codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

ALINORM 07/30/13

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Thirtieth Session
Rome, Italy, 2 - 7 July 2007

REPORT OF THE THIRTY-EIGTH SESSION OF THE

CODEX COMMITTEE ON FOOD HYGIENE

Houston, United States of America, 4 - 9 December 2006

NOTE: *This report includes Codex Circular Letter CL 2006/57-FH*

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CX 4/20.2 **CL 2006/57 - FH**

TO: Codex Contact Points
Interested International Organizations

FROM: Secretary, Codex Alimentarius Commission
Joint FAO/WHO Food Standards Programme
Viale delle Terme di Caracalla, 00100 Rome, Italy

SUBJECT: **Distribution of the report of the Thirty-eighth Session of the Codex Committee on Food Hygiene (ALINORM 07/30/13)**

The report of the Thirty-eighth Session of the Codex Committee on Food Hygiene (CCFH) is attached. It will be considered by the Thirtieth Session of the Codex Alimentarius Commission, (Rome, Italy, 2 – 7 July 2007)

MATTERS FOR FINAL ADOPTION BY THE CODEX ALIMENTARIUS COMMISSION:

1. Draft Code of Hygienic Practice for Eggs and Egg Products at Step 8 (ALINORM 07/30/13 para. 125 and Appendix II)

2. Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria Monocytogenes* in Foods at Step 8 (ALINORM 07/30/13 para. 144 and Appendix III)

3. Draft Principles and Guidelines for the Conduct of Microbiological Risk Management at Step 8 (ALINORM 07/30/13 para. 81 and Appendix IV)

Governments and interested international organizations are invited to comment on the above texts and should do so in writing, preferably by e-mail to Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00100 Rome, Italy : codex@fao.org or fax: +39 06 570.54593), **before 15 April 2007**.

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SUMMARY AND CONCLUSIONS

The Thirty-eighth Session of the Codex Committee on Food Hygiene reached the following conclusions:

MATTERS FOR FINAL ADOPTION BY THE 30TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION:

The Committee:

- agreed to forward the Draft Principles and Guidelines for the Conduct of Microbiological Risk Management to the Commission for adoption at Step 8 (see ALINORM 07/30/13 paras 37 - 81 and Appendix IV);

- agreed to forward the Draft Code of Hygienic Practice for Eggs and Egg Products to the Commission for adoption at Step 8 (see ALINORM 07/30/13 paras 86 - 125 and Appendix II);

-agreed to forward the Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Foods to the Commission for adoption at Step 8 (see ALINORM 07/30/13 paras 126- 145 and Appendix III).

MATTERS FOR ACTION BY THE COMMISSION

The Committee:

-noted that there was no consensus on the removal of restriction on the use of the Lactoperoxidase System in milk and milk products intended for international trade and decided to refer this matter to the Commission (paras 29-32 and 188-195).

NEW WORK

- agreed to consolidate two proposals on broiler chicken into a single one and to initiate new work on the proposed draft Guidelines for Control of *Campylobacter* and *Salmonella* spp. in Broiler (Young Bird) Chicken Meat (para. 203).

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

The Committee:

- did not consider the document on the Elaboration of Risk-based Standards for Microbiological Hazards: Enhancing the Process as this matter was already taken and addressed by the FAO/WHO Expert Meeting, Kiel, 2006 and the Workshop in Bilthoven, the Netherlands, 2006 (para. 9);

- agreed with amendments made to the Proposed Process by Which the Committee on Food Hygiene will Undertake its Work by the CCGP and referred the proposal for the work on the development of the CCFH Risk Analysis Policies document to the CCFH Working Group on Priorities (paras 15-17);

- agreed to split the Principles and Guidelines for the Conduct of Microbiological Risk Management into two documents one on the Principles and Guidelines for Microbiological Risk Management which had been finalized and forwarded to the Commission for final adoption; and other on the Development of Guidelines for the Establishment and Use of Risk Management Metrics which would be supplemental to the above Principles and Guidelines and would be elaborated at a later stage (para. 41);

- agreed to hold the Annex on Application of Food Safety Metrics in Risk Management Decision Making-Pasteurized Liquid Whole Eggs at Step 4 until the progress on Annex on microbiological metrics is made (para. 84);

- agreed to priorities for scientific advice be provided to the Committee by FAO/WHO, and the terms of reference for the FAO/WHO Expert Consultations on fresh produce and on viruses in food, as well as to the question to be posed to risk assessors on the risk reduction in the draft standard for Live and Raw Bivalve Molluscs (paras 209-215);

- agreed to consider Microbiological Criteria on *Listeria monocytogenes* in Ready-to-Eat Foods at the Committee's next session (para. 145);

- agreed to clarify the Scope of the Proposed Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children and returned the document to Step 2 for redrafting by the working group (see para. 156 and para. 160);

- agreed to clarify the Scope of the Proposed Draft Guidelines for the Validation of Food Safety Control Measures and to return the document to Step 2 for redrafting by the working group (see para. 169 and para. 183);

- noted information that Delegation of Cuba was not able to attend the Session due to the visa problems while noting the efforts of the Chairperson and the US Codex Secretariat to facilitate the participation of all member countries (paras 194-195).

MATTERS OF INTEREST TO OTHER COMMITTEES:

CODEX COMMITTEE ON FRESH FRUITS AND VEGETABLES (CCFFV)

The Committee agreed to request FAO and WHO to provide scientific advice on the draft terms of reference for an FAO/WHO expert consultation to support the development of commodity-specific annexes for the Codex Alimentarius *"Code of Hygienic Practice for Fresh Fruits and Vegetables"* (paras 224-231).

CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS (CCFFP)

The Committee endorsed with amendments the hygiene provision of the Proposed Draft Code of Practice for Fish and Fishery Products and did not endorse the Hygiene Provisions in the Draft Standard for Live and Raw Bivalve Molluscs (see paras 217-223).

In regard to marine biotoxins, the Committee is of the opinion that these provisions should be considered under the section on contaminants in the draft Standard and that consideration of these issues were outside the competence of this Committee. The Committee was of the view that the matter of marine biotoxins should be sent to the Committee on Contaminants for their advice and endorsement, if necessary. The Committee noted, however, that the *Principles for the Establishment and Application on Microbiological Criteria for Foods* covered biotoxins and advised that the CCFFP take these Principles into consideration when further developing this section in the standard (para. 223).

LIST OF ABBREVIATIONS

ALA	Asociación Latinoamericana de Avicultura
CAC	Codex Alimentarius Commission
CCGP	Codex Committee on General Principles
CCFH	Codex Committee on Food Hygiene
CRD	Conference Room Document
CCEXEC	Executive Committee of the Codex Alimentarius Commission
EC	European Community
FAO	Food and Agriculture Organization of the United Nations
FSO	Food Safety Objective
HACCP	Hazard Analysis and Critical Control Point System
IBFAN	International Baby Food Action Network
ICBA	International Council of Beverages Associations
ICMSF	International Commission for Microbiological Specifications for Foods
IDF	International Dairy Federation
IFEH	International Federation of Environmental Health
IFT	Institute of Food Technology
ISDI	International Special Dietary Foods Industries
JECFA	Joint FAO/WHO Expert Committee on Food Additives
OIE	Office international des epizooties (World Organization for Animal Health)
PC	Performance Criterion
PO	Performance Objective
SPS	Agreement on the Application of Sanitary and Phytosanitary Measures
WHO	World Health Organization
WTO	World Trade Organization

REPORT OF THE 38th SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE

INTRODUCTION

1. The Codex Committee on Food Hygiene (CCFH) held its Thirty-eighth Session in Houston, Texas, United States of America, from 4 to 9 December 2006, at the kind invitation of the Government of United States of America. Dr Karen Hulebak, Deputy Administrator, Office of Public Health and Science, Food Safety and Inspection Service, United States Department of Agriculture, chaired the meeting. Dr Michael Wehr, Codex Program Coordinator, U.S. Food and Drug Administration, Centre for Food safety and Applied Nutrition served as Vice-Chairperson. The Session was attended by 176 delegates representing 54 member countries, one member organization and 12 international organizations. A complete list of participants, including the Secretariat, is attached as Appendix I.

OPENING OF THE SESSION

2. The Session was welcomed by Dr Edwin Price, Associate Vice-Chancellor and Director Norman E. Borlaug Institute for International Agriculture, Texas and Dr Richard Raymond, Undersecretary for Food Safety, United States Department of Agriculture.

3. Dr Karen Hulebak, while welcoming the delegates to the 38th Session of the CCFH, encouraged them to complete the work on the revision of the Code of Hygienic Practice for Eggs and Egg Products and the Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Ready-to-Eat Foods. She drew the attention of the Committee to the need to use the new working procedures established by this Committee in order to effectively manage its work and to decide on new working items to be taken up by this Committee and emphasized that this would help to reduce the length and cost of the meeting and would allow more time to focus on substantial items. Dr Hulebak pointed out that it was very difficult for the Committee to progress on the elaboration of the Draft Principles and Guidelines for Microbiological Risk Management as new concepts such as: Food Safety Objectives, Performance Objectives and Performance Criteria introduced in this document were not applied in member countries yet, therefore there was a need to take a general decision to hold this matter until experts could elaborate their clear practical application.

4. Following Rule II.5 of the Rules of Procedure of the Codex Alimentarius Commission the Committee was informed about CRD 2 on the division of competence between the European Community and its Member States and noted the clarification of the European Community that the competence on Agenda Item 10 (c) was with the Member States but not mixed as it was indicated in the above CRD 2.

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

5. The Committee accepted the recommendations of the Chairperson and agreed to move Items 5 (a) on the revision of the Code of Hygienic Practice for Eggs and Egg Products and Item 6 (a) on the Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Ready-to-Eat Foods up in the agenda to be considered after Agenda Item 3; to consider the Annex on Microbiological Treatment and the Application of the Food safety Objectives, Performance Objectives and Performance Criteria (Agenda Item 5 (b)) during consideration of Annex III: Examples of the Use of Food Safety Objectives, Performance Objectives and Product Criteria (Agenda item 4 (b)).

6. The Committee also agreed to consider part of Agenda Item 9 on the Management of the Work of the Codex Committee on Food Hygiene dealing with the proposed process by which the CCFH will undertake its work on Agenda Item 2 and to refer the remaining part related to the Iterative Process to the next meeting of the Working Group on Priorities in 2007.

7. The Committee noted that an Annex on Deriving Microbiological Limits and Sampling Plans in Microbiological Criteria from Food Safety Objectives: Example: *Listeria monocytogenes in* Ready-to Eat Foods (Agenda Item 6 (b)) had not been prepared.

8. The Committee also agreed to consider Agenda Item 10 (c) Discussion of the Report of the *Ad Hoc* Working Group for Establishment of CCFH Work Priorities before Agenda Item 10 (a).

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[1] CX/FH 06/38/1; CRD 2 on the division of competence between the European Community and its Member States, prepared by the EC.

9. The Delegation of New Zealand informed the Committee that the original intention of the document on the Elaboration of the Risk-based Standards for Microbiological Hazards: Enhancing the Process introduced in the CCEXEC in 2005 to be considered on Agenda Item 10 (a) was to strengthen the relation between pathogens in the food chain and public health outcomes. Since this matter was addressed by the FAO/WHO Expert Meeting in Kiel in 2006, the workshop on this specific issue held in Brussels in September 2006 in conjunction with the CCGP Working Group meeting on the elaboration of Risk Analysis Principles for Application by Member Governments and the Workshop on Re-examination of Performance Objectives as related to quantitative microbiological risk assessment in Bilthoven, the Netherlands (27 November – 1 December 2006), therefore the Delegation proposed to delete this matter from the Provisional Agenda. The Committee agreed to this proposal.

10. With these amendments the Committee adopted the Provisional Agenda as Agenda for the session.

11. The Delegation of the United States drew the attention of the Committee to CRD 6 and informed the Committee that, in accordance with the newly established CCFH procedures for new work, it expected to submit a request next year for new work on the development of five commodity specific annexes on fresh fruits and vegetables and that this would likely require a request for scientific advice from FAO/WHO. The Delegation indicated that the draft Terms of Reference for an anticipated expert consultation was prepared and proposed to consider this matter in more detail under appropriate Agenda Items.

12. The Committee agreed to introduce this matter under Agenda Item 3 dealing with the FAO/WHO reports on the Joint FAO/WHO Expert Meetings, and to consider it as part of Agenda Item 10 (c) dealing with other requests for scientific advice in more detail, if required.

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

13. The Committee was informed about matters arising from the 28th and 29th Sessions of the Codex Alimentarius Commission, from the 56th Sessions of the Executive Committee and from other Codex Committees. The Committee noted that most of the matters were for information purposes while others would be discussed in more detail under relevant Agenda Items. In particular, the Committee noted the matters of interest to the Committee as follows:

Code of Practice for Handling and Processing of Quick Frozen Foods

14. The Committee noted that the 29th Session of the Commission had established an Intergovernmental *Ad Hoc* Task Force on the Processing and Handling of Quick Frozen Foods in order to finalize the quality and safety provisions for the above Code without the necessity for endorsement of the safety provisions by the CCFH unless the Task Force decides otherwise.

Management of the work of the Committee on Food Hygiene

15. The Committee noted that the CCGP had considered and made amendments to the document on the Proposed Process by Which the Codex Committee on Food Hygiene will Undertake its Work. The Committee agreed with these amendments and to utilize the amended document for the management of its work (see Appendix V).

16. The Committee amended the title by deleting the "proposed" before the process and decided to delete wording in square brackets in the second bullet of the Section on Purpose and the Scope, respectively, as these wordings were redundant.

17. The Committee noted the recommendation of the CCGP to develop the document on the application of risk analysis policies applied by the Food Hygiene Committee that might include interaction between the CCFH and JEMRA for possible inclusion in the Procedural Manual. Therefore the Committee agreed to delete Annex I from the document with the understanding that the wording proposed in this Annex would be considered for incorporation in the above risk analysis policies document. In view of this, the reference to Annex I on iterative process was deleted from paragraph 18 of the document. The proposal for the work on the development of the CCFH Risk Analysis Policies document was referred to the CCFH Working Group on Priorities for its consideration.

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2 CX/FH 06/38/2.

Endorsement of Hygiene Provisions in the Draft Code of Practice for Fish and Fishery Products

18. The Committee noted that the 27th Session of the Codex Committee on Fish and Fishery Products had finalized Sections on Quick Frozen Coated Fish and Fishery Products and Salted Fish and forwarded them for final adoption by the Commission. In accordance with the Codex Relations between Commodity Committees and General Committees, the CCFFP also forwarded the above Sections to the CCFH to endorse the hygiene provisions in these Sections.

19. The Committee also noted that the CCFFP forwarded the Proposed Draft Standard for Live and Raw Bivalve Molluscs to the Commission for adoption at Step 5.

20. Some delegations indicated that with regard to the Proposed Draft Standard for Live and Raw Bivalve Molluscs there were a number of concerns regarding proposed microbiological criteria such as incorrect use of log values or incomplete criteria. It was further proposed to refer the provisions on biotoxins to the Codex Committee on Contaminants in foods.

21. In order to address these matters, the Committee agreed to convene an intra-session *Ad Hoc* Working Group, lead by Norway[3], and to consider their recommendations under Other Business and Future Work (see paras 217-223).

Microbiological Criteria Provision of the Commodity Standards for Commercially Sterile Food Products

22. The Committee noted that this matter had already been addressed by this Committee at its previous Session, therefore there was no need for any action by this Committee.

PROGRESS REPORTS ON THE JOINT FAO/WHO EXPERT MEETINGS ON MICROBIOLOGICAL RISK ASSESSMENT (JEMRA) AND RELATED MATTERS. (Agenda Item 3)[4]

23. The Representatives of FAO and WHO presented this item and provided an overview of the matters of particular relevance to the work of the Committee.

24. The Representative of WHO informed the Committee of the FAO/WHO expert meeting on "The Use of Microbiological Risk Assessment Outputs to Develop Practical Risk Management Strategies: metrics to improve food safety" convened in Kiel, Germany in April 2006, which addressed the request of the 37th session to provide guidance on the use of MRA in the establishment of food safety metrics. Thanking Germany for their support in hosting and organizing this meeting, the Representative highlighted the progress made by the meeting but noted that further work was needed before practical guidance could be developed. The Representative also brought to the Committee's attention an informal workshop on the re-examination of performance objectives as related to quantitative microbiological risk assessment, which was held in Bilthoven, the Netherlands (27 November – 1 December 2006) to follow up on some of the issues raised during the FAO/WHO expert meeting.

25. While thanking FAO and WHO for their work in this area the Delegation of Canada expressed concern that the interpretation of Appropriate Level of Protection (ALOP) within the report of the expert meeting may lead to confusion and considered that it was not consistent with the definition of ALOP developed and used in the SPS Agreement and subsequent interpretative documents where the ALOP is interpreted as a target and not an.outcome. In all references to the ALOP in the SPS Agreement, there is reference to the establishment of measures to achieve the ALOP rather then the results of the application of a set of measures being used to establish the ALOP. In responding the Representative of WHO indicated that additional clarification would be provided in the context of the report of the expert meeting if deemed necessary.

26. The Delegation of Finland, speaking on behalf of the member states present at the current session noted that, given the output of the expert meeting, more work was needed in the area of Food Safety

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[3] Antigua and Barbuda, Australia, Brazil, Canada, European Community, France, Jamaica, Japan, Netherlands, New Zealand, Peru, Thailand, United States, FAO/WHO, IACFO and ICMSF.

[4] CX/FH 06/38/3; CRD 11 (Summary report of a workshop on Re-examination of performance objectives as related to quantitative microbiological risk assessment, RIVM, Bilthoven, the Netherlands (27 November – 1 December 2006) submitted by FAO and WHO).

Objectives (FSOs) and related metrics and that it was important that this work continued to be developed in a transparent manner.

27. The Representative of FAO updated the Committee on the FAO/WHO activities on *Enterobacter sakazakii* and *Salmonella* in powdered infant formula that had taken place since the Committee's 37th session. In particular the Committee's attention was directed to the response to the specific questions raised by its last session, the ongoing work by FAO and WHO to develop a user-friendly web-based *E. sakazakii* risk assessment tool and guidelines for the preparation and use of powdered infant formula.

28. The Representative of WHO informed the Committee of a recent FAO/WHO meeting on enterohaemorrhagic *Escherichia coli* in meat and meat products: approaches for the provision of scientific advice. In summarising the meeting outputs the Representative highlighted the guidance the meeting provided on the design of future risk assessments on this pathogen-product combination as well as to risk managers and Codex on the types of scientific advice needed to address different risk management options.

29. The Representative of FAO informed the Committee that in response to the request from the Commission[5], an expert meeting on the benefits and potential risks of the lactoperoxidase system of raw milk preservation had been implemented in 2005. The Representative highlighted the conclusions and recommendations of the expert meeting to Codex for the consideration of the Committee.

30. With regard to the report on lactoperoxidase the Delegation of Canada noted that it considered that there was still insufficient evidence regarding the safety of this system and indicated that it would provide FAO and WHO with further information on this issue. The Delegation of India, thanked FAO and WHO for its work in this area but noted that it still had concerns regarding the toxicological safety of thiocyanate used in the application of the lactoperoxidase system[6] and suggested that JECFA establish an ADI for thiocyanate. A number of other delegations noted their concerns and were of the view that additional specific information was needed regarding the safety of the system under different conditions of use.

31. In replying to these concerns the Representative of FAO noted that JECFA had already undertaken work on this issue at its 35th session to the extent possible given the available data and considered that the system was safe when used according to the guidelines developed by Codex.

32. The Chairperson noted that this session of the Committee was re-examining the issue of lactoperoxidase in the footnote in this regard that appears in the Code of Hygienic Practice for Milk and Milk Products (CAC/RPC 57-2004). In order to further consider the recommendations of the FAO/WHO report on lactoperoxidase, an intra-session working group[7], led by Japan, was established.

33. The Representative of FAO informed the Committee of the need for FAO and WHO to be aware of the Committees' priorities for the provision of scientific advice to facilitate a timely response to any such requests. The Representative further noted that in 1999 at its 32nd session the Committee developed a list of pathogen-product pairs for which it requested scientific advice based on risk assessment. FAO and WHO sought clarification as to the ongoing validity of that list and also anticipated receiving updated information from the Committee on its priorities during the current session

34. The Chairperson noted that although the Committee had now adopted new procedures for the management of its work it had never declared that the list established in 1999 was obsolete. Therefore, the Committee agreed that FAO and WHO should consider that in future the priorities for scientific advice from the Committee would be based on the discussions of the *ad hoc* working group on priorities. Based of this the Committee would define at each session its priority areas for scientific advice from FAO and WHO.

35. The Delegation of the United States of America informed the Committee that it intended to submit a project proposal for new work on fresh produce for the consideration of the Committee's working group on priorities in 2007 to address emerging public health concerns and indicated that scientific advice would be needed in order to proceed with this matter in a timely manner. An intra-session working group[8] led by the

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5 ALINORM 04/27/41.

6 CRD 5 (comments from India).

7 Australia, Brazil, Canada, European Community, France, Ghana, India, Jamaica, Japan, Kenya, Malaysia, New Zealand, Nigeria, United States of America, IDF, FAO, WHO.

8 Australia, Angola, Canada, Denmark, European Community, France, India, Ireland, Jamaica, Japan, the Netherlands, New Zealand, Nigeria, Norway, Sweden, Switzerland, Thailand, United Kingdom, IFFA, IAFCO, ICMSF, FAO, WHO.

United States was established to review the proposal presented in CRD 6 to request scientific from FAO and WHO on this issue.

36. In responding to the Delegation of the United States of America regarding the availability of FAO/WHO risk assessment documents, the Representative of FAO indicated that guidelines for risk characterization of microbiological hazards in foods would be available in mid-2007.

DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT (Agenda Item 4 (a))[9]

37. The Committee recalled that at its 37th Session it had agreed to forward the Proposed Draft Principles to Step 5 for adoption by the Commission and that after adoption at Step 5 comments were requested at Step 6 of the Procedure.

38. The Delegation of France, speaking as the Chair of the working group which led the preparation of the Code, introduced the history of the document and indicated that comments submitted to the current Session highlighted the need to have more in depth studies and discussions on the practical application of new concepts on metrics (e.g. FSOs, PO and PC) presented in the document. The Delegation proposed to separate the document into two parts, one dealing with the Principles and Guidelines for the Conduct of Microbiological Risk Management which could be progressed more rapidly; and another on practical implementation of new concepts on metrics which could proceed at a different rate.

39. The Committee had quite a lengthy discussion on how to proceed with the development of the document. While a number of delegations supported the splitting of the document, different views were expressed on how to separate Section 6.2, Selection of Microbiological Risk Management Options, between the two documents.

40. The Committee established an informal *Ad Hoc* Working Group led by France in order to address this matter. The Delegation of France informed the Committee that an informal Working Group prepared CRD 17 which was based on the original document presented in Appendix III of ALINORM 06/28/13 and contained proposals on how the current content of the draft Principles and Guidelines could be separated between the two new documents.

41. The Committee agreed to base its discussion on the original Appendix III of ALINORM 06/28/13 and to use CRD 17 for reference purposes. The Committee also agreed to dedicate a reasonable amount of time in order to try to finalize the document on the draft Principles and Guidelines for the Conduct of Microbiological Risk Management without that portion of the document dealing with the concepts on metrics. It also agreed that, if after some time, it appeared that the Committee would not be able to finalize its work on metrics, it would cease discussions on the subject and resume them only when it would be clear as how the concepts of FSOs, PO and PC would be applied in practice.

42. The Committee considered the draft Principles and Guidelines Section by Section and in addition to editorial amendments, made the following observations and agreed to the following changes.

Introduction.

43. In order to clarify the nature of hazards, “microbioal” was inserted in the list of hazards in footnote No 1.

44. The Committee noted that some references in footnotes were incomplete or superseded by newer documents and therefore agreed to clarify and update them throughout the text.

45. Several delegations noted that the current document did not reflect the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius adopted by the Commission for application by Codex or those for use by governments being developed by the CCGP and that further elaboration was needed in this regard. The Committee, noted however, that the current document was consistent with and encompassed most aspects of the risk analysis texts.

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[9] ALINORM 06/28/13, Appendix III; CL 2005/42-FH; CX/FH 06/38/4 (comments from Australia, Brazil, European Community, Japan, Peru, Thailand, the United States of America, ICMSF); CRD 4 (comments from IACFO); CRD 5 (comments from India); CRD 7 (comments from Indonesia); CRD 11 (FAO/WHO Information) and CRD 12 (comments from Thailand); CRD 17 (proposal of the Working Group).

46. The Committee also noted that principles for risk analysis were broad principles and this document meant to serve as a guidance and not to duplicate the risk analysis document and that the third paragraph of the Introduction clearly specified that that the Principles and Guidelines should be read in conjunction with other relevant Codex texts; therefore, it was not necessary to go in such detail in the Guidelines but rather focus consideration on how to avoid conflict between all documents.

Section I Scope

47. The Committee noted that there was a separate document on microbiological risk assessment elaborated by Codex which provided sufficient guidance on the application of microbiological risk assessment within the MRM process, therefore deleted the second sentence in the Scope to this effect.

Section 2 Definitions

48. The Committee agreed to delete the last sentence of the Section on Definitions containing applicability of FSOs and other parameters.

Section 3 General Principles

49. To be consistent with the Working Principles and Section 8 of this document, the Committee clarified 8 Principle 8 to indicate that MRM decisions should be subject to monitoring and review and revision in cases where it was necessary.

50. The Committee did not agree to a proposal to include reference to other legitimate factors in Principle 7 and was of the view that it would be better to address it under Section 4 of the document.

Section 4 General considerations

51. A new second sentence was introduced in the first paragraph to stress that decisions should be timely to achieve the protection of the health of consumers.

52. The second last paragraph of this section was amended to clarify that hazards also would vary depending on consumer food use patterns.

53. The Committee noted that the text of the current Principles and Guidelines provided sufficient guidance on the use of the document and that the correction of the flow chart in Annex I would require substantial amount of work Therefore it agreed to delete Annex and the reference and the to it in the text.

