gloves are used in the handling of food, new gloves should put on before handling or preparing food.

7.5 VISITORS

58. Non-authorized persons and, to the extent possible, children should not be present in food handling areas where food is grown, harvested, stored or prepared.

SECTION 9 – PRODUCT INFORMATION AND CONSUMER AWARENESS

9.1 LOT IDENTIFICATION

59. NoV and HAV can persist for long periods of time in food. As distribution of food between areas and countries complicates traceability, lot identity and integrity should be maintained to facilitate trace back.

9.4 CONSUMER EDUCATION

60. Countries should develop educational programs to make consumers more alert to the risk of viruses in certain ready-to-eat foods, such as raw bivalve molluscs harvested near areas of human habitation, (e.g., presence of sewage plants).

SECTION 10 – TRAINING

OBJECTIVES: Those food handlers engaged in food growing, harvesting or processing who come directly or indirectly in contact with foods should be trained and/or instructed in the control of enteric viruses to a level appropriate to the operations they are to perform.

RATIONALE: Food handlers may be less familiar with controls specific to enteric viruses.

10.1 AWARENESS AND RESPONSIBILITIES

61. Food business operators (primary producers, manufacturers, distributors, retailers and food service/institutional establishments) and trade associations have an important role in providing specific instructions and training for control of viruses. There is a need to increase awareness of stakeholders on foodborne disease outbreaks due to viral infection.

62. It is the responsibility of the managers to educate and train their personnel, to keep control of the level of awareness of the training content, and to have both cleaning and disinfection programmes operational.

63. It is the responsibility of the managers and employers to carry out monitoring to ensure that personnel are undertaking good hygienic practices. Monitoring includes regular observation of personnel hand washing prior to entry into food handling areas.

64. It is the responsibility of the personnel to inform the supervisor or employer when ill with diarrhoea or vomiting, or when having complaints or symptoms indicative of hepatitis or gastrointestinal illnesses. It is also

the responsibility of all personnel to adhere to strict hand washing instructions after returning from the toilet or after being in contact with faecal or vomit matter.

10.2 TRAINING PROGRAMMES

65. Training programmes should contain information on the following:

- The potential for food to be a vehicle of virus transmission if contaminated.
- The potential sources and routes of transmission of human enteric viruses.
- The potential for persistence of infectious virus in/on contaminated foods and food production settings;
- The incubation periods of foodborne viruses, specifically NoV and HAV.
- The duration of virus shedding during and even after recovery from clinical symptoms and the possibility of pre- and post-symptomatic shedding.
- The infectivity of vomit.
- Procedures for cleaning and disinfection of contaminated surfaces.
- Proper hand washing practices and the importance of strict compliance with hand washing instructions at all times, particularly after being in contact with faecal or vomit matter. It is advisable to have documentation of the hand-washing instructions given to each new starting personnel.
- The possibility that if one staff member or household member has a viral illness, other staff members or household members may also be infected.
- The need to stay away from work and not to have direct contact with any ready-to-eat food when having symptoms of gastroenteritis or infectious hepatitis.
- The need to keep children away from food growing fields and food preparation areas, to the extent possible, in HAV endemic areas (since in endemic areas children are a primary source of the virus).
- Procedures for the disposal of contaminated food items.

10.3 INSTRUCTION AND SUPERVISION

66. Extensive training and instructions should be given to all new personnel on the infectivity, transmission and management of foodborne viruses. Incorporation of these instructions into the National Codes of Hygienic Practice would be advisable.

67. Also inspectors or other relevant authorities who inspect fields, post harvest processing plants, and eating facilities should be provided with the above training, and be aware of the instructions.

ANNEX I

CONTROL OF HEPATITIS A VIRUS (HAV) AND NOROVIRUS (NoV) IN BIVALVE MOLLUSCS**INTRODUCTION**

1. For bivalve molluscs, the major, well-documented route of contamination is via human faecal contamination in growing or harvesting areas. Viruses have been observed to persist for 8 to 10 weeks in contaminated live bivalve molluscs and can be detected in the digestive tissue of bivalve molluscs. Recent evidence has shown that some NoV genotypes bind specifically to bivalve molluscs' tissue receptor sites, which could explain why some viruses persist after depuration procedures as currently practiced in the industry. Long-term relay of bivalve molluscs to clean environmental waters can be effective for eliminating the risk of illness from viruses, but often this is impractical due to added costs or lack of clean areas in reasonable proximity to contaminated harvest sites. Furthermore, studies indicate that there may even be a risk of infection if contaminated bivalve molluscs are consumed after insufficient heat treatment. Thus, once viral contamination of bivalve molluscs has occurred, removal or inactivation of the viruses by processes that retain the sensory characteristics of the live molluscs is currently difficult. Therefore, measures should be taken to prevent viral contamination of bivalve molluscs by improving environmental conditions (particularly water quality) in production and harvesting areas.

SECTION 1- OBJECTIVES

2. This annex provides advice to governments on a framework for the reduction of HAV and NoV in bivalve molluscs, with a view towards protecting the health of consumers and ensuring fair practices in food trade. The primary purpose of this annex is to minimize the likelihood of human illness arising from the presence of HAV and NoV in bivalve molluscs. This annex also provides information that will be of interest to the food industry, consumers, and other interested parties.

SECTION 2 - SCOPE, USE AND DEFINITION**2.1 SCOPE**

3. This annex is applicable to bivalve molluscs and focuses on control measures to minimize and/or prevent contamination of bivalve molluscs with HAV and NoV with the aim of preventing or reducing human illness.

2.2 USE

4. This annex on the *Control of Hepatitis A Virus (HAV) and Norovirus (NoV) in Bivalve Molluscs* (Annex I) is a supplement to the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food* and provides additional recommendations for this specific virus-commodity combination. This annex should also be used in conjunction with Sections 2 and 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

2.3 DEFINITIONS

Clean water – See Section 2.1 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

Depuration – See Section 2.3 of CAC/RCP 52-2003.

Growing areas – See Section 2.3 of CAC/RCP 52-2003.

Relaying – See Section 2.3 of CAC/RCP 52-2003.

Relaying areas - See Section 2.3 of CAC/RCP 52-2003.

SECTION 3 - PRIMARY PRODUCTION

5. The main hazard known for the production of bivalve molluscs is microbiological contamination of the waters in which they grow, especially as the bivalve molluscs are often consumed live, raw or partially treated. Since bivalve molluscs are filter-feeders, they concentrate microbiological contaminants to a much higher concentration than is present in the surrounding seawater. The potential for contamination with bacteria and viruses in the growing area is therefore critical for the end product specification and determines the process requirements for further processing.

6. It is important to ensure the seawater quality of growing areas to prevent or minimize viral contamination of bivalve molluscs growing areas. A sanitary survey of growing areas should be conducted prior to the commencement of growing and/or harvesting operations and when climatic conditions such as heavy rainfall

warrant. The sanitary survey of growing areas should include an assessment of possible human faecal contamination sources.

7. The following are examples of factors that should be addressed during the sanitary survey and where possible supplemented by a practical shoreline survey:

- location and extent of the bivalve mollusc fishery;
- type of shellfishery (species, method of harvest, seasonality of harvest);
- location, type and volume of sewage discharges;
- location of river inputs and other potentially contaminated water courses (from maps/nautical charts);
- location of harbours and marinas (from maps/nautical charts);
- hydrographic and hydrometric data;
- existing microbiological data from water quality or shellfish monitoring undertaken in the same area or adjacent areas; and
- areas of recreational bathing.

8. The level of faecal contamination may indicate the potential for the presence of human enteric viruses. To control the hazards, identification and monitoring of growing areas is very important for bivalve molluscs safety. *E. coli*/faecal coliforms are used as indicators of faecal contamination. Monitoring data should be interpreted within the context of the sanitary survey, as viruses may be present in the absence of these bacterial indicators.

9. When there has been a bivalve molluscs-borne outbreak caused by an identified pathogen such as NoV or HAV and the area has been closed, viral testing of the bivalve molluscs or an approach consistent with the requirements of the competent authority should be used as part of the process of reopening the affected area to ensure product safety using either standardized methods or alternative validated methods. Other conditions, including meeting the sanitary survey requirements, should also have been satisfied as a condition of reopening the area. Ideally they should include the identification of sources of pollution/contamination and prevention of future contamination events.

3.1 ENVIRONMENTAL HYGIENE

10. With regard to risks for virus contamination some of the specific areas to be addressed are as follows:

- Growing areas that are contaminated by sewage discharge or disposal of faecal matter from ships, recreational boats and bivalve molluscs harvesting vessels.
- Overflow from sewage treatment plants that may contaminate the growing waters after heavy rainfall.
- Quality of sewage collecting network and private septic tanks.

11. Every effort should be made to eliminate the overflow of untreated or partially treated sewage into growing waters.

12. Sewage treatments should ensure adequate reduction of viral loads and aim to achieve significant reduction of NoV and HAV (Refer to *WHO Guidelines for the safe use of wastewater, excreta and grey water. Volume 3 Waste water and excreta use in aquaculture* (http://whqlibdoc.who.int/publications/2006/9241546840_eng.pdf). Whenever possible, sewage treatment should involve a tertiary treatment step such as UV or ultra-filtration treatment. The use of a prohibition zone for the harvest of bivalve molluscs near a wastewater treatment plant is another option the competent authority may use. Treatment plants should be designed to minimize storm overflows that may affect the fishery. Systems should be put in place to monitor sewage spills and provide prompt notification to the appropriate competent authority as well as the bivalve molluscs industry so that appropriate action (i.e. cessation of harvesting) can be taken.

13. After heavy rainfall, during risk periods (e.g., untreated or partially treated sewage that has or is suspected to have entered a growing area) and/or after overflow from sewage treatment plants, harvesting of bivalve molluscs should cease for a period, until the water and/or bivalve molluscs quality of the harvesting area has been assessed and has been returned to normal background levels for the area. If there is evidence that the area has been impacted by human sewage, testing of water or bivalve molluscs for the presence of indicators

of faecal contamination and/or NoV or HAV, as determined by the competent authority or an equivalent approach to ensure safety, may be an option prior to re-opening.

14. When untreated or partially treated sewage is known or suspected to have entered a growing area it is recommended that bivalve molluscs already harvested from this area should be designated exclusively for virucidal heat treatment (see section 5.2.2) by the processor before release to retail sales. Another option is long term relaying or a combination of depuration and relaying as determined by the competent authority.

15. In addition, suitable precautions should be taken to protect bivalve molluscs from being contaminated by human faecal material, in particular:

- No overboard discharge of human faecal material should occur from harvest (or assisting) vessels around bivalve molluscs growing areas.
- All necessary measures should be taken to prevent contamination of bivalve molluscs by faecal materials on board of harvest vessels.
- Facilities and toilets should be such to ensure that an appropriate degree of personal hygiene can be maintained, especially on harvest vessels.

3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

16. Efforts should be made to restrict the growing and harvesting of bivalve molluscs to areas of clean water only.

17. Records regarding the history of contamination of bivalve molluscs harvesting areas by NoV and HAV should be reviewed in order to determine whether risk periods can be identified for each area. During such periods, the monitoring for contamination levels in risk areas should be reinforced.

