codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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ALINORM 05/28/13

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-Eighth Session

Rome, Italy, 4 - 9 July 2005

REPORT OF THE THIRTY-SEVENTH SESSION OF THE

CODEX COMMITTEE ON FOOD HYGIENE

Buenos Aires, Argentina, 14 - 19 March 2005

NOTE: *This report includes Codex Circular Letter CL 2005/16-FH*

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CX 4/20.2 **CL 2005/16 - 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-seventh Session of the Codex Committee on Food Hygiene (ALINORM 05/28/13)**

The report of the Thirty-seventh Session of the Codex Committee on Food Hygiene (CCFH) is attached. It will be considered by the Twenty-eighth Session of the Codex Alimentarius Commission, (Rome, Italy, 4 – 9 July 2005)

MATTERS FOR ADOPTION BY THE CODEX ALIMENTARIUS COMMISSION:

1. Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria Monocytogenes* in Ready-to-eat Foods at Step 5 (ALINORM 05/28/13 para. 98 and Appendix II)

2. Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management at Step 5 (ALINORM 05/28/13 para. 132 and Appendix III)

3. Proposed Draft Code of Hygienic Practice for Eggs and Egg Products at Step 5 (ALINORM 05/28/13 para. 156 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), with a copy to Mr Amjad Ali, Staff Officer, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 4816,1400 Independence Avenue, SW, Washington, D.C. 20250, USA, Fax +1-202-720-3157, or email Syed.Ali@fsis.usda.gov, **before 15 May 2005**.

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SUMMARY AND CONCLUSIONS

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

MATTERS FOR ADOPTION BY THE 28TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION:

The Committee:

- agreed to forward to the Commission the Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria Monocytogenes* in Ready-to-eat Foods at Step 5 (see ALINORM 05/28/13 paras 58- 98 and Appendix II)

- agreed to forward to the Commission the Principles and Guidelines for the Conduct of Microbiological Risk Management at Step 5 (see ALINORM 05/28/13 paras 100 - 132 and Appendix III)

- agreed to forward to the Commission the Draft Code of Hygienic Practice for Eggs and Egg Products at Step 5 (see ALINORM 05/28/13 paras 135 - 156 and Appendix IV).

MATTERS OF INTEREST TO THE COMMISSION

The Committee:

- agreed to return the Proposed Draft Revision of the Recommended International Code of Practice for Food for Infants and Children to Step 2 for redrafting by the working group (see paras 35 - 57);

- agreed to return Annex II: Deriving microbiological limits and sampling plans in microbiological criteria from food safety objectives; Example: *Listeria Monocytogenes* in ready-to-eat food products, to Step 2 (see para.99);

- agreed to return Annex III to the Proposed Draft Principles and Guidelines for Microbiological Risk Management, in relation to the example of the use of Food Safety Objectives, Performance Objectives, Performance Criteria, Microbiological Criteria, Process and Product Criteria, to Step 2 (see para.133);

- agreed to return to the Proposed Guidelines for the Validation of Food Hygiene Control Measures to Step 2 (see para. 134);

- agreed to develop an Annex to the draft Code of Hygienic Practice for Eggs and Egg Products (see para. 157);

- agreed to place the five proposals for new work areas into the Committee's work management system and prepare the written proposals of them (see paras 166 - 168);

- asked FAO and WHO to address the needs of CCFH for scientific advice (see paras 88- 97 and Appendix VII).

MATTERS OF INTEREST TO OTHER COMMITTEES:

1. CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS (CCFFP)

The Committee endorsed the hygiene provision of the Proposed Draft Code of Practice for Fish and Fishery Products including relevant Sections. The Committee expressed its view that the proposal on *Vibrio* spp. in seafood should consider as priority the following:

a) Assess the outcome of the Risk Assessment on *Vibrio* spp. in seafood and make recommendations on how this should be transformed into Good Hygienic Practice and risk management strategies.

b) Look into the questions put forward by the CCFFP related to the risk profile for *Vibrio* spp.

(see paras 177-191),

2. CODEX COMMITTEE ON PROCESSED FRUITS AND VEGETABLES (CCPFV)

In reply to the request of the Codex Committee on Processed Fruits and Vegetables on whether or not sterilized products, such as preserved tomatoes, needed to comply with the established microbiological criteria requirement related to compliance, the Committee recommended that for Codex commodity standards for products processed according to the Code of Hygienic Practice for Low-Acid and Acidified Canned Foods, such as the Proposed Draft Codex Standard for Canned Preserved Tomatoes, the food hygiene section of these standards should continue to contain the provision relating to microbiological criteria, but with a footnote that indicates that such criteria are not recommended for this type of product. (see paras 175-176)

3. CODEX COMMITTEES ON GENERAL PRINCIPLES (CCGP)

The Committee agreed to forward the amended "Proposed Process by Which the Codex Committee on Food Hygiene will Undertake its Work"(see Appendix V) to the Codex Committee on General Principle for its advice regarding its consistency with established procedures in Codex (see paras18 - 34).

4. CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS (CCFAC)

The Committee agreed to attach the terms of reference for the FAO/WHO Expert Consultation on the uses of active chlorine (see paras170 – 174 and Appendix VI).

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
ICMSF	International Commission for Microbiological Specifications for Foods
IDF	International Dairy Federation
IFT	Institute of Food Technology
IFEH	International federation of Environmental Health
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 37th SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE

INTRODUCTION

1. The Codex Committee on Food Hygiene (CCFH) held its Thirty-seventh Session in Buenos Aires, Argentina, from 14 to 19 March 2005, at the kind invitation of the Government of Argentina. Dr Karen Hulebak, Deputy Administrator, Office of Public Health and Science, Food Safety and Inspection Service, United States Department of Agriculture, chaired the meeting with the co-chair, Dr Andrea Calzetta Resio, Supervisor, Food Approval Office, National Agrifood Safety and Quality Service, Argentina. Dr Michael Wehr served as Vice-Chairperson. The Session was attended by two-hundred and twelve delegates representing fifty-eight Member countries, one member organization and twenty international organizations. A complete list of participants, including the Secretariat, is attached as Appendix I.

OPENING OF THE SESSION

2. The Session was opened by Dr Miguel Campos, Secretary for Agriculture, Livestock, Fisheries and Food, Ministry of Economy, Argentina, Mr. Lino Gutierrez, Ambassador of the United States in Buenos Aires, Dr Merle Pierson, Acting Under Secretary for Food Safety, United States Department of Agriculture.

3. Dr Karen Hulebak, while welcoming the delegates to the 37th Session of the CCFH, encouraged them to complete the work on the Management of the Work of the Committee; to advance as many Step 3 documents to Step 5 as possible, and to make clear decisions regarding the Discussion papers on pathogen specific risk-managements (*Salmonella* spp. in Poultry; Enterohemorragic *E.coli* in Ground Beef and Fermented Sausage; *Campylobacter* in Broiler Chickens; Risk Profile for *Vibrio* spp. in Seafood).

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

4. The Committee accepted the proposal from the Delegation of the United States and agreed that the CRD containing the terms of reference for a FAO/WHO Expert Consultation on the development of practical risk management strategies be considered during the discussion of Agenda Item 5 on the proposed draft Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Ready-to-Eat Foods.

5. The Committee also agreed to the proposal from the Representative of FAO to consider Agenda Item 9 immediately following Item 2.

6. Following the recommendation of the Chairperson, the Committee moved Item 13 (a) on the Discussion Paper on Risk Management Strategies for *Vibrio* spp. in Seafood up in the agenda to be considered along with Items 10, 11, and 12.

7. Due to the pending submission of the CRD containing the Report of the Working Group on the Management of the Work of the Committee, it was agreed to consider Agenda Item 3 when the above CRD, containing the revised document resulting from the Working Group, became available.

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

9. The Delegation of the European Community presented CRD 7 on the division of competence between the European Community and its Member States according to Rule II.5 of the Rules of Procedure of the Codex Alimentarius Commission.

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[1] CX/FH 05/37/1; CRD 7 on the division of competence between the European Community and its Member States, prepared by the EC; CRD 23 (Brazil); CRD 42 (Cuba).

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

10. The Committee was informed about matters arising from the 27th Session of the Commission, from the 54th and 55th 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:

Amendments to the Procedural Manual

11. The Definitions of Risk Analysis Terms related to Food Safety (*Food Safety Objective (FSO), Performance Objective (PO) and Performance Criterion (PC)*), were adopted by the 27th Session of the Commission on an interim basis, for inclusion in the Procedural Manual, with the understanding that the Committee on General Principles would reconsider these definitions if required in the light of the advice of the Committee on Pesticide Residues, the Committee on Food Additives and Contaminants, the Committee on Residues of Veterinary Drugs in Foods, the Committee on Meat Hygiene, and the Committee on Food Import and Export Inspection and Certification Systems.

Risk Analysis

12. Following the request from the CCFH to clarify the appropriateness of their approach in the area of risk analysis, the Committee noted that the Commission endorsed the view of the 54th Session of the Executive Committee[3] that the past and ongoing work by the Committee on Food Hygiene on the Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL-30, 1999) and the proposed draft Principles and Guidelines for the Conduct of Microbiological Risk Management, addressing issues relevant to both member governments and to the Codex, was consistent with the Commission's expectations.

13. The Secretariat recalled the Committee that the matter on antimicrobial resistance would be considered and a final decision taken by the next Session of the Executive Committee and the Commission.

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

14. The Committee noted that the 22nd Session of the Codex Committee on Processed Fruits and Vegetables asked advice of the CCFH as to whether or not sterilized products, such as preserved tomatoes, needed to comply with the requirement related to compliance of the product with the microbiological criteria in Section 6.2 of the Proposed Draft Codex Standard for Canned Preserved Tomatoes and other similar sterile products. The Committee agreed to convene an *Ad Hoc* Working Group led by the United States of America[4] to prepare recommendations on how to respond to this request. It also agreed that this matter would be considered on Other Business and Future Work (see paras 175-176).

Draft Code of Practice for Fish and Fishery Products

15. The Committee noted that the 26th Session of the Codex Committee on Fish and Fishery Products had finalized Sections on Aquaculture, Processing of Shrimps and Prawns, Processing of Cephalopods and Sections on Transport and Retail 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.

16. The Committee also noted that the CCFFP forwarded the relevant sections of the Proposed Draft Standard for Live and Raw Bivalve Molluscs to the CCFH for advice and that the CCFFP encouraged the CCFH to proceed with the work in the area of risk management of *Vibrio* spp. in seafood and to undertake work on viruses, due to the relevance of this work for the development of safety provisions in the above Standard.

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2 CX/FH 05/37/2; CRD 6 (FAO/WHO Guidance to Governments on the Application of HACCP in Small and/or Less Developed Businesses); CRD 12 (European Community); CRD 17 (Matters on the Endorsement of Hygiene Provisions in Sections of Code of Practice for Fish and Fishery Products, Partial Translation into French and Spanish); CRD 20 (Bolivia); CRD 29 (Matters on the Endorsement of Hygiene Provisions in Sections of Code of Practice for Fish and Fishery Products); CRD 42 (Cuba).

3 ALINORM 04/27/4, para. 63.

4 The members will include Argentina, Australia, Italy, Venezuela and ICMSF.

17. In order to respond to these referrals, the Committee agreed to convene an *Ad Hoc* Working Group, lead by Norway[5], and to consider these matters under Other Business and Future Work (see paras 177-192).

DISCUSSION PAPER ON THE MANAGEMENT OF THE WORK OF THE COMMITTEE (Agenda Item 3)[6]

18. The Committee recalled that the 36th Session of the CCFH agreed to consolidate into a single discussion paper the following discussion papers on the Management of the work of the Committee:

- *Proposed draft Process by which the Committee on Food Hygiene could undertake its work in Microbiological Risk Assessment/Risk Managements* (CX/FH 04/5);
- *Development of Process, Procedures and Criteria to establish Priorities for the Work of the Codex Committee on Food Hygiene* (CX/FH 04/5, Add.2);
- *The Development of Options for a Cross-Committee Interaction Process* (CX/FH 04/5, Add.3).

19. At that Session, the Committee had agreed to attach the consolidated document to its report and to circulate it for comments. It further agreed that a Working Group led by the United States would revise the document based on the discussions and the comments submitted at the 36th session and those received in response to the Circular Letter for comments for further discussion at its present session.

20. The Committee further noted that the Working Group agreed to conduct its work through electronic communication and that a meeting of the Working Group was organized prior to the current session to further revise the document prepared by the Working Group.

21. The Delegation of the United Stated introduced the report of the Working Group (CRD 54), which met prior the Session and it was explained that the Discussion Paper (CX/FH 05/37/3) had been revised to incorporate the outcome of the discussion of the Working Group meeting, which addressed how the *ad hoc* Working Group for the Establishment of the CCFH Work Priorities was constituted; clarified checks and balances to ensure that this *ad hoc* Working Group does not inappropriately or non-transparently influence the decision-making process; that the weights suggested for selection and priority setting criteria are appropriate and complete; revising of the section on cross-committee interaction to better take into account the Codex structure and mode of operation; modified the Section on acquiring scientific advice and interaction with FAO/WHO, and also removal of the flow chart at the end of the document.

22. The Committee agreed to "The process by which the Codex Committee on Food Hygiene will undertake it work" as contained in CRD 54 as the basis for its discussion. It considered the document section by section and in addition to some editorial changes it agreed to the following changes.

23. The Committee noted the concern expressed by the delegation of France that some parts of the document might not be in line with established Codex procedures, in particular those regarding the elaboration of Codex standards and related texts and procedures of other Codex Committees. However, the Committee was of the view that these inconsistencies had been taken into account during the revision of the document and also noted that the document would be forwarded to the Codex Committee of General Principles to ensure consistency with established procedures. It was also clarified that the document was intended to be an internal document for the Committee, to be used as a tool to prioritize its work.

Scope

24. The last part of the paragraph was deleted as the Committee considered "microbiological risk assessment" to be implicitly included in scientific advice.

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5 The members will include Argentina, Australia, Brazil, Canada, Cuba, France, Georgia, Germany, Korea, Japan, Malaysia, New Zealand, Peru, Thailand, United States, Urguay, Venezuela, Consumers International and ICMSF.

6 CX/FH 05/37/3; CX/FH 05/37/3, Add. 1(Guatemala, CI); CRD 3 (Japan); CRD 10 (EC); CRD 15 (Thailand); CRD 19 (Bolivia); CRD 22 (Brazil); CRD 28 (Peru); CRD 32 (Secretariat); CRD 41 (South Africa); CRD 43 (India); CRD 46 (Cuba); CRD 49 (Costa Rica); CRD 54 (Report of the Working Group).

Process for Considering Proposals for New Work

25. Following the suggestions of the Codex Secretariat, the Committee agreed to refer to "Proposals for new work" throughout the document and amended the first sentence of the section to state that the "*Ad hoc* Working Group for the establishment of CCFH Work Priorities" be established at each session of the Committee.