Section 5.1 Identification of a microbiological food safety issue

54. The Committee noted that different proposals were put forward in written comments on how to define and address immediate emergency measures/actions presented in square brackets in the fourth paragraph of this section. After some discussion it agreed to substitute “emergency measures” with “actions” and to insert a footnote to this effect to clarify that the WHO International Health Regulations of 2005 might be used in order to provide guidance in public health emergencies and that the Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations (CAC/GL 19-1995) defined food safety emergency. The Committee inserted an additional sentence to clarify that those immediate measures should be temporary, clearly communicated and reviewed within a time frame. The Committee also agreed to insert a sentence specifying how to proceed with provisional MRM decisions when there is a risk for human health but scientific data are not sufficient.

55. The Committee considered how to address situations with insufficient scientific knowledge presented in the fifth paragraph. Different proposals were put forward. Some delegations proposed to modify the first sentence to make it consistent with the Codex Working Principles for Risk Analysis adopted by the Commission. One delegation proposed to delete this paragraph as it was covered by Article 5 of the SPS Agreement. After some discussion, as a compromise, the Committee agreed to modify the first sentence of this paragraph to read:

i) “When there is an evidence that a risk to human health exists but scientific data are insufficient or incomplete, it may be appropriate for countries to select a provisional decision, while obtaining additional information that may inform and, if necessary, modify the provisional decision”

56. The Committee also agreed to add a footnote to the effect that the CCGP is elaborating working principles for risk analysis for application by governments and to remove the square brackets from this paragraph.

Section 5.2 Microbiological risk profile

57. In the last sentence of the first paragraph, the Committee deleted the reference to national governments and newly proposed work within CCFH as it was covered by the more general term of risk manager.

58. The Committee agreed to add an additional sentence to the second paragraph to clarify that national governments may base their MRM decisions on Codex texts when they are available and clarified cases for identification and selection of risk management options.

59. The Committee noted that the wording related to the proposed procedures in relation to the establishment of the CCFH working group and JEMRA were addressed in the agreed process by which the CCFH could undertake its work. Therefore, it agreed to delete the first sentence of the third paragraph and amended the second sentence for clarification purposes.

Section 5.3 Risk assessment policy

60. The Committee noted that the current text of this section did not provide sufficient guidance for risk assessors and risk managers with respect to the responsibility for establishing risk assessment policy and its content and agreed to the proposal of the delegation of Japan to add an additional section to this effect as proposed in their written comments.

Section 5.4 Microbiological risk assessment

61. The Committee clarified the second paragraph so that a MRA can be reviewed not only by the scientists but also by the public if it was appropriate, and also clarified how risk assessors and risk managers could decide on the adequacy of risk assessment. The Committee did not agree with the proposal from the Delegation of Japan to clarify risk management goals contained in written comments in Section 5.4, since the concept was generally covered by the General Principles and Guidelines for Conducting Microbiological Risk Assessment (CAC/GL 30-1999).

Section 6.1.1 Codex

62. The Committee amended the first bullet to clarify the nature of documents elaborated by Codex and moved the text of the third bullet to a footnote to clarify what Codex elaborates when there is a risk to human health but scientific data are insufficient or incomplete.

63. The second bullet of this paragraph was deleted due to restructuring of the document.

Section 6.1.2 Countries

64. The Delegation of India indicated that traceability/product tracing can be a tool towards meeting MRM options but in itself was not an MRM option and proposed either to delete this reference or to keep it in square until the CCFICS would elaborate guidelines. The Committee noted that the principle of traceability/product tracing was already accepted in Codex and agreed to delete this reference in the second bullet as this bullet dealt with specific documents on good practices, but retained the reference to traceability/product tracing without the square brackets in the next to last dash point and consequentially in the fifth bullet in Section 7.3.

65. The Committee changed the reference to specific microbiological metrics to “metrics” and inserted a footnote to this effect to clarify that the term “metrics” was understood according to the Use of Microbiological Risk Assessment Outputs to Develop Practical Risk Managemnt Strategies: Metrics to Improve Food Safety, Kiel, Germany, 2006.

66. Some other bullets of this section were amended for clarification purposes.

Section 6.2 Selection of risk management options

67. The second paragraph of section 6.2 and the last paragraph of section 6.2.1 were amended for clarification purposes.

Section 6.2.2 Risk based MRM options

68. The title was amended to read “MRM options based on risk” for consistency with an earlier decision.

69. The reference to "quantitative" was deleted from the first sentence of first paragraph and the second sentence was reworded to emphasize that risk analysis allowed for the use of traditional risk management options in addition to the development of newer tools.

70. The Committee noted that the second and third paragraphs of this section might be too limiting in its intent and problematic to address at this stage as there were a number of alternative MRM options to microbiological metrics which might be used, therefore decided to move the two paragraphs to the strikeout text of CRD 17. The Committee also noted that the struck text could be used in further elaboration of a document on food safety metrics.

71. Sections 6.2 including 6.2.2.1 on Food Safety Objectives, 6.2.2.2 Performance Objectives, 6.2.2.3 Performance Criterion were deleted in its entirety (see also paras 82-85).

Section 7.2 Countries

72. The Committee decided to remove the square brackets from provisions dealing with provisional MRM options in the fourth and sixth paragraphs.

Section 7.3 Industry

73. The first bullet was amended to clarify that establishing metrics will help to achieve or contribute to establishment of FSOs as well as other regulatory requirements.

74. The last paragraph was amended for clarification purposes.

Section 7.4 Consumers

75. The Committee noted that essential labelling requirements should be "appropriate" in accordance with the Codex General Standard for Prepacked Foods (CODEX STAN 1-1985), and therefore decided to delete references to hygiene handling labels, date labels and public interest messages.

Section 8 Monitoring and review of MRM options

76. The Committee noted that this section mainly dealt with MRM activities but not MRM options therefore amended the title of this section and made consequential changes to this effect in this section and Section 8.2.

Section 8.1 Monitoring

77. The Committee noted that the third paragraph as currently written implied that monitoring activities are always needed along the entire food chain, therefore revised it to emphasize that monitoring activities may be needed at multiple points along the food chain.

Annex II

78. The Committee noted that a number of comments were received on the suggested elements for a risk profile and considered how to address them in view of time constraints. It was suggested that more work was needed to accommodate these comments and that it would be advisable to return it to Step 6 for further elaboration.

79. The Delegation of New Zealand indicated that this Annex did not have regulatory implications and it was a good example for users and therefore supported its retaining as drafted.

80. After some discussion the Committee agreed to retain this Annex as Annex I with the understanding that it could be revised in future.

Status of the Draft Principles and Guidelines for Microbiological Risk Management

81. The Committee agreed to forward the Draft Principles and Guidelines for Microbiological Risk Management to the 30th Session of the Commission for final adoption at Step 8 (see Appendix IV).

ANNEX III: EXAMPLES OF THE USE OF FOOD SAFETY OBJECTIVES, PERFORMANCE OBJECTIVES, PROCESS AND PRODUCT CRITERIA AT STEP 4 (Agenda Item 4 (b))[10]

ANNEX: APPLICATIION OF FOOD SAFETY METRICS IN RISK MANAGEMENT DECISION MAIKING-PASTEURIZED LIQUID WHOLE EGG AT STEP 4 (Agenda Item 5 (b))[11]

82. The Committee considered how to handle the struck out text presented in CRD 17 and Annex III which contained provisions on microbiological metrics. It was agreed that these deletions contained very important material and could be used for consideration in further elaboration of the document on microbiological metrics.

83. The Committee noted that Annex III, Examples of the Use of Food Safety Objectives, Performance Objectives, Process and Product Criteria, consisted of two parts; one dealing with examples and approaches for utilizing quantitative microbiological risk assessment techniques to link the stringency of control measures to hygiene outcomes and a second dealing with metrics to achieve the desired level of public health protection. The Committee also noted that the practical application of metrics within an international or national food safety framework were still at a very early stage of development and required substantial additional work, in particular, the risk assessment tools for linking the establishment of traditional criteria and other guidance for hygienic manufacture, distribution and consumption of foods and its anticipated public health impact.

84. The Committee also noted that the future work on the Annex on Application of Food Safety Metrics in Risk Management decision Making – Pasteurized Liquid Whole Eggs was interrelated with the progress of the work on Annex III, Examples of the Use of Food Safety Objectives, Performance Objectives, Process and Product Criteria, and therefore decided that the consideration of the future work progress on an Annex for the Code on Egg and Egg products would depend on the progress of the work on the Annex on microbiological metrics. The Committee therefore agreed to hold the Annex on Application of Food Safety Metrics in Risk Management Decision Making-Pasteurized Liquid Whole Eggs at Step 4 until the progress on Annex on microbiological metrics is made.

85. The Committee was of the view that more active attempts at the national and international level should be made in order to progress the development of Annex III on microbiological metrics in a timely manner, and therefore agreed to hold this Annex at Step 4 and to establish a physical working group[12] led by the United States working in English only to prepare proposals on how to proceed on this matter. The Committee noted that such a work would require a clear framework on how to proceed, and therefore decided to consider the draft Terms of Reference to be prepared by this working group on Agenda Item 10 Other Business and Future Work (see paras 234-241).

DRAFT CODE OF HYGIENIC PRACTICE FOR EGGS AND EGG PRODUCTS (AGENDA ITEM 5(a))[13]

86. The Committee recalled that the 37th Session of the Committee had agreed to forward the proposed draft Code of Practice for Eggs and Egg Products for adoption at Step5 and that after adoption at Step 5 the draft Code was circulated for comments at Step 6 for consideration at Step 7 at the present Session.

87. The Committee agreed that discussion on a proposed annex to the draft Code of practice (Item 5(b) would be addressed under Item 4 on the Draft Principles and Guidelines for the Conduct of Microbiological Risk Management.

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10 CX/FH 06/38/4-Add.1; CX/FH 06/38/4-Add.2 (comments from Canada, IDF, ICMSF); CRD 5 (comments from India).

11 CX/FH 06/38/5-Add.1; CX/FH 06/38/5-Add.2 (comments from Australia, Canada, Islamic Republic of Iran and ICMSF); CRD 5 (comments from India).

12 Australia, Angola, Belgium, Canada, Denmark, European Community, Finland, France, Germany, India, Ireland, Jamaica, Japan, the Netherlands, New Zealand, Nigeria, Switzerland, Thailand, United Kingdom, ALA, IDF, IFFA, IAFCO, ICMSF, FAO, WHO.

13 ALINORM 05/28/13 Appendix IV, CL 2005/42-FH, CX/FH 06/38/5, CRD 4 (comments of IACFO), CRD 5 (comments from India), CRD 7 (comments from Indonesia), CRD 10 (Information from OIE), CRD (13 (comments from the EC).

88. The Delegation of Australia, speaking as the Chair of the Working Group which led the preparation of the draft Code briefly introduced the document and recalled for the Committee that the draft code remained flexible, in particular, to enable its application by small as well as large-scale industries.

89. The Committee considered the draft Code of Practice section by section and, in addition to editorial changes, made the following observations and amendments.

Introduction

90. It was proposed to insert a phrase "excluding viruses" with a view to specifying that the draft code was not designed to apply to viruses in eggs and egg products. However the Committee agreed to leave the text unchanged, recognizing that the draft code of practice covered a broader range of pathogens including viruses.

Scope

91. Section 2.1

92. It was proposed to add a phrase "egg products" in the second paragraph with a view to inclusion of egg products in the scope. The Committee agreed to delete the second paragraph as it was already covered by the first paragraph and made some changes in the first paragraph for clarity.

93. The Committee noted that the draft Chapter for the OIE Terrestrial Animal Health Code was also designed to address control and prevention of *Salmonella Enteritidis* in laying hens for primary production.

Section 2.4

94. The Committee agreed to include "distributor, transporter, or warehouser" at the end of second bullet point and to include reference to requirement of the competent authority at the end of the first sentence in the third bullet point for clarity.

Section 2.5

95. The Committee corrected a reference to Codex texts in the chapeau sentence and replaced the word "managed" with "kept" for clarity.

96. The Committee did not agree to the proposal to amend the definition for "Incubator egg" since the existing text was sufficient to indicate that once eggs had been placed in the incubator, eggs were no longer fit for human consumption regardless of whether they were fertile or not.

97. The Delegation of the United States, supported by several delegations, proposed to amend the definition for "Table egg" to take into account treatments that modify properties of eggs to enhance microbiological safety as it was considered too restrictive and did not take into account emerging technologies that could improve safety.

98. The Delegation of the European Community opposed this proposal since any modifications could be misleading to consumers.

99. After some discussion, the Committee amended the definition to read: "an egg destined to be sold to the end consumer in its shell and without having received any treatment that significantly modifies its properties"

100. The Delegation of European Community expressed their reservation to this decision.

Primary Production

Section 3.2.1

101. The Committee amended in the last sentence of the fourth paragraph to allow flexibility. In addition, the Committee agreed the following changes:

- could include additional words in changes in chapeau sentence;
- deleted "for the specific use" in the 6th bullet point;
- referred to a withdrawal period in the third dash point under the 6th bullet point;
- deleted the 7th bullet point since the intention of the text was already covered in the 6th bullet point; and,

- added "If a vaccine is used, it should be approved by the competent authority" in the eighth bullet point.

102. The Committee discussed whether to add a new bullet point with regard to destruction of *Salmonella* Enteritidis positive flocks. Several delegations were of the opinion that each country produced eggs according to their national requirements, which did not necessarily require destruction of flocks.

103. After some discussion, the Committee agreed to add this bullet subject to country requirements. The Delegations of India and Thailand expressed their reservation to the decision to not specify "producing" country.

Section 3.2.3.1

104. The Committee deleted a reference to access to surface water by free-range birds in the first bullet point since this was already addressed in the first sentence and did not only apply to this type of production. It was also agreed to add a new footnote to refer to a guideline prepared by FAO/WHO/UNEP (Safe Use of Wastewater, Excreta and Greywater. Volume II, Wastewater Use in Agriculture)[14] and the Code of Hygienic Practice for Meat and Meat Products in relation to the importance of safe water use, as additional guidance.

Section 3.2.3.4

105. The Committee agreed to insert a phrase "applicable regulation and/or" before "the manufacturer's directions," for clarity.

Section 3.3.3

106. The Committee did not agree to the change proposed to the first principle since minimization of microbiological growth was already covered by the fourth paragraph of this section.

Section 3.5

107. In the 8th bullet point, the phrase "and disinfection" was added for consistency.

108. There was an exchange of views on whether "traceability" should be included in the 9th bullet point. Several delegations were of the view that "traceability/product tracing" should be retained as it was important tool for withdrawal and recall procedures. One delegation proposed to retain the square brackets as guidelines on the implementation of traceability/product tracing were still to be elaborated.

109. After some discussion, the Committee agreed to remove the square brackets and add a footnote referring to the adopted Codex principles on traceability/product tracing[15].

Section 5.1

110. The Committee had a discussion on the first and fifth bullet points on how to differentiate between eggs for hatching and fertile eggs. It was indicated that fertile eggs that have been incubated should be listed as unsafe/unsuitable for consumption.

111. The Committee agreed to replace "risk-based control measures" with "control measures based on risk" for consistency.

Section 5.2.1

112. An Observer from IACFO indicated that the existing wording in the first and second principles lacked adequate requirements for temperature and time control, which are important control measures for ensuring the safety and suitability of eggs and egg products for human consumption and proposed to reword them. The Committee did not agree to this proposal and clarified that the text in these two principles provided some flexibility of application to certain situations where no control measures existed.

113. The Committee noted that these two principles did not duplicate each other since the first principle related to eggs in shell and the second one applied to egg products.

Section 5.2.2.1

114. It was agreed to replace the word "processing" with "handling" for clarity.

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[15] Codex Principles for Traceability/Product Tracing as a Tool within a Food Import and Export Inspection and Certification System (CAC/GL 60-2006).

115. In the second principle "sorting" was removed since dirty eggs could get through to the sorting process and be segregated out at that step, therefore eggs could not be always visibly clean prior to sorting.

Section 5.2.2.2

116. For the fourth principle, an alternative text was proposed, with a view to emphasizing a more desirable approach to avoiding cross-contamination from the exterior surface of egg shells to their contents in egg processing.

117. The Committee did not agree to this proposal, noting that in the course of elaboration of the text, more flexible wording was agreed upon to allow for a broader range of practices in processing and that the two principles under the treatments section were enough to ensure that the products were safe and suitable.

118. The Delegations of the United States and European Community expressed their reservation to this decision.

119. The second paragraph of storage and distribution section and the fourth bullet point under the second chapeau sentence wee reworded for clarification purpose.

Section 5.2.3

120. The Committee agreed to a proposal of the observer from ICMSF and added at the end of this section a new sentence "particular attention should be given to specifications indicating controls of pathogens such as *Salmonella* Enteritidis."

Section 8

121. The last bullet point was reworded for clarity.

Section 9.1

122. Concern was expressed that for short shelf life products it was not practical to link record keeping to shelf life, therefore the Committee agreed to reword the second sentence of the last paragraph for clarity.

Section 9.3

123. This section was amended to reflect that labeling should apply to both eggs and egg products.

124. The Committee agreed to delete two references to "Annex I: (Under development)" from the text with understanding that a document on microbiological metrics would be developed in future (see para. 85).

Status of the draft Code of Hygienic Practice for Eggs and Egg Products

125. The Committee agreed to forward the draft Code of Hygienic Practice for Eggs and Egg Products for adoption by the Commission at Step 8 (see Appendix II).

DRAFT GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF *LISTERIA MONOCYTOGENES* IN FOODS (Agenda Item 6 (a))[16]

126. The Committee recalled that at its 37th Session it had agreed to forward the Proposed Draft Guidelines to Step 5 for adoption by the Commission and that after adoption at Step 5 comments were requested at Step 6 of the Procedure.

127. The Delegate of Germany introduced the document and reminded the Committee of the history of its development which arose out of the need for microbiological criteria for *Listeria monocytogenes*. However, due to the need to base these criteria on scientific principles and the new approach to developing microbiological criteria it had been agreed to separate the microbiological criteria from the general guidelines. The Delegation pointed out that there was still a need to take a decision on how to approach the development of microbiological criteria.

128. The Committee considered the draft guidelines Section by Section and in addition to editorial amendments, made the following observations and agreed to the following changes:

[16] ALINORM 05/28/13, Appendix II; CL 2005/42-FH; CX/FH 06/37/6; CRD 3 (comments from IDF).

Introduction

129. The Committee had a discussion on whether there was a need to amend the introduction to indicate that specific measures were necessary to control *Listeria monocytogenes* only if good hygienic practices were not adequate. However, it was pointed out that the measures in this document were based on recommendations of FAO/WHO risk assessments conducted and that mere GHP would not be sufficient to control *Listeria monocytogenes.* The Committee therefore agreed retain this section unchanged.

Section II – Scope

2.1 Scope

130. The Committee did not agree with a proposal to insert a reference to foods where growth of *Listeria* is possible in the first paragraph, second sentence, since this would give the impression that only RTE could support the growth of *Listeria*. However, it agreed to simplify this paragraph to restrict the scope to RTE foods and also for consistency with the objectives of the document and in line with the risk assessment on which the document was based.

131. After some discussion agreed to amend the second paragraph to indicate that measures to control *L. monocytogenes* were in addition to those stipulated in other existing Codes since the current wording gave the impression that certain codes such as the Code of Hygienic Practice for Meat and the Code of Hygienic for Milk and Milk Products would not provide sufficient control measures for *L.monocytogenes* in RTE foods, but be restricted to non-RTE foods only.

Section III – Primary Production

132. The Committee agreed to amend the last paragraph of this section by the insertion of "validation" in addition to verification to indicate that analysis of raw material was an important tool to both validate and verify measures that control *L.monocytogenes*.

Section IV – Establishment: Design and Facilities

Storage

133. It was agreed to delete "minimize growth during holding" since it was recognised that the temperatures expressed would not be sufficient to minimize growth. However, to a question on the suitability of the range of temperatures stipulated, it was clarified that these temperatures took into account current practices and measurement variability and were recommendations of the FAO/WHO risk assessment used in the development of the guidelines.

Section V – Control of Operation

5.2.2 Specific process steps

134. It was agreed to amend the pH to 4.4 since the value of 4.0 was believed to be too stringent and that it was commonly accepted that a pH of 4.4 was sufficient to control *Listeria monocytogenes.*

135. After some discussion on whether validation should apply to single parameters as well as to a combination of parameters, it was agreed that the single parameters indicated in this section such as pH and a_w were already thoroughly validated and did not require further validation, but that validation was necessary for a combination of parameters. In addition, the term "process" was deleted to clarify that validation applied not to the process but to the parameters used.

5.2.3 Microbiological and other specifications

136. The Committee agreed to cross reference this section with the Recommended International Code of Practice-General Principles of Food Hygiene and the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

137. The Committee agreed that the draft Guidelines would clearly benefit from inclusion of microbiological criteria. It was further agreed that taking into account the available scientific data the Working Group led by Germany (see para. XXX) will develop such microbiological criteria to be considered at the 39th Session of the CCFH for potential amendment of the draft Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Foods. This work will be carried out taking into account the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

138. The Representative of WHO indicated that while developing these microbiological criteria, FAO/WHO risk assessments should be taken into account.

5.2.4 Microbiological cross-contamination

139. In the first paragraph it was agreed to also include "catering" as a possible place for cross-contamination.

Section VI – Establishment: Maintenance and Sanitation

140. It was agreed to replace "recontamination" with "contamination" in the second bullet point in the description box, since recontamination was misleading and implied that the product had been contaminated before.

Section VIII – Transportation

Objectives

141. In line with an earlier decision, it was agreed to delete "minimize the growth of *Listeria monocytogenes* in foods that support growth".

Annex I: Recommendations for an environmental monitoring program for Listeria monocytogenes in processing areas

b) Type of sample

142. This section was reworded to provide better clarity.

i) Actions in case of positive results

143. The first paragraph was amended to indicate that an appropriate action plan should not only be designed, but also established to respond to positive findings. The second paragraph was expanded for clarification purposes to indicate that nature of the reaction was dependent upon the likelihood of contamination rather than the risk of contamination as well as the expected use of the product.

Status of the Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Ready-to-Eat Foods

144. The Committee agreed to forward the Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Ready-to-eat Foods, including Annex I, to the 30th session of the Codex Alimentarius Commission for final adoption at Step 8 (see Appendix III).

145. The Committee also agreed to establish a physical working group to be led by Germany[17] with the terms of reference to development of microbiological criteria on *Listeria monocytogenes* in ready-to-eat foods. The Committee agreed that this working group would meet in Berlin, Germany and use English as its working language. The Committee was of the view that this work on microbiological criteria would be completed over two sessions of the Committee (by 2008) for adoption by the CAC in 2009.

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR POWDERED FORMULAE FOR INFANTS AND YOUNG CHILDREN (Agenda Item 7)[18]

146. The Committee recalled that at its last session it had agreed to return the proposed draft Code to Step 2 and that it had requested FAO/WHO to convene an Expert Consultation to examine several matters related to *E. sakazakii* and *Salmonella* in powdered infant formula[19] and a the physical working group lead by the Canada would in the light of the findings of this expert consultation, redraft the draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children for circulation for comments and consideration by this session.

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17 Australia, Austria, Brazil, Canada, China, Denmark, EC, Finland, France, Greece, Hungary, Italy, Jamaica, Japan, Norway, Sweden, Switzerland, the United Kingdom, Uruguay, The United States of America, FAO, WHO, ICMSF, IDF and IFT

18 CX/FH 06/38/7; CX/FH 06/38/7-Add. 1 (comments from Australia, New Zealand, Philippines, Unites States of America, ICMSF, IDF, CIAA, ISDI); CRD 7 (comments from Indonesia); CRD 8 (comments from IACFO and IBFAN); CRD 9 (comments from Brazil); CRD 12 (comments from Thailand); CRD 13 (comments from European Community); CRD 14 (Ghana); CRD 15 (India).

19 ALINORM 05/28/13, paras 54-55.

147. The Delegation of Canada introduced the document and in addition to providing some background into the development of this document and the findings of the FAO/WHO Expert Consultation, explained the difficulties that the Working Group encountered in meeting the terms of reference to develop an Annex A with regard to powdered infant formula for "infants at greatest risk" and Annex B with regard to all powdered infant formula for infants and young children given to it by the Committee.

148. The Delegation indicated that there was no category for products targeted at infants at greatest risk as defined by the WHO/FAO Risk Assessment and there was thus a need to reassess the scope of this Code in relation to the products covered either with regard to age of risk groups (younger than 12 months) or to the type of formulae.

149. The Committee agreed to firstly clarify the scope of the document and to have a general discussion on the form of the document in order to provide guidance to the working group for further development of the Code.

150. There was an exchange of views on whether the current scope was too wide and that products to be covered needed to include those for which there were existing Codex standards. Some delegates were of the view that the scope needed to take into account the age groups of infants most at risk for *E.sakazakii* and *Salmonella* and the products associated with these age groups.

151. Some delegations proposed to limit the scope to those products posing greatest risk to infants such as powdered infant formula (PIF), formulae for special medical purposes intended for infants which can used as a sole source of nutrition for infants, and human milk fortifiers.

152. Some other Delegations opposed the limitation to these products and proposed to broaden the scope of the Code to those products considered in the FAO/WHO Risk Assessment, including follow-up formula. The Delegation of the United States emphasized that it would be difficult to define follow-up formulas based on age as there were regional differences.

153. The Delegation of Canada pointed out that the working group had experienced difficulties with dealing with follow-up formula in light of these regional differences and proposed to exclude this from the scope.

154. Several other delegations highlighted the difficulties faced by developing countries where there was active marketing of follow up formulae and where for several reasons, including cost, products were not necessarily used as intended and were of the view that in order to ensure safety to all infants and young children, all powdered formulae needed to be covered by the Code.

155. As a way forward, the Committee also considered a proposal that in order to progress work on this Code all products should be covered by the Code and that the core of the document could cover general aspects related to GHP and HACCP and that Annexes could be developed to more specifically cover measures to control risks and provide risk management options such as microbiological criteria for *Enterobacter sakazakii* and/or *Salmonella*.

156. After some discussion the Committee agreed that the scope of the document would cover all powdered formula intended for infants and young children and that the core of the document would focus on general aspects related to hygiene. The Committee also agreed that two separate Annexes would be developed that would focus on the specific hygienic practices and microbial criteria for infant formula, formula for special medical purposes for infants, and human milk fortifiers and one on follow-up formula, respectively.