18. In addition to the use of clean water during primary production, other possible control measures for enteric viruses, such as NoV and HAV, include long term relaying or a combination of depuration and relaying.

19. If using short-term or long-term relaying as a means to reduce microbial contaminants, the effectiveness of the treatment is dependent upon the water quality and conditions of the location to which the bivalve molluscs are relayed. The time used for relaying bivalve molluscs should be verified as appropriate by the competent authority having jurisdiction, using standardized protocols for specific virus/molluscs species pairings. The holding time and minimum temperature during long term relaying should be based on the degree of contamination before relaying, the temperature of the water, the bivalve mollusc species involved and local geographic or hydrographic conditions to ensure that contamination levels will be adequately reduced to ensure that virus is not present using validated testing methods. A short-term depuration process commonly reduces low levels of bacterial contamination, and thus contributes to the safety of bivalve molluscs but depuration alone is inadequate in the elimination of viruses.

20. When there is a likelihood or evidence of virus contamination through epidemiological information, environmental events or direct detection of virus or viral RNA, closure of the area, destruction of contaminated bivalve molluscs and/or virucidal heat treatment (see section 5.2.2) before consumption of already harvested bivalve molluscs is recommended. Another option, if verified by the competent authority, is long term relaying or a combination of depuration and relaying.

SECTION 5 - CONTROL OF OPERATION

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.2 Specific process steps

- Heat Treatment: Heat treatments of bivalve molluscs should be validated for their ability to inactivate viruses. An internal temperature of 85 to 90 °C for at least 90 seconds is considered to be a virucidal treatment. However, this degree of cooking would probably render specific bivalve molluscs, such as oysters, unpalatable to consumers. Even though cooking temperatures typically used by consumers may not achieve 90 °C for at least 90 seconds and thus ensure inactivation of viruses, any cooking would reduce viral levels and depending on the initial level of contamination possibly would reduce the risk of causing foodborne infection. For example, it has been reported that an internal temperature of steamed shellfish maintained at 85 to 90 °C for 1 min reduced titers of HAV in cockles by more than 4 log. The possible inability of home or restaurant cooking to provide adequate assurance of consumer protection

from consuming virally contaminated bivalve molluscs in certain circumstances or forms of consumption underlines the importance of harvesting bivalve molluscs from clean water growing areas.

- High Hydrostatic Pressure (HHP): HHP may reduce virus titers in bivalve molluscs with relatively small effects on the character of the meat. The HPP conditions for inactivation depend upon pressure as well as time, temperature and the salinity of the water, e.g. a pressure of 600 MPa applied at 6 °C for five minutes can completely inactivate NoV in oysters. The use of HHP alone or in combination with other inactivation procedures should be validated for the virus of concern in the specific bivalve mollusc species prior to its application.

SECTION 9 – PRODUCT INFORMATION AND CONSUMER AWARENESS

9.1 LOT IDENTIFICATION

21. NoV and HAV can persist for long periods of time in bivalve molluscs. As movements between growing areas and countries complicate traceability of bivalve molluscs, lot identity, harvest site and date, and integrity should be maintained to facilitate trace back to all the growing areas. Because of viral persistence, it is recommended that growing areas be registered for a two month period prior to harvest and that harvest areas also be registered.

9.3 LABELLING

22. Refer to the *General Standard for Labelling of Prepackaged Foods* (CODEX STAN 1-1985) and to the labelling provisions of *the Standard for Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008). Where appropriate, product labels should include information on safe handling practices and storage recommendations.

23. In addition, countries should give consideration to labelling of unpackaged live or raw bivalve molluscs, so that consumers are adequately informed with respect to the safety and true nature (alive or not alive) of these products. In particular, bivalves that are at a high risk of being contaminated with NoV or HAV, should be labelled to alert at-risk consumers to avoid or cook these products, in line with the legislation in the countries where these products are retailed or sold.

9.4 CONSUMER EDUCATION

24. Each country has specific consumption habits; therefore communication programmes pertaining to viruses in relation to the consumption of bivalve molluscs are most effective when established by national governments. Consumers should be made aware of the risk of becoming infected with NoV or HAV after consuming raw or treated bivalve molluscs.

SECTION 10 – TRAINING

10.2 TRAINING PROGRAMMES

25. In addition to the training content mentioned in the main part of this document (section 10.2), appropriate personnel involved in the growing and harvesting of bivalve molluscs should have appropriate training in:

- Control measures to prevent faecal contamination of growing and harvesting areas. Awareness of the lack of correlation between bacterial indicators and viral contamination should also be ensured.
- Control measures to prevent bivalve molluscs from becoming contaminated by contagious food handlers.

ANNEX II

CONTROL OF HEPATITIS A VIRUS (HAV) AND NOROVIRUS (NoV) IN FRESH PRODUCE**INTRODUCTION**

1. Fresh produce is now grown on a large scale in many countries and is transported globally. Outbreaks of viral disease associated with contaminated raspberries, green onions, and leafy greens as well as other produce items are well documented. The contamination of fresh produce may occur at any stage from production to consumption.
2. Fresh produce may become contaminated with viruses through contact with human sewage, e.g., through the use of sewage-contaminated waters for irrigation, washing, or in the application of fertilisers and agrichemicals, or through the seepage of untreated or partially treated sewage into the soil.
3. Fresh produce may also become contaminated by viruses via contaminated hands of food handlers especially if they do not practise appropriate personal hand hygiene (i.e., hand washing). A second important factor in food-handler associated spread of viruses is vomiting that can lead to widespread contamination of the environment.
4. In countries where HAV infection is endemic, children in and around produce production fields may be an important risk factor in the spread of viruses during primary production. Children who are asymptomatic or have unsuspected HAV infection (shedding virus) and are working in the production field or being cared for by a food handler also increase the risk of contaminating fresh produce.

SECTION 1- OBJECTIVES

5. The primary purpose of this annex is to minimise the likelihood of illness arising from the presence of NoV and HAV in fresh produce. The annex also provides information that will be of interest to the food industry, consumers, and other interested parties.

SECTION 2 – SCOPE, USE AND DEFINITION**2.1 SCOPE**

6. This annex covers general hygienic practices for the production, harvesting, processing, packing and storage of fresh produce for human consumption particularly for fresh produce intended to be consumed raw or partially treated. Specifically, this annex is applicable to fresh produce grown in the field (with or without cover) or in protected facilities (hydroponic systems, greenhouses). It concentrates on NoV and HAV in fresh produce and how to prevent fresh produce from becoming contaminated by these viruses during primary production.

7. Recommendations for handling practices to maintain the safety of fresh produce at wholesale, retail, food services or in the home are covered in *General Principles of Food Hygiene* (CAC/RCP 1-1969), the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53 – 2003) and the main part of this document.

2.2 USE

8. This Annex on the *Control of Hepatitis A Virus (HAV) and Norovirus (NoV) in Fresh Produce* (Annex II) is a supplement to the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food* and provides additional recommendations for this specific virus-commodity combination.

2.3 DEFINITION

Clean water - See Section 2.3 of the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003).

SECTION 3 - PRIMARY PRODUCTION

9. Fresh produce is grown and harvested under a wide range of climatic and diverse geographical conditions, using various agricultural inputs and technologies, under varying socioeconomic, hygienic and epidemiological circumstances, and on farms of different sizes. Viral hazards may therefore vary considerably from one type of production to another. In each primary production area, it is necessary to consider the particular agricultural practices that promote the production of safe fresh fruits and vegetables, taking into account the conditions that are specific to the primary production area, type of products, and methods used.

Primary production activities should be conducted following good hygienic practices in order to minimize potential risks of contamination of fresh produce with NoV and HAV.

3.1 ENVIRONMENTAL HYGIENE

10. In the case of NoV and HAV in fresh produce, the main (human) sources of contamination of the production sites that should be specifically regarded are sewage treatment plants effluents, untreated human excreta used as fertilizer, agricultural workers and the personnel hygiene and toilet facilities on-site (Refer to *WHO Guidelines for the safe use of wastewater, excreta and grey water. Volume 2: Wastewater use in agriculture* (World Health Organization 2006 ISBN 92 4 154683 2,v.2; www.who.int/water_sanitation_health/wastewater/gsuweg2/en/index.html). If these sources contaminate water and soil that come into contact with fresh produce, there is a potential risk of contamination with NoV and HAV. Infectious NoV and HAV can persist in the environment, as well as on fresh produce, and it can sometimes survive the shelf life of the products.

11. Sewage treatments should ensure adequate (maximal) reduction of viral loads in treated sewage, as the following could be potential sources of contamination:

- Water contaminated with untreated or partially treated sewage discharges, by overflow from sewage and septic tank systems or from run-off associated with a heavy rainfall that is used for irrigation, washing of produce, or application of fertilizers and agrichemicals.
- Seepage of untreated or partially treated sewage onto/into agricultural soil.

3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

3.2.1 Water for primary production

12. Efforts should be made to use only clean water for the production of food. The assessment of the microbial quality of the sources of water used on the farm for the presence of NoV and HAV should include an assessment of possible human faecal contamination sources of the water (sanitary survey) and, if deemed necessary, testing for faecal contamination. In the case of identified contamination sources of the water used on the farm, corrective actions should be taken to minimize the NoV and HAV risks. The effectiveness of corrective actions should be verified.

13. Testing for *E. Coli* / faecal coliforms is useful to determine the level of faecal contamination of the water. *E. coli* originates from human and animal sources, however, currently it is assumed that NoV and HAV originate from human sources only. The level of faecal contamination may indicate the potential for the presence of NoV and HAV; however, these viruses may be present in the absence of faecal indicators. The frequency of testing for indicators of faecal contamination should be established according to the source of the water (ground water, surface water, wells) and the conditions of the irrigation system.

14. With water delivery techniques that result in exposure of fresh fruits and vegetables (particularly the edible portion) directly to irrigation water, such as with use of overhead sprinklers, the risk of NoV and HAV contamination is considered to be higher as compared to other types of irrigation, such as drip irrigation.

3.2.2 Personnel health, hygiene and sanitary facilities

3.2.3.1 Personnel hygiene and sanitary facilities

15. Personnel hygiene facilities and toilets (permanent or portable), including appropriate hand washing facilities, should be present in close vicinity of the fields where agricultural workers are working.

3.4 CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION

16. Refer to Section 7 for aspects of personnel hygiene in primary production.

SECTION 5 - CONTROL OF OPERATION

17. The control of NoV and HAV in fresh produce should focus on the prevention of contamination of fresh produce with human faecal material, as there are limited effective post-harvest treatments to eliminate viruses available at present.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.2 Specific process steps

- Washing: The washing of fresh produce is not a suitable method to eliminate viruses as the surface type may allow viruses to remain present.
- Chemical treatment: Antimicrobial agents, effective for bacteria, may not be effective for the reduction of NoV and HAV in fresh produce.

SECTION 7 –ESTABLISHMENT: PERSONAL HYGIENE

7.5 VISITORS

18. Non-authorized persons and, to the extent possible, children, should not be on the premises where fresh produce is grown, harvested, washed, packed or stored.

