

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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ALINORM 04/27/13

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-seventh Session

Geneva, 28 June - 03 July 2004

REPORT OF THE THIRTY-SIXTH SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE

Washington D.C., United States of America, 29 March - 03 April 2004

NOTE: *This report includes Codex Circular Letter CL 2004/11-FH*

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CX 4/20.2

CL 2004/11 - 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-sixth Session of the Codex Committee on Food Hygiene (ALINORM 04/27/13)

The report of the Thirty-sixth Session of the Codex Committee on Food Hygiene (CCFH) is attached. It will be considered by the Twenty-seventh Session of the Codex Alimentarius Commission, Geneva, 2004.

A. MATTERS FOR ADOPTION BY THE CODEX ALIMENTARIUS COMMISSION:

1. Draft Code of Hygienic Practice for Milk and Milk Products at Step 8 (ALINORM 04/27/13, Appendix II). See also paras. 15 through 53 of this report.

Governments wishing to comment on the above matter should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts at Step 8 (*Procedural Manual of the Codex Alimentarius Commission*, Thirteenth Edition). Comments or proposed amendments should be sent to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00100 Rome, Italy preferably by e-mail: codex@fao.org or fax: +39 06 570.54593 **before 15 May 2004.**

2. Definitions on Food Safety Objective, Performance Objective and Performance Criterion (ALINORM 04/27/12, Appendix III). See also paras. 63-90 of this report.

Governments wishing to comment on the above matter should do so in writing. Comments should be sent to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00100 Rome, Italy preferably by e-mail: codex@fao.org or fax: +39 06 570.54593 **before 15 May 2004.**

B. REQUEST FOR COMMENTS AND INFORMATION:

1. Discussion Paper on the Management of the Work of the Committee (ALINORM 04/27/13, Appendix IV) See also paras. 54-62 of this report.

Governments and interested international organizations are invited to provide their comments on the above subject matter. Comments should be forwarded to F. Edward Scarbrough, U.S. Manager for Codex, Attn.: S. Amjad Ali, Room 4861 - South Bldg., Food Safety and Inspection Service, United States Department of Agriculture, 1400 Independence Ave. S.W., Washington D.C. 20250, U.S.A. (Fax No.:1.202.720.3157; E-mail: syed.ali@fsis.usda.gov), with a copy to Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00100 Rome, Italy, by Fax: +39 06 570.54593 or E-mail: Codex@fao.org **before 1 July 2004.**

2. Proposed Draft Revision of the Code of Hygienic Practice for Eggs and Egg Products. See also paras. 101-106 of this report.

Governments and interested international organizations are invited to provide their comments on: processing of egg products, including emerging technologies; pasteurisation of eggs and egg products; hygienic provisions related to processing of egg and egg products; advice on the safe use and handling of eggs with particular focus on vulnerable groups; clarification of definitions, including collection and handling, grading and cleaning.

Comments should be forwarded to **Dr Luba Tomaska**, Food Standards Australia New Zealand, 55 Blackall Street, Barton ACT 2600, PO Box 7186, Canberra, MC ACT 2610, fax: 61-2-6271-2278, Email: luba.tomaska@foodstandards.gov.au with a copy to Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00100 Rome, Italy, by Fax: +39 06 570.54593 or E-mail: Codex@fao.org **before 1 July 2004.**

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SUMMARY AND CONCLUSIONS

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

MATTERS FOR ADOPTION BY THE 27TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION:

1. **Draft Code of Hygienic Practice for Milk and Milk Products** (ALINORM 04/27/13, paras. 15-53 and Appendix II).
2. **Definitions on Food Safety Objective, Performance Objective and Performance Criterion** (ALINORM 04/27/13, paras. 63-90 and Appendix III).

MATTERS OF INTEREST TO THE CODEX ALIMENTARIUS COMMISSION

The Committee:

- combined the discussion papers related to the management of its work in one document and agreed to revise the consolidated version of the document on the basis of the discussion at the Committee and written comments submitted and to circulate it for further comments for consideration at its next session (paras. 54-62);
- replied to the request of the 26th Session of the Commission regarding the development of specific guidelines on risk analysis (paras. 70-72);
- agreed to redraft the proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management on the basis of the discussion at the Committee and written comments submitted and to forward the definitions on Food Safety Objectives, Performance Objective and Performance Criterion to the Commission for adoption with the understanding that these definitions would be included in the Procedural Manual (paras. 63-90);
- agreed to redraft the proposed Draft Guidelines on the Application of the General Principles of Food Hygiene to the Management of *Listeria monocytogenes* in Foods and to prepare an Annex to the Guidelines on the establishment of Food Safety Objectives and related performance objective and performance criteria, including microbiological criteria for *Listeria monocytogenes* in Ready-to-Eat Foods (paras. 91-100);
- agreed to revise the proposed draft Code of Hygienic Practice for Egg Products on the basis of the discussion at the Committee and written comments submitted (paras. 101-106);
- agreed to redraft the Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures on the basis of the discussion at the Committee and written comments submitted (paras. 107-125);
- decided to develop risk management guidance documents for *Campylobacter* in Broiler Chickens; for Enterohemorrhagic *Escherichia coli* in ground beef and fermented sausages; and for *Salmonella* in Broiler Chickens. It also agreed to consider the Risk Profile of *Vibrio* spp in Seafoods at its next session (paras. 126-148);
- agreed to proceed with the revision of the Draft Revision of the Recommended International Code of Practice for Foods for Infants and Children at its next session (paras. 149-154);
- agreed to defer the consideration of 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 Matter in Food until the Committee develops its procedures for prioritization of work (paras. 155-157);
- while considering other business, agreed to prepare draft Terms of Reference for the FAO/WHO Expert Consultation on the Uses of Active Chlorine which would include safety/benefit issues; supported the establishment of a Codex/OIE Task Force on Antimicrobial Resistance and agreed to put the discussion paper on Viruses in Food on the list of activities for consideration regarding its prioritization (paras. 158-160).

MATTERS OF INTEREST TO OTHER COMMITTEES:**CODEx COMMITTEE FOR FISH AND FISHERIES (CCFFP)****Hygiene Provisions of the Code of Practice for Fish and Fishery Products and the Draft Standard for Salted Atlantic Herring and Salted Sprat**

The Committee endorsed with minor amendment the food hygiene provisions of the Code of Practice for Fish and Fishery Products and the draft Standard for Salted Atlantic Herring and Salted Sprat with the understanding that the amendment should not cause any delay for the adoption by the Commission (paras. 12-14);

The Committee agreed that the risk profile of *Vibrio* spp. in seafood would be placed on the agenda of its next session in order to discuss how the risk management work on these issues should proceed (para. 137).

CODEx COMMITTEE ON MEAT HYGIENE (CCMH)

The Committee decided to develop risk management guidance documents for *Campylobacter* and *Salmonella* in broiler chickens and for enterohemorrhagic *Escherichia coli* in ground beef and fermented sausages (paras. 126 through 148).

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
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
JECFA	Joint FAO/WHO Expert Committee on Food Additives
OIE	Office international des épizooties
PAHO	Pan American Health Organization
SPS	Agreement on the Application of Sanitary and Phytosanitary Measures
WHO	World Health Organization
WTO	World Trade Organization

REPORT OF THE 36th SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE

INTRODUCTION

1. The Codex Committee on Food Hygiene (CCFH) held its Thirty-sixth Session in Washington, D.C., United States of America, from 29 March to 3 April 2004, at the kind invitation of the Government of the United States of America. Dr Karen Hulebak, Deputy Administrator, Office of Public Health and Science, Food Safety and Inspection Service, United States Department of Agriculture, chaired the meeting and Dr Michael Wehr served as Vice-Chairperson. The Session was attended by 196 participants from 43 Member countries and one Member organization¹ and 21 international organizations. A complete list of participants is given in Appendix I to this report.

OPENING OF THE SESSION

2. The Session was opened by Mr James R. Moseley, Deputy Secretary for the United States Department of Agriculture. Mr Moseley, speaking on behalf of Dr Elsa Murano, U.S.D.A. Undersecretary for Food Safety, noted that Codex has become an essential global organization, both with respect to protecting the health of consumers and facilitating international food trade. He emphasized the importance of the Codex Strategic Objectives and the implementation of the recommendations arising from the Codex Evaluation as means to enhance the effectiveness of Codex. Mr Moseley stressed the importance of Codex in continuing to base its standards on sound science, noting the importance of the work the Committee would be undertaking during the Session with respect to microbiological risk management and risk assessment. Mr Moseley commented upon the importance of the Codex Committee on Food Hygiene to effectively manage a workload that is both large and important. Mr Moseley also observed that the Codex Trust Fund had been implemented with support from the United States and several other countries and that this Session of CCFH was the first time that the fund had been utilized to support the attendance of developing countries at Codex meetings.

3. Dr Karen Hulebak emphasized the importance of the Committee's work products in helping to ensure the production of and trade in safe food, and also pointed out the need for the Committee to establish a strategic, transparent, and orderly mechanism for setting its priorities and managing its own agenda, and in so doing, to maximize its ability to produce effective and timely risk management guidance documents.

ADOPTION OF THE AGENDA (Agenda Item 1)²

4. The Delegation of the United States drew the attention of the Committee to the fact that there were some overlapping areas in the documents in items 5 (a), (b), and (c) and proposed that the Committee convene a working group to merge the three documents in to a consolidated version.

5. Some delegations were of the view that there was a need to consolidate Agenda Items 5 (a) and (b) only, as they were related to the internal work of the Committee. Some delegations were of the view that issues covered under Agenda Item 5 (c) were of horizontal nature relating to cross-committee interactions and that more detailed consideration in the Plenary should be given in order to decide on how these documents might be merged. Other delegations indicated that there was necessity to ensure consistency of merged documents with the document on Proposed Draft Principles and Guidelines for Microbiological Risk Management. After some discussion, the Committee agreed that a Working Group led by the United States would meet during the sessions and to discuss how to restructure and consolidate the documents under Agenda Items 5 (a), (b), and (c) into one and, if possible, prepare a first draft of the document.

6. In order to allow some time for the preparation of the consolidated document, it was also agreed to rearrange the Provisional Agenda, switching Agenda Item 9 with Agenda Items 5 (a), (b), and (c).

7. The Delegation of the Netherlands drew the attention of the Committee to the fact that there was a possibility of advancing the document on the Proposed Draft Principles and Guidelines for Microbiological Risk Management (Agenda Item 6) and proposed to establish a Working Group in order to prepare a proposal for consideration of this item in the Plenary, however no consensus was reached on this proposal.

¹ CRD 10 (EC Annotated Agenda).

² CX/FH 04/1.

8. The Committee adopted the Provisional Agenda as the Agenda for the Session with the above modification.

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES TO THE FOOD HYGIENE COMMITTEE (Agenda Item 2)³

9. The Committee was informed about matters arising from the 26th Session of the Commission, from the 53rd Session of the Executive Committee as well as the report on the FAO/WHO Workshop on the Provision of Scientific Advice to Codex and Member Governments. It noted that most of matters were for information purposes while only others would be discussed in more detail under relevant agenda items. In addition, the Committee noted the matters of interest to the Committee as follows:

Active chlorine

10. The Committee noted the request of the 36th Session of the Codex Committee on Food Additives and Contaminants (CCFAC) (Rotterdam, 22-26 March 2004) to FAO/WHO to convene an Expert Consultation to conduct a comprehensive risk assessment of use of active chlorine, taking into account benefits and risks and that the CCFAC agreed on the need to clearly define the scope of the Consultation. It further noted that CCFAC would prepare clear terms of reference for the aspect relevant to its work and that it requested relevant Committees, including the Committee on Food Hygiene to consider safety/benefit issues relevant to uses of active chlorine within their respective purviews and to elaborate terms of reference for the expert consultation within their mandate and pose questions so that the Expert Consultation could be comprehensive. The Committee agreed to consider this matter on Agenda Item 14 “Other Business and Future Work” (see paras. 158).

Antimicrobial resistance

11. The Committee noted the information from the Representative of WHO regarding the conclusions of the Workshops on Non-human Usage and Antimicrobial Resistance (Geneva, 1-5 December 2003 and Oslo, 15-18 March 2004) and that some conclusions from these workshops were relevant to Committee’s work, therefore it agreed to consider this matter on Agenda Item 14 “Other Business and Future Work” (see para. 159).