157. It was however emphasized that due to variations in production practices for the different products covered by the scope, development of the Annexes would be challenging and that all conditions for manufacture would need to be taken into account.

158. The Committee did not amend the title to reflect the newly clarified scope, but instead indicated that the working group should consider this issue during the further development of the Code.

159. To a question on the difference of the scope between the current Code (Recommended International Code of Hygienic Practice for Foods for Infants and Young Children (CAC/RCP 21-1979) in force and the new Code under development (Proposed Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children), the Committee noted that the Scope of the new Code would focus only on powdered formulae. One delegation noted that a new Code under development covered fewer products.

Status of the Proposed Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children

160. The Committee agreed to return the proposed draft *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* to Step 2 for redrafting by a physical Working Group led by Canada[20]. It agreed that the Working Group would revise the Code taking into account the decisions regarding the scope, the structure of the Code and the written comments submitted to the current session. The Working Group would meet in Ottawa, Canada during May/June 2007 and would use English as its working language. The Committee agreed that the redrafted proposed draft Code would be circulated for comments at Step 3 and be considered at its next session of the Committee.

161. The Committee was of the view to complete the work by 2008 with the intention to submit to the Commission for adoption in 2009.

PROPOSED DRAFT GUIDELINES FOR THE VALIDATION OF FOOD SAFETY CONTROL MEASURES (Agenda Item 8)[21]

162. The Committee recalled that the 36th Session of the Committee agreed that the drafting group revise the proposed draft guideline for further discussion and that the 37th Session of the Committee had not discussed the revised guideline due to time constraints and had agreed to return it to Step2 for redrafting by the Working Group led by the United States of America.

163. The Delegation of the United States of America, speaking as the Chair of the Working Group, introduced the background and contents of the redrafted guidelines and raised the following four points and questions that needed to be clarified by the Committee in order to facilitate the progress of the draft guideline.

i) The current scope of the draft guideline included control measures throughout the entire food chain. Whether the current scope should be retained or whether it needed to be limited, and if so, how;

ii) The working group was previously asked to include information on verification and monitoring to clarify their relationship to validation. However this seemed to be causing confusion and a question was whether this information should be included;

iii) Comments submitted indicated that the inclusion of additional examples would help clarify the document. What examples should be added to facilitate an understanding of validation; and

iv) Whether Annex I (Nature of Food Safety Control Measures) should be retained or removed.

164. The Committee decided not to discuss the draft guidelines in detail and focused its discussion on the above four questions, so as to provide general guidance for further elaboration of the draft guideline. The discussion held and suggestions made are as follows.

Scope of the draft guideline

165. Some delegations expressed concerns that the current scope was too wide and there was difficulty on how and who could validate food safety control measures throughout the entire food chain. It was pointed out that, in practice, such validation was not feasible and suggested that the draft guideline should focus on validation of specified food safety control measures, such as CCPs in a HACCP system.

166. Some delegations expressed the view that there was no need to limit the scope of the guideline and that food safety control measures throughout the entire food chain should be validated aiming at assuring food safety from primary production to consumption.

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[20] Angola, Antigua and Berbuda, Australia, Austria, Belgium, Bolivia, Brazil, China, EC, Finland, France, Germany, Ghana, India, Ireland, Italy, Japan, the Netherlands, New Zealand, Senegal, Spain, Switzerland, the United Kingdom, the United States of America, Uruguay, Consumers International, IBFAN, ICMSF, ILCA, IDF, FAO and WHO.

[21] CX/FH 06/38/8; CX/FH 06/38/8 Add.1; CRD 5 (comments from India); CRD 12 (comments from Thailand), CRD 13 (comments from EC).

167. It was pointed out that if validation were apply to the entire food chain, different approach to validation may have to be used a different points, for example, validation of measures at primary production. It was noted, however, that validation was not always feasible and applicable to all types of food safety control measures and that capability to validate measures was also limited in some food businesses and that these aspects needed to be taken into account.

168. It was suggested that the level of confidence able to be achieved in validating specific control measures should be taken into consideration.

169. After some discussion, the Committee agreed to reword the scope of the draft guideline to indicate that:

- These guidelines apply to validation of control measures at any stage of the food chain.
- These guidelines are intended as guidance to industry and governments on the validation of individual control measures, a limited combination of control measures, or sets of control measures forming a food safety control system, e.g HACCP, GHP.

Inclusion of verification and monitoring to clarify the relation to validation

170. Several delegations were of the opinion that it was important to include verification and monitoring in the draft guidelines, with a view to clarifying their relation to validation and that the meaning and examples of verification should be included.

171. A delegation suggested that the draft guideline should be limited to validation only since inclusion of verification and monitoring would lead to misunderstanding and confusion among government authorities and industries.

172. It was pointed out that some existing Codex texts including the HACCP guideline had caused a range of confusion since the relation of validation and verification was not clearly described.

173. It was also suggested that references to several terms related to food safety control measures including prerequisite programs, validation etc updated in the ISO 22000 Food Safety Management Standard[22] should be considered for inclusion in the draft guideline.

174. After some discussion, the Committee, noting that the draft guideline was designed to address mainly validation, agreed that the draft guideline should also include a brief section on verification and monitoring, illustration of examples and descriptions of how to use them, with a view to providing clear guidance on the understanding of validation and its relation to verification and monitoring.

Inclusion of additional examples to facilitate the understanding of validation

175. An observer suggested that the draft guideline should include examples of product/process criteria used by industry and also descriptions of how they were used.

176. It was pointed out that that, in food safety control systems such as HACCP or GHP, food safety control measures validated by government authorities were of a different nature to those validated by industry, for example, governments validated metrics developed to achieve an appropriate level of protection of consumers, while industry validated control measures set to implement food safety control systems . Therefore it was suggested that examples of the various role of governments and industry should be described.

177. It was pointed out by some delegations that every individual food safety control measure should be validated not only in the HACCP system but also with respect to GHPs and therefore suggested that the draft guideline should take up this point.

178. It was suggested that the draft guideline should also address chemical hazards such as pesticides and contaminants, in addition to microbiological hazards.

179. After some discussion, it was suggested that illustration of validation to control measures for chemical and physical hazards should be included. The Committee agreed to that suggestion.

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[22] ISO 22000 : 2005 “Food safety Management Systems – Requirements for any Organization in the Food Chain”.

Annex I

180. There was an exchange of views on whether the current annex should be deleted. Several delegations proposed to delete the current annex, noting that it had been prepared to provide a general explanation on food safety control measures and that this explanatory material was already covered by the Recommened International Code of Practice-General Principles of Food Hygiene (CAC/RCP 1-1969).

181. Other delegations were of the opinion that a new annex should be developed to provide various practical examples of validation linked to food safety control measures, such as HACCP and GHP.

182. After some discussion, the Committee agreed that the current annex should be deleted and that it should be reworked to include illustration of examples of validation agreed earlier (see paras 174 and 179).

Status of the proposed draft Guidelines for the Validations of Food Safety Control Measures

183. The Committee agreed to return the proposed draft guidelines to Step 2. The Committee agreed that a physical working group, led by the United States of America[23], would revise the proposed draft guideline, taking into account all the written comments submitted and discussion held at the present Session. The revised proposed draft guideline would be circulated for comment at Step 3 and further consideration at Step 4 at the next Session. The Committee agreed that the physical working group would use only English as working language.

184. The Delegation of France expressed its concern regarding the linguistic regime for the Working Groups established by this Committee. The Delegation was of the opinion that the present decision should not set precedent.

185. The Committee was of the view to complete the work in two sessions of the Committee for final adoption at Step 8 by the Commission in 2009.

MANAGEMNT OF THE WORK OF THE COMMITTEE ON FOOD HYGIENE (Agenda Item 9)[24]

186. See Agenda Item 2 (paras 15-17).

OTHER BUSINESS AND FUTURE WORK (Agenda Item 10):

ELABORATION OF RISK-BASED STANDARDS FOR MICROBILOGICAL HAZARDS: ENHANCING THE PROCESS (Agenda Item 10 (a))[25]

187. See Agenda Item 2 (para. 9).

THE USE OF THE LACTOPEROXIDASE SYSTEM FOR MILK AND MILK PRODUCTS IN INTERNATIONAL TRADE (Agenda Item 10b)[26]

188. The Delegation of Japan introduced the findings of the *ad hoc* intra-session working group established to provide recommendations for consideration by the Committee. The Delegation informed the Committee that the Working Group noted the conclusions of the FAO/WHO Report on the Safety of the Use of LP System and the recommendations to remove the restriction of the use of lactoperoxidase in milk and milk products intended for international trade.

189. In addition to safety concerns, some delegations also had concerns about the practical application of the LP system, in particular the difficulties in monitoring to ensure its safe and appropriate use, and its impact on fair practices in food trade.

190. Other delegations indicated their agreement with the recommendations of the report and confirmed that the lactoperoxidase system could be very useful in their developing dairy sectors.

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23 Australia, Brazil, Canada, European Community, Finland, France, Germany, India, Italy, Japan, the Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland, Thailand, FAO, WHO, IACFO, IDF, IFFA and ICMSF.

24 ALINORM 06/29/33, Appendix V.

25 CX/FH 06/38/9.

26 CRD 21 (Report on the *ad hoc* Intra-session Working Group on the Use of Lactoperoxidase System).

191. With regard to the safety concerns raised, the Representatives of FAO and WHO provided additional information on the data and findings of the Lactoperoxidase Expert Meeting and reiterated the information provided under Agenda Item 3. The FAO and WHO clarified that the use and application of the system is clearly described in the guidelines (CAC/GL 13 - 1991) (see paras 30-32).

192. The Working Group could not reach a consensus regarding the removal of the restriction on the use of the LP system in milk and milk products intended for international trade.

193. The Committee agreed with the conclusion of the Working Group and decided to refer the matter to the Commission.

194. The Delegation of Mexico noted the relevance and importance of this work to member countries from Latin America and informed the Committee that the Delegation of Cuba, which had submitted comments, presented in CRD 18, was unable to participate in this discussion due to problems with obtaining a visa for entry into the USA.

195. The Representatives of the FAO and WHO also raised their concerns with the difficulties faced by some countries to attend the Session but acknowledged the efforts of the Chairperson and the US Codex Secretariat to facilitate the participation of all members countries.

REPORT OF THE *Ad-Hoc* WORKING GROUP FOR THE ESTABLISHMENT OF CCFH WORK PRIORITIES (AGENDA ITEM 10(c))[27]

196. The Committee recalled that the 37th Session of CCFH requested countries to prepare written proposals for new work according to the *Process by which the Codex Committee on Food Hygiene will Undertake its Work*[28]. The 37th Session of CCFH also established the *Ad-Hoc* Working Group for Establishment of CCFH Work Priorities, chaired by Australia, to consider submitted new work proposals and provide its recommendations to the Committee.

197. The Committee noted that the Working Group, meeting immediately prior to the 38th Session, considered the following new work proposals received in response to Codex Circular Letter 2005/40-FH.

- Guidelines for the Application of the General Principles of Food Hygiene to the Risk-Based Control of *Salmonella* spp. in Broiler Chickens (prepared by Sweden);
- Guidelines for Risk Management Options for *Campylobacter* in Broiler Chickens (prepared by New Zealand);
- Guidelines for Hygienic Control of *Vibrio* Spp. in Seafood (prepared by the United States); and,
- Development of Guidelines to Control Norovirus in Bivalve Molluscan Shellfish (prepared by The Netherlands).

198. Additionally, the United States advised the Working Group that a proposal for new work on "Guidelines for the Application of the General Principles of Food Hygiene to Risk Based Control of Enterohaemorragic *E. coli* in Ground Beef and Fermented Sausages" would be delayed for one year.

199. The Working Group considered the prioritization of the new work proposals and the need for scientific advice from FAO/WHO associated with the proposals.

200. The Committee noted that the Working Group made the following recommendations to the Committee[29]:

- That the two chicken proposals be consolidated into a single proposal for the development of *Guidelines for the Control of Campylobacter and Salmonella spp. in Broiler (young bird) Chicken Meat* and that this work be given the highest priority for new work to be undertaken by the Committee.

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27 CX/FH 06/38/10; CRD 1 (Report of the Working Group); CRD 5 (comments from India); CRD 12 (comments from Thailand); CRD 19 (Project document: proposal for new work, prepared by New Zealand and Sweden).

28 Endorsed by the Codex Committee on General Principles (ALINORM 06/29/33, paras 45-47).

29 CRD 1 (Report of the *Ad Hoc* Working Group).

- That second priority be given to the development of a *Draft Code of Hygienic Practice for Management of Pathogenic Vibrio parahaemolyticus in Seafood;*
- That new work on *Guidelines for the Control of Norovirus in Bivalve Molluscan Shellfish* not be undertaken at this time but that an FAO/WHO Joint Expert Consultation on "Foodborne Viruses" be undertaken in 2007.

201. The Working Group also developed a draft Terms of Reference for proposed scientific advice from WHO/FAO for future work on viruses in foods (see paras 210-212).

202. The Chairperson recommended that, considering the need to properly manage the Committee's work and to reduce the length of the Committee's sessions, the Committee should agree to undertake only one new work item.

203. After discussion, the Committee, noting the prioritization of proposed new work by the Working Group and the recommendations of the Chairperson, agreed to submit the development of "Proposed Guidelines for Control of *Campylobacter* and *Salmonella* spp. in Broiler (young bird) Chicken Meat" to the 30th Session of the Commission for approval as new work.

204. The Committee considered the scope and form of the Proposed Guidelines, taking into account a proposed Project Document prepared by New Zealand and Sweden.[30] The Committee clarified that the Proposed Guidelines would focus on fresh chicken meat and chicken pieces with the possibility of expanding the scope to other products at a later stage. With respect to the form of the Code, several delegations noted the need to incorporate risk management options based on the results of risk assessment and that the Guidelines should permit incorporation of new thinking on the use of microbiological metrics. Other delegations noted the importance of utilizing the format of the *Recommended International Code of Practice: General Principles of Food Hygiene* (GPFH) incorporating good hygienic provisions and HACCP. The Committee noted that the two approaches were not mutually exclusive, and that a framework based on the GPFH could incorporate all risk management options.

205. The Committee agreed that the Delegations of New Zealand and Sweden would revise the Project Document, taking into account the discussion on the framework of the document, for submission to the 30th Session of the Commission. The Committee agreed to establish a physical Working Group, led by New Zealand and Sweden[31] to develop a Discussion Paper for the next session of the Committee presenting the framework and expected content of the Guidelines as well as specific risk management questions. The working language of the Working Group will be English with every effort made to add French and Spanish languages. The Committee proposed a timeframe of 2011 to complete the work.

206. The Committee also considered the recommendation by the *Ad-Hoc* Working Group for Establishment of CCFH Work Priorities for priority to be given to the development of Guidelines for Hygienic Control of *Vibrio Spp.* in Seafood. Some delegations indicated the importance of proceeding with this work as soon as possible taking into account the workload of the Committee.

207. The Committee agreed to re-establish the *Ad-Hoc* Working Group for Establishment of CCFH Work Priorities that would meet the day before the next Session and accepted the kind offer of India to Chair the Working Group.

208. The Committee emphasized that proposals should be submitted in accordance with the established procedures.

Requests for the provision of scientific advice

209. The Committee considered the needs for scientific advice from FAO/WHO as proposed by the *Ad-hoc* Working Group for Establishment of CCFH Work Priorities.

210. The Committee noted that the *Ad Hoc* Working Group on Priorities agreed that viruses were an important food safety concern, but there was insufficient scientific understanding of the field to make informed decisions on the priority virus-product combinations to be addressed by the Committee Therefore,

[30] CRD 19 (Project document: Proposal for New Work, prepared by New Zealand and Sweden).

[31] Australia, Austria, Belgium, Brazil, Canada, China, Denmark, European Community, Finland, France, Ghana, Hungary, India, Italy, Jamaica, Japan, Kenya, Ireland, Netherlands, Peru, Thailand, United Kingdom, United States, FAO, WHO, ALA, and ICMSF.

the Committee requested FAO and WHO to implement an Expert Consultation on Foodborne Viruses in 2007 with the following Terms of Reference:

Terms of Reference for Proposed Scientific Advice from FAO/WHO for Future Work on Viruses in Food:

- To review the current state of knowledge on viruses in food and their public health and trade impact;
- To review availability and feasibility and the practical consequences of using analytical methods for detecting viruses; and
- To review existing risk profiles and other relevant information pertinent to the evaluation of risks associated with viruses in food.

211. The Objectives of the Expert consultation would be the following:

- To provide the basis for the identification and selection of viruses and product combinations to be addressed in future risk management work;
- To identify the key issues currently faced by risk managers in terms of addressing the problems associated with viruses in food;
- To provide guidance on the different options for management strategies that will be proposed by CCFH and the impact of possible options considered by CCFH in the development of a risk management document;
- To provide guidance on the scientific advice needed for such activities as well as a suggested road map for future work; and
- To identify the data and information needed (data gaps) for risk assessment activities. This would provide guidance for research needs designed for and targeted for the provision of scientific advice.

212. The Committee noted the offer of the Netherlands to host such a meeting in collaboration with FAO and WHO.

***Vibrio parahaemolyticus* in sea food**

213. The Committee agreed with the proposal from the Delegation of Japan to request FAO and WHO to use the risk assessment on *Vibrio parahaemolyticus* in seafood, which they are developing to provide scientific guidance to the Codex Committee on Fish and Fishery Products, to follow up on the recommendations of the CCFH regarding the hygiene provisions in the Proposed Draft Standard for Live and Raw Bivalve Molluscs. The following risk management question is proposed:

- *Estimate the risk reduction from V. parahaemolyticus when the total number of V. parahaemolyticus or the number of pathogenic V. parahaemolyticus, ranges from absence in 25g to 1000 cfu or MPN per gram.*

214. The Representatives of FAO and WHO agreed to take this into consideration in finalising the risk assessment of *V. parahaemolyticus* in seafood.

Salmonella and campylobacter in broiler chicken

215. Following the decision of the Committee to take up new work on the management of *Salmonella* spp. and *Campylobacter* spp. in broiler chickens, it was noted that additional scientific information may be needed in this area. However, the available FAO/WHO risk assessments on *Salmonella* spp. and *Campylobacter* spp. in broiler chicken, among others would first be reviewed by the working group and any further requests for scientific advice in this area would be raised at the next session of the Committee.

216. The Delegation of the United States noted that while CCFH now has a procedure for requesting and prioritizing its own new work, an equivalent procedure for requests for scientific advice has not been established yet.

ISSUES ARISING FROM PREVIOUS DISCUSSIONS

Endorsement of Hygiene Provisions in Codex Standards and Codes of Practice[32]

Proposed Draft Code of Practice for Fish and Fishery Products

217. In accordance with the terms of reference of the Codex Committee on Food Hygiene, the Committee was invited to endorse the hygiene provisions of the Proposed Draft Code of Practice for Fish and Fishery Products, subsections 10.4 and 10.5 of Section10, Quick Frozen Coated Fish and Fishery Products and Section 11, Salted Fish and the Proposed Draft Standard for Live and Raw Bivalve Molluscs.

218. The Committee considered the report of the *ad* hoc intra-session Working Group and agreed to endorse the hygiene provisions in the proposed draft Code of Practice for Fish and Fishery Products (Sections 10.4, 10.5 and 11) with the following amendments:

- to amend subsection 10.4 – Processing Operations – Molluscan Shellfish and subsection 10.5 – Processing Operations – Coated Shrimp of Section 10 Quick Frozen Coated Fish and Fishery Products by adding to the end of the first paragraph, "*It is assumed that the end product will be cooked thoroughly before consumption"* because cooking will control most of the microbiological hazards associated with raw or undercooked molluscan shellfish and shrimp.
- to delete the last bullet point under *technical* guidance in point 11.4.4 Dry salting, since proper guidance on this was given in 6th bullet point of Section 11.1 General and to include microbiological contamination as a potential hazard in point 11.5.3 Weighing, Wrapping and Packaging in Section 11 Processing of Salted and Dried Salted Fish.

Draft Standard for Live and Raw Bivalve Molluscs

219. The Committee agreed that the hygiene provisions were not suitable for endorsement at this time and recommended that the text on Hygiene and Handling in section I-5.3 (i – iii) dealing with microbiological criteria be revised to address the requirements of the *Principles for the Establishment and Application on Microbiological Criteria for Foods;* that CCFFP should describe the scientific basis for these criteria; provide sampling plans; describe actions to be taken; review the manner in which the two sets of microbiological criteria for *E.coli* and the one for faecal coliforms were presented; clarification was needed as to why a 3-class sampling plan was proposed; analytical methods for *Salmonella* and *V.parahaemolyticus* be included and, clarification be provided on why a method dating back to 1970 was proposed for faecal coliforms, and whether more recent methods, were not considered.

220. In the case of indicators for faecal contamination, the Committee requested scientific justification for providing two options and further recommended that only one microbiological criterion be set as an indicator of faecal contamination.

221. With regard to the proposed criterion for *Vibrio parahaemolyticus*, clarification is necessary on whether this level was for pathogenic strains or for the most probable number of all strains of *V. parahaemolyticus.*

222. The Committee also recommends asking FAO/WHO and ICMSF for advice and assistance with the development of microbiological criteria.

223. In regard to marine biotoxins, the Committee is of the opinion that these provisions should be considered under the section on contaminants in the draft Standard and that consideration of these issues were outside the competence of this Committee. The Committee was of the view that the matter of marine biotoxins should be sent to the Committee on Contaminants for their advice and endorsement, if necessary. The Committee noted, however, that the *Principles for the Establishment and Application on Microbiological Criteria for Foods* covered biotoxins and advised that the CCFFP take these Principles into consideration when further developing this section in the standard.

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[32] CX/FH 06/38/2; CRD 16 (Report of the *ad hoc* Intra-session Working Group).

Fresh produce

224. The Delegation of the United States of America reported on the output of the intra-session working group on draft terms of reference for an FAO/WHO expert consultation to support the development of commodity-specific annexes for the Codex Alimentarius *"Code of Hygienic Practice for Fresh Fruits and Vegetables"*.[33] It was noted that there was broad support for this proposal within the working group and further pathogen-commodity combinations of interest had been identified.

225. The Delegation of Finland requested that *Yersinia paratuberculosis* in root vegetables and leafy green, and viruses on leafy greens also be considered in this request. The Delegation also noted that since the list was extensive it may be possible to group commodities according to production and handling processes.

226. The Delegation of the Netherlands noted that the issue relating to viruses may be covered in the expert meeting to address foodborne viruses and efforts should be made to ensure that both expert consultations were complementary.

227. Several Delegations noted the importance of this document taking into consideration the increasing number of reported fodborne outbreaks related to fresh produce.

228. The Representative of FAO noted the extensive nature of the request and clarified that FAO and WHO would need to identify the most efficient process to address this specific request.

229. In responding to a request of the FAO Representative, the Delegation of the United States clarified that it intended to propose new work at the next session to develop commodity specific guidelines which would be annexes to the current code of good hygiene practices for fresh fruit and vegetables. It was noted that in originally developing that code, it was envisaged that over time, a series of commodity specific annexes, which follow the General Principles – Food Hygiene but address in more detail aspects related to the control of specific hazards of concern in specific products would be added.

230. The Representative of FAO also requested Delegations to provide any available information to support the proposed new work to FAO and WHO in a timely manner. It was noted that given the extensive list of pathogen–commodity combinations identified, it would be necessary to rank these according to risk and address them in a prioritised manner. It was also agreed that a Circular Letter would be sent by the Codex Secretariat requesting information on this issue to facilitate the provision of scientific advice. The specific questions to be included would be developed by FAO and WHO.

231. The Committee agreed to request FAO and WHO to provide scientific advice on this issue according the terms of reference attached as Appendix VI.

Other matters

232. The Representative from WHO noted that FAO and WHO already had one pending request for scientific advice on the use of active chlorine from the 37th session and this would be addressed in the coming year. Given the limited resources of both organizations it was pointed out that additional resources would be required to address these requests. The Representatives from FAO and WHO thanked the United States and the Netherlands who were providing assistance in areas of active chlorine and viruses. The Delegation of the United States also indicated that it would provide resources to FAO and WHO for the work on fresh produce.

233. The Chairperson thanked FAO and WHO for their work on the provision of scientific advice and suggested that other Delegations consider how they could further assist FAO and WHO with additional resources to support their efforts in providing scientific advice to the Committee.

Terms of Reference for the development of an Annex for the development of Draft Guidelines for the Establishment and Use of Risk Management Metrics for the Management of Microbial Food Safety Hazards[34]

234. The Delegation of the United States introduced CRD 22 and indicated that food safety control authorities have traditionally employed various criteria (e.g., process criteria, microbiological criteria) and

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33 CRD 20 (Draft terms of reference for an FAO/WHO expert consultation to support the development of commodity-specific annexes for the Codex Alimentarius *"Code of hygienic practice for fresh fruits and vegetables"* prepared by the United States of America and Ad Hoc Working Group).

34 CRD 22 (prepared by the United States).

related requirements as means for establishing and communicating the stringency of food safety systems for the control of microbiological hazards, comparing the equivalence of different control strategies, and verifying achievement of the desired level of control. However, these requirements have often been established without the benefit of a framework that allows these metrics to be:

- applied in a consistent manner,
- related to the desired level of public health protection to be achieved,
- communicated effectively to stakeholders,
- verified to determine if the desired level of compliance is being achieved,
- validated to ensure that they are capable of providing the intended level of public health protection, and
- verified to ensure that they continue to provide the intended level of public health protection.

235. The Delegation emphasized that there was a need for a common understanding of how these food safety metrics should be developed and implemented has become even more important with the advent of microbial risk assessment tools and concepts that allow the levels of hazards in foods to be more directly related to public health outcomes. The effective use and interpretation of these risk assessment tools is often highly technical and complex, therefore often a challenge for risk managers, industry and other stakeholders, who are generally not experts in these advanced techniques.

236. The Delegation proposed that the Committee consider and agree on Terms of Reference for future work on microbiological metrics as proposed in CRD 22.

237. Several delegations expressed a general support for the proposed Terms of Reference.

238. A proposal was made to include the concept of validation in the 7th bullet of Objectives; however the Committee noted that it was not clear how compliance could be validated.