26. The Committee considered the proposal of the Working Group regarding the arrangements for the selection of the Chair and Chair-Elect of the *ad hoc* Working Group, specifically that "the officers will rotate among the Codex Regions according to an arranged progression to ensure the officers include both a developed and a developing country. The officers will serve from one CCFH session to the next and the Chair-Elect will serve as the Chair in the following session year". The Committee did not include these provisions and agreed to further discuss these arrangements at its next session in order to provide more time to better evaluate a number of issues and ensure the appropriate balance between geographical representation and efficiency of work.

27. The Committee agreed that this was a "living" document, which could, if necessary, be reviewed and improved at subsequent sessions of the CCFH.

28. In paragraph 4, the process for undertaking new work, was clarified to take account of the explanations of the Codex Secretariat with regard to the procedure for issuing Circular Letters. It was also clarified that new work and/or revision of an existing standard might be proposed by the Committee on its own initiative, by referral to CCFH by another Codex subsidiary body or by individual Member(s).

29. The language was clarified to better illustrate the process by which a proposal for new work is considered by the *ad hoc* Working Group.

30. The Delegation of Paraguay supported by Argentina proposed that the new work should be of interest to members of more than one geographical region.

Prioritization of Proposals for New Work

31. The language of paragraph 9 was clarified to better describe the process of prioritization when resources are limiting.

Obtaining Scientific Advice

32. The Committee agreed that scientific advice will be typically sought through FAO and WHO but that in certain situations the Committee may seek advice from other scientific institutions. The Committee deleted the reference to the establishment of a "CCFH Task Force" to provide scientific advice to the Committee. The Delegation of India was of the view that scientific advice should be sought only from FAO and WHO and, hence, suggested to delete the relevant sentence mentioned in square brackets.

Conclusion

33. The Committee agreed to forward the amended "Proposed Process by which the Codex Committee on Food Hygiene will undertake its work" (see Appendix V) to the Codex Committee on General Principle for its advice on its consistency with established procedures in Codex.

34. The Committee decided to immediately begin to use this Process on an interim basis for the management of its work. The Committee agreed to convene an *ad hoc* Working Group, to be chaired by Australia, before its next session to develop recommendations for consideration by the CCFH on the acceptance, revision and/or rejection of proposals for new work.

PROPOSED DRAFT REVISION OF THE RECOMMENDED INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR FOOD FOR INFANTS AND CHILDREN (Agenda Item 4)[7]

35. The Committee recalled that at its last session, it had been agreed that a Working Group led by Canada should proceed with the revision of the *International Code of Hygienic Practice for Food for Infants and Children* (CAC/RCP 21-1979), including the development of microbiological criteria for *Enterobacter sakazakii* and other relevant microorganisms. The Committee had agreed to revise the Code and emphasized the need: to take into consideration the range of microorganisms of concern, including the availability of appropriate microbiological methods; to control the safety of infant formula by applying control measures during production and after reconstitution; to identify and define high risk infant populations; to provide more specific guidance for hospitals, day care centres, food handlers and caregivers for infants; to develop specific information and/or recommendations on the labelling regarding the preparation, use and handling of powdered infant formula for users; to consider the need for realistic expectations about implementation of controls that depends on consumer behaviour; to take into account the situation in developing countries; to carefully consider the use of commercially sterile liquid infant formula with regard to microbiological aspects and secondary recontamination; and, to consider other foods for infants that contain powdered infant formula.

36. The Delegation of Canada introduced the document and explained that the Working Group, which met in November 2004 in Ottawa (Canada), had considered the issues raised by the Committee and the recommendations of the report of the FAO/WHO Expert Meeting on "*Enterobacter sakazakii* and other microorganisms in powdered infant formula" (Microbiological Risk Assessment Series No. 6) and the information in the "what if" scenarios from the preliminary risk assessment. From the FAO/WHO Expert Meeting Report, and in the context of the potential contamination for *E. sakazakii*, infants of less that 1 year were at particular risk: "Among infants, those at greatest risk for *E. sakazakii* infection are neonates (≤28 days), particularly pre-term infants, low-birth-weight infants and immunocompromised infants"[8]. It was also explained that, based on this information, the definitions for "infants" and for "infants at greatest risk" were included in the Code. The Delegation indicated that the identification of the population at greatest risk had an impact on the Scope of the Code and many comments had been provided by countries on whether or not follow-up formula should be included, considering that these products were intended for infants of more than 6 months of age. The Delegation also indicated that products for different age groups might require different microbiological specifications to reflect the susceptibility at different ages.

37. It was indicated that the use of Good Hygienic Practices and HACCP had been emphasized in Section 5 of the Code, "Control of Operations", as a response to the suggested risk management interventions identified by the preliminary risk assessment, i.e. i) reducing the inherent and environmental contamination; and ii) shortening the time to consumption of reconstituted products".

38. The Delegation noted that Section 9 "Product Information and Consumers Awareness" had been developed taking into consideration the recommendations of the FAO/WHO Expert Meeting that: in situations where infants were not breast-fed, caregivers needed to be provided with sufficient information to understand that powdered infant formula do not receive a terminal sterilization; that infant formula must be prepared and handled under Good Hygienic Practices; and that emphasis should be given to educating users, rather than solely relying on specific information on product labelling. The Delegation pointed out: that the use of hot water had not been recommended as a lethal step at the point of preparation due to the danger of scalding from handling hot water and the problem of clumping of formula during mixing; the risk of not cooling the reconstituted formula properly before feeding; and, the potential for a reduction in nutritional components. The Delegation also indicated that the Working Group proposed that FAO/WHO consider the possibility of continuing work to provide for additional scientific advice on *Enterobacter sakazakii* and other microorganisms in powdered infant formula.

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7 CX/FH 05/37/4; CX/FH 05/37/4, Add. 1 (Australia, Iran, Mexico, New Zealand, Switzerland, USA, IBFAN, CI, IDF, ISDI, IR); CRD 5 (Japan); CRD 18 (Thailand); CRD 20 (Bolivia); CRD 23 (Brazil); CRD 27 (ISDI); CRD 34 (EC); CRD 37 (Indonesia); CRD 38 (China); CRD 39 (South Africa); CRD 40 (India); CRD 42 (Cuba); CRD 49 (Costa Rica) and CRD 53 (Honduras).

8 Page XV, para 3 of the Executive Summary of the Meeting Report on "*Enterobacter sakazakii* and other microorganisms in powdered infant formula", FAO/WHO Expert Meeting on *Enterobacter sakazakii* and Other Microorganisms in Powdered Infant Formula

39. The Committee congratulated the Working Group for the work accomplished, which resulted in a significantly improved document. It was observed, that although the document incorporated important concepts needed to assure the safety of powdered infant formula, several issues required further discussion.

40. The Committee considered the proposed draft Code and made general comments on the following sections:

Title

41. The Committee considered the proposal of the Working Group to change the title of the Code and agreed to rename it as "*Code of Hygienic Practice for Powdered Formulae for Infants and Young Children"*.

Introduction

42. The Committee noted the comments made by some delegations that the "Introduction" should contain similar information for both *E. sakazakii* and *Salmonella;* better characterize the aspect of risk; and should describe potential mechanisms of contamination of infant formula, e.g. through: i) raw materials used; ii) contamination of the formula or other dry ingredients after pasteurization; and iii) contamination of the formula when reconstituted just prior to feeding. It was also suggested that every effort should be taken to find ways to minimize or, if possible, to eliminate the presence of pathogens and to provide caregivers with information that would allow them to assess the information and the choices available to ensure the safe use of these products.

Scope

43. The Committee had an extensive discussion on the scope of the document. Divergent views were expressed as to the scope of the document. Some delegations proposed to narrow the scope of the Code to a few products, e.g. powdered infant formulae which present greater risk to infants, and to focus on *E. sakazakii* and *Salmonella* contamination; while other delegations were in favour of broadening the scope of the Code to include a number of powdered formulae for infant and young children with focus on *E. sakazakii* and *Salmonella* and other microorganisms.

44. The arguments in support of narrowing the scope of the Code included: the urgent need to finalise a text addressing *E. sakazakii* contamination and the recommendations of the FAO/WHO preliminary risk assessment; the different risks posed by the different types of powdered formulae; the need for more science and time to establish control measures that are proportionate to the risk for the different combination of pathogens/powdered formulae.

45. The arguments in support of broadening the scope of the Code included: the similarity of the processing techniques used for the production of powdered formula for infants and children; the limited number of commercially available products for "infants at greatest risks", i.e. neonates (≤ 28 days), particularly pre-term infants, low-birth weight infants or immuno-compromised infants; the risk characterization; the extensive range of products that could be contaminated by *E. sakazakii* and *Salmonella* as highlighted in the FAO/WHO preliminary risk assessment; the data showing that *E. sakazakii* and *Salmonella* were causing diseases in all age groups; and the fact that powdered formulae products were often used by multiple age-groups.

46. The Committee agreed on the need to make rapid progress on this document and noted that the next Session of the Committee was scheduled in November 2006. In recognising the value of the arguments expressed in favour of the different positions, the Committee agreed to develop a core document which addressed all types of powdered formula for infants and young children, namely: powdered infant formula, follow-up formula, formula for Special Medical Purposes (FSMP) intended for infants, and human milk fortifiers, but excluding cereal-based products.

47. The Committee agreed that the Code would include two annexes: Annex A addressing powdered formula for "infants at greatest risk" (as defined by the FAO/WHO Expert Meeting) and with a focus on *E. sakazakii* and *S. enterica*; and, Annex B addressing all powdered products for infants (i.e. a person of not more that 12 months[9]) and young children (i.e. persons from the age of more than 12 months up to three years[10]), with a focus on *E. sakazakii, Salmonella* and other microorganims.

48. The Observer from IDF suggested to develop an additional Annex that, similarly to the document for the Control of *Listeria monocytogenes* in Ready-to-Eat Foods (see Agenda Item 5), would address the risk issues, i.e. "Food Safety Objective" and related "Performance Objective" and "Performance Criteria" and provide justification for the microbiological criteria set in the other Annexes; however the Committee did not agree to this proposal.

49. In considering the definition for "Infants at greatest risks" in the FAO/WHO preliminary risk assessment, some delegations were of the opinion that the definition should also encompass children born from immuno-compromised mothers and malnourished children. No consensus was reached on this proposal.

50. The Delegation of Uruguay, supported by other delegations, was of the view that the document should consider the use of an alternative term to "human milk fortifiers", for example "human milk complements".

Labelling

51. Several delegations were of the view that both sections on labelling and education be carefully considered and take account of the "at risk population" and the new structure of the Code. It was suggested that information on labelling concerning the preparation and use of powdered formula should cover appropriate actions to minimise microbiological risks and should be prominently displayed. Some delegations expressed their concern for the use of warning statements that could create confusion and inappropriate actions and stressed the need to consider means, other than product labelling, to provide information on the risk of powdered formula and appropriate alternatives or handling methods. It was also suggested to address in sections on labelling and education the issue of the holding time prior to consumption of reconstituted formula.

52. The Delegation of Cuba suggested that sections labelling and education should contain provisions aimed at promoting breast feeding and the use of human milk banks.

53. The Committee agreed that labelling provisions were very important for this Code, and therefore invited interested parties to submit their comments to the Working Group in order to make attempts to better address labelling issues there.

Terms of Reference for additional work of FAO/WHO on "Enterobacter sakazakii and other microorganisms in powdered infant formula"

54. Following the request of the Representative of FAO, the Committee established an *ad hoc* Working Group to better clarify the scope and the issues to be addressed by an FAO/WHO Expert Consultation for additional scientific advice on "*Enterobacter sakazakii* and other microorganisms in powdered infant formula".

55. The Committee considered a proposal, prepared by the *ad hoc* Working Group, and agreed to request FAO/WHO to convene an Expert Consultation to look at the following issues:

i. Taking into consideration any existing and new information on *E. sakazakii* and existing and new data on *Salmonella*[11], identify if possible the distribution of cases linked to the different types of powdered formula[12] as a function of age, and define specifically the age groups and other groups of infant and young children at greatest risk.

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9 Recommended International Code of Hygienic Practice for Food for Infants and Children (CAC/RCP 21-1979).

10 Recommended International Code of Hygienic Practice for Food for Infants and Children (CAC/RCP 21-1979).

11 The need for any risk assessment work on Salmonella will be reviewed following an initial literature review and consideration of available data.

12 "Powdered formula" is used here to describe powdered infant formula, follow-up formula, formula for Special Medical Purposes (FSMP) intended for infant, and human milk fortifiers, as described in Section 6.1 of the 2004

ii. Review the dose-response and growth models of *E. sakazakii*, using new data that is becoming available.

iii. Evaluate specific control measures for different manufacturing operations (depending on data provided by manufacturers of powdered formula), which could minimise product contamination by *E. sakazakii* and evaluate how microbiological criteria for Enterobacteriaceae can be used as an indication of process hygiene.

iv. a) In light of new data submitted by ISDI/industry request that the risk assessment be updated to take into consideration this new information and make the output available to the Working Group (in charge of redrafting the proposed draft Code – see para. 56) for the development of microbiological criteria;

b) Use the risk assessment to evaluate the risk reduction associated with various control measures, microbiological criteria and sampling plans.

v. Request that the aspects of the risk assessment model addressing preparation, storage and handling of powdered formula be revisited to ensure that all currently used preparation procedures are evaluated.

56. The Committee noted the offer of the Delegation of Canada, Chair of the Working Group, to request ICMSF to revisit and re-examine the issue of microbiological criteria for *E. sakazakii*, *Salmonella* and Enterobacteriaceae, and associated 2 and 3 class sampling plans, taking into account new information available from ISDI/industry and the outputs of the risk assessment.

STATUS OF THE PROPOSED DRAFT REVISION OF THE INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR FOOD FOR INFANTS AND CHILDREN

57. The Committee agreed to return the renamed 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[13]. It agreed that the Working Group would revise the Code taking into account the decisions regarding the scope and the structure of the Code, the above discussion and the written comments submitted at the present session. 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.

PROPOSED DRAFT GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF *LISTERIA MONOCYTOGENES* IN FOODS (Agenda Item 5)[14]

58. The Committee recalled that the 36th Session of the CCFH returned the proposed draft Guidelines to Step 2 and agreed that a drafting group led by Germany would revise the Guidelines based on the written comments and the discussion at the session. In addition, it was decided that a sub-group of the drafting group would prepare an annex (Annex II) to the guidelines on the establishment of FSO's and related performance objectives and criteria, including microbiological criteria for *Listeria monocytogenes* in ready-to-eat foods.

59. The Delegate of Germany introduced the document and informed the Committee that the drafting group that met in Berlin (Germany) in September 2004 had revised the Guidelines on the basis of the comments submitted at the 36th Session of CCFH and had elaborated Annex II, "Deriving Microbiological Limits and Sampling Plans in Microbiological Criteria from Food Safety Objectives: *Listeria monocytogenes* in Ready-to-Eat Foods" (see also paras 86-99).