ENDORSEMENT OF HYGIENE PROVISIONS IN THE CODEX STANDARDS AND CODES OF PRACTICE (Agenda Item 3)

PROPOSED DRAFT CODE OF PRACTICE FOR FISH AND FISHERY PRODUCTS⁴

DRAFT STANDARD FOR SALTED ATLANTIC HERRING AND SALTED SPRAT⁵

12. In accordance with the terms of reference of the Codex Committee on Food Hygiene, the Committee was invited to endorse the hygiene provisions of the Proposed Draft Code of Practice for Fish and Fishery Product, including Section 2.2 and 2.6 of Definitions; Section 6 – Aquaculture and Section 10 – Processing of Quick Frozen Coated Fish Product and of the draft Standard for Salted Atlantic Herring and Salted Sprat.

13. The Committee agreed to amend the third bullet of Section 10.3.5.1 “Sawing” to read “*saw dust must not collect on the saw-table and must be collected in special containers under adequate hygienic conditions, if used for further processing*” for consistency with the language used in the fourth bullet. The amendment should not cause any delay for the adoption by the Commission.

³ CX/FH 04/2; CRD 11 (Report of the FAO/WHO Workshop on the Provisions of Scientific Advice to Codex and Member Countries); CRD 12 (Matters Referred by the Codex Alimentarius Commission and/or Other Codex Committees).

⁴ ALINORM 04/27/18, Appendix V; Comments submitted by India (CRD 22) and Indonesia (CRD 29).

⁵ ALINORM 04/27/18, Appendix II; Comments submitted by Indonesia (CRD 29).

Status of the Endorsement of the Hygiene Provisions of the Proposed Draft Code of Practice for Fish and Fishery Product, and of the draft Standard for Salted Atlantic Herring and Salted Sprat

14. The Committee endorsed the hygiene provisions of the Proposed Draft Code of Practice for Fish and Fish Products, including Section 2.2 and 2.6 of Definitions; Section 6 – Aquaculture and Section 10 – Processing of Quick Frozen Coated Fish Product as amended above. It also endorsed the hygiene provisions of the draft Standard for Salted Atlantic Herring and Salted Sprat as proposed by the Committee on Fish and Fishery Products.

DRAFT CODE OF HYGIENIC PRACTICE FOR MILK AND MILK PRODUCTS (Agenda Item 4)⁶

15. The Committee noted that the 26th Session of the Codex Alimentarius Commission adopted the proposed draft Code of Hygienic Practice for Milk and Milk Products at Step 5 as proposed by the 35th Session of the CCFH.

16. The Committee first considered the outstanding issues, which were retained in square brackets, as follows:

Section 2.5 Definitions

Food Safety Objective

17. In noting that concrete progress had been done on the elaboration of a definition of “Food Safety Objective” and that the definition would be considered under Agenda Item 6 “Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management”, the Committee agreed to delete the square brackets and the definition and to retain the term, while adding a footnote referring to the Definition which occurs in the Principles and Guidelines (under development). Consequentially, the Committee agreed to retain the term “Food Safety Objective” without square brackets throughout the draft Code.

Validation

18. In recognizing the ongoing work on the development of “Proposed draft Guidelines for the Validation of Food Hygiene Control Measures” (Agenda Item 9), the Committee agreed to delete the square brackets and the definition and to retain the term, while adding a footnote referring to the Definition which occurs in the Guidelines (under development). Consequentially, the Committee agreed to retain the term “Validation” without square brackets throughout the draft Code.

Annex II Appendix B “Microbiocidal Measures”

Irradiation

19. The Committee noted the Appendices to Annex II contained examples of control measures applied around the world. In recognizing that irradiation was not an example of a microbiocidal measure and was not known to be practiced for milk and milk products at this time, the Committee agreed to delete the term and the description. It also deleted reference to irradiation in the third paragraph of Appendix B as a consequential change.

2.2 Process management

12 log reduction of *C. botulinum*

20. It was noted that the occurrence of *C. botulinum* in milk was extremely rare and/or insignificant, and that no cases of botulism linked to sterile milk had been reported, therefore, *C. botulinum* would not have had any relevance. The Committee deleted the text in square brackets.

IDF Standard 48.1969 (under review)

21. The Committee was informed that the IDF Standard was still under development, therefore, it deleted the reference to this standard.

⁶ ALINORM 03/13A, Appendix III; Comments submitted by Australia, Brazil, Canada, Egypt, Mexico, New Zealand, Switzerland, Uruguay, IDF (CX/FH 04/4), Argentina, Thailand (CX/FH 04/4-Add.1), EC (CRD 14), India (CRD 23), Indonesia (CRD 31) and Cuba (CRD 32).

22. The Committee next considered the draft Code section by section. In addition to several minor editorial amendments, the Committee agreed to the following changes:

Section 2.1 Scope

23. The Committee agreed to move a sentence from the Annex clarifying that the Code did not contain provisions for the production of raw drinking milk to the base Code. It also acknowledged that the Code, once adopted, would encompass dried milk; thus, the *Code of Hygienic Practice for Dried Milk* (CAC/RCP 31/1983) could be revoked.

Section 2.3 Overarching principles applying to the production, processing and handling of all milk and milk products

24. In recognizing that good agriculture practices are important measures applied at primary production to ensure the safety and suitability of milk and milk products and that there was not a formal definition of this term, the Committee added a reference to good agriculture practices in the narrative of the third bullet.

Section 2.4 Relatives Roles of Milk Producers, Manufacturers, Distributors and Competent Authorities

25. The Committee added the terms “retailers”, “transporters” and “consumers” to the title of the Section and added the term “retailers” in the second and third paragraph to emphasize the continuum of controls that are applied from production to consumption and in particular the role of retailers.

Section 2.6 Suitability

26. The Committee amended the third bullet to specify that management system should be based on HACCP principles. In addition, it changed “perished” to “spoiled” in the second indent of the fourth bullet for clarity purpose.

Section 3 Primary production

27. The Committee added “safety and” before “suitability” and changed “effectiveness” with “stringency” in the last paragraph of the section for clarity and consistency with the scope of the Code.

Section 3.2.3.1 Feeding

28. In recognizing that the definition of “contaminant” in the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003), encompassed any biological or chemical agent, foreign matter or other substances not intentionally added to food which may compromise safety or suitability, the Committee deleted “microbiological or chemical” from the first paragraph.

Section 3.2.3.3 Veterinary Drugs

29. The Committee amended the first paragraph to specifically refer to veterinary drugs authorized by the competent authority for consistency with the language used in other part of the Code. It also added a footnote to the Annex to refer that the treatment with veterinary drugs should be consistent with the Code of Practice to Minimize and Contain Antimicrobial Resistance, under development in the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF).

Section 5.1 Control of Food Hazards

30. The Committee recognized that when control measures should be designed so as to achieve a specified level of hazard control, it was too restrictive to give consideration to the establishment of Food Safety Objective only, therefore, it agreed to refer in a generic way to “FSOs and/or related objectives and criteria” and to amend, as appropriate, the rest of the Code consequentially.

31. To better highlight the specific procedures required for the implementation of the HACCP principles, the Committee divided the last paragraph of the Section into two.

Section 5.1.1 Hazard Identification; 5.1.2 Control Measure Selection

32. The Committee agreed on the following changes to align the Section with the language used in the HACCP Annex to the International Recommended Code of Practice: General Principles of Food Hygiene:

- Amended the title of Section 5.1.1 to “Hazard Identification and Evaluation”;
- Changed the second principle to refer to “the severity of its adverse health effects and reasonable likelihood of occurrence”;

33. In Section 5.1.2, the Committee agreed on the following changes:

- Amended the principle to read, “Following hazard evaluation, control measures and control measure combinations should be selected that will prevent, eliminate or reduce the hazards to acceptable levels.”
- Deleted the beginning of the second paragraph to start with “The next step...” and struck out the third paragraph.

Section 5.5 Water

34. In recognizing that in certain conditions, the source of water was not always potable but that potable water should be made available, the Committee amended the principle to read “Dairy processing establishments should have potable water available, ...”.

Section 10.2 Training programs

35. For consistency with changes in section 2.4, the Committee added a reference to retail of milk in the first paragraph of the section.

Annex I – Guidelines for the Primary production of Milk**Section 3.2.3.3 Veterinary Drugs**

36. The Committee inserted a footnote to the Section’s title to refer to the Code of Practice to Minimize and Contain Antimicrobial Resistance, under development in the CCRVDF.

Section 3.2.4 Hygienic milking

37. In recognizing that automatic milking is used and that foremilk from each teat contains higher number of microorganisms than the milk that is subsequently drawn by the same teat, the Committee amended the last paragraph of the Section to clarify that: the milker should check the milk of each animal for organoleptic or chemical/physical indicators; the milk that does not appear normal should not be used for human consumption; and, foremilk from each teat should be discarded or collected separately, and not used for human consumption, unless it can be shown that it does not affect the safety and suitability of the milk.

Section 3.3.2 Milk Storage Equipment

38. In the Additional Provisions for the Production of Milk Used for Raw Milk Products, the Committee changed the term whey to milk products, to make the text more comprehensive.

Section 3.4 Record Keeping

39. A last bullet was added to refer to records of equipment cleaning.

Annex II – Guidelines for the Management of Control Measures during and after Processing**Section 4 Definitions - Pasteurization**

40. The Committee considered it more appropriate to refer to “pathogenic microorganisms” instead of “harmful microorganisms” to emphasize the focus on the control measures aimed at controlling hazards of public health concern.

41. The Committee agreed, in order to ensure consistency with wording used in other parts of the body of the Code, to transfer the definition of “process criteria” into part 2.5 “Definitions” of the main Code.

Section 5.1.1 Hazard Identification

42. The Committee amended the fifth paragraph to clarify that the role of the manufacture or other appropriate party was to document the conditions that specific sanitary measure are successfully applied. The sixth paragraph was amended to refer to control measures, as more appropriate term.

Section 5.2.1.2 Distribution of Finished Products – Perishable products

43. The Committee amended the first paragraph to recognize that validation might not be necessary when selected storage conditions are well established; a bullet point was added to the second paragraph to refer to product presented for retail sale.

Appendix A: Microbiostatic Control Measures

44. The Committee amended Appendix A as follows:

- In the description of pH reduction, the term “minimum pH value for preventing growth” was changed to “pH value for preventing growth” for clarity purpose;
- The example of “Pulse high-intensity light” was moved to Appendix B as typical example of microbiocidal control measure;
- The range of water activity values for preventing microorganism growth was broaden to 0.90 and 0.96 to encompass more pathogens and the reference to minimum was deleted.

45. The Delegation of Cuba while referring to CRD 32, called the attention of the Committee to the results of the most recent meeting of the FAO Global Lactoperoxidase Group of Experts, held in South Africa in February 2004. The Delegation noted that the meeting concluded that there was no scientific basis for the exclusion of milk and milk products treated by using the lactoperoxidase system from international trade.

46. In this regard, the Committee noted that the 26th Session of the Codex Alimentarius Commission had considered this matter and endorsed the clarifications provided by the 35th Session of the CCFH and that future consideration of this matter would depend on the availability of adequate microbiological and chemical risk assessments of process.⁷

47. The Delegation of Cuba informed the Committee that it was undertaking research on the use of lactoperoxidase system and that Cuba would provide the updated scientific information when available. In the light of the above, the Delegation reiterated their request to reconsider the exclusion of milk and milk products treated by using the lactoperoxidase system for international trade.

Appendix B: Microbiocidal Control Measures

48. The Committee agreed to refer to Centrifugation instead of Bactofugation® as the latter was a registered trade mark.

Section 1.2 Process Management

49. The Committee changed the term “process performance” to “performance criteria” as more appropriate.

50. In sub-section “Verification of process”, it amended the first paragraph to recognize that other methods than alkaline phosphatase reaction could be used to demonstrate that appropriate heat treatment has been applied to pasteurized products.

Section 2.2 Process Management

51. The Committee agreed to delete the phrase “thermal processing” in the second paragraph noting that the phrase was too limiting.