239. The Representative of WHO proposed to amend the title to make it clear that this document would be supplemental to the Principles and Guidelines for Conduct of Microbiological Risk Management and suggested to delete “major” in the second objective as it was not necessary to specify the scope of food safety metrics. The Representative also proposed to combine objectives 5 and 6 and to cover all other formats of MRA and give a special consideration regarding deterministic versus probabilistic risk assessment.

240. The Committee after some discussion agreed that the Terms of Reference of the Working Group would be those described in CRD 22 taking into account comments made at the current session.

241. The Committee was of the view that the work on this document could be completed in 2009 and for adoption by the Commission in 2010.

OTHER MATTERS

Ave atque vale

242. The Committee noted the forthcoming retirement of Dr Paul Teufel (Germany) and Jaap Jansen (The Netherlands) after their long years of outstanding contribution to the work of the Codex Committee on Food Hygiene. The Committee expressed its sincere appreciation for their long and devoted work to the goals of the Committee and wished them good health and long life in the years to come.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 11)

243. The Committee was informed that the 39th Session of the CCFH, was currently scheduled in India, from 29 October to 3 November 2007, with venue to be determined by the host Governments and the Codex Secretariat.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by:	Reference in ALINORM 07/30/13
Draft Code of Hygienic Practice for Eggs and Egg Products	8	Governments, 30th Session of the CAC	para. 125 and Appendix II
Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Foods	8	**Governments**, 30th Session of the CAC	para. 144 and Appendix III
Draft Principles and Guidelines for the Conduct of Microbiological Risk Management	8	**Governments, 30**th Session of the CAC	para. 81 and Appendix IV
Annex: Application of Food Safety Metrics in Risk Management Decision Making	4	Working Group led by the United States, 39th CCFH	paras 84-85
Annex: Application of Food Safety Metrics in Risk Management Decision Making – Pasteurized Liquid Whole Eggs	4	Held at Step 4 until progress on Annex on microbiological metrics is made	para. 84
Proposed Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children	2/3	Working Group led by Canada, Governments, 39th CCFH	para. 160
Proposed Draft Guidelines for the Validation of Food Safety Control Measures	2/3	Working Group lead by the United States, governments, 39th CCFH	para. 183
Microbiological Criteria for *Listeria monocytogenes* in Ready-to-Eat Foods	2/3	Working Group led by Germany, Governments, 39th CCFH	para.145
New Work			
Proposed Draft Guidelines for the Control of *Campylobacter* and *Salmonella* spp. in Broiler (Young Bird) Chicken Meat	2/3	59th CCEXEC, 30th Session of the CAC, Working Group led by New Zealand and Sweden, Governments, 39th CCFH	paras 203-205
CCFH Risk Analysis Policies	-	CCFH WG on Priorities, 39th CCFH	paras 15-17

Appendix I

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Appendix II

DRAFT CODE OF HYGIENIC PRACTICE FOR EGGS AND EGG PRODUCTS

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(at Step 8 of the Elaboration Procedure)

INTRODUCTION

This *Code of Hygienic Practice for Eggs and Egg Products* is intended to provide guidance for the safe production of eggs and egg products. This Code supersedes the Codex Code of Hygienic Practice for Egg Products (CAC/RCP 15-1976, as amended in 1978 and 1985). A hazard analysis approach was used in determining the controls presented in this Code. The FAO/WHO document below was used to provide a risk-based foundation for the revised Code.

- Risk assessments of *Salmonella* in eggs and broiler chickens. Microbiological Risk Assessment Series 1. FAO/WHO 2002 (ISBN 92-5-104873-8). http://www.fao.org/DOCREP/005/Y4393E/Y4393E00.HTM

This Code of Hygienic Practice for Eggs and Egg Products takes into consideration, to the extent possible, the differing egg and egg product production systems and processing procedures used by countries. This code focuses primarily on eggs produced from domesticated chickens. The principles may also be applied to the hygienic practices for egg production from other domesticated egg producing bird species (e.g. duck, quail and goose). Therefore, the code is, of necessity, a flexible one to allow for different systems of control and prevention of contamination of eggs and egg products.

This Code addresses the two main sources of contamination of eggs:

1. internally during egg formation, and
2. externally, at any point at or after laying.

It takes into consideration the possibility of illness in the general population due to the consumption of eggs or egg products contaminated by *Salmonella* species, other enteric pathogens or other contaminants, as well as the susceptibility to illness of sectors of the population such as the elderly, children, and immunocompromised individuals. For microbiological contamination, this approach is consistent with the approach identified by the Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods (Rome, Italy, 30 April – 4 May 2001).

1 OBJECTIVES

The objective of this Code is to ensure the safety and suitability[1] of eggs and egg products by applying the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1- 1969) to the particular case of eggs and egg products. The document describes the specific considerations for food hygiene and safety associated with all methods of primary production and processing of eggs and egg products, including the adequate measures for small-scale producers and processors.

2 SCOPE AND USE OF THE DOCUMENT

2.1 SCOPE

This Code applies to the primary production, sorting, grading, storing, transport, processing, and distribution of eggs in shell and egg products of such eggs produced by domesticated birds and intended for human consumption. Traditional delicacy eggs (e.g. Balut, 1000 year old eggs) are not within the scope of this code.

2.2 USE OF THE DOCUMENT

The provisions of this document are supplemental 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 also references other Codex Standards, Codes or Guidelines, including the labelling standards and the *Codex Code of Hygienic Practice for the Transport of Foods in Bulk and Semi-Packed Food* (CAC/RCP 47-2001), when they apply to the hygienic production of eggs and egg products.

This document consists of a series of principles, explanatory narratives and guidelines.

Principles, shown in **bold text**, are a statement of the goal or objective that is to be achieved. *Explanatory narratives*, shown in *italicized text*, serve to explain the purpose of the stated principle. Additional information to assist in the application of the stated principle is shown in normal text.

[1] Safety and suitability as defined in the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1- 1969).

Principles that are applicable to all phases of production, handling and processing of eggs and egg products are given in Section 2.3.

This Code is flexible to allow for different productions systems, size of operation and different systems of control of hazards during production, handling and processing of eggs and egg products.

Recognition of the Production and Processing of Eggs by Small-Scale/Less Developed Egg Producers/Businesses

In the context of this Code, the expression "small-scale egg producer" refers to production systems based on the number of birds, or where automated collecting and sorting/grading machines are not generally used, or where water and other requirements are in poor supply thus limiting the number of birds that can be kept. The maximum number of birds permitted in small-scale establishments may be set down in national legislation, codes of practice or other guidelines.

Flexibility in the application of these requirements in this Code may apply to less developed egg producers, i.e. those producers with larger flocks that have less developed systems, and/or economic, water and/or power supply constraints, preventing investment in modern grading and packaging processes and infrastructure.

Flexibility in the application of requirements on the primary production of eggs by small-scale and/or less developed egg producers can be exercised, where necessary. However, any microbiological or other control measures used should be sufficient to obtain safe and suitable eggs and egg products.

Such flexibility is indicated throughout the Code by the use of a parenthetical statement "where practicable" placed next to the particular provision where the flexibility is needed.

Further guidance on the issues facing small and less developed businesses, particularly in relation to implementing HACCP is under development and can be found in FAO/WHO *Guidance to Governments on the Application of HACCP in Small and/or Less Developed Businesses* (FAO/WHO, October 2006)

2.3 PRINCIPLES APPLYING TO THE PRODUCTION, HANDLING AND PROCESSING OF ALL EGGS AND EGG PRODUCTS

The following principles should apply, where appropriate and practicable, to the production, handling and processing of all eggs and egg products.

- **From primary production to the point of consumption, eggs and egg products should be subject to control measures intended to achieve the appropriate level of public health protection.**

  The Code is aimed at encouraging the safe production of eggs and egg products for human consumption, and gives relevant guidance to producers and processors, large and small, on the application of control measures throughout the entire food chain. It recognizes that there is a need for continuous, effective effort or controls, which should be applied, by primary producers in addition to processors, in assuring the safety and suitability of eggs and egg products.

  Good hygienic, agricultural and manufacturing practices should be identified during primary production, shell egg processing and egg product processing. Such practices should be applied throughout the food production chain so that eggs and egg products are safe and suitable for their intended use.

  Both the relationship and impact of one part of the food production chain on another part should be identified to ensure that potential gaps in the chain are dealt with through communication and interaction between those in the production chain. Information should be obtained to cover one step forward and one step back through to final food preparation.

  No part of this Code should be used without consideration of what takes place in the production chain prior to the particular measure being applied or what will take place subsequent to a particular step. The Code should only be used within the context of an understanding that there is a continuous system of controls that are applied from the breeding flock and sourcing of the laying flock to consumption of the end product. Good hygienic practice should also apply when handling eggs during food preparation.

- **Wherever appropriate, hygienic practices for eggs and egg products should be implemented within the context of HACCP systems as described in the Annex to the *Recommended International Code of Practice – General Principles of Food Hygiene.***

  There should be an understanding of the hazards associated with eggs, at each stage in egg production, handling, grading, packaging, transporting and processing so as to minimize contamination. It is principally the responsibility of the producer, where practicable, to conduct a hazard analysis within the context of developing a control system based on HACCP and thus to identify and control hazards associated with flock management and egg production. Similarly it is principally the responsibility of the processor to conduct a hazard analysis to identify and control hazards associated with egg processing.

  This principle is presented with the recognition that there are limitations to the full application of HACCP principles at the primary production level of eggs. In the case where HACCP is not implemented at the producer level, good hygienic, agricultural and animal husbandry practices should be followed.

- **Control measures should be effective and validated, where practicable.**

  The overall effectiveness of the control measures should be validated according to the prevalence of hazards in the egg, taking into consideration the characteristics of the individual hazards(s) of concern, established Food Safety Objectives/Performance Objectives and level of risk to the consumer.

  Small and less developed businesses that do not have resources to validate the effectiveness of their control measures should implement appropriate control measures required by their country. Where there are no legal requirements, such businesses should follow recommendations in industry-recognised guidelines or follow practices established as safe, where practicable.

2.4 RELATIVE ROLES OF EGG PRODUCERS, PROCESSORS AND TRANSPORTERS

All parties involved in the egg production chain share responsibility for food safety. This can include those involved in primary production, handling, grading, packaging, processing, supplying, distributing and commercial cooking of eggs and egg products for human consumption. In order to achieve this common goal, respective parties should pay attention to the following responsibilities:

- Good communication and interaction should exist between egg producers, processors and others in the chain so that an effective chain of controls is maintained from breeding of the laying flock to production of eggs to consumption. This can help to ensure that appropriate and complementary hygiene practices are applied at each stage of the chain and that appropriate and timely action is taken to resolve any food safety problems that may arise.
- Primary producers should apply good hygienic, agricultural and animal husbandry practices consistent with food safety, and adapt their operations as appropriate and practicable to meet any specifications for specific hygiene controls to be applied and/or any standards to be achieved as may be agreed with the processor, distributor, transporter or warehouser.
- Processors should follow good manufacturing and good hygienic practices, especially those presented in this Code and in the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969) or those required by the competent authority. The processor may have to implement controls, or adapt their manufacturing processes, based on the ability of the egg producer to minimize or prevent associated hazards.
- Producers and/or processors should communicate any recommendations for safe handling and storage of eggs and egg products during distribution and transportation, and their subsequent use by food businesses.

- Distributors and transporters, wholesalers, retailers and those involved in food preparation at any facility should ensure that eggs and egg products under their control are handled and stored properly and according to the producers and/or processors instructions.
- Information to consumers should include advice on safe handling, storage and preparation of eggs.

2.5 DEFINITIONS

Definitions of general expressions are included in the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969). For the purpose of this code, the following terms have the definition stated:

Breaking – the process of intentionally cracking the egg shell and separating its pieces to remove the egg contents.

Breeding flock – a group of birds kept for the purpose of production of the laying flock.

Broken/leaker egg – an egg showing breaks of both the shell and the membrane, resulting in the exposure of its contents.

Candling – examining the interior condition of an egg and the integrity of the shell by rotating or causing the egg to rotate in front of or over a light source that illuminates the contents of the egg.

Cracked egg – *an* egg with a damaged shell, but with intact membrane

Dirty egg – an egg with foreign matter on the shell surface, including egg yolk, manure or soil.

Domesticated birds – members of the Class Aves that are kept for the production of eggs intended for human consumption.

Egg laying establishment – the facilities and the surrounding area where primary production of eggs takes place.

Egg product – all, or a portion of, the contents found inside eggs separated from the shell, with or without added ingredients, intended for human consumption.

Incubator egg – an egg that has been set in an incubator.

Microbiocidal treatment is a control measure that practically eliminates the number of microorganisms, including pathogenic microorganisms present in a food or reduces them to a level at which they do not constitute a health hazard.

Pasteurization – a microbiocidal control measure where eggs or egg products are subjected to a process, using heat to reduce the load of pathogenic microorganisms to an acceptable level to ensure safety.

Shelf life – the period during which the egg or egg product maintains its safety and suitability.

Table egg – an egg destined to be sold to the end consumer in its shell and without having received any treatment significantly modifying its properties.

3 PRIMARY PRODUCTION

It is recognised that some of the provisions in this Code may be difficult to implement in areas where primary production is conducted in small holdings in both developed and developing countries and also in areas where traditional farming is practised. Therefore, the Code is, of necessity, a flexible one to allow for different systems of control and prevention of contamination of eggs during primary production.

These principles and narratives supplement those contained in Section 3 of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969) and the general principles presented in Section 2.3 above.

Egg producers should take all reasonable measures to reduce the likelihood of hazards occurring in or on eggs during primary production.

Primary production activities can significantly impact on the safety of eggs and egg products. Bacterial contamination of eggs can occur during formation, thus the practices used at this phase of production are a key factor in reducing the potential for microorganisms to be present in or on eggs.

It is recognised that microbiological hazards can be introduced both from the primary production environment and from the breeding and laying flocks themselves. Pathogens such as Salmonella Enteritidis (SE) can be transmitted vertically from breeder flocks to commercial laying flocks, and horizontally from other layers, feed and/or environment and hence to eggs. Importantly, the presence of Salmonella in the laying and/or breeding flock increases the possibility of Salmonella in the egg.

Thus the preventative role of good hygienic and agricultural practice in the primary production of eggs is critically important. Appropriate animal husbandry practices should be respected and care should be taken to assure that proper health of the breeding and laying flocks is maintained. Further, lack of good agricultural, animal feeding and veterinary practices and inadequate general hygiene by personnel and equipment during egg handling, and/or collection may lead to unacceptable levels of bacterial and other contamination (such as physical and chemical) during primary production.

The focus for primary producers is to reduce the likelihood that such hazards will occur during the primary production phase of the chain. Likewise, in certain primary production situations, the occurrence of food safety hazards may be less avoidable which may result in the application of more stringent control measures during subsequent processing in order to ensure safety and suitability of the finished product. The degree to which primary production practices control the likelihood of occurrence of a food safety hazard in or on eggs will have an impact on the nature of controls needed during the subsequent processing of eggs.

Contamination of eggs during primary production should be minimized.

Producers should obtain domesticated birds from breeding stock that have been subject to control measures to reduce and, if possible eliminate, the risk of introducing into laying flocks, poultry diseases and pathogenic organisms transmissible to humans. The breeding flock should be subject to a programme which will monitor the effect of the control measures.

Laying flock management is key to safe primary production of eggs. Laying flocks are managed under a wide range of climatic conditions using various agricultural inputs and technologies, and on farms of various sizes. However in backyard poultry farms and small scale producers, the number of birds maintained is very small and, accordingly, the systems and hygienic conditions of production may vary. Hazards may vary between one type of production system and another. In each egg laying establishment, it is necessary to consider the particular agricultural practices that promote the safe production of eggs, the type of products (e.g., unsorted eggs, eggs for the table egg market, eggs strictly for breaking) and production methods used.

The microbial load of eggs should be as low as achievable, using good egg production practices, taking into account the requirements for subsequent processing. Measures should be implemented at the primary production level to reduce as far as possible the initial load of pathogenic microorganisms affecting safety and suitability. Such measures would permit the application of microbiological control measures of lesser stringency and still ensure product safety and suitability.

3.1 ENVIRONMENTAL HYGIENE

The egg laying establishment should be appropriate for the primary production of eggs such that sources of potentially harmful substances are minimized and are not present at unacceptable levels in or on eggs.

Where practicable, producers could identify and evaluate the immediate surroundings and previous use (indoor and outdoor) of the egg laying establishment in order to identify hazards. Potential sources of contamination from the egg laying establishment including the immediate environment should be identified. This could include contamination associated with previous uses of the land, presence of contaminants, polluted surface water, potential microbial and chemical hazards from contamination by faeces, and other organic waste that could be introduced into the egg laying establishment. This is particularly relevant in the case of free range foraging by domesticated birds.

Primary production should not be carried out in areas where the presence of potentially harmful substances in the egg laying establishment would lead to an unacceptable level of such substances in or on eggs. The potential for contamination from, for example, agricultural chemicals, hazardous wastes, etc. should be considered. The potential for the introduction of disease from wild birds and animals should also be considered.

The evaluation process could include the following:

- Identification of previous and present usage of the primary production area and the adjoining sites to determine potential microbial, chemical and physical hazards and determine sources of environmental contamination, for example by faeces or other organic waste, that could be introduced into the egg laying establishment.
    - Sites/uses of concern can include crops grown, feed lot, animal production, hazardous waste site, sewage treatment site, and mining extraction site.
- Identification of points of access to the site by domesticated and wild animals, including access to water sources used in primary production, to determine potential faecal and other contamination of the soils and water and the likelihood of contamination of eggs.
    - Existing practices should be reviewed to assess the prevalence and likelihood of uncontrolled deposits of animal faeces coming into contact with eggs.
    - As much as possible, domestic and wild animals, including wild birds as well as rodents should be prevented from entering egg laying establishments.
- Identification of the potential for contamination of egg laying establishments by leaking, leaching or overflowing manure storage sites and flooding from polluted surface waters.

If previous uses cannot be identified, or the evaluation leads to the conclusion that hazards exist, where practicable, the sites should be tested for contaminants of concern. Additionally, periodic monitoring of the environment and forage, and judicious selection and use of fertilizers and agricultural chemicals should occur.

If contaminants are present at levels which may result in the egg or egg product being harmful to human health, and corrective or preventive actions have not been taken to minimize identified hazards, the sites should not be used until such actions have been applied.

Care should be taken to minimize access to contaminated water or to environmental contaminants to the extent practicable in order to avoid diseases transmissible to birds or to humans or the likelihood of contamination of eggs.

3.2 HYGIENIC PRODUCTION OF EGGS

Provisions in this section are equally relevant to all egg producers.

3.2.1 Flock Management and Animal Health

Eggs should come from flocks (both breeding and laying) in good health so that flock health does not adversely affect the safety and suitability of the eggs.

Good animal husbandry practices should be used to help maintain flock health and resistance to colonization by pathogenic organisms. These practices should include timely treatment for parasites, minimizing stress through proper management of human access and environmental conditions and use of appropriate preventive measures for example, veterinary medicines and vaccines.

The Salmonella Enteriditis *Risk Assessment has shown that reducing the prevalence of Salmonella* Enteritidis *infected flocks is anticipated to result in a reduction in the risk of human illness from the consumption of Salmonella* Enteritidis *positive eggs*[2].

Flock management is critical in reducing the risk of human illness from the consumption of eggs. Good husbandry practices should also be used to reduce the likelihood of pathogens (i.e. avian disease) and thus reduce the use of veterinary drugs. Where drug treatment occurs, its use should be appropriate and should consider possible antimicrobial resistance[3]. In particular, measures to prevent disease could include:

[2] Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods, FAO Headquarters, Rome, Italy 30 April – 4 May 2001, page 13.

[3] Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005).

- Evaluating the health status of domesticated birds relative to avian diseases and where practicable, colonization by pathogenic organisms transmissible to humans and always taking action to ensure only healthy birds are used.
- Taking preventive measures, including managing human access, to reduce the risk of transferring micro-organisms that may impact on food safety to, or from, or between, flocks.
- Using, where permitted, appropriate vaccines as part of an overall flock management program, including as measures when introducing new birds.
- Regularly checking the flock and removing dead and diseased birds, isolating sick birds, and investigating suspicious or unknown causes of illness or death to prevent further cases.
- Disposing of dead birds in a manner that prevents recycling of diseases to the laying flock by either pests or handlers.
- Treating birds only with veterinary drugs where permitted, prescribed by a veterinarian and in a manner that will not adversely impact on the safety and suitability of eggs, including adhering to the withdrawal period specified by the manufacturer or veterinarian.
  - Only those medicinal products and medicinal premixes that have been authorized by the relevant authority for inclusion in animal feed should be used.
  - Where birds/flocks have been treated with veterinary drugs that can be transferred to eggs, their eggs should be discarded until the withholding period for the particular veterinary drug has been achieved. Established maximum residue levels (MRLs), including those established by Codex, for residues of veterinary drugs in eggs, may be used to verify such measures.
  - The veterinarian and/or the producer/layer establishment owner/manager or the collection center should keep a record of the products used, including the quantity, the date of administration, the identity of the flock and withdrawal period.
  - Appropriate sampling schemes and testing protocols should be used to verify the effectiveness of on-farm controls of veterinary drug use and in meeting established MRLs.
  - Veterinary drugs should be stored appropriately and according to manufacturer's instructions.
- Particularly for countries where *Salmonella* Enteritidis has been associated with poultry or eggs, monitoring for SE through faecal testing and the use of a vaccination protocol may reduce the risk of human illness[4]. If a vaccine is used, it should be approved by the competent authority. Monitoring for SE can also include environmental testing of litter, dust, ventilation fans etc.
- Disposing of eggs from infected flocks still in production that represent a risk to human or flock health, in a safe manner or specifically diverting them to a process that ensures elimination of a hazard.
- Where practicable, destruction of *Salmonella* Enteridis positive flocks or slaughter in accordance with country requirements.
- Ensuring visitors, where necessary, wear appropriate protective clothing, footwear and head covering to reduce the risk of introducing hazards or spreading hazards between flocks. Visitor movement should be controlled to minimize likelihood of transfer of pathogens from other sources.

3.2.2 Areas and Establishments for Egg Laying Systems

Egg laying areas and establishments should, to the extent practicable, be designed, constructed, maintained and used in a manner that minimizes exposure of domesticated birds or their eggs to hazards and pests.

Improperly protected and maintained areas and premises for the housing of flocks and laying of eggs, particularly for free range and barn production systems may contribute to the contamination of eggs.

[4] Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods, FAO Headquarters, Rome, Italy 30 April – 4 May 2001, page 17.

Taking into account climatic conditions, production systems including those used to provide feed, water, shelter, control temperature and predators and manage interactions between birds should be designed, constructed, maintained and used in a manner to minimize the likelihood of transfer of foodborne pathogens to the egg, either directly or indirectly[5].

The following should be considered, where practicable, in the assessment of areas and establishments used for egg laying:

- The internal design and layout of housing should not adversely affect the health of the birds and should permit compliance with good hygienic practices.
- The facilities used to house flocks should be cleaned and disinfected in a way that reduces the risk of transfer of pathogens to the next flock. An 'all-in, all-out' step for each poultry house should be followed, where feasible, taking into consideration multi-aged poultry houses. Such a process would give the opportunity to eliminate rodents and insects before the next flock is introduced.
- A plan should be in place to detect any failure in cleaning and disinfection programs and ensure that corrective actions are taken.
- Use of litter should be managed to reduce the risk of introducing or spreading hazards.
- Water delivery systems should be protected, maintained and cleaned, as appropriate, to prevent microbial contamination of water.
- Drainage systems and systems for storing and removal of manure should be designed, constructed and maintained so as to prevent the likelihood of contaminating the water supply or eggs.

Access to egg laying establishments by other animal species (i.e. dogs, cat, wild animals and other birds) that may adversely affect the safety of the eggs should be minimized.

The egg laying establishments should, as far as practicable, be kept clean. Accumulations of broken eggs, manure, or any other objectionable materials should be minimized in order to reduce the likelihood of contact with eggs and to minimize attracting pests into the establishment.

3.2.3 General Hygienic Practice

3.2.3.1 Watering

Water should be managed in a way that minimizes the potential for the transmission of hazards, directly or indirectly, into or on the egg.

Water used in primary production operations should be suitable for its intended purpose and should not contribute to the introduction of microbiological or chemical hazards into or on eggs.

Contaminated water may contaminate feed, equipment or laying birds leading to the potential introduction of hazards in or on eggs.

As water can be a source of contamination, treatment of drinking water to reduce or eliminate pathogens including *Salmonella* should be considered.

- Potable water should be used, or if potable water is not available for some or all purposes, water should be of a quality that does not introduce hazards to humans consuming the eggs[6]. Access to surface water, where it introduces hazards, should be denied.
- Potential sources of contamination of water from chemical runoff or improperly managed faeces should be identified and controlled to the extent practicable to minimize the likelihood of contaminating eggs.
- Appropriate safety and suitability criteria that meet the intended outcomes should be established for any water used in egg production.

[5] Although evaluation of the importance of such interventions for reducing the risk of human illness based on existing data was inconclusive. Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods, FAO Headquarters, Rome, Italy 30 April – 4 May 2001, page 17.

[6] Safe Use of Wastewater, Excreta and Greywater. Volume II, Wastewater Use in Agriculture. WHO/FAO/UNEP, 2006 and The Code of Hygienic Practice for Meat (CAC/RCP 58-2005).

- Where practicable, good purchasing practices for water could be used to minimize the risk associated with hazards in the water and may include using vendor assurances or contractual agreements.
- Where possible, water should be regularly tested to ensure that water supplied to the birds is of a quality that does not introduce hazards in or on the egg.

Any reuse of water should be subject to a hazard analysis including assessment of whether it is appropriate for reconditioning. Critical control point(s) should be identified, as appropriate, and critical limit(s) established and monitored to verify compliance.

- Water recirculated or recycled for reuse should be treated and maintained in such a condition that no risk to the safety and suitability of eggs results from its use.
- Reconditioning of water for reuse and use of reclaimed, recirculated and recycled water should be managed in accordance with HACCP principles.

3.2.3.2 Feeding[7]

Feed for the laying and/or breeding flock should not introduce, directly or indirectly, microbiological or chemical contaminants into eggs that present an unacceptable health risk to the consumer or adversely affect the suitability of eggs and egg products.