SECTION 10 – TRAINING

10.2 TRAINING PROGRAMMES

19. Personnel involved in growing, harvesting, processing and storage of fresh produce should have appropriate training in:

- The general characteristics of NoV and HAV and their resistance to various environmental conditions, e.g. conditions of sewage treatment, temperature.
- Personal hygiene (*see* Section 7, main document).
- Control measures to prevent faecally contaminated water being used in primary production and processing.
- The risks associated with the use of human waste excreta as a fertilizer.
- Control measures to prevent fresh produce becoming contaminated by contagious food handlers.

Appendix IV**PROPOSED DRAFT ANNEX TO CODE OF HYGIENIC PRACTICE FOR FRESH FRUITS AND VEGETABLES (CAC/RCP 53-2003)****ANNEX IV: ANNEX FOR MELONS****(At Step 5/8 of the Procedure)****INTRODUCTION**

Melons, such as cantaloupe, watermelon, and honeydew, are often consumed alone, mixed with other foods in salads and other dishes and as garnishes. They are popular in meals and as snacks, and in some countries melons are a regular part of the diet. The popularity of melons has remained high as they are readily available in many countries all year round. In recent years there has been a focus on marketing not only whole melons, but pre-cut products, convenience products in packages, or in salad bars to appeal to consumers. Adding to consumer appeal for melons is the availability of new varieties that are seedless and the introduction of sweeter hybrid varieties.

Like other fresh fruits and vegetables that are eaten raw, the safety of melon products depends on maintaining good hygienic practices along the food chain during primary production, packing, processing, retail, and at the point of consumption. International outbreak data and reported illnesses raise concerns regarding the safety of melon products. There have been a number of outbreaks associated with melon consumption with a large number being caused by *Salmonella* spp¹. Additionally other pathogens, such as *Listeria monocytogenes* have been associated with foodborne outbreaks from melons. The major risk factors that have been identified as contributing to melon outbreaks include: poor temperature control (including extended holding at ambient temperature and poor cold storage), infected food handlers and poor personal hygiene. As fresh and pre-cut melon products move through the food chain, there is also the potential for the introduction, growth and survival of foodborne pathogens due to cross contamination (arising from poor hygiene practices for personnel, transport, retail outlets, utensils or consumers). Moreover, morphological characteristics of certain types of melons, for instance netted rind, will be prone to attachments by microbial pathogens. Fresh melons are consumed without further processing treatment that would eliminate or inactivate pathogens, if present.

SECTION 1 - OBJECTIVES

Hygienic recommendations for the primary production of fresh fruits are covered in general under the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003). The primary purpose of this Annex is to provide specific guidance on how to minimize microbiological hazards during primary production through packing and transport of fresh melons, including fresh melons processed for the pre-cut market and consumer use.

SECTION 2 - SCOPE, USE AND DEFINITION**2.1 Scope**

This annex covers specific guidance related to all areas, from primary production to consumption, of fresh melons that are intended to be consumed without further microbiocidal steps.

2.2 Use

This Annex follows the format of the *General Principles of Food Hygiene* (CAC/RCP 1-1969) and should be used in conjunction with it and other applicable codes such as the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003) and Annex I, the *Annex for Ready-to-Eat Fresh Pre-cut Fruits and Vegetables*, and the *Code of Practice for Packaging and Transport of Fresh Fruits and Vegetables* (CAC/RCP 44-1995).

¹ Report of the FAO to the Codex Committee on Food Hygiene Working Group on the development of an Annex on melons for the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003)

2.3 Definitions

Refer to definitions in the *General Principles of Food Hygiene* and the *Code of Hygienic Practice for Fresh Fruits and Vegetables*. In addition, the following expressions have the meaning stated:

Cull means to remove any product that shows signs of physical damage (such as skin breaks or decay).

Ground spot means the point of direct contact where melons sit directly on the soil or on top of thin plastic mulch.

Melons in this document refers to whole and/or pre-cut cantaloupe (also known as muskmelons and rockmelons), honeydew, watermelon and other varieties of melons.

SECTION 3 - PRIMARY PRODUCTION

Fresh melons are grown in production sites indoors (e.g., greenhouses) and outdoors, harvested, and either field-packed or transported to a packing establishment.

3.1 Environmental hygiene

Potential sources of environmental contamination should be identified prior to production activities. This is important because contamination that occurs during production may not be removed during subsequent steps. In addition, melons grown in warm, humid conditions may favour growth and survival of foodborne pathogens. Growers should take steps to minimize the potential for contamination from any sources identified.

Particular attention should be given to potential sources of faecal contamination in the melon production area and to vectors which may introduce faecal contamination to the production and handling areas. These vectors include, but are not limited to, humans, domestic and wild animals, or indirectly from contaminated water, insects, or fomites such as dust, tools and equipment.

3.1.1 Location of the production site

Consideration of production site location should include an evaluation of the slope and the potential for runoff from nearby fields, the flood risk as well as hydrological features of nearby sites in relation to the production site.

The proximity of high risk production sites, such as animal production facilities, hazardous waste sites and waste treatment facilities, should be evaluated for the potential to contaminate melon production fields or the water sources used with microbial or other environmental hazards via, for example, run-off, faecal material, aerosols or organic waste. When the risks are serious these production sites should not be used for melon production.

When the environmental assessment identifies a potential food safety risk, measures should be implemented to minimize contamination of melons at the production site. Consideration should be given to changing the landscape surrounding melon production fields, such as the construction of a shallow ditch to prevent runoff from entering the fields, to reduce the potential for pathogen contamination of melons in the production site. The effects of some environmental events, such as heavy rains, cannot be controlled. For example, heavy rains may increase melons' exposure to pathogens if soil contaminated with pathogens splashes onto melon surfaces. Consideration could be given to harvesting earlier if the weather forecasts heavy rain or to delaying harvest and performing extra washing when heavy rains have recently occurred.

3.1.2 Wild and domestic animals and human activity

Many animal species (e.g., insects, birds, amphibians, chickens, feral pigs, livestock and domestic or wild dogs) and humans that may be present in the production environment are known to be potential carriers of foodborne pathogens. Animals are a common source of contamination of surface water that may be used for irrigation. The following should be considered:

- Domestic and wild animals should be excluded from production and handling areas, to the extent possible, using appropriate biological, cultural, physical and chemical pest control methods. Methods selected should comply with local, regional, and national environmental and animal protection regulations.
- Melon production and handling areas should be properly maintained to reduce the likelihood of

vector attraction. Activities to consider include efforts to minimize standing water in fields, restrict access by animals to water sources (may be based on local ordinances for public irrigation systems), and keep production sites and handling areas free of waste and clutter.

- Melon production sites and handling areas should be evaluated for evidence of the presence of wildlife or domestic animal activity (e.g., presence of animal faeces, hairs/furs, large areas of animal tracks, burrowing, or decomposing remains). Where such evidence exists, growers should evaluate the risks and whether the affected sections of the melon production sites should be harvested.

3.2 Hygienic primary production of melons

Special consideration should be given to production practices specific to melon production because of the unique characteristics of the melons and the rind of some melons and because melons frequently contact soil directly during growth and development. Melons may have smooth or netted rind surfaces. Netted rind surfaces, in contrast to smooth rind surfaces, provide an environment where microbial pathogens may more easily adhere to, survive on, and become more difficult to eliminate during post-harvest practices. It is recommended that growers use production practices that prevent or minimize contact of melons, particularly those with netted rinds, with soil, soil amendments (including natural fertilizers) or irrigation water.

Some growers place melons on cups (i.e., small plastic pads) or plastic mulch-covered beds (wider and more elevated during the wet season), or halved bamboo segments to minimize direct melon-to-soil contact and thereby reduce ground spot development. Melons also may be hand-turned multiple times by agricultural workers during the growing season to prevent sunburn or ground spot development or covered with biodegradable materials such as rice straw to prevent sunburn. Melon rind ground spots have been demonstrated to have significantly greater microbial populations than non-ground spot areas and, therefore, may be more susceptible to microbial contamination. If cups or biodegradable materials are used underneath melons, the following are recommended:

- Use plastic mulch under cups to minimize cup and melon contact with the soil.
- Ensure cups are clean and sanitary before setting them under the melons.
- Ensure that employees follow good hygienic practices when turning melons on the cups or during harvesting operations.
- Use biodegradable materials only once to prevent cross-contamination.

3.2.1.1 Water for primary production

Growers should identify the sources of water used on the farm (municipality, re-used, irrigation water, reclaimed wastewater, discharge water from aquaculture, well, open canal, reservoir, rivers, lakes, farm ponds, etc.). It is recommended that growers assess and manage the risk posed by these waters as follows:

- Assess the potential for microbial contamination (e.g., from animals, human habitation, sewage treatment, manure and composting operations) and the water's suitability for its intended use. Reassess the potential for microbial contamination if events, environmental conditions (e.g., temperature fluctuations, heavy rainfall, etc.) or other conditions indicate that water quality may have changed.
- Identify and implement corrective actions to prevent or minimize contamination. Possible corrective actions may include fencing to prevent large animal contact, proper maintenance of wells, filtering water, not stirring the sediment when drawing water, building settling or holding ponds, and water treatment facilities. Settling or holding ponds that are used for subsequent irrigation may attract animals or in other ways increase the microbial risks associated with water for irrigating melons. If water treatment is needed, consult with water safety experts.
- Determine if microbial and chemical testing should be done to evaluate the suitability of water for each intended use. Analytical testing may be necessary after a change in irrigation water source, flooding or a heavy rainfall when water is at a higher risk of contamination. If testing, determine and document.
 - What tests need to be performed, (e.g., which pathogens and/or sanitary indicators)

- Which parameters should be noted (e.g., temperature of water sample, water source location, and/or weather description),
 - How often tests should be conducted,
 - What the test outcomes indicate, and
 - How tests will be used to define corrective actions.
- Frequency of testing should depend on the source of the irrigation water (less for adequately maintained deep wells, more for surface waters) and the risks of environmental contamination, including intermittent or temporary contamination (e.g., heavy rain, flooding, etc.).
 - If water testing is limited to non-pathogenic indicators, frequent water tests may be useful to establish the baseline water quality so that subsequent changes in the levels of contamination can be identified.
 - If the water source is found to have unacceptable levels of indicator organisms or is contaminated with foodborne pathogens, corrective actions should be taken to ensure that the water is suitable for its intended use. Testing frequency should be increased until consecutive results are within the acceptable range.

3.2.1.1.1 Water for irrigation

Netted melon rind surfaces, in contrast to smooth rind surfaces, may foster greater attachment and survival of foodborne pathogens. For this reason, the quality of irrigation water and type of irrigation method used is an important consideration. Growers should consider the following:

- Avoid overhead irrigation methods, particularly with netted rind melons, because wetting the outer rind of melons increases the risk of pathogen contamination. Overhead irrigation also enhances downy mildew infection in melons.
- Subsurface or drip irrigation presents the least risk of contaminating melon surfaces. For 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 melon rinds.

3.2.1.1.2 Water for fertilizers, pest control and other agricultural chemicals

Clean water, should be used in the application of aqueous fertilizers, pesticides and other agricultural chemicals that are directly applied to the surface of melons, especially close to harvest. Foodborne pathogens can survive and grow in many agrichemical solutions, including pesticides.

