

C O D E X A L I M E N T A R I U S C O M M I S S I O N



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



**World Health
Organization**

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REP 11/FH

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

C O D E X A L I M E N T A R I U S C O M M I S S I O N

Thirty-fourth Session

Geneva, Switzerland, 4 - 9 July 2011

REPORT OF THE FORTY-SECOND SESSION OF THE

C O D E X C O M M I T T E E O N F O O D H Y G I E N E

Kampala, Uganda, 29 November – 3 December 2010

NOTE: *This report includes Codex Circular Letter CL 2010/57-FH*

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of
the United Nations



World Health
Organization

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CX 4/20.2

CL 2010/57-FH

TO: Codex Contact Points
Interested International Organizations

FROM: 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-second Session of the Codex Committee on Food Hygiene (REP11/FH)

The report of the Forty-second Session of the Codex Committee on Food Hygiene (CCFH) is attached. It will be considered by the Thirty-fourth Session of the Codex Alimentarius Commission, (Geneva, Switzerland, 4 – 9 July 2011).

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 for the Control of *Campylobacter* and *Salmonella* spp. in Chicken Meat (REP11/FH para.63 and Appendix III); and
2. Proposed Draft Revision of the Recommended International Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters (REP11/FH para. 116 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 2011.**

REQUEST FOR COMMENTS

Proposed Draft Standards and Related Texts at Step 3 of the Procedure

3. Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food (REP 11/FH para. 86 and Appendix IV).

Governments wishing to submit comments should do so in writing to: Dr Enne de Boer, email: enne.de.boer@vwa.nl or fax: +31 575 588200 with a copy to the Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme: codex@fao.org or fax: +39 06 570.54 593 **before 31 March 2011.**

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SUMMARY AND CONCLUSIONS

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

MATTERS FOR ADOPTION BY THE 34TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION:

The Committee agreed to forward for adoption at Step 5/8:

- Proposed Draft Guidelines for the Control of *Campylobacter* and *Salmonella* spp. in Chicken Meat (para 63 and Appendix III); and
- Proposed Draft Revision of the Recommended International Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters for adoption at Step 5/8 (para. 116 and Appendix V).

MATTERS FOR ACTION BY THE COMMISSION

- The Committee agreed to request the removal of section 4.4 of the *Standard for Natural Mineral Waters* (CODEX STAN 108-1981) as a consequence to the decision to include microbiological criteria in the Proposed Draft Revision of the Recommended International Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters (CAC/RCP 33-1985) (para. 115).

NEW WORK

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

- Guidelines for Control of Specific Zoonotic Parasites in Meat: *Trichinella spiralis* and *Cysticercus bovis* (REP11/FH, paras 137 and Appendix VI); and
- Annex on melons to the Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003) (REP11/FH, paras 142 and Appendix VII).

MATTERS OF INTEREST TO THE COMMISSION AND/OR TO FAO/WHO

The Committee agreed to:

- return the Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food to Step 3 for comments and further consideration at its next session (para. 86 and Appendix IV).
- return the Proposed Draft Revision of the Principles for the Establishment and Application of Microbiological Criteria for Foods to Step 2 for redrafting, circulation for comments at Step 3 and consideration at its next session (para. 127).
- agreed to request FAO/WHO to:
 - (i) review the status of knowledge on parasites in food and their public health and trade impact; and
 - (ii) issue a call for data and to evaluate the pathogen specific hazards associated with various types of melons and the role of various agricultural and manufacturing practices in enhancing or mitigating these hazards in melons (para. 144)

MATTERS OF INTEREST TO OTHER COMMITTEES

Committee on General Principles

The Committee agreed to review its 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 recommendation in CL 2010/1-GP) and did not discuss the amendment of the definition for hazard following the decision of the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) not to amend the definition (paras 6- 7).

Committee on Fish and Fishery Products

The Committee endorsed the hygiene provisions Draft Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish with amendments and the hygiene provisions of the Draft Standard for Fish Sauce without amendment (paras 9 - 10 and Appendix II)

INTRODUCTION

1. The Codex Committee on Food Hygiene (CCFH) held its Forty-second session in Kampala, Uganda from 29 November to 3 December 2010, at the kind invitation of the Governments of the United States of America and Uganda. Dr Emilio Esteban, of the United States of America, chaired the Session and Dr Friday Agaba, of Uganda, served as co-Chair. The Session was attended by 230 delegates representing 75 member countries, one member organization and 11 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 the His Excellency the President of the Republic of Uganda, represented by His Excellency the Vice President Professor Gilbert Bukenya. The Committee was also addressed by Mr Jerry Lanier, the Ambassador of the United States of America to Uganda, Dr Karen Hulebak, the Chairperson of the Codex Alimentarius Commission, the Honourable Dr Richard Nduhuura, Minister of State for Health of Uganda, Dr Ben Manyindo, Vice Chairperson of the Codex Alimentarius Commission and Ms Karen Stuck, US Codex Manager. All speakers reiterated the importance of the work of the Committee in meeting the dual mandate of Codex to protect the health of consumers and to ensure fair practices in the food trade. It was noted that a number of items on the Agenda of the Committee were of significance to Uganda and the African region, in particular, the work on natural mineral waters and the control of *Campylobacter* and *Salmonella* species in chicken meat.

Division of Competence

3. 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

4. The Committee adopted the Provisional Agenda as its Agenda for the session and agreed to discuss Item 6, Proposed Draft Revision of the *Recommended International Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Minerals* before Item 5, the Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses.

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

5. The Committee noted the information presented in CX/FH 10/42/2 and the update on the work of the *ad hoc* Task Force on Antimicrobial Resistance and made the following comments and/or decisions as follows:

Codex Committee on General Principles (CCGP)

Working Principles for Risk Analysis

6. The Committee agreed to review its 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. The Delegation of the European Union was requested to prepare a proposal in this regard for consideration by the next session of the Committee.

Definition of Hazard

7. The Committee considered the request from Committee on General Principles (CCGP) on the proposal to amend the Codex definition for hazard. Noting that the proposal was in relation to nutrient risk assessment and the decision of the 32nd session of the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) not to amend the definition, the Committee agreed that further discussion on this matter was no longer necessary.

¹ CX/FH 10/42/1; CRD 1 (Division of competence between the European Union and its Member States, prepared by the European Union);

² CX/FH 10/42/2; CRD 7 (comments of Canada); CRD 8 (comments of Nigeria); CRD 9 (comments of the European Union); CRD 23 (Report of the in-session Working Group on endorsement); CRD 19 (comments of Japan); CRD 21 (comments of Egypt).

Endorsement of hygiene provisions from the Committee on Fish and Fishery Products (CCFFP)

8. In accordance with its terms of reference, the CCFH considered the endorsement of hygiene provisions in the Draft Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish and in the Draft Standard for Fish Sauce. In view of the considerable comments received, the Committee agreed to convene an in-session working group, led by Japan, to consider this endorsement.

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

9. The Committee considered the report of the in-session working group (CRD 23) and agreed to endorse the hygiene provisions in the Draft Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish with amendments (*see* Appendix II). The amendments were to better reflect relevant published information and to provide more precise text from a scientific and technical point of view. Since temperature abuse has a direct impact on the safety and shelf-life of products, a new paragraph was added prior to the Table to explain that time/temperature integrators could be a useful tool to determine if the product had been temperature abused and deleted any particular reference to time/temperature integrators in the Table. The last row of the Table in Annex 2 was deleted because the use of the temperature range stipulated was an example of mild temperature abuse and was not appropriate.

Draft Standard for Fish Sauce

10. The Committee endorsed the hygiene provisions without amendments.

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

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

11. 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.

12. Referring to the request of the 40th session of the Committee to develop “a decision-support tool for the control of *Campylobacter* and *Salmonella* in chicken meat”, the Representative indicated that the work on this web-based tool was now almost complete. The feedback on the “decision support tool” received during the last session of the Committee was acknowledged and that, together with the output of an expert peer review process, had been used as a basis for its revision and finalization. Details of the tool and its functionality were provided during a lunchtime demonstration and the Representative indicated that FAO and WHO were interested in hearing from delegations who would like to pilot test the tool and/or contribute to the development of case studies on its application. The Committee was also informed that future work in this area included the development of a database on control measures to support application of this tool.

13. Secondly, the Representative reported on the development of a “web-based tool to assess the performance of microbiological sampling plans”. This tool was being developed to assist FAO and WHO member countries to address issues related to sampling and has been subject to expert peer review to facilitate its finalisation. FAO and WHO are currently seeking expressions of interest from delegations with regard to the development of case studies and pilot testing of this tool.

14. Given the relevance of the FAO/WHO Expert Meeting on the Benefits and Risks of the Use of Chlorine-Containing Disinfectants in Food Production and Food Processing to Item 4, the Representative provided a summary of the outcome of that meeting and highlighted the overall conclusion that the identified residues of chlorine containing disinfectants and disinfection by-products did not raise health concerns based on estimated dietary exposures. Reference was also made to the activities of both organizations relevant to the control of *Salmonella* and *Campylobacter* in certain countries in East Africa.

15. Following the request of the 41st session of the Committee to address a number of issues relating to predictive risk models and testing methodology for *Vibrio parahaemolyticus* and *Vibrio vulnificus* in seafoods, it was noted that JEMRA had implemented an Expert Meeting to address these issues in September 2010. Direct replies to the requests of the Committee were provided in CX/FH 10/42/3 and the Representative highlighted the need for further guidance from the Committee on the next steps to be taken.

³ CX/FH 10/42/3, CRD 3 (comments of Kenya); CRD 6 (comments of Japan); CRD 9 (comments of the European Union); CRD 21 (comments of Egypt).

16. Finally, the Representative noted that this year JEMRA was celebrating its 10th anniversary and took the opportunity to express extensive appreciation of FAO and WHO to all the experts, data providers and donors who had contributed to JEMRA. It was noted that it was their contributions, which made the work of JEMRA possible.

17. The Chairperson expressed appreciation to FAO and WHO for the provision of extensive and high quality scientific advice in a timely manner, which greatly facilitated the work of the Committee over the past 10 years. This sentiment was echoed by the Committee.

18. Specific appreciation was expressed by several Delegations for the work undertaken on the development of the two web-based tools noting that these tools facilitated a more risk-based approach to the management of *Campylobacter* and *Salmonella* in chicken meat as well as in the application of sampling plans. In addition, the development of a database to support the application of the “decision support tool for the control of *Campylobacter* and *Salmonella* in chicken meat” was considered by several Delegations to be an important and necessary step, and FAO/WHO were encouraged to proceed with this work.

19. A number of Delegations highlighted the importance of the work of JEMRA for developing countries and welcomed recent FAO/WHO initiatives to stimulate data collection and encourage the application of risk-based approaches in these countries. FAO/WHO were requested to consider extending initiatives such as those underway in East Africa to other countries, regions (e.g. West Africa) and commodities (e.g. fish). While noting their appreciation for FAO and WHO capacity development activities several Delegations highlighted the need for ongoing support.

20. With regard to the future work on *Vibrio* spp. in seafood, the Delegation of Japan highlighted the importance of continuing with this work but considered that the next step should focus on methodology and data collection. This approach was supported by several other Delegations. In noting these recommendations, the Representative of FAO stated that there was potential to use existing frameworks such as those provided by the Global Foodborne Infections Network (GFN)⁴ to facilitate this work. However, this would be a resource intensive activity, which would require support and resources from member countries as well as FAO and WHO, particularly those countries with a high level of expertise in this area. In addition, it was noted that some of the proposed aspects such as method validation were outside the remit of FAO and WHO and so could not be addressed as proposed. In light of these discussions, the Committee recommended that FAO and WHO continue with this work in the following manner:

- Step 1: Provide recommendations on a range of test methods for quantifying *V. parahaemolyticus* (total and pathogenic (e.g. tdh+, trh+)) and *V. vulnificus* in seawater and bivalves and facilitate performance evaluation of the proposed methodologies;
- Step 2: Develop data collection strategies (that would facilitate the collection of data) by countries to support the modification/development of models with a broader scope than those which currently exist;
- Step 3: Encourage the collection of data in different regions, in different bivalve species and for geographically diverse strains of pathogenic *V. parahaemolyticus* and *V. vulnificus* according to the data collection strategy and using recommended test methods; and
- Step 4: To modify/develop risk assessment models that could be used to address a range of risk management questions in a number of different regions and products, when adequate data becomes available.

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

21. In addition to information provided in CX/FH 10/42/3-Add.1, the Observer from OIE informed the Committee of ongoing work on zoonotic parasites, in particular the *ad hoc* Group on zoonotic parasites. This Group had updated the current OIE *Terrestrial Animal Health Code* Chapter 8.13 on trichinellosis to put more emphasis on achieving control of the infestation and preventing foodborne illness in humans by implementation of control measures at the farm level. The Observer also noted that advice on *Cysticercus bovis* would be prepared and published in the form of OIE recommendations or as part of a general chapter on biosecurity procedures in livestock farming, for inclusion in the Veterinary Public Health section of the OIE *Terrestrial Animal Health Code*.

⁴ For more information see www.who.int/gfn/en/

22. The Observer informed the Committee that the OIE considered that any future work of Codex on trichinellosis should take into account the work of OIE and that it would continue to give support and cooperation to such work to ensure that control measures are applied consistently throughout the farm-to-fork continuum.

23. The Delegation of the European Union welcomed the close cooperation established between Codex and the OIE and noted that the opportunity for continued cooperation between the Codex and OIE on the question of zoonotic parasites in meat, if the proposal for new work to be discussed under Item 8 was accepted.

24. The Committee expressed its appreciation to the OIE for the information and noted that the information would be of relevance under Items 4 and 8, in particular.

PROPOSED DRAFT GUIDELINES FOR THE CONTROL OF *CAMPYLOBACTER* AND *SALMONELLA* SPP. IN CHICKEN MEAT (Agenda Item 4)⁵

25. The Committee recalled that at its 41st session it had agreed to return the proposed draft guidelines to Step 2 for further elaboration by an electronic working group led by New Zealand and Sweden, circulation for comments at Step 3 and consideration at the current session of the Committee.

26. The Delegation of Sweden, in introducing the report of the working group, as presented in document CX/FH 10/42/4, recalled the history of the development of the Guidelines. The Working Group had taken into consideration all written comments submitted at the 41st CCFH and the working group, as instructed, had ensured that the revised document remained as close as possible to the structure and content of the document submitted at the 41st CCFH.

27. The Committee noted that the only substantial change in the revised document was the reintroduction of data on the use of Tri-Sodium Phosphate (TSP) for decontamination of chicken carcasses. While the FAO/WHO Technical Meeting on *Salmonella* and *Campylobacter* in Chicken Meat (Rome, Italy, May 2009) had excluded the use of TSP, this was not due to a food safety concern but the fact that information available at that meeting indicated that TSP was no longer being used and that there were concerns regarding employees safety. The Working Group had recommended that the Committee consider the revised document for further advancement in the Step procedure.

General comments

28. At the proposal of the Chairperson, the Committee considered a revised version of paragraph 14, resolution of which would unblock the situation that had prevented the 41st CCFH considering the document in detail. The proposed paragraph highlighted that the use of control measures in the primary production-to-consumption food chain were subject to approval by the competent authority, where appropriate, and allowed for the use of control measures other than those mentioned as examples in the document. The Committee agreed to the proposed paragraph, which represented a compromise solution to the different proposals and allowed for flexibility by recognizing that the competent authorities should decide on the specific control measure to be approved. It was noted that the revised paragraph also allowed for new technologies to be used without amending the document.

Specific comments

29. In view of the above decision, the Committee agreed to consider the document in detail with a view to progress it in the Step procedure and to focus its discussion on substantial issues in view of the extensive revision made by the working groups (physical and electronic) to improve the logical flow and readability of the document.

30. The Committee noted that, for consistency with the use of literature references in other Codex documents, Section 14 “Scientific References” should be deleted and only relevant references Codex, FAO, WHO and OIE documents would be updated, where necessary, and included as footnotes in the document.

⁵ CX/FH 10/42/4; CX/FH 10/42/4-Add.1 (comments of Argentina, Brazil, Canada, Colombia, Costa Rica, Ghana, Honduras, Jamaica, Japan, Kenya, Mexico, Paraguay, Peru, Philippines, United States of America, Uruguay and IACFO); CRD 3 (comments of Kenya); CRD 8 (comments of Nigeria); CRD 9 (comments of the European Union); CRD 10 (comments of India); CRD 11 (comments of South Africa); CRD 12 (comments of Mali); CRD 13 (comments of Ghana); CRD 14 (comments of Thailand); CRD 18 (comments of Uganda); CRD 21 (comments of Egypt).

31. The Committee reviewed the document in detail and in addition to some editorial changes and amendments to the French and Spanish version, agreed to the following changes.

1. Introduction

32. In paragraph 2, the reference to the work of the Committee on Food Hygiene was changed with the specific reference to the *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CAC/GL 63-2007) as the work of CCFH had been finalized and the text adopted by the Commission.

33. The last sentence of the second bullet in paragraph 3 was amended to clarify why the benefit of a hazard-based measure could not be precisely quantified without a specific risk assessment.

34. In the first sentence of paragraph 4, “and review” was added after “a rigorous scientific evaluation” to better describe the process followed in the development of the Guidelines.

2. Objectives

35. The first two sentences of paragraph 7 were merged and the text simplified by deleting reference to “significant reduction in foodborne disease” since there was no quantitative link established between the proposed control measures and the risk reduction.

3.1. Scope

36. In paragraph 10, the term “food pathway” was changed to “food chain” for consistency with other Codex texts. The Committee agreed to amend the term throughout the document.

37. The Committee noted that the Guidelines applied to chicken meat produced in typical “industrial” systems and that the specific needs of small scale operations could be addressed in the future in an Appendix to the Guidelines. It also noted that more specific measures for the control of *Salmonella* in eggs could be addressed in an Appendix to the *Code of Hygienic Practice for Egg and Eggs Products* (CAC/RCP 15-1976) in the future.

3.2. Use

38. The Committee agreed to add a reference to the *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004) in paragraph 11 and to delete paragraph 12, the content of which was replicated in paragraph 24.

39. In paragraph 13, a new sentence was inserted after the third sentence to clarify that where no quantifiable outcome was mentioned for a specific control measure it should be kept in mind that the effect might be different between *Salmonella* and *Campylobacter*. The sentence referring to Section 14 was deleted in view of the decision to delete the section on scientific references.

4. Definitions

40. The reference to slaughterhouse in the definition of “crate” was deleted to recognize that the use of crates was not limited to the transport of chicken to the slaughterhouse.

6. Risk Profiles

41. The specific titles of the risk profiles on *Salmonella* and *Campylobacter* in broiler chicken were added in paragraph 19.

7.1 Generic flow diagram for application of control measures

42. The Committee added a new step “Re-hanging (optional)” between the “hock cutting” and “venting” steps in the “Process Flow Diagram 3: Step 15 – Dress”, recognizing that this step could be necessary to carry out the evisceration process.

7.2 Availability of control measures at specific process flow steps address in these Guidelines

43. The title of the table was amended to make it consistent with the title of section 7.2.

8. Control measures for Steps 1 to 11 (Primary Production)

44. The Committee added a reference to the *Code of Hygienic Practice for Meat* (CAC/RCP 58-2005) as the Code included several control measures applicable to the primary production of chicken.

8.1 Step 1: Manage grandparent flocks

45. The Committee noted that although biosecurity measures applied to several steps, the document included reference to these measures only in those steps where their application was significant for the control of *Campylobacter* and *Salmonella*.

46. In the second sentence of paragraph 25, “by the competent authority” was deleted to allow for more flexibility.

8.3 Step 3: Parent hatchery

47. The second sentence in paragraph 32 was revised to read “Trace back of contamination to the infected breeding” as more appropriate and a similar revision was made in the second sentence of paragraph 36.

8.9 Step 9: Manage chicken

48. The Committee agreed to add a new sentence at the beginning of paragraph 39 making a more general reference to biosecurity measures and personnel hygiene, in a similar way to that used in Step 1 “Management of grandparent flock” and Step 5 “Manage parent stock”.

49. A new paragraph was added after paragraph 40, to include the use of fly screens as a specific measure for the control of *Campylobacter*. The table on Availability of Specific Control Measures was amended accordingly.

8.11 Step 11: Transport to slaughterhouse

50. In paragraph 44 “sanitized” was changed to “disinfected” for consistency with the terminology used in the *Code of Hygienic Practice for Meat* (CAC/RCP 58-2005). Consequential changes were also made throughout the document.

9.1 Step 12: Receive at slaughterhouse

51. Paragraph 45 was amended to recognize that before slaughtering it was important to obtain information about the flock, in particular in relation to the *Salmonella* and *Campylobacter* status. In paragraph 48, the example of ways to minimize cross-contamination to other flocks was amended to allow for other interventions.

9.4 Step 15: Dress

52. In paragraph 54, the Committee added “running water” in the first bullet and a new bullet “Disposal or reprocessing of carcasses with extensive faecal contamination”. Paragraph 55 was amended to ensure consistency in the terminology and to improve its clarity.

9.8 Step 19: Chill carcass (air or immersion)

53. The Committee agreed to add “and washing action” at the end of paragraph 79, for completeness.

9.11 Step 22: Pack whole carcass and portion

54. The Committee amended paragraph 91 by adding “and storage” to recognize the importance of proper storage of chicken meat, along with handling, in limiting the growth of *Campylobacter* and *Salmonella*.

55. Paragraph 93 was deleted as the reference did not fit the criteria.

10.4 Step 28: Retail / Food service

56. The Committee revised paragraph 100 to make it more generic and to recognise the role of enforcement authorities and retailers in preventing cross-contamination. In paragraph 102 it was specified that retailers might also provide customers with the means to sanitise their hands before and after handling chicken meat.

57. Paragraph 105 was amended to clarify that thawing should be carried out in a manner that minimises growth of microorganisms and prevents cross-contamination.

10.6 Step 30: Consumer

58. In recognising that washing of chicken meat might facilitate cross-contamination but that in some regions this measure was used to remove debris and other impurities, the Committee revised paragraph 113 to indicate that information to consumers should discourage washing of chicken meat in the kitchen but, when deemed necessary, washing of chicken should be carried out in a manner that minimises the possibility of cross-contamination.

12. Validation

59. The Committee added a sentence at the end of paragraph 128 to make it clear that validation of a control measure is a prerequisite to its implementation.

13.2. Review

60. The Committee added a new sentence in paragraph 150 to recognise that additional data from industry would significantly increase the value of a trend analysis conducted by the regulatory authorities.

Conclusions

61. In view of the agreement reached on paragraph 14, the detailed revision of the document and the absence of any outstanding issues, the Committee agreed that the document was ready to further progress in the Step procedure and to be adopted by the Commission.

62. The Committee further noted that FAO/WHO would include all scientific references removed from the document on the website of the “decision-support tool for the control of *Campylobacter* and *Salmonella* in poultry”.

Status of the Proposed Draft Guidelines for the Control of *Campylobacter* and *Salmonella* spp. in Chicken Meat

63. The Committee agreed to forward the proposed draft Guidelines for the Control of *Campylobacter* and *Salmonella* spp. in Chicken Meat to the Commission for adoption at Step 5/8 with the recommendation to omit Steps 6 and 7 (see Appendix III).

PROPOSED DRAFT GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF VIRUSES IN FOOD (Agenda Item 5)⁶

64. The Committee recalled that at its 41st session it had agreed to establish a physical working group, led by The Netherlands, to revise the proposed draft Guidelines for circulation for comments at Step 3 and consideration at the current session.

65. The Delegation of The Netherlands presented document CX/FH 10/42/5 and reported that the working group had taken into consideration all comments made at the last session and that, in an attempt to facilitate discussion at this session, it had prepared a revised draft taking into account further written comments made to this session and proposed that this document (CRD 16) be used for discussion. The key changes made were more of a structural nature to simplify the document and to remove repetitions between the main body and the annexes.

66. The Committee considered CRD 16 and noting that the structure and text of the document still needed improvements, agreed to consider the document section by section and to focus on key changes and comments for the further revision of the document with a view to its finalization by the next session.

67. The Delegation of The Netherlands introduced the major changes made to each section. The Committee made the following amendments and comments or proposals:

Introduction

68. It was agreed to amend the second last paragraph to more accurately reflect that cooking of bivalves and fresh produce might not ensure total reduction of viral contamination and to cross-reference Annex I section 5.2.2.

Section II – Scope, Use and Definitions

69. This section was amended to more clearly illustrate that the guidelines were applicable to all foods with a focus on ready-to-eat foods.

⁶ CX/FH 10/42/5; CX/FH 10/42/5-Add.1 (comments of Argentina, Australia, Bolivia, Brazil, Canada, Japan, Kenya, Mexico, New Zealand, Peru, Philippines, United States of America, Uruguay and IACFO); CRD 3 (comments of Kenya); CRD 10 (comments of India); CRD 11 (comments of South Africa); CRD 12 (comments of Mali); CRD 14 (comments of Thailand); CRD 16 (proposal for a revised draft Guideline prepared by The Netherlands); CRD 17 (comments of Nicaragua); CRD 18 (comments of Uganda); CRD 21 (comments of Egypt); and CRD 22 (comments of the European Union).

Section III – Primary production / harvesting area

70. The second paragraph of section 3.2 was deleted as it was already covered in section 3.4.

71. In section 3.3, the last part of the 3rd paragraph was deleted so as not to specify how often a container could be used but rather to focus on the fact that containers should be in a good clean condition and should not be damaged.

72. The Committee did not support a proposal to include in section 3.4 reference to examples of specific molecular methods for testing to confirm that NoV shedding had stopped in faecal materials of infected food handlers in primary production for ready-to-eat food as these methods were not widely available and their results were difficult to interpret. The Delegation of Japan was however of the opinion that these were only examples and could be included in this document for use in certain circumstances for high risk populations

Section V – Control of Operation

73. The Committee agreed that consideration should be given to a more appropriate location of the subsections 5.1.1, 5.1.2, 5.1.3 and 5.1.4, and agreed to introduce a chapeau paragraph in section 5.1 to provide a simple principle on hazard controls for viruses.

74. It was noted that regular checking for HAV infection of workers was not practical for many countries in particular countries where HAV was endemic and that it relied on serological testing which was costly and not always reliable. However, in noting that such testing was a control measure that could be considered together with other control measures, it was agreed to amend the last bullet point of section 5.1.2 to indicate that checking for HAV infection of workers was useful and could be carried out where feasible and appropriate.

75. It was agreed to recommend that section 5.2.1 be revised to take into account that conventional cooking was not always sufficient to inactivate viruses, especially in bivalves and to consider referencing the appropriate section in the Annex for control of HAV and NoV in bivalve molluscs.

76. The title of 5.2.2 was amended by replacing “steps” with “procedures” to better reflect the contents of this section and that the first paragraph should be extended to include pH control for enveloped viruses.

77. In noting that the paragraph on irradiation was specific to UV radiation treatment, it was agreed to change its title to “UV irradiation”. It was recommended that an additional paragraph be inserted to address ionising irradiation treatment.