52. The Committee agreed to add a sentence to the last paragraph on “verification of process” reflecting that other methods can be used to verify the delivery of a process.

⁷ ALINORM 03/41, paras. 221-222.

Status of the Draft Code of Hygienic Practice for Milk and Milk Products

53. The Committee forwarded the draft Code of Hygienic Practice for Milk and Milk Product to the Commission for final adoption to Step 8 (see Appendix II). It also requested the Commission to revoke the Code of Hygienic Practice for Dried Milk (CAC/RCP 31-1983), which provisions were covered by the new Code.

DISCUSSION PAPERS ON THE MANAGEMENT OF THE WORK OF THE COMMITTEE (Agenda Item 5)

PROPOSED DRAFT PROCESS BY WHICH THE COMMITTEE ON FOOD HYGIENE COULD UNDERTAKE ITS WORK IN MICROBIOLOGICAL RISK ASSESSMENT/RISK MANAGEMENT (AGENDA ITEM 5A)⁸

DISCUSSION PAPER ON THE DEVELOPMENT OF PROCESS, PROCEDURES AND CRITERIA TO ESTABLISH PRIORITIES FOR THE WORK OF THE CODEX COMMITTEE ON FOOD HYGIENE (AGENDA ITEM 5B)⁹

DISCUSSION PAPER ON THE DEVELOPMENT OF OPTIONS FOR A CROSS COMMITTEE INTERACTION PROCESS (AGENDA ITEM 5C)¹⁰

54. As agreed during the adoption of the agenda (see para. 6), the Committee considered agenda items 5 (a), (b), and (c) on the basis of a consolidated document (CRD 2) prepared by a Working Group, which met during Sessions.

55. In introducing the document, the Delegation of the United States stated that the basic assumptions of the discussion paper were that:

- The document was an internal guide to the CCFH unless directed otherwise by Commission, and did not need to go through the Step process;
- Procedures would be consistent with the CAC umbrella procedures for the conduct of work within Codex Alimentarius;
- The document would articulate how the CCFH would implement the general procedures outlined in the CAC framework;
- The document would be available to other committees so that they are aware of the internal procedures used by the CCFH;
- Within the CCFH, the document would have the same weight as the Procedural Manual, but was limited to the internal operations of the CCFH; and,
- Procedures for cross-committee interactions would focus on how the CCFH would operate, and would not instruct other committees how they should operate.

56. The Delegation of the United States asked the Committee instructions on the general content of the document and revisions required for its further development.

57. The Committee noted that the document, once finalized by the Committee, should be included in the Procedural Manual, after endorsement by the CCGP and adoption by the Commission.

58. The Committee expressed its appreciation to the Working Group for the fast and valuable work. In noting that there had not been enough time to study the document in detail, it decided to focus its discussion on major issues to be considered by the drafting group, so as to provide general guidance, as follows:

59. The Committee agreed to delete Appendix 2 “Suggested elements to include in a microbiological risk management risk profile” and to include it in the proposed draft Principles and Guidelines for the Conduct of Microbiological Risk Management.

⁸ CX/FH 04/5; Comments submitted by Argentina, Canada, Ghana (CX/FH 04/5-Add.1), EC (CRD 15), Indonesia (CRD 33) and Peru (CRD 40).

⁹ CX/FH 04/5-Add.2; Comments submitted by EC (CRD 15) and Indonesia (CRD 33).

¹⁰ CX/FH 04/5-Add.3; Comments submitted by USA (CRD 8) and India (CRD 24).

60. It was suggested that the document should be further simplified and shortened and that, in revising the document, the Working Group should take into account the following points:

- Written comments submitted at the Session;
- Impact on international food trade and potential regional impacts among the criteria for new work;
- Criteria for new work and prioritization should be transparent, consistent and as objective as possible;
- Weighing of the criteria (both new work and prioritization) and the need to meet more than one criteria;
- Frequency and modality of CCFH work on prioritization (e.g. every session *versus* every three years; during the adoption of the Agenda *versus* Working Group meeting; etc.);
- Consistency with proposed draft Principles and Guidelines for the Conduct of Microbiological Risk Management and explore the possibility to maintain a skeleton of the risk profile in the document;
- Focus on process rather than on product;
- Include discussion of implementation of Food Safety Objective, Performance Objective, Performance Criterion and Microbiological Criteria in the Committee's risk management products;
- Be consistent with the Codex criteria for the establishment of work priorities.

Status of the Discussion Papers on the Management of the Work of the Committee

61. The Committee agreed to attach to this report the consolidated document, without the Appendix on Risk Profile, and to circulate it for comments (see Appendix IV). It further agreed that a working group led by the United States, with the assistance of the Australia, Canada, EC, Finland, India, Japan, the Netherlands, New Zealand, Norway, Sweden and United Kingdom will meet during the year to revise the document based on the above discussion and written comments submitted at the present Session and received in response to the Circular Letter, for circulation, comments and further discussion at its next Session.

62. The Committee agreed to hold a meeting of the working group on the Sunday immediately prior to its next Session to discuss the revised document and comments received and to present a report to the Session.

PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT (Agenda Item 6)¹¹

63. The Committee recalled that the 35th Session of the CCFH requested the drafting group led by France to redraft the document for circulation and consideration at the current session.

64. While introducing the document, the Delegation of France highlighted main changes made by the drafting group throughout the text and explained how the document was revised in order to accommodate guidance provided by the last session of the Committee.

65. The Delegation of France drew the attention of the Committee to the fact that further work was necessary in order to make the document more consistent with the proposed draft "Process by which the Committee on Food Hygiene could Undertake its Work in Microbiological Risk Assessment/Risk Management (Agenda Item 5a) and that there was a need to have a clear guidance from the Committee regarding Section on definitions, especially on Food Safety Objectives, Performance Objective and Performance Criterion, parts of texts that were left in square brackets especially in Section on Principles and in relation to regional differences; and to expand the chapter on implementation of microbiological risk management decisions. The Delegation also indicated that many comments presented in several CRDs could be incorporated in the text during the further elaboration of the document.

¹¹ CX/FH 04/6; Comments submitted by Mexico, United States of America, IDF (CX/FH 04/6, Add. 1); Switzerland (CRD 7); ICMSF (CRD 13); EC, Thailand (CRD 16), India (CRD 30), Indonesia (CRD 34), Argentina (CRD 37) and Peru (CRD 39).

66. The Committee expressed its sincere appreciation to the Delegation of France and their drafting partners for their work. It decided to consider the document section by section focusing on major unresolved issues and to provide general guidance in the subsequent elaboration of the document.

Introduction and Scope

67. The Committee noted that the Commission had adopted at its 26th Session Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, which provided guidance in the framework of Codex so that food safety and health aspects of Codex standards and related texts be based on risk analysis.

68. It was proposed to clarify the Scope and better define whether the document was applicable to the Codex or to member governments. In this regard, it was pointed out that in the document it was already stated that it was applicable to Codex and to member governments however it was necessary to clarify in each relevant section what was applicable to member governments or to Codex or to both.

69. Several delegations were of the view that the Committee should not wait until the Committee on General Principles finalize the document on Working Principles for Risk Analysis for Application by governments and suggested to proceed with the elaboration of the Principles and Guidelines for the Conduct of Microbiological Risk Management applicable to both governments and Codex as this guidance was urgently needed. However, one delegation was of the view that this document should be prepared for application by Codex only.

70. While considering this matter, the Committee also noted the request of the 26th Session of the Commission that relevant Committees develop or complete specific guidelines on risk analysis in their respective areas, for inclusion in the Procedural Manual. In this regard, it agreed to report to the Commission that the Committee:

- Had developed the Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL-30, 1999) document, which provided guidance on microbiological risk assessment for microbiological hazards in foods. The document was written with the aim of providing advice to member governments and to the Codex;
- Was currently developing the Principles and Guidelines for the Conduct of Microbiological Risk Management addressing issues that would be relevant to both member governments and to the Codex.

71. The Committee noted that both these documents covered many aspects of communication including between risk assessors and risk managers in ways that were relevant both to member governments and Codex.

72. The Committee requested the Commission's advice whether this course of action was consistent with the Commission's expectations.

73. Some delegations pointed out that there was an urgent need to proceed with the elaboration of the Principles and Guidelines for the Conduct of Microbiological Risk Management as the concept of FSOs which was included in the Guidelines was already introduced in other Codex documents and that delay in the consideration might have a negative impact in their further development.

74. The Committee agreed to continue work on the document. It requested the drafting group to articulate more clearly the applicability of the document in the Scope and better describe how different provisions could be applied by the Codex and/or by member governments in subsequent sections of the document.

Definitions

75. The Committee had a lengthy debate regarding the definition of Food Safety Objectives (FSOs). Several delegations were of the view that this definition should be limited to microbiological hazards only as it was within the purview of the document while others were of the opinion that FSOs should not be limited only to microbiological hazards as the broader concept of FSO include chemical, physical hazards, and that this was already introduced in other Codex documents under development, such as the draft Code of Hygienic Practice for Milk and Milk Products (see para. 17).

76. The Committee considered several amendments to the definitions and ways to proceed. After an extensive exchange of views, the Committee agreed to the proposals of a Working Group, which was convened during the Session, and agreed on broader definitions of FSOs, Performance Objective (PO) and Performance Criterion (PC) that apply to all types of hazards.

77. Some delegations were of the opinions that the definition of risk managers was too restrictive and not consistent with Principle 3, which stated that industry had the responsibility for producing a safe food. It was suggested that the drafting group discuss this definition and its use throughout the text.

Section 2 General Principles

78. Recognizing that limited time was available for discussion of the document, the following major suggestions were made:

- to amend the first sentence of Principle 2 to read: “The microbiological safety of food is typically assured by an integration of controls in primary production, product design and processing, and the application of good hygienic practice and safe handling, during the manufacturing, labeling, distribution, storage, retail and preparation, such that the desired level of risk management is achieved”;
- to consider Principle 3 in order to better reflect that not only industry but other stakeholders within the food chain have food safety responsibilities;
- to modify the first part of Principle 5 to emphasize that the whole process and not only the basis for decisions, should be transparent and communicated.

79. Different views were expressed in relation to Principle 6 on the dual roles of Risk Assessors and Risk Managers, especially in small or developing countries; however, it was pointed out that, irrespective of whether the roles were separated or combined, the scientific integrity and unbiased nature of the process should always be retained. It was further noted that explanatory text associated with this principle need to be consistent with that which appears in equivalent text in the General Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL 30-1999).

80. It was proposed to provide a more clear explanation on issues of general and specific applicability in Principle 7 and to take into account the reports of Kiel consultations¹² for basis in further elaboration of this Principle.

Section 5 Preliminary Microbiological Risk Management Activities

81. It was noted that the concept of regional differences in relation to certain pathogens had been acknowledged by the Committee. Therefore, it was proposed to add a new principle to this effect to read: “In the interest of safeguarding human health and minimizing the incidence of food-borne diseases, the existence of regional differences in the prevalence and level of various pathogens in the food chain should be recognized and taken into account in the Microbiological Risk Management process” and it was suggested that the remaining text on regional differences could be deleted.

82. It was also indicated that there was a need to further clarify and articulate the concept on regional differences.

83. As draft Principle 5 envisaged stakeholders’ involvement in the MRM policy, it was suggested that greater emphasis on this, especially in Sections 5 through 8, be given.

Section 6.2.2

84. Different views were expressed on the need to incorporate the aspects of shelf-life in the document and one Delegation suggested that because of this concept and the complexity of the subject, the Committee consider new work in this area.

¹² The Interaction between Assessors and Managers of Microbiological Hazards in Food, Report of a WHO Expert Consultation, Kiel, Germany, 21-23 March 2000 and Principles and Guidelines for Incorporating Microbiological Risk Assessment in the Development of Food Safety Standards, Guidelines and Related Texts, Report of a Joint FAO/WHO Consultation, Kiel, Germany, 18-22 March 2002.

Section 7 Selection of MRM options and implementation of MRM decisions

85. It was suggested to provide clearer separation and explanation in the Section on various options for risk management decisions and to simplify the flow chart on the overall framework for managing food-borne risks.