The improper procurement, manufacturing and handling of animal feed may result in the introduction of pathogens and spoilage organisms to the breeding and laying flock and the introduction of chemical hazards, such as pesticide residues and other contaminants, which can affect the safety and suitability of eggs and egg products.

Producers should take care where appropriate, during production, transportation, preparation, processing, procurement, storage, and delivery of feed to reduce the likelihood of introducing hazards into the production system.

- To minimize the risk associated with hazards in the feed, good purchasing practices for feed and feed ingredients should be employed. This may include using vendor assurances, contractual agreements and/or purchasing batches of feed that have had microbiological and chemical analysis and are accompanied by certificates of analysis.
- Feed should be managed so that it does not become moldy or contaminated from waste including faeces.
- As feed can be a source of contamination, heat or other treatment of feed to reduce or eliminate pathogens including *Salmonella* should be considered.
- When the egg producer processes their own feed, information should be kept about its composition, the origin of the ingredients, relevant processing parameters and where practicable, the results of any analyses of the finished feed.
- The owner should keep a record of relevant information concerning feed.

3.2.3.3 Pest control

Pests should be controlled using a properly designed pest control program as they are recognized as vectors for pathogenic organisms.

Any pest control measures should not result in unacceptable levels of residues, such as pesticides, in or on eggs.

Pests such as insects and rodents are known vectors for the introduction of human and animal pathogens into the production environment. Improper application of chemicals used to control these pests may introduce chemical hazards into the production environment.

A properly designed pest control program should be used, that considers the following:

- Before pesticides or rodenticides are used, all efforts should be made to minimize the presence of insects, rats and mice and reduce or remove places which could harbour pests.

[7] Codex Recommended Code of Practice on Good Animal Feeding (CAC/RCP 54 – 2004).

  - As cages/pens/enclosures/coops (if used) attract such pests, measures such as proper design, construction and maintenance of buildings (if applicable), effective cleaning procedures and removal of faecal waste should be used to minimize pests.
  - Mice, rats and wild birds are attracted to stored feed. Any feed stores should be located, designed, constructed and maintained so as to be, where practicable, inaccessible to pests. Feed should be kept in pest proof containers.

- Bait should always be placed in "bait stations" so that they are obvious, cannot be accessed by animals or insects they are not intended for and can be identifiable and found easily for checking.
- If it is necessary to resort to chemical pest control measures, the chemicals should be approved for use in food premises and used in accordance with the manufacturer's instructions.
- Any pest control chemicals should be stored in a manner that will not contaminate the laying environment. Such chemicals should be stored in a safe manner. They should not be stored in wet areas or close to feed stores or be accessible by birds. It is preferable to use solid baits, wherever possible**.**

3.2.3.4 Agricultural and Veterinary Chemicals

Procurement, transport, storage and use of agricultural and veterinary chemicals should be undertaken in such a way that they do not pose a risk of contaminating the eggs, flock or the egg-laying establishment.

- Transport, storage and use of agricultural and veterinary chemicals should be in accordance with the manufacturer's instructions.
- Storage and use of agricultural and veterinary chemicals on the egg laying establishment should be evaluated and managed, as they may represent a direct or indirect hazard for the eggs and flock.
- Agricultural and veterinary chemical residues should not exceed limits established by the Codex Alimentarius Commission or as per national legislation.
- Workers that apply agricultural and veterinary chemicals should receive training in the proper application procedures.
- Agricultural and veterinary chemicals should be kept in their original containers. Labels should have the name of the chemical substances and the instructions for their application.
- Equipment used to apply or administer agricultural and veterinary chemicals should be stored or disposed of in a manner that does not represent a direct or indirect hazard for the eggs and flock
- Empty agricultural and veterinary containers should be disposed of according to applicable regulation and/or the manufacturer's directions and should not be used for other purposes.
- Where possible and practicable, producers should keep records of agricultural and veterinary chemical applications. Records should include information on the date of application, the chemical used, the concentration, method and frequency of application, the purpose for using the chemical applications and where it was applied.

3.3 COLLECTION, HANDLING, STORAGE AND TRANSPORT OF EGGS

Eggs should be collected, handled, stored and transported in a manner that minimizes contamination and/or damage to the egg or egg shell, and with appropriate attention to time-temperature considerations, particularly temperature fluctuations.

Appropriate measures should be implemented during disposal of unsafe and unsuitable eggs to protect other eggs from contamination.

Proper collection, whether using manual or automated methods, handling, storage and transport of eggs are important elements of the system of controls necessary to produce safe and suitable eggs and egg products. Contact with unsanitary equipment and foreign materials or methods that cause damage to the shell, may contribute to egg contamination.

Whether manual or automated methods are used to collect eggs, producers should minimize the time between egg laying and further handling or processing. In particular, the time between egg laying and controlled temperature storage should be minimized.

Methods used to collect, handle, store and transport eggs should minimize damage to the shell, and avoid contamination and practices should reflect the following points:

- Cracked and/or dirty eggs should be excluded from the table egg trade.
- Cracked and/or dirty eggs should be directed to a processing or packing establishment, as appropriate, as soon as possible after collection (see Section 5.1).
- Hygienic practices, which take into account time and temperature factors, should be used to protect the egg from surface moisture in order to minimize microbial growth.
- Where appropriate, broken and/or dirty eggs should be segregated from clean and intact eggs.
- Broken eggs and incubator eggs should not be used for human consumption and be disposed of in a safe manner.

Egg processors should communicate any specific requirements at farm level (i.e. time/temperature controls) to the egg producer.

Selection

Eggs from different species of poultry and/or farm production systems (e.g. free range, barn and caged eggs) should be segregated as appropriate.

3.3.1 Egg collection equipment

Collection equipment should be made of materials that are non-toxic and be designed, constructed, installed, maintained and used in a manner to facilitate good hygiene practices.

It is important to prevent any damage to the eggshells by collecting equipment since such damage can lead to contamination and consequently adversely affects the safety and suitability of eggs and egg products. It is also important that the equipment is maintained to a standard of cleanliness adequate to prevent contamination of the eggs.

Where used, egg collecting equipment and containers should be cleaned and disinfected regularly, or if necessary replaced, and with sufficient frequency to minimize or prevent contamination of eggs.

Single use containers should not be reused.

Egg collecting equipment should be maintained in proper working condition and this should be periodically verified.

3.3.2 Packaging and storage

Egg packaging and packaging equipment should be designed, constructed, maintained and used in a manner that will minimize damage to the eggshell and avoid the introduction of contaminants in or on eggs.

Wherever eggs are stored, it should be in a manner that minimizes damage to the eggshell and avoids the introduction of contaminants, or growth of existing microorganisms in or on eggs, giving consideration to time and temperature conditions.

Any egg packaging, storage or associated equipment should not transfer substances to eggs that will present a health risk to the consumer.

Where permanent equipment is used, it should be corrosion resistant and easy to clean and disinfect or if necessary able to be dismantled and reassembled.

Storage temperatures, times and humidity should not have a detrimental effect on the safety and suitability of eggs. The time and temperature conditions and humidity for egg storage at the farm should be established taking into account the hygienic condition of the eggs, the hazards that are reasonably likely to occur, the end use of the eggs, and the intended duration of storage.

3.3.3 Transport, Delivery Procedures and Equipment

Whenever eggs are transported, it should be in a manner that minimizes damage to the egg or eggshell and avoids the introduction of contaminants in or on eggs.

Personnel and vehicular access should be adequate for the hygienic handling of eggs, such that contamination is not introduced onto the farm and thus in or on eggs.

Lorries, trucks or other vehicles or equipment, which carry the eggs, should be cleaned at a frequency necessary to prevent contamination flow between farms or premises and thus of eggs.

The time and temperature conditions for the transport and delivery of eggs from the producer should be established taking into account the hygienic condition of the eggs, the hazards that are reasonably likely to occur, the end use of the eggs, and the intended duration of storage.

- These conditions may be specified in legislation, in codes of practice, or by the processor receiving the eggs in collaboration with the egg producer and transporter and the relevant authority.

Delivery procedures should be adequate for the hygienic handling of eggs.

3.4 CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION

3.4.1 Cleaning and maintenance of egg laying establishments

Egg laying establishments should be cleaned and maintained in a manner that ensures the health of flocks and safety and suitability of eggs.

Cleaning and disinfection programs should be in place, and their efficacy should be periodically verified and an environmental monitoring program implemented where possible and practicable.

These programs should include procedures for routine cleaning while birds are in the poultry house. Full cleaning and disinfection programmes should be applied when poultry houses are empty.

De-populated poultry house cleaning procedures should cover cleaning and/or sanitising nest boxes/cages, poultry houses, disposing of contaminated litter, nesting materials and faeces from diseased birds and, where necessary, safe disposal of eggs from infected flocks and dead or diseased birds.

The egg-laying establishment should be safe for the re-entry of new stock.

3.4.2 Personnel hygiene, health, and sanitary facilities

3.4.2.1 Personnel hygiene

Hygiene and health requirements should be followed to ensure that personnel who come directly into contact with eggs are not likely to contaminate them.

Hygiene and health requirements should be followed to ensure that personnel who come directly into contact with birds are not likely to transmit illness between birds.

Personnel should understand and follow preventative measures specifically relating to the handling of birds and/or eggs, so as to prevent introducing hazards from one to the other, from other facilities or from cross contamination of birds from personnel.

Personnel should be adequately instructed and/or trained to handle eggs and domesticated birds to ensure the use of good hygienic practices that will minimize the risk of egg or flock contamination.

3.4.2.2 Health status

Personnel should be in good health and not introduce diseases or illness likely to affect flock health or the safety and suitability of eggs.

People known, or suspected, to be suffering from, or to be a carrier of a disease or illness likely to be transmitted to birds or through eggs should not be allowed to enter any bird facility or egg collection or handling area, if there is a likelihood of their contaminating the birds or the eggs. Any person so affected should immediately report illness or symptoms of illness to the management.

3.4.2.3 Personal cleanliness

Personnel who have direct contact with eggs should maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing, footwear and head covering that is not likely to introduce contamination into egg laying areas.

Personnel should wash their hands before starting work that involves the handling of eggs, each time they return to handling areas after a break, immediately after using the toilet, and after handling anything which may contaminate eggs.

3.4.2.4 Sanitary facilities

Facilities should be available to ensure that an appropriate degree of personal hygiene can be maintained.

Facilities should:

- Be located in close proximity to wherever eggs or domesticated birds are handled;
- Be constructed to facilitate hygienic removal of wastes and avoid contamination of facilities, equipment, raw materials and the immediate environment;
- Have adequate means for hygienically washing and drying hands and disinfecting footwear; and
- Be maintained under sanitary conditions and in good repair at all times.

3.5 DOCUMENTATION AND RECORD KEEPING

Records should be kept, as necessary and where practicable, to enhance the ability to verify the effectiveness of the control systems. Documentation of procedures can enhance the credibility and effectiveness of the food safety control system.

With respect to food safety, records should be kept on:

- Prevention and control of avian diseases with an impact on public health;
- Identification and movement of birds and eggs;
- Use of agricultural and pest control chemicals;
- Nature and source of feed, feed ingredients and water;
- Use of veterinary drugs/medicines;
- Results of testing where testing is performed;
- Health status of personnel;
- Cleaning and disinfection; and
- Traceability/product tracing[8] and recall.

4 ESTABLISHMENT: DESIGN AND FACILITIES

Section 4 of the *Recommended International Code of Practice: General Principles of Food Hygiene* applies to both the processing of eggs for the table egg market and the processing of egg products.

The following guidelines are supplemental to Section 4 of the *Recommended International Code of Practice: General Principles of Food Hygiene* for establishments that produce egg products.

Where practicable, separate areas should be allocated for:

- Storage of egg and untreated egg product;
- Breaking and microbiocidal treatment of eggs;
- Packing of microbiocidally treated egg product;

[8] Refer to Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System (CAC/GL 60-2006)

- Storage of microbiocidally treated liquid and frozen egg products and other liquid or frozen ingredients as appropriate;
- Storage of microbiocidally treated dried egg product and other dry ingredients as appropriate; and
- Storage of cleaning and sanitising materials

Work areas for raw and treated product should be separated via physical barriers.

5 CONTROL OF OPERATION

These guidelines are supplemental to those set forth in Section 5 of the *Recommended International Code of Practice: General Principles of Food Hygiene*.

This section refers to control measures that should be taken to prevent, eliminate or reduce hazards when processing eggs for the shell egg market (i.e. table eggs) and when producing egg products. These measures should be used in conjunction with good hygienic and animal husbandry practices for the primary production of eggs as per Section 3 in order to provide an effective system of control of microbiological and other hazards that can occur in or on eggs and egg products.

These principles are also intended to enhance and supplement those aspects of the *Recommended International Code of Practice-General Principles of Food Hygiene* HACCP Annex (CAC/RCP 1- 1969,), which are essential to the successful design of a system of food safety controls for shell eggs and egg products. The users of this document are encouraged to implement the guidelines contained in the HACCP Annex when designing a HACCP system.

5.1 CONTROL OF FOOD HAZARDS

Eggs and egg products should be safe and suitable.

Table egg

Unsafe or unsuitable eggs[9] include:

- Incubator eggs
- Broken/leaker eggs
- Eggs with bacterial or fungal rots
- Eggs contaminated with faeces.
- Eggs stored for hatching for sufficient time to adversely affect the safety and suitability.

Table eggs should be clean and intact.

All efforts should be made to avoid production of dirty eggs. However, dirty eggs may be used for table eggs if permitted by the relevant authorities, in accordance with country requirements, and if cleaned appropriately.

Egg Products

- *Cracked or dirty eggs that are not suitable for human consumption as table eggs should be directed to processing (e.g. washing and breaking followed by a microbiocidal treatment) or be disposed of in a safe manner.*
- *Broken/leaker eggs should not be used to produce egg products and should be disposed of in a safe manner.*
- *Cracked eggs may be used in egg products, but should be processed with minimum delay.*
- *Dirty eggs should be visibly clean prior to breaking and processing.*
- *Other unsafe or unsuitable eggs should not be used for egg products and should be disposed of in a safe manner.*

[9] Refer to definition of food safety and food suitability in the Recommended Code of Practice-General Principles of Food Hygiene (CAC/RCP 1-1969) Section 2.3 Definitions.

Control measures based on risk should be in place to ensure that process and product specifications are met and the hazards in or on eggs and egg products are effectively identified and controlled.

Control measures used should achieve an appropriate level of public health protection. Where possible, measures should be based on HACCP principles.

These measures should allow the identification and removal of eggs and egg products that are not suitable for human consumption. They should also address the need to control pathogen growth throughout handling, cleaning, sorting and grading, packaging, processing, storage and distribution and have a sound basis in good hygiene practice. It is important that control measures are applied during primary production and processing to minimize or prevent the microbiological, chemical or physical contamination of eggs.

Processors should only use eggs that have been produced in accordance with the Code.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.1 Temperature and Time Issues

From receipt of eggs, through handling, sorting and grading, washing, drying, treatment, packing, storage and distribution to point of consumption, consideration should be given to time and temperature and humidity conditions for eggs such that the growth of pathogenic microorganisms will be minimized and the safety and suitability of the eggs will not be adversely affected.

Temperature fluctuations should be minimized as much as possible.

Storage and handling conditions, including those during cleaning, grading and packaging should be such that moisture on the shell surface is minimized.

As eggs are perishable products, particular attention should be paid to temperature conditions throughout storage and distribution, noting that lower storage and distribution temperatures lend themselves to longer shelf life and minimize microbial growth, for example of *Salmonella* Enteritidis.

From receipt of raw/untreated egg product, through processing, treatment, packaging, storage and distribution to point of consumption, consideration should be given to time and temperature conditions for egg products such that the growth of pathogenic microorganisms will be minimized and the safety and suitability of the egg products will not be adversely affected.

Storage conditions should be such that the potential for microbial contamination, the growth of microbial pathogens and the risk to human health is minimized.

5.2.2 Specific Process Steps

5.2.2.1 Handling of table eggs

Eggs should be handled during all stages of cleaning, sorting, grading, packing, storing and distribution in a manner that avoids damage, minimizes moisture on the shell surface and prevents contamination.

Handling of shell eggs can result in damage to eggs. Eggs should be handled in a manner that avoids damage and contamination, including minimising moisture on the egg shell surface.

Activities involved in shell eggs handling may be done by the primary producer, the processor or others involved in the egg production chain. Wherever in the production chain these activities are done, they should be done in accordance with this code.

Eggs intended for the table egg market should be visibly clean prior to grading and packing.

Sorting, grading, and where appropriate, washing processes should result in clean eggs.

(i) Sorting, Grading and Packing

Sorting, grading and packing of the egg refers to the stage between primary production and retail or further processing, where the whole egg may undergo one or more activities to prepare it for either the table egg market or for processing into egg products.

Cracked, dirty, and unsafe/unsuitable eggs should be segregated from clean and intact eggs.

Cracked eggs should be segregated (for example, by candling) and sent for processing (see Section 5.2.2) or disposed of in a safe manner.

Dirty eggs may be cleaned and if appropriately cleaned, used for the table egg market or the egg product industry in accordance with country requirements. Dirty eggs sent for processing should be clearly labelled that they are not suitable as table eggs,.

The cleaning process used should not damage or contaminate the eggs. Incorrect cleaning of eggs can result in a higher level of contamination of eggs than existed prior to cleaning.

Broken/leaker and other unsuitable eggs should be segregated from eggs suitable for human consumption.

Broken/leaker and other unsuitable eggs should be identified in such a way that they cannot be used for human consumption, for example, by appropriate labelling or the use of a de-characterising agent (an additive that makes it clearly visible that the eggs should not be processed into human food, e.g. a denaturing agent).

Cleaning

- Where permitted by the relevant authority, a cleaning process may be used to remove foreign matter from the shell surface, but this should be carried out under carefully controlled conditions so as to minimize damage to the shell surface.
- Cleaning can be used to reduce the bacterial load on the outside of the shell.
- If dry cleaning is undertaken, the methods used should minimize damage to the protective cuticle and, where appropriate, be followed by oiling of the shell using a suitable food grade oil.

Washing, disinfection and drying

Where washing is permitted by the relevant authority, it should be carried out under carefully controlled conditions so as to minimize damage to the shell and prevent contamination of the egg contents.

- Eggs should not be soaked prior to or during washing.
- Water used for washing should be suitable and not adversely affect the safety and suitability of the egg, giving consideration to appropriate water temperature, pH, and quality, and egg temperature.
- If cleaning compounds such as detergents and sanitizers are used, they should be suitable for use on eggs and not adversely affect the safety of the egg.
- If eggs are washed, they should be dried to minimize moisture on the surface of the shell that can lead to contamination or growth of mold.
- Washing should be followed by effective sanitising of the shell and, where appropriate, with subsequent oiling of the shell using a suitable food grade oil.

(ii) In shell treatment

Where table eggs are treated to eliminate pathogens (e.g. in-shell pasteurization) the treatment should not adversely affect the safety or suitability of the egg.

(iii) Storage and distribution

Eggs should be stored and transported under conditions that will not adversely affect the safety and suitability of the egg.

Eggs are perishable products.

- Storage conditions should minimize moisture on the shell surface.
- Lower temperatures minimize microbial growth and extend shelf life of the eggs.
- Temperature fluctuations during storage and distribution should be minimized.

(iv) Shelf life for table eggs[10]

The growth of pathogenic and/or spoilage microorganisms to unacceptable levels may affect the shelf life of eggs.

The shelf life of eggs is influenced by a number of factors, such as:

- Storage conditions including temperature, temperature fluctuation and humidity
- Methods and treatments
- Type of packaging

Shelf life of table eggs should be established by the grader/packer, consistent with requirements of relevant authorities, based on:

- information from the producer on the time since lay, time and temperature in storage and transport;
- type of packaging;
- likelihood of microbial growth, due to reasonably anticipated temperature abuse during storage, distribution, retail, sale and handling by the consumer under reasonably foreseeable conditions of distribution, storage and use.

Where processors clearly advise on egg packaging that eggs are to be refrigerated, others in the food chain, including retailers should follow the processors' advice, unless it is expressly made as a recommendation to the consumer (e.g. that the conditions of refrigeration should be fulfilled after purchasing).

5.2.2.2 Egg Product Processing

Processors should be satisfied that the egg products they produce are safe and suitable for human consumption.

Eggs for processing should be visibly clean prior to breaking and separating.

Cracked eggs may be processed. Broken eggs should not be processed and should be disposed of in a safe manner.

Dirty eggs should be disposed of in a safe manner or may be cleaned in accordance with 5.2.2.1.

Separating the egg contents from the shell should be done in a manner that will, as far as possible, avoid cross-contamination between the shell and egg contents, avoid contamination by personnel or from equipment, and that permits examination of egg contents.

(i) Treatments

Egg products should be subjected to a microbiocidal treatment to ensure the products are safe and suitable.

All operations subsequent to the treatment should ensure that the treated product does not become contaminated.

Hygienic manufacturing and personnel practices should be in place to manage the risk of contamination from the food contact surfaces, equipment, and personnel, packaging material and between raw egg and processed egg products.

Microbiocidal treatments, including heat treatment, should be validated to show they achieve the desired reduction in the number of pathogenic microorganisms and result in a safe and suitable product.

Where heat treatment is used, consideration should be given to time and temperature combinations.

Pasteurized liquid egg products should be cooled rapidly immediately after pasteurization and maintained under refrigeration.

[10] Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods, FAO Headquarters, Rome, Italy 30 April – 4 May 2001, page 14.

(ii) Untreated Egg Products

Egg products that have not had a microbiocidal treatment should only be directed to further processing to ensure their safety and suitability.

Where untreated egg products leave a grading/processing premises, they should be labeled that the product has not been treated.

(iii) Storage and distribution

Egg products should be stored and transported under conditions that will not adversely affect the safety and suitability of the product.

Egg products, including those that can be stored at ambient temperatures, should be protected against external agents and contamination, e.g. direct sun light, excessive heating, moisture, external contaminants, and from rapid temperature changes which could adversely affect the integrity of the product packaging or the safety and suitability of the product.

(iv) Shelf life for egg products

The shelf life of egg products is influenced by a number of factors, such as:

- Storage conditions including temperature, temperature fluctuation and humidity
- Processing methods and treatments
- Type of packaging

Shelf life of egg products should be established by the processor, consistent with requirements of relevant authorities, based on:

- Applied microbiological control measures, including storage temperatures, e.g. storage under refrigeration, freezing or ambient;
- Methods and treatments applied to product;
- Type of packaging;
- Likelihood of post process contamination and type of potential contamination under reasonably foreseeable conditions.

The safety and suitability of the egg product should be assured and, where necessary, demonstrated that it would be retained throughout the maximum period specified.

Shelf life determination may be done at the plant level by testing products subjected to the storage conditions specified or by predicting microbial growth in the product under the specified storage conditions. Reasonably anticipated temperature abuse should be integrated into the study or be taken into account by applying an appropriate safety factor (e.g., by shortening the maximum durability specified in the labeling or by requiring lower storage temperatures).

5.2.3 Microbiological and Other Specifications

Refer to the *Recommended International Code of Practice- General Principles of Food Hygiene,* (*Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997)).

Information that may be useful for establishing specifications could include:

- Flock health status (including pathogen status);
- Pathogen load in/on eggs;
- Agricultural and veterinary chemical status;
- Age of eggs;
- Handling methods; and
- Microbiocidal treatments.

Particular attention should be given to specific indicating control of pathogens such as *Salmonella* Enteritidis.

5.3 INCOMING MATERIAL REQUIREMENTS

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

Depending upon the end use of the egg, certain specific microbiological criteria for incoming ingredients may be appropriate to verify that the control systems have been implemented correctly.

5.4 PACKAGING

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

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).

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).

6 ESTABLISHMENT: MAINTENANCE AND SANITATION

These guidelines are supplemental to those set forth in Section 6 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

6.1 MAINTENANCE AND CLEANING

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

6.2 CLEANING PROGRAMS

Handling, packaging and processing of eggs uses a variety of equipment with sensitive electronic controls. Where wet cleaning may damage or result in the contamination of the equipment, alternative cleaning programs should be considered.

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).

6.5 MONITORING EFFECTIVENESS

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

7 ESTABLISHMENT: PERSONAL HYGIENE

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

8 TRANSPORTATION

These principles and guidelines are supplemental to those set forth in Section 8 of the *Recommended International Code of Practice: General Principles of Food Hygiene* and, as appropriate, those set forth in *Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food* (CAC/RCP 47 – 2001).

Eggs and egg products should be transported in a manner that will minimize breakage, damage and contamination.

Mobile containers and tankers should be cleaned and disinfected prior to being refilled.

Egg haulers (driver or individual in charge of transport to and from packing facility) should use vehicles suitable for transporting eggs, which permit easy and thorough cleaning.

Piping, connectors and valves used for filling and discharge of liquid egg should be of a suitable design and be cleaned, disinfected and stored as appropriate.

Eggs should be transferred between establishments promptly. Eggs should be maintained at an appropriate temperature, including avoiding fluctuations in temperatures that will result in condensation of water on the shell surface.

9 PRODUCT INFORMATION AND CONSUMER AWARENESS

These principles and guidelines are supplemental to those contained in Section 9 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

9.1 LOT IDENTIFICATION

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

Documentation can enhance the credibility and effectiveness of the food safety control system, especially when it includes measures that permit a client to refer to their supplier on the history of a product. Labelling and record keeping also aid in the implementation of other emergency and corrective actions.

Where appropriate and practicable, a system should be in place that allows the identification of the egg layer establishment, transporter, grading/packing premises and processor where eggs and egg products were produced..

The system should be easy to audit. Records should be kept for a period of time sufficient to permit efficient traceback investigations of the eggs and/or egg products. It is important to ensure that all parties involved in this system are adequately informed and trained in its implementation.

9.2 PRODUCT INFORMATION

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

9.3 LABELLING

Egg and egg products should be labelled in accordance with the Codex *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985).

Processors and food manufacturers awareness

Processors and food manufacturers that use egg products should follow labelling instructions.

9.4 CONSUMER EDUCATION

Where appropriate, advice should be made available to consumers on the safe handling, use, preparation and consumption of eggs.