60. The Committee considered the draft guidelines Section by Section. In addition to minor editorial amendments, the Committee agreed to the following changes:

Meeting Report "*Enterobacter sakazakii* and other microorganisms in powdered infant formula" (Microbiological Risk Assessment Series, No. 6).

13 The members will include Belgium, EC, France, Germany, Italy, Japan, the Netherlands, Spain, Switzerland, the United Kingdom, the United States of America, Uruguay, FAO/WHO, IBFAN, ICMSF and IDF

14 CX/FH 05/37/5; CX/FH 05/37/5 Add. 1 (USA and IDF), CRD 11 (EC); CRD 24(Brazil); CRD 33 (Germany); CRD 52 (United States in collaboration with Australia and Germany).

Title

61. The Committee noted that in the title of document CX/FH 05/37/5 the term "control" had inadvertently been left between square brackets and corrected this.

Introduction

62. The Committee discussed the length and contents of this section, particularly the bullet points related to the risk assessments performed by the USFDA/FSIS and FAO/WHO. It was agreed that the issues brought forth by several delegates, regarding additional factors that are important to consider, could be addressed in the relevant sections of the main body text.

Section I – Objectives

63. The words "public health and facilitating trade" were replaced with "the health of consumers and ensuring fair practices in food trade" in order to be consistent with Codex language. The term "ready-to-eat" was added just before the word "foods" at the end of the second sentence to clarify the type of foods to be addressed by the Guidelines.

Section II – Scope

2.1 Scope

64. The first sentence was modified by adding "are intended for ready-to-eat foods" after "These guidelines", to focus the scope of the document. The second sentence was amended in order to emphasize that control measures can be implemented not only to "prevent" but also to "minimize" contamination and/or growth of *L. monocytogenes* of ready-to-eat (RTE) foods during processing and after purchase by the consumer. The phrase "in all foods" was added to the end of the fourth sentence for clarification.

65. As recommended by the Delegation of Uruguay, additional text was added at the end of the section to specify that the Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1- 19969, Rev. 4, 2003) and other Codex Codes should be suitable to control *L. monocytogenes* in most foods, and that additional measures contained in the Guidelines were designed to control *L. monocytogenes* in RTE foods.

2.2 Definitions

66. The phrase "For the purpose of these Guidelines, the following definitions apply:" was added to the beginning of the section to align with the language used in other Codex texts.

67. Several delegations expressed their concern about the clarity of the definition for "ready-to-eat food", therefore it was decided to replace the word "processing" with "listericidal steps", to be more precise with regards to these Guidelines, and the related footnote was removed.

Section III – Primary Production

68. In the first introduction paragraph, the phrase "or inhibit the growth of" was added after "inactivate" to more accurately describe the effects that the mentioned treatments can have on *L. monocytogenes.* Additionally, animal husbandry was mentioned as being encompassed by good agricultural practices.

Section V – Control of Operation

5.2.1 Time and temperature control

69. After some discussion, the Committee agreed to alter the text of the section. The first paragraph was split into two, in which it highlighted that the control of the time/temperature combination for food storage was necessary and that temperature abuse could result in a reduction in shelf-life. The text was amended to specify that the product temperature should not exceed 6 ºC (preferably 2 – 4 ºC), as recommended in the United States FDA/FSIS and FAO/WHO risk assessments on *L. monocytogenes* in RTE foods. This change was made throughout the document, where applicable.

70. In the new third paragraph of this section a sentence was added to indicate that when establishing a product shelf-life, it should be considered that temperature abuses may allow the growth of *L. monocytogenes,* if present, when appropriate intrinsic factors are not included in the product.

5.2.2 Specific process steps

71. Several changes were introduced to better clarify the context of the text and to specify that products that have undergone a listericidal treatment may be contaminated/recontaminated before final packaging and, therefore, additional control measures may be applied. In recognizing that irradiation was not authorized in all countries, "where accepted" was added. A new paragraph was added at the end of the section in relation to the application of control measures to raw, ready-to-eat foods for controlling *L. monocytogenes.*

5.2.3 Microbiological and other specifications

72. The Committee agreed that these specifications will be addressed in Annex II.

5.2.4 Microbiological cross-contamination

73. In the second paragraph, "a change of footwear" was added as an additional example of a control measure. "Alternatively" was replaced with "Where this is not practicable" in the third paragraph and the phrase "for recycled water" was added after "chlorination" in the fourth paragraph. There was some concern by several delegations about the acceptance of the use of chlorinated water in food processing. The Secretariat clarified that the use of chlorinated water was included in some Codes of Practice such as the Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering (CAC/RCP 39 – 1993) and the Code of Practice for Fish and Fishery Products.

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

74. A new sentence was added to the end of the first paragraph to indicate that, in addition to environmental testing, food product testing can also be used in verifying the effectiveness of control measures.

Section VI – Establishment: Maintenance and Sanitation

75. In the last sentence of the introductory text box, "control" was replaced with "the effectiveness of control measures" to clarify the point being made.

6.1.2 Cleaning procedures and methods

76. In the second paragraph, a new sentence was added to note that *L. monocytogenes* has the ability to form biofilms on a variety of surfaces. A sentence was added to the third paragraph indicating that the development of antimicrobial resistance should be considered in the application and use of disinfectants in the processing environment. "Bottle brushes" was added among the examples of cleaning equipment.

Section VIII – Transportation

8.1 General

77. To improve the clarity of the section, "to prevent the growth of *L. monocytogenes* in ready-to-eat foods that support growth" was removed from the first paragraph and "under pressure" was removed from the second paragraph.

Section IX – Product Information and Consumer Awareness

9.3 Labelling

78. The word "may" was replaced with "should" through out the paragraph to more strongly emphasize the advice provided in relation to the consideration of labelling certain RTE foods and the information to be included in such labels.

9.4 Communication Programs

79. The title of the Section was changed to "Consumer Education" for consistency with the corresponding section of the Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1- 1969, Rev. 4, 2003). In the first bullet point, new text was added at the end: "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;".

80. Under the second bullet point a new sub-item was added regarding the use of thermometers in home refrigerators.

Section X – Training

81. The objective was modified to specify that only those engaged in food operations that come directly or indirectly in contact with RTE foods should be trained and/or instructed in the control of *L. monocytogenes,* to a level appropriate to the operations they are to perform.

10.1 Awareness and responsibilities

82. In order to broaden the concept of the paragraph, "instruction and" was placed in front of "training".

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

c) Target organisms

83. A footnote was added to the end of this section addressing the attributes of an appropriate indicator organism that could be monitored in place of *L. monocytogenes.*

e) Frequency of sampling

84. "*Listeria* spp. and/or" was added before "*L. monocytogenes"* to reflect the inclusion of the same in paragraph 'c'.

i) Actions in case of positive results

85. At the end of the first paragraph, "A review of hygiene procedures and controls should be considered." was added to provide additional guidance.

Annex II: Deriving microbiological limits and sampling plans in microbiological criteria from food safety objectives; Example: Listeria monocytogenes in ready-to-eat food products

86. The Delegation of Germany recalled the decision of the 36th Session of the Committee to elaborate Annex II and provided an overview of the work that had been undertaken. The Delegation explained that this annex attempted to address the challenge of deriving microbiological criteria from food safety objectives (FSO's). The Working Group reported on the difficulties encountered in undertaking this task, which were further compounded by the lack of any guidance in this new area. The result was a highly technical draft document which, as well as providing microbiological limits and a sampling plan based on an FSO and PO, also attempted to provide guidance on how such a limit was derived.

87. The Committee expressed its appreciation to the Delegation of Germany for their work on this annex including the conceptual advances made with regard to deriving microbiological limits from FSO's. However, it was noted that considerable work was still needed to achieve the objectives of Annex II and decided not to discuss Annex II in detail.

88. Due to the importance of this work and the need for further guidance on the conceptual and practical aspects of deriving microbiological limits from FSO's, the Delegation of the United States of America suggested that the work would greatly benefit from scientific advice from FAO/WHO. In relation to this and in response to the request from FAO/WHO for input on their proposal to implement an expert consultation on the *Development of practical risk management strategies based on microbiological risk assessment outputs* (as described in Annex II of CX/FH 05/37/9) the Delegation presented CRD 52. The purpose of the CRD was to request FAO/WHO to develop, as part of their proposed expert consultation, scientific advice on concepts, methods, and practical examples of how FSO's, POs, and Performance Criteria (PC) can be related to established public health goals, and translated into more traditional metrics such as process criteria, product criteria, and microbiological criteria.

89. The Committee focused their discussion on CRD 52 to ensure that it adequately described the needs of CCFH in this area, especially on how the output of the proposed FAO/WHO expert consultation could contribute to the work on this Annex.

90. There was general support expressed in the Committee for the concepts outlined in Annex II, although some delegations noted the need to consider the FSO/PO concepts within the broader framework of risk management.

91. The Delegation of New Zealand, while supporting the request for advice to be addressed to FAO/WHO, proposed that it was important to firstly provide a context for the FSO/PO concept as one of several types of risk management options. The Delegation noted that this was especially important when it is acknowledged that derivation of a PO requires the availability of an appropriate risk assessment and also needs to be able to accommodate different expressions of appropriate level of protection (ALOP) e.g. broad public health goals, point estimates of risk. The Delegation indicated that for these reasons other types of risk management options would continue to have prominence in the short term. The Committee agreed to include these issues in the request to FAO/WHO.

92. The Committee agreed to the proposal from the Delegation of Japan, to include in CRD 52 a request to consider additional approaches for risk management when it is not possible to apply the FSO/PO concept.

93. The Delegation of the Netherlands, speaking on behalf of the Member Countries of the European Community present at the current session, while indicating support for the philosophy and content of CRD 52, noted that the questions in the CRD were very ambitious. The Delegation stressed the need to strive to reach the outlined goals and proposed that successful cooperation with all relevant parties would be very important.

94. The Representative of WHO clarified the linkage between the request for scientific advice as proposed in CRD 52 and the FAO/WHO consultation described in Agenda Item 9 (Annex 2, CX/FH 05/37/9). The Representative indicated that FAO/WHO were presently trying to better define the scope and format of the scientific advice to be developed to meet the needs of Codex, FAO and WHO member countries. The Representative, while confirming the commitment of FAO and WHO to provide advice on the application of risk assessment to risk management, noted the complexity of the work to be undertaken and the importance of putting FSO in context within a risk based management system and available risk management options. The Representative further highlighted the need to better establish and understand the linkage between FSO and its associated metrics and risk management interventions aimed at risk reduction since both use similar quantitative expressions.

95. The Observer from ICMSF noted the importance of this work and in particular the development of a "how-to" guidance document that the Committee could use as a reference in its work. The complexity of the issue to be addressed by a consultation warranted careful and extensive preparation.

96. The Committee agreed to attach a revised version of CRD 52 to the report (see Appendix VII) with the understanding that it will assist FAO and WHO to evaluate needs of CCFH for the provision of scientific advice. The Committee noted that it was up to FAO/WHO to then determine the exact scope of the consultation and to select appropriate experts; however, it urged FAO/WHO to urgently address their needs, as outlined in Appendix VII.

97. The Observer from Consumers International proposed that a communication expert be involved to help ensure that the consultation effectively conveys the new conceptual and technical information to CCFH, FAO/WHO member countries, and other interested parties.

STATUS OF THE PROPOSED DRAFT GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF *LISTERIA MONOCYTOGENES* IN READY-TO-EAT FOODS

98. The Committee agreed to forward the Proposed 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 28th session of the Codex Alimentarius Commission for adoption at Step 5 (see Appendix II).

99. The Committee further agreed to return Annex II: Deriving microbiological limits and sampling plans in microbiological criteria from food safety objectives; Example: *Listeria monocytogenes* in ready-to-eat food products, to Step 2 and requested the Working Group[15] led by Germany to further develop Annex II taking into account the report of the FAO/WHO expert consultation on the application of risk assessment to risk management when it becomes available. The revised Annex II will then be circulated for comments and further discussion by the Committee.

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[15] The members will include Austria, Canada, China, Denmark, EC, Finland, France, Greece, Hungary, Italy, Japan, Norway, Sweden, Switzerland, the United Kingdom, Uruguay, The United States of America, FAO, WHO, ICMSF, IDF and IFT

PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT (Agenda Item 6)[16]

100. The Committee recalled that the 36th Session of the CCFH requested the Drafting Group led by France to redraft the document for circulation and consideration at the current session and that a Working Group was convened prior to this session to consider comments received and prepare a revised version of the document.

101. The Delegation of France introduced CRD 36 and highlighted main changes throughout the document made by the Drafting Group which met in Brussels (29 September – 1 October 2004) and the Working Group which met before the current session of the Committee. The Delegation pointed out that the 27th Session of the Commission had confirmed that the work on the document, addressing issues of relevance to both member governments and Codex, was consistent with the Commission's expectations in relation to risk analysis. The document was further simplified, and new sections on responsibility for "Selecting Microbiological Risk Management (MRM) options" and "Risk-based MRM options" were added. The Delegation also pointed out that sections on Food Safety Objectives (FSO), Performance Objective (PO), Performance Criteria (PC) and Microbiological Criteria (MC) were rewritten following adoption of these definitions by the Commission.

102. The Delegation indicated that additional work was necessary on Annex III on "Food Safety Objectives, Performance Objectives, Performance Criterion, Microbiological Criterion, Process and Product Criteria", especially on how these definitions could be used in elaborating microbiological specifications for food products, and that the proposed forthcoming FAO/WHO Expert Consultation could be very useful in providing the guidance on how these definitions could be applied in practice. The Delegation recommended to proceed with the elaboration of Annex III at a different pace to the main body of the document and, and expressed the view that the main body of the document might be proposed for advancement to the Step 5 of the Elaboration Procedure.

103. The Committee noted that the document was significantly improved and expressed sincere appreciation to the Delegation of France and members of the Drafting Group for their hard work. The Committee decided to discuss the document Section by Section and to concentrate on major issues in order to be able to advance it in the Elaboration Procedure. In addition to minor editorial changes, the following amendments were made throughout the document.

General comments

104. The Committee noted problems with the Spanish translation of some parts and that footnotes in the English and Spanish versions had different numbers, therefore it was essential to fix these in the subsequent revision of the Code.

Introduction

105. The Committee amended the last sentence of the second paragraph by splitting it into two sentences to clarify that risk analysis helps to protect the health of consumers and ensures fair practices in food trade; and separated the concept of facilitation of judgement of equivalence of food safety measures into a separate sentence.

Definitions

106. The Committee clarified in reference to footnote 3 that the definition of Risk Manager had been derived from the definition of risk management and not vice-versa. This footnote was moved from the definition of Risk Management to that of Risk Manager.

Section 3 General principles for MRM

107. It was proposed to combine Principles 2 and 7, as it seemed that the both covered the food chain, however the Committee did not agree to this proposal.