Status of the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management

86. The Committee noted that the CCGP had referred the matter of definitions of FSOs to the relevant committees for consideration regarding their applications to specific food safety issues.

87. The Committee agreed to forward the definitions on Food Safety Objective, Performance Objective and Performance Criterion to the Committee on General Principles for endorsement and subsequent adoption by the Commission, with the understanding that these definitions would be included in the Procedural Manual (see Appendix III).

88. The Committee also agreed to return the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management to Step 2 for revision by the drafting group led by France, with assistance of Argentina, Australia, Austria, Belgium, Canada, China, EC, Denmark, Finland, Germany, Hungary, India, Ireland, Italy, Japan, Netherlands, New Zealand, Norway, Sweden, the United Kingdom, the United States, ICMSF and IDF taking into account written comments submitted and the above discussion. The Committee noted that there was a need for the drafting group to meet physically and accepted the kind offer of the Delegation of the EC to provide the venue and facilities for the drafting group meeting. The revised document prepared by the drafting group will be circulated for comments at Step 3 before the next session of the Committee.

89. The Committee also agreed that a Working Group would be convened on the Saturday before the next session of the CCFH to review the comments received and, if appropriate to prepare a revised version of the Principles and Guidelines for consideration by the Committee.

90. The Committee noted that numerous comments of various nature were presented in CX/FH 04/6-Add.1 and in CRDs and therefore requested the drafting group to take them into account in further elaboration of the document.

PROPOSED DRAFT GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE [MANAGEMENT] OF *LISTERIA MONOCYTOGENES* IN FOODS (Agenda Item 7)¹³

91. The 35th Session of the CCFH agreed that a drafting group led by Germany would revise the proposed draft Guidelines at Step 2 for circulation, comments and further consideration at its next Session.¹⁴

92. The Delegation of Germany introduced the proposed draft Guidelines and informed the Committee about major discussions and numerous changes made by the drafting group.

93. The Committee decided not to discuss the proposed draft Guidelines in detail and focused its discussions on major issues to be considered by the drafting group, so as to provide general guidance to the drafting group, as follows:

General Comments:

94. The Committee thanked Germany and the drafting group for its work on the document and emphasized the practical information and guidance it provided in controlling *Listeria* in foods. Due to the scope of the document, it was suggested to revise the title of the document to “Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Ready-to-Eat Foods”. It was also suggested that the Scope should focus on Ready-to-Eat Foods that support the growth of *Listeria monocytogenes*.

¹³ CX/FH 04/7; Comments submitted by Canada, United States of America (CX/FH 047-Add. 1), EC (CRD 17), Peru (CRD 45) and Brazil (CRD 47).

¹⁴ ALINORM 03/13A, para. 109.

Specific Comments:**Section 5. Control of Operation**

95. It was suggested to refer to the reduction of the occurrence of *Listeria monocytogenes* in food instead of minimizing the risk of listeriosis.

Section 5.2.3 Microbiological and other specifications

96. Due to the decision reached on the definitions of Food Safety Objective (FSO), Performance Objective, and Performance Criterion (see paras. 75-76), it was agreed to initiate work on the establishment of FSOs and related performance objective and performance criteria, including microbiological criteria, and to include this information in an Annex to the Guidelines. The concepts included in the Principles and Guidelines for the Conduct of Microbiological Risk Management (CX/FH 04/6) should be applied in this Annex. In this regard, it was noted that the report of the FAO/WHO Expert Consultation on Risk Assessment of *L. monocytogenes* in Ready-to-Eat Food (to be published shortly) would provide data for this work. In order not to delay the further development of the Guidelines, it was agreed to proceed on the parallel development of the main guideline document and the Annex.

Section 9. Product Information and Consumer and Industry Awareness

97. It was suggested to consider the wording related to the provision of information to health care providers from the boxed area of the scope and to add wording on the need to validate information and consumer awareness programs to ensure that they are understandable and useful in guiding their target audience to make appropriate choices.

Section 9.1. Communication Programs

98. It was suggested to delete the wording concerning the programs to provide guidance for health care providers that facilitate rapid diagnosis of foodborne listeriosis as outside the scope of the Guidelines.

Section 9.2. Labelling

99. It was noted that it was more appropriate to refer to “ready-to-eat food” instead of “ready-to-eat raw foods”.

Status of the Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the [Management] of *Listeria monocytogenes* in Foods

100. The Committee returned the proposed draft Guidelines to Step 2 and agreed that a drafting group led by Germany with the assistance of Austria, Canada, China, Denmark, EC, Finland, France, Greece, Hungary, Italy, Japan, Norway, the United Kingdom, Uruguay, the United States of America, ICMSF, IDF and IFT would revise the proposed draft Guidelines based on the written comments received and the above discussion for circulation, comments at Step 3 and further consideration at its next Session. In addition, it agreed that a sub-group of the drafting group with the participation of the above listed countries and organizations plus Sweden, Switzerland, FAO and WHO would prepare an Annex to the Guidelines on the establishment of FSOs and related performance objective and performance criteria, including microbiological criteria for *Listeria monocytogenes* in Ready-to-Eat Foods for circulation, comments and further consideration at its next Session. The Committee noted the offer of FAO/WHO to make available experts to assist the sub-group in this work.

PROPOSED DRAFT REVISION OF THE CODE OF HYGIENIC PRACTICE FOR EGG PRODUCTS (Agenda Item 8)¹⁵

101. The 35th Session of the CCFH returned the proposed draft Revision of the Code of Hygienic Practice for Eggs and Egg Products to Step 2 for revision by the drafting group led by Australia, for additional comment and further consideration at its next session¹⁶.

102. In presenting the document, the Delegation of Australia noted that there was still a need for more information and guidance by the Committee on the structure, content and level of detail of the Code and on the nature of processing technologies to be incorporated.

103. The Committee generally supported the work of the drafting group in the further development of the Code and with the approach covering the whole food chain and the improved structure. However, it recognised the need for further elaboration. Therefore, the Committee decided not to discuss the proposed draft revised Code in detail and focused its discussions on matters to be considered by the drafting group so as to provide general guidance.

104. In addition to the written comments, it was suggested to further consider the Definitions, to provide practical guidance on Primary Production, to obtain more information on processing technologies and to consider the inclusion of that information, and to expand the Section on Product Information and Consumer Awareness to include more information on the safe handling and cooking of eggs in the home.

105. To assist in the preparation of the revised Code, the Committee agreed to request through a Circular Letter information on: processing of egg products, including emerging technologies; pasteurisation of eggs and egg products; hygienic provisions related to processing of egg and egg products; advice on the safe use and handling of eggs with particular focus on vulnerable groups; clarification of definitions, including collection and handling, grading and cleaning. The importance of responding to CL in good time in assisting drafting group was emphasized.

Status of the Proposed Draft Revision of the Code of Hygienic Practice for Eggs and Egg Products

106. The Committee agreed that the drafting group led by the Australia with the assistance of Argentina, Belgium, Canada, EC, Hungary, India, the Netherlands, New Zealand, Spain, Sweden, Switzerland, the United Kingdom, the United States of America, and ALA, would revise the proposed draft revised Code. The Committee agreed that the Code would be revised at Step 2 based on the above discussions and written comments submitted at the current meeting and submitted in response to the Circular Letter, for circulation, comments at Step 3 and further consideration at its next Session.

PROPOSED DRAFT GUIDELINES FOR THE VALIDATION OF FOOD HYGIENE CONTROL MEASURES (Agenda Item 9)¹⁷

107. The 35th Session of the CCFH returned the proposed draft Guidelines for the Validation of Food Hygiene Control Measures to Step 2 for revision by the drafting group led by the United States for circulation, additional comment and further consideration at the current meeting.¹⁸

108. The Delegation of the United States introduced the proposed draft Guidelines and informed the Committee about major discussions and numerous changes made by the electronic drafting group.

¹⁵ CX/FH 04/8; Comments submitted by Argentina, Canada, Colombia, Iran, Mexico, USA (CX/FH 04/8-Add. 1), EC, Thailand (CRD 3), India (CRD 25), Indonesia (CRD 35) and Peru (CRD 41).

¹⁶ ALINORM 03/13A, para. 156.

¹⁷ CX/FH 04/9; Comments submitted by Ghana, Iran, Mexico (CX/FH 04/9, Add. 1), Switzerland (CRD 7), EC, Thailand (CRD 18), India (CRD 26), Peru (CRD 43) and Brazil (CRD 46).

¹⁸ ALINORM 03/13A, para. 164.

109. The Committee decided not to discuss the proposed draft Guidelines in detail and focused its discussions on major issues to be considered by the drafting group, so as to provide general guidance, as follows:

General Comments

110. The Committee expressed appreciation for the significant progress done by the drafting group in the preparation of the document and for the general approach of the document. It was suggested: to further explore the relationship of validation with respect to good hygienic practice, HACCP and Risk Assessment; to consider validation in the context of equivalency; to clarify the respective roles of industry and the competent authority in validation and verification; to simplify the document to facilitate its application in smaller and less developed businesses; to consider whether the document could be presented as a stand-alone document or an attachment/annex to another document on food hygiene; and to clarify the relationship between these guidelines and other similar documents developed or under development by other organizations and, in particular with the draft ISO 22000 Food Safety Management Standard. The Delegation of the United States noted that ISO should align itself with Codex rather than other way around.

111. With regard to the ISO 22000, the Committee was informed of the decision of the 53rd Session of the Executive Committee (February 2004) that the Codex Secretariat establish preliminary contact with the International Organization for Standardization (ISO) to obtain information on the current status of food safety-related work within the ISO and present its findings to the 54th Session of the Executive Committee, together with the implications to the work being undertaken by Codex.¹⁹

Specific Comments on the Sections

Section II. Scope

112. It was suggested to broaden the scope of the document to include all types of validation, including validation of control measures and to clarify the roles and responsibility of the competent authority and the industry in validation.

Section III. Definitions

113. The Committee noted that “Food Safety Control System” was the only new definition contained in the document, while the other definitions were taken from other Codex texts (i.e. Control Measure, Monitoring, Validation, Verification) and from the WTO SPS Agreement (i.e. Appropriate Level of Protection - ALOP).

114. It was suggested: to develop a definition of “validation” that could be applied to the work of other Codex Committees for inclusion in the Codex Procedural Manual and to consider the development of definition of “validation” consistent with the ISO definition; to develop a definition of “validation of control measures”.

Section IV. Nature of Control Measures

115. It was suggested: to clarify the term “food animals” in the second bullet of “Controlling initial levels of hazard(s)”; to be more specific when referring to environmental control and to keep the document within the Codex mandate; and, to remove the examples in the second bullet of “Reducing the level of hazard(s)” as they were inappropriate.

Section V. Concept and Nature of Validation

116. In noting the difficulties in validating good agricultural practices, good hygiene practices etc, it was suggested to consider the degree to which different types of control measures can be validated.

¹⁹ ALINORM 04/27/3, para. 99.

Validation vs. Verification and Monitoring

117. It was suggested to add appropriate examples for verification and monitoring and to include a separate heading emphasizing the importance that Governments establish Food Safety Objectives, (FSOs) and Performance Objectives (POs) as far as possible in order to facilitate the evaluation of the effectiveness of Food Safety Control Systems.

Relationship of HACCP to the Appropriate Level of Protection

118. It was suggested: to revise the relation between ALOP and validation; to reconsider the subsection in the light of the revised definitions of Food Safety Objective (FSO) and Performance Objective (PO) (see paras. 75-76); to consider validation in the context of equivalency; to change the terms “broad public health goals” to “identified risks” as ALOP under the SPS agreement refer to protection against an identified risk; and, to modify the first example to read “reasonable assurance of no harm”.

Relationship of HACCP to Validation of Food Hygiene Control Measures

119. It was suggested to further clarify the link between HACCP principles and validation of the management measures and to stress that the pertinence and efficacy of the HACCP plans in terms of food safety should be validated by the industry, on a scientific basis, without prejudice of the individual management measures or of the set of management measures combinations.

Section VI. Steps prior to Validation

120. It was suggested to add a new paragraph on the evaluation of technical and administrative feasibility and cost implications and their relationship to ALOP.

Section VII. Design of Food Safety Control Systems

121. It was suggested to clarify the different types of validation required in various food safety control systems (e.g. single system, combined system, entire food safety control system).