10 TRAINING

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

Appendix III

DRAFT GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF *LISTERIA MONOCYTOGENES* IN FOODS

At Step 8 of the Elaboration Procedure

Table of Content

INTRODUCTION

Listeria (L.) monocytogenes is a Gram-positive bacterium that occurs widely in both agricultural (soil, vegetation, silage, faecal material, sewage, water), aquacultural, and food processing environments. *L. monocytogenes* is a transitory resident of the intestinal tract in humans, with 2 to 10% of the general population being carriers of the microorganism without any apparent health consequences.[1] In comparison to other non-spore forming, foodborne pathogenic bacteria (e.g., *Salmonella* spp., enterohemorrhagic *Escherichia coli*), *L. monocytogenes* is resistant to various environmental conditions such as high salt or acidity. *L. monocytogenes* grows at low oxygen conditions and refrigeration temperatures, and survives for long periods in the environment, on foods, in the processing plant, and in the household refrigerator. Although frequently present in raw foods of both plant and animal origin, sporadic cases or outbreaks of listeriosis are generally associated with ready-to-eat, refrigerated foods, and often involves the post-processing recontamination of cooked foods.

L. monocytogenes has been isolated from foods such as raw vegetables, raw and pasteurised fluid milk, cheeses (particularly soft-ripened varieties), ice cream, butter, fermented raw-meat sausages, raw and cooked poultry, raw and processed meats (all types) and raw, preserved and smoked fish. Even when *L. monocytogenes* is initially present at a low level in a contaminated food, the microorganism may multiply during storage in foods that support growth, even at refrigeration temperatures.

L. monocytogenes causes invasive listeriosis wherein the microorganism penetrates the lining of the gastrointestinal tract and then establishes infections in normally sterile sites within the body. The likelihood that *L. monocytogenes* can establish a systemic infection is dependent on a number of factors, including the number of microorganisms consumed, host susceptibility, and virulence of the specific isolate ingested. Almost all strains of *L. monocytogenes* appear to be pathogenic though their virulence, as defined in animal studies, varies substantially. Listeriosis is an infection that most often affects individuals experiencing immunosuppression including individuals with chronic disease (e.g., cancer, diabetes, malnutrition, AIDS), foetuses or neonates (assumed to be infected *in utero*), the elderly and individuals being treated with immunosuppressive drugs (e.g., transplant patients). The bacterium most often affects the pregnant uterus, the central nervous system or the bloodstream. Manifestations of listeriosis include but are not limited to bacteremia, septicaemia, meningitis, encephalitis, miscarriage, neonatal disease, premature birth, and stillbirth. Incubation periods prior to individuals becoming symptomatic can be from a few days up to three months. *L. monocytogenes* can also cause mild febrile gastro-enteritis in otherwise healthy individuals. The public health significance of this type of listeriosis appears to be much lower than that of invasive listeriosis.

Available epidemiological data show invasive listeriosis occurs both as sporadic cases and outbreaks, with the former accounting for the majority of cases. Invasive listeriosis is a relatively rare, but often severe disease with incidences typically of 3 to 8 cases per 1,000,000 individuals and fatality rates of 20 to 30% among hospitalised patients.[2] During recent years, the incidence of listeriosis in most countries has remained constant, with a number of countries reporting declines in the incidence of disease. These reductions likely reflect the efforts in those countries by industry and governments (a) to implement Good Hygienic Practice (GHP) and apply HACCP to reduce the frequency and extent of *L. monocytogenes* in ready-to-eat foods, (b) to improve the integrity of the cold chain through processing, distribution, retail and the home to reduce the incidence of temperature abuse conditions that foster the growth of *L. monocytogenes*, and (c) to enhance risk communication, particularly for consumers at increased risk of listeriosis. However, further actions are needed to achieve continuous improvement of public health by lowering the incidence of human foodborne listeriosis worldwide. Periodically transitory increases in incidence have been noted in several countries. These have been associated typically with foodborne outbreaks attributable to specific foods, often from specific manufacturers. In such cases, the incidence of listeriosis returned to prior baseline values after the causative food was removed from the market, and consumers received effective public health information pertaining to appropriate food choices and handling practices.

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1 FAO (2000): Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods. FAO, Food and Nutrition Paper No. 71.

2 FAO and WHO (2001): Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods: Risk characterisation of Salmonella spp. in eggs and broiler chickens and *L. monocytogenes* in ready-to-eat foods. FAO, Food and Nutrition Paper No.72.

Listeriosis has been recognised as a human disease since the 1930's, however, it was not until the 1980's, when there were several large outbreaks in North America and Europe, that the role that foods play in the transmission of the disease was fully recognised. Foods are now considered to be the major vehicle for *L. monocytogenes*. A variety of specific foods have been implicated in outbreaks and sporadic cases of listeriosis (e.g., processed meats, soft cheeses, smoked fish, butter, milk, coleslaw). The foods associated with listeriosis have been overwhelmingly ready-to-eat products that are typically held for extended periods at refrigeration or chill temperatures.

The large number of ready-to-eat foods in which *L. monocytogenes* is at least occasionally isolated has made it difficult to effectively focus food control programs on those specific foods that contribute the greatest risk to foodborne listeriosis. As a means of addressing this and a number of related questions, several formal quantitative risk assessments have been undertaken to address issues related to the relative risks among different ready-to-eat foods and the factors that contribute to those risks. Available governmental risk assessments currently include (1) a comparative risk assessment of 23 categories of ready-to-eat foods conducted by the U.S. Food and Drug Administration and the Food Safety and Inspection Service (FDA/FSIS, 2003)[3], (2) a comparative risk assessment of four ready-to-eat foods conducted by FAO/WHO JEMRA at the request of the Codex Committee on Food Hygiene[4], and (3) a product/process pathway analysis conducted by the U.S. Food Safety and Inspection Service for processed meats[5], which examined the risk of product contamination from food contact surfaces.

Each of these assessments articulates concepts that countries can use to identify and categorise those ready-to-eat products that represent a significant risk of foodborne listeriosis. Five key factors were identified as contributing strongly to the risk of listeriosis associated with ready-to-eat foods:

- Amount and frequency of consumption of a food
- Frequency and extent of contamination of a food with *L. monocytogenes*
- Ability of the food to support the growth of *L. monocytogenes*
- Temperature of refrigerated/chilled food storage
- Duration of refrigerated/chilled storage

A combination of interventions is generally more effective in controlling the risk rather than any single intervention (FDA/FSIS, 2003)[3].

In addition to the factors above, which influence the number of *L. monocytogenes* present in the food at the time of consumption, the susceptibility of an individual is important in determining the likelihood of listeriosis.

The risk assessments that have been conducted have consistently identified the impact that the ability of a food to support the growth of *L. monocytogenes* has on the risk of listeriosis. Those foods that are able to support growth during the normal shelf life of a product increase substantially the risk that the food will contribute to foodborne listeriosis. Control of growth can be achieved by several different approaches, including reformulation of the product such that one or more of the parameters influencing the growth of the bacterium (e.g., pH, water activity, presence of inhibitory compounds) is altered so the food no longer supports growth. Alternatively, strict control of temperature so that ready-to-eat foods never exceed 6°C (preferably 2°C- 4°C) and/or shortening the duration of the product refrigerated/chilled shelf life are other means for assuring that growth to any significant degree does not occur before the product is consumed.

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[3] FDA/FSIS, 2003. Quantitative assessment of the relative risk to public health from foodborne *Listeria monocytogenes* among selected categories of ready-to-eat foods at www.cfsan.fda.gov

[4] FAO/WHO, 2004. Risk assessment of *Listeria monocytogenes* in ready-to-eat foods. Technical Report. Microbiological Risk Assessment Series, No. 5.

[5] FSIS Rule Designed to Reduce Listeria monocytogenes in Ready-to-Eat Meat & Poultry at http://www.fsis.usda.gov/factsheets/fsis_rule_designed_to_reduce_listeria/index.asp

Many of the ready-to-eat products that are associated with foodborne listeriosis include a step in their production that is listericidal. Thus, the frequency and level of contamination of these products with *L. monocytogenes* is typically associated with the recontamination of the product prior to final packaging or from subsequent handling during marketing or home use. Thus, another strategy to control foodborne listeriosis is to reduce recontamination of the product and/or to introduce an additional mitigation treatment after final packaging. Control of the frequency and level of contamination is likely to be influenced strongly by factors such as attention to the design and maintenance of equipment and the integrity of the cold chain, the latter clearly being identified as a risk factor (i.e., the temperature of refrigerated/chilled storage).

Some ready-to-eat foods do not include a listericidal treatment. Product safety in those instances is dependent on steps taken during primary production, processing, and subsequent distribution and use to minimise or reduce contamination/recontamination and to limit growth through maintaining the cold chain and limiting the duration of refrigerated storage.

The FAO/WHO risk assessment also clearly indicated that in order for food control programmes to be effective, they must be capable of consistently achieving the degree of control required; the risk of listeriosis is largely associated with failures to meet current standards for *L. monocytogenes*, be they at 0.04 or 100 CFU/g. The analyses conducted within that risk assessment clearly indicate that the greatest risk associated with ready-to-eat products is the small portion of the products with high contamination levels of *L. monocytogenes.* Thus, a key component of a successful risk management program is assurance that control measures (e.g., preventing contamination and growth of the pathogen) can be achieved consistently.

SECTION I - OBJECTIVES

These guidelines provide advice to governments on a framework for the control of *L. monocytogenes* in ready-to-eat foods, with a view towards protecting the health of consumers and ensuring fair practices in food trade. Their primary purpose of these guidelines is to minimise the likelihood of illness arising from the presence of *L. monocytogenes* in ready-to-eat foods. The guidelines also provide information that will be of interest to the food industry, consumers, and other interested parties.

SECTION II - SCOPE

2.1 Scope

These guidelines are intended for ready-to-eat foods and are applicable throughout the food chain, from primary production through consumption. However, based on the results of the FAO/WHO risk assessment, other available risk assessments and epidemiological evaluations, these guidelines will focus on control measures that can be used, where appropriate, to minimize and/or prevent the contamination and/or the growth of *L. monocytogenes* in ready-to-eat foods. These guidelines highlight key control measures that affect key factors that influence the frequency and extent of contamination of ready-to-eat foods with *L. monocytogenes* and thus the risk of listeriosis. 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 control of foodborne pathogens in all foods. 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 *L. monocytogenes.*

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 of hygienic practice should be suitable to control *L. monocytogenes* in non ready-to-eat foods. However, the additional measures described in the following guidelines should be consulted and implemented, as necessary to control *L. monocytogenes* in ready-to-eat foods.

2.2 Definitions

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

Definitions of the "Principles and Guidelines for the Conduct of Microbiological Risk Management" apply.

Ready-to-eat food – Any food which 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 listericidal steps.

SECTION III - PRIMARY PRODUCTION

Many ready-to-eat foods receive one or more treatments during processing or preparation that inactivate or inhibit the growth of *L. monocytogenes*. For these foods animal health and general application of good agricultural practices, including animal husbandry, should be sufficient to minimise the prevalence of *L. monocytogenes* at primary production.

In those ready-to-eat foods that are manufactured without a listericidal treatment, extra attention at primary production is needed to assure specific control of the pathogen (e.g., control of *L. monocytogenes* mastitis in dairy cattle and sheep where the milk will be used to make raw milk cheeses, frequency of *L. monocytogenes* in raw milk as related to the feeding of inadequately fermented silage, high levels of *L. monocytogenes* in pork for fermented sausages resulting from wet feeding systems, faecal contamination of fresh produce), including increased focus on personal hygiene and water management programs at the primary production sites.

Analysis of raw material for *L. monocytogenes* can be, where appropriate, an important tool for validating and verifying that the control measures at the primary production level are adequately limiting the frequency and level of contamination to that needed to achieve the required level of control during subsequent manufacturing.

3.1 Environmental Hygiene

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

3.2 Hygienic Production of Food Sources

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

3.3 Handling, Storage and Transport

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

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).

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

Objectives:

Equipment and facilities should be designed, constructed and laid out to ensure cleanability and to minimise the potential for *L. monocytogenes* harbourage sites, cross-contamination and recontamination.

Rationale:

- The introduction of *L. monocytogenes* into the ready-to-eat processing environment has resulted from inadequate separation of raw and finished product areas and from poor control of employees or equipment traffic.
- Inability to properly clean and disinfect equipment and premises due to poor layout or design and areas inaccessible to cleaning has resulted in biofilms containing *L. monocytogenes* and harbourage sites that have been a source of product contamination
- The use of spray cleaning procedures that aerosolize the microorganism has been linked to the spread of the *L. monocytogenes* in the processing environment.
- Inability to properly control ventilation to minimise condensate formation on surfaces in food processing plants may result in the occurrence of *L. monocytogenes* in droplets and aerosols which can lead to product contamination.

4.1 Location

4.1.1 Establishments

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

4.1.2 Equipment

Whenever possible, equipment should be designed and placed in a manner that facilitates access for efficient cleaning and disinfection, and thus avoid the formation of biofilms containing *L. monocytogenes* and harbourage sites.

4.2 Premises and Rooms

4.2.1 Design and Layout

Whenever feasible, premises and rooms should be designed to separate raw and finished ready-to-eat product areas. This can be accomplished in a number of ways, including linear product flow (raw to finished) with filtered airflow in the opposite direction (finished to raw) or physical partitions. Positive air pressure should be maintained on the finished side of the operation relative to the "raw" side (e.g., maintain lower air pressures in raw areas and higher pressures in finished areas).

Where feasible, the washing areas for food equipment involved in the manufacture of the finished product should be located in a separate room from the finished product processing area. This latter area should be separate from the raw ingredient handling area and the cleaning area for equipment used in the handling of raw ingredients in order to prevent recontamination of equipment and utensils used for finished products. Rooms where ready-to-eat products are exposed to the environment should be designed so that they can be maintained as dry as possible; wet operations often enhance the growth and spread of *L. monocytogenes*.

4.2.2 New construction/renovations

Due to the ability of *L. monocytogenes* to survive in the plant environment for long periods of time, disturbances caused by construction or modification of layouts can cause reintroduction of *L. monocytogenes* from harbourage sites to the environment. Where appropriate, care should be taken to isolate the construction area, to enhance hygienic operations and to increase environmental monitoring to detect *Listeria* spp. during construction/renovation (see Section 6.5).

4.2.3 Temporary/mobile premises and vending machines

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

4.3 Equipment

4.3.1 General

Due to the ability of *L. monocytogenes* to exist in biofilms and persist in harbourage sites for extended periods, processing equipment should be designed, constructed and maintained to avoid, for example, cracks, crevices, rough welds, hollow tubes and supports, close fitting metal-to-metal or metal-to-plastic surfaces, worn seals and gaskets or other areas that cannot be reached during normal cleaning and disinfection of food contact surfaces and adjacent areas.

Racks or other equipment used for transporting exposed product should have easily cleaned cover guards over the wheels to prevent contamination of the food from wheel spray.

Cold surfaces (e.g., refrigeration units) can be sources for psychrotrophic bacteria, especially *L. monocytogenes*. Condensate from refrigeration unit pans should be directed to a drain via a hose or drip pans should be emptied, cleaned and disinfected on a regular basis.

Insulation should be designed and installed in a manner that it does not become a harbourage site for *L. monocytogenes* .

4.3.2 Food control and monitoring equipment

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

4.3.3 Containers for waste and inedible substances

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

4.4 Facilities

4.4.1 Water supply

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

4.4.2 Drainage and waste disposal

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

4.4.3 Cleaning

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

4.4.4 Personnel hygiene facilities and toilets

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

4.4.5 Temperature control

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

4.4.6 Air quality and ventilation

Control of ventilation to minimise condensate formation is of particular importance in *L. monocytogenes* control, since the organism has been isolated from a wide variety of surfaces in food processing plants. Wherever feasible, facilities should be designed so that droplets and aerosols from condensates do not directly or indirectly contaminate food and food contact surfaces.

4.4.7 Lighting

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

4.4.8 Storage

Where feasible and appropriate for the food product, and where food ingredients and products support growth of *L. monocytogenes*, storage rooms should be designed so that a product temperature should not exceed 6°C, (preferably 2°C - 4°C). Raw materials should be stored separately from finished, processed products.

SECTION V - CONTROL OF OPERATION

Objectives:

Processing operations should be controlled to reduce the frequency and level of contamination in the finished product, to minimise the growth of *L. monocytogenes* in the finished product and to reduce the likelihood that the product will be recontaminated and/or will support the growth of *L. monocytogenes* during subsequent distribution, marketing and home use.

Rationale:

For many ready-to-eat products listericidal processes[6] can ensure appropriate reduction in risk. However, not all ready-to-eat products receive such a treatment and other ready-to-eat products may be exposed to the environment and thus may be subject to potential recontamination. Prevention of cross-contamination, strict control of time and temperature for products in which *L. monocytogenes* can grow and formulation of products with hurdles to *L. monocytogenes* growth can minimise the risk of listeriosis.

5.1 Control of the food hazard

Control of *L. monocytogenes* for many ready-to-eat products 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 *L. monocytogenes*.

The factors and attributes described below are components of Good Hygienic Practice programs that will typically require elevated attention to control *L. monocytogenes* and may be identified as critical control points in HACCP programs where *L. monocytogenes* is identified as a hazard.

5.2 Key aspects of hygiene control systems

5.2.1 Time and temperature control

The risk assessments done by the U.S. FDA/FSIS and FAO/WHO on *L. monocytogenes* in ready-to-eat foods demonstrated the tremendous influence of storage temperature on the risk of listeriosis associated with ready-to-eat foods that support *L. monocytogenes* growth. It is therefore necessary to control the time/temperature combination used for storage.

Monitoring and controlling refrigerated storage temperatures are key control measures. The product temperature should not exceed 6°C (preferably 2°C - 4°C). Temperature abuse that may occur supporting the growth of *L. monocytogenes* could result in a reduction of product shelf life.

The length of the shelf-life is another important factor contributing to the risk associated with foods that support *L. monocytogenes* growth. The shelf-life of such foods should be consistent with the need to control the growth of *L. monocytogenes.* Since *L. monocytogenes* is able to grow under refrigeration temperatures, the length of the shelf-life should be based on appropriate studies that assess the growth of *L. monocytogenes* in the food. Shelf-life studies and other information are important tools facilitating the selection of the length of shelf-life. If they are conducted, they should account for the fact that appropriate low temperatures may not be maintained throughout the entire food chain until the point of consumption. Temperature abuses may allow the growth of *L. monocytogenes*, if present, unless appropriate intrinsic factors are applied to prevent such growth. This should be taken into account when establishing shelf life.

5.2.2 Specific process steps

Listericidal processes should be validated to ensure that the treatments are effective and can be applied consistently (see Section V of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

In some products single parameters, such as a pH less than 4.4, a water activity less than 0.92 or freezing, may be relied upon to prevent *L. monocytogenes* growth. In other products a combination of parameters is used. Validation should be undertaken to ensure the effectiveness of these parameters in situations where combinations of parameters or bacteriostatic conditions are relied upon.

Products supporting the growth of *L. monocytogenes* that have undergone a listericidal treatment may be contaminated/recontaminated before final packaging. In these cases, additional control measures may be applied if necessary, (e.g., freezing the product, shortening the shelf life, reformulation of the product) to limit the extent of or prevent *L. monocytogenes* growth. Alternatively, a post-packaging listericidal treatment may be necessary (e.g. heating, high pressure treatment, irradiation, where accepted).

In raw, ready-to-eat food (e.g. lettuce), that support the growth of *L. monocytogenes*, that may be contaminated, specific control measures may be applied if necessary to limit the extent of or prevent the growth of *L. monocytogenes* (e.g. acid wash).

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[6] Any appropriate treatment that kills listeria.

5.2.3 Microbiological and other specifications

Refer to the *RecommendedInternational Code of Practice-General Principles of Food Hygiene(CAC/RCP 1-1969) and Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1979).*

5.2.4 Microbiological cross-contamination

Microbiological cross-contamination is a major issue with respect to *L. monocytogenes.* It can occur through direct contact with raw materials, personnel, aerosols and contaminated utensils, equipment, etc.. Cross-contamination can occur at any step where the product is exposed to the environment, including processing, transportation, retail, catering, and in the home.

Traffic flow patterns for employees, food products, and equipment should be controlled between raw processing, storage area(s) and finished area(s) to minimise the transfer of *L. monocytogenes*. For example, a change of footwear or automated foam sprayers can be an effective alternative to footbaths where people, carts, forklifts and other portable equipment must enter an area where ready-to-eat foods are exposed. Another example is to use a colour coding system to identify personnel assigned to specific areas of the plant.

Utensils, pallets, carts, forklifts and mobile racks should be dedicated for use in either the raw area or the finished product area to minimise cross-contamination. Where this is not practical, they should be cleaned and disinfected before entry into the finished product area.

Reused brines and recycled process water used in direct contact with finished product should be discarded or decontaminated (e.g. chlorination for recycled water, heat treatment, or some other effective treatment) with sufficient frequency to ensure control of *L. monocytogenes*.

Ready-to eat foods that do not support the growth of *L. monocytogenes* but may have low levels of this pathogen should not be a source of contamination to other ready-to-eat foods that may support the growth of this pathogen. Consideration should be given to the fact that some ready-to-eat foods with special handling requirements (for example ice cream), that are handled after opening may present a lower risk for being a vector for cross contaminating other ready-to-eat foods, because such specially handled product is rapidly consumed. Other ready-to-eat products, however, with special formulation (for example dry fermented sausage), that are handled after opening may present a higher risk of being a vector for cross contaminating other ready-to-eat products if neither ready-to-eat product is rapidly consumed.

5.2.5 Physical and chemical contamination

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

5.3 Incoming material requirements

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

5.4 Packaging

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

5.5 Water

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

5.5.1 In contact with food

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

5.5.2 As an ingredient

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

5.5.3 Ice and steam

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).

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

Based on the determined level of risk associated with the presence of *L. monocytogenes* in a given food product, a decision may be taken to recall the contaminated product from the market. In some instances, the need for public warnings should be considered.

5.9 Monitoring of effectiveness of control measures for *L. monocytogenes*

An effective environmental monitoring program is an essential component of a *Listeria* control program, particularly in establishments that produce ready-to-eat foods that support growth and may contain *L. monocytogenes*. Testing of food products can be another component of verification that control measures for *L. monocytogenes* are effective (see Section 5.2.3).

Recommendations for the design of an environmental monitoring program for *L. monocytogenes* in processing areas are given in Annex 1.

SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION

Objectives:

To provide specific guidance on how preventive maintenance and sanitation procedures, along with an effective environmental monitoring program can reduce contamination of food with *L. monocytogenes*, particularly when the foods support growth of *L. monocytogenes*:

Well structured cleaning and disinfection procedures should be targeted against *L. monocytogenes* in food processing areas where ready-to-eat foods are exposed to reduce

- the likelihood that the product will be contaminated after processing,
- the level of contamination in the finished product.

Rationale:

Basic cleaning and disinfection programs are critical to assuring control of *L. monocytogenes.* An environmental monitoring program for *Listeria* in processing areas where ready-to-eat foods are exposed is necessary to assess the effectiveness of control measures and, therefore, the likelihood of contamination of the food.

6.1 Maintenance and Cleaning

6.1.1 General

Establishments should implement an effective, scheduled preventive maintenance program to prevent equipment failures during operation and the development of harbourage sites. Equipment failures during production increase the risk of *L. monocytogenes* contamination as equipment is being repaired. The preventive maintenance program should be written and include a defined maintenance schedule.

The preventive maintenance program should include scheduled replacement or repair of equipment before it becomes a source of contamination. Equipment should be inspected periodically for parts that are cracked, worn or have developed spaces where food and moisture accumulate (i.e., harbourage sites). Preventive maintenance should include periodic examination and maintenance of conveyors, filters, gaskets, pumps, slicers, filling equipment, and packaging machines and support structures for equipment. Air filters for bringing outside air into the plant should be examined and changed based on manufacturer's specification or more frequently based on pressure differential or microbiological monitoring.

Wherever possible, tools used for maintenance of equipment to which ready-to-eat foods are exposed should be dedicated to the finished product area. Such tools should be washed and disinfected prior to use. Maintenance personnel in the finished product area should comply with the same hygiene requirements as the finished product production employees. Food contact surfaces on equipment should be cleaned and disinfected after maintenance work, prior to production use. Equipment that could have become contaminated during maintenance work on facility utilities, e.g. air system, water system, etc., or remodelling, should be cleaned and disinfected prior to use.

6.1.2 Cleaning procedures and methods

Experience indicates that over-reliance on the chemicals alone for cleaning can lead to increased levels of microbial contamination. The chemicals must be applied at the recommended use-concentration, for sufficient time, at the recommended temperature and with sufficient force (i.e., turbulence, scrubbing) to remove soil and biofilm. Instances of *L. monocytogenes* contamination have been linked, in particular, to insufficient manual scrubbing during the cleaning process.

Research and experience further indicates that *L. monocytogenes* does not possess an unusual ability to resist disinfectants or attach to surfaces. However, it is noted that *L. monocytogenes* has the ability to form biofilms on a variety of surfaces.

Solid forms of disinfectants (e.g., blocks of quarternary ammonium compounds (QAC)) can be placed in the drip pan of refrigeration units and solid rings containing disinfectants can be placed in drains to help control *L. monocytogenes* in drains. Granulated forms of disinfectants such as QAC, hydrogen peroxide and peroxyacetic acid can be applied to floors after routine cleaning and disinfecting. The development of antimicrobial resistance should be considered in the application and use of disinfectants.

The equipment used for cleaning, e.g. brushes, bottle brushes, mops, floor scrubbers, and vacuum cleaners should be maintained and cleaned so they do not become a source of contamination. The cleaning equipment should be dedicated either for raw areas or finished areas, and easily distinguishable (e.g., colour-coded cleaning tools).

To prevent aerosols from contacting ready-to-eat foods, food contact surfaces and food packaging materials, high-pressure water hoses should not be used during production or after equipment has been cleaned and disinfected.

It has been shown that *L. monocytogenes* can become established and persist in floor drains. Therefore, drains should be cleaned and disinfected in a manner that prevents contamination of other surfaces in the room. Utensils for cleaning drains should be easily distinguishable and be dedicated to that purpose to minimise the potential for contamination.