78. The last paragraph on newer technologies was amended to reflect that, only if possible, methodologies that can distinguish between infectious and non-infectious materials should be applied when virucidal treatments are validated with the hazard/food combination. The last sentence on validation and approval was deleted as not applicable.

79. The Committee agreed with the recommendation of the Observer from IACFO that section 5.8 be amended to include language providing for risk-based recall decisions and public warning for HAV and NoV where appropriate.

Section VII – Establishment: Personal hygiene

80. In the third paragraph of section 7.3, the last three sentences relating to how hands should be washed, the use of disposable paper towel and non-hand operable taps were deleted as these measures were considered too prescriptive.

81. Section 7.4 was amended for consistency with section 6.8 of the *Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering* (CAC/RCP 39-1993) and to more clearly indicate that hand-washing was essential after handling any contaminated material.

Section X - Training

82. In section 10.1, “call” was replaced by “inform the employer” for clarity.

83. For purposes of flexibility, the second last sentence of section 10.2 was amended to indicate that, to the extent possible, children should be kept away from growing fields and food preparation areas in HAV endemic areas and as a consequence a similar amendment was made in section 5.1 of Annex II.

Annex I

84. The Committee agreed to keep heat treatment condition as an example in paragraph 3 of primary production and to delete the sentence related to performance of accredited laboratories. While noting that water quality was essential to preventing viral contamination, it was recommended that consideration also be given to addressing other environmental conditions of the production and harvesting areas.

Conclusion

85. The Committee 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, open to all interested parties and working in English only, to prepare a revised proposed draft Guideline based on the written comments at Step 3 and the recommendations and discussions at this session. It was further agreed that a physical working group, led by The Netherlands, open to all interested parties and with interpretation in English, French and Spanish would meet immediately prior to the next session to consider comments submitted and to prepare a proposal for consideration by the next session to facilitate the finalization of the proposed draft Guidelines.

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

86. The Committee agreed to return the Proposed Draft Guidelines on the Application of General Principles to the Control of Viruses in Food to Step 3 for comments and consideration by the next session (*see* Appendix IV).

PROPOSED DRAFT REVISION OF THE RECOMMENDED INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR COLLECTING, PROCESSING AND MARKETING OF NATURAL MINERAL WATERS (Agenda Item 6)⁷

87. The Committee recalled that at its 41st session it had agreed to start new work on the revision of the *Recommended International Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters* (CAC/RCP 33-1985) and that a physical Working Group, led by Switzerland, would develop the proposed draft revision of the Code for circulation for comments at Step 3 and consideration by the current session of the Committee.

88. The Delegation of Switzerland, in introducing the report of the working group, highlighted the major agreements reached as reflected in CX/FH 10/42/6 and the recommendation that, if there was agreement on Annex I on microbiological criteria, consideration should be given to the deletion of section 4.4 of the *Standard for Natural Mineral Waters* (CODEX STAN 108-1981).

89. The Delegation highlighted the fact that natural mineral water is clearly distinguishable from ordinary drinking water as laid down in the definition for natural mineral water in section 2.1 of the *Standard for Natural Mineral Waters*.

90. The Delegation informed the Committee that it had prepared a revised proposal (CRD 20) taking into account all written comments at Step 3 and proposed that the Committee consider this document as the basis for its discussion.

91. The Committee considered CRD 20 section by section and, in addition to some editorial changes and amendments to the Spanish version, agreed to the following changes⁸.

General comments

92. A Delegation requested clarification on how the current document could be used in conjunction with the WHO Guidelines on Drinking Water Quality and, in particular, how the concept of water safety might be adopted in natural mineral water harvesting. It was clarified that the WHO Guidelines were not applicable to natural mineral waters due to the specificity of the product, as outlined in its definition, and that the WHO Guidelines were only used to provide the rationale for the parameters presented in the table in the Annex on microbiological criteria.

⁷ CX/FH 10/42/6; CX/FH 10/42/6-Add.1 (comments of Argentina, Australia, Brazil, Colombia, the European Union, Japan, Kenya, Peru, Philippines, United States of America and ICBWA); CRD 3 (comments of Kenya); CRD 8 (comments of Nigeria); CRD 10 (comments of India), CRD 11 (comments of South Africa), CRD 12 (comments of Mali), CRD 17 (comments of Nicaragua), CRD 18 (comments of Uganda), CRD 20 (revised proposal by Switzerland), and CRD 21 (comments of Egypt).

⁸ Numbers of paragraphs in this section correspond to those in CRD 20.

Specific comments

Section I - Objectives

93. In the first bullet point “guarantee” was replaced by “ensure” for consistency with terminology used in Codex texts. Consequential changes were also made throughout the document.

2.3 Definitions

94. The definitions for “containers” and “packaging materials” were amended to better clarify that containers were those vessels made from food-grade packaging material to be filled with natural mineral water whereas packaging material could be any materials food grade or not.

3.1.4 Protective Measures

95. Paragraph 17 was amended to more clearly indicate that if the protection zone was bordered by areas not under the control of producers/manufacturers, it was still their responsibility to develop measures and monitoring programmes to avoid contamination of the zones.

3.2.2 Protection of the extraction area

96. Paragraph 31 was transferred to this section as a new paragraph (20bis) as it was considered more applicable to the section.

3.2.3 Materials and 3.2.4 Equipment and Reservoirs

97. Paragraph 21 was amended by referring to “inert” material for consistency with section 3.3.3 and transferred to section 3.2.4, as more appropriate. As a consequence, section 3.2.3 Materials was deleted.

98. Paragraph 22 was amended for purposes of clarity and to better reflect that the design and construction of equipment and reservoirs should be such so as to avoid contamination of the natural mineral water rather than to minimize hazards to human health.

3.3 Handling, Storage and Transport of Natural Mineral Waters Intended for Bottling

99. “Transport” was deleted from the title as not applicable to natural mineral waters and “bottling” was replaced with “packaging” so as not to exclude other forms of packaging. Consequential changes were also made throughout the document.

3.3.1 Technical aspects

100. “Extraction facilities” was replaced by “handling and storage” as more appropriate.

4.2 Premises and Rooms

101. In paragraph 39, “aerial debris” was replaced by “suspended particles” since debris could be broken pieces or fragments and too big to be aerial while suspended particles could be aerosol or cloud dust. The 2nd and 3rd sentences of this paragraph were merged and restructured to better explain the reason why labelling machines inside filling rooms should have effective exhaust systems.

4.3 Equipment

102. In recognizing that the use of lubricants was necessary for the maintenance of the equipment and as a precaution in case of leakages, paragraph 42 was amended to reflect that it was necessary to verify that lubricants were suitable for food use, but that care should be taken to avoid their coming into contact with the natural mineral water.

4.4.2 Drainage and Waste Disposal

103. In light of the new definition for container, “waste disposal containers” were changed to “waste disposal bins” as more appropriate.

4.4.3 Cleaning

104. A new paragraph (45bis) was inserted to more clearly mention that cleaning facilities as per subsection 4.4.3 of the *General Principles of Food Hygiene* should be available.

4.4.8 Storage

105. A new paragraph (51bis) was inserted to retain important provisions regarding facilities for storage of waste and inedible material, from the current Code in force.

5.2.2.2. Treatment

106. In paragraph 58, “chemical” was replaced by “adsorption” to clarify the filtration process and not to imply the use of chemical treatments which were not allowed for natural mineral waters.

5.2.5 Physical and Chemical Contamination

107. In paragraph 72, “primary packaging material” was replaced by “containers and closures” as more appropriate.

5.5 Water

108. To avoid confusion and in line with the *General Principles of Food Hygiene*, paragraph 76 was amended to more accurately refer to section 5.5.1 of these principles.

Annex I: Microbiological Criteria

109. The Committee recalled that one of the objectives in revising the Code was to align the microbiological criteria with those of the *Standard for Natural Mineral Waters*. It was noted that those parameters in the Table were from the Standard and that in addition, aerobic mesophilic count (heterotrophic plate count) was included as an important indicator and that the method for this count was ISO 6222-1999.

110. Some delegations and an observer questioned the need for the use of all four faecal indicators and the suitability of *Pseudomonas aeruginosa* as an indicator as it was not a typical food related criterion and more applicable to medical applications. It was therefore proposed to limit the number of indicators as the use of multiple indicators could be costly to manufacturers.

111. Some other delegations and observers reiterated that the task of the work was to align the microbiological criteria with those of the *Standard for Natural Mineral Waters*, that there was no need to change anything as this was widely used standard industry practice that had been proved appropriate to ensure a high level of safety of natural mineral waters due to the fact that they were not subjected to the hygiene control measures usually applied to bottled water, in particular disinfection.

112. In recognition of the need for flexibility, it was agreed to amend paragraph 99 to indicate that manufacturers could choose all or a subset of the faecal indicators as appropriate in accordance with any requirements set by the competent authority. In addition, a new paragraph was added to clarify that competent authorities could use all or a subset of the criteria as appropriate to verify the effectiveness of general hygiene programmes in the food operational environment as well as to verify control measures in facilities employing HACCP or other food safety control systems. In line with this the Table was amended to clearly illustrate which criteria were faecal indicators and which were process control indicators.

113. The column “M” and the associated note were deleted as not applicable to a 2-class plan.

Rationale for the parameters chosen

114. The section on spore-forming sulphite-reducing anaerobes was amended to clarify that these bacteria were considered faecal indicators.

Conclusion

115. In view of the consensus reached on the document, it was agreed to progress it in the Step procedure for adoption by the Commission. As a consequence of the decision on Annex I on microbiological criteria, the Committee agreed to request the Commission to remove section 4.4 of the *Standard for Natural Mineral Waters* and to reference the Code as prescribed in the Procedural Manual.

Status of the Proposed Draft Revision of Recommended International Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters

116. The Committee agreed to forward the Proposed Draft revision of the *Recommended International Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters* to the Commission for adoption at Step 5/8 with the recommendation to omit Steps 6 and 7 (see Appendix V).

PROPOSED DRAFT REVISION OF THE *PRINCIPLES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA FOR FOODS* (Agenda Item 7)⁹

117. The Committee recalled the decision of the 41st session to start new work on the revision of the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997) and that a physical working group led by Finland and co-chaired by Japan would develop the proposed draft revision of the Principles for circulation for comments at Step 3 and consideration by the current session of the Committee.

118. The Delegation of Finland, in introducing the report of the working group, highlighted the progress that had been made. Particular attention was drawn to the restructuring of the document, the change of title, the intended users of the document, the revised definition of a microbiological criterion (MC), the efforts to address the linkage between MC and the new microbiological risk management (MRM) metrics and the proposed structure of examples to be developed in the future to illustrate the various applications of MC.

119. The working group requested feedback from the Committee on the changes made to date, the proposed examples and a further list of issues as defined in paragraph 31 of CX/FH 10/42/7.

General comments

120. The importance of this work for developing as well as developed countries was emphasised.

121. While noting that there was still significant work to be carried out on this document and with the objective of providing the necessary guidance to facilitate such work, the Committee made the following comments and recommendations for the further development of the document:

- Further consider the main document taking into account the comments received before and during the current session, giving particular attention to the need for the guidelines to be more user-friendly and adequately flexible so that they could be used by countries with different levels of capacity and expertise on these issues.
- Give consideration to the concept of MC being categorised into: those which contribute to GHP (e.g. MC for indicator organisms), hazard-based MC (e.g. for a specific pathogen in a specific commodity) and those which are risk-based (e.g. linked to an ALOP, FSO).
- Ensure that relevant information from the current principles (CAC/GL 21-1997) is adequately captured in the proposed draft revision.
- In addressing the issues of uncertainty and variability, take into account the previous and ongoing work of the Codex Committee on Methods of Analysis and Sampling (CCMAS).
- While guidance on the establishment of MC for animal feed would be useful this was considered to be of lower priority and that in many cases the guidance in relation to food, processes and processing environments would equally apply to feed.
- Develop examples to illustrate the practical application of MC for different purposes based on paragraphs 47-61 of document CX/FH 10/42/7 as an annex to the main document; these were considered important in terms of ensuring the practical nature of the guidelines.
- Initiate development of an annex on the more technical and statistical aspects of MC and sampling; although complex, this was considered to be a critical component of the guidelines.
- Give consideration to indicator organisms in the guidelines, which were noted to be a valuable tool particularly in monitoring of process hygiene.
- Further elaborate on the relationship between MC and MRM metrics taking into consideration recent progress that had been made on the application of the MRM metrics.
- Undertake efforts to elaborate some text on communication issues related to MC in both the main body of the document, and in the examples to be developed.

⁹ CX/FH 10/42/7; CX/FH 10/42/7-Add.1 (comments of Argentina, Australia, Brazil, Costa Rica, Guinea Bissau, Kenya, Malaysia, Mexico, Nicaragua, Peru, Philippines and United States of America); CRD 3 (comments of Kenya); CRD 4 (comments of Japan); CRD 5 (comments of Japan); CRD 9 (comments of the European Union); CRD 10 (comments of India); CRD 11 (comments of South Africa), CRD 12 (comments of Mali).

122. In noting these suggestions, the Delegations of Finland and Japan highlighted the challenges that lay ahead in the further development of the document and requested the input of countries and observers, in particular to facilitate the development of the annexes on examples and the technical and statistical aspects.

123. Given the complexity of this issue, the importance of training material to facilitate the application of the proposed draft guidelines was highlighted. While training on the application of the guidelines was still premature, the ongoing work of FAO and WHO on the development of a tool to assess the performance of sampling plans was considered very useful and the collaborative efforts of national governments, FAO, WHO and ICMSF to facilitate capacity development in the general area of sampling were welcomed by the Committee.

Conclusions

124. In light of the discussion, the Committee agreed that the document be returned to Step 2 for further elaboration.

125. The Committee agreed to establish a physical working group led by Finland and co-chaired by Japan, open to all interested parties and with interpretation in English, French and Spanish, to meet in Brussels in the second quarter of 2011 with the following terms of reference:

- Further consider the main document taking into account the comments received before and during the current session;
- Elaborate an Annex with practical examples on the establishment and application of MC; and
- Initiate development of an Annex to address the statistical and mathematical aspects of establishing MC including the elaboration of a sampling plan.

126. To facilitate the further development of the document and its annexes, taking into account the comments received before and during the current session, the working group would use electronic means to do its preparatory work and facilitate broad participation.

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

127. 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 revision by the above working group. The revised version would be circulated for comments at Step 3 and considered by the next Session of the Committee.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 8)

DISCUSSION OF THE REPORT OF THE WORKING GROUP FOR ESTABLISHMENT OF CCFH WORK PRIORITIES¹⁰

128. The Delegation of Finland, 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.

129. The working group had recommended the Committee consider two new work proposals for the elaboration of: (i) Guidance for the control of *Trichinella spiralis* and *Cysticercus bovis* in meat (first priority); and (ii) Annex on tomatoes and/or melons to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003) (second priority).

130. The working group had also recommended that the Committee consider how to deal with outstanding issues, including possible revision and/or revocation of codes of hygienic practices and to request FAO and WHO to review the current status of knowledge of parasites in food and their public health and trade impact.

131. The Committee noted that in view of the finalisation of work on *Campylobacter* and *Salmonella* in chicken meat (Item 4) and on the revision of the *Code of Practice on Natural Mineral Waters* (Item 6), it could accommodate both these new work items in its workplan.

132. The Committee considered the two proposals as follows.

¹⁰ CX/FH 10/42/8; CRD 2 (Report of the CCFH working group for the establishment of CCFH work priorities); CRD 13 (comments of Ghana); CRD 15 (comments of the United States of America); CRD 21 (comments of Egypt).

Guidelines for Control of Specific Zoonotic Parasites in meat: *Trichinella spiralis* and *Cysticercus bovis*

133. The Committee noted the ongoing work of the OIE on zoonotic parasites and that the chapter on trichinellosis (Chapter 8.13 of the OIE *Terrestrial Animal Health Code*) was being revised, would be distributed for comments in February 2011 and that adoption was expected by 2012. The revised chapter was dealing with methods for on-farm prevention of *Trichinella* infection in pigs and for safe trade of fresh meat and meat products derived from pigs and equines and would not overlap with the proposed new work. The Committee was also informed that although *Cysticercus bovis* was not an OIE-listed disease, the OIE was considering the development of general recommendations for the control of this disease on-farm to be published on the OIE website¹¹.

134. The Delegation of the United States of America, supported by others, expressed concern about the proposal because of the ongoing work of OIE on zoonotic parasites and because of other areas of potential work, e.g., commodity specific annexes to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* which had greater public health significance. The Delegation proposed consideration of this proposal for new work on parasites after the OIE had completed its work.

135. The Committee further noted that the new work would reference OIE documents with regard to controls at primary production and focus on control measures applicable to subsequent steps of the meat chain with the aim at modernising meat hygiene systems and at optimising the use of resources by applying risk analysis principles to different types of traditional meat hygiene procedures thus ensuring the proportionality of the measure in relation to the risk. It was further stressed that the proposed new work was complementary to ongoing OIE work, that OIE test methods for *Trichinella* would be referred to in the document and that this work would strengthen Codex collaboration with OIE in line with Goal 4 “Promoting Cooperation between Codex and Other Relevant International Organizations” of the Codex Strategic Plan 2008-2013.

136. The Committee highlighted the public health and trade importance of foodborne parasites and the need to address these foodborne parasites in a horizontal manner by developing a general guidance document, which would provide a framework in which annexes on specific parasite / commodity combinations could be addressed. However, it was noted that, in order to undertake this work there was a need for a review of all available information on parasites to better assess the global problem associated with them, the commodities involved and the related public health issues and that this work could be carried out in parallel to the proposed new work.

137. Based on the recommendations of the working group, the Committee agreed 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 forward the project document for new work to the 65th Session of the Executive Committee and the 34th Session of the Commission for approval as new work (see Appendix VI).

138. The Committee agreed to establish a physical working group, co-chaired by the European Union and New Zealand, open to all interested parties and with interpretation in English, French and Spanish, 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 next session of the Committee, pending approval of the Commission. The physical working group was tentatively scheduled to be held in Brussels (Belgium) in the second quarter of 2011, back-to-back with the physical working Group on microbiological criteria (see Item 7).

Annex to the Code of Hygienic Practice for Fresh Fruits and Vegetables

139. The Committee noted that the working group had not made any recommendation of whether the work should focus on both tomatoes and melons and agreed that it would be preferable to start work focusing on melons only, in view of the global public health significance of this commodity, as highlighted by FAO/WHO Expert Meeting on Microbiological Hazards in Fresh Fruits and Vegetables.

¹¹ www.oie.int

140. The Committee noted that a number of public health incidents in the United States of America, as well as in other countries, justified this work and that it was necessary to identify the critical points and design preventive measures for their control. It also noted that this work was part of an overall request for the development of appendices to the *Code of Hygienic Practice for Fresh Fruits and Vegetables*, made at its 39th Session¹².

141. The Committee indicated that the work could be initiated without specific scientific advice from FAO/WHO. However, it was noted that FAO and WHO had mechanisms in place to allow the collection of relevant information and for provision of specific scientific advice if needed.

142. Based on the recommendations of the working group, the Committee agreed 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 forward the project document for new work to the 65th Session of the Executive Committee and the 34th Session of the Commission for approval as new work (see Appendix VII).

143. The Committee agreed to establish a physical working group, led by the Canada and co-chaired by the United States of America, open to all interested parties and with interpretation in English and French, to develop a proposed Annex on Melons to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003) for circulation for comments at Step 3 and consideration by the next session of the Committee, pending approval of the Commission. The physical working group was tentatively scheduled to be held in Canada in the second quarter of 2011.

Other matters

144. In view of the above discussions, the Committee agreed to request FAO and WHO:

- To review the current status of knowledge on parasites in food and their public health and trade impact in order to provide the CCFH with advice and guidance on the parasite-commodity combinations of particular concern, the issues that need to be addressed by risk managers and the options available to them; and
- To issue a call for data and to evaluate the pathogen-specific hazards associated with various types of melons and the role of various agricultural and manufacturing practices in enhancing or mitigating these hazards. Consideration should be given to how these products are marketed and handled by consumers and the impact of this on foodborne illnesses.

145. The Committee further agreed to request the Codex Secretariat to include in the Circular Letter inviting proposals for new work information on requests which were assigned lower priority in previous meetings, along with the list of existing codes of hygienic practice that could be revised and/or revoked, on the basis of a proposal made at the 33rd CCFH (Ref. CX/FH 00/14).

146. The Committee noted that risk profiles should be attached to any new proposals in accordance with CCFH procedures laid down in the Procedural Manual.

147. The Committee thanked the Delegation of Finland for their excellent work in chairing the working group and accepted the offer of the Delegation of Thailand to chair the next working group, which will meet the day before the next session of the Committee.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 9)

148. The Committee was informed that the 43rd Session of the CCFH was tentatively scheduled to be held in the United States of America from 5 to 9 December 2011. The exact time and venue would be determined by the host Government in consultation with the Codex Secretariat.

¹² ALINORM 8/31/13, paras 157-159.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by:	Reference in REP11/FH
Proposed Draft Guideline for the Control of <i>Campylobacter</i> and <i>Salmonella</i> spp in Chicken Meat	5/8	Governments 34 th CAC	para. 63 and Appendix III
Proposed Draft Revision of the Recommended International Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters (CAC/RCP 33-1985) and the consequential amendment to the Standard for Natural Mineral Waters (Section 4.4)	5/8	Governments 34 th CAC	paras 116 and 115 and Appendix V
Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food	3	Governments Physical Working Group (The Netherlands) 43 rd CCFH	para. 86 and Appendix IV
Proposed Revision of Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997)	2/3	Physical Working Group (Finland / Japan) Governments 43 rd CCFH	para. 127
Guidelines for Control of Specific Zoonotic Parasites in Meat: <i>Trichinella spiralis</i> and <i>Cysticercus bovis</i>	1/2/3	34 th CAC, Physical Working Group (EU / NZ) Governments 43 rd CCFH	paras 137 and Appendix VI
Annex on Melons to the Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003)	1/2/3	34 th CAC Physical Working Group (Canada / USA) 43 rd CCFH	paras 142 and Appendix VII
Discussion paper on the review of the risk analysis principles and procedures applied by the Codex Committee on Food Hygiene.	-	EU	para. 6

APPENDIX I**LIST OF PARTICIPANTS
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Appendix II**ENDORSEMENT OF FOOD HYGIENE PROVISIONS****PROPOSED DRAFT STANDARD FOR SMOKED FISH, SMOKE-FLAVOURED FISH AND SMOKE-DRIED FISH****6. HYGIENE AND HANDLING****6.1 General Provisions**

The products covered by the provisions of this standard shall be prepared and handled in accordance with the appropriate sections of the recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969) and other relevant Codex texts such as codes of practice and codes of hygienic practice, such as the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).

6.2 Microbiological criteria

The products shall comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria in Foods (CAC/RCP 21-1997).

6.3 Parasites

Products covered by this Standard shall not contain living parasites and particular attention needs to be paid to cold smoked or smoke-flavoured products, which should be frozen before or after smoking if a parasite hazard is present (see Annex I). Viability of nematodes and cestodes and trematodes shall be examined according to Section 8.9 and/or 8.10.

6.4 *Listeria monocytogenes*

The ready to eat products shall comply with microbiological criteria for *Listeria monocytogenes* in ready to eat foods which was elaborated in the Annex II of 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).

6.5 *Clostridium botulinum*

Toxins of *Clostridium botulinum* are not allowed in smoked fish, smoke-flavoured fish and smoke-dried fish products. The formation of *Clostridium botulinum* toxin can be controlled through an application of a combination of science-based options such as packaging type, storage temperature, and water activity e.g. by use of salt in the water phase. Examples are shown in the Table in Annex 2, which addresses these control options.

~~Countries where the products are to be consumed may allow these products in an uneviscerated state or may require evisceration, either before or after processing in such a way as to minimize the risk of *Clostridium botulinum*.~~

6.6 Histamine

The product shall not contain histamine that exceeds 20 mg/100g fish flesh. This applies only to susceptible species (e.g. *Scombridae*, *Clupeidae*, *Engraulidae*, *Coryfenidae*, *Pomatomidae*, *Scombresosidae*).

6.7 Other Substances

The products shall not contain any other substances in amounts, which may present a hazard to health in accordance with standards established by the Codex Alimentarius Commission, and the final product shall be free from any foreign material that poses a threat to human health.

ANNEX 1 (to the Proposed Draft Standard for Smoked Fish, Smoke-flavoured fish and Smoke-dried fish)

PROCEDURES SUFFICIENT TO KILL PARASITES

Any method used to kill parasites shall be acceptable to the competent authority having jurisdiction.

Where freezing is required to kill parasites (i.e. cold smoked fish and smoke flavoured fish), the fish must be frozen either before or after processing to a temperature time combination sufficient to kill the living parasites.

Examples of freezing processes that may be sufficient to kill some or all parasites are:

- Freezing at -20°C at the thermal centre of the product for 24 hours (for *Anisakis* species and *Pseudoterranova decipiens* only);¹
- Freezing at -35°C at the thermal centre of the product for 15 hours (all parasites)²⁻⁵;
- Freezing at -20°C at the thermal centre of the product for 168 hours (7 days)¹⁻⁴²⁻⁵ (all parasites).

¹ FAO Fisheries Technical Paper 444 (Assessment and management of seafood safety and quality, 2004)

² Bier, J. 1976. Experimental Anisakiasis: Cultivation and Temperature Tolerance Determinations. J. Milk Food Technol. 39:132-137.

³ Deardoff, T.L. et al. 1984. Behavior and Viability of Third-Stage Larvae of *Terranova* sp. (Type HA) and *Anisakis simplex* (Type I) Under Coolant Conditions. J. of Food Prot. 47:49-52.

⁴ Health and Welfare Canada (1992) (in consultation with Canadian Restaurant and Food Service Association, Fisheries Council of Canada, and Fisheries and Oceans Canada). Code of practice for the preparation of raw, marinated, and partially cooked fin fish.

⁵ USFDA - Centre for Food Safety & Applied Nutrition (June 2001), Fish and Fisheries Products Hazards and Controls Guidance, Chapter 5 Parasites, 3rd Edition.

ANNEX 2 (to the Proposed Draft Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish)

Examples of combinations of product attributes that minimise the likelihood of *Clostridium botulinum* toxin formation

Countries where the products are to be consumed can be expected to make their science-based risk management choices with the assistance of this framework, e.g., select some options and exclude others, based on conditions within the country (e.g., nature and enforcement of refrigeration and shelf life controls; transportation times and conditions; variability in amount of salt in the aqueous phase that could occur despite best efforts to achieve a required percentage, etc.), and the level of protection that the country chooses for itself for this particular risk. This table applies to smoked fish and smoke-flavoured fish where the smoke flavour is provided by smoke condensates. If the smoke flavour is imparted by artificial flavour blends, then 5% aqueous phase salt would be required in order to provide complete protection at any temperature over 3°C . This table does not apply to smoke-dried fish because the required water activity of 0.85 or below inhibits the growth of all foodborne pathogens so that refrigeration is not required.