Section VIII. Approach to Validation

122. In noting that in the second paragraph it was indicated that in some cases on-farm practices would be essential food hygiene control measures and will need to be validated, it was suggested to explicitly name which on-farm practices include essential food hygiene control measures to be validated in order to avoid any misinterpretations.

Section IX. Limitations to Validation

123. It was suggested: in the first paragraph, to use a more specific and practical approach when referring to the incorporation of significant safety factors into the control measures established for the product; in the second bullet, to indicate that it is necessary to validate that the observed gap does not exceed the pre-established levels; and, to modify the last bullet to read: “Lack of technical expertise and information: lack of technical expertise and information can also be a limitation to validation in case of small scale producer/manufactures, especially in the developing countries. Necessary assistance should be provided by national and international organizations.”

124. It was also suggested to add a new bullet to address the need for validation of control measures that lie beyond the responsibility of the producers or processors and the means (e.g. statistical studies using time/temperature monitoring devices) required to validate them.

Status of the Proposed draft Guidelines for the Validation of Food Hygiene Control Measures

125. The Committee returned the draft Guidelines to Step 2. It agreed that a drafting group led by United States, with the assistance of Argentina, Australia, Canada, France, Germany, New Zealand, Norway, Peru, Spain, Sweden, Thailand, Uruguay, ICMSF, IDF and IFEH, would revise the proposed draft Guidelines on the basis of the written comments submitted at the current Session and the above suggestions for circulation, comment at Step 3 and further consideration at the next session of the Committee.

REPORTS OF THE AD HOC FAO/WHO EXPERT CONSULTATIONS ON RISK ASSESSMENT OF MICROBIOLOGICAL HAZARDS IN FOODS AND RELATED MATTERS (Agenda Item 10)²⁰

126. The Representative of FAO provided the Committee with an update of the microbiological risk assessment activities undertaken by FAO and WHO. The Committee was reminded that the risk assessments on *Salmonella* in eggs and broiler chickens and *Listeria monocytogenes* in ready-to-eat foods had now been completed. Further work had been undertaken on the risk assessment on *Campylobacter* spp. in broiler chickens and five different scenarios were evaluated to allow a comparison of general and specific risk reduction strategies. The Committee was also informed that progress had been made on the risk assessments on *Vibrio* spp. in seafood that should facilitate the discussion of this issue at the Committee's next Session.

127. The Representative of FAO requested the Committee to consider the utility of this work in the development of risk management guidance and highlighted the need for further guidance from the Committee in terms of undertaking risk assessment work on enterohemorrhagic *Escherichia coli*.

GENERAL CONSIDERATION OF THE RISK MANAGEMENT PAPERS

128. The Delegation of New Zealand strongly supported the microbiological risk management work of the Committee but noted that the manner in which the outcomes of the microbiological risk assessment activities of FAO and WHO could be best used in the development of risk management guidance by the Committee was yet to be determined. The Committee agreed that a decision needed to be made concerning the format of risk management guidance documents that the Committee wanted to develop, taking into consideration its work in other areas including the elaboration of "Principles and Guidelines for the Conduct of Microbiological Risk Management".

129. Several delegations noted that the division of risk management tasks between this and other committees had to be considered to avoid duplication of work and ensure that the work of this Committee provided the specialized risk management guidance that was needed to address current and future food safety concerns. The Committee agreed that the working groups would consider existing codes and guidance documents to avoid duplication.

130. The Committee considered two model formats for risk management guidance documents:

- The Recommended International Code of Practice: General Principles of Food Hygiene together with Annexes. Such annexes could include information on risk management options, expanded consideration of primary production issues, etc.
- The format for a microbiological risk management guidance document as outlined in Appendix II of the "Discussion Paper on the Management of the Work of the Committee", which was available to the Committee as CRD 2.

131. Several delegations expressed reservations regarding the applicability of the Recommended International Code of Practice: General Principles of Food Hygiene as a model for the further development of these risk management papers indicating that it did not adequately reflect new developments in the area of microbiological risk management and risk based approaches, which linked management strategies with a reduction in the burden of food borne disease. Other delegations were of the opinion that this was a workable approach but that in using this approach certain issues would require special attention. In particular, consideration of how such guidance would fit in with HACCP and guidance to competent authorities on the implementation of these risk management documents would be needed.

132. The Delegation of Germany reminded the Committee of the positive experience of the *Listeria* Working Group in using the International Recommended Code of Practice – General Principles of Food Hygiene approach to advance the work on developing guidance for the control of *Listeria monocytogenes*. The Delegation highlighted the flexibility of this approach and indicated that the inclusion of annexes enabled the consideration of risk based management options. The Delegation also cautioned the Committee that the Working Group had previously tried to use the alternative format under consideration and found it was not practical.

²⁰ CX/FH 04/10.

133. This link between the development of these management documents and the “Discussion Paper on the Management of the Work of the Committee” was noted. It was highlighted that this discussion paper was defining the way in which the Committee would work in the future and in developing management documents on these pathogen commodity combinations the Committee should begin moving in that direction. It was also suggested that developing risk management guidance documents for pathogen-commodity combinations according to this new process would give the Committee useful experience for the optimisation of the format of future risk management guidance documents.

134. Although there were some suggestions to postpone further development of the pathogen commodity risk management papers until the new format for risk management guidance documents was further clarified next year, it was noted that the significance of these pathogens in terms of food safety was considerable and therefore the Committee decided to continue to progress these documents in the coming year.

135. As there was no clear consensus as to the type of risk management guidance documents to develop and considering that the new format for such documents to be developed by the Committee was still being elaborated, it was decided that the most useful way for the Committee to proceed would be to develop two types of risk management guidance documents – one based on the international code of practice and the other based on the draft format for risk management guidance documents, presented to the Committee in CRD2. The Committee was of the opinion that this would allow it to better evaluate each approach at its next session while at the same time proceeding with the work on these pathogen-commodity combinations of concern.

136. The Committee noted that the development of risk management guidance documents on these pathogen/commodity combinations had not yet been approved as new work by the Commission. In order to submit these as proposals for new work, the Committee would need to complete project documents for consideration by the Executive Committee. It was agreed that these documents would also be prepared by the Working Groups for submission by the next session of the Committee.

137. The Committee agreed that the risk profile of *Vibrio* spp. in seafood would be put on the agenda of its next Session in order to discuss how the risk management work on that issue should proceed.

DISCUSSION PAPER ON RISK MANAGEMENT STRATEGIES FOR *CAMPYLOBACTER* SPP. IN POULTRY (Agenda Item 10a)²¹

138. The Delegation of the Netherlands introduced this discussion paper and indicated that it had been further refined since the 35th session of the CCFH. In particular the working group had focussed on the identification of risk management options and included some new concepts to approaching risk reduction. The Committee was reminded that its 35th session had not made any specific recommendations with regard to the format of the document and in order to progress this work further the Committee should now provide the working group with clear guidance on the format of the document.

Status of the Discussion Paper on Risk Management Strategies for *Campylobacter* spp. in Poultry

139. The Committee agreed that the drafting group led by the Netherlands, with the assistance of Australia, Belgium, Canada, China, Denmark, EC, Finland, Japan, the Netherlands, New Zealand, Norway, Philippines, Sweden Thailand, the United Kingdom, the United States of America, and ALA would progress with the development of this paper in the microbiological risk management guidance document format presented in CRD 2. In order to reflect this it was decided to change the title to “Discussion Paper on Guidelines for Microbiological Risk Management Options for *Campylobacter* in Broiler Chickens”.

²¹ CX/FH 04/10 – Add. 1, CRD 1 (Additional information submitted by the Netherlands and its drafting partners); Comments submitted by EC (CRD 19).

DISCUSSION PAPER ON THE RISK PROFILE FOR ENTEROHEMORRHAGIC *ESCHERICHIA COLI* (EHEC) INCLUDING THE IDENTIFICATION OF THE COMMODITIES OF CONCERN INCLUDING SPROUTS, GROUND BEEF AND PORK (Agenda Item 10b)²²

140. The Delegation of the United States introduced this discussion paper and expressed its appreciation to their drafting partners for their assistance in its preparation. Following the request of the 35th CCFH, additional information had been solicited by Circular Letter on the top five serotypes of human EHEC isolates, the top five commodities of concern and animal husbandry practices that should be included in the risk profile. The discussion paper had been updated accordingly. The Delegation of the United States informed the Committee that in order to proceed with this work clear guidance was needed as to the format of the risk management document to be developed and the specific food commodity to be considered.

141. Based on the risk profile the Delegation of the United States proposed that future work focus on ground beef. The similarity, at least with respect to the ingredients, of fermented sausage to ground beef was noted and the drafting group was requested to also consider this commodity. The representative of WHO noted that the biggest outbreak of food borne illness caused by EHEC was linked to sprouts and cautioned the Committee against limiting its work to one commodity only.

142. The Committee noted that the risk profile was a good starting point to begin risk management work on EHEC but observed that several gaps still needed to be addressed. They welcomed the global approach taken in the risk profile discussion paper and highlighted the importance of primary production in the development of risk management guidance.

143. The Committee noted that no risk assessment had yet been undertaken for this pathogen and suggested this could be the next step.

Status of the Discussion Paper on Risk Management Strategies for Enterohemorrhagic *Escherichia coli*

144. The Committee agreed that the drafting group led by the United States, with the assistance of Austria, Australia, Canada, China, EC, France, Germany, Japan, the Netherlands, New Zealand and Sweden would progress with the development of this paper in the format of the Recommended International Code of Practice: General Principles of Food Hygiene together with an Annex. The Committee agreed that the Working Group would take a systematic approach to reviewing the available information and, according to the type of risk management document to be developed, identify very specific questions for any necessary risk assessment work or specific scientific advice. It also agreed to change the title to “Discussion Paper on 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”.

DISCUSSION PAPER ON RISK MANAGEMENT STRATEGIES FOR *SALMONELLA* IN POULTRY (Agenda Item 10c)²³

145. In introducing this discussion paper the Delegation of Sweden informed the Committee that it had been revised taking into consideration information received from members as a result of a Circular Letter. A literature survey was also undertaken and relevant information incorporated into the discussion paper. The Delegation of Sweden requested clear guidance from the Committee on whether and how to proceed and also on the final format to be used for the document.

²² CX/FH 04/10-Add. 2

²³ CX/FH 04/10-Add.3; Comments submitted by Australia, Thailand, Mexico (CRD 5), EC (CRD 20), India (CRD 27), Indonesia (CRD 36) and Peru (CRD 38).

Status of the Discussion Paper on Risk Management Strategies for *Salmonella* in Poultry

146. The Committee agreed that the drafting group led by Sweden, with the assistance of Australia, Canada, China, Czech Republic, Denmark, EC, France, Germany, the Netherlands, New Zealand, Thailand, the United States of America, and ALA would progress with the development of this paper in the format of the Recommended International Code of Practice: General Principles of Food Hygiene together with Annexes as may be appropriate. In order to reflect this it was decided to change the title to “Discussion Paper on Guidelines for the Application of the General Principles of Food Hygiene to the Risk Based Control of *Salmonella* in Broiler Chickens”.

147. The Committee noted that particular consideration needed to be given to primary production and that if necessary this could be addressed in an Annex.

148. The Committee noted numerous comments were submitted in CX/FH 04/10-Add.3 and in CRDs and requested the drafting group to take them into account in further development of document.

DISCUSSION PAPER ON THE PROPOSED DRAFT REVISION OF THE RECOMMENDED INTERNATIONAL CODE OF PRACTICE FOR FOODS FOR INFANTS AND CHILDREN (Agenda Item 11)²⁴

JOINT FAO/WHO MEETING ON *ENTEROBACTER SAKAZAKII* AND OTHER MICROORGANISMS IN POWDERED INFANT FORMULA [Agenda Item 11 (a)]²⁵

149. At the 35th session of the CCFH, the Committee agreed to revise the Recommended International Code of Hygienic Practice for Foods for Infants and Children, particularly for dried infant formula. The Committee also agreed that the United States would update the Risk Profile of *Enterobacter sakazakii* in Powdered Infant Formula. In addition, FAO and WHO were requested to convene an expert consultation on the *Enterobacter* genus, including *E. sakazakii*, and *Clostridium botulinum*, which was held in February 2004.²⁶

150. The Delegation of Canada presented the discussion paper and requested the Committee to provide comments on the suggested structure and the content and invited delegations to propose additional inclusions for updating the Code.