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16 CX/FH 05/37/6; CX/FH 05/37/6-Add.1 (Canada, United States, Venezuela, Consumers International and IDF); CRD1 (Guatemala); CRD 2 (Argentina); CRD 4 (Japan); CRD 9 (European Community); CRD 16 (Thailand); CRD 21 (Brazil); CRD 31 (Peru); CRD 36 (Revised Annotated CX/FH 05/37/06); CRD 43 (India); CRD 46 (Cuba); CRD 53 (Honduras).

108. The Delegation of the United States drew the attention of the Committee to the fact that Article 5.1 of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) focussed on the risks to human health while the current Principle 7 took into consideration regional differences in hazards, and therefore proposed to remove the reference to "hazards" in order make this Principle consistent with the above Article of the SPS Agreement and to include reference to regional risk management differences in Risk management options. This view was supported by several delegations.

109. The Delegation of Denmark pointed out that Principle 7 was very important and that the reference to "hazard" should be retained as it was a measurable operational parameter, whereas "risk" was a derived estimate and not directly measurable. Several other delegations supported Denmark and indicated that concepts of regional differences in relation to hazards were recognized in Article 6 of the SPS Agreement and that the reduction of prevalence in hazards, e.g. *Salmonella,* was necessary to achieve reduction in risk of illnesses.

110. After an extensive discussion, the Committee agreed to amend Principle 7 to read: "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". It was also agreed to retain the original footnote 11.

Section 4 General considerations

111. The delegation of India proposed to delete in the second paragraph the example of "feeds" as it was already covered by primary production and also to delete the last sentence regarding domestic and imported products as superfluous. The Committee did not agree to these proposals as it was of the view that feeds were not always covered by primary production and that last sentence was essential in order to equally treat both domestic and imported products.

112. The Committee amended the penultimate sentence of the fourth paragraph to make it more consistent with the language used in the SPS Agreement. The reference to the "extent possible" was deleted from the last sentence in the sixth paragraph.

Section 5.1 Identification of a microbiological food safety issue

113. In considering paragraph 4, the Delegation of Argentina pointed out that the only case in which the adoption of immediate decisions was permitted without any further scientific consideration, was when an emergency situation took place, and proposed that the wording "immediate decisions" be replaced by "emergency measures". The Committee agreed to put this wording in square brackets for further comments and consideration at its next session.

114. The Committee decided to put in square brackets the entire last paragraph of this section due to the lack of consensus on the application of the precautionary approach for further comments and consideration.

Section 5.2 Microbiological risk profile

115. The Committee noted that MRM options can, but not necessarily would "typically", take the form of a risk management guidance document entering the Codex Step process, and therefore amended the last sentence of last paragraph to this effect.

(new) Section 5.3 Risk assessment policy

116. The Delegation of Japan pointed out that it was necessary to have some guidance for governments in relation to the risk assessment policy, therefore the Committee agreed to include a new Section 5.3 in the document and a consequential change was made to the flow chart (Annex I) to provide guidance in this regard.

Section 5.3 Microbiological Risk Assessment (new Section 5.4)

117. The Committee agreed to reinstate the phrase "developing and/or evaluating and deciding on" and put the wording "deciding on provisional MRM options" in square brackets in the last sentence of the last paragraph for further comments and consideration at its next session.

Section 6.1 Identification of available MRM options for Codex and countries

118. The Committee noted that when selecting MRM options for implementation, risk managers may not always select the "most appropriate" MRM options and changed them to "acceptable" in the first sentence.

Section 6.1.1 Codex

119. The wording in the last paragraph of this section, in regard to the position of precaution, was aligned with the decision taken by the 24th Session of the Commission.

Section 6.1.2 Countries

120. The Delegation of Argentina proposed to delete the reference to "traceability/product tracing" in the second bullet of this section or to defer the consideration on this matter at the later stage as there was not yet Codex guidance on how "traceability/product tracing" could be applied in practice; and proposed that the same approach should be taken on other sections of the document where this term appeared. This view was supported by several delegations.

121. Several other delegations were of the view that the concept of traceability/product tracing was very important for microbiological risk management and did not agree to this proposal. It was also noted that traceability/product tracing was already used in several countries.

122. The Codex Secretariat clarified that the 27th Session of the Commission, while adopting a definition on traceability/product tracing, requested the Committee on Food Export and Import Inspection and Certification Systems (CCFICS) to initiate the work on principles for its application.

123. The Delegation of New Zealand pointed out that of basic components of food control programmes, such as the availability of systems for tracing of products and their recall, should not be included as risk management options within this document and expressed the view that they are prerequisite requirements and should not be considered as options in application of a risk management framework.

124. After some discussion the Committee agreed to put the square brackets around "traceability/product tracing" and consequentially throughout the text where this term appeared.

125. The Delegation of the European Community expressed its reservation to this decision and pointed out that "traceability/product tracing" was already defined and proposed to add a footnote to the existing definition (Procedural Manual, 14th Edition) in addition to ongoing CCFICS work.

126. In the fifth bullet, the Committee noted that terms "safe harbour" or "default" measures were not commonly used and difficult to translate into other languages, therefore substituted them with "relevant" in this and subsequent sections; it further clarified that "such parties" should be replaced by industry, which was described in footnote 6.

127. The sixth bullet in relation to prohibiting marketing of foods/feeds was deleted as some delegations considered that this example was too restrictive.

Section 6.2.2.2 Performance objective (PO)

128. The Committee noted that the current wording in relation to the establishment of generic PO by countries and industry as presented in the last part of the fourth paragraph might be confusing; therefore it deleted the last three sentences.

Section 7.2 Countries

129. The Committee noted that the concept on the selection of provisional MRM options required further consideration, therefore put paragraph 4 and the related wording in the last sentence of the sixth paragraph in square brackets.

Annex I

130. The Committee amended the diagram adding an arrow between the boxes "Evaluating the results of the risk profile" and "Immediate public health concern"; and deleted arrows between boxes "Evaluating the results of the risk profile" and "Immediate and/or [provisional] decision". An additional arrow was inserted between "Immediate and/or [provisional] decision" and "Monitoring and review of MRM options". The latter was linked to the box "Identification and Selection of MRM options".

Annex II

131. In order to be consistent with the title, the sections on Purpose and Scope and rationale were deleted.

An additional bullet in relation to occurrence of hazard in the food chain was added to the first paragraph.

STATUS OF THE PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR MICROBIOLOGICAL RISK MANAGEMENT

132. The Committee agreed to forward the Proposed Draft Guidelines for Microbiological Risk Management to the 28th Session of the Commission for adoption at Step 5.

133. The Committee noted that Annex III, in relation to the examples of the use of Food Safety Objectives, Performance Objectives, Performance Criteria, Microbiological Criteria, Process and Product Criteria required significant work and would benefit from the output of the FAO/WHO expert consultation on the application of Risk Assessment of Risk Management and scientific input from FAO/WHO. Therefore the Committee decided to return it Step 2 to the Working Group led by United States[17] for further comments and consideration by the Committee.

PROPOSED DRAFT GUIDELINES FOR THE VALIDATION OF FOOD HYGIENE CONTROL MEASURES (Agenda Item 7)[18]

134. Due to time constraints in this meeting the Committee did not discuss this item and agreed to return the document to Step 2 for redrafting by the Working Group led by the United States.[19]

PROPOSED DRAFT REVISION OF THE CODE OF HYGIENIC PRACTICE FOR EGGS AND EGG PRODUCTS (Agenda Item 8)[20]

135. The Committee recalled that 36th Session of the CCFH had agreed that the drafting group led by Australia would revise the proposed draft Revision of the Code of Hygienic Practice for Eggs and Egg Products at Step 2 based on the discussion of the session and written comments submitted at the session and in response to the Circular Letter, for circulation, comments at Step 3 and further consideration at its present session.

136. In presenting the proposed draft Code, the Delegation of Australia highlighted the significant progress made such as; the more clarified definitions and the guidance on egg processing technology, including pasteurization of eggs and egg products; the more practical guidance on the primary production of eggs including the small scale farming practices in the food chain.

137. The Committee considered the Code Section by Section and in addition to minor changes and some corrections to the French and Spanish version of the draft Code, agreed to the following:

2.1 Scope

138. To improve the clarity, “primary products”, “transport” and “distribution” were added in the first paragraph. The text related to the definition of “egg” was moved to this section. The last sentence of the first paragraph and the second paragraph were deleted as unnecessary.

2.3 Principle applying to the production, handling and processing of all eggs and egg products

139. To clarify that the Code aimed at ensuring the safety of eggs in all stages of food chain, “throughout the entire food chain” was added in the first paragraph (in Italic) following the first principle.

Control measures should be effective and validated, where appropriate.

140. “Performance Objectives” was inserted in the first paragraph for consistency with the previous decision regarding the Risk Management policy.

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17 The members will include Argentina, Australia, Belgium, Canada, Denmark, Finland, France, Germany, Ireland, Italy, Japan, Republic of Korea, New Zealand, Netherlands, Norway, ICMSF, IDF, IFEH, FAO and WHO.

18 CX/FH 05/37/7; CX/FH 05/37/7-Add.1 (Canada, Venezuela, IDF); CX/FH 05/37/2-Add.2 (Argentina); CRD 5 (Japan); CRD 14 (EC); CRD 18 (Thailand); CRD 20 (Bolivia); CRD 24 (Brazil); CRD 30 (Peru); CRD 37 (Indonesia); CRD 43 (India); CRD 46 (Cuba); CRD 53 (Honduras).

19 The members include Australia, Canada, France, Germany, Italy, New Zealand, Norway, Spain, Sweden, Thailand, IDF, IFEH and ICMSF

20 CX/FH 05/37/08; Comments submitted by Argentina, Canada, Venezuela, the United States of America (CX/FH 04/37/8-Add. 1), Japan (CRD5), Brazil (CRD25), European Community (CRD35), Indonesia (CRD37), India (CRD44), Cuba (CRD46), Honduras (CRD53)

141. Recognising the diverse levels of facility conditions and capacities in small and less developed businesses, the last sentence was modified to allow for more flexibility.

Definitions

Egg

142. The definition of Egg was deleted and the text was inserted in the Scope section (see para 138).

Microbiocidal treatment

143. The example of pasteurization was deleted as the section contains a definition of Pasteurization.

3. Primary production

144. The sentence of the second principle was simplified to "Contamination of eggs during primary production should be minimized."

3.1 Environmental hygiene

145. To allow for more flexibility, the first and third paragraphs were changed by replacing "should" with "could".

3.2.1 Flock Management and Animal Health

146. The Committee accepted to add a footnote referring to the discussion paper on *Salmonella* being reviewed by CCFH. To draw attentions to the possible antimicrobial resistance due to the usage of veterinary drugs, a sentence and a foot note were added in the third paragraph.

3.2.2 Areas and Establishment for Egg Laying Systems

147. Considering diversities of egg laying systems and conditions, "where practicable" was added in the fourth paragraph and "should" was replaced with "could".

3.2.3.1 Watering

148. "Where practicable" was added to the fourth bullet point to allow for more flexibility in the use of good purchasing practices for water.

3.4.1 Cleaning and maintenance of egg laying establishments

149. To place more emphasis on the importance of disinfection and cleaning when facilities are empty, the last part of the third paragraph was modified to read "full cleaning and disinfection programme should be applied when poultry houses are empty".

3.5 Documentation and record keeping

150. It was agreed to put "Traceability" in square brackets awaiting the work on this subject in CCFICS.

4. Establishment: Design and facility

151. "Where practicable" was added of the beginning of the third paragraph to allow for more flexibility. The "raw" in the first bullet point was deleted as redundant.

5.1 Control of food hazards

Eggs and egg products should be safe and suitable / table eggs should be cleaned and intact.

152. Considering the fertile eggs marketed for human consumption in several countries and the need to differentiate between eggs for hatching and fertile eggs, it was agreed that "eggs intended for hatching" should be considered to be unsafe or unsuitable eggs for human consumption. Additionally, a new bullet "Other unsafe and unsuitable eggs should not be used for egg products" was added in Egg Products.

153. Taking into account the diverse practices applied to dirty eggs in different parts of the world, it was agreed to modify the sentence under the second principle as "All efforts should be made to avoid production of dirty eggs. However, dirty eggs may be used for table eggs, in accordance with country's requirements, if cleaned appropriately."

154. Considering that broken/ leaker eggs should also be disposed of in a safe manner, relevant language was added in the second bullet point under the second principle.

5.2.2.2 Egg Product Processing

155. In the fourth principle, an additional wording "and that permits examination of egg contents" was added.

STATUS OF THE PROPOSED DRAFT REVISION OF THE CODE OF HYGIENIC PRACTICE FOR EGGS AND EGG PRODUCTS

156. The Committee agreed to forward the draft Code to the 28th Session of the Commission for adoption at Step 5.

157. The Delegation of the United States introduced CRD 51 describing the need and rationale for a future Annex providing further guidance on the development of risk analysis metrics (e.g., FSO, PO, PC, process criteria) for microbiocidal treatments for eggs and egg products. The Committee agreed that a Drafting Group led by the United States[21] would develop the Annex to the draft Code which would specify the effective microbiocidal treatment including pasteurization as well as the application of the FSO, PO and PC.[22]

REPORTS OF THE AD HOC EXPERT CONSULTATIONS ON RISK ASSESSMENT OF MICROBIOLOGICAL HAZARDS IN FOODS AND RELATED MATTERS (Agenda Item 9)[23]

158. The Representatives of FAO and of WHO presented the document and provided an overview of FAO/WHO activities relevant to the Committee's work. Issues of particular relevance to the agenda of this Session were brought to the attention of the Committee.

159. The Representative of FAO provided an update of work that had been undertaken by FAO/WHO in response to the request of the 36th Session of the Committee to continue risk assessment work on *E. sakazakii* in powdered infant formula and informed the Committee that FAO/WHO were planning to convene a technical meeting within the coming year to finalise this risk assessment work. The Committee was invited to provide FAO/WHO with guidance on any additional scientific advice needed so that this could be considered in the finalisation of the risk assessment (see also para. 96). With regard to their work in this area the Representative of WHO informed the Committee of the draft resolution by the WHO Executive Board for endorsement at the forthcoming World Health Assembly requesting that Codex urgently complete work underway to address the risk of microbiological contamination in powdered infant formula.

160. The Committee was informed of two new FAO/WHO initiatives relevant to the Committees work i) the implementation of a consultation process on the *Development of practical risk management strategies based on microbiological risk assessment outputs* (as described in Annex 2 of CX/FH 05/37/9) and ii) the establishment of a network on viruses in foods. The Committee was invited to provide feedback to FAO and WHO on these new initiatives and to better define their needs in these areas.

161. The Representatives of FAO and WHO noted the risk assessment questions and request for scientific advice provided in document CX/FH 05/37/11 and advised the Committee of the need for some clarifications before forwarding the request to FAO/WHO. The Delegation of the United States of America pointed out that the request for scientific advice was limited to the Appendix 2 of the *Discussion Paper on Guidelines for the Application of the General Principles on Food Hygiene to the Risk Based Control of Enterohemorrhagic Escherichia coli in Ground Beef and Fermented Sausages* (CX/FH 05/37/11).