3.2.1.1.4 Water for harvesting and other agricultural uses

Clean water should be used for other agricultural purposes, such as dust abatement, hydration, use as a lubricant, and to maintain roads, yards, and parking lots in areas where melons are grown. This would include water used to minimize dust on dirt roads within or near melon production sites.

3.2.1.2 Manure, biosolids and other natural fertilizers

Manure, biosolids and other natural fertilizers may contain human or animal waste, animal parts or products, or be composed primarily of plant materials. Because of this, foodborne pathogens may be present and may persist for weeks or even months, particularly if treatment of these materials is inadequate.

Growers should consider the following when using any of these materials:

- Use proper treatment by physical, chemical or biological methods to reduce the risk of potential human pathogen survival.
- Composting, if done properly, can be a practical and efficient method to inactivate foodborne pathogens in manure. In general, only fully decomposed animal waste or plant material should be applied to melon fields.
- When using aerobic composting methods, regularly and thoroughly turn compost heaps to ensure that all of the material will be exposed to elevated temperatures because pathogens can survive for months on the heap surface.

- When using anaerobic methods, special consideration should be given to determine the length of time needed to inactivate pathogens that may be present.
- Use of untreated and/or partially treated manure, biosolids, and other natural fertilizers should not be used after plant emergence or after a transplant is put into the soil, unless it can be demonstrated that product contamination will not occur.

3.2.3 Personnel health, hygiene and sanitary facilities

The following should be considered:

- Where appropriate, each business operating primary production operations should have written Standard Operating Procedures (SOPs) that relate to health, hygiene and sanitary facilities. The SOPs should address worker training, facilities and supplies to enable agricultural workers to practice proper hygiene, and company policies relating to expectations for worker hygiene as well as illness reporting.
- All agricultural workers should properly wash their hands using soap and clean running water before handling melons, particularly during harvesting and post-harvest handling. Agricultural workers should be trained in proper techniques for hand washing and drying.
- If gloves are used, a procedure for glove use in the field should be documented and followed. If the gloves are reusable, they should be made of materials that are easily cleaned and disinfected, and they should be cleaned regularly and stored in a clean area. If disposable gloves are used, they should be discarded when they become torn, soiled, or otherwise contaminated.
- Non-essential persons, casual visitors and, to the extent possible, children, should not be allowed in the harvest area as they may present an increased risk of contamination.

3.2.3.1 Personnel hygiene and sanitary facilities

Growers should consider providing areas away from the field and packing lines for agricultural workers to take breaks and eat. For worker convenience, these areas should provide access to toilet and hand-washing facilities so that agricultural workers can practice proper hygiene.

As far as possible, sanitary facilities should be located close to the field and readily accessible to the work area.

- Sanitary facilities should be located in a manner to encourage their use and reduce the likelihood that agricultural workers will relieve themselves in the field. Facilities should be present in sufficient number to accommodate all personnel.
- Portable facilities should not be located or cleaned in cultivation areas or near irrigation water sources or conveyance systems. Growers should identify the areas where it is safe to put portable facilities.
- Facilities should include clean running water, soap, toilet paper or equivalent, and single use paper towels or equivalent. Multiple use cloth drying towels should not be used. Hand sanitizers should not replace hand washing and should be used only after hands have been washed.
- If clean running water is not available, an acceptable alternative hand washing method should be recommended by the relevant competent authority.

3.2.3.2 Health status

The following should be considered:

- Growers should be encouraged to note symptoms of diarrhoeal or food-transmissible, communicable diseases, and reassign agricultural workers as appropriate.
- Agricultural workers should be encouraged and, where feasible, be motivated with appropriate incentives to report symptoms of diarrhoeal or food-transmissible, communicable diseases.
- Medical examination of agricultural workers should be carried out if clinically or epidemiologically indicated.

3.2.3.3 Personal cleanliness

When personnel are permitted to continue working with cuts and wounds covered by water proof dressings, they should wear gloves to cover the bandages thereby providing a secondary barrier between them and the melons they handle.

3.2.4 Equipment associated with growing and harvesting

Standard operating practices should be developed for the maintenance, cleaning and disinfecting operations of growing and harvesting equipment. In addition:

- Agricultural workers should be trained to follow the SOPs.
- Cutting equipment used to harvest melons should be thoroughly cleaned and disinfected before use and cutting edges should be kept smooth and sharp.

3.3 Handling, storage and transport

Melons such as cantaloupe are harvested based on the melon's stage of maturity as judged by the formation of an abscission zone between the vine and the melon. After the vine is separated from the melon, a stem scar is left on the fruit. Melon stem scars may provide a potential route for entry of foodborne pathogens, if present, to the edible portion of the melons. It is recommended that post-harvest handling practices be implemented to minimize stem scar and rind infiltration, such as during washing operations, of foodborne pathogens into the edible portions of melon flesh. Where appropriate, written SOPs should be developed and implemented for safe handling, storage and transport of melons. It should be considered that the length of storage for melons at a recommended temperature depends on the stage of maturity when melons are harvested.

3.3.1 Prevention of cross-contamination

Specific control methods should be implemented to minimize the risk of cross-contamination from microorganisms associated with manual harvesting methods. The following should be considered:

- The field should be evaluated for the presence of hazards or contamination prior to harvest to determine if the field should be harvested.
- Particularly with manual harvesting, as well as field packing operations, good personal hygiene should be implemented to prevent surface contamination of melons.
- Proper cleaning and disinfection of equipment should be done since knives, if improperly used, can wound melon rinds and provide a point of entry for contaminants that may be in soil and water.
- Avoid setting melons directly on soil after removal from the vine and before loading into transport vehicle to avoid contaminating the melon with contaminants in the soil.
- Harvest containers that come into contact with melons should not be used for purposes other than holding product (e.g., should not hold personal items, waste, etc.).

Melons are susceptible to damage during harvest and post-harvest handling operations. The following should be considered:

- When padding is used with post-harvest handling equipment to prevent damage to melons, it should be constructed of material that can be cleaned and disinfected. Ensure that padding is cleaned and disinfected before and during use.
- Minimize mechanical damage such as rind punctures, cracks, and bruising, as these wounds may provide entry points for pathogens and sites for microbial survival and multiplication.
- Train agricultural workers to recognize and not harvest damaged melons.
- Dispose of culled melons in a way that melon culls will not attract animal and insect pests. This will reduce the potential for contaminating melons still on the vine.

3.3.2 Storage and Transport from the production site to the packing/processing facility

Refer to the *Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food* (CAC/RCP 47-2001)

- Transportation of fresh melons should be managed to reduce or control the risk of contamination. Each transporter should have its own SOP for shipping containers/trailers to confirm that they are clean, sanitary and in good structural condition.
- Fresh melons should not be transported in vehicles used previously to carry animals, animal manure or biosolids and pesticides unless they are adequately cleaned and disinfected. Receptacles and vehicles and/or containers, when being used to transport melons, are not to be used for transporting anything which may result in contamination of melons.
- Where conveyances and/or containers are used for transporting anything in addition to foodstuffs or for transporting different foodstuffs at the same time, there should, where necessary, be effective separation of products.
- When not in use, cleaned harvest containers and transport trailers should be covered and kept in a location and in a manner to prevent possible contamination (e.g., such as from pests, birds, rodents, dust, water, etc.).
- Damaged containers or transport trailers should be repaired or replaced.

3.4 Cleaning, maintenance and sanitation

3.4.1 Cleaning programs

The following should be considered:

- Harvesting equipment, including knives, pruners, machetes, that come into direct contact with melons should be cleaned and disinfected at least daily or as the situation warrants.
- Clean water should be used to clean all equipment directly contacting melons, including farm machinery, harvesting and transportation equipment, containers and knives.

3.4.2 Cleaning procedures and methods

Cleaning and disinfection programs should not be carried out in a location where the rinse water might contaminate melons.

Where appropriate or necessary, cleaning and disinfecting procedures should be validated to ensure their effectiveness.

SECTION 4 –ESTABLISHMENT: DESIGN AND FACILITIES

Refer to the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Ready-to-eat Foods* (CAC/GL 61-2007).

The provisions below apply to packing and processing establishments of melons.

4.2 Premises and rooms

4.2.1 Design and layout

It is important to consider the sanitary design and layout for packing/processing equipment and the establishment because of the seasonal nature of the melon harvest. Packing/processing establishment operations may be used only a few months of the year and thus be dormant for many months, leaving them susceptible to pest infestations. When dormant, packing/processing establishment should be appropriately protected from pest infestations. Their design should allow thorough cleaning and disinfection of food contact surfaces to ensure microbial pathogens do not become established in the facility or on the equipment.

4.4 Facilities

4.4.2 Drainage and waste disposal

Adequate drainage is critical to packing, cooling and processing facilities to avoid the risk of contaminating melons. To ensure adequate drainage of standing water, consider the following:

- Drainage in the facility should be designed with sloped floors to effectively drain standing water.
- Floors should be kept as dry as possible using appropriate methods.
- Standing water should be removed or pushed to the drains.
- Drains should be cleaned periodically to prevent build-up of biofilms that may contain organisms of concern (e.g., *Listeria monocytogenes*).
- Areas for garbage recyclables and compostable waste should be identified and all waste should be stored and disposed of in a manner to minimize contamination.
- Waste should be disposed of on a frequent basis to avoid attracting pests (e.g., flies, rodents).

SECTION 5 - CONTROL OF OPERATION

5.1 Control of food hazards

Prevention of contamination is a key control point for all produce operations, including melon operations. Establishments should pay special attention to product flow and segregation of incoming soiled and outgoing washed product to avoid cross-contamination. If melons pass over brushes during the operations, care should be taken to ensure they do not damage or cross-contaminate the melons. They should be routinely inspected, cleaned and adjusted as needed.

5.2 Key aspects of hygiene control systems

5.2.2 Specific process steps

5.2.2.1 Post-harvest water use

Water is often used in dump tanks to transport melons from field containers into the packing or processing establishment. If the temperature of the water in the dump tank is cold and the internal temperature of the melons is hot from field heat, a temperature differential is created that may aid in the infiltration of microbial pathogens into the rind and/or the edible portion of the fruit. The following should be considered when using post-harvest water:

- Clean water should be used in dump tanks. Disinfectants may reduce, but will not eliminate microbial pathogens if present, as they are primarily used to disinfect the water.
- It is recommended that the time melons remain in dump tank water be minimized.
- Minimize or avoid fully submerging melons in colder dump tank water. When submerged, water is more likely to infiltrate into the melons.
- Where appropriate, the pH, soil (including organic) load, turbidity, water hardness, product throughput capacity should be controlled and monitored to ensure the efficacy of the antimicrobial treatment.
- Water temperatures should be higher than the internal temperatures of melons, so as to minimize the risk of water infiltration.

5.2.2.2 Chemical treatments

Fungicides may be applied to melons by use of an aqueous spray or immersion to extend the post-harvest life of the fruit. The following are recommended:

- Clean or preferably potable water should be used in water-based chemical treatments to ensure that the water used is of sufficient microbial quality for the intended use and does not contaminate the melons with foodborne pathogens.
- If hot water treatments are used as an alternative to post-harvest chemical fungicide treatments, it is recommended that the water temperature and time be evaluated and monitored to ensure that the water temperature and time is maintained and that antimicrobial agents are present in the water at sufficient levels for the temperature used.