151. The Representative of the WHO informed the Committee about the FAO/WHO Meeting on *Enterobacter sakazakii* and other microorganisms in powdered infant formula and introduced the key outcomes of this meeting. He urged the Committee to expedite its work on this issue. It was proposed to revise the current microbiological criteria and to elaborate specific criteria for *E. sakazakii* in the light of the recommendations of the above meeting. It was also suggested that the revision on criteria should progress as fast as possible.

152. During the Committee’s discussion the following issues were emphasized:

- the need to take into consideration the range of microorganisms of concern including the availability of appropriate microbiological methods;
- the need to control the safety of infant formula by applying control measures during production and during and after reconstitution;
- the need to identify and define high risk infant populations;
- the necessity to provide more specific guidance for hospitals, day-care centres, food handlers, and caregivers for infants;
- the development of specific information and/or recommendations on the labeling regarding the preparation, use, and handling of powdered infant formula for users;
- the need for realistic expectations about implementation of controls that depends on consumer behavior;

²⁴ CX/FH 04/11; Comments submitted by EC (CRD 4) and India (CRD 28).

²⁵ CX/FH 04/12; CX/FH 04/12-Add.1; Comments submitted by ESPHAN (CRD 6).

²⁶ CX/FH 03/13, paras. 172-173.

- the necessity to take into account the situation in developing countries (e.g. availability of boiling water and refrigerators for keeping bottles with reconstituted milk);
- to carefully consider the use of commercially sterile liquid infant formula with regard to microbiological aspects and secondary recontamination;
- to consider other foods for infants that contain powdered infant formula (e.g. foods containing both cereals and powdered infant formula).

153. The Representative from FAO informed the Committee that the framework for a more extensive risk assessment model had been developed and could be further elaborated to facilitate the revision of the Code. The Committee agreed that this would be useful and requested JEMRA to further develop the model.

154. The Committee agreed that a working group, lead by Canada, with assistance of 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 to proceed with the revision of the International Code of Hygienic Practice for Foods for Infants and Children and development of microbiological criteria on *E. sakazakii* and other relevant microorganisms. The Committee agreed to proceed with this work as quickly as possible.

PROPOSED DRAFT GUIDELINES FOR THE REUSE OF PROCESSING WATER IN FOOD PLANTS (Agenda Item 12)²⁷

DISCUSSION PAPER ON THE PROPOSED DRAFT GUIDELINES FOR EVALUATING OBJECTIONABLE MATTER IN FOOD (Agenda Item 13)²⁸

155. The Committee noted that at its 34th Session it had agreed that in view of its heavy workload and the need to prioritise work, it decided to discontinue the consideration of the above Agenda Items for the time being, with the understanding that this decision would be reviewed at its 36th Session.

156. Due to the long Agenda and the fact that procedures for prioritization of the work of the Committee were not yet in place, the Committee agreed with the proposal of the Chairperson and deferred consideration of these Agenda Items and to consider these two items again when the Committee had established its procedures for acceptance and prioritization of work.

157. Some delegations, while not opposing to this decision, pointed out that the Guidelines on Water Reuse deserved particular attention.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 14)

OTHER BUSINESS

Active chlorine

158. The Committee agreed that a drafting group lead by Canada with assistance of Austria, Denmark, EC, France, Ireland, Japan, Republic of Korea, the Netherlands, the United States of America and IDF would prepare draft terms of reference for the FAO/WHO Expert Consultation on the uses of active chlorine which would include safety/benefit issues and prepare questions within its terms of reference of the Committee.

Antimicrobial resistance

159. The Committee noted the information of the Representative of WHO on this matter and suggested the Commission to take into account the outcome of the FAO/WHO/OIE consultative process in the deliberation of a future policy for Codex work in the area of antimicrobial resistance. In particular, the Committee supported the establishment of a Codex/OIE Task Force to develop broad risk management options for antimicrobial resistance related to non-human use of antimicrobials. In doing this, efficient interaction between this Task Force and the CCFH and relevant Codex committees should be ensured.

²⁷ CX/FH 01/9; CX/FH 01/9-Add.1; Comments submitted by Switzerland (CRD 7), EC (CRD 21), India (CRD 28) and Peru (CRD 42).

²⁸ Comments submitted by India (CRD 28).

Viruses in food

160. The Committee agreed with the proposal of the Delegation of the Netherlands to put the discussion paper on Viruses in Food, which had been considered at the 32nd session of the CCFH, on the list of activities for consideration regarding prioritization.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 15)

161. The Committee noted the kind offer of the Delegation of Argentina to co-host the 37th Session of the CCFH, tentatively scheduled from 14 to 19 March 2005, subject to confirmation by the host Governments and the Codex Secretariat.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by:	Reference in ALINORM 03/13A
Draft Code of Hygienic Practice for Milk and Milk Products	8	Governments , 27 th Session of the CAC	paras. 15-53 and Appendix II
Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management	2	Governments , France, 37 th CCFH	paras. 63-90
Proposed Draft Guidelines for the Control of <i>Listeria monocytogenes</i> in Foods	2	Germany , 37 th CCFH	paras. 91-100
Proposed Draft Revision of the Code of Hygienic Practice for Egg Products (CAC/RCP 30-1983)	2	Australia , 37 th CCFH	paras. 101-106
Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures	2	United States , 37 th CCFH	paras. 107-125
Proposed Draft Revision of the Recommended International Code of Practice for Foods for Infants and Children (CAC/RCP 21-1979 (amended 1981))	1,2,3	27th Session of the CAC, Canada, Governments , 37 th CCFH	paras. 149-154
Discussion Paper on the Management of the Work of the Committee		Governments , United States of America, WG, 37 th CCFH	paras. 54-62 and Appendix IV
Discussion Paper on the Guidelines for Microbiological Risk Management Options for <i>Campylobacter</i> spp. in Broiler Chickens		Netherlands , 37 th CCFH	paras. 138-139
Discussion paper on the Guidelines for thee Application of the General Principles of Food Hygiene to the Risk Based Control of Enterohemorrhagic <i>E. coli</i> in Ground Beef and Fermented Sausages		United States , 37 th CCFH	paras. 140-144
Discussion paper on the Guidelines for thee Application of the General Principles of Food Hygiene to the Risk Based Control of <i>Salmonella</i> spp. in Broiler Chicken		Sweden , 37 th CCFH	paras. 145-148

Appendix I

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Appendix II

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DRAFT CODE OF HYGIENIC PRACTICE FOR MILK AND MILK PRODUCTS

INTRODUCTION

Milk and milk products are a rich and convenient source of nutrients for people in many countries and international trade of milk-based commodities is significant. The purpose of this Code is to provide guidance to ensure the safety and suitability of milk and milk products to protect consumers' health and to facilitate trade. The Code satisfies the food hygiene provisions in the Codex Alimentarius *Procedural Manual* under "Relations Between Commodity Committees and General Committees" for use in the various dairy standards.

All foods have the potential to cause food borne illness, and milk and milk products are no exception. Dairy animals may carry human pathogens. Such pathogens present in milk may increase the risk of causing food borne illness. Moreover, the milking procedure, subsequent pooling and the storage of milk carry the risks of further contamination from man or the environment or growth of inherent pathogens. Further, the composition of many milk products makes them good media for the outgrowth of pathogenic microorganisms. Potential also exists for the contamination of milk with residues of veterinary drugs, pesticides and other chemical contaminants. Therefore, implementing the proper hygienic control of milk and milk products throughout the food chain is essential to ensure the safety and suitability of these foods for their intended use. It is the purpose of this Code to provide guidance to countries so that their appropriate level of public health protection for milk and milk products may be achieved. It is also the purpose of this code to prevent unhygienic practices and conditions in the production, processing, and handling of milk and milk products, as in many countries milk and milk products form a large portion of the diet of consumers especially infants, children, and pregnant and lactating women. This document is formatted in accordance with the *Recommended International Code of Practice-General Principles of Food Hygiene*, CAC/RCP 1-1969, Rev. 4, 2003. This Code presents principles for the hygienic production and manufacture of milk and milk products and guidance on their application. This Code takes into consideration, to the extent possible, the various production and processing procedures as well as the differing characteristics of milk from various milking animals used by member countries. It focuses on acceptable food safety outcomes achieved through the use of one or more validated food safety control measures, rather than mandating specific processes for individual products.

1 OBJECTIVES

The objective of this Code is to apply the recommendations of the *Recommended Code of Practice: General Principles of Food Hygiene* to the particular case of milk and milk products. It also provides guidance on how to achieve the general requirements contained in the hygiene sections of the Codex commodity standards for milk products.

2 SCOPE AND USE OF THE DOCUMENT

2.1 SCOPE

This Code applies to the production, processing and handling of milk and milk products as defined in the *General Standard for the Use of Dairy Terms*¹ (CAC/STAN 206-1999). Where milk products are referred to in the code it is understood that this term also includes composite milk products. The scope of this Code does not extend to the production of raw drinking milk.

This Code applies to products in international trade. It may also serve as a basis for national legislation.

2.2 USE OF THE DOCUMENT

The provisions of this document are supplemental to and must be used in conjunction with, the *Recommended International Code of Practice-General Principles of Food Hygiene*, CAC/RCP 1-1969, Rev. 4, 2003.

¹ This code applies to the milk and milk products obtained from all milking animals.

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

Over-arching principles that are applicable to all phases of production, processing and handling of milk and milk products are given in Section 2.3.

Specific principles and their associated explanatory narratives and guidelines are given in the appropriate section.

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. Guidelines for the application of the stated principle are shown in normal text.

The annexes are an integral part of this Code. They provide guidelines for different approaches to the application of the principles. The purpose of the guidelines contained in the annexes is to explain and illustrate how principles in the main body of this code may be met in practice. Thus, the *Recommended International Code of Practice-General Principles of Food Hygiene*, the main body of this Code and its annexes must be used together to obtain complete guidance on the hygienic production of milk and milk products.

2.3 OVERARCHING PRINCIPLES APPLYING TO THE PRODUCTION, PROCESSING AND HANDLING OF ALL MILK AND MILK PRODUCTS

The following overarching principles apply to the production, processing and handling of all milk and milk products.

- **From raw material production to the point of consumption, dairy products produced under this Code should be subject to a combination of control measures, and these control measures should be shown to achieve the appropriate level of public health protection.**
- **Good hygienic practices should be applied throughout the food chain so that milk and milk products are safe and suitable for their intended use.**

No part of this Code should be used without consideration of what takes place in the chain of events 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 continuum of controls that are applied from production to consumption.

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

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

- **Control measures should be validated as effective.**

The overall effectiveness of the system of control measures should be subject to validation. Control measures or combinations thereof should be validated according to the prevalence of hazards in the milk used, taking into consideration the characteristics of the individual hazards(s) of concern and established Food Safety Objectives and/or related objectives and criteria. Guidance on validating control measures should be obtained from the *Codex Guidelines for the Validation of Food Hygiene Control Measures* (under development).

2.4 RELATIVE ROLES OF MILK PRODUCERS, MANUFACTURERS, DISTRIBUTORS, RETAILERS, TRANSPORTERS, CONSUMERS, AND COMPETENT AUTHORITIES

Although the responsibility lies with the manufacturer for ensuring that the foods manufactured are safe and suitable, there is a continuum of effective effort or controls needed by other parties, including milk producers, to assure the safety and suitability of milk products. It is important to recognize that distributors, competent authorities and consumers also have a role in ensuring the safety and suitability of milk and milk products.

The interrelationship and impact of one segment of the food chain on another segment is important to ensure that potential gaps in the continuum are dealt with through communication and interaction between the milk producer, the manufacturer, the distributor and the retailer. While it is principally the responsibility of the manufacturer to conduct the hazard analysis within the context of developing a control system based on HACCP and thus to identify and control hazards associated with the incoming raw materials, the milk producer should also have an understanding of the hazards associated with milk, so as to assist in minimizing their presence in the raw material.