As an alternative to aqueous phase salt, certain time/temperature parameters can minimise the likelihood that *C. botulinum* will grow in the product. *C. botulinum* cannot grow and produce toxin below 3°C or below a water activity of 0.94. Other time/temperature combinations exist that similarly control the formation of toxin¹. Where enforcement of shelf life as well as consumer acceptance of shelf life are norms, the country may select a system that relies on the combination of existing storage temperature conditions (i.e. during transport, retail storage, and consumer storage) and shelf life limitations.

~~However, in countries where consumer acceptance and regulatory enforcement of shelf life are not norms, continuous monitoring, such as that provided by time/temperature integrators on consumer packages can be~~

¹ Skinner, G.E. and Larkin, J.W. (1998) Conservative prediction of time to *Clostridium botulinum* toxin formation for use with time-temperature indicators to ensure the safety of foods. (Journal of Food Protection 61, 1154-1160.

~~an important adjunct to shelf life monitoring in the country where the product will be consumed. The necessity for time/temperature integrators exists because, unlike freezing, temperature control through refrigeration is not a visual condition and cannot be determined without an additional monitoring control.~~

Temperature-abuse has a direct impact on the safety and shelf-life of the products. Time/temperature integrators may be a useful tool to determine if the products have been temperature-abused.

Product Temperature During Storage	PACKAGING	WATER ACTIVITY CONTROLLED BY AQUEOUS PHASE SALT (<i>NaCl</i>)	COMMENTS
(0°C to 3°C) <u>Below 3°C</u>	Reduced Oxygen (including vacuum packaging and modified atmosphere packaging) <u>Any packaging</u>	No maximum water activity is needed. <u>Not applicable</u>	<i>C. botulinum</i> toxin cannot form below 3°C. Temperature monitoring is needed for each package, e.g. time temperature integrators, to ensure that the temperature does not exceed 3°C. The country where the product is consumed may require temperature monitoring for each package to ensure that the time temperature combination does not permit the production of <i>Clostridium botulinum</i> toxin.
≥3°C to 5°C	Aerobically Packaged*	No maximum <u>minimum</u> water activity is needed. Nonetheless, where there is a reasonable possibility of severe time/ temperature abuse, the country where the product is being consumed might choose an aqueous phase salt barrier of at least 3% to 3.5% (w/w) as an additional barrier.	When these products are packaged aerobically, 5°C is the maximum recommended storage temperature for the control of pathogens generally and for quality. <u>The purpose of the aerobic packaging is not to provide sufficient oxygen to prevent growth and toxin formation of <i>C. botulinum</i>.</u> In air-packaged products, aerobic spoilage organisms provide sensory signs of spoilage before the formation of toxin by <i>C. botulinum</i> . However, even <u>In addition</u> , in air packaging it is possible for anaerobic micro-environments to exist and toxin may form if the product is subject to severe time/temperature abuse. For that reason, the country where the product is consumed may still require aqueous phase salt as a barrier to growth of non-proteolytic strains of <i>C. botulinum</i> if there are concerns about the ability of transporters, retailers or consumers to maintain time/temperature control.
Frozen (< or = -18°C)	Reduced Oxygen (including vacuum packaging and modified atmosphere) <u>Any packaging</u>	No maximum water activity is needed. <u>Not</u> <u>applicable</u>	<i>C. botulinum</i> toxin cannot form when product is frozen. In the absence of adequate aqueous phase salt, toxin production can occur after thawing so, labelling information about the need for the consumer to keep the product frozen, to thaw it under refrigeration, and to use it immediately after thawing, is important. The country where the product is consumed may require temperature monitoring for each package to ensure that the time temperature combination does not permit the production of

Product Temperature During Storage	PACKAGING	WATER ACTIVITY CONTROLLED BY AQUEOUS PHASE SALT (<i>NaCl</i>)	COMMENTS
			Clostridium botulinum toxin after thawing. <u>Time/temperature integrators may be a useful tool to determine if the product has been temperature-abused. Temperature-abused has a direct impact on the safety and shelf-life of the product.</u>
$\geq 3^{\circ}\text{C}$ to 5°C	Reduced Oxygen (including vacuum + modified atmosphere packaging)	Aqueous phase salt at minimum level of between 3% & 3.5% (w/w) may be selected by the country where the product is to be consumed.	Aqueous phase salt at a minimum level of between 3 and 3.5% (w/w) (aqueous phase salt) in combination with <u>refrigeration chilling</u> will significantly delay (or prevent) toxin formation. For that reason, the country where the product is consumed may should still require the higher aqueous phase salt as a barrier to growth of non-proteolytic strains of <i>C. botulinum</i> if there are concerns about the ability of transporters, retailers or consumers to maintain time/temperature control <u>temperature abuse of the product.</u>

*Packaging material having an oxygen permeability greater than 2,000 cc/m²/24hrs at 24 °C and 1 atmosphere and must maintain a temperature of $\leq 4^{\circ}\text{C}$ and a labelled shelf-life not to exceed 14 days from the date initially packaged or packaging materials having an oxygen permeability greater than 10,000 cc/m²/24 hrs.

Appendix III**PROPOSED DRAFT GUIDELINES FOR THE CONTROL OF *CAMPYLOBACTER* AND
SALMONELLA IN CHICKEN MEAT****(At Step 5/8 of the Procedure)****Table of contents**

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6.	Risk profiles
7.	Primary production-to-consumption approach to control measures
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7.2	Availability of control measures
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1. INTRODUCTION

1. Campylobacteriosis and salmonellosis are the two most frequently reported food borne diseases worldwide and chicken meat is considered to be one of the most important food vehicles. The burden of the diseases and the cost of control measures are highly significant in many countries and contamination with zoonotic *Campylobacter* and *Salmonella*¹ has the potential to severely disrupt trade between countries.

2. The Guidelines apply a risk management framework (RMF) approach as advocated in the Codex *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CAC/GL 63-2007). “Preliminary Risk Management Activities” and “Identification and Selection of Risk Management Options” are represented by the guidance developed for control measures at each step in the food chain. Following sections on “Implementation” and “Monitoring” complete application of all the components of the RMF.

3. The Guidelines build on general food hygiene provisions already established in the Codex system and develop potential control measures specific for *Campylobacter* and *Salmonella* of public health relevance in chicken meat. In this context, the Guidelines give effect to the Codex Alimentarius Commission (CAC) commitment to developing standards that are based on sound science and risk assessment². Potential control measures for application at single or multiple steps are presented in the following categories:

- Good hygienic practice (GHP) - based. They are generally qualitative in nature and are based on empirical scientific knowledge and experience. They are usually prescriptive and may differ considerably between countries.

- Hazard-based. They are developed from scientific knowledge of the likely level of control of a hazard at a step (or series of steps) in a food chain, have a quantitative base in the prevalence and/or concentration of *Campylobacter* or *Salmonella*, and can be validated as to their efficacy in hazard control at the step. The benefit of a hazard-based measure cannot be exactly determined without a specific risk assessment; however, any significant reduction in pathogen prevalence and / or concentration is expected to provide significant human health benefit.³

4. Examples of control measures that are based on quantitative levels of hazard control have been subjected to a rigorous scientific evaluation and review in development of the Guidelines. Such examples are illustrative only and their use and approval may vary amongst member countries. Their inclusion in the Guidelines illustrates the value of a quantitative approach to hazard reduction throughout the food chain and, where the web-based decision tool is applied, the likely level of public health protection that may result from particular food-chain scenarios and choices of control measures at the national level.

5. The Guidelines are presented in a flow diagram format so as to enhance practical application of a primary production-to-consumption approach to food safety. This format:

- Demonstrates differences and commonalities in approach for control measures for *Campylobacter* and *Salmonella*.
- Illustrates relationships between control measures applied at different steps in the food chain.
- Highlights data gaps in terms of scientific justification / validation for GHP-based control measures.
- Facilitates development of HACCP plans at individual premises and national levels.

¹ Human pathogens of public health relevance only. For the purposes of this document, all references to *Salmonella* and *Campylobacter* relate only to human pathogens.

² Objective 2 “Promoting widest application of scientific principles and risk analysis” of the Codex Strategic Plan 2008-2013 and the first Statement of Principle relating to the Role of Food Safety Risk Assessment “Health and safety aspects of Codex decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances” Codex Procedural Manual,-

³ JEMRA, 2002. Risk Assessments of *Salmonella* in Eggs and Broiler Chickens. FAO/WHO Microbial Risk Assessment Series No. 2. Joint FAO/WHO Expert Committee for Microbial Risk Assessment. JEMRA, 2009. Risk Assessment of *Campylobacter* spp in Broiler Chickens, Technical Report. FAO/WHO Microbial Risk Assessment Series No. 12 Joint FAO/WHO Expert Committee for Microbial Risk Assessment

- Assists in judging the equivalence⁴ of control measures for chicken meat applied in different countries.

6. In doing so, the Guidelines provide flexibility for use at the national (and individual primary production and processing) level.

2. OBJECTIVES

7. The primary objective of these Guidelines is to provide information to governments and industry on the control of *Campylobacter* and *Salmonella* in chicken meat to reduce foodborne disease from this source whilst ensuring fair practices in the international food trade. The Guidelines provide a scientifically sound international tool for robust application of GHP- and hazard-based approaches to control of *Campylobacter* and *Salmonella* in chicken meat according to national risk management decisions.

8. It is not the intention of the Guidelines to set quantitative limits for *Campylobacter* and *Salmonella* in chicken meat in international trade. Rather, the Guidelines follow the example of the overarching Codex *Code of Hygienic Practice for Meat* (CAC/RCP 58-2005) and provide an “enabling” framework which countries can utilise to establish control measures appropriate to their national situation.

3. SCOPE AND USE OF THE GUIDELINES

3.1. Scope

9. These Guidelines apply to control of all *Campylobacter* and *Salmonella* that may contaminate chicken meat (*Gallus gallus*) and cause food borne disease. The primary focus is on chicken meat in the form of broiler carcasses and portions, with the exclusion of offals. These Guidelines can be applied to other classes of chickens, e.g. end-of-lays, as appropriate.

10. The Guidelines apply to all steps in a “primary production-to-consumption” food chain for chicken meat produced in typical “industrial” systems. While the biosecurity provisions in this document have been developed primarily for controlled-environment housing systems they also have applicability to other housing systems.

3.2. Use

11. The Guidelines develop specific guidance for control of *Campylobacter* and *Salmonella* in chicken meat according to a “primary production-to-consumption” food chain approach, with potential control measures being considered at each step, or group of steps, in the process flow. The Guidelines are supplementary to and should be used in conjunction with the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1 – 1969), the *Code of Hygienic Practice for Meat* (CAC/RCP 58-2005), the *International Code of Practice for the Processing and Handling of Quick Frozen Foods* (CAC/RCP 8-1976) and the *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004).

These general and overarching provisions are referenced as appropriate in the Guidelines and their content is not duplicated in these Guidelines.

12. The Guidelines systematically present GHP-based control measures and examples of hazard-based control measures. GHP is a pre-requisite to making choices on hazard-based control measures. Examples of hazard-based control measures are limited to those that have been scientifically evaluated as being effective under conditions of commercial use. Where no quantifiable outcome is mentioned for a specific control measure, it should be kept in mind that the effect may be different between *Salmonella* and *Campylobacter*. Countries should note that these hazard-based control measures are indicative only and the references provided should be reviewed to assist application. The quantifiable outcomes reported for control measures are specific to the conditions of particular studies and would need to be validated under local commercial conditions to provide a meaningful estimate of hazard reduction⁵. Government and industry can use choices on hazard-based control measures to inform decisions on critical control points (CCPs) when applying HACCP principles to a particular food process.

⁴ Codex *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CAC/GL 53-2003).

⁵ FAO/WHO, 2009. Technical Meeting on *Salmonella* and *Campylobacter* in chicken meat. 4-8 May 2009, Rome, Italy.

13. Several hazard-based control measures as presented in these Guidelines are based on the use of chemical decontaminants to reduce the prevalence and/or concentration of *Campylobacter* and/or *Salmonella* in broiler carcasses. The use of these control measures, including chemical decontaminants where relevant, in the primary production-to-consumption food chain, is subject to approval by the competent authority, where appropriate. Also these Guidelines do not preclude any other choice of a hazard-based control measure that is not included in the examples.

14. Provision of flexibility in application of the Guidelines is an important attribute. They are primarily intended for use by government risk managers and industry in the design and implementation of food safety control systems.

15. The Guidelines should be useful when judging the equivalence of different food safety measures for chicken meat in different countries

4. DEFINITIONS

Batch	A subset of a flock. A group of chickens sent together to a slaughterhouse at the same time.
Broiler	Birds of the species <i>Gallus gallus</i> selectively bred and reared for their meat rather than eggs.
Chicken	Birds of the species <i>Gallus gallus</i> .
Competitive exclusion⁶	The administration of defined ⁷ or undefined bacterial flora to poultry to prevent gut colonisation by enteropathogens, including <i>Salmonella</i> .
Crate	Container used to transport live chickens.
Epidemiological unit⁶	A group of animals with a defined epidemiological relationship that share approximately the same likelihood of exposure to a pathogen. This may be because they share a common environment (e.g. animals in a pen), or because of common management practices. Usually, this is a herd or a flock. However, an epidemiological unit may also refer to groups such as animals belonging to residents of a village, or animals sharing a communal animal handling facility. The epidemiological relationship may differ from disease to disease, or even strain to strain of the pathogen.
Establishment⁶	The premises in which animals are kept.
Flock⁶	A number of animals of one kind kept together under human control or a congregation of gregarious wild animals. For the purposes of the Terrestrial Code, a flock is usually regarded as an epidemiological unit.
Module	A structure containing crates / cages that facilitates loading and unloading.
On-line Reprocessing	Additional washing step that may be used (instead of trimming or washing off-line) as a control measure for faecal or ingesta contamination.
Partial depopulation	Incomplete harvest of chickens from a growing flock.
Total depopulation	Full harvest of chickens from a growing flock.

⁶ This definition is taken directly from the OIE Terrestrial Animal Health Code. www.oie.int

⁷ Probiotics are defined competitive exclusion products

5. PRINCIPLES APPLYING TO CONTROL OF *CAMPYLOBACTER* AND *SALMONELLA* IN CHICKEN MEAT

16. Overarching principles for good hygienic practice for meat are presented in the *Code of Hygienic Practice for Meat* (CAC/RCP 58-2005) section 4: *General Principles of Meat Hygiene*. Two principles that have particularly been taken into account in these Guidelines are:

- i. The principles of food safety risk analysis should be incorporated wherever possible and appropriate in the control of *Campylobacter* and *Salmonella* in chicken meat from primary production to consumption
- ii. Wherever possible and practical, Competent Authorities should formulate risk management metrics⁸ so as to objectively express the level of control of *Campylobacter* and *Salmonella* in chicken meat that is required to meet public health goals.

6. RISK PROFILES

17. Risk profiles are an important part of “Preliminary Risk Management Activities” when applying a RMF to a food safety issue. They provide scientific information to risk managers and industry in the design of food safety control systems that are tailor-made to individual food production and processing systems.

18. The contents of these Guidelines are predicated on two extensive risk profiles on *Salmonella* and *Campylobacter* in broiler chicken:

Food Safety Risk Profile for *Salmonella* species in broiler (young) chicken, June 2007⁹

Food Safety Risk Profile for *Campylobacter* species in broiler (young) chicken, June 2007¹⁰

7. PRIMARY PRODUCTION-TO-CONSUMPTION APPROACH TO CONTROL MEASURES

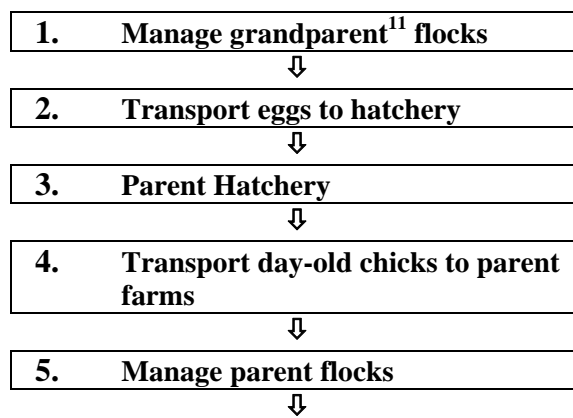
19. These Guidelines incorporate a “primary production-to-consumption” flow diagram approach so as to identify all steps in the food chain where control measures can potentially be applied. It facilitates a systematic approach to the identification and evaluation of all potential control measures. Consideration of all steps in the food chain allows different combinations of control measures to be developed. This is particularly important where differences occur in primary production and processing systems between countries and risk managers need the flexibility to choose risk management options that are appropriate in the national context.

7.1. Generic flow diagram for application of control measures

20. A generic flow diagram is presented in sequence on the following pages.

21. Individual premises will have variations in process flow and should adapt design of HACCP plans accordingly.

Process Flow Diagram 1: Primary production to Consumption

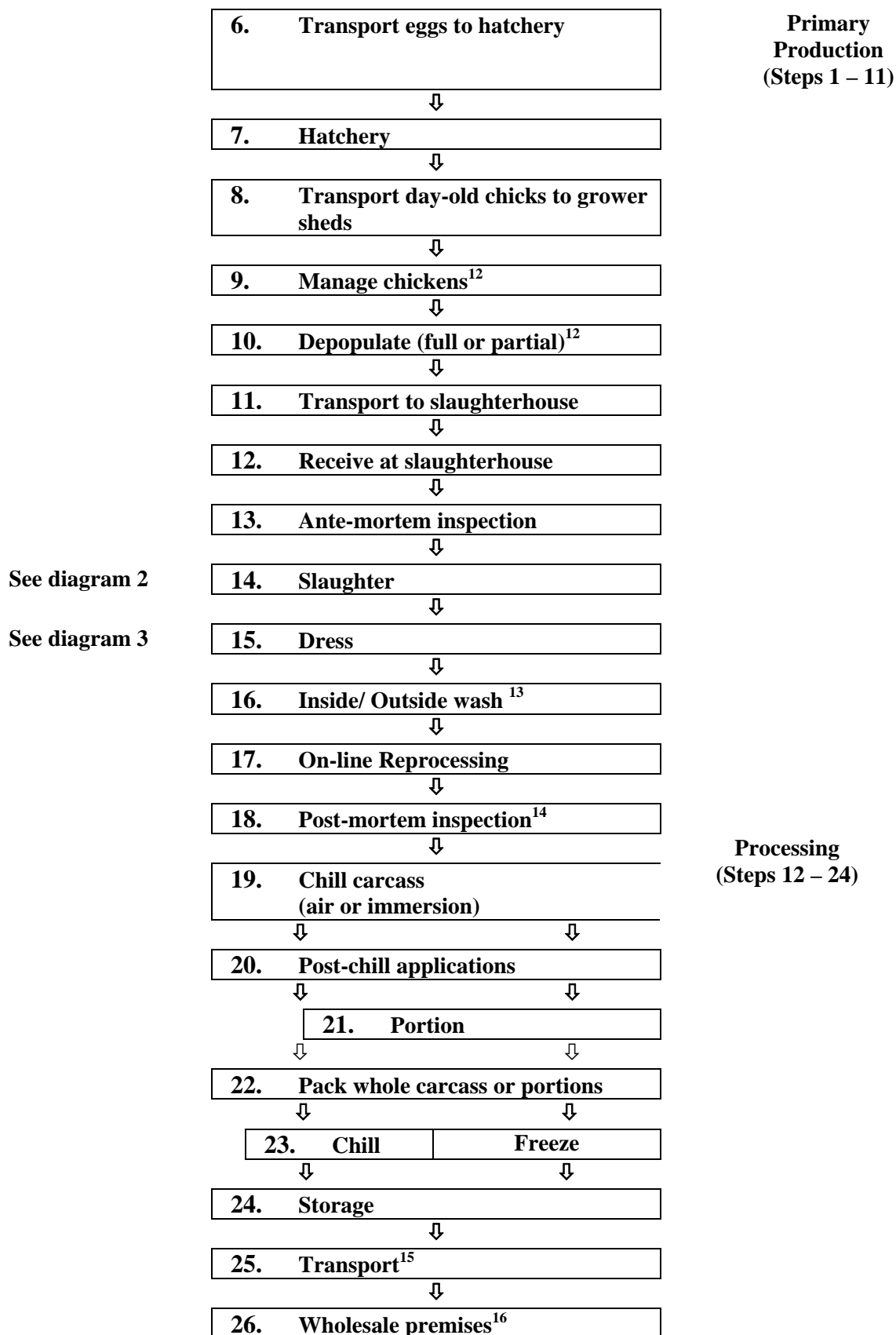


⁸ *Principles and Guidelines for the Conduct of Microbiological Risk Management* (MRM) CAC/GL 63-2007.

⁹ <ftp://ftp.fao.org/codex/ccfh40/fh40rpsl>

¹⁰ <ftp://ftp.fao.org/codex/ccfh40/fh40rpcb>

¹¹ Steps 1 – 4 also apply to great grandparents and elite breeding flocks



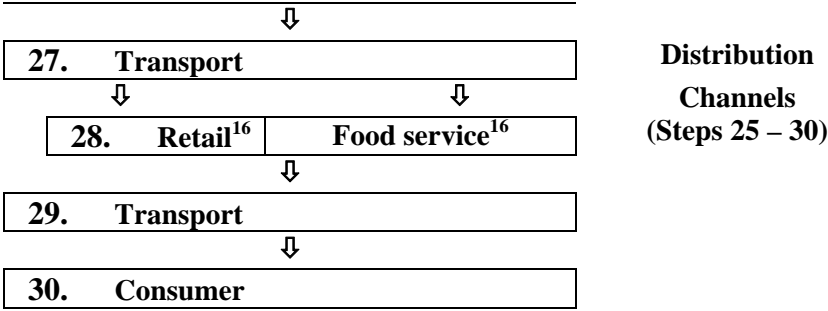
¹² May include ante-mortem inspection

¹³ May occur throughout the process

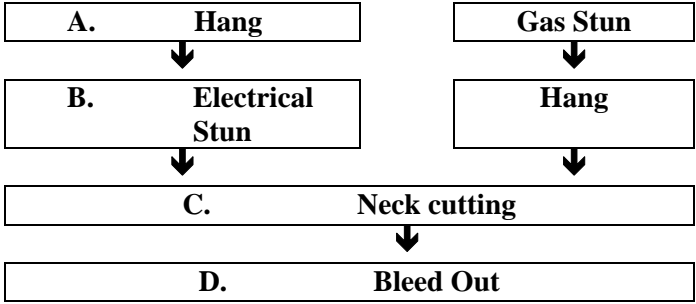
¹⁴ May occur before the inside / outside wash

¹⁵ May go direct to retail / food service

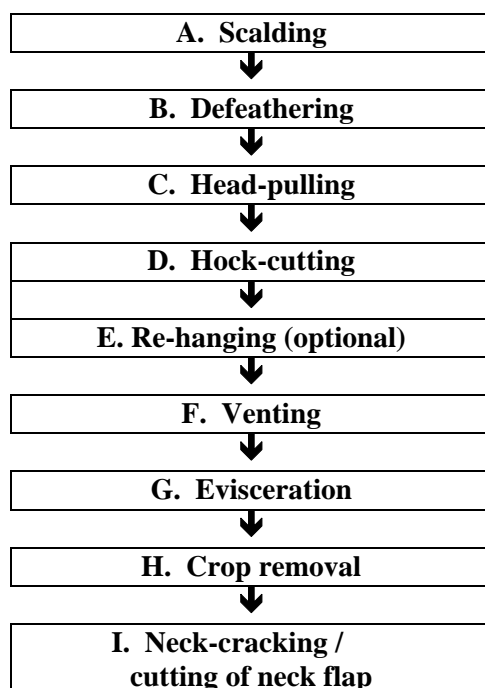
¹⁶ Including storage



Process Flow Diagram 2: Step 14 - Slaughter



Process Flow Diagram 3: Step 15 - Dress^{17, 18}



7.2. Availability of control measures at specific process flow steps addressed in these Guidelines

22. The intent of the following table is to illustrate where specific control measures for *Campylobacter* and/or *Salmonella* have been identified in relation to each of the process flow steps at different sections of the food chain. Control measures are indicated by a tick and their details are provided in these Guidelines or the OIE Terrestrial Animal Health Code¹⁹ in the case of GHP. A blank cell means that a specific control measure for *Campylobacter* and/or *Salmonella* has not been identified for the process flow step.

Availability of Specific Control Measures at Steps in the Process Flow

Process Step	GHP-based control measures		Hazard-based Control Measures	
	<i>Campylobacter</i>	<i>Salmonella</i>	<i>Campylobacter</i>	<i>Salmonella</i>
1. Grand Parent Flocks ↓		OIE +✓		
2. Transport to Hatchery ↓		OIE +✓		
3. Parent Hatchery ↓		OIE +✓		
4. Transport to Parent Farms ↓		OIE		
5. Manage Parents ↓		OIE		
6. Transport to Hatchery ↓		OIE +✓		
7. Hatchery ↓		OIE +✓		

¹⁷ These process steps are generic and the order may be varied as appropriate

¹⁸ Washing/rinsing may take place at a number of steps during dressing

¹⁹ Refer to web site: www.oie.int.

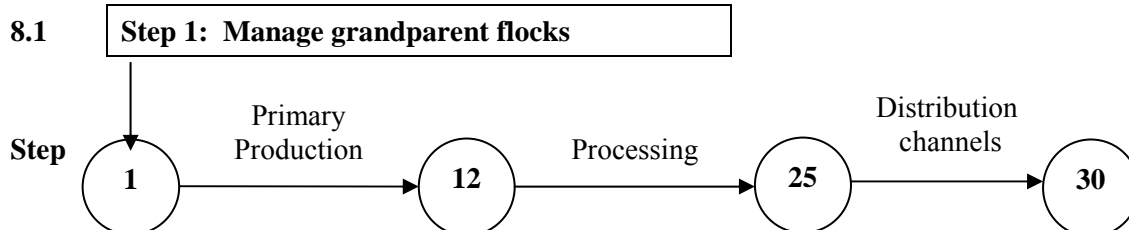
Process Step	GHP-based control measures		Hazard-based Control Measures	
	<i>Campylobacter</i>	<i>Salmonella</i>	<i>Campylobacter</i>	<i>Salmonella</i>
8. DOC to Grower Sheds ↓		OIE		
9. Manage Chickens ↓		OIE +✓	✓	
10. Depopulate ↓		OIE		
11. Transport to Slaughterhouse ↓	✓	OIE		
12. Receive at Slaughterhouse ↓		✓		
13. A-M Inspection ↓				
14. Slaughter ↓				
15. Dress ↓				✓
16. Inside / Outside Wash ↓			✓	✓
17. On-line Reprocessing ↓			✓	✓
18. P-M Inspection ↓				
19. Chill Carcass ↓	✓	✓	✓	✓
20. Post-Chill Applications ↓			✓	✓
21. Portion ↓		✓		
22. Pack ↓		✓	✓	✓
23. Chill or Freeze ↓			✓	
24. Storage ↓		✓		
25. Transport ↓				
26. Wholesale ↓		✓		
27. Transport ↓				
28. Retail or Food Service ↓		✓	✓	✓
29. Transport ↓				
30. Consumer		✓	✓	✓

8. CONTROL MEASURES FOR STEPS 1 TO 11 (PRIMARY PRODUCTION)

23. These Guidelines on primary production are supplementary to, and should be used in conjunction with, the:

- OIE Terrestrial Animal Health Code¹⁹ (applies to *Salmonella* only):
 - Chapter 6.4 “Hygiene and Disease Security Procedures in Poultry Breeding Flocks and Hatcheries”²⁰, and
 - Chapter 6.5 “Prevention, Detection and Control of *Salmonella* in Poultry”.
- *Code of Practice on Good Animal Feeding* CAC/RCP 54-2004.
- *Code of Hygienic Practice for Meat* CAC/RCP 58-2005

Note: specific provisions from the OIE Terrestrial Animal Health Code and Animal Feed documents are not provided in these Guidelines.