5.2.2.3 Cooling melons

- Forced air cooling operations can avoid the risk of melon infiltration with cooling water, but also may spread product contamination if forced-air cooling equipment is not cleaned and disinfected regularly.
- Water that is used in hydro-coolers should be potable. Water that is used only once and not recirculated is preferable.
- If water is used for cooling and is recirculated, it should be evaluated and monitored to ensure that disinfectant levels are sufficient to reduce the potential risk of cross-contaminating melons.
- Cooling and cold storing melons as soon as possible after harvest is recommended to prevent multiplication of foodborne pathogens, if present, on or from the rind surface of melons.
- Cooling equipment should be cleaned and disinfected on a regular basis according to written procedures to ensure that the potential for cross-contamination is minimized.

5.2.2.5 Cutting, slicing and peeling melons

- Melons should be washed with potable water before cutting or peeling.
- Before cutting or other processing, a further reduction in microbial contamination may be achieved by scrubbing in the presence of a sanitizer or application of an alternative surface decontamination process such as hot water, steam or other treatments.
- Cutting or peeling knife blades should be cleaned and disinfected on a regular basis according to written procedures to reduce the potential for cross-contaminating melons during the cutting or peeling process.
- Knife blade disinfecting solutions should be monitored to ensure that the disinfectant is present at sufficient levels to achieve its intended purpose and does not promote the potential for cross-contamination.
- It is recommended that pre-cut melons should be wrapped/packaged and refrigerated as soon as possible and distributed under refrigeration temperatures (i.e., 4 °C or less).

5.2.3 Microbiological and other specifications

Microbiological testing can be a useful tool to evaluate and verify the effectiveness of safety and sanitation practices, provide information about an environment, a process, and even a specific product lot, when sampling plans and methodology are properly designed and performed. The intended use of information obtained (e.g., evaluating the effectiveness of a sanitation practice, evaluating the risk posed by a particular hazard, etc.) can aid in determining what micro-organisms are most appropriate to test for. Test methods should be selected that are validated for the intended use. Consideration should be given to ensure proper design of a microbiological testing program. Trend analysis of testing data should be undertaken to evaluate the effectiveness of food safety control systems.

5.2.4 Microbiological cross-contamination

- Where dry dump stations are used for unloading field containers (e.g., bins, gondolas, trailers, or wagons), melon contact surfaces (including padding materials to protect melons from physical damage) should be constructed of material that can be cleaned and disinfected.
- Where wet dump stations are used for unloading field containers, the containers should not be directly immersed into dump tanks, where they have been in direct contact with the soil, to reduce the potential for product cross-contamination with field or road debris.

5.3 Incoming material requirements

- Avoid using whole melons that have visible signs of decay or damaged rinds (e.g., mechanical damage or cracking) due to the increased risk for microbial contamination in melons.
- Damaged or decayed melons should be discarded in a manner that does not serve to attract pests.

5.7 Documentation and records

Where practicable, a written food safety control plan that includes a written description of each of the hazards identified in assessing environmental hygiene, as well as the steps that will be implemented to address each hazard, should be prepared by the business operating the primary production. The description should include, but is not limited to, the following: an evaluation of the production site, water and distribution system, manure use and composting procedures, personnel illness reporting policy, sanitation procedures and training programs.

The following are examples of the types of records that should be retained:

- Microbiological testing results and trend analyses
- Water monitoring and test results
- Employee training records
- Pest control records
- Cleaning and sanitation reports
- Equipment monitoring and maintenance records
- Inspection/audit records

5.8 Recall procedures

In the event of a foodborne illness outbreak associated with melons, maintaining appropriate records of production, processing, packaging and distribution may help to identify the source of contamination in the melon food chain and facilitate product recalls. Growers/packers/processors/distributors should consider developing and maintaining a traceability/product tracing system. The traceability/product tracing system should be designed and implemented according to the principles for *Traceability/Products Tracing as a Tool within a Food Inspection and Certification System* (CAC/GL 60-2006), especially to enable the withdrawal of the products, where necessary.

Detailed records should be kept that link each supplier of the product with the immediate subsequent recipient of the melons throughout the food chain. The information needed to link each supplier should include, if available, the packer name, address, and phone number, date packed, date released, type of melon (e.g., cantaloupe, watermelon, etc.) including brand name, lot identification and number of lots, and transporter.

SECTION 6 – ESTABLISHMENT: MAINTENANCE AND SANITATION

6.1 Maintenance and Cleaning

6.1.1 General

Food contact surfaces should be cleaned and disinfected before the start of the season and throughout the melon season to ensure microbial pathogens do not become established in the facility or on the equipment.

6.3 Pest control systems

Melons have a very high sugar content and are extremely attractive to flies and other insects that may cross-contaminate melons. It is recommended that an aggressive melon cull disposal and waste removal program be implemented to reduce the potential for insect-to-melon contamination.

SECTION 8 – TRANSPORTATION

Refer to the *Code of Practice for the Packaging and Transport of Fresh Fruits and Vegetables* (CAC/RCP 44-1995)

SECTION 9 – PRODUCT INFORMATION AND CONSUMER AWARENESS

9.4 Consumer education²

² “The WHO Five Keys to Safer Food” message and its supporting materials offer simple and clear guidance for food handlers including consumers on safe food handling (http://www.who.int/foodsafety/publications/consumer/en/5keys_en.pdf).

The following should be considered:

- All stakeholders – government, industry, consumer organizations and the media – should work together to communicate clear consistent messages on handling melons safely to avoid giving contradictory advice and causing confusion.

Consumer information on handling melons safely should cover:

- Avoiding the selection of melons with damaged rinds or rotten areas.
- Transporting to home. Increase in product temperature during transportation can be considerable. Time in transit for pre-cut melons between retail/market and the home should be kept as short as possible.
- Storage/ refrigeration of whole and pre-cut melons. Whole melons should preferably be stored in a cool environment. All prepackaged and pre-cut melons should be refrigerated as soon as possible.
- Once removed from the refrigerator, pre-cut fruit should be consumed as soon as possible.
- Washing and/or scrubbing whole melons, particularly the netted varieties, (i.e., cantaloupes) using potable running water and where appropriate, disinfectant solutions. Pre-cut products should not be rewashed.
- Correct hand washing methods³.
- Cross-contamination. Consumers need to handle, prepare, and store melons safely to avoid cross-contamination with pathogens from various sources (e.g., hands, sinks, cutting boards, utensils, raw meats).

SECTION 10 – TRAINING

10.2 Training programs

Personnel involved in primary production, packing, processing or transport operations of melons should receive training appropriate to their tasks and should be periodically assessed while performing their duties to ensure tasks are being completed correctly. Training should be delivered in a language and manner to facilitate understanding of what is expected of them and why, and should emphasize the importance of using hygienic practices. A well-designed training program considers the barriers to learning of the trainees and develops training methods and materials to overcome those barriers.

All agricultural workers should be trained in proper use of hygiene facilities. Training could include, for example, toilet use, proper disposal of toilet paper or equivalent, and proper hand washing and drying procedures.

The following training considerations should be addressed:

- Longstanding entrenched trainee behaviours, attitudes or personal beliefs
- Transient nature of workforce with no prior training in food safety and hygiene
- Concerns about children/infants who may accompany parents working in the production site with the potential for transfer of pathogens with a human reservoir
- Diverse cultural, social and traditional practices
- Literacy and education level
- Language and dialect of trainees
- Need to make food safety practices realistic and easy to implement (identify enabling factors, motivators and incentives)
- Raising awareness among trainees of the symptoms and signs of disease and encourage them to act upon it (taking personal responsibility for health)

³ WHO Guidelines on Hand Hygiene in Health Care.

Training programs should be repeated periodically, and updated whenever there is a change in the product, process or staff and monitored for effectiveness and modified when necessary.

Increased emphasis on training in cold chain logistics and management is recommended, in line with advancing knowledge and technologies for both refrigeration and temperature monitoring and expanding international trade.

Appendix V**PROPOSED REVISION OF THE RISK ANALYSIS PRINCIPLES AND PROCEDURES APPLIED BY THE CODEX COMMITTEE ON FOOD HYGIENE****(for adoption)****I. SCOPE**

1. This document addresses the respective applications of risk analysis principles and procedures by the Codex Committee on Food Hygiene (CCFH) as the risk management body and the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA) as the risk assessment body. This document should be read in conjunction with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* to which these principles are supplemental.

II. PRIORITIZATION OF PROPOSALS FOR NEW WORK

2. The Committee prioritizes its proposals for new work at each CCFH meeting, when appropriate. This is usually carried out by the Committee after consideration of the recommendations from an *ad hoc* Working Group. This *ad hoc* Working Group considers the priority of proposals for new work taking into account the current workload of the Committee, and in accordance with the “Criteria for the Establishment of Work Priorities” and if necessary, additional criteria to be prepared by the Committee. If CCFH resources are limited, proposals for new work or existing work may need to be delayed in order to advance higher priority work. A higher priority should be given to proposals for new work needed to control an urgent public health problem.

III. PRELIMINARY RISK MANAGEMENT ACTIVITIES

3. The CCFH arranges to develop a risk profile for bringing forward newly proposed work. The risk profile is a description of a food safety problem and its context that presents in a concise form, the current state of knowledge related to a food safety issue, describes potential microbiological risk management (MRM) options that have been identified by CCFH, if any, and the food safety policy context that will influence further possible actions. Scientific data may be commissioned from a range of sources so as to support a continuous science and risk based approach.

4. Members, who wish to make a request for inclusion of a new item in the priority list of future work of CCFH, should prepare a project document in accordance with Part 2-1 of the Elaboration Procedure (Codex Procedural Manual) and provide a preliminary risk profile, based on the template in Annex 1 of the *Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007)*. The proposals for new work should indicate the specific nature or outcome of the new work being proposed (e.g., new or revised code of hygienic practice, risk management guidance document). CCFH identifies the priority of all the new topics, submitted for its consideration, based on the *Criteria for the Establishment of Work Priorities (Codex Procedural Manual)*. The CCFH may also identify areas on which inputs from JEMRA are needed and make an appropriate request to JEMRA.

5. CCFH is responsible for developing the risk management questions to be addressed by JEMRA in its risk assessments and additionally has the responsibility for establishing the general risk assessment policy under which JEMRA will conduct its risk assessments for CCFH.

6. When referring pathogen-commodity combinations to JEMRA, the CCFH may also refer a range of MRM options, with a view to obtaining JEMRA’s guidance on the attendant risks and the likely risk reductions associated with each option.

IV. RISK ASSESSMENT

7. CCFH commissions JEMRA, through FAO/WHO, as the body primarily responsible for performing international risk assessments upon which CCFH and the Codex Alimentarius Commission (CAC) will base MRM options. For matters, which cannot be addressed by JEMRA, this document does not preclude the possible consideration of recommendations arising from other internationally recognized expert bodies, as approved by the Commission.

8. There are instances where progress on the work of the Committee will require an international risk assessment or other expert scientific advice.. When commissioning such work, the Committee should follow the structured approach given in the *Principles and Guidelines for the Conduct of Microbiological Risk*

Management (CAC/GL 63-2007) and the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*.