162. The Representative of FAO informed the Committee of the progress made by FAO/WHO in addressing the request of the 35th session of the CCFH, to develop guidelines on the obstacles to the application of HACCP and approaches to overcome them in small and less developed businesses (SLDBs). The full text of the FAO/WHO draft document "Guidance to Governments on the Application of HACCP, in small and/or less developed business" was provided in CRD 6. The Representative of FAO indicated that a web-based resource was being developed by the organization to provide information on national approaches relevant to the application of HACCP in SLDBs to compliment the guidance document.

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21 The member will include Argentina, Australia, Denmark, Japan, Sweden, Thailand, New Zealand, ALA and ICMSF

22 CRD 51 (United States)

23 CX/FH 05/37/9; CRD 6 (FAO/WHO); CRD 13 (EC)

163. The Representative of FAO noted that this was an important opportunity to share the draft document and advised the Delegations that further information and/or clarifications could be provided during the session.

164. The Representative of FAO drew the attention of the Committee to the fact that that FAO/WHO were in the process of organising an expert review / technical meeting to consider available data on potential risks and benefits of the use of the lactoperoxidase system. In response to the concerns expressed the Delegation of Cuba at the delay to this work and the need to provide scientific advice on this issue in a timely manner, the Representative of FAO advised that the findings of the expert review would be provided to the next session of the Committee.

165. The Committee was also informed of the criteria to be used by FAO and WHO for prioritising requests from all Codex committees for scientific advice as agreed at the 55th Session of the Executive Committee[24].

DISCUSSION PAPER ON THE GUIDELINES FOR THE APPLICATION OF THE GENERAL PRINCIPLES OF FOOD HYGIENE TO THE RISK BASED CONTROL OF *SALMONELLA* SPP. IN BROILER CHICKENS (Agenda Item 10)[25]

DISCUSSION PAPER ON THE GUIDELINES FOR THE APPLICATION OF THE GENERAL PRINCIPLES OF FOOD HYGIENE TO THE RISK BASED CONTROL OF ENTEROHEMORRHAGIC *ESCHERICHIA COLI* IN GROUND BEEF AND FERMENTED SAUSAGES (Agenda Item 11)[26]

DISCUSSION PAPER ON THE GUIDELINES FOR RISK MANAGEMENT OPTIONS FOR *CAMPLYOBACTER* IN BROILER CHICKENS (Agenda Item 12)[27]

RISK PROFILE OF *VIBRIO* SPP. IN SEAFOOD (Agenda Item 13 a)[28]

DISCUSSION PAPER ON THE VIRUSES IN FOOD (Agenda Item 13 b)[29]

166. Due to time constraints the Committee considered these five agenda items together.

167. The Committee recalled that it had previously agreed to a process for considering new work (see Agenda Item 3). While recognizing that these Discussion Papers had been considered during several sessions, the Committee agreed that it would be appropriate to utilize the newly established process to further consider possible further work on these items.

168. The Committee agreed, therefore, to place all five proposals for new work areas into the Committee's work management system (see Appendix V) and identified the following countries to prepare written proposals.

> SWEDEN: *Guidelines for the Application of the General Principles of Food Hygiene to the Risk-Based Control of Salmonella spp. In Broiler Chickens.*
>
> UNITED STATES: G*uidelines for the Application of the General Principles of Food Hygiene to the Risk-Based Control of Enterohemorraghic Escherichia coli in Ground Beef and Fermented Sausages.*
>
> NEW ZEALAND: *Guidelines for Risk Management Options for Campylobacter in Broiler Chickens.*

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24 ALINORM 05/28/3, para 75

25 CX/FH 05/37/10; CRD 18 (Thailand); CRD 20 (Bolivia); CRD 26 (Brazil); CRD 37 (Indonesia); CRD47 (Cuba); CRD 48 (European Community); CRD 49 (Costa Rica); CRD 50 (India).

26 CX/FH 05/37/11; CRD 20 (Bolivia); CRD 47 (Cuba); CRD 48 (European Community); CRD 53 (Honduras).

27 Document was not prepared.

28 CX/FH 05/37/14; CRD 45 (European Community); CRD 47 (Cuba); CRD 49 (Costa Rica).

29 CX/FH 05/37/14; CRD 45 (European Community); CRD 47 (Cuba); CRD 49 (Costa Rica).

UNITED STATES: *Vibrio spp in Seafood*

THE NETHERLANDS: *Viruses in Food*

Other matters

169. The Committee also recalled that at its 36th Session it had agreed to defer work for the time being on the *Proposed Draft Guidelines for the Reuse of Processing Water in Food Plants* and the *Discussion Paper on the Proposed Draft Guidelines for Evaluating Objectionable Material in Food.* The Delegation of the United States recommended that the Committee cease work on these items and indicated that it would not be resubmitting the *Discussion paper on the Proposed Draft Guidelines for Evaluating Objectionable Material in Food* for consideration for new work. In noting the significant current and expected future workload and the continuing low priority of the item of the *Proposed Draft Guidelines for the Reuse of Processing Water in Food Plants,* the Delegation of the United States recommended the Commission to discontinue work on the item. The proposal was not considered due to time constraints.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 13)

DRAFT TERMS OF REFERENCE FOR THE FAO/WHO EXPERT CONSULTATION ON THE USES OF ACTIVE CHLORINE[30] (Agenda Item 13 c)[31]

170. The Delegation of Canada introduced this Agenda Item and indicated that the 36th Session of the Codex Committee on Food Additives and Contaminants (CCFAC) had requested FAO/WHO, to convene an Expert Consultation to conduct a comprehensive risk assessment on the uses of active chlorine, taking into account benefits and risks. The Committee noted that its task was to consider risk/benefit issues relevant to uses of active chlorine within their respective purviews and to elaborate terms of reference and specific questions within their mandate to ensure a comprehensive Consultation. The Delegation of Canada suggested that the Committee's discussion should focus on the Questions for Consideration contained in this document.

171. The Delegation of the Netherlands, speaking on behalf of the member countries of the European Union present at the session, indicated that the use of active chlorine for food decontamination purposes or in relation to food processing is not permitted in many countries. The Observer from the IDF indicated that the inclusion of food contact surfaces may overly broaden the scope of the risk assessment, however, the Committee, in light of ensuring a comprehensive risk assessment, concluded that this was a necessary consideration as chlorine is widely used in the cleaning of food contact surface to control microbiological contamination.

172. The Committee clarified that the third bullet in questions for consideration, related to the relative efficacy of alternative technologies should be in comparison to chlorine, and the fifth bullet was amended to include consideration of the growth of pathogenic micro-organisms following the (partial) removal of the initial flora by application of antimicrobial substances. In evaluating the antimicrobial effectiveness of active chlorine or their alternatives, the importance of considering other characteristics of the food in addition to pH, water characteristics, location in the production process, and purity of the active chlorine compounds was emphasised and included in elements requiring elaboration.

173. In the interest of undertaking a comprehensive risk assessment, two issues related to quality concerns (organoleptic changes in the product and the effect of antimicrobial treatment on water retention), were included in the terms of reference in elements requiring consideration. However the validity of their inclusion was questioned, as it was considered that, while they were important issues, it is unlikely that they will be adequately covered by the risk assessors.

174. The Committee agreed to attach the terms of reference for the FAO/WHO expert consultation on the uses of active chlorine (see Appendix VI).

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30 Aspects relevant to CCFH

31 CX/FH 05/37/15; CRD 8 (EC); CRD 26 (Brazil); CRD 47 (Cuba); CRD 50 (India); CRD 53 (Honduras)

OTHER BUSINESS

Hygiene Provisions of Codex Commodity Standards for Commercially Sterile Products

175. In reply to the request of the Codex Committee on Processed Fruits and Vegetables (see para. 14) the Committee agreed to the proposals of the *Ad Hoc* Working Group, as presented in CRD 55, and recommended that for Codex commodity standards for products processed according to the Code of Hygienic Practice for Low-Acid and Acidified Canned Foods, such as the *Proposed Draft Codex Standard for Canned Preserved Tomatoes,* the food hygiene section of these standards should continue to contain the provision relating to microbiological criteria, but with a footnote that indicates that such criteria are not recommended for this type of product.

176. Thus the provision should appear as follows:

> The products should comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).[1]
>
> [1]. For products that are rendered commercially sterile in accordance with the *Recommended Code of Hygienic Practice for Low-Acid and Acidified Canned Food* (CAC/RCP 23-1979, Rev 1-1989), microbiological criteria are not recommended as they do not offer benefit in providing the consumer with a food that is safe and suitable for consumption.

ENDORSEMENT OF HYGIENE PROVISIONS IN THE CODEX STANDARDS AND CODES OF PRACTICES[32]

Proposed draft Code of Practice for Fish and Fishery Products

177. In accordance with the terms of reference of the Codex Committee on Food Hygiene, the Committee was invited to endorsed the hygiene provisions of the Proposed Draft Code of Practice for Fish and Fishery Products, including Section 2.2, 2.14, 2.15, 2.17 and 2.18 of Definitions; Section 6 - Aquaculture, Section 14 – Processing of Shrimps and Prawns, Section 15 – Processing of Cephalopods, Section 17 - Transport and Section 18 – Retail.

178. As agreed earlier (see para. 17), the Committee considered the report of the *Ad Hoc* Working Group (CRD 56) presented by the Delegation of Norway and agreed on the following amendments proposed by the Working Group:

Section 14 - Processing of Shrimps and Prawns

Section 14.2.4 Chilled Storage

179. The sentence "Refer to Section 8.1.2 "Chilled Storage" for general information concerning fish and fishery product" (from Section 9 – Frozen Surimi) is to be inserted at the beginning of this Section.

Section 14.2.11 Cooking Process

180. Potential hazards: The term "*undercooking*" should be substituted by the term "*Survival of pathogenic micro-organisms due to insufficient cooking"*

Section 14.2.13 Cooling

181. The third bullet in this section should be amended to state:

"Only cold /iced potable water or clean water should be used for cooling and should not be used for further batches although for continuous operations a top-up procedure and maximum run-length will be defined"

182. This basis for the inclusion of the reference to the use of clean water was due to provision in the Codex General Principles of Food Hygiene (CAC/RCP 1- 1969, Rev. 4-2003, section 5.5.1) to use clean sea water for chilling purposes, provided this does not constitute a hazard to the safety and suitability of food.

183. The Delegation of Thailand stressed the importance that where clean water is used, processors need to ensure that the water does not contain harmful micro-organisms or substances at a level that may affect the health of the consumer. It was noted that the term "clean water" is a general term without specific microbiological or chemical parameters.

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[32] CRD 17 (Matters from CAC, CCEXEC, and Endorsements); CRD 29 (FAO – Fish Codes), CRD 56 (Report of the Working Group).

Section 14.2.16 Weighing, Packing and Labelling of All Products

184. The sentence "Refer to Section 8.4.4 "Wrapping and Packing" and Section 8.5. "Packaging, Labels & Ingredients" (from Section 9 – Frozen Surimi) is to be inserted at the beginning of this Section. Sections 8.4.4 and 8.5 are addressing the potential hazard of microbiological contamination.

Section 14.2.18 Frozen Storage of End Product

185. The sentence "Refer to Section 8.1.3."Frozen storage" for general information concerning fish and fishery product." (from Section 9 – Frozen Surimi) is to be inserted at the beginning of this Section as Section 8.1.3 is addressing the potential hazard of microbiological pathogens.

186. The Observer of Consumers International expressed its concern with reports of overuse and misuse of antimicrobial compounds in aquaculture and the links to antimicrobial resistance. This issue has not been addressed in the *Code of Practice for Fish and Fishery Products* and the need to review this Code of Practice at the earliest opportunity, was stressed, as part of future Codex work on antimicrobial resistance.

STATUS OF THE ENDORSEMENT OF THE HYGIENE PROVISIONS OF THE PROPOSED DRAFT CODE OF PRACTICE FOR FISH AND FISHERY PRODUCTS

187. The Committee endorsed the hygiene provisions of the Proposed Draft Code of Practice for Fish and Fishery Products, including Section 2.2, 2.14, 2.15, 2.17 and 2.18 of Definitions; Section 6 - Aquaculture, Section 14 – Processing of Shrimps and Prawns, Section 15 – Processing of Cephalopods, Section 17 - Transport and Section 18 – Retail as amended above.

Viruses and Risk Management of Vibrio spp.

188. The Committee appreciated the interest and input of CCFFP on *Vibrio* spp. in seafood and viruses related to the safety of bivalve molluscs and acknowledged that further work in this area would be essential for CCFFP. The Committee acknowledged the forwarded relevant Sections of the Proposed Draft Standard for Live and Raw Bivalve Molluscs, in order to strengthen cooperation and interaction between the Committees.

189. The Committee noted that the five FAO/WHO risk assessments on *Vibrio* spp. have not yet been completed and a risk profile is only available for *Vibrio parahemolyticus*. Additional work on risk management strategies for other *Vibrio* spp. would require risk profiles for these pathogen/commodity combinations.

190. Due to the very heavy workload, the Committee noted that any additional work on *Vibrio* spp. and viruses with regard to bivalve molluscs should be subjected to CCFH prioritization procedures (see also paras below).

Risk management of *Vibrio* spp.

191. To the proposal from CCFFP that the Committee continue to work on *Vibrio* spp. risk management with emphasis on bivalve molluscs, the Committee was of the view that the proposal on *Vibrio* spp. (see para 168) should consider as priority the following:

a) Assess the outcome of the Risk Assessments on *Vibrio* spp. in seafood and make recommendations on how this should be transformed into Good Hygienic Practice and risk management strategies.

b) Look into the questions put forward by the CCFFP related to the risk profile for *Vibrio* spp. (ALINORM 04/27/18 para 128), and take them into account when considering work for the Committee.

Viruses in Seafood

192. The Committee noted the recommendation of the *Ad Hoc W*orking Group to pursue work on a risk profile on viruses in food and focus early work on viruses in seafood in general, with emphasis on bivalve molluscs (see also para. 168).