To achieve an effective continuum, the various parties should pay attention, in particular, to the following responsibilities.

- Producers should ensure that good agricultural, hygienic and animal husbandry practices are employed at the farm level. These practices should be adapted, as appropriate, to any specific safety-related needs specified and communicated by the manufacturer.
- Manufacturers should utilize good manufacturing and good hygienic practices, especially those presented in this Code. Any needs for additional measures with regard to controlling hazards during primary production should be effectively communicated to suppliers to enable the milk producer to adapt their operations to meet them. Likewise, the manufacturer may have to implement controls or adapt their manufacturing processes based on the ability of the milk producer to minimize or prevent hazards associated with the milk. Such additional needs should be supported by an adequate hazard analysis and should, where appropriate, take into consideration technological limitations during processing, and/or market demands.
- Distributors, transporters and retailers should assure that milk and milk products under their control are handled and stored properly and according to the manufacturer's instructions.
- Consumers should accept the responsibility of ensuring that milk and milk products in their possession are handled and stored properly and according to the manufacturer's instructions.
- In order to effectively implement this Code, competent authorities should have in place legislative framework (e.g., acts, regulations, guidelines and requirements), an adequate infrastructure and properly trained inspectors and personnel. For food import and export control systems, reference should be made to the *Codex Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997). Control programmes should focus on auditing relevant documentation that shows that each participant along the chain has met their individual responsibilities to ensure that the end products meet established food safety objectives and/or related objectives and criteria.

It is important that clear communications and interactions exist between all parties to help assure good practices are employed, that problems are identified and resolved in an expeditious manner, and that the integrity of the entire food chain is maintained.

2.5 DEFINITIONS

Definitions contained in the *Codex General Standard for the Use of Dairy Terms* (CAC/STAN 206- 1999) are incorporated into this document by reference. Definitions relevant to a particular annex (e.g., heat treatment definitions) will be contained in the relevant annex.

Avoid – To keep away from, to the extent reasonably practicable. This term will be used when it is possible, in theory, to have no contamination or to constrain a particular practice.

Control Measure – Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.²

Food Safety Objective³

² For purposes of this Code, a control measure encompasses any action or activity used to eliminate a hazard or reduce it to an acceptable level. In addition the term refers to any action or activity taken to reduce the likelihood of the occurrence of a hazard in milk or milk products. Thus, control measures include both process controls such as heating, cooling, acidification, etc., as well as other activities such as general hygiene and pest control programmes, etc.

Minimize – To reduce the likelihood of occurrence or the consequence of an unavoidable situation such as microbiological growth.

Process criteria⁴ - The process control parameters (e.g. time, temperature) applied at a processing step.

Raw milk – Milk (as defined in Codex General Standard for the Use of Dairy Terms) which has not been heated beyond 40°C or undergone any treatment that has an equivalent effect.

Shelf Life – The period during which the product maintains its microbiological safety and suitability at a specified storage temperature and, where appropriate, specified storage and handling conditions.

Validation⁵

2.6 SUITABILITY

Food Suitability as defined in the *Recommended International Code of Practice-General Principles of Food Hygiene, CAC/RCP 1 - 1969, Rev. 4, 2003* is: “Assurance that food is acceptable for human consumption according to its intended use”.

For the purposes of this Code, Suitability includes:

- The concept of wholesomeness and soundness.
- Only matters relating to hygiene. Matters relating to grade, commercial quality or compliance to standards of identity are not included.

Additionally:

- Suitability of milk and milk products may be achieved by observing good hygienic practice as outlined in the *Recommended International Code of Practice: General Principles of Food Hygiene, CAC/RCP 1 - 1969, Rev. 4, 2003* and specified in detail in this Code. The use of a management system based on HACCP principles is an effective way of ensuring suitability and demonstrating that suitability is achieved.
- Milk and milk products may not be suitable if the milk or milk product, for example:
 - Is damaged, deteriorated or perished to an extent that makes the milk or milk product unfit for its reasonable intended use; or
 - Contains any damaged, deteriorated or spoiled substance that makes the milk or milk product unfit for its reasonable intended use; or
 - Contains a biological or chemical agent, or other matter or substance, that is foreign to the nature of the food and that makes the milk or milk product unfit for its reasonable intended use.
- The “intended use” is the purpose for which the product is specifically stated or could reasonably be presumed to be intended having regard to its nature, packaging, presentation and identification.

3 PRIMARY PRODUCTION

These principles and guidelines supplement those contained in Section 3 of the *Recommended International Code of Practice-General Principles of Food Hygiene, CAC/RCP 1 - 1969, Rev. 4, 2003* and the general principles presented in Section 2.3 above. Details on specific approaches to the production of milk are given in Annex I of this Code.

Principles Applying to the Primary Production of Milk:

³ This term is defined in “Principles and Guidelines for the Conduct of Microbiological Risk Management” (under development by the Codex Committee on Food Hygiene)

⁴ This term is defined in “Guidelines for the Validation of Food Hygiene Control Measures” (under development by the Codex Committee on Food Hygiene)

⁵ This term is defined in “Guidelines for the Validation of Food Hygiene Control Measures” (under development by the Codex Committee on Food Hygiene)

Milk should not contain any contaminant at a level that jeopardizes the appropriate level of public health protection, when presented to the consumer.

Because of the important influence of primary production activities on the safety of milk products, potential microbiological contamination from all sources should be minimized to the greatest extent practicable at this phase of production. It is recognized that microbiological hazards can be introduced both from the farm environment and from the milking animals themselves. Appropriate animal husbandry practices should be respected and care should be taken to assure that proper health of the milking animals is maintained. Further, lack of good agricultural, animal feeding and veterinary practices and inadequate general hygiene of milking personnel and equipment and inappropriate milking methods may lead to unacceptable levels of contamination with chemical residues and other contaminants during primary production.

Contamination of milk from animal and environmental sources during primary production should be minimized.

Note: A contaminant is “any biological or chemical agent, foreign matter, or other substances not intentionally added to food which may compromise food safety or suitability” (Recommended International Code of Practice: General Principles of Food Hygiene).

The microbial load of milk should be as low as achievable, using good milk production practices, taking into account the technological requirements for subsequent processing.

Measures should be implemented at the primary production level to reduce the initial load of pathogenic microorganisms and microorganisms affecting safety and suitability to the extent possible to provide for a greater margin of safety and/or to prepare the milk in a way that permits the application of microbiological control measures of lesser stringency than might otherwise be needed to assure product safety and suitability.

USE OF THIS SECTION

Guidelines for applying the principles in this section are contained in Annex I. The guidelines are intended to result in raw material that is acceptable for further processing and that will ultimately result in the level of protection required for the particular finished milk product.

Annex I provides details of the general approach that should be used for the primary production of milk intended for further processing of an unspecified nature. Additional provisions to be used in the production of milk intended for the manufacture raw milk products are identified in relevant sections of the annex. Flexibility in the application of certain aspects of the primary production of milk for small holder dairy farms is also provided for. Milk produced according to the provisions of this section should be subjected to the application of control measures described in Annex II.

3.1 ENVIRONMENTAL HYGIENE

Water and other environmental factors should be managed in a way that minimizes the potential for the transmission, directly or indirectly, of hazards into the milk.

Contaminated water, and for example pests (such as insects and rodents), chemicals and the internal and external environments where the animals are housed and milked, may contaminate feed, equipment or milking animals leading to the introduction of hazards into milk.

Water used in primary production operations should be suitable for its intended purpose and should not contribute to the introduction of hazards in milk.

3.2 HYGIENIC PRODUCTION OF MILK

3.2.1 Areas and Premises for Milk Production

Areas including premises used for the production of milk should be designed, situated, maintained and, to the extent practicable, used in a manner that minimizes the introduction of hazards into milk.

Improperly protected and maintained premises for the holding and milking of dairy animals have been shown to contribute to the contamination of milk.

3.2.2 Animal Health

The health status of milking animals and herds should be managed in a manner that addresses the hazards of concern for human health.

Milk should come from animals in good health so that, considering the end use, it does not adversely affect the safety and suitability of the end product.

It is important to prevent the spread of zoonotic diseases among animals and from animals (including milking animals) to milk. Milk and milk products produced from milk obtained from certain diseased animals has been known to be neither safe nor suitable for human consumption.

Maintenance of healthy milking animals has been shown to reduce the likelihood that human pathogens will be introduced into the milk via the mammary gland or from the faeces.

3.2.3 General Hygienic Practice

3.2.3.1 Feeding

With consideration given to the end use of the milk, forage and feed for lactating animals should not introduce, directly or indirectly, contaminants into milk in amounts that present an unacceptable health risk to the consumer or adversely affect the suitability of milk or milk products.

It has been shown that improper procurement, manufacturing and handling of animal feed can result in the introduction of pathogens and spoilage organisms to milking animals and the introduction of chemical hazards such as pesticide residues, mycotoxins and of other contaminants which can affect the safety and suitability of milk or milk products.

3.2.3.2 Pest control

Pests should be controlled, and in a way that does not result in unacceptable levels of residues, such as pesticides, in the milk.

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

3.2.3.3 Veterinary Drugs

Animals should only be treated with veterinary drugs authorized by the competent authority for the specific use and in a manner that will not adversely impact on the safety and suitability of the milk, including adherence to the withdrawal period specified.

Milk from animals that have been treated with veterinary drugs that can be transferred to milk should be discarded appropriately until the withdrawal period specified for the particular veterinary drug has been achieved.

Residues of veterinary drugs in milk should not exceed levels that would present an unacceptable risk to the consumer.

The improper use of veterinary drugs has been shown to result in potentially harmful residues in milk and milk products, and may affect the suitability of milk intended for the manufacture of cultured products.

3.2.4 Hygienic Milking

Milking should be carried out in such a manner that minimizes contamination of the milk being produced.

Effective hygienic practice during milking is an important element of the system of controls necessary to produce safe and suitable milk and milk products. Failure to maintain adequate sanitation and employee practices has been shown to contribute to the contamination of milk with undesirable or pathogenic microorganisms or chemical or physical hazards.

3.3 HANDLING, STORAGE AND TRANSPORT OF MILK

With consideration given to the end use of the milk, handling, storage and transport of milk should be conducted in a manner that will avoid contamination and minimize any increase in the microbiological load of milk.

Proper handling, storage and transport of milk are important elements of the system of controls necessary to produce safe and suitable milk and milk products. Contact with unsanitary equipment and foreign materials are known causes of milk contamination. Temperature abuse is known to increase the microbiological load of milk.

3.3.1 Milking Equipment

Milking equipment should be designed, constructed, installed, maintained and used in a manner that will avoid the introduction of contaminants into milk.

Milking equipment is normally designed and constructed according to recognized standards that avoid the introduction of contaminants into milk. Equipment selected for installation on dairy farms should meet recognized design and construction standards. Recognized guidelines also exist for the proper use, cleaning and maintenance of milking equipment; such guidelines should be followed to avoid transfer of disease between animals through milking equipment and to help ensure obtaining milk that is safe and suitable.

Milking equipment should be operated in a manner that will avoid damage to udder and teats and that will avoid the transfer of disease between animals through the milking equipment.

It is important to prevent any damage to udder and teats by milking equipment since such damage can lead to infections and consequently adversely affect the safety and suitability of milk and milk products.

3.3.2 Storage Equipment

Milk storage tanks and cans should be designed, constructed, maintained and used in a manner that will avoid the introduction of contaminants into milk and minimize the growth of microorganisms in milk.

3.3.3 Premises for, and Storage of, Milk and Milking-Related Equipment

Premises for the storage of milk and milking-related equipment should be situated, designed, constructed, maintained and used in a manner that avoids the introduction of contaminants into milk.

Whenever milk is stored, it should be stored in a manner that avoids the introduction of contaminants into milk and in a manner that minimizes the growth of microorganisms.

3.3.4 Collection, Transport and Delivery Procedures and Equipment

This section also covers the activities of personnel involved in the transport of milk.

Milk should be collected, transported and delivered without undue delay, and in a manner that avoids the introduction of contaminants into milk and minimizes the growth of microorganisms in the milk.

Note: See Section 10 for provisions on the training of personnel involved in the collection, transport and delivery of milk.