9. In seeking an international risk assessment to be conducted by FAO/WHO (e.g., through JEMRA), CCFH should consider and seek advice on whether:

- i. Sufficient scientific knowledge and data to conduct the needed risk assessment are available or obtainable in a timely manner. (An initial evaluation of available knowledge and data will typically be provided within the Risk Profile.)
- ii. There is a reasonable expectation that a risk assessment will provide results that can assist in reaching risk management recommendations related to control of the microbiological hazard without unduly delaying the adoption of the needed microbiological risk management guidance.
- iii. Risk assessments performed at the regional, national and multinational levels that can facilitate the conduct of an international risk assessment are available.

10. If the Committee decides to request that a microbiological risk assessment or other scientific advice be developed, the Committee will forward a specific request to FAO/WHO, the risk profile document, a clear statement of the purpose and scope of the work to be undertaken, any time constraints facing the Committee that could impact the work, and in the case of a risk assessment, the specific risk management questions to be addressed by the risk assessors. The Committee will, as appropriate, also provide FAO/WHO with information relating to the risk assessment policy for the specific risk assessment work to be undertaken. FAO/WHO will evaluate the request according to their criteria and subsequently inform the Committee of its decision on whether or not to carry out such work together with a scope of work to be undertaken. If FAO/WHO respond favourably, the Committee will encourage its members to submit their relevant scientific data. If a decision is made by FAO/WHO not to perform the requested risk assessment, FAO/WHO will inform the Committee of this fact and the reasons for not undertaking the work (e.g., lack of data, lack of financial resources).

11. FAO/WHO will ensure that the selection of experts and other procedures follow the principles and procedures in the *FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition* and in accordance with the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/GL 30-1999).

12. JEMRA should:

- strive to base its risk assessments, on relevant data from different parts of the world, including that from developing countries;
- identify and communicate to CCFH in its assessments any information on the applicability and any constraints of the risk assessment to the general population and to particular sub-populations and will, as far as possible, identify potential risks to populations of potentially enhanced vulnerability, e.g., infants, immuno-compromised population;
- communicate to CCFH the magnitude and source of uncertainties in its risk assessments. When communicating this information, JEMRA should provide CCFH with a description of the methodology and procedures by which JEMRA estimated any uncertainty in its risk assessment;
- communicate to CCFH the basis for all assumptions and the level of uncertainty in risk assessment outcomes as well as key factors contributing to uncertainty in its risk assessment.

13. The FAO/WHO will provide the results of the microbiological risk assessment(s) to the Committee in a format and fashion to be determined jointly by the Committee and FAO/WHO. As needed, the FAO/WHO will provide scientific expertise to the Committee, as feasible, to provide guidance on the appropriate interpretation of the risk assessment.

14. Microbiological risk assessments carried out by FAO/WHO (JEMRA) will operate under the framework contained in the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/RCP 30-1999).

V. RISK MANAGEMENT

15. Risk management options may include provisions contained in Codex standards, guidelines, codes of practice or related texts.

16. The MRM options recommended by the CCFH to the CAC should be based on the policies stated in the following paragraphs and shall take into account all relevant assumptions and uncertainties described by JEMRA.

17. Elaboration of 'Guidelines' or 'Codes of Hygienic Practices' could include Microbiological Criteria (MC) and/or provide enabling tools/procedures for countries to apply other MRM metrics (e.g., FSO, PO, PC), as outlined in Annex II of the MRM document (CAC/GL 63-2007), to address a food safety risk.

18. In cases where JEMRA has performed a risk assessment and CCFH or the CAC determines that additional scientific guidance is necessary, CCFH or CAC may make a specific request to JEMRA to provide further scientific guidance necessary for recommending on an appropriate MRM option.

19. CCFH decides, on a case-by-case basis, the need to elaborate 'Guidelines' or 'Codes of Hygienic Practices', and/or to establish an 'MC', or provide enabling tools/procedures for countries to apply other MRM metrics. In most cases, elaboration of a 'Guideline' or a 'Code of Hygienic Practices' is the preferred MRM option and should address food safety concerns in a diverse array of situations that prevail globally. It also provides the necessary flexibility to address/manage the risk to an acceptable level in the most efficient and appropriate manner. Also, for certain products that are intended for consumption by sensitive sub-populations (e.g., infant foods, foods specially meant for the elderly people, pregnant women, immunocompromised persons, etc.), it may be necessary for the CCFH to establish MCs and/or provide enabling tools/procedures for countries to apply other MRM metrics.

20. Where appropriate, other legitimate factors relevant to the health protection of consumers and for the promotion of fair practices in food trade, may also be considered by the CCFH, as described in the *Statement of Principles Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which Other Factors are Taken into Account* (Codex Procedural Manual). When establishing MRM options, CCFH shall clearly state when it applies any considerations based on other legitimate factors and specify its reasons for doing so.

21. Wherever possible, CCFH should consider establishing MCs for those pathogens – food combinations for which JEMRA is able to provide a quantitative microbiological risk assessment. Recommendations by CCFH should be based on the outcomes of the risk assessment taking into account differences in regional and national food consumption patterns and dietary exposure. The applicable guidance provided in the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997) shall be utilized by the CCFH for establishment of MCs.

22. Where MCs are established, methods of analysis and sampling plans shall be provided, including validated reference methods.

VI. RISK COMMUNICATION

23. In accordance with the *Working Principles of Risk Analysis for Application in the Framework of the Codex Alimentarius*, the CCFH, in co-operation with JEMRA, should ensure that the risk analysis process is fully transparent and thoroughly documented and that the results are made available to the members in a timely manner. The CCFH recognises that communication between risk assessors and risk managers is critical to the success of risk analysis activities. To this end, the CCFH and JEMRA should utilise the guidance on interaction provided in paras 24 through 29.

24. In order to ensure transparency of the risk assessment process in JEMRA, the CCFH may provide comments on the guidelines related to assessment procedures being drafted or published by JEMRA.

VII. INTERACTION BETWEEN RISK MANAGER (CCFH) AND RISK ASSESSOR (JEMRA)

25. The CCFH recognizes that an iterative process between risk managers and risk assessors is essential for adequate undertaking of any microbiological risk assessment and development of MRM options. In particular, a dialogue between the CCFH and JEMRA is desirable to thoroughly assess the feasibility of the risk assessment, to assure that the risk assessment policy is clear, and to ensure that the risk management questions posed by the CCFH are appropriate.

26. In certain instances when the subject matter would benefit from additional interaction with other Codex Committees, other FAO/WHO expert consultations and/or other specialized international scientific bodies, these should be included into the iterative process.

27. It is essential that communications between CCFH and JEMRA are timely and effective.

28. CCFH is likely to receive questions from JEMRA relating to the requested microbiological risk assessment(s). The questions may include those needed to clarify the scope and application of the risk assessment, the nature of the MRM options to be considered and key assumptions to be made regarding the risk assessment. Likewise, the CCFH may pose questions to JEMRA to clarify, expand, or adjust the risk assessment to better address the risk management questions posed or to develop the MRM options.

29. CCFH may recommend to the CAC to discontinue or modify work on an MRM option if the iterative process demonstrates that: (a) completion of an adequate risk assessment is not feasible; or (b) it is not possible to provide appropriate MRM options.

30. CCFH and JEMRA should ensure that their respective contributions to the risk analysis process result in outputs that are scientifically based, fully transparent, thoroughly documented and available in a timely manner to members.

Appendix VI**PROCESS BY WHICH THE CODEX COMMITTEE ON FOOD HYGIENE WILL UNDERTAKE ITS WORK****Purpose**

1. The following guidelines are established to assist the CCFH to:

- Identify, prioritize and efficiently carry out its work; and
- Interact with FAO/WHO and their scientific bodies as the need arises.

Scope

2. These guidelines apply to all work undertaken by the CCFH and encompass: guidelines and procedures for proposing new work; criteria and procedures for considering the priorities for proposed and existing work; procedures for implementing new work; and a process by which CCFH will obtain scientific advice from FAO/WHO.

Process for Considering Proposals for New Work

3. To facilitate the process of managing the work of the Committee, CCFH may establish an *ad hoc* Working Group for the Establishment of CCFH Work Priorities (“*ad hoc* Working Group”) at each Session, in accordance with the Guidelines on Physical Working Groups.

4. The Codex Committee on Food Hygiene will, normally, employ the following process for undertaking new work.

- i. A request for proposals for new work and/or revision of an existing standard will be issued in the form of a Codex Circular Letter, if required.
- ii. Proposals for new work received in response to the Codex Circular Letter will be transmitted to the Host of the *ad hoc* Working Group as well as the CCFH Host government and Codex Secretariats.
- iii. The Host of the *ad hoc* Working Group will collate the proposals for new work in a document that will be distributed by the Codex Secretariat to Codex members and observers for review and comment within a specified time frame.
- iv. The *ad hoc* Working Group will meet as decided by the Committee, normally on the day prior to the plenary session of CCFH to develop recommendations for consideration by the Committee during the CCFH session. The *ad hoc* Working Group will review the proposals for new work along with comments submitted. It will verify the completeness and compliance with the prioritization criteria of the proposals for new work and make recommendations to the Committee on whether the proposals for new work should be accepted, denied, or returned for additional information.
- v. If accepted, a recommendation will be provided on the priority of the proposal for new work compared to pre-established priorities. The priority of the proposals for new work will be established using the guidelines outlined below, taking into account the ‘Criteria for the Establishment of Work Priorities’¹. Proposals for new work of lower priority may be delayed if resources are limiting. Proposals for new work of lower priority not recommended may be reconsidered at the next CCFH session. If the *ad hoc* Working Group recommends that a proposal for new work be “denied” or “returned for revision,” a justification for this recommendation will be provided.
- vi. At the CCFH session, the *ad hoc* Working Group Chair will introduce the recommendations of the *ad hoc* Working Group to the Committee. The CCFH will decide whether a proposal for new work and/or revision of an existing standard is accepted, returned for revision, or denied. If accepted, a project document², which may include amendments agreed upon by the Committee, will be

¹ Codex Alimentarius Commission, *Procedural Manual*.

² The elements of a project document are described in the Codex Alimentarius Commission, *Procedural Manual*.

prepared by the CCFH and submitted to the Codex Alimentarius Commission (CAC) with a request for approval of the proposed new work.

Proposals for New Work

5. In addition to the provisions applying to proposals for new work in the Procedural Manual, the proposals for new work should include a Risk Profile³, as appropriate. The proposals for new work should indicate the specific nature or outcome of the new work being proposed (e.g., new or revised code of hygienic practice, risk management guidance document).

6. The proposals for new work will typically address a food hygiene issue of public health significance. It should describe in as much detail as possible, the scope and impact of the issue and the extent to which it impacts on international trade.

7. The proposal for new work may also:

- address an issue that affects progress within CCFH or by other committees, provided it is consistent with the mandate of CCFH;
- facilitate risk analysis activities; or
- establish or revise general principles or guidance. The need to revise existing CCFH texts may be to reflect current knowledge and/or improve consistency with the *General Principles of Food Hygiene* (CAC/RCP 1-1969).