Floor drains should not be cleaned during production. High-pressure hoses should not be used to clear or clean a drain, as aerosols will be created that spread contamination throughout the room. If a drain backup occurs in finished product areas, production should stop until the water has been removed and the areas have been cleaned and disinfected. Employees who have been cleaning drains should not contact or clean food contact surfaces without changing clothes, and washing and disinfecting hands.

6.2 Cleaning Programs

The effectiveness of sanitation programs should be periodically verified and the programs modified as necessary to assure the consistent achievement of the level of control needed for a food operation to prevent *L. monocytogenes* contamination of ready-to-eat food and ready-to-eat food contact surfaces.

6.3 Pest control systems

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

6.3.1 General

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

6.3.2 Preventing access

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

6.3.3 Harbourage and infestation

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

6.3.4 Monitoring and detection

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

6.3.5 Eradication

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).

6.5 Monitoring effectiveness

Environmental monitoring (see 5.9) can also be used to verify the effectiveness of sanitation programs such that sources of contamination of *L. monocytogenes* are identified and corrected in a timely manner. Recommendations for the design of an environmental monitoring program in processing areas are given in Annex 1.

SECTION VII - ESTABLISHMENT: PERSONAL HYGIENE

Objectives:

To prevent workers from transferring *L. monocytogenes* from contaminated surfaces to food or food contact surfaces.

Rationale:

Workers can serve as a vehicle for cross-contamination and should be aware of the steps that need to be taken to manage this risk.

7.1 Health status

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

7.2 Illness and injuries

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

7.3 Personal cleanliness

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

7.4 Personal behaviour

Employee hygienic practices play an important role in preventing contamination of exposed ready-to-eat foods with *L. monocytogenes*. For example, employees who handle trash, floor sweepings, drains, packaging waste or scrap product, should not touch the food, touch food contact surfaces or food packaging material, unless they change their smock or outer clothing, wash and disinfect hands, and wear clean new gloves for tasks requiring gloves. Adequate training and supervision should be provided to assure hygienic practices are accomplished.

7.5 Visitors

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

SECTION VIII – TRANSPORTATION

Objectives:

Measures should be taken where necessary to:

- protect food from potential sources of contamination including harbourage sites for *L. monocytogenes* in transportation equipment and to prevent the co-mingling of raw and ready-to-eat product;
- provide an adequately refrigerated environment (so that product temperature should not exceed 6°C, preferably 2°C - 4°C).

Rationale:

Food may become contaminated during transportation if not properly protected**.**

If refrigeration is inadequate, food may support the growth of *L. monocytogenes* to higher levels..

8.1 General

Transportation is an integral step in the food chain and should be controlled, particularly the product temperature which should not exceed 6°C (preferably2°C - 4°C).

Transportation vehicles should be regularly inspected for structural integrity, cleanliness, and overall suitability when unloading ingredients and prior to loading finished products. In particular, the structural integrity of transportation vehicles (e.g., tanker trucks) should be monitored for stress cracks that act as harbourage sites for *L. monocytogenes*. Tankers should be dedicated to transport either ingredients or finished products.

8.2 Requirements

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

8.3 Use and Maintenance

Food transportation units, accessories, and connections should be cleaned, disinfected (where appropriate) and maintained to avoid or at least reduce the risk of contamination. It should be noted that different commodities may require different cleaning procedures. Where necessary, disinfection should be followed by rinsing unless manufacturer's instruction indicates on a scientific basis that rinsing is not required.[7] A record should be available that indicates when cleaning occurred.

SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS

Objectives:

Consumers should have enough knowledge of *L. monocytogenes* and food hygiene such that they:

- understand the importance of shelf-life, sell-by or use-by dates written on food label;
- can make informed choices appropriate to the individual's health status and concomitant risk of acquiring foodborne listeriosis;

[7] Code of Hygienic Practice for the Transport of Food in Bulk and Semi-packed Food (CAC/RCP 47-2001).

- prevent contamination and growth or survival of *L. monocytogenes* by adequately storing and preparing ready-to-eat foods.

Health care providers should have appropriate information on *L. monocytogenes* in foods and listeriosis to give advice to consumers and in particular susceptible populations

Rationale:

Consumers (in particular, the susceptible populations), health care providers, need to be informed about ready-to-eat foods supporting growth of *L. monocytogenes,* food handling, preparation practices and avoidance of certain foods by susceptible populations.

9.1 Lot identification

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

9.2 Product information

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

9.3 Labelling

Countries should give consideration to labelling of certain ready-to-eat foods so that consumers can make an informed choice with regard to these products. Where appropriate, product labels should include information on safe handling practices and/or advice on the time frames in which the product should be eaten.

9.4 Consumer Education

Since each country has specific consumption habits, communication programs pertaining to *L. monocytogenes* are most effective when established by individual governments.

Programs for consumer information should be directed:

- at consumers with increased susceptibility to contracting listeriosis, such as pregnant women, the elderly and immunocompromised persons;
  to help consumers make informed choices about purchase, storage, shelf-life labelling and appropriate consumption of certain ready-to-eat foods that have been identified in relevant risk assessment and other studies, taking into consideration the specific regional conditions and consumption habits;
- to consumers to educate them on household practices and behaviours that would specifically keep the numbers of *L. monocytogenes* that may be present in foods, to as low a level as possible by
  - setting refrigerator temperatures so that product temperatures should not exceed 6°C (preferably 2°C - 4°C) since the growth of *L monocytogenes* is considerably reduced at temperatures below 6°C;
  - frequently washing and disinfecting the household refrigerator since *L. monocytogenes* can be present in many foods and grow at refrigerator temperatures, and thus contribute to cross-contamination;
  - respecting the shelf-life dates written on ready-to-eat foods;
  - using of thermometers inside home refrigerators.

Programs for health care providers should, in addition to information provided to consumers, be designed to provide them with guidance that

- facilitates rapid diagnosis of foodborne listeriosis;
- provides means to rapidly communicate information on preventing listeriosis to their patients, particularly those with increased susceptibility.

SECTION X - TRAINING

Objective:

Those engaged in food operation who come directly or indirectly in contact with ready-to-eat foods should be trained and/or instructed in the control of *L. monocytogenes* to a level appropriate to the operations they are to perform..

Rationale:

Controls specific to *L. monocytogenes* are generally more stringent than routine Good Hygiene Practices.

10.1 Awareness and responsibilities

Industry (primary producers, manufacturers, distributors, retailers and food service/institutional establishments) and trade associations have an important role in providing specific instruction and training for control of *L. monocytogenes*.

10.2 Training programs

Personnel involved with the production and handling of ready-to-eat food should have appropriate training in:

- the nature of *L. monocytogenes*, its harbourage sites, and its resistance to various environmental conditions to be able to conduct a suitable hazard analysis for their products;
- control measures for reducing the risk of *L. monocytogenes* associated with ready-to-eat foods during processing, distribution, marketing, use and storage;
- the means for verifying effectiveness of control programs, including sampling and analytical techniques;

10.3 Instruction and supervision

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

10.4 Refresher Training

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

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ANNEX I: RECOMMENDATIONS FOR AN ENVIRONMENTAL MONITORING[8] PROGRAM FOR *LISTERIA MONOCYTOGENES* IN PROCESSING AREAS

Manufacturers of ready-to-eat foods should consider the potential risk to consumers in the event their products contain *L. monocytogenes* when they are released for distribution. The necessity for an environmental monitoring program is highest for ready-to-eat foods that support *L. monocytogenes* growth and that are not given a post-packaging listericidal treatment. Recontamination has led to many of the recognised outbreaks of listeriosis. One effective element of managing this risk is to implement a monitoring program to assess control of the environment in which ready-to-eat foods are exposed prior to final packaging.

A number of factors (a – i) should be considered when developing the sampling program to ensure the program's effectiveness:

a) Type of product and process/operation

The need[9] for and extent of the sampling program should be defined according to the characteristics of the ready-to-eat foods (supporting or not supporting growth), the type of processing (listericidal or not) and the likelihood of contamination or recontamination (exposed to the environment or not). In addition, consideration also needs to be given to elements such as the general hygiene status of the plant or the existing history of *L. monocytogenes* in the environment.

b) Type of samples

Environmental samples consist of both food contact and non food contact surface samples. Food contact surfaces, in particular those after the listericidal step and prior to packaging, have a higher probability of directly contaminating the product, while for non food contact surfaces the likelihood will depend on the location and practices.

Raw materials may serve as a source of environmental contamination and may therefore be included in the monitoring program.

c) Target organisms

While this document addresses *L. monocytogenes*, effective monitoring programs may also involve testing for *Listeria* spp; their presence is a good indicator of conditions supporting the potential presence of *Listeria monocytogenes*. Where appropriate and shown to be valid, other indicator organisms may be used[10].

d) Sampling locations and number of samples

The number of samples will vary with the complexity of the process and the food being produced.

Information on appropriate locations can be found in published literature, can be based on process experience or expertise or in plant surveys. Sampling locations should be reviewed on a regular basis. Additional locations may need to be sampled depending on special situations such as major maintenance or construction or when new or modified equipment has been installed.

e) Frequency of sampling

The frequency of environmental sampling would be based primarily on the factors outlined under sub-heading "Type of product and process/operation". It should be defined according to existing data on the presence of *Listeria* spp. and/or *L. monocytogenes* in the environment of the operation under consideration.

In the absence of such information sufficient suitable data should be generated to correctly define the appropriate frequency. These data should be collected over a sufficiently long period as to provide reliable information on the prevalence of *Listeria* spp. and/or *L. monocytogenes* and the variations over time.

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8 Environmental monitoring is not to be confused with monitoring as defined in the HACCP.

9 Products such as in pack pasteurised foods which are not further exposed to environment may not necessarily require a monitoring.

10 Attributes contributing to the scientific support of the use of an indicator organism in view of a specific pathogen include: similar survival and growth characteristics; a shared common source for both organisms; direct relationship between the state or condition that contributes to the presence of the pathogen and the indicator organism; and practical, isolation, detection or enumeration methods for the potential indicator organism.

The frequency of environmental sampling may need to be increased as a result of finding *Listeria* spp. and/or *L. monocytogenes* in environmental samples. This will depend on the significance of the findings (e.g. *L. monocytogenes* and a risk of direct contamination of the product).

f) Sampling tools and techniques

It is important to adapt the type of sampling tools and techniques to the type of surfaces and sampling locations. For example sponges may be used for large flat surfaces, swabs may be more appropriate for cracks and crevices or scrapers for hard residues.

g) Analytical methods

The analytical methods used to analyse environmental samples should be suitable for the detection of *L. monocytogenes* and of other defined target organisms. Considering the characteristics of environmental samples it is important to demonstrate that the methods are able to detect, with acceptable sensitivity, the target organisms. This should be documented appropriately.

Under certain circumstances it may be possible to composite (pool) certain samples without loosing the required sensitivity. However, in the case of positive findings additional testing will be necessary to determine the location of the positive sample.

Fingerprinting isolates by one or more of the available genetic techniques (e.g., pulsed field gel electrophoresis, ribotyping) can provide very useful information about the source(s) of *L. monocytogenes* and pathway(s) that lead to contamination of the food.

h) Data management

The monitoring program should include a system to record the data and their evaluation, e.g. performing trend analyses. A long-term review of the data is important to revise and adjust monitoring programs. It can also reveal low level, intermittent contamination that may otherwise go unnoticed.

i) Actions in case of positive results

The purpose of the monitoring program is to find *L. monocytogenes* or other target organisms if present in the environment. Generally manufacturers should expect to find them occasionally in the processing environment. Therefore an appropriate action plan should be designed and established to adequately respond to positive findings. A review of hygiene procedures and controls should be considered.

The manufacturer should react to each positive result; the nature of the reaction will depend upon the likelihood of contaminating the product and the expected use of the products.

The plan should define the specific action to be taken and the rationale. This could range from no action (no risk of recontamination), to intensified cleaning, to source tracing (increased environmental testing), to review of hygienic practices up to holding and testing of product.

Appendix IV

DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT (MRM)

(at Step 8 of the Procedure)

DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT (MRM)

INTRODUCTION

Diseases caused by foodborne microbial hazards[1] constitute a world-wide public health concern. During the past several decades, the incidence of foodborne diseases has increased in many parts of the world. Foodborne threats occur for a number of reasons. These include microbial adaptation, changes in the food production systems, including new feeding practices, changes in animal husbandry, agronomic process and food technology, increase in international trade, susceptible populations and travel, change in lifestyle and consumers demands, changes in human demographics and behaviour. The globalisation of food markets has increased the challenge to manage these risks.

Effective management of risks arising from microbial hazards is technically complex. Food safety has been traditionally, and will continue to be, the responsibility of industry operating an array of control measures relating to the food hygiene within an overall regulatory framework. Recently, risk analysis, involving its component parts of risk assessment, risk management and risk communication, has been introduced as a new approach in evaluating and controlling microbial hazards to help protecting the health of consumers and ensure fair practices in food trade. It could also facilitate the judgement of equivalence of food safety control systems.

This document should be read in close conjunction with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius[2] and the Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL 30 – 1999). Countries, organisations and individuals involved with MRM are encouraged to utilise these guidelines in concert with technical information developed by the World Health Organisation, the Food and Agriculture Organisation and the Codex Alimentarius (e.g. FAO/WHO Expert Consultation on Risk Management and Food Safety-Paper N°65, Rome 1997, WHO Expert Consultation - The Interaction between Assessors and Managers of Microbial Hazards in Food, Kiel, Germany, March 2000 - The Principles and Guidelines for Incorporating Microbiological Risk Assessment in the Development of Food Safety Standards, Guidelines and Related Texts, Report Kiel, Germany, March 2002 – The Use of Microbiological Risk Assessment Outputs to Develop Practical Risk Management Strategies: Metrics to improve food safety, Kiel, Germany, April 2006.

1. SCOPE

These principles and guidelines provide a framework for the MRM process and are intended for use by Codex and countries[3], as appropriate. They also provide guidance on the application of microbiological risk assessment (MRA) within the MRM process. Where specific recommendations apply only to Codex, or only to countries, this is so noted in the text. This document also provides useful guidance for other interested parties in implementing risk management options, such as industry[4] and consumers who are involved in MRM on a day-to-day basis.

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1 Foodborne microbial hazards include (but are not limited to) pathogenic bacteria, viruses, algae, protozoa, fungi, parasites, prions, toxins and other harmful metabolites of microbial origin.

2 See Codex Alimentarius Commission, *Procedural Manual*, 16 Edition. Note that the development of working Principles for Risk Analysis to be applied by Governments is under consideration by the CCGP (see ALINORM 06/29/33).

3 For the purpose of this document, each time the terms “country”, “government”, “national” are used, the provision applies both to Codex Members (Rule I) and Codex Member Organisations (Rule II), i. e. regional economic integration organisation (REIO) – see Codex Alimentarius Commission, Procedural Manual – 16th Edition

4 For the purpose of this document, it is understood that industry includes all relevant sectors associated with the production, storage and handling of food, from primary production through retail and food service level (adapted from Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius).

2. DEFINITIONS

The definitions of risk analysis terms related to food safety incorporated in the Procedural Manual of the CAC[5], shall apply. See definitions of **hazard, risk, risk analysis, risk assessment, hazard identification, hazard characterisation, dose-response assessment, exposure assessment, risk characterisation, risk management, risk communication, risk assessment policy, risk profile, risk estimate, food safety objective (FSO), performance objective (PO), performance criterion (PC), traceability/product tracing and equivalence.**

The definitions from *The Guidelines for the Application of the HACCP System*[6], e.g. **control measure, step** or **critical control point**, the definition of a **microbiological criterion** included in *The Principles for the Application of Microbiological Criteria for Food (CAC/GL 21-1997)* and the definition of **interested parties** included in *The Working Principles for Risk Analysis for Application in the Framework of the Codex*[7] shall apply too.

The definition of the appropriate level of protection (**ALOP**) is the one in the WTO Agreement on the application of sanitary and phytosanitary measures (SPS agreement).

The definitions of **validation**, **verification** and **food safety control system** are under development in the draft *Guidelines for the Validation of Food Safety Control Measures.*

Risk manager[8] is defined as follows: a national or international governmental organisation with responsibility for MRM.

3. GENERAL PRINCIPLES FOR MRM

•PRINCIPLE 1: Protection of human health is the primary objective in MRM.

•PRINCIPLE 2: MRM should take into account the whole food chain.

•PRINCIPLE 3: MRM should follow a structured approach.

•PRINCIPLE 4: MRM process should be transparent, consistent and fully documented.

•PRINCIPLE 5: Risk managers should ensure effective consultations with relevant interested parties.

•PRINCIPLE 6: Risk managers should ensure effective interaction with risk assessors.

•PRINCIPLE 7: Risk managers should take account of risks resulting from regional differences in hazards in the food chain and regional differences in available risk management options.

•PRINCIPLE 8: MRM decisions should be subject to monitoring and review and, if necessary, revision.

4. GENERAL CONSIDERATIONS

Codex and government decisions and recommendations have as their primary objective the protection of the health of consumers. Decision making should be timely to achieve that objective. In the MRM process, the ALOP is a key concept, as it is a reflection of a particular country's expressed public health goals for foodborne risks.

MRM should address the food chains as individual continuums, when considering means for controlling the public health risks associated with food. This should typically include primary production (including feeds, agricultural practices, and environmental conditions leading to the contamination of crops and animals), product design and processing, transport, storage, distribution, marketing, preparation, and consumption. This should include both domestic and imported products to the extent feasible.

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5 Codex Alimentarius Commission, Procedural Manual, 16th Edition

6 Annex to CAC/RCP 1-1969

7 Codex Alimentarius Commission, Procedural Manual, 16th Edition

8 The definition of Risk Manager is derived from the definition for risk management which does not include all of the individuals who are involved in the implementation phase and related activities associated with MRM, i.e., MRM decisions are largely implemented by industry and other interested parties. The focus of the definition on risk manager is restricted to governmental organizations with authority to decide on the acceptability of risk levels associated to foodborne hazards.

MRM should follow a structured approach that includes preliminary MRM activities, identification and selection of MRM options, implementation of MRM activities, and monitoring and review of the options taken.

In order to facilitate a broader understanding by interested parties, MRM process should be transparent and fully documented. Risk managers should articulate and implement uniform procedures and practices to be used in the development and implementation of MRM, the determination of MRA policy, establishment of MRM priorities, allocation of resources (e.g. human, financial, time) and determination of the factors[9] to be used in the evaluation of MRM options. They should ensure that the options selected protect the health of consumers, are scientifically justifiable, proportionate to the risk identified and are not more restrictive of trade or technological innovation than required to achieve the ALOP. Risk managers should ensure that decisions are practicable and effective, and where appropriate, enforceable.

Risk managers should ensure effective and timely consultation with all relevant interested parties and provide a sound basis for understanding the MRM decision, its rationale and implications. The extent and nature of public consultation will depend on the urgency, complexity and uncertainties related to the risk and the management strategies being considered. Decisions and recommendations on MRM should be documented, and where appropriate clearly identified in Codex or national standards and regulations, so as to facilitate a wider understanding of the conduct of MRM.

The mandate given by risk managers to risk assessors relating to the conduct of an MRA should be as clear as possible. Interaction should allow risk managers to be informed by risk assessors of any constraints, data gaps, uncertainties, assumptions and their impact on the MRA. Where there is disagreement among the risk assessors, the risk managers should be informed of the minority opinions and these differences should be documented.

MRM decisions regarding foodborne hazards will vary according to the regional microbial conditions. MRM should take into account the diversity of production methods and processes, inspection, monitoring and verifications systems, sampling and testing methods, distribution and marketing systems, consumer food use patterns, consumers' perception and the prevalence of specific adverse health effect.

MRM should be an iterative process and decisions made should be subject to timely review, taking into account all relevant newly generated data, with a goal toward further risk reduction and public health improvement.

5. PRELIMINARY MICROBIOLOGICAL RISK MANAGEMENT ACTIVITIES

5.1 Identification of a microbiological food safety issue

A food safety issue arises where one or more foodborne microbial hazard(s) are known or thought to be associated with one or many food(s) and thus requires consideration of a risk manager. The risk manager follows the MRM process to evaluate and where necessary manage the associated risk. At the start of this process, the food safety issue should be clearly identified and communicated from the risk managers to risk assessors, as well as affected consumers and industry.

Food safety issue identification may be performed by the risk manager or be the result of collaboration between different interested parties. Within Codex, a food safety issue may be raised by a member government, or by an intergovernmental or observer organisation.

Food safety issues may be identified on the basis of information arising from a variety of sources, such as surveys of the prevalence and concentration of hazards in the food chain or the environment, human disease surveillance data, epidemiological or clinical studies, laboratory studies, scientific, technological or medical advances, lack of compliance with standards, recommendations of experts, public input, etc.

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[9] See Codex Alimentarius Commission, Procedural Manual, 16th Edition

Some food safety issues may require that an immediate action[10] be taken by the risk manager without further scientific consideration (e.g. requiring withdrawal / recall of contaminated products). Countries will often not be able to delay taking an immediate action when there is an imminent public health concern demanding an urgent response. Such measures should be temporary, clearly communicated as well as subject to review within a time frame.

When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, it may be appropriate for countries to select a provisional decision, while obtaining additional information that may inform and, if necessary, modify the provisional decision**.** In those instances, the provisional nature of the decision should be communicated to all interested parties and the timeframe or circumstances under which the provisional decision will be reconsidered (e.g. reconsideration after the completion of a MRA) should be articulated when the decision is communicated initially).

5.2 Microbiological risk profile

The risk profile is a description of a food safety problem and its context that presents in a concise form, the current state of knowledge related to a food safety issue, describes potential MRM options that have been identified to date, when any, and the food safety policy context that will influence further possible actions. The **Annex** provides information about suggested risk profile elements for guidance to risk managers at the national level, and for bringing forward newly proposed work within CCFH.

Consideration of the information given in the risk profile may result in a range of initial decisions, such as commissioning an MRA, gathering more information or developing risk knowledge at the level of the risk manager, implementing an immediate and/or temporary decision (see section 5.1 above). National governments may also base their MRM decisions on Codex standards, recommendations and guidance where available. In some cases, the risk profile could give enough information for identification and selection of MRM options. In other cases, no further action may be needed.

The risk profile provides an initial analysis that describes possible MRM options. The MRM options can take the form of a draft MRM guidance document that will be introduced into the Codex step process (e.g., codes of practice, guidance documents, microbiological specifications, etc.).

5.3 Risk assessment policy

Refer to the Working Principles for Risk Analysis for the Application in the Framework of the Codex Alimentarius[11]. National governments should establish a MRA policy relevant to their circumstances, in advance of the microbiological risk assessment.

Risk assessment policy setting is a risk management responsibility, which should be carried out in full collaboration with risk assessors. Establishing a risk assessment policy protects the scientific integrity of the risk assessment and offers guidance to balance value judgements, policy choices, adverse health parameters for presenting risk to human health, source of data to be considered, and management of data gaps and uncertainties during the course of the assessment. The risk assessment policy could be of a generic nature or MRA-specific, and should be documented to ensure consistency, clarity and transparency.

5.4 Microbiological risk assessment

Risk managers may commission an MRA to provide an objective, systematic evaluation of relevant scientific knowledge to help make an informed decision.

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[10] The International Health Regulation (2005) Agreement gives provisions for appropriate measures in case of public health emergencies, including food related events (www.who.int/csr/ihr/ihrwha58_3-en.pdf). The Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situation (CAC/GL 19-1995) defines a **food safety emergency** as a situation whether accidental or intentional that is identified by a competent authority as constitutes a serious and as yet uncontrolled foodborne risk to public health that requires urgent action. Emergency measures may be part of immediate action.

[11] See Working Principles of Risk Analysis for Application in the Framework of the Codex Alimentarius (Codex Alimentarius Commission, Procedural Manual, 16th Edition).

The risk manager should refer to the *Principles and Guidelines for the Conduct of MRA* (CAC/GL-30 (1999). It is important to ensure that a clear mandate is given to risk assessors and that the MRA meets the needs of the risk manager. It is also important that the MRA be adequately reviewed by the scientific community and if appropriate, the public.

The outputs of the MRA should be presented by risk assessors in such a manner that they can be properly understood and utilised by risk managers in the evaluation of the suitability of different MRM options to manage the food safety issue. Generally, the presentation is conveyed in two different formats: a fully detailed technical report and an interpretative summary for a broader audience.

For the best use of an MRA, risk managers should be fully informed of the strengths and limitations (key assumptions, key data gaps, uncertainty and variability in the data, and their influences on the outcomes), including a pragmatic appreciation of uncertainties associated to the MRA study and its outputs. Risk managers, in consultation with risk assessors, should then decide whether the MRA is in developing and/or evaluating and deciding on suitable MRM activities, or deciding on provisional MRM options**.**

6. IDENTIFICATION AND SELECTION OF MRM OPTIONS

6.1 Identification of the available MRM options for Codex and countries

The risk manager needs to ensure that MRM options are identified and the acceptable one(s) selected for subsequent implementation by relevant interested parties. In this, risk managers need to consider the suitability of MRM options to reduce the risk posed by a food safety issue to an appropriate level and any practical issues regarding the implementation of the selected MRM options that need to be managed.

Examples of potential MRM options (used either alone or in combination) available for Codex or countries, as appropriate are listed below.

6.1.1 Codex

- elaboration of standards and related texts[12];

6.1.2 Countries

- establish regulatory requirements;
- develop (or encourage the development of) specific documents and guides e.g. Good Agricultural Practices (GAP), Good Manufacturing Practices (GMP), Good Hygienic Practices (GHP), HACCP;
- adopt or adapt Codex standards and related texts to the national situation;
- define an FSO for a particular food safety issue, leaving flexibility to industry to select appropriate control measures to meet it;
- establish control measures specifying relevant requirements for industry that do not have the means to establish appropriate measures themselves or who adopt such control measures, including as appropriate metrics[13] at specific stages of the food/feed[14] chain where they are of critical importance to the performance of the overall chain;
- establish requirements for inspection and audit procedures, certification or approval procedures;

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[12] When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Codex Alimentarius Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as code of practice, provided that susch a text would supported by the available scientific evidence, Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, Codex Alimentarius Commission, Procedural Manual, 16 Edition.

[13] See the Principles and Guidelines for Incorporating Microbiological Risk Assessment in the Development of Food Safety Standards, Guidelines and Related Texts, Report of Kiel, Germany, March 2002.