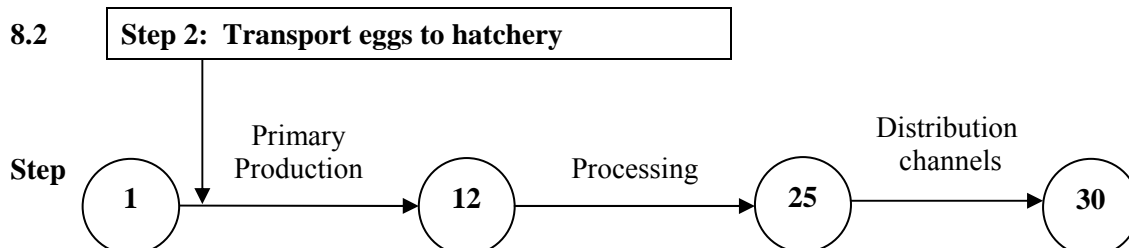


8.1.1 GHP-based control measures

24. Control of *Campylobacter* and *Salmonella* in grandparent flocks is strengthened by the application of a combination of biosecurity and personnel hygiene measures. The particular combination of control measures adopted at a national level should be determined in consultation with relevant stakeholders.

For *Salmonella*

25. The breeder flock should be kept free from *Salmonella* to prevent transmission of infection.
26. Where a flock is found to be *Salmonella*-positive a range of responses, detailed in the OIE Terrestrial Animal Health Code¹⁹, Chapter 6.5 “Prevention, Detection and Control of *Salmonella* in Poultry”, should be taken.
27. Feed should be treated, stored and delivered in a manner that minimises the presence of *Salmonella*. Breeder feed should preferably be delivered in dedicated vehicles used only for feed transports.
28. The use of control measures such as live and inactivated vaccines, competitive exclusion and some water and feed additives e.g. organic acids or formaldehyde may require approval by the competent authority, to permit their use.

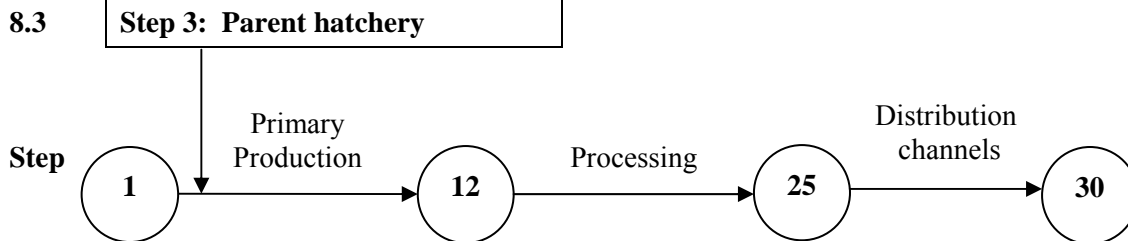


²⁰ Currently under revision.

8.2.1 GHP-based control measures

For *Salmonella*

29. Only eggs from *Salmonella*-negative flocks should be sent for hatching. When this is not practical, the eggs from *Salmonella*-positive flocks should be transported separately from other eggs.

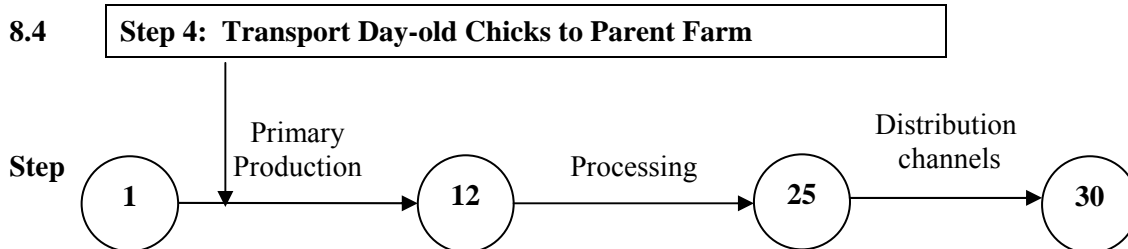


8.3.1 GHP-based control measures

For *Salmonella*

30. If possible, only eggs from *Salmonella*-negative flocks should be hatched.

31. Where the use of eggs from flocks that are known to be contaminated is unavoidable, they should be kept separate and hatched separately from eggs from other flocks. Trace back of contamination to the infected breeding flocks should be performed and control measures should be reviewed.

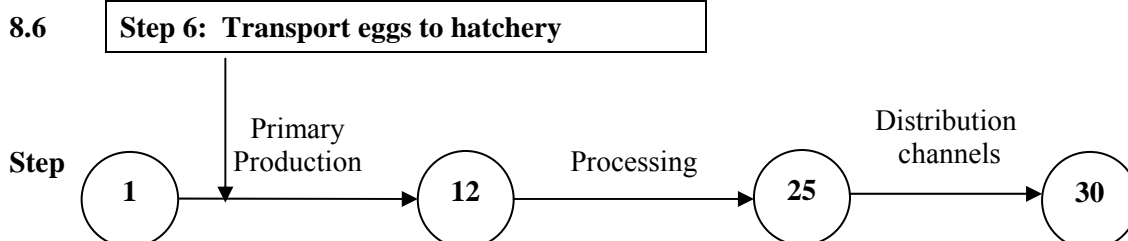


8.4.1 GHP-based control measures

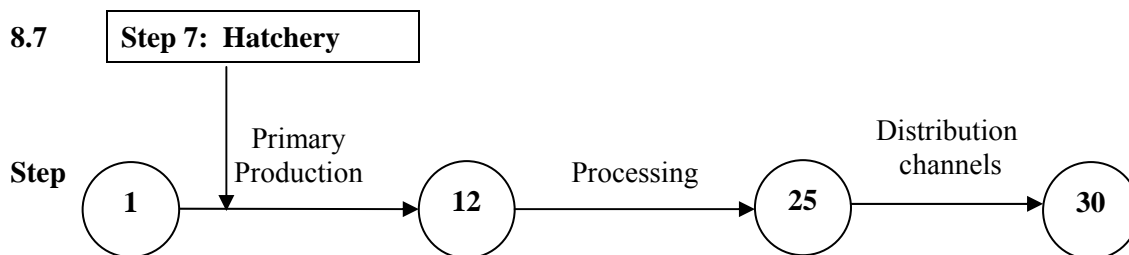
32. Personnel involved in the transportation of day-old chicks to parent flocks should not enter any livestock buildings and should prevent cross contamination of day old chicks during loading and unloading.

8.5 **Step 5: Manage parent flocks**

33. The control measures described at Step 1 apply at this Step.

**For *Salmonella***

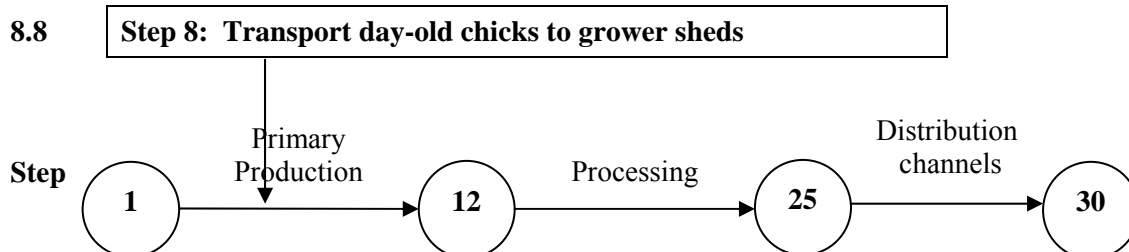
34. Only eggs from *Salmonella*-negative flocks should be sent for hatching. When this is not practical, the eggs from *Salmonella*-positive flocks should be transported separately from other eggs.



8.7.1 GHP-based control measures

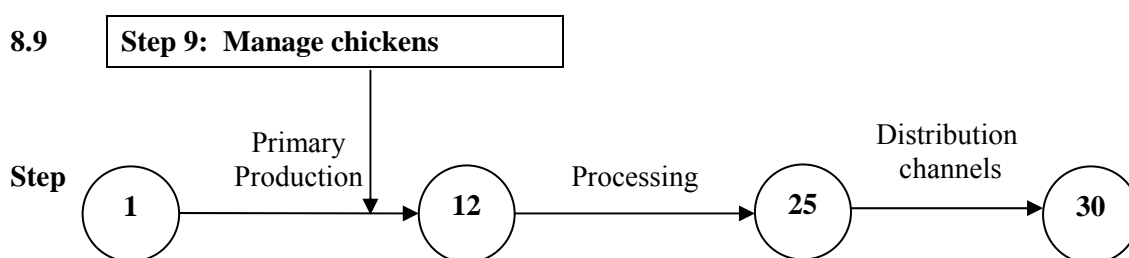
For *Salmonella*

35. Where the use of eggs from flocks that are known to be contaminated is unavoidable, they should be kept separate and hatched separately from eggs from other flocks and the chicks should be kept isolated from other flocks. Trace back of contamination to the infected breeding flocks should be performed and control measures should be reviewed.



8.8.1 GHP-based control measures

36. Personnel involved in the transportation of day-old chicks should not enter any livestock buildings.
37. Personnel should follow appropriate biosecurity procedures to avoid cross contamination of day old chicks during loading and unloading. All live bird transport crates and modules should be cleaned, disinfected and dried to the greatest extent practicable before re-use.



8.9.1 GHP-based control measures

38. Control of *Campylobacter* and *Salmonella* in flocks is strengthened by the application of a combination of biosecurity and personnel hygiene measures. The particular combination of control measures adopted at national level should be determined in consultation with relevant stakeholders. In particular, a pest control programme should be designed according to local conditions.

For *Salmonella*

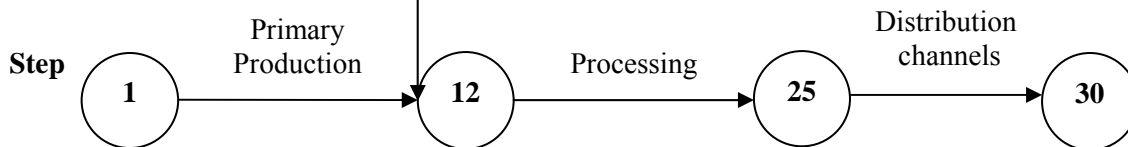
39. The use of specific control measures such as competitive exclusion bacteria, organic acids in pre-slaughter drinking water and organic acids or formaldehyde in feed, may require approval by a competent authority to permit their use.

8.9.2 Hazard-based control measures

For *Campylobacter*

40. The use of fly screens to reduce or eliminate fly infestation in broiler houses has been shown to decrease the percentage of *Campylobacter* spp.-positive flocks from 51.4% to 15.4%.

8.10 Step 10: Depopulate (full or partial)



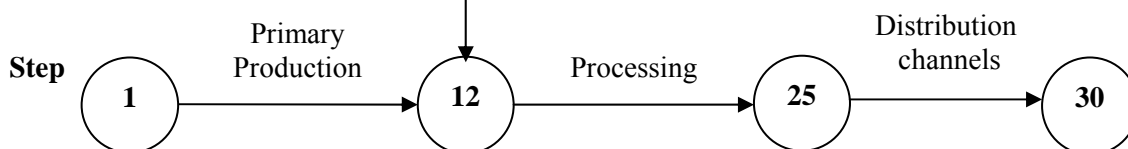
8.10.1 GHP-based control measures

41. Full depopulation of the flock should be carried out where possible. Where this is not practicable and partial depopulation is practised, particular attention should be paid to strict biosecurity and hygiene of catchers and the equipment they use.

42. It is preferable that sheds being partially depopulated are scheduled for catching ahead of those being fully depopulated on the same day.

43. When feed withdrawal is practised, water additives such as lactic acid may be used to lower post-harvest crop contamination.

8.11 Step 11: Transport to slaughterhouse



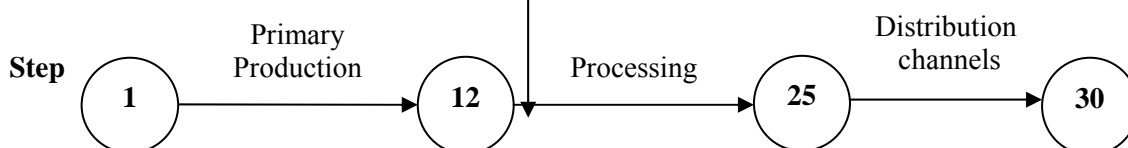
8.11.1 GHP-based control measures

For *Campylobacter* and *Salmonella*

44. All live bird transport crates and modules should be cleaned, disinfected and dried to the greatest extent practicable, before reuse.

9. Control measures for Steps 12 to 24 (Processing)

9.1 Step 12: Receive at slaughterhouse



9.1.1 GHP-based control measures

45. Where appropriate to the national situation, information about the flock, in particular about *Salmonella* and/or *Campylobacter* status should be provided in a timely manner to enable logistic slaughter and/or channelling of poultry meat to treatment.

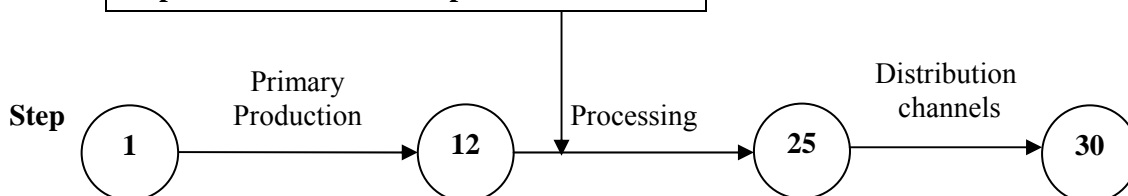
46. Flocks, where practical, should be slaughtered after 8-12 hours feed withdrawal in order to reduce the likelihood of contamination of carcasses by faecal material and ingesta.

47. Stress to chickens should be minimised, e.g. by dim lighting, minimal handling and avoiding delays in processing.

For *Salmonella*

48. If flocks that are positive for *Salmonella* are presented for slaughter this should be done in a manner that minimises cross contamination to other flocks, e.g. by slaughtering them at the end of the day, or all on one day and preferably the last day(s) of the working week or through other effective interventions.

9.2 Step 13: Ante-mortem inspection

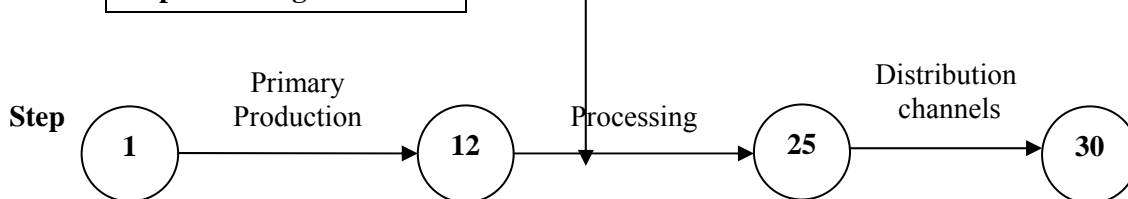


9.2.1 GHP-based control measures

49. Moribund, unhealthy or otherwise unsuitable chickens should not be processed.

50. Where numbers of chickens that are dead on arrival, moribund, unhealthy or otherwise unsuitable for processing exceed expected levels, the processor should notify the relevant responsible person, e.g. the competent authority, the farmer, veterinarian, catcher or transportation company, so that appropriate preventative and/or corrective action can be taken.

9.3 Step 14: Slaughter



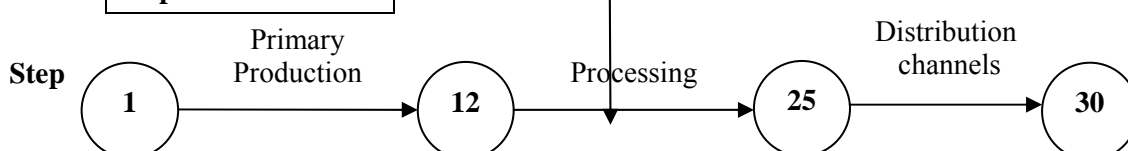
9.3.1 GHP-based control measures

51. Positive flocks may be diverted for specific processing and/or treatment according to national food safety policies.

52. Measures should be taken to minimise bird stress at live hanging, e.g. use of blue light, breast comforter, suitable line speed.

53. Bleeding should be substantially completed before scalding in order to prevent inhalation of scald water and to reduce the amount of blood entering the scalding tank.

9.4 Step 15: Dress



9.4.1 GHP-based control measures

54. So as to minimise contamination²¹ of carcasses, control measures may include:

- Washing with abundant potable running water
- Trimming
- Disposal or reprocessing of carcasses with extensive faecal contamination
- Use of chemical decontaminants approved by the competent authority
- Use of other physical methods approved by the competent authority.

55. These control measures can be applied alone or in combination at key process steps. Multiple control measures may not always be additive.

56. Where re-hang of carcasses is necessary, it is preferable that this is done mechanically so as to reduce cross-contamination.

57. All chickens which drop on the floor should be condemned, or reprocessed under specific conditions as determined by the competent authority. Any dropped product should trigger corrective actions as appropriate, such as trimming and re-washing.

9.4.1.1 Scalding

58. Contamination during scalding can be minimised by:

- The use of counter-current flow
- High flow rates of water with adequate agitation
- Having an optimum scalding temperature²² to minimise levels of *Campylobacter* and *Salmonella*
- Use of approved²³ chemicals e.g. pH regulators.

59. Other factors that should be taken into account when designing process control systems that minimise contamination during scalding include:

- Degree of agitation
- Use of multi-staged tanks
- Pre-scald wash systems
- Raising the temperature at processing breaks high enough for a long enough time to kill *Campylobacter* and *Salmonella* in the scalders
- Tanks being emptied and cleaned at end of a processing period
- Tanks being cleaned and disinfected at least daily
- Hygiene measures applied to reused/recycled water.

9.4.1.2 Defeathering

60. Cross contamination at defeathering can be minimised by:

- Ensuring appropriate fasting of chickens prior to slaughter
- Prevention of feather build-up on equipment
- Continuous rinsing of equipment and carcasses
- Regular adjustment and maintenance of equipment

²¹ Decontamination of carcasses will likely reduce, but not eliminate *Salmonella* and *Campylobacter* bacteria on broiler carcasses and broiler meat

²² Taking into consideration, suitability requirements (i.e. not affecting the skin)

²³ The competent authority may require processing aids to be approved.

- Particular attention to cleaning moving parts
- Regular inspection and replacement of plucker fingers.

9.4.1.3 Head pulling

61. Head pulling should be carried out in such a manner that leakage from the crop is prevented. Heads should be pulled downwards to reduce contamination due to crop rupture.

9.4.1.4 Evisceration

62. Rupture of the viscera and spread of faeces can be minimised by:

- Limiting size variation in batches so that birds of similar sizes are processed together
- Careful adjustment and regular maintenance of machinery.

9.4.1.5 Crop removal

63. Where possible, crops should be extracted in a manner that is likely to limit carcass contamination.

9.4.2 Hazard-based control measures

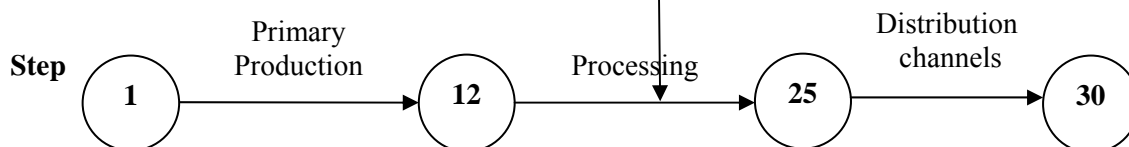
For *Salmonella*

64. Spray applications of 20-50 ppm chlorinated water following defeathering and carcass evisceration have been shown to reduce the prevalence of *Salmonella*-positive broiler carcasses from 34% to 26% and from 45% to 36% respectively.

65. Immersion in Tri Sodium Phosphate (TSP) has been shown to reduce prevalence of *Salmonella*-positive carcasses from 72% to 4%

9.5

Step 16: Inside/outside wash



9.5.1 GHP-based control measures

66. The inside and outside of all carcasses should be thoroughly washed, using pressure sufficient to remove visible contamination. Appropriate equipment should be used to ensure direct water contact with the carcass. The removal of contaminants may be aided by the use of brushing apparatus installed in line with the inside/outside wash.

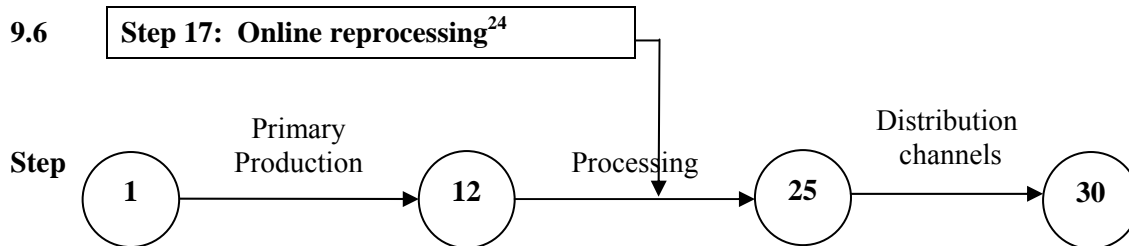
9.5.2 Hazard-based control measures

For *Campylobacter*

67. Carcass washing systems with 1-3 washers using water with 25-35ppm total chlorine have been shown to reduce levels of *Campylobacter* by about 0.5 log₁₀ CFU/ml of whole carcass rinse sample. Post-wash sprays using Acidified Sodium Chlorite (ASC) or TSP may further reduce *Campylobacter* levels by an average of 1.3 log₁₀ CFU/ml or 1.0 log₁₀ CFU/ml of whole carcass rinse sample respectively.

For *Salmonella*

68. Inside/outside washing using a spray application of 20-50 ppm chlorinated water has been shown to reduce the prevalence of *Salmonella*-positive broiler carcasses from 25% to 20%. A second inside/outside washing following upon the first resulted in a reduction of *Salmonella*-positive broiler carcasses from 16% to 12%.



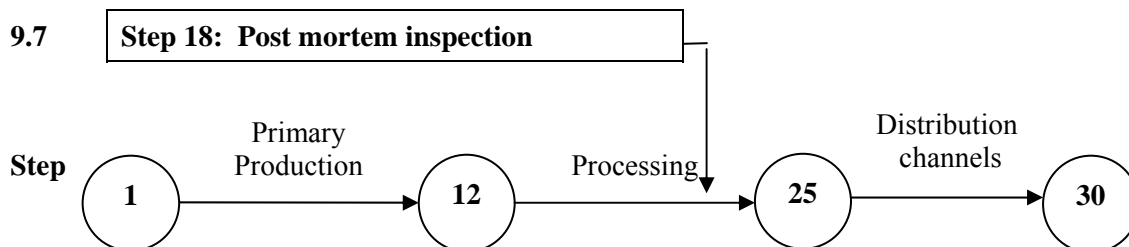
9.6.1 Hazard-based control measures

For *Campylobacter* and *Salmonella*

69. An on-line reprocessing spray system incorporating ASC has been shown to reduce *Campylobacter* in the whole carcass rinse sample by about 2.1 log₁₀ CFU/ml and to reduce the prevalence of *Salmonella*-positive carcasses from 37% to 10%.
70. Dipping carcasses in 10% TSP reduced *Campylobacter* by 1.7 log₁₀ CFU/g neck skin and the MPN of *Salmonella* was reduced from 1.92 log₁₀ CFU/g neck skin to undetectable levels.

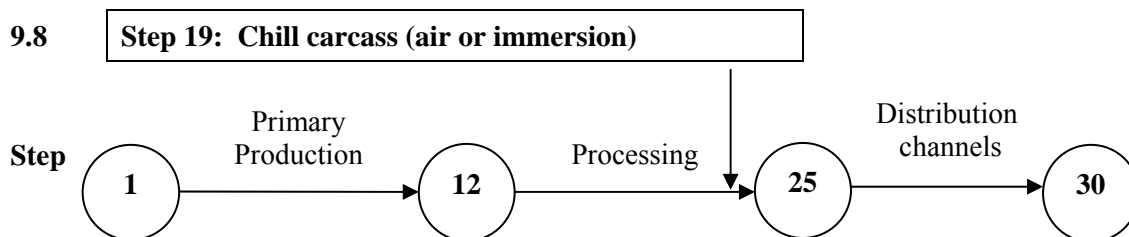
For *Salmonella*

71. The use of ASC (750ppm, pH 2.5, spray application) has in one industrial setting been shown to reduce *Salmonella* prevalence on carcasses from about 50% to levels below detection. In another industrial setting *Salmonella* prevalence was reduced by 18% (700-900ppm, pH 2.5, spray application).
72. A pre-chill ASC spray reduced the *Salmonella* prevalence on carcasses from 17% to 9%. Dipping carcass parts in ASC reduced the *Salmonella* prevalence from 29% to 1%.
73. Spray application of 8-12% TSP immediately before carcass chilling was shown to reduce *Salmonella* prevalence from 10% to 3%.



9.7.1 GHP-based control measures

74. Line speeds and the amount of light should be appropriate for effective post-mortem inspection of carcasses for visible contamination, organoleptic defects and relevant gross pathology.



9.8.1 GHP-based control measures

75. Chicken meat should be chilled, using air or immersion chilling, as quickly as possible to limit the growth of micro-organisms on the carcass. Design and operation of chilling systems should ensure that the target temperature of chilled carcasses is achieved by the time carcasses exit the chiller.

²⁴ Where approved by the Competent Authority.

9.8.1.1 Air chilling

76. If water sprays are used during air chilling to prevent desiccation of carcasses, they should be arranged to minimise cross contamination.

9.8.1.2 Immersion Chilling

77. Where considered necessary for control of *Campylobacter* and *Salmonella*, processing aids may be added to the chiller water²⁵. These should be approved by the competent authority and may include, among others:
- Free chlorine (as produced by chlorine gas, sodium-hypochlorite, calcium hypochlorite tablets or electrolytically generated hypochlorous acid)
 - Organic acids (e.g. citric, lactic or peracetic acid)
 - Other oxidants (e.g. hydrogen peroxide, peroxy acids, chlorine dioxide, acidified sodium chlorite)
78. The use of chlorine in the chill tank may not act as a decontaminating agent by acting directly on the contaminated carcass. However, there would be a washing off effect by the water itself, and the addition of chlorine at a level sufficient to maintain a free residual in the water would then inactivate *Campylobacter* and *Salmonella* washed off, preventing re-attachment and cross-contamination.
79. Water (including recirculated water) should be potable and the chilling system may comprise of one or more tanks. Chilled water can be used or ice may be added to it. Water flow should be counter-current and may be agitated to assist cooling and washing action.
80. Following chilling, any excess water should be allowed to drain away from the carcasses to minimise cross-contamination of carcasses at subsequent steps in the processing chain.