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

193. The Committee was informed that the 38th Session of the CCFH, was tentatively scheduled in Washington, DC, United States of America, from 14 to 19 November 2006, subject to confirmation by the host Governments and the Codex Secretariat.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by:	Reference in ALINORM 04/27/13
- Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Ready-to-eat Foods	5	**Governments**, 28th Session of the CAC	para. 98 and Appendix II
-Annex II: Deriving microbiological limits and sampling plans in microbiological criteria from food safety objectives; Example; Listeria monocytogenes in ready-to-eat food products	2/3	**Germany**, 38th CCFH	para. 99
- Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management	5	**Governments,** 28th Session of the CAC	para. 132 and Appendix III
- Annex III (in relation to the examples of the use of Food Safety Objectives, Performance Objectives, Performance Criteria, Process and Product Criteria)	2/3	**United States**, 38th CCFH	para.133
- Proposed Draft Code of Hygienic Practice for Eggs and Egg Products	5	**Governments**, 28th Session of the CAC	para.156 and Appendix IV
- Annex (in relation to the guidance on the development of risk analysis metrics (e.g., FSO,PO,PC, process criteria) for microbiocidal treatments for eggs and egg products	1,2,3	**United States,** 38th CCFH	para.157
Proposed Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children	2/3	**Canada,** Governments, 38th CCFH	para. 57
Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures	2/3	**United States**, 38th CCFH	para. 134
Written proposal for new work on the Guidelines for the Application of the General Principles of Food Hygienic to the Risk-Based Control of *Salmonella* spp. in Broiler Chickens		**Sweden**, 38th CCFH	paras 166-168
Written proposal for new work on the Guidelines for the Application of the General Principles of Food Hygienic to the Risk-Based Control of Enterohemorrhagic *E. coli* in Ground Beef and Fermented Sausages		**United States**, 38th CCFH	paras 166-168
Written proposal for new work on theGuidelines for Risk Management Options for *Campylobacter* in Broiler Chickens		**New Zealand,** 38th CCFH	paras 166-168
Written proposal for new work on *Vibrio* spp. in Seafood		**United States,** 38th CCFH	paras 166-168
Written proposal for new work on Viruses in Food		**The Netherlands,** 38th CCFH	paras 166-168

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APPENDIX II

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

At Step 5 of the Elaboration Procedure

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ANNEX II: (Under development)

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).

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, which are the foods predominantly associated with sporadic cases or outbreaks of listeriosis. 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, Rev. 4-2003) 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, Rev. 4-2003) and other applicable codes of hygienic practice should be suitable to control *L. monocytogenes* in non ready-to-eat foods. However, additional measures as described in the following guidelines are needed 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 "Proposed Draft 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 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, Rev. 4-2003).

3.2 Hygienic Production of Food Sources

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003).

3.3 Handling, Storage and Transport

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003).

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, Rev. 4-2003).

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.

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 6.3).

4.2.3 Temporary/mobile premises and vending machines

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene.

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 any 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, Rev. 4-2003).

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, Rev. 4-2003).

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, Rev. 4-2003).

4.4.2 Drainage and waste disposal

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003).

4.4.3 Cleaning

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003).

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, Rev. 4-2003).

4.4.5 Temperature control

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003).

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.

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) to minimise growth during holding. 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.

[6] Any appropriate treatment that kills Listeria.

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, Rev.4-2003).

In some products single parameters, such as a pH less than 4.0, 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 process effectiveness in situations where combinations of parameters or bacteriostatic conditions are used.

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).

5.2.3 Microbiological and other specifications

(currently under development)

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 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, 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 lower risk for being a vector for cross contaminating other ready-to-eat foods, because 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 higher risk for being a vector for cross contaminating other ready-to-eat products because neither ready-to-eat products may be 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, Rev. 4-2003).

5.3 Incoming material requirements

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003).

5.4 Packaging

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003).

5.5 Water

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003).

5.5.1 In contact with food

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003).

5.5.2 As an ingredient

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003).

5.5.3 Ice and steam

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003).

5.6 Management and supervision

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003).

5.7 Documentation and records

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003).

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 recontaminated 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 equipment such as support structures for equipment, 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. Equipment food contact surfaces 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, Rev. 4-2003).

6.3.1 General

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003).

6.3.2 Preventing access

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003).

6.3.3 Harbourage and infestation

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003).

6.3.4 Monitoring and detection

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003).

6.3.5 Eradication

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003).

6.4 Waste management

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003).

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, Rev. 4-2003).

7.2 Illness and injuries

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003).

7.3 Personal cleanliness

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003).

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, Rev. 4-2003).

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) that minimises the growth of *L. monocytogenes* in foods that support growth.

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, Rev. 4-2003).

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;
- 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, Rev. 4-2003).

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[7] Code of Hygienic Practice for the transport of food in bulk and semi-packed food (CAC/RCP 47-2001)

9.2 Product information

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003).

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;
  - use 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, Rev. 4-2003).

10.4 Refresher Training

Refer to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003)

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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 RTE 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 a prior to packaging, present a higher risk of directly contaminating the product, while for non food contact surfaces the risk will depend on the location.

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 formal 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 anticipated action plan should be designed 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 risk of contaminating the product.

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.

ANNEX II: (Under development)

APPENDIX III

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

(at Step 5 of the Procedure)

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PROPOSED 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[3]. 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).

1. SCOPE

These principles and guidelines provide a framework for the MRM process and are intended for use by Codex and countries[4], 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**[5] and consumers who are involved in MRM on a day-to-day basis.

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

2 Adopted by the 26th session of the Commission (see ALINORM 03/41). Note that the development of working Principles for Risk Analysis to be applied by Governments is under consideration by the CCGP (see ALINORM 04/27/33A).

3 See CAC/GL-30 (1999).

4 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 Procedural Manual – 14th Edition – p. 6.

5 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[6], 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*[7], 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*[8], and the definition of **interested parties** included in *The Working Principles for Risk Analysis for Application in the Framework of the Codex*[9] 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 hygiene control measures*[10].

Risk manager[11] is defined as follows: a national or international governmental organisation with responsibility for MRM.

For the purpose of this document, the FSO, PO and PC shall apply to microbial hazards.

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[12] differences in hazards in the food chain and regional differences in available risk management options.

•PRINCIPLE 8: MRM decisions should be subject to review and revision.

4. GENERAL CONSIDERATIONS

Codex and government decisions and recommendations have as their primary objective the protection of the health of consumers. 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.

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6 Procedural Manual, 14th Edition (pp.43-47, English version)

7 Annex to CAC/RCP 1-1969, Rev. 4-2003

8 See CAC/GL 21 - 1997

9 See ALINORM 03/41

10 Document CX/FH 04/9

11 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.

12 See CX/FH 98/13 on the meaning of the word "regional"

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.

MRM should follow a structured approach that includes preliminary MRM activities, identification and selection of MRM options, implementation of MRM options, 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[13] 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 and 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 use patterns associated with food, consumers' perception and the prevalence of specific adverse health.

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.

Annex I illustrates the typical components of the MRM process.

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.

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13 See Procedural Manual, 14th Edition : Criteria for the Consideration of the others factors (p.188)

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..

Some food safety issues may require that an [immediate decision/emergency measure] be taken by the risk manager without further scientific consideration (e.g. withdrawal / recall of contaminated products). Countries will often not be able to delay taking an [emergency] action when there is an immediate public health concern demanding an urgent response.

[Where scientific knowledge is insufficient, it may be appropriate to apply a precautionary approach through provisional decisions[14]**.** 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. **Annex II** 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 [provisional] decision (see section 5.1 above). In some cases, no further action may be needed.

Within CCFH, the compilation of a risk profile may result in the establishment of a working group to evaluate the food safety issue in the international context, considering the results of any FAO/WHO Joint expert consultation on MRA (JEMRA) or national MRA concluded or ongoing. The risk profile provides the Committee with an initial analysis and recommendations related to 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[15]. National governments should establish a MRA policy relevant to their circumstances, in advance of the microbiological risk assessment.

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.

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 can be reviewed by the scientific community parties.

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[14] See the Draft working principles for risk analysis to be applied by countries, under consideration by the CCGP (see ALINORM 04/27/33A)

[15] See Section on Risk Assessment Policy – p. 102-103 (Procedural Manual – 14th Edition – English version). This reference should be extended as soon as the Codex Alimentarius Commission adopts the Proposed Draft Working Principles for Risk Analysis for Food Safety, currently under elaboration.

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 adequate to proceed further in developing and/or evaluating and deciding on suitable MRM options, [or deciding on provisional MRM options] if some elements of the MRA need further study**.**

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 acceptable level and any practical issues regarding the implementation of the selected MRM options that need to be managed.

Examples of 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;
- furnishing of data that demonstrate relationships between different risk estimates and FSOs,
- compilation of an appropriate guidance document, including specific recommendations and practices. When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence. [16] .

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 , [traceability/product tracing];
- adapt Codex recommendations and guidance documents 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 POS, PCs and MCs at specific stages of the food/feed[17] 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;
- require import certificates for certain products;

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16 Statement adopted by the 24th Session of the Commission (ALINORM 01/41 para. 81)

17 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.

- promulgate awareness and develop educational and training programs to enforce or stipulate that:
  - prevention of contamination and/or introduction of hazards is addressed at all relevant stages in the food/feed chain;
  - rapid withdrawal/recall of food procedures are in place, including appropriate [traceability/product tracing] for effectiveness;
  - properly labelling with 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 practical should generally involve 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 various 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 (see below).

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 as far as possible some flexibility in options that the industry can use to achieve the desired level of control.

6.2.2 Risk-based MRM options

The increasing adoption of risk analysis is allowing more quantitative and 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 development of new MRM tools such as FSO, PO and PC and the enhancement of the scientific basis of existing MRM tools such as microbiological criteria (MC).

It is difficult to relate control measures directly to an ALOP, particularly when it is implicit or expressed in qualitative terms (such as “reasonable certainty of no harm”[18]), and not in quantitative terms (such as a “number of illnesses/year”). Therefore the concept of FSO has been introduced. Effective MRM typically requires that additional risk-based milestones be established at particular steps in the food chain to ensure the ultimate food safety outcome. As a means of addressing this need, PO and PC have been introduced.

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[18] See OECD document

There is a hierarchy between the concepts of FSO, PO and PC. Conceptually, an FSO is derived from the ALOP, whereas a PO and/or a PC are derived from an FSO. However, also in the absence of an ALOP or an FSO, the concepts of PO and PC may be potential options for risk managers to guide the establishment of process requirements in operational practice. The availability of a MRA can help in deciding upon the need and for choosing the best step where to apply PO, PC or particular control measures.

6.2.2.1 Food Safety Objective (FSO)

A food safety objective is defined as **"***the maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP)*". Because of the link between FSO and ALOP, FSOs are established only by national competent authorities. Codex can help in establishing FSOs, for instance through recommendations based on national or international MRAs. FSOs are seldom verifiable as regulatory standards as they apply at the time of consumption. They should be given effect by actions at earlier stages in the food chain by the competent authority and/or the individual food business operator (e.g. food manufacturer) setting POs, PCs or MCs, as appropriate.

There are two approaches to establishing an FSO. One is based on an observation of the public health status, mainly with the help of epidemiological surveys (see section 8). The other is based on experimental or other scientific evidence to develop a risk characterisation curve linking hazard levels to disease incidence. If such a curve is available for a given hazard, it can be a helpful basis to relate the FSO to the ALOP.

In countries, FSOs can be used:

- to express the ALOP (whether explicit or implicit) as a more useful parameter for the industry and other interested parties;
- to encourage change in industry food safety control systems, or in the behaviour of consumers, in order to enhance the safety of certain products;
- for communication to parties involved in food trade;
- as a performance target for entire food chains to enable industry to design its operational food safety control system (through establishing appropriate POs, PCs and other control measures and interaction between the participants of the food chain in question).

Notably, FSOs may not be universally common and may take into account regional differences.

6.2.2.2 Performance Objective (PO)

A performance objective is defined as "*the maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable"*.

The frequency and/or concentration of a hazard at individual steps throughout the food chain can differ substantially from the FSO. Therefore, the following generic guidelines should apply:

- If the food is likely to support the growth of a microbial hazard between the point of the PO and consumption, then the PO will necessarily have to be more stringent than the FSO. The difference in stringency will depend on the magnitude of the increase in levels expected;
- If it can be demonstrated and-validated that the level of the hazard will decrease after the point of the PO (e.g. cooking by the final consumer), the PO may be less stringent than the FSO. By basing a PO on the FSO, the frequency of cross-contamination could also be factored into the control strategy. For example, establishing a PO for frequency of salmonellae contamination of raw poultry earlier in the food chain would contribute to a reduction of illness associated with poultry mediate cross- contamination in the steps to follow;
- If the frequency and/or concentration of the hazard is not likely to increase or decrease between the point of the PO and consumption, then the PO and the FSO would be the same. An MRA can assist in determining such relationships.

An MRA can also provide the risk manager with knowledge of hazard levels possibly occurring at specific steps in the chain and of issues regarding the feasibility in practice to comply with a proposed PO/FSO. In designing their food safety control system such that the PO (set by government or the individual food business) and the FSO (set by government) are met, the individual food business)will have to make provisions respecting their ability to consistently meet these standards in operational practice, including consideration of a margin of safety.

The individual food business may find it beneficial to establish its own POs. The POs should normally not be universally common and should take into account the position of the business within the food chain, the various conditions at the subsequent steps in the food chain (probability and extent of pathogen growth under specified storage and transport conditions, shelf-life, …) and the intended use of the end products (domestic consumer handling, …). Although POs are generally not intended to be verified by analytical means, compliance with POs may need to be verified by other means, such as:

- establishment of a statistically-based MC for end products;
- monitoring and recording of pertinent validated control measures;
- surveillance or screening programs on the prevalence of a microbial hazard in a food (especially relevant for POs established by competent authorities).

6.2.2.3 Performance Criterion (PC)

A performance criterion is defined as "*the effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO"*.

PCs are generally set by individual food business. However, PCsmay be set by national governments, for a specific control measure, where its application by industry is generally uniform and/or as advice to food businesses that are not capable of establishing PCs themselves.

The PC can be expressed e.g., in terms of a desired reduction (or acceptable increase) in the concentration and/or frequency of a hazard in the course of a particular control measure, e.g. the result of a particular treatment.

Generally, PC either relate to a control measure with a microbiocidal and/or microbiostatic effect. A PC for a microbiocidal control measure (e.g. heat treatment) expresses the desired reduction of the microbial population that occurs during the application of the control measure. A PC for a microbiostatic control measure (e.g. chilling) expresses the maximum increase in the microbial population that is acceptable under the various conditions during which the measure is applied.

Such PCs are often translated by industry or sometimes by competent authorities, into **process criteria**[19] or **product criteria**. For example, if a PC indicated that a heat treatment should provide a 5-log reduction of a hazard, then the corresponding process criterion would stipulate e.g. the specific time and temperature combination(s) that would be needed to achieve the PC. Similarly, if a PC required that an acidification treatment of a food reduces the rate of growth of a hazard to less than 1-log in two weeks, then the product criterion would be the specific acid concentration and pH that would be needed to achieve the PC. The concepts of process criteria and product criteria have been long recognised and used by industry and competent authorities.

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[19] For the purposes of this document a process criterion is understood to mean " parameters of a control measure that if properly applied have been established as meeting, either alone or in combination with other control measures, a performance criterion" and a product criterion is understood to mean "a physical or chemical attribute of a product that if properly applied as a control measure has been established as meeting, either alone or in combination with other control measures, a performance criterion."

6.2.2.4 Microbiological Criterion (MC)

Consequent to the introduction of the concepts of FSO/PO/PC, the role of MC may expand. There will still be a use for MC in assessing compliance of tested lots or consignments of food/feed when there is no information available on how or under what conditions the food/feed was produced. Obviously, MC may also find utility to verify the continuing effectiveness of all or part of a food safety control system (e.g. HACCP). As such, MC may provide an objective means of verifying that a PO or PC (or a FSO) is met.