[14] In those instances where the presence of hazards in feed may affect the safety of foods derived from an animal, the microbiological profile of feed should be considered.

- require import certificates for certain products;
- promulgate awareness and develop educational and training programs to communicate that:
  - prevention of contamination and/or introduction of hazards should be addressed at all relevant stages in the food/feed chain;
  - rapid withdrawal/recall of food/feed procedures are in place, including appropriate traceability/product tracing for effectiveness;
  - properly labelling includes information that instructs the consumer regarding safe handling practices and, where appropriate, briefly informs the consumer of the food safety issue;

6.2 Selection of MRM options

The selection of MRM options should be based on their ability to mitigate the risks effectively and on the practical feasibility and consequences of the options. Where available, an MRA can often help in the evaluation and selection of MRM options.

The selection of MRM options that are both effective and feasible should generally include consideration of the following:

- planned control of hazards (e.g. with HACCP) is more effective than detecting and correcting food safety control system failures (e.g., lot-release microbiological testing of finished products);
- the population may be exposed to multiple potential sources of a particular hazard;
- the suitability of the option to be monitored, reviewed and revised during subsequent implementation;
- the capacity of the food businesses to manage food safety (e.g. human resources, size, type of operation). For instance, a more traditional approach may be selected for small and less developed food businesses, rather than an FSO driven approach

6.2.1 Responsibility for selecting MRM options

The primary responsibility for selecting appropriate MRM options lies with the risk manager.

Risk assessors and other interested parties play an important role in this process by providing information that permits the evaluation and, if appropriate, comparison of different MRM options.

Whenever feasible, both Codex and countries should attempt to specify the level of control or risk reduction that is necessary (i.e. establish the stringency required for food safety control systems), while providing to the extent feasible some flexibility in options that the industry can use to achieve the appropriate level of control.

6.2.2 MRM options based on risk

The increasing adoption of risk analysis is allowing more transparent approaches for relating ALOP to the required stringency of the food safety control system, and for the comparison of MRM options for their suitability and, possibly, equivalence. This has allowed the use of traditional MRM options as well as the development of new MRM tools, e.g. FSO, PO and PC and the enhancement of the scientific basis of existing MRM tools, e.g. microbiological criteria (MC).

7. IMPLEMENTATION OF MRM OPTIONS

Implementation involves giving effect to the selected MRM option(s) and verifying compliance, i.e. assuring that the MRM option(s) is/are implemented as intended. Implementation may involve different interested parties, including competent authorities, industry and consumers. Codex does not implement MRM options.

7.1 International intergovernmental organisations

Developing countries may need specific assistance in developing and selecting implementation strategies as well as in the area of education. Such assistance should be provided by international intergovernmental organisations, e.g. FAO and WHO, and developed countries in the spirit of the SPS Agreement.

7.2 Countries

The implementation strategy will depend on the MRM option(s) selected and should be developed within a consultative process with interested parties. Implementation can occur at different points in the food/feed chain and may involve more than one segment of the industry and consumers.

Once an MRM option is selected, risk managers should develop an implementation plan that describes how the option will be implemented, by whom, and when. In some situations, a stepwise phase-in implementation strategy could be considered, e.g. different sized establishments or different sectors, in part based on risk and/or capability. Guidance and support may need to be provided in particular for small and less developed businesses.

To ensure transparency, risk managers should communicate decisions on MRM options to all interested parties, including the rationale, and how those affected will be expected to implement. To the extent imports will be affected, other governments should be informed of the decision(s) and rationale in order to ensure their own MRM strategies to achieve equivalence.

If the MRM options selected are provisional, the rationale and the expected timeframe for finalising the decision should be communicated.

Governments should ensure an appropriate regulatory framework and infrastructure, including adequately trained personnel and inspection staff, in order to enforce regulations and verify compliance. Inspection and targeted sampling plans may be applied at different steps of the food chain. The competent authorities should ensure that industry applies the appropriate good practices and, within the application of the HACCP system, does effectively monitor CCPs and implement corrective actions and verification steps.

Governments should define an evaluation process to assess whether the MRM options have been properly implemented. This process should allow for adjustment of the implementation plan or of the MRM options, if the options selected are not successful in achieving the required level of control over the hazard. This is intended to provide short-term evaluation to allow modification, particularly for provisional MRM options, versus longer-term monitoring and review, as discussed in 8.1 and 8.2.

7.3 Industry

Industry is responsible for developing and applying food safety control systems to give effect to the decisions on MRM options. Depending on the nature of the MRM option, this may require activities such as:

- Establishing metrics that will achieve or contribute to established FSOs or other regulatory requirements;
- The identification of PC and design and implementation of appropriate combinations of validated control measures;
- Monitoring and verification of the food safety control system or relevant parts thereof (e.g. control measures, good practices)
- Application, as appropriate, of sampling plans for microbiological analyses;
- Development of plans for corrective actions, that may include withdrawal/recall procedures, traceability/product tracing etc;
- Effective communication with suppliers, customers and/or consumers, as appropriate;
- Training or instruction of staff and internal communication.

Industry associations may find it beneficial to develop and provide guidance documents, training programs, technical bulletins and other information that assists industry to implement control measures.

7.4 Consumer

Consumers can enhance both their personal and the public's health by being responsible for, adhering to, being informed of and following food safety-related instructions. Multiple means of providing this information to consumers should be undertaken, such as public education programs, appropriate labelling, and public interest messages. Consumer organisations can play a significant role in getting this information to consumers.

8. MONITORING AND REVIEW

8.1 Monitoring

An essential part of the MRM process is the on-going gathering, analysing, and interpreting of data related to the performance of food safety control systems, which, in this context is referred to as monitoring. Monitoring is essential to establish a baseline for comparing the effectiveness of new MRM activities. It also may provide information which the manager may use to determine what steps may be taken to achieve further improvements in the extent or efficiency of risk mitigation and public health. Risk management programs should strive for continual improvement in public health.

Monitoring activities related to measuring the state of public health are in most cases the responsibility of national governments. For instance, surveillance of human populations and the analysis of human health data on a national level are generally conducted by countries. International organisations such as WHO provide guidance for establishing and implementing public health monitoring programs.

Monitoring activities respecting microbial hazards may be needed at multiple points along the entire food chain to identify food safety issues and to assess public health and food safety status and trends. Monitoring should provide information on all aspects of risks from specific hazards and foods relevant to MRM, and is key to the generation of data for the development of a risk profile or an MRA as well as for the review of MRM activities. Monitoring should also include evaluating the effectiveness of consumer communication strategies.

Monitoring activities can include the collection and analysis of data derived from:

- surveillance of clinical diseases in humans, as well as diseases in plants and animals that can affect humans;
- epidemiological investigations of outbreaks and other special studies;
- surveillance based on laboratory tests of pathogens isolated from humans, plants, animals, foods, and food processing environments for pertinent foodborne hazards;
- data on environmental hygiene practices and procedures;
- behavioural risk factor surveillance of food worker and consumer habits and practices.

When establishing or re-designing monitoring systems in countries, the following aspects should be considered:

- A public health surveillance system should be able to estimate the proportion of illnesses and death that is truly foodborne and the major food vehicles, processes, and food handling practices responsible for each hazard;
- Interdisciplinary teams of epidemiologists and food safety experts should be formed to investigate foodborne illness to identify the food vehicles and the series of events that lead to illnesses;
- Microbiological and/or physicochemical indicators of a particular intervention should be considered together with human disease data to evaluate programmatic impact on public health;
- Countries should work towards harmonisation of surveillance definitions and reporting rules, protocols, and data management systems, to facilitate comparison between countries of incidence and trends of the illnesses and microbiological data in the food chain.

8.2 Review of MRM activities

The effectiveness and appropriateness of the MRM activities selected, and of the implementation thereof, need to be reviewed. Review is an integral part of the MRM process and ideally should take place at a predetermined moment in time or whenever relevant information becomes available. Criteria for review should be established as part of the implementation plan. Review may lead to a change in the MRM activities

Planning periodic review of MRM activities is the best way to assess whether or not the expected consumer health protection is delivered. On the basis of a review of the information collected through the various appropriate monitoring activities, a decision may be taken to amend the MRM activities implemented or to substitute the option for another one.

MRM activities should be reviewed when new activities or new information (e.g., emerging hazard, virulence of a pathogen, prevalence and concentration in foods, sensitivity of sub-populations, changes in dietary intake patterns) become available.

Industry and other interested parties (e.g. consumers) can suggest the review of MRM options. Evaluation of the success of MRM activities in industry may include reviewing the effectiveness of the food safety control system and its pre-requisite programs, results of product testing, the incidence and nature of product withdrawals/recalls and consumer complaints.

The results of review and the associated actions that risk managers are considering to take, as a consequence of the review, should be made public and communicated to all interested parties.

ANNEX

SUGGESTED ELEMENTS TO INCLUDE IN A MICROBIOLOGICAL RISK PROFILE

A risk profile should present, to the extent possible, information on the following.

1. Hazard-food commodity combination(s) of concern :
    - Hazard(s) of concern;
    - Description of the food or food product and/or condition of its use with which problems (foodborne illness, trade restrictions) due to this hazard have been associated;
    - Occurrence of the hazard in the food chain.
2. Description of the public health problem :
    - Description of the hazard including key attributes that are the focus of its public health impact (e.g., virulence characteristics, thermal resistance, antimicrobial resistance);
    - Characteristics of the disease, including;
        - Susceptible populations;
        - Annual incidence rate in humans including, if possible, any differences between age and sex;
        - Outcome of exposure;
        - Severity of clinical manifestations (e.g., case-fatality rate, rate of hospitalisation);
        - Nature and frequency of long-term complications;
        - Availability and nature of treatment;
        - Percentage of annual cases attributable to foodborne transmission.
    - Epidemiology of foodborne disease;
        - Aetiology of foodborne diseases;
        - Characteristics of the foods implicated;
        - Food use and handling that influences transmission of the hazard;
        - Frequency and characteristics of foodborne sporadic cases;
        - Epidemiological data from outbreak investigations;
    - Regional, seasonal, and ethnic differences in the incidence of foodborne illness due to the hazard;
    - Economic impact or burden of the disease if readily available;
        - Medical, hospital costs;
        - Working days lost due to illness, etc.
3. Food Production, processing, distribution and consumption :
    - Characteristics of the commodity (commodities) that are involved and that may impact on risk management;
    - Description of the farm to table continuum including factors which may impact the microbiological safety of the commodity (i.e., primary production, processing, transport, storage, consumer handling practices);

- What is currently known about the risk, how it arises with respect to the commodity's production, processing, transport and consumer handling practices, and who it affects;
- Summary of the extent and effectiveness of current risk management practices including food safety production/processing control measures, educational programs, and public health intervention programs (e.g., vaccines);
- Identification of additional risk mitigation strategies that could be used to control the hazard.

4. Other Risk Profile Elements :
   - The extent of international trade of the food commodity;
   - Existence of regional/international trade agreements and how they may affect the public health impact with respect to the specific hazard/commodity combination(s);
   - Public perceptions of the problem and the risk;
   - Potential public health and economic consequences of establishing Codex MRM guidance document.
5. Risk Assessment Needs and Questions for the Risk Assessors :
   - Initial assessments of the need and benefits to be gained from requesting an MRA, and the feasibility that such an assessment could be accomplished within the required time frame;
   - If a risk assessment is identified as being needed, recommended questions that should be posed to the risk assessor;
6. Available Information and Major Knowledge Gaps Provide, to the extent possible, information on the following :
   - Existing national MRAs on the hazard/commodity combination(s) including, if possible;
   - Other relevant scientific knowledge and data that would facilitate MRM activities including, if warranted, the conduct of an MRA;
   - Existing Codex MRM guidance documents (including existing Codes of Hygienic Practice and/or Codes of Practice);
   - International and/or national governmental and/or industry codes of hygienic practice and related information (e.g., microbiological criteria) that could be considered in developing a Codex MRM guidance document;
   - Sources (organisations, individual) of information and scientific expertise that could be used in developing Codex MRM guidance document;
   - Areas where major absences of information exist that could hamper MRM activities including, if warranted, the conduct of an MRA

Appendix V

PROCESS BY WHICH THE CODEX COMMITTEE ON FOOD HYGIENE WILL UNDERTAKE ITS WORK

Purpose

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

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

Scope

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

Process for Considering Proposals for New Work

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

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

i. A request for proposals for new work and/or revision of an existing standard will be issued in the form of a Codex Circular Letter, if required.

ii. Proposals for new work received in response to the Codex Circular Letter will be transmitted to the Host of the ad hoc Working Group as well as the CCFH Host government and Codex Secretariats.

iii. The Host of the *ad hoc* Working Group will collate the proposals for new work in a document that will be distributed by the Codex Secretariat to Codex members and observers for review and comment within a specified time frame.

iv. The *ad hoc* Working Group will meet as decided by the Committee, normally on the day prior to the plenary session of CCFH to develop recommendations for consideration by the Committee during the CCFH session. The *ad hoc* Working Group will review the proposals for new work along with comments submitted. It will verify the completeness and compliance with the prioritization criteria of the proposals for new work and make recommendation**s** to the Committee on whether the proposals for new work should be accepted, denied, or returned for additional information.

If accepted, a recommendation will be provided on the priority of the proposal for new work compared to pre-established priorities. The priority of the proposals for new work will be established using the guidelines outlined below, taking into account the 'Criteria for the Establishment of Work Priorities'[1]. Proposals for new work of lower priority may be delayed if resources are limiting. Proposals for new work of lower priority not recommended may be reconsidered at the next CCFH session. If the *ad hoc* Working Group recommends that a proposal for new work be "denied" or "returned for revision," a justification for this recommendation will be provided.

v. At the CCFH session, the *ad hoc* Working Group Chair will introduce the recommendations of the *ad hoc* Working Group to the Committee. The CCFH will decide whether a proposal for new work and/or revision of an existing standard is accepted, returned for revision, or denied. If

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[1] Codex Alimentarius Commission, *Procedural Manual*, 16th Edition.

accepted, a project document[2], which may include amendments agreed upon by the Committee, will be prepared by the CCFH and submitted to the Codex Alimentarius Commission (CAC) with a request for approval of the proposed new work.

Proposals for New Work

5. In addition to the provisions applying to proposals for new work in the Procedural Manual, the proposals for new work should include a Risk Profile[3], as appropriate. The proposals for new work should indicate the specific nature or outcome of the new work being proposed (e.g., new or revised code of hygienic practice, risk management guidance document).

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

7. The proposal for new work may also:

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

Prioritization of Proposals for New Work

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

Obtaining Scientific Advice

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

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

i. Sufficient scientific knowledge and data to conduct the needed risk assessment are available or obtainable in a timely manner. (An initial evaluation of available knowledge and data will typically be provided within the Risk Profile.)

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2 The elements of a project document are described in the Codex Alimentarius Commission, *Procedural Manual*, 16th Edition.

3 Definition of a risk profile is "the description of the food safety problem and its context" (Codex Alimentarius Commission, *Procedural Manual*, 16th Edition). The elements of a risk profile are provided in the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management.

4 Codex Alimentarius Commission, *Procedural Manual*, 16th edition.

ii. There is a reasonable expectation that a risk assessment will provide results that can assist in reaching risk management decisions related to control of the microbiological hazard without unduly delaying the adoption of the needed microbiological risk management guidance.

iii. Risk assessments performed at the regional, national and multinational levels that can facilitate the conduct of an international risk assessment are available.

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

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

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

14. Microbiological risk assessments carried out by FAO/WHO (JEMRA) will operate under the framework contained in the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/RCP 020-1999).

Appendix VI

TERMS OF REFERENCE FOR AN FAO/WHO EXPERT CONSULTATION TO SUPPORT THE DEVELOPMENT OF COMMODITY-SPECIFIC ANNEXES FOR THE CODEX ALIMENTARIUS *"CODE OF HYGIENIC PRACTICE FOR FRESH FRUITS AND VEGETABLES"*

BACKGROUND

Public health officials and consumers alike recognize that fresh fruits and vegetables play an important role in a healthy diet, providing important vitamins, minerals, and phyto-nutrients. As consumption of fresh fruits and vegetables increases, so has the incidence of fresh produce serving as a vehicle for foodborne illness. Most produce is grown in a natural environment, and is, therefore, vulnerable to contamination with pathogens from multiple sources, including agricultural and post-harvest water, ill workers, the presence of wild or domestic animals or animal waste, and unsanitary equipment and facilities. The safety of fresh produce is a global issue covering both the countries that import fresh fruits and vegetables and the countries that supply them. In many instances countries both export and import produce. For example, despite the United States being a major provider of fresh produce, approximately 35% of the fresh produce it consumes is imported. Given the role of fresh produce in a healthy diet, it is critical that these foods are as safe as possible.

In 2003, the CCFH elaborated a "*Code of Hygienic Practice for Fresh Fruits and Vegetables*" to address Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) to help control microbial hazards associated with all stages of the production of fresh fruits and vegetables from primary production to packing. The code provides a general framework of recommendations to allow uniform adoption by this sector, regardless of the diverse environmental conditions encountered or the commodities to which it might be applied. The code of practice is, of necessity, a flexible one to allow for different systems of control and prevention. This Code also recognizes that it should be a living document, foreseeing the need for revisions as science advances. Since this code of practice was established, experience in produce safety has grown exponentially. In implementing current GAP and GMP recommendations, it has become apparent that public health would benefit from the availability of more detailed, commodity-specific guidance. This need is being met, in part, through industry efforts. For example, several U.S. industry groups have developed commodity-specific supply chain guidance documents. However, the global nature of produce production, processing, and marketing requires an international perspective, and both public health and international trade in produce could be enhanced by the systematic development and elaboration of a series of commodity-specific annexes to the current "*Code of Hygienic Practice for Fresh Fruits and Vegetables*." A prerequisite for consideration of the development of such guidance in a timely manner is a review of the available scientific and technological data. Furthermore, such a review would be beneficial to many, if not most member countries of CCFH. Accordingly, the 38th Session of CCFH requests that such scientific advice be provided by the FAO/WHO. The advice should be based on the solicitation of experts on the identification, impact, and practical application of GAPs and GMPs on the safety of produce.

The expert consultation should focus on the specific commodities that have been associated with the highest incidence of foodborne outbreaks. The consultation should consider the entire farm to table continuum including processing and marketing and with a focus on the factors at primary production that contribute to the risk of foodborne disease, especially environmental hygiene, water for primary production, and personnel health, personnel hygiene and sanitary facilities. While the greatest information needs are associated with primary production, the expert consultation should also consider 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.

The selection of commodities should be based on their public health impact and should focus on the most significant pathogens associated with the commodity. An initial evaluation of available epidemiological data suggests that the commodities of primary concern would likely include (a) leafy green vegetables (enterohemorrhagic *Escherichia coli, Salmonella enterica, Shigella* spp., *Yersinia pseudotuberculosis*, type A hepatitis virus, noroviruses), (b*)* tomatoes *(Salmonella enterica*), (c) melons (*Salmonella enterica,* (d) green onions (type A hepatitis virus, norovirus, enterohemorrhagic *Escherichia coli*) (e) sprouted seeds (*Salmonella enterica,* enterohemorrhagic *Escherichia coli*), (f) herbs (*Salmonella* enterica, *Shigella* spp., *Cyclospora cayatenensis*) and (g) berries (*Cyclospora cayatenensis*, *Cryptosporidium parvuum*) and root

vegetables (*Yersinia pseudotuberculosis*). Where possible, the expert consultation should rank the relative risk of product becoming contaminated by the risk factors above; and recommend quantitative criteria for implementing effective preventive controls. Where it is not possible to establish quantitative criteria, the expert panel should be asked to consider qualitative criteria for use by producers and packers to assist them in determining when and how to institute effective preventive controls. The expert consultation should also be asked to recommend practical procedures that could be used by competent authorities, producers, packers, and other interested parties in verifying the effectiveness of mitigation strategies and other preventive controls in minimizing the incidence of microbial contamination of fresh produce.

QUESTIONS FOR CONSIDERATION

The following represent examples of the types of questions that will likely need to be addressed by the expert consultation on a commodity basis to elicit information and analyses that would be beneficial to CCFH and member countries.

Environmental Hygiene

What is the role of wild animals, especially in high concentrations, as a potential source of contamination?

- What is the relative contribution from wild animals and other environmental reservoirs as a source of human pathogens in the production environment?
- What are the most important types of animals and pathogens that they may carry?
- Is there evidence of a population density above which risk of contamination of fresh produce and subsequent consumer illness is most likely to occur? (Could we apply an Integrated Pest Management approach where "surveys" are routinely conducted for pests in a field but no action is taken unless the population exceeds a given density for a given pest?
- Are there specific times during the production cycle when exposure of the production environment to high densities of wild life produces the greatest risk that fresh produce will be contaminated?
- Are there specific mitigations (e.g., removing animal attractants and harborage in the production environment) that can be used to minimize ingress of wild and domestic animals into growing areas while avoiding significant adverse impacts on native fauna and water shed conservation?

Are there specific proximity and topographical features, weather events, or other considerations that should be considered when assessing the potential for a production area to have a high risk of harvested produce being contaminated with foodborne pathogens?

- What is the relative importance of fields being in proximity of animal production facilities, urban and suburban environments, animal refuges, etc.?
- What are the primary vehicles and vectors for transmission of zoonotic, pathogenic microorganisms from animal rearing facilities to produce production areas?
- Are buffer zones a viable risk mitigation strategy and if so, what size zone is required?
- Is periodic flooding of production areas of concern and, if so, what time intervals are needed before the land is used for the production of different classes of fresh produce?
- Are there specific land uses that pose a risk to subsequent production of fresh produce and what strategies can be employed to mitigate those risks?
- What is the significance of detection of pathogens in the environment where produce is being grown e.g., *E coli* O157:H7 in waterways, *Salmonella* in ponds and canals or ditches in close proximity to growing fields?

Soil Amendments/Fertilizers

Under what conditions can fertilizers derived from animal or human waste be safely employed for the production of fresh and fresh-cut produce?

- What criteria and testing requirements should be employed to verify that fertilizers derived from animal waste are free of potential pathogens?
- Does the use of "green" fertilizer (i.e., composted plant waste) represent any significant risk in relation to increasing the likelihood that pathogenic microorganisms will be present on fresh or fresh-cut produce?
- Does the "plowing under" of field waste represent any significant risk in relation to subsequent crops having an increased likelihood that pathogenic microorganisms will be present on fresh and fresh-cut produce?

Water

What are the primary hazards associated with fresh produce for which water is an important source or vehicle?

What is the relative risk associated with different forms of irrigation and what are the conditions under which these forms of irrigation can be safely employed?

What are the relative risks associated with different sources of water used for irrigation?

- Does the distribution system substantially contribute to the risk of contamination?
- What are the practical, cost effective strategies that can be employed to protect water supplies and their distribution systems and to minimize the potential for agricultural water to serve as a source of contamination of fresh produce or spreading contamination in the production environment?
- Is there evidence of a time interval between exposure of the crop to a given quality of water and harvest of fresh produce at which the risk is higher or lower?
- What national and international microbiological criteria currently exist for different agricultural water sources and how effective are these criteria for mitigating the risks associated with their use with fresh produce? Are there additional criteria that would be beneficial?
- Are there specific time intervals or events after which water sources should be tested?

What are the relative risks associated with other uses of water in the primary production environment (e.g., pesticide applications, cleaning of equipment)?

- How effective are current criteria for the use of agricultural water sources for non-irrigation uses in mitigating the risks associated with their use with fresh produce?

What are the relative risks associated with uses of water in the packing environment?

- How effective are current criteria for water uses in the produce packing environment?
- What is the potential for water used for transport of produce in the packing environment (e.g., fluming) to serve as a means of cross-contamination? What are the conditions of use that mitigate this potential?
- What are the conditions of water use that foster infiltration of pathogenic microorganisms into fresh produce and how can this be avoided? What is the level of uptake of microorganisms that can be expected in the absence of factors contributing to infiltration?
- What is the efficacy of water washes on the removal of pathogenic microorganisms from fresh produce?

Personnel Health, Personnel Hygiene and Sanitary Facilities.

What is the potential for farm workers to serve as a source of contamination for fresh and fresh-cut produce? What is the potential for food workers in packaging, processing, distribution, and marketing facilities to serve as a source of contamination for fresh fresh-cut produce?

- Can public health data on the incidence and prevalence of enteric/parasitic disease among farm workers and food workers and characterization of carrier status provide useful

information for hazard identification for different produce production areas? What are the disease surveillance systems that need to be in place to collect such data?

- What mitigation strategies (e.g., improved health status, provision of toilet and handwashing facilities, training and accountability, protective clothing) are available to reduce the risk of foodborne disease attributable to farm workers as a source of contamination and what are the relative risk reductions that can be achieved by these mitigations?

Packing/Post-harvest Process Operations

Does conducting post-harvest processes (e.g., removal of wrapper leaves, coring) in the field at the time of harvesting represent any increased risk of contamination of fresh or fresh-cut produce? Do current technologies and practices effectively eliminate any increased risk?

What washing / disinfection mitigation technologies are currently available, feasible, and practical for reducing the levels of pathogenic microorganisms on fresh and fresh-cut produce? What degree of risk reduction can be expected from these technologies?

Does infiltration of pathogenic microorganisms into the interior of the produce play a significant role in reducing the effectiveness of washing and disinfection treatments designed to reduce contamination?

What additional technologies are available for reducing the levels of pathogenic microorganisms on fresh and fresh-cut produce? What degree of risk reduction can be expected from these technologies? Are there any barriers to their application?

Maintenance of the Cold Chain

What portion of the risk of foodborne disease associated with fresh and fresh-cut produce is attributable to failure to maintain the cold chain?

Are there any practical technologies that are available that can be used by industry, competent authorities, and/or consumers to verify that fresh and fresh-cut produce have been maintained under continual refrigeration?

Is there increased risk of foodborne disease associated with further extending the shelf-life of fresh and fresh-cut produce?

Utilization of Existing Information

Wherever feasible, the expert consultation should identify and make use of existing risk assessments or risk evaluations that have been performed by national governments or recognized scientific organizations.

Time Frame

The results of the expert consultation would be most effective if completed within the next 18 months. This should include periodic reports to the CCFH and consultations with any working group established to amend the current code or develop annexes to the code.