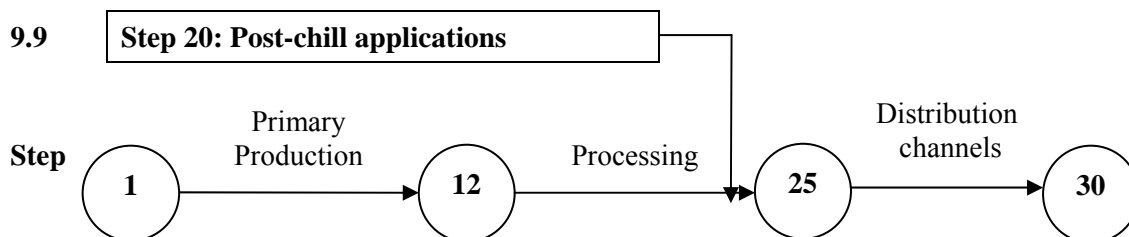
9.8.2 Hazard-based control measures

For *Campylobacter*

81. Forced air chilling (blast chilling) may reduce the concentration of *Campylobacter* on chicken carcasses by 0.4 log₁₀ CFU/carcass.
82. Immersion chilling has been shown to reduce concentrations of *Campylobacter* by 1.1-1.3 log₁₀ CFU/ml of carcass rinse.

For *Salmonella*

83. Immersion chilling in water treated with 20ppm or 34 ppm chlorine or 3ppm or 5 ppm chlorine dioxide reduced *Salmonella* prevalence from 14% in controls to 2% (20ppm Cl₂), 5% (34ppm Cl₂), 2% (3ppm ClO₂) and 1% (5 ppm ClO₂) respectively.



9.9.1 Hazard-based control measures

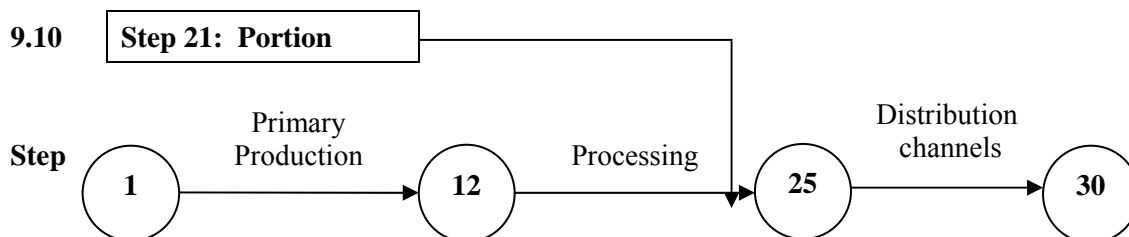
For *Campylobacter*

84. Immersing whole carcasses in 600-800ppm ASC at pH 2.5 to 2.7 for 15 seconds immediately post-chill, has been shown to reduce *Campylobacter* by 0.9-1.2 log₁₀ CFU/ml of whole carcass rinse sample.

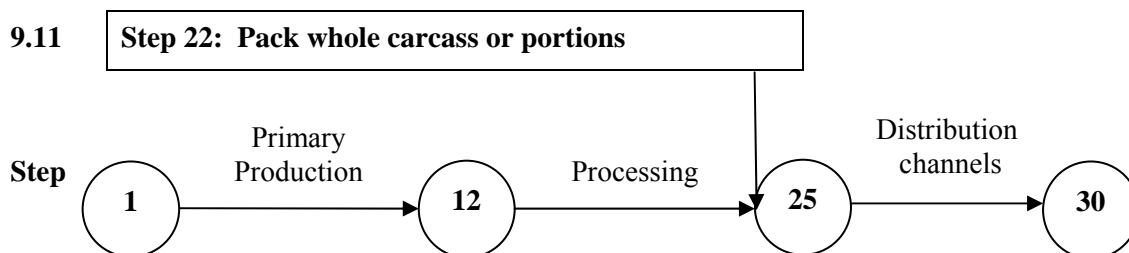
²⁵ A variety of processing aids are reviewed in: FAO/WHO: Benefits and Risks of the Use of Chlorine-containing Disinfectants in Food Production and Food Processing. FAO/WHO 2009

For *Salmonella*

85. The use of ASC (750 ppm, pH \approx 2.5, immersion dip) post-chill has been shown to reduce prevalence of *Salmonella* positive carcasses from 16% to a level below detection.⁵
86. Spray applications of 20-50 ppm chlorinated water have been shown to reduce the prevalence of *Salmonella*-positive carcasses from 10% to 4%.
87. A chlorine dioxide generating system applied as a dip at 5ppm post-chill resulted in 15-25% reduction in *Salmonella* prevalence.⁵
88. Spraying carcasses immediately after spin chilling with 10% TSP resulted in a reduction of *Salmonella* prevalence from 50% to 6%.

**9.10.1 GHP-based control measures****For *Salmonella***

89. Chilled carcasses should be held in temperature controlled environments and processed as soon as possible, or with the addition of ice to minimise the growth of *Salmonella*.

**9.11.1 GHP-based control measures**

90. Care should be taken when packaging to minimise external contamination of the pack, e.g. by use of leakproof packaging or absorbent pads.
91. Pre-packed chicken products intended to be cooked by the consumer should be labelled²⁶ with safe handling, cooking and storage instructions as appropriate to the National situation.

For *Salmonella*

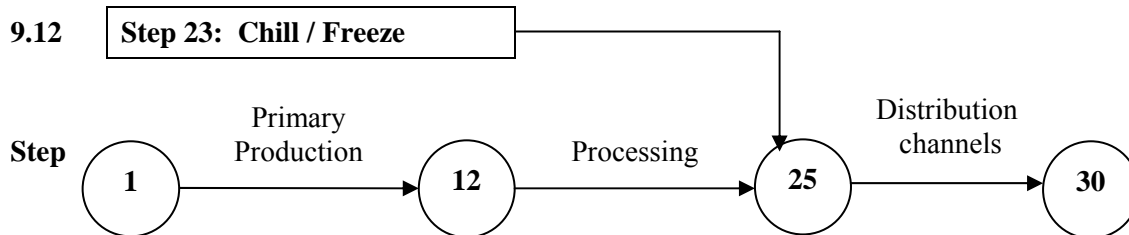
92. Chilled carcasses should be held in temperature controlled environments and processed as soon as possible or with the addition of ice to minimise the growth of *Salmonella*.

9.11.2 Hazard-based control measures**For *Campylobacter* and *Salmonella***

93. Various doses of Gamma rays or electron beams²⁷ applied to warm, chilled, or frozen carcasses have been shown to be effective at eliminating *Campylobacter* and *Salmonella*. Where irradiation is permitted, levels should be validated and approved by the competent authority.

²⁶ Refer to *General Standard for the Labelling of Pre-packaged Foods* (CODEX STAN 1-1985) and WHO's "Prevention of food-borne disease: Five keys to safer food"

²⁷ Refer to *General Standard for Irradiated Foods* (CODEX STAN 106-1983)

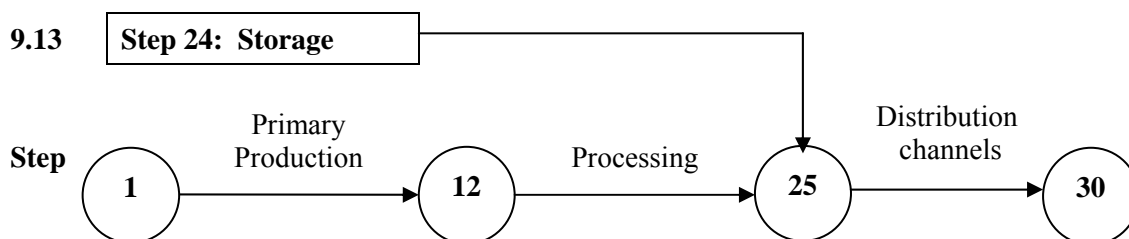


9.12.1 Hazard-based control measures

For *Campylobacter*

94. Freezing of naturally contaminated carcasses followed by 31 days of storage at -20 degrees C has been shown to reduce *Campylobacter* by 0.7 to 2.9 log₁₀ CFU/g.

95. Crust freezing using continuous carbon dioxide belt freezing of skinless breast fillets has been shown to give a reduction of *Campylobacter* of 0.4 log₁₀ CFU/fillet.



9.13.1 GHP-based control measures

For *Salmonella*

96. Products should be stored at temperatures preventing growth of *Salmonella*.²⁸

10. Control measures for Steps 25 to 30 (Distribution channels)

97. For GHP-based control measures for all aspects of transport, refer to the Recommended International Code of Practice – General Principles of Food Hygiene and the Code of Hygienic Practice for Meat.

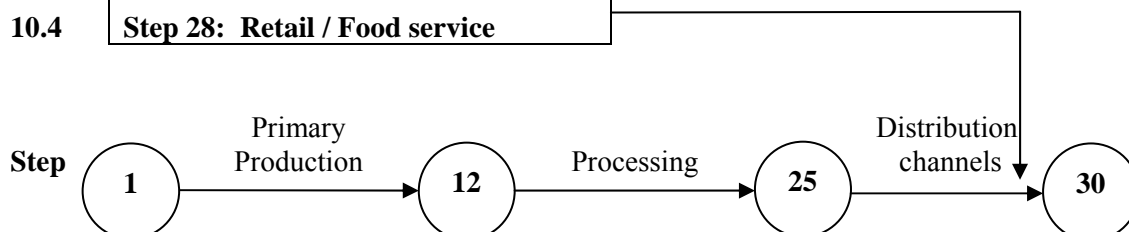
10.1 **Step 25: Transport**

10.2 **Step 26: Wholesale Premises**

For *Salmonella*

98. Products should be stored at temperatures preventing growth of *Salmonella*.

10.3 **Step 27: Transport**



10.4.1 GHP-based control measures

10.4.1.1 Retail

99. Hygiene measures should be in place to prevent cross-contamination between raw chicken meat and other food.

²⁸ Packaging in modified atmosphere does not prevent growth of *Salmonella* if temperature abuse occurs.

100. Retailers should separate raw and cooked products.

101. Hands should be washed and sanitized before and after handling raw chicken meat. Retailers may also provide customers with the means to sanitise hands after handling raw chicken meat packs.

102. Where product is packed at retail for individual selection by customers, packs should be leak-proof where possible. Extra packaging should be supplied at the display counter to allow customers to separate chicken from other purchases.

10.4.1.2 Food service

103. For GHP-based control measures, also refer to the *Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering* (CAC/RCP 39-1993).

104. Thawing of frozen chicken should be carried out in a manner that minimises the potential for growth of microorganisms and prevent cross contamination.²⁹ Washing of raw chicken carcasses should not be carried out as it is likely to spread contamination.

105. Food service operators should be fully trained in and aware of the differences between raw and cooked chicken products in relation to food safety and ensure separation at all times.

106. Food service operators should have hygiene measures in place that minimise cross-contamination between raw chicken and hands, contact surfaces and utensils, and should prevent contamination of other foods.

For Salmonella

107. Products should be stored at temperatures preventing growth of *Salmonella*.

10.4.2 Hazard-based control measures

For Campylobacter and Salmonella

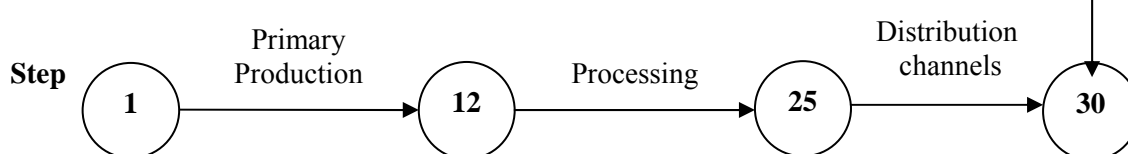
108. Chicken meat should be cooked according to a process that is capable of achieving at least a 7 log reduction in both *Campylobacter* and *Salmonella*.³⁰

10.5

Step 29: Transport

10.6

Step 30: Consumer



10.6.1 GHP-based control measures

109. Consumer education should focus on handling, hand washing, cooking, storage, thawing, prevention of cross contamination, and prevention of temperature abuse. The WHO Five keys to safer food³¹ assists in this process.

110. Special attention should be paid to the education of all persons preparing food, and particularly to persons preparing food for the young, old, pregnant and immuno-compromised.

²⁹ Refer to the *International Code of Practice for the Processing and Handling of Quick Frozen Foods* (CAC/RCP 8-1976)

³⁰ Cooking chicken meat thoroughly will eliminate *Campylobacter* and *Salmonella*. It has been shown that cooking chicken meat to 165°F (74°C) minimum internal temperature, with no hold time, will give at least a 7 log₁₀ reduction in both *Campylobacter* and *Salmonella*.

³¹ <http://www.who.int/foodsafety/consumer/5keys/en/>

111. The above information to consumers should be provided through multiple channels such as national media, health care professionals, food hygiene trainers, product labels, pamphlets, school curriculae and cooking demonstrations.

112. Washing of raw chicken in the kitchen should be discouraged so as to minimise the possibility of contamination of other foods and surfaces that come in contact with food and humans. Where deemed necessary washing of raw chicken carcasses and/or chicken meat, should be carried out in a manner which minimises the possibility of contamination of other foods and surfaces that come in contact with other foods and humans

113. Consumers should wash and disinfect food contact surfaces after raw chicken preparation to significantly reduce the potential for cross-contamination in the kitchen.

For *Salmonella*

114. Products should be stored at temperatures preventing growth of *Salmonella*.

10.6.2 Hazard-based control measures

For *Salmonella* and *Campylobacter*

115. Chicken meat should be cooked according to a process that is capable of achieving at least a 7 log reduction in both *Campylobacter* and *Salmonella*³²

11. RISK-BASED CONTROL MEASURES

116. GHP provides the foundation for most food safety control systems. Where possible and practicable, food safety control systems should incorporate hazard-based control measures and risk assessment. Identification and implementation of risk-based control measures can be elaborated by application of a risk management framework (RMF) process as advocated in the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (MRM) (CAC/GL 63-2007).

117. While these guidelines provide generic guidance on development of GHP-based and hazard-based control measures for *Campylobacter* and *Salmonella*, development of risk-based control measures for application at single or multiple steps in the food chain are primarily the domain of competent authorities at the national level. Industry may derive risk-based measures to facilitate application of process control systems.

11.1. Development of risk-based control measures

118. Competent authorities operating at the national level should develop risk-based control measures for *Campylobacter* and *Salmonella* where possible and practical.

119. Risk modelling tools used to explore risk management options and contribute to risk management decisions should be fit for purpose.

120. The risk manager needs to understand the capability and limitations of risk modelling tools they have selected³³.

121. When developing risk-based control measures, competent authorities may use the quantitative examples of the likely level of control of a hazard at certain steps in the generic food chain in this document, as a peer-reviewed scientific resource⁵.

122. Competent authorities formulating risk management metrics⁸ as regulatory control measures should apply a methodology that is scientifically robust and transparent.

11.2. Availability of a web-based decision tool

³² Cooking chicken meat thoroughly will eliminate *Campylobacter* and *Salmonella*. It has been shown that cooking chicken meat to 165°F (74°C) minimum internal temperature, with no hold time, will give at least a 7 log₁₀ reduction in both *Campylobacter* and *Salmonella*.

³³ **Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL 30-1999)**

123. FAO/WHO through JEMRA has developed a web-based decision support tool³⁴ for exploring the potential for development of risk-based control measures for *Campylobacter* and *Salmonella* in the raw chicken meat food chain at the national level.³⁵

124. This web-based tool can be used to estimate relative risk reduction and/or ranking consequential to:

- implementation of a specific control measure at a particular step in the food chain (from primary production through to consumption)
- implementation of a particular combination of control measures at different steps in the food chain
- modelling of different food chain scenarios to that presented in this document

125. Industry may also make use of the decision support tool when designing premises-specific food safety programmes that may differ in availability of specific control measures.

126. The user of the decision support tool at the national level should:

- Take responsibility for the appropriateness of the scientific data that is introduced
- Be aware of the uncertainty that inevitably accompanies risk modelling and in conjunction with the risk manager, use the web-based tool to *explore* risk management options and *inform* risk management decisions, rather than provide a prescriptive base
- Not use the tool to impose specific scientific assumptions

12. IMPLEMENTATION OF CONTROL MEASURES

127. Implementation⁸ involves giving effect to the selected control measure(s), development of implementation plan, communication on the decision on control measure(s), ensuring regulatory framework and infrastructure for implementation, and evaluation process to assess whether the control measure(s) have been properly implemented. Validation of control measures should be carried out prior to their implementation.

12.1 Validation of control measures

128. Refer to the *Guidelines for the Validation of Food Safety Control Measures* (CAC/GL 69 -2008).

Note: GHP-based control measures are not subject to validation.

12.2 Prior to Validation

129. Prior to validation of the hazard-based control measures for *Campylobacter* and/or *Salmonella*, the following tasks should be completed:

- Identification of the specific measure or measures to be validated. This would include consideration of any measures approved by the competent authority and whether any measure has already been validated in a way that is applicable and appropriate to specific commercial use, such that further validation is not necessary.
- Identification of any existing food safety outcome or target, established by the competent authority or industry. Industry may set stricter targets than those set by the competent authority.

12.3 Validation

130. Validation of measures may be carried out by industry and/or the competent authority.

131. Where validation is undertaken for a measure based on hazard control for *Campylobacter* and/or *Salmonella*, evidence will need to be obtained to show that the measure is capable of controlling *Campylobacter* and/or *Salmonella* to a specified target or outcome. This may be achieved by use of a single measure or a combination of measures. The *Guidelines for the Validation of Food Safety Control Measures* (CAC/GL 69 -2008) provides detailed advice on the validation process (section VI).

³⁴ Initiated after FAO/WHO Technical Meeting on *Salmonella* and *Campylobacter* in chicken meat. Rome 4-8 May 2009. **Trialed** November 2009. Reviewed April 2010.

³⁵ www.mramodels.org

12.4 Implementation

132. Refer to the *Code of Hygienic Practice for Meat* (CAC/RCP 58-2005), section 9.2.

12.4.1 Industry

133. Industry has the primary responsibility for implementing, documenting, applying and supervising process control systems to ensure the safety and suitability of chicken meat, and these should incorporate GHP and validated measures for control of *Campylobacter* and/or *Salmonella* (HACCP) as appropriate to national government requirements and industry's specific circumstances.

134. The documented process control systems should describe the activities applied including any sampling procedures, specified targets e.g. performance objectives or performance criteria, set for *Campylobacter* and/or *Salmonella*, industry verification activities, and corrective and preventive actions.

135. The competent authority should provide guidelines and other implementation tools to industry as appropriate, for the development of the process control systems.

12.4.2 Regulatory systems

136. The competent authority may choose to approve the documented process control systems for GHP and HACCP and stipulate verification frequencies. Microbiological testing requirements should be provided for verification of HACCP systems where specific targets for control of *Campylobacter* and/or *Salmonella* have been stipulated.

137. The competent authority may choose to use a competent body to undertake specific verification activities in relation to the industry's process control systems. Where this occurs, the competent authority should stipulate specific functions to be carried out.

12.5 Verification of control measures

138. Refer to section 9.2 of the *Code of Hygienic Practice for Meat* (CAC/RCP 58-2005) and section IV of the *Guidelines for the Validation of Food Safety Control Measures* (CAC/GL 69 -2008).

12.5.1 Industry

139. Industry verification should demonstrate that all control measures for *Campylobacter* and/or *Salmonella* have been implemented as intended. Verification should include observation of processing activities, documentary checks, and sampling for *Campylobacter* and/or *Salmonella* testing as appropriate.

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

12.5.2 Regulatory systems

141. The competent authority and/or competent body should verify that all regulatory control measures implemented by industry comply with regulatory requirements as appropriate for control of *Campylobacter* and/or *Salmonella*.

13. Monitoring and review

142. Monitoring and review of food safety control systems is an essential component of application of a risk management framework (RMF)⁸. It contributes to verification of process control and demonstrating progress towards achievement of public health goals.

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

13.1 Monitoring

144. Monitoring should be carried out at appropriate steps³⁶ in the food chain using randomized or targeted sampling as appropriate. Examples of the utility of monitoring systems for *Campylobacter* and/or *Salmonella* in broiler chickens may include:

- Sampling (e.g. environmental, blood, faecal) of breeders and hatcheries for determination of general *Salmonella* status.
- Faecal sampling of chickens prior to delivery to slaughter to determine flock status and permit logistic scheduling and/or channelling of positive chickens for specific processing steps e.g. to heat treatment or freezing.
- Caecal or cloacal sampling for *Campylobacter* at delivery to determine slaughter flock status for epidemiological investigations.
- Whole bird rinse, neck skin or other sampling at the end of primary processing (normally after immersion or air chilling) to verify compliance with hazard-based regulatory or company performance goals.
- Sampling of retail product to determine contamination trends post-processing.
- National or regional surveys for establishing baseline levels of contamination and assisting in formulation of regulatory performance goals within the food chain.

145. Regulatory monitoring programmes should be designed in consultation with relevant stakeholders, with the most cost-efficient resourcing option being chosen for collection and testing of samples. Given the importance of monitoring data in risk management, sampling and testing components should be standardized on a national basis and be subject to quality assurance.

146. The type of data collected in monitoring systems should be appropriate for the outcomes sought³⁷.

147. Monitoring information should be made available to relevant stakeholders in a timely manner e.g. to producers, processing industry, consumers.

148. Wherever possible, monitoring information from the food chain should be combined with human health surveillance data and food source attribution data to validate risk-based control measures and verify progress towards risk-reduction goals. Activities supporting an integrated response include:

- Surveillance of clinical salmonellosis and campylobacteriosis in humans.
- Epidemiological investigations including outbreaks and sporadic cases.

13.2 Review

149. Monitoring data on *Campylobacter* and *Salmonella* and associated risks should be reviewed on a periodic basis to provide information on the effectiveness of risk management decisions and actions. Results from *Campylobacter* and *Salmonella* spp. should be shared with competent authorities so that the information could be integrated in trend analysis.

150. Periodic review of monitoring data at relevant process steps should be used to inform future decisions on selection of specific control measures, and provide a basis for their validation.

151. Information gained from monitoring in the food chain should be integrated with public health surveillance, food source attribution data, and withdrawal and recall data, where available to evaluate and review the effectiveness of control measures.

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

³⁶ Recommendations on surveillance in poultry flocks for *Salmonella* are provided in the OIE Terrestrial Animal Health Code, Chapter 6.5 “Prevention, Detection and Control of *Salmonella* in Poultry

³⁷ Enumeration and sub-typing of microorganisms generally provides more information for risk management purposes than presence or absence testing.

13.2.1 Public health goals

153. Countries should consider the results of monitoring and review when setting public health goals³⁸ for food-borne campylobacteriosis and salmonellosis and when evaluating progress. Monitoring of the food chain in combination with source attribution and human health surveillance data are important components.

³⁸ International organisations such as WHO provide guidance for establishing and implementing public health monitoring programmes. WHO Global Foodborne Infections Network (GFN) <http://www.who.int/salmsurv/en/>

Appendix IV**PROPOSED DRAFT GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF
FOOD HYGIENE TO THE CONTROL OF VIRUSES IN FOOD****(At Step 3 of the Procedure)****INTRODUCTION****SECTION I- OBJECTIVES****SECTION II - SCOPE, USE AND DEFINITION**

2.1 SCOPE

2.1.1 *Food chain***2.1.2 *Roles of governments, industry and consumers***

2.2 USE

2.3 DEFINITIONS

SECTION III - PRIMARY PRODUCTION/ HARVESTING AREA

3.1 ENVIRONMENTAL HYGIENE

3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

3.3 HANDLING, STORAGE AND TRANSPORT

3.4 CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

4.1 LOCATION

4.2 PREMISES AND ROOMS

4.3 EQUIPMENT

4.4 FACILITIES

4.4.4 *Personnel hygiene facilities and toilets***4.4.4.1 *Changing facilities and toilets*****4.4.4.2 *Hand washing facilities*****SECTION V - CONTROL OF OPERATION**

5.1 CONTROL OF FOOD HAZARDS IN RELATION TO VIRAL CONTAMINATION

5.1.1 *Identify sources of viral contamination***5.1.2 *Implement effective control procedures*****5.1.3 *Monitor control procedures to ensure their continuing effectiveness*****5.1.4 *Review control procedures periodically, and whenever the operations change***

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.1 *Time and temperature control***5.2.2 *Specific process steps***

5.3 INCOMING MATERIAL REQUIREMENTS

5.4 PACKAGING

5.5 WATER

5.6 MANAGEMENT AND SUPERVISION

5.7 DOCUMENTATION AND RECORDS

5.8 RECALL PROCEDURES

SECTION VI – ESTABLISHMENT: MAINTENANCE AND SANITATION

6.1 MAINTENANCE AND CLEANING

6.1.1 General

6.1.2 Cleaning procedures and methods

6.2 CLEANING PROGRAMMES

6.3 PEST CONTROL SYSTEMS

6.4 WASTE MANAGEMENT

6.5 MONITORING EFFECTIVENESS

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INTRODUCTION

In recent years, viruses have been increasingly recognized as important causes of foodborne diseases. Viruses are very small micro-organisms, ranging in size from 18 to 400 nanometers, whereas bacteria generally range in size from 0.5 to 5 micrometers. In addition to size, other structural and biological differences exist between viruses and 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. Some human viruses can be transmitted directly from person-to-person, but also indirectly via virus-contaminated water, air, soil, surfaces or food. 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.

The human enteric viruses *most frequently involved in foodborne outbreaks* are norovirus (NoV) and hepatitis A virus (HAV), but 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 gastro-enteritis (e.g. NoV), enterically transmitted *hepatitis* (e.g. HAV, that migrates to the liver where it manifests disease), and a third group which replicates in the human intestine, but only cause illness after they migrate to other organs such as the central nervous system (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.

Noteworthy *characteristics* 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 10^7 particles per gram of stool) or in vomit, only a few viral/infectious particles (1 to 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.
- Viruses transmitted by the faecal-oral route can persist in foodstuffs or in the environment in soil, water, marine sediments or bivalve molluscs or on various inanimate surfaces for months. 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 survival to heat and drying.
- Hand sanitizing-agents may not be as effective for virus inactivation as compared to traditional hand washing practices. Moreover, 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 as common as is the case for many bacterial pathogens, such as *Salmonella* and *Campylobacter*, however, it does occur, e.g., for HEV.

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

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.