For the purpose of food safety control system validation, monitoring or verification, the extent of analytical testing (and consequently the elements constituting the MC) depends on the risk and consequence of loss of control, the degree of uncertainty associated with the control of the hazard, the degree of confidence required, and the statistical methods being employed.

In general, an MC will have to be more stringent than the PO or PC upon which it is based, in order to assure that the PO is being met with a specified level of confidence. Care must be taken to ensure that the basic assumptions underlying the selection of the parameter to be measured are scientifically valid (e.g., the assumption that the presence and extent of contamination of a food with *Escherichia coli* is directly related to the extent of faecal contamination).

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 provisionalMRM 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 appropriate targets (POs) that will achieve or contribute to established FSOs;
- 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][20] 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 information, etc…, and otherwise assist 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, hygienic handling labels, date labels, and public interest messages. Consumer organisations can play a significant role in getting this information to consumers.

8. MONITORING AND REVIEW OF MRM OPTIONS

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. Ongoing monitoring is essential to establish a baseline for comparing the effectiveness of new MRM options. 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 are needed 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 options. 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;

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[20] See on-going work of the CCFICS

- surveillance based on laboratory tests of pathogens isolated from humans, plants, animals, foods, and food processing environments for pertinent foodborne hazards;
- environmental hygienic data on 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 options

The effectiveness and appropriateness of the MRM options 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 option(s) selected and implemented.

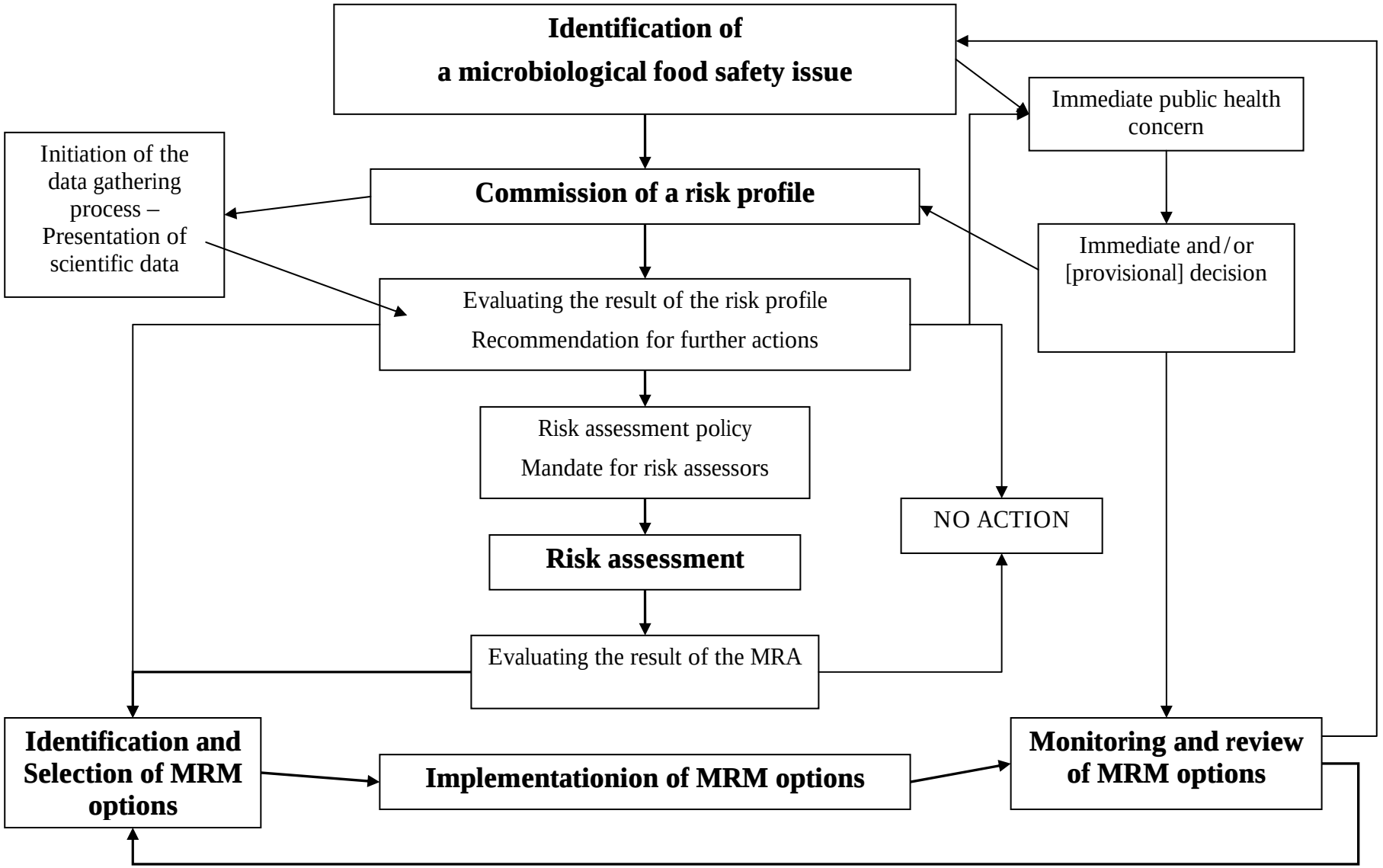
Planning periodic review of MRM options is the best way to assess whether or not the expected consumer health protection is delivered. On the basis of a review of the information collected through the various appropriate monitoring activities, a decision may be taken to amend the MRM option implemented or to substitute the option for another one.

MRM options should be reviewed when new options 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 options 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 (including Codex) consider to take, should be made public and communicated to all interested parties.

ANNEX I: Overall framework for managing foodborne risks



ANNEX II

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 o Annual incidence rate in humans including, if possible, any differences between age and sex
        - Outcome of exposure o Severity of clinical manifestations (e.g., case-fatality rate, rate of hospitalisation)
        - Nature and frequency of long-term complications
        - Availability and nature of treatment o 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

ANNEX III: (Under development)

APPENDIX IV

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR EGGS AND EGG PRODUCTS

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ANNEX I (Under development)

INTRODUCTION

This International Code of Hygienic Practice for Eggs and Egg Products is intended to provide guidance for the safe production of eggs and egg products. The 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.

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, Rev. 4, 2003) 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 and egg products of domesticated birds, intended for human consumption. Traditional delicacy eggs (e.g. Balut, 1000 year old eggs) are not within the scope of this code.

This Code applies to eggs in the shell, produced by domesticated birds, for human consumption.

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, Rev. 4, 2004).

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*, when they apply to the hygienic production of eggs and egg products.

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

[1] Safety and suitability as defined in the *Recommended International Code of Practice: General Principles of Food Hygiene* (CAC/RCP 1- 1969, Rev. 4, 2003).

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.

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

The Code is a flexible one 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 *Guidance to Governments on the Application of HACCP in Small and/or Less Developed Businesses* (document in preparation by FAO/WHO).

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. Guidance on validating control measures should be obtained from the Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures *(under development).*

  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.
- 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, Rev. 4, 2003). 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 General Principles of Food Hygiene*. 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 managed 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 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* 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 (SE)[2] *Risk Assessment has shown that reducing the prevalence of* SE *infected flocks is anticipated to result in a reduction in the risk of human illness from the consumption of* SE *positive eggs*[3].

[2] CX/FH 05/37/10- Discussion paper on the Guidelines for the Application of the General Principles of Food Hygiene to the Risk-Based Control of Salmonella spp. is being reviewed by the Codex Committee on Food Hygiene.

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

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[4]. In particular, measures to prevent disease include:

- 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 permitted for the specific use, 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 and the identity of the flock.
  - 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.
- Where permitted, treating new stock with veterinary drugs.
- Particularly for countries where SE 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[5]. 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.
- 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.

[4] Proposed Draft Code of Practice to Minimize and Contain Antimicrobial Resistance (ALINORM 05/28/31, Appendix VIII) sent by 15th CCRVDF to the 28th CAC for adoption.

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

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.

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[6].

The following could 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 animals 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 management 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.

[6] 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

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. In the case of free-range production, bird access to surface water, such as after rain, is acceptable except where the source is of suspect quality e.g. stagnant ponds. 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.
- 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.

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

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.
  - 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 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.
- 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 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 of 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
- [Traceability[8]] and recall.

[8] Refer to principles on traceability under development in the Codex Committee on Food Inspection and Import and Export Certification Systems: Discussion Paper on Traceability/Product Tracing in the Context of Food Inspection and Certification Systems (CX/FICS 04/13/6)

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;
- 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, Rev. 4, 2004), 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 intended for hatching.

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.

[9] Refer to definition of safe and suitable in the Recommended Code of Practice General Principles of Food Hygiene Section 2.3 Definitions.

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) and be disposed of in a safe manner.*
- *Broken/leaker eggs should not be used to produce egg products or 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.*

Risk-based control measures 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 (SE).

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 Processing 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.

Processing 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 processing 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 sorting, 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 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 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 microbiological growth, due to reasonably anticipated temperature abuse during storage, distribution, retail, sale and handling by the consumer.

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.

[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.

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.

(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.

Dried 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.

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.

5.3 INCOMING MATERIAL REQUIREMENTS

Refer to the *Recommended International Code of Practice- General Principles of Food Hygiene*.

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*.

5.5 WATER

Refer to the *Recommended International Code of Practice- General Principles of Food Hygiene*.

5.6 MANAGEMENT AND SUPERVISION

Refer to the *Recommended International Code of Practice- General Principles of Food Hygiene*.

5.7 DOCUMENTATION AND RECORDS

Refer to the *Recommended International Code of Practice- General Principles of Food Hygiene*.

5.8 RECALL PROCEDURES

Refer to the *Recommended International Code of Practice- General Principles of Food Hygiene*.

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.*

6.1 MAINTENANCE AND CLEANING

Refer to the *Recommended International Code of Practice- General Principles of Food Hygiene*.

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*.

6.4 WASTE MANAGEMENT

Refer to the *Recommended International Code of Practice- General Principles of Food Hygiene*.

6.5 MONITORING EFFECTIVENESS

Refer to the *Recommended International Code of Practice- General Principles of Food Hygiene*.

7 ESTABLISHMENT: PERSONAL HYGIENE

Refer to the *Recommended International Code of Practice- General Principles of Food Hygiene*.

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 Foodstuffs in Bulk and Semi-Packed Foodstuffs*. (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 avoid 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*.

9.1 LOT IDENTIFICATION

Refer to the *Recommended International Code of Practice- General Principles of Food Hygiene*.

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 no shorter than the shelf life 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*.

9.3 LABELLING

Egg products should be labelled in accordance with the Codex *General Standard for the Labelling of Prepackaged Foods* (Codex Standard 1-1985, Rev. 1 – 1991).

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*.

ANNEX I: (Under development)

APPENDIX V

MANAGEMENT OF THE WORK OF THE CODEX COMMITTEE ON FOOD HYGIENE

The Proposed 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 other Codex Committees, Task Forces, and 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; the approach to interaction of CCFH with other Codex Committees and/or Task Forces on items of mutual interest; 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 will establish an *ad hoc* Working Group for the Establishment of CCFH Work Priorities ("*ad hoc* Working Group") at each Session.

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

ii. New work and/or revision of an existing standard may be proposed by the Committee on its own initiative, by another Codex subsidiary body upon referral to CCFH or by an individual member or members.

iii. Proposals for new work received in response to the Codex Circular Letter will be transmitted to the *ad hoc* Working Group Chair by the Host Country and Codex Secretariats.

iv. The Chair 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.

v. The *ad hoc* Working Group will meet on the day before the opening 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 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.

vi. At the CCFH session, the *ad hoc* Working Group Chair will introduce the recommendations of the *ad hoc* Working Group to the Committee. The CCFH will decide whether a proposal for new work and/or revision of an existing standard is accepted, returned for revision, or denied. If accepted, a project 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. As specified in the Codex *Procedural Manual*, work undertaken by the CCFH should fall within its Terms of Reference, should be consistent with the strategic plan and the general procedures established by the Codex Alimentarius Commission, and should meet the Codex *Criteria for the Establishment of Work Priorities*.

6. The proposals for new work shall be in written form and consistent with, and include the specified elements of the project document[3] required for approval of new work by the Codex Alimentarius Commission. The proposals for new work will include a Risk Profile[4], 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).

7. 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.

8. The proposal for new work may also:

- address an issue that affects progress within CCFH or by other committees;
- 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, Rev. 4-2003).

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1 Codex *Procedural Manual*, 14th Edition.

2 The elements of a project document are described in the Codex *Procedural Manual*, 14th Edition.

3 Specifications for project document as approved by CAC at its 27th Session. Codex Procedural Manual, 14th Editions.

4 Definition of a risk profile is "the description of the food safety problem and its context" (Codex *Procedural Manual*, 14th Edition). The elements of a risk profile are provided in the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management.

Prioritization of Proposals for New Work

9. The Committee will prioritize its proposals for new work at each CCFH meeting. 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. The recommendations will include a prioritization of proposals for new work that meet the criteria specified by the CAC[5] and if necessary, additional criteria specified in a Terms of Reference the *ad hoc* Working Group to be prepared by the Committee to. 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 proposal for new work needed to control an urgent public health problem.

10. The A*d hoc* Working Group will also assess and provide recommendations to CCFH on the need for cross-committee interactions (see below).

11. If the proposed new work will benefit from the acquisition of additional expert scientific advice such as an international risk assessment, the need for obtaining the advice from FAO/WHO should also be considered in prioritizing work (see below).

Process for Commencement of Proposals for New Work within CCFH

12. Upon approval of the proposal for new work and/or revision of an existing standard by the CAC, the work will be undertaken through the Codex Step Procedure as provided for in the Codex *Procedural Manual "Procedures for the Elaboration of Codex Standards and Related Texts"*.

13. An electronic or physical working group may be established to assist the Committee to undertake the work. Working groups established by the Committee will follow the criteria established by CAC.[6]

14. As necessary and appropriate, CCFH work will request a risk assessment or other expert scientific advice from FAO/WHO using the procedure outlined below.

Obtaining Scientific Advice

15. 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, etc.), 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). The Committee will also keep in mind the Codex *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*[7].

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

i. Sufficient scientific knowledge and data to conduct the needed risk assessment are available or obtainable in a timely manner. (An initial evaluation of available knowledge and data will typically be provided within the Risk Profile.)

ii. There is a reasonable expectation that a risk assessment will provide results that can assist in reaching risk management decisions related to control of the microbiological hazard without unduly delaying the adoption of the needed microbiological risk management guidance.

iii. Risk assessments performed at the regional, national and multinational levels that can facilitate the conduct of an international risk assessment are available.

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5 ALINORM 05/28/33; Appendix V.

6 Criteria developed for adoption by the Commission. See report of the 21st CCGP, ALINORM 05/28/33, Appendices V and VI.

7 Codex *Procedural Manual,* 14th edition.

17. 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[8]. While CCFH establishes its own priorities it is recognized that any requests to FAO/WHO for scientific advice including risk assessments will be subject to FAO/WHO work prioritization criteria as agreed at the 55th session of CCEXEC[9]. 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).