Prioritization of Proposals for New Work

8. The Committee will prioritize its proposals for new work at each CCFH meeting, if required. This will be carried out by the Committee after consideration of the recommendations from the *ad hoc* Working Group. The *ad hoc* Working Group will consider the priority of proposals for new work taking into account the current workload of the Committee, and in accordance with the “Criteria for the Establishment of Work Priorities” and if necessary, additional criteria to be prepared by the Committee. If CCFH resources are limited, proposals for new work or existing work may need to be delayed in order to advance higher priority work. A higher priority should be given to proposals for new work needed to control an urgent public health problem.

Obtaining Scientific Advice

9. There are instances where progress on the work of the Committee will require an international risk assessment or other expert scientific advice. This advice will be typically be sought through FAO/WHO (e.g. through JEMRA, *ad hoc* expert consultations), though in certain instances such advice may be requested from other specialized international scientific bodies. When undertaking such work, the Committee should follow the structured approach given in the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007) and the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*⁴.

10. In seeking an international risk assessment to be conducted by FAO/WHO (e.g., through JEMRA), CCFH should consider and seek advice on whether:

- i. Sufficient scientific knowledge and data to conduct the needed risk assessment are available or obtainable in a timely manner. (An initial evaluation of available knowledge and data will typically be provided within the Risk Profile.)
- ii. There is a reasonable expectation that a risk assessment will provide results that can assist in reaching risk management decisions related to control of the microbiological hazard without unduly delaying the adoption of the needed microbiological risk management guidance.
- iii. Risk assessments performed at the regional, national and multinational levels that can facilitate the conduct of an international risk assessment are available.

³ Definition of a risk profile is “the description of the food safety problem and its context” (Codex Alimentarius Commission, *Procedural Manual*). The elements of a risk profile are provided in the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007).

⁴ Codex Alimentarius Commission, *Procedural Manual*.

11. If the Committee decides to request that a microbiological risk assessment or other scientific advice be developed, the Committee will forward a specific request to FAO/WHO, the risk profile document, a clear statement of the purpose and scope of the work to be undertaken, any time constraints facing the Committee that could impact the work, and the case of a risk assessment, the specific risk management questions to be addressed by the risk assessors. The Committee will, as appropriate, also provide FAO/WHO with information relating to the risk assessment policy for the specific risk assessment work to be undertaken. FAO/WHO will evaluate the request according to their criteria and subsequently inform the Committee of its decision on whether or not to carry out such work together with a scope of work to be undertaken. If FAO/WHO respond favourably, the Committee will encourage its members to submit their relevant scientific data. If a decision is made by FAO/WHO not to perform the requested risk assessment, FAO/WHO will inform the Committee of this fact and the reasons for not undertaking the work (e.g., lack of data, lack of financial resources).

12. The Committee recognizes that an iterative process between risk managers and risk assessors is essential throughout the process described above and for the adequate undertaking of any microbiological risk assessment and the development of any microbiological risk management guidance document or other CCFH document(s).

13. The FAO/WHO will provide the results of the microbiological risk assessment(s) to the Committee in a format and fashion to be determined jointly by the Committee and FAO/WHO. As needed, the FAO/WHO will provide scientific expertise to the Committee, as feasible, to provide guidance on the appropriate interpretation of the risk assessment.

14. Microbiological risk assessments carried out by FAO/WHO (JEMRA) will operate under the framework contained in the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/RCP 30-1999).

Appendix VII**PROJECT DOCUMENT****REVISION TO THE CODE OF HYGIENIC PRACTICE FOR SPICES AND DRIED AROMATIC PLANTS (CAC/RCP 42-1995)****1. The purposes and scope of the Standard**

The purpose and scope of the work is to revise and update the existing *Code of Hygienic Practice for Spices and Dried Aromatic Plants* (CAC/RCP 42-1995).

2. Its relevance and timeliness

Review of the literature reveals that a number of pathogens can be found in spices at retail, but only *Salmonella* spp. and *Bacillus* spp. (*subtilis* and *pumilis*) have been reported to be associated with foodborne outbreaks attributed to spice consumption.¹⁻¹⁵ During the period 1973-2009, 12 spice-attributed outbreaks were identified internationally, despite the challenges associated with tracing an outbreak to a complex food minor ingredient. These outbreaks resulted in at least 1,688 documented human illnesses, 127 hospitalizations and one death.¹⁻¹⁵ The actual health burden from these outbreaks was likely much larger: the U.S. Centers for Disease Control and Prevention estimate that there are 28 undiagnosed cases of salmonellosis for every documented case.¹⁶ Infants and children were the primary population impacted by 33 percent of the spice-attributed outbreaks, including the largest (~1000 illnesses) outbreak.^{5,6,8,11} *Salmonella* spp. were identified as the etiologic agent in 83 percent of the outbreaks, including all large-scale outbreaks.²⁻¹⁵ *Bacillus* spp. were identified in two small outbreaks.^{1,4,9} Multiple strains of *Salmonella* spp. or *Bacillus* spp. were found in the spices/spice-containing foods associated with four of the outbreaks.^{1,4,8,9,11} While pathogen growth in the food may have played a role in some of the outbreaks, it was not likely a contributing factor in three of the largest outbreaks, which involved low-moisture foods.^{2,8,11} Traceback investigations of the two most recent outbreaks of salmonellosis found the outbreak strain(s) in both the imported spice packs and in the spice/food processing environment (spice grinding and packaging and food manufacturing, respectively).^{2,17,18}

Several additional factors influence the number of illnesses arising from pathogen-containing spices. Use of spices in foods is increasing world wide.¹⁹ For example, spice per capita consumption in the United States, as measured by disappearance data, averaged 3.5 lbs/year in 2008 and has been increasing annually at an average rate of 0.05 lbs/person/year for 40 years.²⁰ Spices may be added to foods after the final lethality step in food preparation.^{2,8,11} Spice lots can be very large, so that a single contaminated lot could serve millions to tens of millions of consumers.²¹ Finally, for *Salmonella*-contaminated spices, the dose required to cause illness is small, with a probability of illness of approximately 0.25% for consumption of just one *Salmonella* cell, based on the 2002 FAO/WHO dose-response function.²²

3. The main aspects to be covered

The proposed revision would provide consistency with the *General Principles of Food Hygiene* (CAC/RCP 1-1969). Material will be moved to appropriate sections consistent with those in the *General Principles of Food Hygiene*, and material that repeats recommendations in the *General Principles* will be deleted. Sections will be added; e.g., Objectives and Control of Operation. The revision will incorporate the current thinking and industry guidance for preventive controls; e.g., control of raw material sourcing, application of process treatments to eliminate microbial hazards, validation of process treatments, physical separation of the processing facility into pre- and post-treatment or finished product areas, restriction of wet cleaning to appropriate areas, control of water in the environment, and regular product and environmental sampling. The working group would address whether certain spices present unique situations that warrant an annex with commodity-specific guidelines and whether an annex on specifications, including microbiological criteria, is needed.

4. An assessment against the *Criteria for the Establishment of Work Priorities*

4.1 Assessment with respect to the General Criterion: Consumer protection from the view of health, food safety, ensuring fair practices in food trade and taking into account the identified needs of developing countries.

The proposed work is directed primarily at control of microbial hazards such as *Salmonella* spp., which are common public health problems world-wide. However, the hygienic production of spices also covers chemical contaminants, such as aflatoxin, and filth, indicative of production under unsanitary conditions. These are common issues resulting in rejection of spices by countries and by food business operators. This revision will provide useful guidance, in particular to developing countries, on the hygienic production of spices to help minimize contamination and the resulting rejection of spice shipments. Spices are part of the basic diet worldwide and, therefore, widely traded with many spices originating from developing countries.

4.2 Assessment with respect to criteria applicable to general subjects:

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

Data on the millions of tons of spices produced each year, along with the countries that import and export them, can be obtained through FAOSTAT. The United States is one of the largest importers of spices, in both volume and value basis, with imports coming from more than 140 countries.²³ Analysis of 2007-2009 U.S. Food and Drug Administration (U.S. FDA) import surveillance data indicates that *Salmonella* violation rates for spices are approximately twice the rate for all other foods (including raw and ready-to-eat foods).²¹ Violation rates are not strongly associated with spice type or country of origin, although a few spices and source countries do have statistically larger or smaller violation rates than the rest.²¹ A small study of spices found positive for *Salmonella* at U.S. import revealed that levels are generally low (≤ 1 MPN/g) but not significantly different from the few values reported in the literature for spice/spice-containing products associated with outbreaks.^{3,6,8,21} More research is needed to fully describe the distribution of *Salmonella* levels in spices throughout the farm-to-table continuum. This study also demonstrated that the presence of multiple strains of *Salmonella* in *Salmonella*-positive spice is not uncommon.²¹

Analysis of U.S. foodborne outbreaks, food recall events, and primary reports to the Reportable Food Registry (RFR—an electronic registry in the United States where industry or public health officials report foods that have a reasonable probability of causing serious adverse health effects or death) demonstrates that *Salmonella*-contaminated spices are found in processing and retail settings.²⁴ The “Spices & Seasonings” food category in the RFR had the largest number of *Salmonella* primary reports (19 percent) in the first year of reporting.²⁴ During 2008-2009, eight primary recalls (recalls from the firm where the violation was first identified) were associated with spices, including 116 different products (or 19 percent of all food products recalled).²¹ Poor supplier control was determined to be a root cause of all of the spice-associated recalls investigated.²¹

Spices may be sourced from jurisdictions that lack sound regulatory frameworks for food safety and that have limited monitoring and enforcement, even when there are applicable laws or regulations. By providing guidance that can be applied by all countries, this document will decrease the potential for impediments to international trade and enhance global food safety.

Consideration of the global magnitude of the problem or issue

There is potential for contamination of spices from multiple sources during growing, harvesting, processing, and transporting. Spices are widely traded throughout the world. Spices are in large part sourced from developing countries. Most countries in the world import at least some spices. Thus the issue of contaminated spices is global and should be addressed by a code of hygienic practice that incorporates current science- and risk-based information about appropriate control measures.

5. Relevance to the Codex Strategic Objectives

The proposed work directly relates to the following Codex Strategic Goals from the 2008-2013 strategic plan:

Goal 1: Promoting sound regulatory frameworks

The development of a revised code of hygienic practice for spices is consistent with the direction elaborated under Goal 1; i.e., CAC will develop international standards, guidance and recommendations based on scientific principles for the reduction of health risks along the entire food chain. The public health risk from pathogens such as *Salmonella* in spices warrants enhancing the current code of hygienic practice for spices to better reflect the current scientific information to address this hazard at multiple points in the food chain. These guidelines can provide important information for developing countries seeking to achieve higher levels of food safety.

Goal 2: Promoting widest and consistent application of scientific principles and risk analysis

There has been a recent focus in a number of countries on controlling *Salmonella* in low-moisture foods such as spices. Several recent guidance documents have been developed based on industry experience and the application of scientific principles. The U.S. FDA is in the process of completing a risk profile on spices to inform decision-making on appropriate preventive controls to reduce the risk from microbial pathogens.²⁵ Incorporating the most current scientific knowledge into a revised code of hygienic practice for spices is consistent with this goal. In addition, Codex promotes validation of food safety control measures, which would be a feature of the enhanced code of hygienic practice for spices.