NoV¹. Data from at least 4 continents show that this is a major public health issue worldwide, although data from developing countries are sparse. HAV and rotavirus were identified as the major foodborne viruses that cause severe disease and significant mortality. Like HAV and NoV, HEV is transmitted by the fecal-oral route. HEV has been found to be responsible for sporadic and epidemic acute hepatitis, especially in developing countries. HEV is usually associated with contaminated drinking water, but has also been linked to eating raw deer meat, undercooked pork liver or wild boar meat. Other emerging viruses, such as the Severe Acute Respiratory Syndrome (SARS)-coronavirus, Nipah virus and Highly Pathogenic Avian Influenza virus (HPAI) H5N1, all of zoonotic nature, have been linked to food or postulated to be transmitted via food, but currently there is not sufficient data to elaborate on these emerging viruses in this context.

NoV Norovirus 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 seasonal peaks have been observed when looking at reported outbreaks, but other than in the case of shellfish these are particularly associated with healthcare infections rather than foodborne infections. The incubation period, i.e., the period between exposure to the virus and onset of symptoms, 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 in their stool while having symptoms, but this may also occur before the onset of symptoms, and may continue to shed 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 immunosuppressed individuals. Some NoV infections occur without resulting in apparent symptoms. A vaccine against NoV is not available at present.

HAV The hepatitis A virus is a cause of acute viral hepatitis. The incidence of HAV infection varies considerably among and within countries. In most developing countries, where hepatitis A infection is often 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 developed countries, however, HAV infections are less common as a result of increased standards of public health such as access to safe drinking water, sanitation and hygiene. In these countries very few persons are infected in early childhood, and the majority of adults remain susceptible to infection by HAV. Later in life, 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 HAV 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 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 illness. A vaccine against HAV is available. Some HAV infections occur without symptoms.

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

There are currently no effective, realistic and validated risk management options to eliminate viral contamination of both bivalves and fresh produce prior to consumption. Cooking of bivalves and fresh produce may not ensure total reduction of viral contamination. 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 and ready-to-eat foods).

Recently, the number of available detection methods for foodborne viruses in food matrices has increased, reflecting the recognition of the significance of foodborne viral disease. Since most foodborne viruses cannot be cultured *in vitro*, detection methods are based on molecular amplification techniques. Molecular methods, such as *real-time* reverse transcription polymerase chain reaction methods (real time RT-PCR) are rapid and are not labour intensive, and have facilitated the analysis of large numbers of samples. They can also be designed to be quantitative or semi-quantitative. However these methods can not be used to

distinguish between infectious and non-infectious virus material. While molecular detection methods may not be able to give an estimate of human health, these methods, once validated for the intended purpose and widely available, will be useful in outbreak investigations as well as in auditing and monitoring of control systems.

SECTION I- OBJECTIVES

The primary purpose of these guidelines is to give guidance on how to minimize the risk of illness arising from the presence of human enteric viruses in foods, and more specifically from norovirus (NoV) and hepatitis A virus (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 II - SCOPE, USE AND DEFINITION

2.1 SCOPE

2.1.1 Food chain

These guidelines are applicable to all foods (with a focus on ready-to-eat-food) throughout the food chain, from primary production through consumption, and are necessary to control human enteric viruses in foods. They should not compromise controls in place for any other pathogens.

2.1.2 Roles of governments, industry and consumers

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

2.2 USE

These guidelines should be used in conjunction with Good Hygienic Practices (GHPs), as specified in the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) and other applicable codes such as *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003) and *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

These guidelines follow the format of the Codex *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969). The annex to the control of hepatitis A virus (HAV) and norovirus (NoV) in bivalve molluscs (ANNEX I) and the annex to the control of hepatitis A virus (HAV) and norovirus (NoV) in fresh produce (ANNEX II) are supplements to these guidelines and include additional recommendations targeting at these specific virus-commodity combinations.

2.3 DEFINITIONS

For the purpose of these guidelines, refer to definitions of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) and *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and *Code of Hygienic Practice for fresh Fruits and Vegetables* (CAC/RCP 53-2003). In addition the following expressions have the meaning stated:

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

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

HAV – hepatitis A virus.

NoV - norovirus, formerly known as Norwalk-like virus or small round structured virus (SRSV).

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, which is normally eaten without further steps which could remove viruses or eliminate their infectivity.

SECTION III - 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 faecally contaminated water or soil or by infected food handlers.

3.1 ENVIRONMENTAL HYGIENE

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969), *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53 –2003).

Potential sources of environmental contamination should be identified prior to production activities. Sources of viral contamination of food at the primary production site include water, soil, manures or fertilizers (not properly treated) contaminated by faeces of human or animal origin. Sites that have potential to contaminate the production site via run-off, faecal material, (vomit-derived) aerosols or organic waste, for example, should be evaluated. During primary production, efforts should be made to ensure that food, e.g. bivalve molluscs and fresh produce has contact with clean water only. Assessment of environmental conditions is particularly important because subsequent steps during production may not be adequate to remove contamination.

3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969), *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53 –2003) and *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).

In addition to faecal contamination, food sources should also be protected from faecal contamination and vomit or vomit-derived aerosols, since products exposed to vomit or faecal matter in primary production areas could become contaminated and pose a risk to human health. Hygiene and health requirements should be followed to ensure that personnel who come directly into contact with food during production are not likely to contaminate the product.

The source of water used for 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. Irrigation water for fresh produce should come from a source determined to be safe and applied using an appropriate method. Also during harvesting of foods, clean water should be used.

Natural fertilizers may contain human pathogenic viruses that persist for weeks or months. Proper treatments such as heat, chemical or biological treatments of biosolids, manures and waste by-products will reduce the risk of potential human virus survival.

3.3 HANDLING, STORAGE AND TRANSPORT

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

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.

Harvesting containers should be in a good clean condition and should not be damaged.

3.4 CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969). In addition, the following aspects of personal hygiene in primary production areas are of major importance for food safety:

Food handlers with clinical symptoms of gastroenteritis (diarrhoea and/or vomiting) or with symptoms of acute hepatitis (fever, headache, fatigue combined with dark urine and light stools, or jaundice), should be excluded from food handling and should not be present in the food handling area, 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 the first diarrhea event and in any case directly after these events. Any person with symptoms of acute hepatitis should seek medical advice. In the case of gastroenteritis, staff should only be allowed to return to work after a period without symptoms of diarrhoea and vomiting (e.g., period of 48 hours) or in the case of hepatitis, staff should only be allowed to return to work after disappearance of jaundice, having had a complete medical examination. As shedding of viruses such as NoV or HAV, may continue after their symptoms have subsided (post-symptomatically) (e.g., NoV can be present in the stool on average for 4 weeks up to 8 weeks), training and instructions should be given to everybody on the infectivity, transmission and disinfection of foodborne viruses, and strict hand hygiene instructions should be followed at all times. When one of the staff members presents or calls in with symptoms of gastroenteritis or hepatitis, other staff members may also be (asymptomatically) infected. When a family/house member of a staff member has symptoms of gastroenteritis or hepatitis, the staff member may be (asymptomatically) infected too, and/or serve as a vector carrying infectious virus on their person. In these specific situations, all staff members should comply with strict hand hygiene measures, and in the case of hepatitis all staff members should seek medical advice. Actually compliance with acceptable standards of hand hygiene practice remains important at all times. Vaccination against hepatitis A should be recommended to immunize food handlers 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. A regular monitoring for HAV infection of food handlers is recommended especially in endemic areas.

SECTION IV - 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.

4.1 LOCATION

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

4.2 PREMISES AND ROOMS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

4.3 EQUIPMENT

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

4.4 FACILITIES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969), in addition:

4.4.4 Personnel hygiene facilities and toilets

4.4.4.1 Changing facilities and toilets

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

- be located in proximity to the production area,
- not be open directly to food handling areas,
- be in sufficient numbers to accommodate personnel,
- be culturally appropriate,
- be of appropriate design to ensure hygienic removal of wastes,
- have adequate means for hygienically washing and drying hands,
- be maintained under sanitary conditions and good repair,

- be appropriately cleaned and disinfected (see 6.2 cleaning programmes) and
- preferably be separate for guests and employees of the establishment.

4.4.4.2 Hand washing facilities

Hand washing facilities should be within close proximity to the toilets and positioned so that the employee must pass by them before returning to the food handling area. A reminder of the hand washing instructions should be visibly present for all users of these facilities.

SECTION V - 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 IN RELATION TO VIRAL CONTAMINATION

Control of enteric virus such as NoV and HAV in food will typically require a stringent application of Good Hygienic Practice, and other supportive programs. These prerequisite programs, together with HACCP provide a successful framework for the control of enteric virus.

5.1.1 Identify sources of viral contamination

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

In addition with regard to risks for virus contamination some of the specific areas to be addressed are as follows:

- Food comes in contact with faecal material or faecally contaminated water of either human or animal sources during the production phase (irrigation, washing, freezing/icing).
- A food handler handles (ingredients for) food without compliance with strict hygienic practice while being contagious with viruses or after being in contact with faecal material or vomit matter, or after being in contact with other infected staff members. This is especially important when food is intimately handled by bare hands instead of utensils, such as commonly practiced in food service establishments. A person can be contagious prior, during or after illness or even without experiencing symptoms.
- A person vomits within the food production or preparation area.
- Cleaning and disinfection after a vomiting event in the production or food preparation area.
- Cleaning and disinfection after an event of diarrhoea of an employee, visitor or guests of the establishment.
- Raw ingredients contaminated with viruses are introduced into the premises, as this may lead to contamination of food handler's hands, or other food or surfaces.

5.1.2 Implement effective control procedures

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

In addition with regard to procedures to control viruses in food some of the specific areas to be addressed are as follows:

- Only potable water should be used as an ingredient in food and in operations involving food contact surfaces for the production of food to avoid food becoming contaminated with faecal material of human or animal origin.
- Exclusion of food handlers, or any person, with clinical symptoms of gastroenteritis (diarrhoea and/or vomiting) or with symptoms of acute hepatitis (fever, headache, fatigue combined with dark urine and light stools, or jaundice), from food handling, or from being present in the (primary) production area. A person should be excluded from the primary production or preparation area, if possible, before the onset of vomiting or the first diarrhoea event and in any case directly after these events. Food handlers should only be allowed to return to work after a period without symptoms of gastroenteritis (e.g. period of 48 hours) or in case of symptoms of hepatitis following medical advice.

- Any food possibly contaminated by vomit particles or by aerosols containing vomit particles should be disposed of. Any food handled by the ill person during that day (or the day before) should be considered a risk and should be discarded.
- In case of gastroenteritis, allow recovered persons to return to work only after a period (e.g. of 48 hours) without symptoms of diarrhoea and vomiting provided that they comply with strict hand hygiene instructions, and are preferably assigned temporarily to activities not directly involving food handling. In the case of hepatitis, allow individuals to return to work only after disappearance of jaundice, under the condition that they comply with strict hand hygiene plus a medical examination and advice.
- Vaccination against HAV infection can be considered as a preventive measure, 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.
- Have cleaning and disinfection programmes which include disinfectant agents able to inactivate enteric viruses and disinfect equipment, and include a checklist of which surfaces should be disinfected (see 6.1.2).
- Regular checking for HAV infection of workers of food service establishments could be useful, where feasible and appropriate.

5.1.3 *Monitor control procedures to ensure their continuing effectiveness*

5.1.4 *Review control procedures periodically, and whenever the operations change*

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 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

5.2.1 *Time and temperature control*

Processes aimed at inhibition of microbial growth, such as cooling or freezing, will not affect virus infectivity enough to yield safe foods (e.g., for HAV there is less than 1 log reduction in infectious units after 5 cycles of freezing and thawing and less than 1 log after storage at refrigerator temperatures for 1 week).

The effects of heat treatment on virus infectivity in foods are highly dependent on virus (sub)-type and food matrix. Commonly used cooking procedures are considered adequate treatments to destroy viral infectivity in most 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; 71.7 °C for 15–20 seconds) pasteurization, but NoV and HAV are unlikely to be completely inactivated at those treatments. Complete inactivation also depends upon initial levels of any viral contaminant.

5.2.2 *Specific process procedures*

HAV is very stable at low pH and more than 3 log inactivation may occur only at pH < 3, a pH that is not always acceptable for the sensorial quality of foods.

Reducing water activity (RWA): RWA may accelerate degradation or inactivation rates of viruses, the effects of RWA on virus infectivity in foods (or on fomites) are, however, highly dependent on virus (sub)type and food matrix and can not yet be considered an effective generic measure to reduce viral loads.

High hydrostatic pressure (HHP): The effects of HHP on virus infectivity in foods are highly dependent on virus (sub)type and food matrix and may be considered a measure to reduce viral loads for some virus(types) present in specified matrices.

Gamma Irradiation: Studies on the effect of irradiation on virus infectivity in foods are limited. 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.

Newer technologies or combinations are being developed. Prior to implementation in the food production chain, virucidal treatments should be validated with the hazard/food combination and if possible to use methodologies that can be used to distinguish between infectious and non-infectious material to ensure that

they are effective and can be applied consistently. Some treatments might be subject to prior approval by the competent authority.

5.3 INCOMING MATERIAL REQUIREMENTS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

Preferably only use raw ingredients from production plants with an adequate food safety management system, this includes the use of clean or potable water (see also annex I and II), adequately trained personnel, high personnel hygiene and good health supervision system.

5.4 PACKAGING

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

Modified atmosphere packaging (MAP) is a method that aims at inhibition of microbial growth. Since human viruses do not grow in foods, this method is not a suitable strategy to reduce virus infectivity.

5.5 WATER

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

5.6 MANAGEMENT AND SUPERVISION

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

All employees and managers should understand the importance of personnel hygiene to reduce the chance of viral contamination of food, i.e., importance of compliance with hand washing instructions, exclusion from the premises of food handlers or any persons with symptoms of gastroenteritis or acute hepatitis or those recovering from these infections, and how to disinfect surfaces when contaminated. It is advisable to have documentation of the hand-washing instructions given to each new starting employee, in addition to displaying hand-washing instructions in each of the personnel hygiene facilities and toilets. Regular observation of employee hand washing prior to entry into food handling areas should be practiced.

5.7 DOCUMENTATION AND RECORDS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

5.8 RECALL PROCEDURES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

SECTION VI – ESTABLISHMENT: MAINTENANCE AND SANITATION

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

RATIONALE: Many disinfectants recommended for use in food establishments are not effective against enteric viruses, such as the non-enveloped NoV or HAV.

6.1 MAINTENANCE AND CLEANING

6.1.1. General

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

6.1.2 Cleaning procedures and methods

Cleaning: Each establishment should have a documented regular cleaning procedure. Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*. In addition, for

Disinfection: establishments should also have a procedure for the disinfection of surfaces possibly contaminated with enteric viruses, such as NoV or HAV. Disinfection, preceded by cleaning, should take place after each vomiting event in premises or rooms, after reported symptoms of gastroenteritis (diarrhoea and/or vomiting) or symptoms indicative of hepatitis (fever, headache, fatigue combined with dark urine and light stools, or jaundice) of one or more of the employees. Cleaning and disinfection should include all surfaces both in the bathroom and (as a preventive measure) in food production areas (e.g., equipment, utensils, telephones, keyboards, etc.), as viruses in vomit, aerosols and faecal matter are persistent and can stay infectious for a long period.

Ideally, disposable gloves, a disposable facemask and a disposable apron should be worn during cleaning and disinfection by a person trained in cleaning-up infectious material, because of the exposure to highly infectious pathogens. Any spillage or contamination with faeces or vomit should be dealt with immediately, and food handling in the same area(s) should be stopped. Dispose of any food possibly contaminated by vomit particles or by aerosols containing vomit particles. Any food handled by the ill person during that day (or the day before (NoV), or longer (HAV)) could be a risk and disposal of implicated products should be considered. Absorbent material such as paper towels and tissues may be used to limit the spread of liquid soiling and then be disposed of. Surfaces should be cleaned prior to disinfection to ensure effective disinfection.

For surface disinfection, solutions of ≥ 1000 ppm free chlorine consistently show > 3 log reduction in viral infectivity within 5 min at room temperature. Freshly constituted hypochlorite solutions (e.g., using tablets) are preferable. The solution is corrosive, and needs to be thoroughly removed afterwards. 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.

UV irradiation at >40 mWs/cm² (=mJ/cm²) causes > 3 log 10 reduction of feline calicivirus (FCV) and murine norovirus (MNV), which have been used as models for human NoV and HAV, and this treatment can be considered for reducing viral infectivity on surfaces, in aerosols and in water.

Most other surface disinfectants lack efficacy (i.e., consistently cause less than a 3 log reduction in infectivity) against enteric viruses at manufacturer's recommended concentrations and exposure times. In fact, it is well recognized that the majority of chemical disinfectants currently used in both institutional, domestic environments, and in the food industry do not effectively inactivate HAV. New compounds and/or methods can be considered if they show virucidal activity of >3 log for non-enveloped viruses in standardized carrier tests.

6.2 CLEANING PROGRAMMES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

The programmes should take into account the specific cleaning and disinfection procedures that should be applied to ensure elimination of virus infectivity. These cleaning and disinfection 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), and be applied immediately after a vomiting event or after notification of illness (gastro-enteritis, hepatitis) of food handlers. The disinfection should be thorough on all surfaces (e.g., equipment, utensils, telephones, keyboards, etc.) that may have been contaminated by ill persons or by (airborne-transmitted) vomit particles, using effective disinfection agents (see also above, 6.1.2.).

6.3 PEST CONTROL SYSTEMS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

6.4 WASTE MANAGEMENT

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

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.

6.5 MONITORING EFFECTIVENESS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

SECTION VII – 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 hygiene control by food handlers, particularly in relation to the prevention of NoV and HAV contamination.

7.1 HEALTH STATUS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

Diarrhoea and vomiting can be caused by infectious (e.g., NoV, *Staphylococcus*, *Salmonella*) or non-infectious agents (e.g., toxins). 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 infectious. Persons reporting 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 (see 3.4). The most important examples of enteric viruses related to gastroenteritis and hepatitis that can be transmitted via food (handlers) are NoV and HAV, respectively. Refer to the Introduction-Section of these guidelines for the incubation and contagious periods of both of these viruses.

7.2 ILLNESS AND INJURIES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*. In addition, refer to *Section III, chapter 3.4 of this document*.

7.3 PERSONAL CLEANLINESS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

Personal hygiene of food handlers is critical. Food handlers should be aware of the high infectivity 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).

Hands should be washed before handling of food. The most effective way of preventing spread of viruses is thorough hand washing. Hands should be lathered with soap then washed for a minimum of 20 seconds with running water.²

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, cleaning toilets) or after being in contact with vomit. The use of disposable hand towels should be encouraged.

Gloves, if used in the handling of food products, should be maintained in a sound, clean and sanitary condition. The wearing of gloves does not exempt the operator from having thoroughly washed hands.

7.4 PERSONAL BEHAVIOUR

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*.

In addition, money, tickets, etc., should not be handled at the same time as food. Hands should be thoroughly washed after any contact with contaminated material before preparing food and to put new gloves.

7.5 VISITORS

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

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

Avoid presence of non-authorized persons during food handling or on premises where food is grown, harvested, stored or prepared.

SECTION VIII – TRANSPORTATION

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

SECTION IX – PRODUCT INFORMATION AND CONSUMER AWARENESS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969). Countries should give consideration to labeling of certain ready-to-eat foods, such as raw bivalve molluscs, so that consumers can make an informed choice with regard to these products and be adequately informed about the risks associated with the consumption of raw or partially treated products that may be contaminated with viruses during production.

SECTION X – TRAINING

OBJECTIVES: Those workers engaged in food growing 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: Workers may be less familiar with controls specific to enteric viruses.

10.1 AWARENESS AND RESPONSIBILITIES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

In addition, it is the responsibility of the employee to inform the employer when ill with diarrhoea or vomiting complaints or symptoms indicative of hepatitis. It is also the responsibility of the employee to adhere to strict hand washing instructions after returning from the toilet or after being in contact with faecal or vomit matter. It is the responsibility of the managers to educate and train their employees, to keep control of the level of awareness of the training content, and to have both cleaning and disinfection programmes operational. It is the responsibility of employers and managers to carry out some monitoring to ensure that employees are undertaking good hygiene practice. Monitoring includes regular observation of employee hand washing prior to entry into food handling areas.

10.2 TRAINING PROGRAMMES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

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 even after recovery from clinical symptoms; the possibility of asymptomatic shedding; the infectivity of vomit; procedures for cleaning and disinfection of contaminated surfaces; the need for strict compliance with hand washing instructions at all times and the need for washing of hands after being in contact with faecal or vomit matter. Training should also emphasize that if a staff member calls in sick, it is likely that other members may be (asymptomatically) infected too, and, in addition, if a household member is ill, it is likely that the staff member may be (asymptomatically) infected too and strict hand hygiene is required. Staff members should also be taught to stay away from work and not to have direct contact with any ready-to-eat food if they have symptoms of gastroenteritis or hepatitis. Moreover training should also emphasize the need to the extent possible, to keep children away from food growing fields and food preparation areas in HAV endemic areas. Training materials should be provided to those inspectors or other relevant authorities who inspect fields, post harvest processing plants, and eating facilities.

10.3 INSTRUCTION AND SUPERVISION

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

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

10.4 REFRESHER TRAINING

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

ANNEX I

CONTROL OF HEPATITIS A VIRUS (HAV) AND NOROVIRUS (NOV) IN BIVALVE MOLLUSCS

INTRODUCTION

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 norovirus (NoV) binds specifically to bivalve molluscs tissue receptor sites, which could explain why some viruses persist after depuration procedures as currently practiced in the industry. Furthermore, studies indicate that there may even be a risk of infection if contaminated bivalve molluscs are consumed partially treated. 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 by improving the water quality in bivalve molluscs harvesting areas.

SECTION I- OBJECTIVES

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 II - SCOPE, USE AND DEFINITION

2.1 SCOPE

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.

In many instances, these control measures are articulated in a general manner in the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) as part of the general strategy for the control of foodborne pathogens in all foods. More specific control measures for bivalve molluscs can be found in the *Code of Practice for Fish and Fishery products* (CAC/RCP 52-2003, Section 7) and the “*Standard for Live and Raw bivalve Molluscs* (Codex Stan 292-2008) and the WHO Guidelines for the safe use of wastewater, excreta and grey water. Volume 3: Wastewater and excreta use in aquaculture (World Health Organization 2006 ISBN 92 4 154684 0; www.who.int/water_sanitation_health/wastewater/gsuweg3/en/index.html). In providing these guidelines, it is assumed that these General Principles of Food Hygiene are being implemented. Those principles that are restated reflect the need for special attention for the control of viruses.

2.2 USE

This annex follows the format of the Codex *Recommended International Code of Practice - General Principles of Food Hygiene*- CAC/RCP 1-1969. The major issues are covered in Section III.

2.3 DEFINITIONS

Definitions of the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007) and *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) apply.

SECTION III - PRIMARY PRODUCTION

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 or raw or partially treated. Since molluscs are filter-feeders, they concentrate microbiological contaminants to a much higher concentration than is present in the surrounding seawater. 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.

It is important to ensure the seawater quality of growing areas by improving sewage treatment efficiency for virus removal/inactivation and avoid discharging of untreated sewage in the surroundings of the bivalve molluscs growing areas. The sanitary survey of harvesting and/or growing water should include an

assessment of possible human faecal contamination sources. To control the hazards, identification and monitoring of growing areas is very important for bivalve molluscs safety. *E. coli* and/or faecal coliforms are used as indicators for faecal contamination. Monitoring data should be interpreted within the context of the sanitary survey, as viruses may be present in the absence of *E. coli*/ faecal coliforms/total coliforms. A short-term depuration process commonly reduces low levels of bacterial contamination, and thus contributes to the safety of bivalve molluscs but depuration, as usually performed, is ineffective in the elimination of viruses.

When there is a likelihood or evidence of virus contamination through epidemiological information, environmental events or direct detection through virological analysis, closure of the area, virucidal heat treatment (e.g. achieve internal temperature 90°C for at least 90 seconds) before consumption or long term relaying for already harvested shellfish are recommended. The holding time and minimum temperature during long term relaying is determined by the official agency having jurisdiction, according to the degree of contamination before relaying, the temperature of the water, the bivalve molluscs species involved and local geographic or hydrographic conditions to ensure that contamination levels will be adequately reduced.

When there has been a shellfish-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 equivalent approach to ensure safety should be used as part of the process of reopening the affected harvesting area depending on the requirements of the official agency, using either standardized methods or alternative validated methods. Other conditions, including meeting the sanitary surveys requirements, should also have been satisfied as a condition of reopening the area. Ideally they should include the identification of sources of pollution/contamination.

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) and the *Standard for Live and Raw bivalve Molluscs* (CODEX STAN 292-2008). In addition:

3.1 ENVIRONMENTAL HYGIENE

Refer to the *Code of Practice for Fish and Fishery Products, section 7* (CAC/RCP 52-2003).

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 shellfish 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.

Every effort should be made to eliminate the overflow of untreated or partially treated sewage into growing waters. Sewage treatments should ensure adequate reduction of viral loads and should aim to achieve significant reduction of NoV and HAV and should when ever possible involve a tertiary treatment step such as UV treatment or ultra-filtration treatment. Treatment plants should be designed in such a way as to eliminate the number of storm overflows per year that may affect the fishery. Systems should be put in place to monitor sewage spills and provide prompt notification to the appropriate official agency as well as the shellfish industry so that appropriate action (i.e. cessation of harvesting) can be taken.

After heavy rainfall, during risk periods and/or after overflow from sewage treatment plants, harvesting of bivalve molluscs should be halted for a period, until the water and/or shellfish quality of the harvesting area has been checked and has been returned to normal backgrounds levels for the area. If there is a belief that the area has been impacted by human sewage, testing of water or bivalve molluscs for the presence of NoV or HAV or an equivalent approach to ensure safety may be an option prior to re-opening. Relaying of the implicated molluscs is another possibility, although new contamination may occur during the relaying period, as the area involved is likely to be susceptible to new contamination events.

When raw or partially treated sewage is known or suspected to have entered a growing area it is recommended that shellfish already harvested from this area should be designated exclusively for virucidal heat treatment (e.g. achieve internal temperature 90°C for at least 90 seconds) before consumption. Alternatively long term relaying is recommended. Such depuration and relaying treatments should be validated with respect to viral inactivation or removal.

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

- No overboard discharge of human faecal material should occur from harvest (or assisting) vessels around shellfish growing areas.

- All necessary measures should be taken to prevent contamination of bivalve molluscs by faecal materials on board of harvest vessels.
- Personal hygiene and facilities should be such to ensure that an appropriate degree of personal hygiene can be maintained.

3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

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

Records regarding the history of contamination of 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 of areas should be reinforced.

SECTION V - CONTROL OF OPERATION

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*, *Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003)* and the *Standard for Live and Raw bivalve Molluscs (Codex Stan 292-2008)*. In addition:

5.1 CONTROL OF FOOD HAZARDS IN RELATION TO VIRAL CONTAMINATION

5.1.1 Identify sources of viral contamination

- Inadequate post-harvest treatment (e.g. heat-treatment) of products, where appropriate.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.2 Specific process steps

Heat treatments of bivalve molluscs should be validated for their ability to inactivate viruses (see 5.2.1, main document). Even though cooking may not guarantee total inactivation of viruses, it would reduce their levels and reduce the risk of causing foodborne infection. The degree of cooking required to reliably inactivate NoV and HAV would, however, probably render oysters unpalatable to consumers. Also the possible inability of home or restaurant cooking to provide adequate guarantees of consumer protection from consuming virally contaminated bivalve shellfish in certain circumstances or forms of consumption underlines the importance of harvesting bivalve molluscs from clean water growing areas.