18. 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). The iterative process is described in Annex I.

19. 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 at Committee session or working group, as feasible, to provide guidance on the appropriate interpretation of the risk assessment.

20. 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).

Providing for Cross-Committee Interaction to Conduct CCFH Work

21. It is noted that there are already some mechanisms in place to facilitate cross-committee interactions through the regular agenda item, Matters Referred, from the CAC and other Codex Committees. It is also noted that the Codex Committee structure and mandates of Codex Committees and task forces is being subjected to external review. The outcome of this review may affect the interaction of CCFH with other Codex Committees. The need for guidance to facilitate interaction between CCFH and other committees will be further considered after the CAC responds to this external review.

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8 Codex *Procedural Manual*, 14th Edition, p. 46 (definition of risk assessment policy) and pp. 102-104 (working principles relating to risk assessment policy).

9 ALINORM 05/28/3 (para 75).

Annex I

ITERATIVE PROCESS BETWEEN THE CODEX COMMITTEE ON FOOD HYGIENE AND FAO/WHO FOR THE CONDUCT OF MICROBIOLOGICAL RISK ASSESSMENT

The Codex Committee on Food Hygiene recognizes that an iterative process between risk managers and risk assessors is essential for the adequate undertaking of any microbiological risk assessment and the development of any microbiological risk management guidance document or other CCFH document(s). In particular, dialogue between the Committee and FAO/WHO is desirable to thoroughly assess the feasibility of the risk assessment, to assure that risk assessment policy are clear, and to ensure that the risk management questions posed by the Committee are appropriate. If FAO/WHO agrees that the requested risk assessment proposed in the Risk Profile is feasible and will be undertaken, a series of planned interactions between the FAO/WHO JEMRA and the Committee or its Working Group established to develop the risk management guidance document should be scheduled to assure effective interaction. In certain instances when the subject matter would benefit from additional interaction with other Codex Committees or other FAO/WHO risk assessment bodies, these committees should be included into the iterative process.

It is essential that communications between these entities are timely and effective. Any intermediary (i.e., Working Group) assigned by the Committee to serve as a liaison with the FAO/WHO (JEMRA) will need to report the progress and facilitate decision making in both a timely and effective manner so that progress in the development of a risk assessment (and the CCFH work products derived from it) is not unduly delayed.

The Committee and/or its liaison (i.e., the Working Group) is likely to receive questions from FAO/WHO or the designated risk assessment body (e.g., JEMRA) relating to the requested microbiological risk assessment(s). The questions may include those needed to clarify the scope and application of the risk assessment, the nature of the risk management control options to be considered, key assumptions to be made regarding the risk assessment, and the analytical strategy to be employed in the absence of key data needed to perform the risk assessment. Likewise, the Committee and/or its liaison (i.e., the Working Group) may pose questions to FAO/WHO or their designation (JEMRA) to clarify, expand, or adjust the risk assessment to better address the risk management questions posed or to develop and/or understand the risk management control options selected. Timely, appropriate responses are needed for these interactions.

The Committee may elect to discontinue or modify work on a risk assessment if the iterative process demonstrates that: 1) completion of an adequate risk assessment is not feasible; or 2) it is not possible to provide appropriate risk management options. However, FAO/WHO may decide to continue the work if it is considered necessary to meet the needs of their member countries.

APPENDIX VI

TERMS OF REFERENCE FOR THE FAO/WHO EXPERT CONSULTATION ON THE USES OF ACTIVE CHLORINE (ASPECTS RELEVANT TO CCFH)

QUESTIONS FOR CONSIDERATION

CCFH recommends that the terms of reference for the expert consultation to be conducted by FAO/WHO include consideration of the microbiological benefits from the treatment of food, food processing water, or food contact surfaces with different forms of active chlorine and the potential risks that might arise if these compounds were no longer available. The primary benefits include elimination of potential contamination with pathogenic and non-pathogenic microorganisms from the direct treatment of foods with active chlorine, and the elimination of contamination or cross contamination from food processing water and food contact surfaces. Accordingly, the microbiological risks of concern, if these agents are no longer available, are potential increases in foodborne disease due to increased contamination with pathogenic microorganisms and decreases in food quality and availability due to increases in non-pathogenic spoilage microorganisms. The risk assessment to be conducted by Expert Consultation should focus on specific microbial hazards (e.g., specific pathogens) and specific spoilage issues associated with particular foods or food processing environments that are currently controlled by the use of active chlorine. Risks considered should include whether the treatment itself or elimination of such treatment could result in increased exposure to microbial hazards under some conditions and decreased availability of foods.

The risks and factors that should be considered by the expert consultation include:

- the risk of increased exposure to microbial hazards or increased microbial loads associated with different types of food or food processing surfaces
- the availability of alternative technologies or treatments that could be used as an alternative to active chlorine in order to control microbiological contamination
- the relative efficacy of alternative technologies or treatments both in terms of effectiveness and relative cost of application in comparison to chlorine
- the risks associated with the application of alternative technologies or treatments
- potential “unintended consequences” arising from the reduction or substitution in the use of active chlorine as an antimicrobial treatment (e.g., the generation of mutagenic compounds due to the application of heat treatments, the emergence of antimicrobial resistance in response to alternative antimicrobials, the growth of pathogenic micro-organisms following the (partial) removal of the initial flora by application of antimicrobial substances).

The consultation should focus on consideration of data on which pathogen/food spoilage microorganism-food commodity combinations are currently controlled effectively by active chlorine treatments. If feasible, the consultation should consider the effectiveness of active chlorine compounds in a quantitative manner to determine if reductions in the levels of active chlorine compounds could be realized without increasing substantially the risk of foodborne disease or food spoilage.

Elements Requiring Elaboration

In evaluating the antimicrobial effectiveness of active chlorine (or their alternatives), the expert consultation should be cognizant of and take into account:

- the differential activity of active chlorine in different types of food due to factors such as time and temperature of application, pH or other characteristics of the food matrix, the level of organic material, water characteristics, the point in the food production process or processing line in which chlorine is used and purity of the active chlorine compounds
- the differential activity of active chlorine as a result of physical state of the medium (e.g., liquid vs. solid, surface vs. interior)
- the different susceptibility of microorganisms on food contact surfaces versus those present in biofilms
- the evaluation of the organoleptic changes in the product following antimicrobial treatment
- evaluation of the effect of antimicrobial treatment on water retention in fresh meat

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

Since the results of the expert consultation are needed to determine if any further consideration of active chlorine should take place within CCFAC, the final report of the risk assessment should be completed within 48 months.

APPENDIX VII

NEEDS OF CCFH FOR THE PROVISION OF SCIENTIFIC ADVICE BY FAO/WHO ON THE APPLICATION OF RISK ASSESSMENT TO RISK MANAGEMENT

Introduction

During the course of the past ten years, the Codex Committee on Food Hygiene (CCFH) has been developing and embracing a risk analysis framework in which it would undertake and carry out its work related to the provision of practical guidance and standards for control of microbiological hazards in foods. This has included the development of new concepts and approaches, such as the application of food safety objectives (FSOs), performance objectives (POs), and performance criteria (PCs), in order to relate public health goals to the level of stringency required for food safety control measures and systems. These new parameters could then be translated into more traditional measures of food safety control stringency such as process criteria, product criteria, and microbiological criteria. However, it has become evident that during the conduct of current projects within CCFH, particularly in relation to the development of the *Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CX/FH 05/37/6, 2005), and the *Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of* Listeria monocytogenes *in Ready-to-eat Foods* (CX/FH 05/37/05), that the work of CCFH would be greatly simplified if there was a single FAO/WHO JEMRA document that could serve as a reference for the concepts, techniques and practical examples of how these new metrics can be determined and interrelated.

At the 37th Session of the Codex Committee on Food Hygiene, the FAO/WHO reported on plans to conduct during 2005 a consultation on "Development of Practical Risk Management Strategies Based on Microbiological Risk Assessment Outputs" (CX/FH 05/37/9). The FAO/WHO proposed that such a consultation be undertaken to address the needs of Codex and member countries. As a means to ensure that the consultation provides information useful to current and future work of CCFH, FAO/WHO requested that CCFH articulate areas of interest that be could addressed as part of the broad goals of the consultation.

Purpose

The purpose of this document is to formally request that FAO/WHO develop, within the framework of ad hoc expert consultations, scientific advice on concepts, methods, and practical examples of (1) how POs and PCs can be related to established public health goals and/or FSOs, and how POs and PCs can, in turn, be translated into more traditional measures of food safety system stringency such as process criteria, product criteria, and microbiological criteria. The ultimate goal of this request would be the availability of a reference document that provides a means for CCFH to address its risk analysis responsibilities, and that ideally could be cited as the explanatory text for the tools that CCFH and countries could use to reach decisions related to these risk management measures. In developing the following terms of reference, the drafters have been particularly cognizant of the current and future needs to relate available risk assessments to the risk management work currently underway in CCFH, including the "*Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management*," the "*Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of* Listeria monocytogenes," the "*Discussion Paper on the Guidelines for the Application of the General Principles of Food Hygiene to the Risk Based Control of* Salmonella *spp. in Poultry*," the "*Discussion Paper on the Guidelines for the application of the General Principles of Food Hygiene to the Risk Based Control of Enterohemorrhagic* Escherichia coli *in Ground Beef and Fermented Sausages*," the "*Discussion Paper on the Guidelines for Risk Management Options for* Campylobacter *in Broiler Chickens*," and the "*Risk Profile for* Vibrio *spp. in Seafood*."

Background

Previous international expert consultations and the development of risk management frameworks by both CCFH and individual member countries have made significant progress on the development of a general framework based on risk analysis for linking public health goals for control of foodborne disease with the degree of stringency required of food safety measures to achieve those goals. This involves a process using

risk assessment techniques to establish the relationship between incidence and severity of disease and the frequency and extent of contamination, i.e. establishment of a FSO. From this relationship and knowledge of the dynamics of pathogen growth, survival, and inactivation, the framework calls for the establishment of scientifically defensible POs and PCs at specific points within the food chain. A major limitation in translating FSOs to POs and PCs is the clear articulation of practical concepts and methods by which the variability and uncertainty identified in the assessment of risk can be evaluated and considered in the decision making process. Practical guidance on how to establish a PO or PC based on a FSO is critical to advancing the application of the microbiological risk management principles being developed by CCFH.

The risk management principles currently being developed within CCFH have also highlighted the desirability of using POs and/or PCs to serve as the basis for more scientifically establishing traditional control measures. These include microbiological criteria, product criteria, and process criteria that are employed to establish the level of control required and verifying that that level of control is achieved. However, there is currently limited practical guidance available on how to interrelate these two classes of food control measures (i.e., PO/PC and microbiological criteria/process criteria/product criteria), particularly in relation to sampling and analytical requirements.

While the general framework has been established, there have been few attempts to actually use it. Thus, CCFH and its members countries and international organizations are still not fully cognizant of the details that would have to be addressed in successfully developing a risk analysis based system wherein public health goals define the criteria used to establish the required level of food safety stringency.

Questions for Consideration

The overarching questions that should be addressed by the consultation are what are the means and methods for achieving the following goals and what are the limitations associated with such a risk analysis based approach?

- Establish the context of the FSO/PO concept as a part of a risk management option in relation to the application of a risk based approach
- Establish a FSO that is based on different expressions of ALOP.
- Establish one or more POs at specified points along the food chain that can be related to a FSO,
- Derive, when appropriate, a PC based on an established PO for a specified site along the food chain,
- Derive metrics for food safety stringency (e.g., microbiological criteria, product criteria, process criteria) that can be used to verify that a PO is being met, and
- Assess the impact that compliance to these metrics has on the ability to achieve the public health goals and the stringency and verification required of the system.

In considering these questions, the consultation should provide practical advice and techniques for establishing one or more of the metrics above, when one or more of the metrics “upstream or downstream in the food chain” has not been determined (e.g., establishment of an FSO without an ALOP, establishment of a PO without a FSO and/or ALOP). The consultation should also provide clear advice on the limitations associated with this approach and additional approaches where it is not possible to apply the FSO/PO concept.

In addressing each of these methodological areas, the consultation should provide advice and recommended methods for addressing the diversity that is likely to occur within the food industry in the ingredient sources, manufacturing technologies, marketing strategies, and consumption profiles. In addition, the consultation should provide clear guidance on strategies for verifying that the different metrics are being met, including articulation of methods for assessing the “statistical confidence” for verification strategies. The consultation should provide specific recommendations regarding the types and extent of data that will be needed to deal adequately with the uncertainty and variability associated with food products, particularly those in international trade. Likewise, the consultation should provide specific advice on how to calculate the statistical confidence of strategies for verifying the effectiveness of food control systems.

The development of well articulated realistic examples of how these concepts and techniques can be applied is critical to CCFH being able to adopt a risk analysis approach to its work. There is a wide range of food each with its unique characteristics and hazards. Likewise, there are diverse sites along the food chain where

foods can be become contaminated. Thus, a single example is likely to be insufficient to adequately describe the different approaches that may be required to fully consider the subject matter. Accordingly, the consultation is requested to consider the four product/pathogen pairs listed below. These have been selected to provide examples to include different sites of contamination (e.g., post-processing, primary production, during preparation), modes of disease (e.g., infection of general population, infection of specific susceptible populations, intoxication), potential mitigations (e.g., primary production, processing, marketing), and likely sites for the establishment of POs (i.e., primary production, manufacturing, marketing, and preparation). They have also been selected, in part, because of the availability of a risk assessment or extensive scientific knowledge and/or the need for such information in conjunction with a CCFH project currently underway.

- *Listeria monocytogenes* in a smoked fish
- *Salmonella* and *Campylobacter* in raw broilers
- *Staphylococcus aureus* enterotoxin in a crème-filled pastry
- *Vibrio parahaemolyticus* in raw oysters

Utilization of Existing Information

Wherever feasible, the expert consultation should identify and make use of exiting risk evaluations and risk assessments, particularly in relation to the development of examples pertinent to the current activities of CCFH. In developing methods and practical examples, the consultation should be aware of and take into consideration frameworks and technical information developed by the World Health Organization, the Food and Agriculture Organization and the Codex Alimentarius (e.g., *Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CX/FH 05/37/6, 2005), *WHO Expert Consultation - The Interaction between Assessors and Managers of Microbial Hazards in Food*, (Kiel, Germany, March 2000), and *WHO Expert Consultation - The Principles and Guidelines for Incorporating Microbiological Risk Assessment in the Development of Food Safety Standards, Guidelines and Related Texts*, (Kiel, Germany, March 2002), "Microorganisms in Foods 7: Microbiological Testing in Food Safety Risk Management," (ICMSF, 2002).

Time Frame

Since the results of the consultation are needed to provide concepts, techniques, and examples needed as reference material for the completion of several active documents being developed by CCFH, the final report of the consultation is needed in 14 months.