Goal 5: Maximum and effective participation of members

The development of a revised code of hygienic practice for spices should generate interest in participation from developing countries, which are the primary source for many spices. We anticipate conducting this revision through an electronic working group using email exchanges and web meetings designed to foster increased participation, as occurred with the development of the leafy greens annex to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003).

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

This work is a revision of the existing *Code of Hygienic Practice for Spices and Dried Aromatic Plants* (CAC/RCP 42-1995) to ensure consistency with the *General Principles for Food Hygiene* (CAC/RCP 1-1969). The *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 30-1999) may be applicable, depending on the approach agreed to by the working group on the need for such criteria. Additionally, guidance in the *Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food* (CAC/RCP 47-2001) may also be applicable.

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

We anticipate there may be need for scientific advice from FAO/WHO (JEMRA) on the pathogen-specific hazards associated with various types of spices and the role of various agricultural and manufacturing practices in enhancing or mitigating these hazards. Such an evaluation should also take into consideration how these products are marketed and handled by consumers and the impact of this on foodborne illnesses. Specifically, JEMRA could conduct a feasibility study to determine if sufficient data are available or collected on the prevalence and level of pathogens, the potential for growth before or in the absence of a lethality treatment step, and the potential for recontamination after a lethality treatment for different spices for the purpose of conducting a quantitative risk assessment.

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

In addition to scientific advice and technical input from JEMRA, technical input may be needed from the International Commission on Microbiological Specifications for Foods, in particular assistance on the development of microbiological criteria if the working group decides that the development of microbiological criteria is appropriate.

9. The proposed time-line 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

Proposed timeline-

- Consideration for new work by 43rd Session, 2011
- Consideration for new work by CAC, 2012
- Development of document by an electronic working group
 - o Step 3 at 2012 and 2013 Sessions of CCFH,
 - o Step 5 (or 5/8) at 2014 Session of CCFH
 - o Ready for adoption at Step 5 or Step 5/8 by CAC at the 2015 Session or adoption at Step 8 at the 2016 Session of the CAC.

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Appendix VIII**PROJECT DOCUMENT****ELABORATION OF A COMMODITY-SPECIFIC ANNEX TO THE CODE OF HYGIENIC PRACTICE FOR FRESH FRUITS AND VEGETABLES (CAC/RCP 53-2003)****ANNEX ON BERRIES****Background**

The 61st Session Executive Committee agreed on the prioritization of products made and the 31st Session of the Session of the Codex Alimentarius Commission, approved the proposal to prepare Commodity-Specific Annexes to the Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003), taking into account impacts on health, trade and other relevant factors including environmental issues and the decision; starting with leafy green vegetables (concluded in 2009) and continued with an annex on melons. According to the rank on the list of priorities (outcome of FAO's Expert meeting)¹ of the fresh fruits and vegetables of concern and the associated hazards, Berries, Tomatoes and green onions have been considered priority products to prepare Commodity-Specific Annexes.

Berries production worldwide is expressive as reckoned in FAOStat Production Crops values (2009), including blueberries (311,959 ton), cranberries (409,707 ton), raspberries (486,889 ton) and strawberries (4,178,152 ton). These fruits have a crescent relevance for the international trade as a result increasing consumption of fresh produce and globalization (changes/optimization of production and distribution) as pointed out by Linch (2009)², with increasing awareness of the problem on the part of public health officials.

Berries are currently associated with foodborne diseases within the broadest range of different etiological agents, from virus (hepatitis, norovirus)¹, to bacteria (*E.coli* O26, O157:H7)^{3,4} and protozoa (*Trypanosoma cruzi*, *Cyclospora*)⁵.

Since 2006 until 2009, there have been at least 5 outbreaks (36 cases) in which berries were confirmed or suspected (USA). FAO's Expert meeting¹ also reported berries as a vehicle for foodborne illness in France, Sweden, Finland and New Zealand. The outbreaks were mainly related to virus, but *E.coli* (O26) is also related. A recent outbreak (2011) by *E.coli* O157:H7 indicated contamination of strawberries distributed on roadside stands and farmers' marketstands. The berries related with the notified outbreaks in the US were the blueberries, strawberries, blackberries, raspberries and açai berries.

In 2006, a total of 178 cases of acute Chagas disease were reported from the Amazonian state of Pará, Brazil. Eleven occurred in Barcarena and were confirmed by visualization of parasites on blood smears. Using cohort and case-control studies, the implicated oral transmission by consumption of açai berries fruits was evidenced (Nóbrega et al, 2009).

1. The purposes and scope of the Standard

The proposed Annex would address safety matters specific to berries in line with the Codex's aim to protect consumers' health and to ensure fair trade practices, providing advice to governments on the application of food hygiene provisions.

The necessary supplementary requirements of berries to the General Principles relies on the necessity to provide a common reference for these fruits that shares the same characteristic of being small and highly

¹ Report - Microbiological hazards in fresh fruits and vegetables of reference for an FAO/WHO Expert Consultation to support the development of commodity-specific annexes for the Codex Alimentarius.

² The growing burden of foodborne outbreaks due to contaminated fresh produce: risks and opportunities. *Epidemiol. Infect.* (2009), 137, 307–315.

³ Non-O157 Shiga toxin-producing *E. coli* (STEC) outbreaks, United States. CDC Foodborne Outbreak Online Database (2006)

⁴ Fresh Strawberries From Washington County Farm Implicated In *E. coli* O157 Outbreak In NW Oregon. At <http://oregon.gov/ODA/FSD/strawberries.shtml> (2011)

⁵ Oral Transmission of Chagas Disease by Consumption of Açai Palm Fruit, Brazil. *Emerg Infect Dis.* (2009) April; 15(4): 653–655.

dependent on manipulation during production, harvesting and processing amid the broad range of etiological agents and diversity in nature.

The annex on Berries to the Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003) is envisioned to encompass an annex on berries (e.g. strawberries, raspberries, cranberries, blueberries, blackberries and açai berries), to address epidemiological evidences that suggests they are of primary public health concern^{1,2}.

2. Its relevance and timeliness

The revision is proposed within the framework of the ongoing work of the Codex Committee on Food Hygiene on the development of Commodity-Specific Annexes to the Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003), which countries will be able to use to develop their own risk management strategies for the control of microbial hazards. This may assist in providing a harmonized approach for this product internationally. This is also in compliance with the recommendation of the Codex Alimentarius Commission to move towards simpler, horizontal, and inclusive standards, when possible, in order to facilitate their application by governments.

3. The main aspects to be covered

The proposed annex will mainly provide additional recommendations onto those safety provisions of the main Code that need to be detailed/specified along the berries production chain in view of current primary production, processing and trade practices as well as new developments in science and technology. The annex will also highlight those safety matters that are essential for the safety of the full range of berries in order to align them with the main Code. In addition, the annex will attempt to simplify provisions that have already been addressed by the main Code and may provide the essentials to improve safety of the product.

4. An assessment against the *Criteria for the Establishment of Work Priorities*

The following criteria were found relevant for the proposed Annex on Berries to the Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003):

4.1 *Volume of production and consumption in individual countries and volume and pattern of trade between countries including international and regional market potential*

Worldwide trade in 2009 under FAOStat⁶, “Export quantity” for Cranberries (99,729 ton), raspberries (57,505 ton), Strawberries (712,171 ton) and Açai berries (not available).

Aside the low quantity values the value of global trade in 2009 (FAOStat) is significant as for Strawberries (US\$ 1,764,457,000), with Spain, USA and Egypt as the main exporters; Blueberries (US\$ 286,657,000) with USA, Canada and Poland as the main exporters, Cranberries (US\$ 292,553,000) with Canada, Chile and USA as the main exporters; Raspberries (US\$ 242,020,000) with Poland, Spain and Serbia as the main exporters; and Açai berries (US\$ 10,000,000) Brazil.

Berries are produced and traded worldwide and in recent years exports and imports have been booming.

Data from MDIC⁷ (Brazilian Ministry of Commerce) reports Berries imports as a booming commodity with increases of imported strawberries (8,000 ton in 2009 up to 140,541 ton in 2011); and Raspberries (10,000 ton in 2009 up to 35,262 ton in 2011).

4.2. *Coverage of the main consumer protection and trade issues by existing or proposed general standards*

Specific provisions, in particular safety provisions such as primary production and environmental hygiene, handling, storage and transport, cleaning, maintenance and sanitation, as well as processing of berries, have been also identified as important to address epidemiological issues as stated on the outcome of FAO’s Expert meeting¹ (see also Section 3).

4.3 *Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body*

None identified.

5. Relevance to the Codex Strategic Objectives

⁶ FAOStat can be accessed at: <http://faostat.fao.org>

⁷ MDIC data can be accessed at: <http://aliceweb.desenvolvimento.gov.br>

The proposed annex meets the criteria outlined in,

Goal 1 – Promoting sound regulatory frameworks of the Strategic Plan 2008-2013 of the Codex Alimentarius Commission. In particular, *Goal 1.1 - Review and develop Codex standards and related texts for food safety* taking into account the scientific and technological developments, to ensure that they: emphasize a horizontal approach; employ an approach to food safety that is based on risk and that addresses the entire food chain. In addition, this new annex is consistent with the need to provide additional recommendations on those safety provisions of the main Code that need to be detailed/specified along the berries production chain in view of current primary production, processing and trade practices as well as new developments in science and technology as pointed out on the outcome of FAO's Expert meeting¹. The results of this work will assist in promoting sound national food control infrastructure and promote the safety of foods entering domestic and international trade by expanding Good Agricultural Practices and Good Manufacturing Practices to help control microbial hazards on berries. This may in turn facilitate trade and market access, besides improvement of safety of berries at national and international level.

Goal 2: Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis

This work will establish sound working principles for the analysis and identification of microbial hazards associated with the production of berries. By understanding the relative risk of various practices, the most effective mitigation strategies can be implemented to ensure the greatest public health benefit.

Goal 4: Enhance Capacity to Respond Effectively and Expeditiously to New Issues, Concerns and Developments in the Food Sector

By taking on this work and expanding its expertise with specific commodities, Codex will enhance its capacity and will be able to respond more quickly and effectively to commodity-specific safety issues.

Goal 5: Promoting Maximum Membership and Participation

By developing commodity-specific annexes to the Code, there is an opportunity for the CAC to reach out to member countries that may have an interest in a particular commodity for participation where they might not typically be involved.

Goal 6: Promoting Maximum Application of Codex Standards

Developing an annex to the Code which incorporates commodity-specific recommendations and the most up-to-date science currently available will make the document more relevant to potential users, thus expanding the application of these Codex standards.

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

The proposed work would directly modify the Code of Hygienic Practice for Fresh Fruits and Vegetables through the addition of a commodity-specific annex.

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

Assistance from the FAO/WHO Joint Expert Committee on Microbiological Risk Assessment may be needed.

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

None identified.

9. The proposed time-line 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

A five-year timeline is proposed for the completion of the annex for berries. A proposed draft annex would be ready for initial discussion by CCFH in 2012, with a proposed date for adoption at Step 5 in 2014 and adoption by the CAC in 2016.