The effects of high hydrostatic pressure (HHP) on virus infectivity in foods are highly dependent on virus (sub)type and food matrix and may be considered a measure to reduce viral loads for some virus(types) present in specified matrices. As an example, infectious HAV titers could be reduced > 3 log at a HHP of 500 MPa for 5 min in salty water and >3 log in oysters at a HHP of 400 MPa for 1 min.

SECTION IX – PRODUCT INFORMATION AND CONSUMER AWARENESS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)* and *Code of Practice for Fish and Fishery Products (CAC/RCP52-3003, section 7)*. In addition:

LOT IDENTIFICATION

NoV and HAV can persist for long periods of time in bivalve molluscs. Movements between growing areas and countries complicate traceability of bivalve molluscs. Lots should be identified with information from areas where molluscs were grown and such areas should be registered (legally categorized). Because of viral persistence it is important not only to register the area of harvest, but also all growing areas for a two month period prior to harvest.

9.4 CONSUMER EDUCATION

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)* and *Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003, section 7)*.

In addition, each country has specific consumption habits; therefore communication programmes pertaining to viruses are most effective when established by individual governments. Consumers should be made aware of the risk of becoming infected with NoV or HAV after consumption of bivalve molluscs, either raw or partially treated.

SECTION X – TRAINING

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

10.1 AWARENESS AND RESPONSIBILITIES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) and *Code of Practice for Fish and Fishery Products*, (CAC/RCP 52-2003, section 7).

In addition, industry (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.

10.2 TRAINING PROGRAMMES

In addition to the training content mentioned in the main part of this document (section 10.1), appropriate personnel involved in the growing and harvesting of bivalve molluscs should have appropriate training in:

- Personal hygiene (Section 7, Main document);
- Means to identify potentially infected workers;
- Control measures to prevent faecal contamination of growing and harvesting areas;
- Control measures to prevent bivalve molluscs from becoming contaminated by contagious food handlers;
- The general characteristics of HAV and NoV and their resistance to various environmental conditions, e.g. sewage treatment, temperature;
- The availability and basic characteristics of methods appropriate to analyse shellfish for the presence of viruses; including the interpretation of negative or positive viral test results.

ANNEX II

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

INTRODUCTION

Fresh produce is now grown on a large scale in many countries and is transported globally. Outbreaks of viral disease associated with contaminated green onions and raspberries, as well as other produce items are well documented¹. The contamination of fresh produce may occur at any stage from production (sources include contaminated water or soil, inadequately treated fertiliser and infected food handlers) to consumption (source include infected food handlers).

Contact with human sewage can be a cause of pre-harvest contamination of fresh produce items through the use of sewage-contaminated waters in irrigation, washing, the application of fertilisers and agrichemicals, or through the seepage of contaminated sewage into the soil or (surface) waters.

Fresh produce may also become contaminated by viruses via contaminated hands of food handlers due to not practising appropriate personal hygiene if they are shedding viruses themselves with or without symptoms, after visiting the toilet, after changing diapers, after cleaning toilet areas or any other activity potentially likely to contaminate hands. A second important factor in food-handler associated spread of viruses is vomiting that can lead to widespread contamination of the environment.

SECTION I- OBJECTIVES

This annex provides advice to governments on a framework for the control of NoV and HAV in fresh produce, with a view towards protecting the health of consumers and ensuring fair practices in food trade. 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 II – SCOPE, USE AND DEFINITION

2.1 SCOPE

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.

Although it is important for the safety of fresh produce, this annex does not provide recommendations for handling practices to maintain the safety of fresh produce at wholesale, retail, food services or in the home, since those are covered in the *Recommended International Code of Practice - 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

This annex follows the format of the *Codex Recommended International Code of Practice - General Principles of Food Hygiene*- (CAC/RCP 1-1969). The major issues are covered in Section III.

2.3 DEFINITIONS

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) and *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53 – 2003).

SECTION III - PRIMARY PRODUCTION

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. Procedures associated with primary production should be conducted under good hygienic conditions and should minimize potential risks from fresh produce contaminated with NoV and HAV.

Potential sources of contamination include:

- Sewage-contaminated surface waters which can be a cause of pre-harvest contamination of fresh produce items when used for irrigation, washing, or for the application of fertilizers and agrichemicals;
- Sewage seeping into the soil;
- Contamination of fresh produce during growing, harvesting and packing by infected food handlers either directly by contaminated hands, or indirectly by vomiting or defecating in the production site;
- The presence of young children and
- The lack of appropriate personnel health and hygiene procedures and sanitary facilities.

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)* and *Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53 – 2003)* and *Annex on Fresh Leafy Vegetables*.

3.1 ENVIRONMENTAL HYGIENE

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)* and *Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53 – 2003)*, and *Annex on Fresh Leafy Vegetables* and *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)*

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, human excreta used as fertilizer, agricultural workers and the sanitary facilities on-site. 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 HAV and NoV can persist in the environment, as well as on fresh produce, and it can sometimes survive the shelf life of the products.

Sewage treatments should ensure adequate (maximal) reduction of viral loads in treated sewage, as the following could be potential risk factors:

- Irrigation water that is not free from sewage discharges;
- Overflow from sewage and septic tank systems after heavy rainfall that may contaminate the surface water used for production of fresh produce;
- Seepage of sewage into soil and
- Land contaminated with pathogenic human viruses.

3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

Refer to the *Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53 – 2003)*, *Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53 – 2003)*, and *Annex on Fresh Leafy Vegetables*.

3.2.1 Water for growing and harvesting

Efforts should be made to use only clean water and suitable soil 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. 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. It needs to be verified whether the corrective actions were effective.

Testing for *E. coli* and/or *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 should be established according to the source of the water (ground water, surface water, wells) and the conditions of the irrigation system.

With water delivery techniques that result in exposure of the edible portion of fresh fruits and vegetables directly to irrigation water, the risk of NoV and HAV contamination is considered to be higher as compared with other types of irrigation.

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

4.4 FACILITIES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*, in addition:

4.4.4 Personnel hygiene facilities and toilets

Sanitary facilities (permanent or portable), including appropriate hand washing facilities, should be present in close vicinity of the fields.

SECTION V - CONTROL OF OPERATION

Refer to *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)* and *Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53 – 2003)* and *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)*. In addition:

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

5.1 CONTROL OF FOOD HAZARDS IN RELATION TO VIRAL CONTAMINATION

5.1.1 Identify sources of viral contamination

- Use of contaminated water during the whole production process.

5.1.2 Implement effective control procedures

- Avoid presence of non-authorized persons, including children (to the extent possible), on premises where food is grown, harvested, washed or stored.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.2 Specific process steps

5.2.2. Chemical treatment

Antimicrobial agents, effective for bacteria, may not be effective for the reduction of NoV and HAV in fresh produce. Any (new) antiviral treatment should be validated prior to its use in the production phase. It should be clearly stated for which viruses it has been shown to be virucidal.

SECTION X – TRAINING

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*. In addition:

10.1 AWARENESS AND RESPONSIBILITIES

Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)* and *Code of Hygienic Practice for Fruits and Vegetables (CAC/RCP 53-2003)*.

In addition, industry (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.

10.2 TRAINING PROGRAMMES

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. sewage treatment, temperature;
- Personal hygiene (see Section 7, Main document);

-
- Control measures to prevent faecally contaminated water being used in primary production;
 - Control measures to prevent fresh produce becoming contaminated by contagious food handlers.

Appendix V**PROPOSED DRAFT REVISION OF THE CODE OF HYGIENIC PRACTICE FOR COLLECTING, PROCESSING AND MARKETING OF NATURAL MINERAL WATERS (CAC/RCP 33-1985)****(At Step 5/8 of the Procedure)****INTRODUCTION**

1. This Code recommends appropriate hygienic practices for collecting natural mineral waters, their treatment, bottling, packaging, storage, transport, distribution and sale for direct consumption, so as to guarantee a safe, healthy and wholesome product. These hygienic practices are particularly important, because some hygiene control measures usually applied to bottled waters cannot be used for natural mineral waters.

SECTION I – OBJECTIVES

2. The Code of hygienic practice for collecting, processing and marketing of natural mineral waters

- Identifies the necessary requirements that have to be fulfilled in order to ensure the distribution of natural mineral waters that are safe and suitable for human consumption.
- Recommends an approach based on the principles of the *Recommended International Code of Practice - General Principles of Food Hygiene* (abbreviated in this document as *General Principles of Food Hygiene*).
- Recommends conducting a specific hazard analysis in the overall context of the application of principles such as HACCP to the production of natural mineral waters.
- Provides guidance containing conditions specifically linked to natural mineral waters.

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

3. This Code applies to all packaged natural mineral waters offered for sale as food. It does not apply to natural mineral waters sold or used for other purposes.

2.2 USE OF THE DOCUMENT

4. *This Code is supplemental to and should be used in conjunction with the General Principles of Food Hygiene.*

5. In many instances, the control measures are articulated in a general manner in the *General Principles of Food Hygiene* as part of the general strategy for food safety. In providing this Code, it is assumed that the General Principles of Food Hygiene are implemented.

6. The use of this Code may require modifications and amendments that take into account such factors as regional differences due to specific environmental and hydro-geological conditions.

2.3 DEFINITIONS

7. For the purpose of this Code, definitions contained in the *General Principles of Food Hygiene* apply.

8. In addition, the following definitions also apply:

Natural mineral waters - all waters meeting the definitions in Section 2 of the *Codex Standard for Natural Mineral Waters* (CODEX STAN 108 - 1981).

Adequate - sufficient to accomplish the intended purpose of this Code.

Aquifer - a saturated geological unit below the surface that yields water in sufficient quantities under normal hydraulic conditions.

Watershed- the surface area upstream of the ground water resource within which precipitations can either directly or indirectly enter the ground water system and which can contribute to recharge the aquifer.

Containers - any vessels made from food-grade packaging material intended to be filled with natural mineral waters.

Ground water - Waters such as spring water, artesian water, and well water originating from subsurface aquifers. Ground waters may be classified broadly as protected or unprotected ground water. Protected ground waters are not directly influenced by surface water or the surface environment.

Handling of natural mineral waters - any manipulation with regard to collecting, treating, filling, packaging, storing, distribution and sale of natural mineral waters.

Packaging material – any materials, food grade or not, e.g. foil, film, metal, paper, wax-paper, etc.

Perimeter of protection / protection zone - area where human and animal activities need to be monitored and managed to protect the water from contamination.

Pests – any animals capable of directly or indirectly contaminating natural mineral waters.

Recharge – The process by which water enters an underground aquifer through faults, fractures or direct absorption.

Recharge rate – The quantity of water per unit of time that replenishes or refills an aquifer.

Reservoir - For the purposes of this document a reservoir is a holding tank.

Safe yield – Sustainable quantity of water per unit of time that may flow from a spring or be pumped continuously from a well or a borehole without depleting that resource beyond its ability to be replenished naturally.

Spring - An underground formation from which natural mineral waters discharge naturally from the ground.

SECTION III - PRIMARY PRODUCTION

9. Refer to Section III of the *General Principles of Food Hygiene*.

3.1 ENVIRONMENTAL HYGIENE - Protection of aquifers

3.1.1 AUTHORIZATION

10. Any spring, well or drilling intended for the collection of natural mineral waters should be approved by the official authority having jurisdiction.

3.1.2 DETERMINATION OF THE GENESIS OF THE NATURAL MINERAL WATERS

11. As far as it is methodologically possible in each case, a precise analysis should be carried out on the origin of natural mineral waters, the period of their residence in the ground before being collected and their chemical and physical qualities.

3.1.3 PERIMETER OF PROTECTION

12. Areas, wherein natural mineral waters might be contaminated or their chemical, physical, radiological and microbiological qualities otherwise deteriorated, should be determined. Where indicated by hydro-geological conditions and considering the risks of contamination several perimeters with separate dimensions may be provided for.

13. Hydro-geological studies by qualified experts should be carried out to determine and to describe the watershed.

14. Hydro-geological studies should include:

- Location of the extraction points
- Determination of the extent and properties of the aquifer containing the ground water resource
- Location and extent of the watershed
- Degree and nature of natural protection against contamination
- Surface water features, identifying those interacting with the ground water resource
- Other water abstractors, identifying those exploiting the same ground water resource

- Chemistry and quality of the ground water resource
- Determination of the ground water recharge rate and safe yield
- Travel times for ground water between recharge zone and extraction point(s)

3.1.4 PROTECTIVE MEASURES

15. All possible precautions should be taken within the perimeter of protection to avoid any contamination of, or external influence on, the chemical, physical, radiological and microbiological qualities of natural mineral waters. It is recommended that regulations be established for the disposal of liquid, solid or gaseous waste, the use of substances that might deteriorate natural mineral waters (e.g. by agriculture) as well as for any possibility of accidental deterioration of natural mineral waters by natural occurrences such as a change in the hydro-geological conditions. Consideration should be given to the following potential contaminants: bacteria, viruses, protozoa, fertilizers, hydrocarbons, detergents, pesticides, phenolic compounds, toxic metals, radioactive substances and other soluble organic or inorganic substances. Even where nature provides apparently sufficient protection against surface contamination, activities particularly likely to result in contamination, such as mining, construction, etc., should be taken into consideration.

16. An evaluation of the adverse impacts of potential threats to the quantity and quality of the water supply should be performed. The evaluation should normally include:

- Review of land ownership and land use (current and historic) for the perimeter of protection;
- Collection of data on contaminants, contamination incidents and legal controls applicable to protecting waters from contamination;
- Evaluation for each land use or activity.

17. Protection zones and monitoring programmes should be defined using the finding of the evaluation. At a minimum, the protection zone should encompass property owned by the producer, but as much as reasonably possible extend to other areas not under their control. Different levels of protection are required depending on proximity to the water source and potential risks.

3.2 HYGIENIC EXTRACTION AND COLLECTION OF NATURAL MINERAL WATERS

3.2.1 EXTRACTION

18. The extraction of natural mineral waters (from springs, natural or drilled wells) should be performed in conformity with the hydro-geological conditions in such a manner as to prevent any water other than the natural mineral waters from entering or, should there be pumping facilities, prevent any extraneous water from entering by reducing the supply. The natural mineral waters thus collected or pumped should be protected in such a way that they will be safe from contamination whether caused by natural occurrence or actions or neglect or ill will.

19. The extraction facilities should be managed to prevent any other water, such as flood water or shallow seepage, from entering. It should also be managed in a hygienic manner to prevent any natural or manmade contamination.

3.2.2 PROTECTION OF THE EXTRACTION AREA

20. In the immediate surroundings of springs and wells, precautionary measures should be taken to ensure that contaminants cannot enter the extraction area. The extraction area should be inaccessible to non authorized persons by providing adequate devices (e.g. enclosure). Any activity not aiming at the collection of natural mineral waters should not be allowed in this area.

21. Roadways, areas used by wheeled traffic and areas serving the establishment which are within its boundaries or in its immediate vicinity should have a hard paved surface suitable for wheeled traffic. There should be adequate drainage and provision should be made for the protection of the extraction area, where appropriate. Adequate road signage may be provided to call the attention of road users to the existence of a natural mineral waters extraction area.

3.2.3 EQUIPMENT AND RESERVOIRS

22. Equipment used for extraction of natural mineral waters and reservoirs should be designed and constructed in order to avoid contamination of natural mineral waters and to maintain their original

characteristics.

23. The pipes, pumps or other possible devices coming into contact with natural mineral waters and used for its collection should be made of inert material as to ensure that the original characteristics and qualities of natural mineral waters will not be changed.

3.2.4 EXPLOITATION OF NATURAL MINERAL WATERS, MONITORING

24. The condition of the extraction facilities, areas of extraction and perimeters of protection as well as the quality of the natural mineral waters should periodically be examined. To monitor the stability of the chemical and physical parameters of the natural mineral waters, allowing for natural variations, automatic or manual measurements of the typical characteristics should be carried out and documented.

25. Periodic monitoring should include the following basic parameters:

- Appearance, odour and taste
- Physical: flow rate, temperature, electrical conductivity, piezometric level
- Physico-chemical: pH
- Chemical: according to water characteristics, content of carbon dioxide

26. Microbiological monitoring at the source should meet the criteria of the Table in Annex I of this document and should be performed at a frequency that enables the appropriate hygienic management.

27. Should there be a failure to meet the limits of the established criteria, the necessary corrective measures are immediately to be taken and recorded.

3.3 HANDLING AND STORAGE OF NATURAL MINERAL WATERS INTENDED FOR PACKAGING

3.3.1 TECHNICAL ASPECTS

28. Methods and procedures for maintaining the handling and storage facilities should be hygienic and not be a potential health hazard to humans or a source of contamination to natural mineral waters. From the hygiene standpoint, servicing of the handling and storage installations should meet the same standards as those required for the packaging or treatment.

3.3.2 STORAGE AT THE POINT OF EXTRACTION

29. The quantity of natural mineral waters stored at the point of extraction should be as low as possible. The storing should furthermore ensure protection against contamination or deterioration.

30. Water should be stored for a time as short as possible, in order to minimise potential for contamination and to avoid stagnant water. The design and operation of the reservoirs should restrict the time from point of extraction to bottling to a minimum. The reservoir should be enclosed to protect water from environmental contamination. Air entering the headspace of reservoirs should be filtered or treated to prevent contamination of the water. Air filters should have a pore size of 0.45 µm or less.

3.3.3 PIPING AND RESERVOIRS

31. Any piping or reservoir used in the processing of natural mineral waters from its source to the bottling facilities, the latter included, should comply with the necessary requirements set by the official authority having jurisdiction and be made of inert material approved for food contact such as ceramic and stainless steel that prevents any deterioration, be it by water, handling, servicing or disinfection.

3.4 CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION

32. The water extraction and supply network should be properly managed and maintained, and cleaned or disinfected to protect all components from risk of chemical, physical and microbiological contamination. For the extraction facilities itself, the disinfection regime should be designed to take account of the risks and its operational regime. For example, a constantly flowing spring may require sanitation only at times of intervention.

33. A detailed contingency plan should also be developed in collaboration with appropriate experts and authorities in order to react as quickly as possible to exceptional events (e.g. contamination of the groundwater resource, earthquake, forestfires, as appropriate for the specific location) so that consequences

can be minimised. This plan should be part of the global crisis management system of the operating company.

34. Any reservoir should be properly cleaned and if necessary disinfected and kept in good condition so as to not to present any potential for contamination to natural mineral waters and of modification of the original characteristics of natural mineral waters.

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

35. Refer to Section IV of the *General Principles of Food Hygiene*.

4.1 LOCATION

36. Refer to *General Principles of Food Hygiene*.

4.2 PREMISES AND ROOMS

37. The filling equipment (rinser, filler, capper) should be protected by a cabinet under positive pressure filtered air or in a room under sterile air filtration with positive pressure. It is advised to restrict operations in this particular area to a minimum by confining it to the open container activities of rinsing, filling and capping.

38. Operations such as labelling, coding, shrink wrapping, etc. can generate considerable suspended particles therefore, it is preferable to exclude these activities from the rinsing, filling and capping areas. The use of hot glues and ink jet equipment may result in change in taste and odour if used inside filling rooms, and this is why labelling machines inside filling rooms should have effective exhaust systems.

4.3 EQUIPMENT

39. As water is one of nature's most effective solvents, care should be taken when selecting water contact materials. This should include the materials used in the manufacture of pumps, pipes, filling equipment, etc.

40. Food-grade stainless steel is the most appropriate material for equipment in contact with water. Alternative materials should be inert materials approved for food contact that do not impart an odour or taste to the water or alter its composition.

41. It is essential to verify that lubricants used are suitable for food use. However, care should be taken to avoid lubricants from coming into contact with natural mineral water.

4.4 FACILITIES

4.4.1 WATER SUPPLY

42. Natural mineral waters, potable water, non potable water for steam production or for refrigeration or any other use should be carried in completely separated lines. It would be desirable that these lines are differentiated, e.g. by different colours. Steam used on surfaces in direct contact with natural mineral waters should contain no substances which may be hazardous to health or may contaminate the natural mineral water.

4.4.2 DRAINAGE AND WASTE DISPOSAL

43. Pipes or drain systems and sewage waters, as well as waste disposal bins located in the perimeter of protection, should be constructed and maintained so as not to present a risk of contamination of aquifers.

Effective measures should be taken to prevent the unauthorized reuse of rejected containers – particularly those bearing company logos and other identification. Rejected containers waiting disfigurement, destruction or authorized collection should be stored securely.

4.4.3 CLEANING

44. Refer to *General Principles of Food Hygiene*.

44. Where appropriate, adequate facilities for cleaning and disinfection of working implements and equipment should be provided. These facilities should be constructed with corrosion resistant materials, capable of being easily cleaned, and should be fitted with suitable means of supplying hot and cold water in sufficient quantities.

4.4.4 PERSONAL HYGIENE FACILITIES AND TOILETS

45. Refer to *General Principles of Food Hygiene*.

4.4.5 TEMPERATURE CONTROL

46. Refer to *General Principles of Food Hygiene*.

4.4.6 AIR QUALITY AND VENTILATION

47. Refer to *General Principles of Food Hygiene*.

4.4.7 LIGHTING

48. Refer to *General Principles of Food Hygiene*.

4.4.8 STORAGE

49. Materials storage should be separated into allocated areas for packaging materials, closures and bottles and, where possible also different types of bottles such as glass, PET, PE, PC and PVC.

50. It is advised to store packaging materials in a clean and dry area, away from any chemical vapours and under an effective pest control program.

51. Facilities should be provided for the storage of waste and inedible material prior to removal from the establishment. These facilities should be designed to prevent access to waste or inedible material by pests and to avoid contamination of natural mineral water, potable water, equipment, buildings or roadways on the premises.

SECTION V - ESTABLISHMENT: CONTROL OF OPERATION

52. Refer to Section V of the *General Principles of Food Hygiene*.

5.1 CONTROL OF FOOD HAZARDS

53. Refer to the *General Principles of Food Hygiene*.

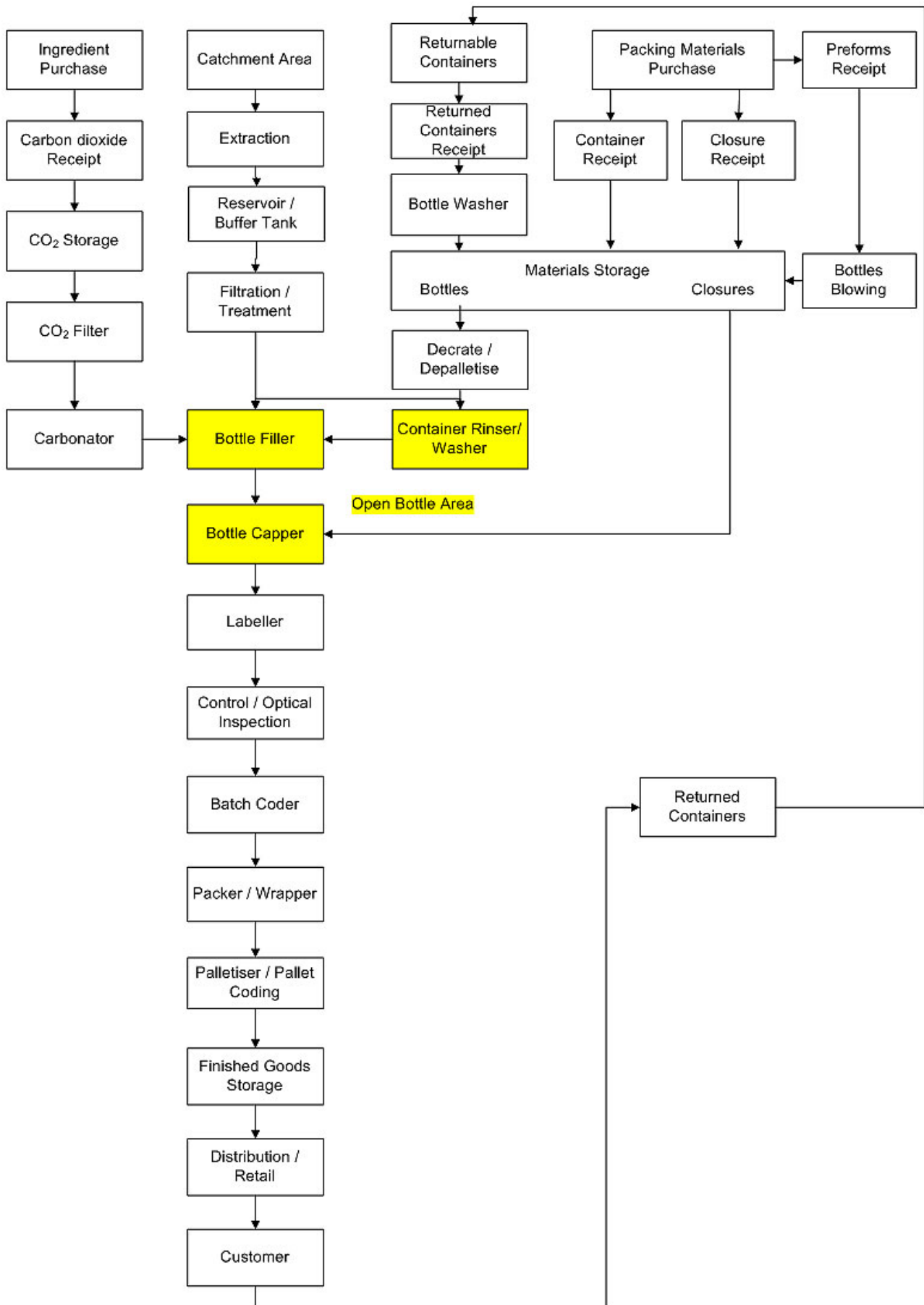
5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

54. Natural mineral waters intended for packaging should meet all standards (*i.e.* chemical, microbiological, physical, radiological) established by the official authority having jurisdiction.

55. A hazard analysis, from catchment through distribution, which takes into consideration microbiological, physical, chemical and radiological hazards, should be undertaken according to HACCP principles. This should provide the basis for determining the appropriate combination of control measures to reduce, eliminate or prevent, as necessary, these hazards to the production of safe natural mineral waters.

5.2.2 SPECIFIC PROCESS STEPS

Example of a Process Flow for Natural Mineral Waters



5.2.2.1 BUFFER TANK

56. Product is best kept in constant flow from source to bottling. The design and operation of the buffer tanks should restrict the time from storage to bottling to a minimum as determined based on the hazard analysis. Air entering the headspace of tanks should be filtered or treated to prevent contamination of product water.

5.2.2.2 TREATMENT

57. Natural mineral waters may not be subjected to any treatments other than those permitted by the *Codex Standard for Natural Mineral Waters* (CODEX STAN 108-1981).

58. When necessary and subject to the approval of the competent authority having jurisdiction, treatments to remove or reduce unstable constituents and health-related substances may include adsorption and particulate (mechanical) filtration such as achieved with surface filters (e.g. pleated membrane filters) or depth filters (e.g. sand or compressed fibre-cartridge-filters), oxygenation (O₂) and aeration.

59. All treatments of natural mineral waters should be carried out under controlled conditions to avoid any type of contamination.

60. Any treatment of natural mineral waters may introduce the possibility of contamination. Therefore, approved treatments, which are part of the process, should be subjected to HACCP principles.

5.2.2.3 CONTAINER RINSER / WASHER

61. The design for refillable containers should enable easy multiple cleaning and disinfection. Effective washers should be in place.

62. Rejected containers (contaminated or non-cleanable) should be segregated and then managed in a way to avoid the potential for putting the container back on the line by mistake.

63. The outlet of the washer should be adequately protected. Conveyors from the outlet of the washing machine to the filling machine should be covered to protect the containers from contamination. Cleaned and disinfected containers should be all the time protected by covers when on conveyors, loading tables etc. Conveyor covers should be so designed as to protect containers from above and laterally from dust and other airborne particles.

5.2.2.4 LABELLER

64. Labelling inside the filling room is not recommended. If engineering or personnel organization constraints require the labellers to be in the filling room, they should be separated from the filler as far as possible and a hooded vent should be installed (except where cold glue is used) to adequately remove any fumes from the labeller, solvents and glue. In such cases the air circulation systems should be designed in order to avoid cross-contamination from the fumes.

5.2.3 MICROBIOLOGICAL AND OTHER SPECIFICATIONS

65. Refer to the *Principles for the Establishment and Applications of Microbiological Criteria* (CAC/GL 21-1997).

66. Microbiological monitoring of natural mineral waters should meet the specifications of the Table in Annex I of this document and should be performed at a frequency that enables the appropriate hygienic management.

5.2.4 MICROBIOLOGICAL CROSS-CONTAMINATION

67. Refer to the *General Principles of Food Hygiene*.

5.2.5 PHYSICAL AND CHEMICAL CONTAMINATION

68. Where glass bottles are used, periodic inspection requirements and defined procedures in case of breakage should be put in place in particular during the washing and filling steps of the glass bottles.

69. Special measures should be taken when filling glass bottles with carbonated water to avoid explosion and to protect the product from glass fragment.

70. Dedicated optical device should be installed to monitor the neck finish of glass bottles as well as the presence of glass fragments inside. Defective bottles should be automatically discarded from the line

(detection/rejection device). Any packaged natural mineral water containing glass fragments should be considered unacceptable.

5.3 INCOMING MATERIAL REQUIREMENTS

71. Raw materials (i.e. CO₂) and processing materials (e.g. filtration media) should be purchased from approved suppliers and conform to mutually agreed specifications.

72. Consideration should be given to ensuring that no sensorial and microbiological contaminants arise from contact of CO₂, either with the final product or with containers and closures used for the bottling of natural mineral water.

5.4 PACKAGING

73. Containers should be stored in a way that prevents contamination from volatile compounds, airborne contaminants, pests and malicious acts.

74. Packaging materials should be stored in a dry place and be protected against heat, dust, pests and chemicals.

75. The use of recycled plastic packaging materials should be authorised by the official authority having jurisdiction.

5.5 WATER

76. Refer to Section 5.5.1 of the *General Principles of Food Hygiene*.

5.6 MANAGEMENT AND SUPERVISION

77. Refer to the *General Principles of Food Hygiene*.

5.7 DOCUMENTATION AND RECORDS

78. Refer to the *General Principles of Food Hygiene*.

5.8 RECALL PROCEDURES

79. Refer to the *General Principles of Food Hygiene*.

SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION

80. Refer to Section VI of the *General Principles of Food Hygiene*.

6.1 MAINTENANCE AND CLEANING

81. Adequate precautions should be taken to prevent natural mineral waters from being contaminated during cleaning or disinfection of rooms, equipment or utensils, by water and detergents or by disinfectants and their solutions. Detergents and disinfectants should be suitable for the purpose intended and should be acceptable to the official authority having jurisdiction. Residues of these agents on a surface which may come in contact with natural mineral waters should be removed by thorough rinsing with potable water or preferably with natural mineral water.

82. The cleaning products should be odour-free.

83. If a bottling line is exclusively used for the bottling of natural mineral waters, a cold cleaning and disinfecting process should be considered as a minimum. CIP/COP (cleaning in place/cleaning out place) operations should be carried out on a regular basis. The cleaning and disinfecting agents should penetrate all areas of product flow (CIP) and should cover the operational surfaces (COP).

84. Painting works should not be undertaken during production time. Care should be taken in the selection of paint used. It is advisable to select paint specifically for use in a food manufacturing environment and with minimum odour. It cannot be emphasized enough that the odour of paint will be absorbed by water and may give a taste taint. It may be advisable to select a paint, which includes a mould inhibitor.

6.2 CLEANING PROGRAMS

85. Refer to the *General Principles of Food Hygiene*.

6.3 PEST CONTROL SYSTEMS

86. Refer to the *General Principles of Food Hygiene*.

Toxic baits should not be used for internal pest control.

87. Insect stunning devices, if and where used, should be carefully located so that stunned insects and fragments of them do not fall into open containers or closures. Use of glue boards' type insect monitor devices is recommended. Trays should be large enough to catch falling insects. The instruments should be regularly maintained and cleaned out.

6.4 WASTE MANAGEMENT

88. Refer to the *General Principles of Food Hygiene*.

6.5 MONITORING EFFECTIVENESS

89. Refer to the *General Principles of Food Hygiene*.

SECTION VII - ESTABLISHMENT: PERSONAL HYGIENE

90. Refer to *Section VII of the General Principles of Food Hygiene*.

SECTION VIII – TRANSPORTATION AND STORAGE OF PACKAGED NATURAL MINERAL WATERS

91. Refer to *Section VIII of the General Principles of Food Hygiene*.

92. Care should be taken to ensure a minimum temperature to prevent freezing of natural mineral waters which, due to expansion, is liable to cause breakage and/or explosion of containers and/or increase the potential for failure during distribution and consequent risk to the safety of the consumer. It should also be noted that following a severe cold spell there is an increased potential for condensation developing on containers which can give rise to damaged/mouldy labels and damp secondary packaging.

93. Storage and transportation of packaged natural mineral waters at excessive high or low temperatures should be avoided as it may result in quality reduction (e.g. risk of compound migration from primary packaging materials).

SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS

94. Refer to *Section IX of the General Principles of Food Hygiene*.

95. Refer to *Section VI of the Codex Standard for Natural Mineral Waters (CODEX STAN 108-1981)*.

SECTION X - TRAINING

96. Refer to *Section X of the General Principles of Food Hygiene*.

ANNEX I: MICROBIOLOGICAL CRITERIA

97. Natural mineral waters should be of such a microbiological quality that they will not present a risk to the health of the consumer (in particular regarding pathogenic microorganisms including parasites).

98. The production of microbiologically safe packaged natural mineral waters is dependent on maintaining a high level of hygienic control – from the protection of the aquifer, the extraction and up to the bottling and capping.

99. The following microbiological criteria (see Table) are intended to be used by manufacturers to verify the effectiveness of the implemented hygiene control measures as outlined in this Code of Hygienic Practice. Manufacturers may choose to perform all or a subset of the faecal indicator tests in the Table, as appropriate, in accordance with any requirements set by the competent authority.

91. Competent authorities can use all or a subset of the following microbiological criteria, as appropriate, to verify the effectiveness of (a) general hygiene programs in the food operation environment and (b) control measures in facilities employing HACCP or other food safety control systems.

Table: Microbiological Criteria, Point of application: at source, and during production and end-product

Parameters	n	c	m	Class Plan	Method ¹
<i>E. coli</i> ³	5	0	n.d. in 250 ml	2 ^a	ISO 9308-1
Total coliforms ³	5	0	n.d. in 250 ml	2 ^a	ISO 9308-1
Enterococci ³	5	0	n.d. in 250 ml	2 ^a	ISO 7899-2
spore-forming sulphite-reducing anaerobes ³	5	0	n.d. in 50 ml	2 ^b	ISO 6461/2
<i>Ps. aeruginosa</i> ⁴	5	0	n.d. in 250 ml	2 ^a	ISO 16266-2006
Aerobic mesophilic count / heterotrophic plate count ^{2,4}	5	0	100 cfu/ml	2 ^c	ISO 6222-1999

¹ Other methods that provide equivalent sensitivity, reproducibility, and reliability can be employed if they have been appropriately validated (e.g., based on ISO/TR/13843).

² Point of application: only at source, during production and within 12 hours following bottling.

³ Faecal indicator

⁴ Process control indicator

Where n = number of samples that must conform to the criteria: c = the maximum allowable number of defective sample units in a 2-class plan: m = a microbiological limit which, in a 2-class plan separates good quality from defective quality.

n.d. = not detectable

Performance of the sampling plan:

^a. Assuming a log normal distribution and an analytical standard deviation of 0.25 log cfu/ml, this sampling plan would provide 95% confidence that a lot of water containing a geometric mean concentration of 2.3 cfu/l, corresponding to 1 cfu per 422 ml, would be detected and rejected based on any of the five samples testing positive.

^b. Assuming a log normal distribution and an analytical standard deviation of 0.25 log cfu/ml, this sampling plan would provide 95% confidence that a lot of water containing a geometric mean concentration of 11.3 cfu/l, corresponding to 1 cfu per 88 ml, would be detected and rejected based on any of the five samples testing positive.

^c. Assuming a log normal distribution and an analytical standard deviation of 0.25 log cfu/ml, this sampling plan would provide 95% confidence that a lot of water containing a geometric mean concentration of 93 cfu/ml would be detected and rejected based on any of the five samples exceeding 100 cfu/ml.

Corrective actions:

The typical action to be taken when there is a failure to meet the above criteria would be to (1) prevent the affected natural mineral water from being released for human consumption and (2) determine and correct the root cause of the failure and (3), as appropriate, review monitoring procedures and prerequisite programs.

Rationale for the parameters chosen:*E. coli*

E. coli is considered one of the most suitable indicators of faecal contamination.

Total coliforms

Coliforms can originate from faecal contamination or from the environment. Coliforms which can occur naturally in soil, water and vegetation, indicate possible contamination from airborne sources or from product contact surfaces that have not been effectively disinfected. Coliforms are normally not present in natural mineral water sources. Therefore, they are considered as an indicator of contamination of the water at source or during the bottling process.

Enterococci

Enterococci are a sub-group of faecal streptococci. Compared to *E. coli* and coliforms they tend to survive longer in the water environment and are therefore used as an additional indicator of faecal contamination.

Spore-forming sulphite-reducing anaerobes

The spores of this group of bacteria are very resistant towards various kinds of environmental stresses. Spore-forming sulphite-reducing anaerobes can originate from faecal contamination and due to the length of their survival in unfavourable environments, they are usually used as an indicator of faecal contamination.

Pseudomonas aeruginosa

Pseudomonas aeruginosa is not a normal component of the natural flora of natural mineral waters. When detected, it is usually in low numbers but *Pseudomonas aeruginosa* can survive and grow in natural mineral waters. Therefore, its presence is considered as an indicator of contamination of the water at source or during the bottling process.

Aerobic mesophilic count / heterotrophic plate count

The aerobic mesophilic count / heterotrophic plate count is part of the natural flora of natural mineral waters and is used as a process management indicator. A limited increase in the counts is normal from source to the bottling. Numbers increasing over a certain level can indicate deterioration in cleanliness, stagnation or development of biofilms.

Appendix VI**PROJECT DOCUMENT****PROJECT DOCUMENT FOR NEW WORK ON “GUIDELINES FOR CONTROL OF SPECIFIC ZOOTIC PARASITES IN MEAT: *TRICHINELLA SPIRALIS* AND *CYSTICERCUS BOVIS*”**

A proposal for new work in the area of meat hygiene under the umbrella of the CCFH represents a continuation of standards development for priority zoonoses that may be transmitted by meat and meat products¹. With the adjournment of the Codex Committee on Meat Hygiene (CCMH) in 2006 following completion of the new “Code of Hygienic Practice for Meat”, progressing priority new work under the umbrella of CCFH would reflect an efficient and flexible approach to meeting Member country’s needs. If required, New Zealand (as chair of CCMH) would be very willing to organise and provide technical assistance to an intersession working group.

This proposal has already been discussed and noted by the 64th Session of the Codex Executive Committee (CCEXEC) in June 2010 (see paragraph 178 of Alinorm 10/33/3A).

1. Purpose and scope of the new work

The purpose of the proposed new work is to provide risk-based guidance on control of priority biological hazards in meat. It is envisaged that initial work would be on control measures for *Trichinella spiralis* in pigs, together with parallel work on *Cysticercus bovis* in cattle.

The scope of the proposed new work would include:

- Identification of specific control measures that may be applied
- Application of a farm-to-plate approach in identifying and evaluating risk management options
- Provision of quantitative guidance on testing / control regimes (depending on different prevalence's in country, region or farming system) to be applied in order to ensure consumer protection.
- Reference to current OIE standards, and avoiding duplication of relevant components.

2. Relevance and timeliness

With the rapid uptake of risk-based approaches to food hygiene by national governments and the subsequent re-evaluation of their food control systems, problems in trade can arise from inadequate knowledge of the value of specific measures in reducing public health risks. This is particularly important in the case of meat hygiene.

A risk-based approach to meat hygiene requires re-evaluation of traditional practices and re-focusing of regulatory and industry resources proportionate to risks. While this approach is now strongly advocated by national governments and the recently adopted Codex Code of Hygienic Practice for Meat presents a detailed framework for implementation, there has been very uneven uptake on a global basis. As a consequence, the import requirements for meat and meat products of most countries represent an unbalanced and inconsistent mix of “new” (risk-based) and traditional procedures and tests.

At the final session of the CCMH before adjourning *sine die* in 2005, the Committee discussed the need for Appendices providing guidance on risk-based control measures for specified hazards. CCMH was highly supportive in principle but considered that the guidance in the new code of practice needed time to bed in before more specific work was undertaken.

As governments modernise their meat hygiene systems, it is evident that in the national situation, some traditional control measures for meat and meat products in trade as now applied can be singularly inappropriate in terms of proportionality to risk. Routine slaughterhouse testing of pig meat for *Trichinella* and intensive post mortem inspection for *Cysticercus bovis* are two such examples. These two cases provide strongly contrasting examples for application of risk analysis principles to different types of traditional meat hygiene procedures.

The need for risk-based guidance from Codex for these biological hazards is a global issue. These parasites exist at some level in the large majority of countries throughout the world and traditional control measures are a fixture of the import requirements of most countries. In the absence of a Codex standard that facilitates

¹ Other work currently being undertaken is “Draft guidelines for the Control of *Salmonella* and *Campylobacter* in Chicken Meat”

application of risk-based control measures at the national level, trade problems and wasting of food control resources will continue to occur at a significant level. In addition, outcomes in terms of risk reduction are highly questionable in many trade situations.

The guidelines would provide a consistent and transparent technical base for establishing national control measures and this should satisfy judgement of equivalence by importing countries where such measures differ from their own.

The proposed work could lead on to further risk-based evaluation of other priority meat-borne hazards that are causing problems in trade.

3. Main aspects to be covered

The proposed guidelines would be based on Codex principles for food safety risk analysis and provide both qualitative and quantitative advice for implementation of specific control measures at the national level. Depending on the decision of the Committee, the work on *T. spiralis* could precede that on *C. bovis*, or both sets of guidance could be developed in parallel.

The preamble to the guidelines would describe the nature and epidemiology of the hazards, drawing heavily on cross-referencing to OIE texts so as to not duplicate existing material.

Similarly, a description of good hygienic practice at farm level would rely heavily on existing OIE texts.

Risk analysis principles governing the identification, selection, validation, verification and monitoring of control measures would be presented.

The format of the body of the guideline would be similar to that utilised in the “Draft guidelines for the Control of *Salmonella* and *Campylobacter* in Chicken Meat” now in the CCFH step process i.e. a process flow approach that identifies possible control measures at different steps in the food chain. However, the guideline would be much simpler than that referred to above because of the very limited number of specific control measures available². Specific control measures for *T. spiralis* other than on-farm GHP and feedback loops if a positive animal / positive line is detected are essentially limited to laboratory testing (and cooking). Specific control measures for *C. bovis* other than on-farm GHP and feedback loops if a positive animal / positive line is detected are essentially limited to post mortem inspection and further (Company) inspection during boning.

Provision of quantitative guidance would be based on levels of detection of infected animals that is afforded by implementation of specific control measures. This guidance would include calculations of residual non-detection rates where there are different prevalence's in a country, region or farming system e.g. comparing outcomes where prevalence of infection is medium, low, or negligible. In the case of *C. bovis*, outcomes would be compared using different intensities of post mortem inspection.

It is not envisaged that the Codex standard would apply a risk assessment model to determine actual levels of consumer protection afforded in different exposure scenarios. However, a qualitative narrative would be provided, drawing on outcomes from risk assessment models that have been developed by some countries.

A description of recommended on-farm responses when infected animals are detected, proportionate to likely risks to consumers in different detection scenarios, would be a key part of the guidelines.

CCFH could proceed on the basis of the content of the draft guidelines to set a risk-based standard for *T. spiralis* and/or *C. bovis* for meat and meat products in trade. OIE have set such a standard for BSE. And there are precedents in other CCFH work e.g. *Cronobacter sakuzakii* in infant formula.

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

4.1. General criterion

The proposed work is clearly focused on meat-borne hazards to human health that commonly exist throughout the world, albeit at very different prevalences in different countries. In the case of *C. bovis*, suitability of product is also an issue.

In terms of fair practices in trade, undifferentiated application of traditional meat hygiene controls without a consideration of the equivalence of different approaches in different countries is a significant problem in trade. As well as wasting scarce food control resources in some situations, product wastage and undue cross-

² Noting that control measures based on GHP will largely be dealt with by reference to OIE texts

contamination consequential to traditional approaches can cause further inequities.

4.2. Criteria applicable to general subjects

In respect of “Diversification of national legislations and apparent resultant or potential impediments to international trade”, it is highly apparent from review of importing country requirements that considerable differences currently exist. Nowadays many importing countries require full testing on all the consignments of pork for *Trichinella spiralis* and of beef for *Cysticercus bovis* even when the risk in the exporting country has been demonstrated as being low or even negligible. For example, in Europe, Denmark and Belgium have been officially declared as having a negligible risk for *Trichinella* but are nevertheless requested by importing countries to carry out full testing. Notwithstanding this, many countries now have risk analysis principles embedded in their national legislation and are committed to application of the principle of equivalence as stated in the WTO SPS Agreement. Availability of Codex guidelines would greatly assist a flexible approach to import requirements based on the proportionality of risk.

The guidelines would also significantly contribute to judging the equivalence of different control measures by importing countries where measures applied by exporting countries differ from their own.

In respect of “Scope of work and establishment of priorities between the various sections of the work”, CCFH could decide to progress the work on *T. spiralis* ahead of that on *C. bovis*, or develop both sets of guidance in parallel (as has been the case with “Draft guidelines for the Control of *Salmonella* and *Campylobacter* in Chicken Meat”).

In respect of “Work already undertaken by other international organisations in this field and/or suggested by the relevant international intergovernmental bodies”, OIE texts provide extensive general information but do not progress to risk-based guidance in a manner that would reduce current problems in international trade.

5. Relevance to Codex strategic goals

5.1. Goal 1: Promoting sound regulatory frameworks

The proposed work is a direct reflection of Codex strategic goals and recent national legislative frameworks in that standards for food in international trade should be based on science and risk assessment to the greatest extent practicable.

A Codex guideline of the nature intended would provide a strong reference point for harmonising national regulatory requirements on a global basis.

Further, Codex advocates validation, verification and monitoring of food control measures to assure risk-based performance and these aspects would be a feature of the proposed guidelines.

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

The food safety risk analysis principles and the farm-to-plate approach advocated by the Codex will provide the core structure for development of the guidelines. Quantitative aspects of the guideline will reflect the Codex principle that application of control measures should be proportional to risk.

5.3. Goal 3: Strengthening Codex work management capabilities

With the adjournment of the CCMH in 2006 following completion of the new “Code of Hygienic Practice for Meat”, progressing priority new work under the umbrella of CCFH would reflect an efficient and flexible approach to meeting Member country’s needs. If required, New Zealand (as chair of CCMH) would be very willing to organise and provide technical assistance to an intersession working group.

5.4. Goal 4: Promoting maximum and effective participation of members.

The proposed work would promote Codex objectives in this area.

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

The proposed work relates to a number of “horizontal” Codex texts as referred to above and the intent of these horizontal texts would be fully realised in guidelines that are developed.

Options for locating the guidelines once adopted by the Codex Alimentarius Commission (CAC) are either:

- As an Appendix to the CCMH Code of Hygienic Practice for Meat, with a view to further Appendices for other priority hazards over time

or

- As a CCFH risk-based guideline for a specific hazard / food product combination.

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

While JEMRA provides risk assessment advice and peer review for microbiological hazards in foods, there has been no call yet on JEMRA expertise to date for risk assessment of other biological hazards such as parasites. Irrespective of this, the principles of risk assessment are similar for all types of biological hazards (and in fact are more readily applied to parasites that do not multiply in the food). Consequently, it is foreseen to request JEMRA to provide scientific advice and peer review.

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

A close cooperation with OIE on these matters will be essential to avoid duplication of work and gaps. The proposed work will benefit from the technical input and expertise of OIE, particularly as regards preventive measures at primary production level, with a view to develop a farm-to -plate approach.

9. Proposed timeline for completion of the new work

November 2010:	Endorsement of new work proposal by CCFH
May 2011:	First physical working group to prepare draft guidelines
July 2011:	Approval of new work by CAC
November 2011:	Consideration of proposed draft guidelines at Step 2 by CCFH, and advancement to Step 3
May 2012:	Electronic working group to further development guidelines
July 2012:	Advance to Step 4
November 2012:	Consideration of proposed draft guidelines at Step 5 by CCFH, and advancement to Step 5/8
July 2013:	Adoption by CAC

Appendix VII**PROJECT DOCUMENT****ELABORATION OF A COMMODITY-SPECIFIC ANNEX TO THE *CODE OF HYGIENIC PRACTICE FOR FRESH FRUITS AND VEGETABLES*****1. Purpose and Scope of the New Work**

The purpose of the proposed new work is to provide to member countries and industry, within the framework of annexes to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (the Code), guidance on control of microbial hazards associated with specific fresh fruits and vegetables. The scope of the new work, as approved by the 31st Session of the Codex Alimentarius Commission, encompasses several annexes to the Code for commodities that epidemiological evidence suggests are of primary public health concern, including leafy green vegetables, tomatoes, melons, green onions, sprouted seeds, herbs, berries, and root vegetables. The Committee began the process by developing a commodity-specific annex for leafy green vegetables, which was adopted by the Commission at its 33rd session.

2. Relevance and Timeliness

Outbreaks of foodborne illness due to contamination of fresh fruits and vegetables have been reported world-wide with increasing regularity. The global nature of produce production, processing, and marketing requires an international perspective in addressing this problem.

In the United States, between 1996 and 2008 there have been more than 80 outbreaks involving more than 10,000 illnesses and 15 deaths associated with produce. Leafy greens were the cause of most of the outbreaks, followed by tomatoes and melons. Since 2000, there have been 13 outbreaks in which tomatoes were confirmed or suspected as the source and 11 in which melons were confirmed or suspected. In several instances where a source was identified, the outbreak was the result of sources from outside of the U.S. All but one of the outbreaks were caused by *Salmonella*.

3. Main Aspects to Be Covered

- Review the advice from expert consultations conducted by FAO/WHO regarding the safety of agricultural and manufacturing practices for fresh produce, as well as guidance available from other sources.
- Develop a draft annex to the current *Code of Hygienic Practice for Fresh Fruits and Vegetables* for melons.

4. Assessment against the Criteria for the Establishment of Work Priorities**General Criterion**

Consumer protection from the point of view of health, food safety, ensuring fair practice in food trade, and taking into account the identified needs of developing countries: This new work will enhance consumer protection by reducing microbial hazards associated with fresh produce.

Criteria Applicable to General Subjects

(a) *Diversification of national legislations and apparent resultant or potential impediments to international trade:* This new work will provide scientific guidance, in the form of annexes to the Code, which countries will be able to use to develop their own risk management strategies for the control of microbial hazards in melons. This may assist in providing a harmonized approach for these products internationally.

(b) *Scope of work and establishment of priorities between the various sections of the work:* The scope of the new work is envisioned to encompass additional annexes to the Code for commodities that epidemiological evidence suggests are of primary public health concern. The Committee is proposing to continue the process by developing commodity-specific annex for melons.

(c) *Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies):* The new work does not duplicate work undertaken by other international organizations and it builds on work undertaken previously by CCFH in elaborating the *Code of Hygienic Practice for Fresh Fruits and Vegetables*.

5. Relevance to the Codex Strategic Objectives

The work proposed falls under all six Codex strategic objectives:

Objective 1: Promoting Sound Regulatory Framework

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 associated with various produce commodities.

Objective 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 various agricultural and manufacturing practices in the production of fresh produce. By understanding the relative risk of various practices, the most effective mitigation strategies can be implemented to ensure the greatest public health benefit.

Objective 3: Promoting Linkages between Codex and other Multilateral Regulatory Instruments and Conventions

The involvement of FAO and WHO in Codex activities has already formed a close link and their involvement in this effort, through expert consultations as needed for the development of the commodity-specific annexes, will continue to support this linkage.

Objective 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.

Objective 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.

Objective 6: Promoting Maximum Application of Codex Standards

Developing annexes to the Code which incorporate 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 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 commodity-specific annexes.

7. Identification of Any Requirement for and Availability of Expert Scientific Advice

FAO/WHO held an expert consultation on microbiological hazards in fresh leafy vegetables and herbs. The scope of this consultation included evaluation of pathogen-specific hazards associated with leafy green vegetables and herbs and the role of various agricultural and manufacturing practices in enhancing or mitigating these hazards for consumers. FAO/WHO focused on the identification, impact, and practical application of GAPs and GMPs on the safety of produce. The consultation considered the entire farm-to-table continuum including processing and marketing. The consultation focused on the factors at primary production that contribute to the risk of foodborne disease, especially environmental hygiene, water for primary production and packing, and personnel health, personnel hygiene and sanitary facilities. The expert consultation also considered packing establishments, field packing operations, and other post-harvest handling facilities, particularly key aspects of hygiene control systems such as post-harvest water use, worker health and hygiene, cleaning/sanitizing of equipment and facilities, and the maintenance of the cold chain. Similar consultations may be needed for other commodities.

8. Identification of Any Need for Technical Input to the Standard from External Bodies That Can Be Planned For

None identified.

9. Proposed Timeline for Completion of the New Work, Including Start Date, the Proposed Date for Adoption at Step 5, and the Proposed Date for Adoption by the Commission; the Timeframe for Developing a Standard Should Not Normally Exceed 5 Years

A five-year timeline is proposed for the completion of the annex for melons. A draft template for the annex would be ready for initial discussion by CCFH in 2011, with a proposed date for adoption at Step 5 in 2013 and adoption by the CAC in 2015.