Milk transport tankers and cans should be designed, constructed, maintained and used in a manner that will avoid the introduction of contaminants into milk and minimize the growth of microorganisms in milk.

3.4 DOCUMENTATION AND RECORD KEEPING

Records should be kept, as necessary, to enhance the ability to verify the effectiveness of the control systems.

4 ESTABLISHMENT: DESIGN AND FACILITIES

These principles and guidelines are supplemental to those contained in Section 4 of the *Recommended International Code of Practice-General Principles of Food Hygiene*, CAC/RCP 1 - 1969, Rev. 4, 2003 and to the general principles presented in Section 2.3 above.

4.1 EQUIPMENT

Equipment should be designed and installed such that as far as possible dead ends or dead spots in milk pipelines do not occur.

Where dead ends or dead spots occur, special procedures should ensure they are effectively cleaned or otherwise do not permit a safety hazard to occur.

5 CONTROL OF OPERATION

These principles and guidelines are supplemental to those contained in Section 5 of the *Recommended International Code of Practice-General Principles of Food Hygiene*, CAC/RCP 1 - 1969, Rev. 4, 2003 (including the Annex on *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application*) and to the overarching principles presented in Section 2.3 above.

USE OF THIS SECTION

This section contains principles for the control of operation that are intended to be applied in such a manner as to result in meeting acceptable levels of relevant hazards specified as Food Safety Objectives and/or related objectives and criteria, or end product criteria that have been established to express the level of protection for the specific situation. Guidelines for applying the principles with respect to physical, chemical and microbiological hazards are provided in this section as well. Details given in Annex II provide guidance on the establishment and management of control measures used to achieve safety and suitability during and after processing.

For the effective implementation of the provisions in this Section, milk should be produced in accordance with Section 3 and Annex I of this Code.

5.1 CONTROL OF FOOD HAZARDS

The combination of control measures should effectively control the identified hazards in milk and milk products.

The combination of control measures should be designed in a systematic way, and the chosen combination should be adapted to the hygiene status of the milk and raw materials used with consideration given to the relevant microbiological, chemical and physical hazards of concern and to the establishment of Food Safety Objective(s) and/or related objectives and criteria.

Where appropriate control measures and/or control measure combinations are chosen to control hazards that are reasonably likely to occur, the procedures described in sections 5.1.1 to 5.1.3 and corresponding guidelines contained in Annex II should be implemented in order to minimize or prevent the likelihood of a health risk to the consumer.

The following procedures are intended to enhance and supplement those aspects of the HACCP Annex to the *International Recommended Code of Practice: General Principles of Food Hygiene*, which are critical to the successful design of a system of food safety controls.

5.1.1 Hazard Identification and Evaluation

All potential hazards should be identified.

This should be done before control measures are selected and is the first step in the hazard analysis.

The identification should be based on the initial descriptions developed during preliminary steps and on experience, external information, as well as epidemiological and other historical data that have been associated with the type of food under consideration, the type of raw materials and ingredients used, and that may be introduced during processing and distribution. To insure a comprehensive approach, the various step(s) in the manufacturing process, from material selection through processing and distribution, where a hazard may occur or be introduced should be identified.

Each potential hazard should be evaluated to determine the severity of its adverse health effects and reasonable likelihood of occurrence.

Potential hazards that are determined to have severe adverse health effects and/or are reasonably likely to occur should be subject to control by the system of control measures.

5.1.2 Control Measure Selection

Following hazard evaluation, control measures and control measure combinations should be selected that will prevent, eliminate, or reduce the hazards to acceptable levels.

The next step in the hazard analysis process is to select control measures that will be effective in controlling those hazards. A number of such control measures are further described in Annex II, Parts A and B.

Guidance on how to provide reference validations of individual control measures or control measure combinations against individual hazards in various media is given in *Guidelines for the Validation of Food Hygiene Control Measures* (CCFH document under development).

5.1.3 Establishment of Process Criteria

Process criteria for control measures should be established in order for the process to be applied in a manner that will meet the performance required, i.e., assure the adequate delivery of the control measure.

Process criteria should be established at such intensities that the control measures actually deliver the expected performance, taking into account normal process deviations.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.1 Temperature and Time Controls

From milk production through to finished products, products should be stored at appropriate temperatures and for appropriate times such that the growth or development of a food safety hazard will be minimized and the product's suitability will not be adversely affected.

Because milk and many milk products have a sufficient moisture content to support the growth of pathogens, temperature and time controls represent key microbiological control measures to control growth throughout the manufacturing process, from the handling of milk to the distribution and storage of perishable milk products (e.g., pasteurized drinking milk, desserts, and soft cheeses, depending on shelf life). For instance, for liquid milk, increased storage temperature will decrease the shelf life.

5.2.1.1 Management of products within the plant

Incoming milk

When arriving at the dairy plant, and provided that further processing does not allow otherwise, the milk should be cooled and maintained at such temperatures as necessary to minimize any increase of the microbial load of the milk.

The principle of "first arrived, first processed" should apply.

Intermediate Products

Intermediate products that are stored prior to further processing should, unless further processing does not allow it, be kept under such conditions that limit/prevent microbial growth or be further processed within a short time period.

The ultimate safety and suitability of milk and milk products, as well as the intensity of the control measures that need to be applied during processing, depends not only on the initial microbial load upon receipt at the dairy plant but also on preventing the growth of microorganisms. Application of proper storage temperatures and management of raw materials is an essential factor in minimizing microbial growth. The ability of a product to meet intended Food Safety Objectives and/or related objectives and criteria is dependent upon the proper application of the control measures, including time and temperature controls.

There should be adequate stock rotation, based on the principle of “first in, first out”.

5.2.1.2 Distribution of Finished Products

It is essential that milk and milk products be kept at an appropriate temperature in order to maintain their safety and suitability from the time it is packaged until it is consumed or prepared for consumption.

While the storage temperature should be sufficient to maintain the product’s safety and suitability throughout the intended shelf life, the appropriate storage temperature will vary depending upon whether the product is perishable or non-perishable. For perishable products, the distribution system should be designed to maintain adequate low-temperature storage to ensure both safety and suitability. For non-perishable products designed to be shelf-stable at ambient temperature, extremes of temperature should be avoided, primarily to assure maintaining suitability. Reasonably anticipated temperature abuse should be taken into account in designing the normal patterns of distribution and handling.

5.2.1.3 Establishment of Shelf Life

It is the responsibility of the manufacturer to determine the shelf life of the product and the conditions for storage.

Limitation of shelf life is a control measure that, in many cases, is decisive for the safety and suitability of the product. The corresponding storage conditions are an integral aspect of product shelf life.

5.2.2 Specific Process Steps

Annex II, Appendices A and B contain examples of processes used during the manufacture of milk products that can control hazards that are reasonably likely to occur. These processes include both extrinsic and intrinsic factors that influence the growth of microorganisms.

***Extrinsic factors** refer to factors impacting the product from the environment in which the food is placed. Examples include temperature, time, and relative humidity of the air.*

***Intrinsic factors** refer to internal factors in the product itself (food matrix), influenced by or as consequence of extrinsic factors, that have an impact on the growth and/or survival of microorganisms. Examples include water activity, pH, nutrient availability, competition of microorganisms, and bacteriocins or other growth inhibitors.*

5.2.3 Microbiological and Other Specifications

Where they are employed, microbiological criteria, including those used to verify the effective application of control measures within the framework of HACCP principles, should be developed in accordance with the *Principles for the Establishment and Application of Microbiological Criteria for Foods*, CAC/GL 21-1997, including the use of a risk assessment approach as specified in the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment*, CAC/GL 030-1999.

5.2.3.1 Incoming Milk

Manufacturers should establish incoming milk criteria that take into account the end use of the milk and the conditions under which the milk was produced.

Depending upon the end use of the milk, particularly for milk used in the production of raw milk products, certain specific microbiological criteria may be appropriate to verify the microbiological quality of the milk used as raw material.

Corrective action taken for non-compliance with incoming milk criteria should be commensurate with the potential risks presented by the non-compliance.

Incoming milk that is out of compliance with established criteria indicates that the control measure system is not working properly and corrective action should be taken to identify and resolve causative problems.

5.2.3.2 Microbiological criteria

Microbiological criteria may be necessary to be established at different points in the process for carrying out the design of control measure combinations and for the verification that the control system has been implemented correctly

In some cases, for example where more comprehensive control measures are put into place to ensure the safety and suitability of milk (such as may be the case for raw milk intended to be used in the production of raw milk products), it may be necessary to establish criteria for in-process product, intermediate product or finished product in order to verify that the more comprehensive set of control measures have been properly carried out.

5.2.4 Microbiological cross contamination

The flow of the product and of the ingredients within equipment and through the processing facility should maintain a forward progression from raw material receipt to finished product packaging so as to avoid cross contamination.

The flow of the water, air, effluents, and milk should be carefully evaluated to ensure that the potential for cross-contamination does not occur. Similarly, the flow of personnel should be evaluated to ensure that their actions couldn't contaminate milk.

There should be adequate separation of areas with different levels of contamination risk.

Milk products that have been returned from other locations should be identified, segregated and stored in a clearly designated area.

Where there is the potential for cross-contamination between end products and raw materials or intermediate products, and from contaminated areas such as construction and rebuilding areas, consideration should be given to a physical separation, such as by the application of barrier hygiene (the application of physical or mechanical barriers to prevent or minimize the transfer of contaminants or potential sources of contaminants) and wet/dry area segregation.

5.2.5 Physical and Chemical Contamination

Preventive measures should be implemented to minimize risks of contaminating milk and milk products with physical and chemical hazards and foreign substances.

Avoiding physical and chemical contamination of milk and milk products during processing requires the effective control of equipment maintenance, sanitation programmes, personnel, monitoring of ingredients and processing operations.

Preventive measures should include those that will minimize the potential for cross contamination of allergenic components and/or ingredients that may present in other products to a milk product in which these components and/or ingredients are not supposed to be present.

5.3 INCOMING MATERIAL (OTHER THAN MILK) REQUIREMENTS

Ingredients used for the processing of milk products should be purchased according to specifications, and their compliance with these specifications should be verified.

Contaminated ingredients have been known to lead to unsafe/unsuitable milk products, since these ingredients are often added during processing where no further control measures are applied.

Preferably, specifications for raw materials should be established such that their use will result in a safe and suitable product. No raw material should be accepted if it is known to contain chemical, physical or microbiological contaminants that would not be reduced to an acceptable level by normal sorting and/or processing. Raw materials should, where appropriate, be inspected and sorted before processing. Any claims that raw materials meet safety and suitability specifications should be verified periodically.

5.4 WATER

Dairy processing establishments should have potable water available, which prior to its first use, should meet the criteria specified by the competent authorities having jurisdiction and should be regularly monitored.

Water recirculated for reuse should be treated and maintained in such a condition that no risk to the safety and suitability of food results from its use.

Proper maintenance of water conditioning systems is critical to avoid the systems becoming sources of contamination. For example, filter systems can become sources of bacteria and their metabolites if bacteria are allowed to grow on the organic materials that have accumulated on the filter.

Appropriate safety and suitability criteria that meet the intended outcomes should be established for any water used in dairy processing.

These criteria depend upon the origin and the intended use of the water. For example, reuse water intended for incorporation into a food product should at least meet the microbiological specifications for potable water.

Reconditioning of water for reuse and use of reclaimed, recirculated and recycled water should be managed in accordance with HACCP principles.

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.

6 ESTABLISHMENT: MAINTENANCE AND SANITATION

These principles and guidelines are supplemental to those contained in Section 6 of the *Recommended International Code of Practice-General Principles of Food Hygiene*, CAC/RCP 1 - 1969, Rev. 4, 2003.

6.1 MAINTENANCE AND CLEANING

Processing areas should be kept as dry as possible.

Use of dry cleaning methods, and limiting the use of water in processing areas, helps to avoid the spread of contamination by water. Wet cleaning (other than Cleaning-in-Place) has been known to lead to milk product contamination due to the production of aerosols.

All food product contact surfaces in piping and equipment, including areas that are difficult to clean such as by-pass valves, sampling valves, and overflow siphons in fillers should be adequately cleaned.

6.2 CLEANING PROGRAMMES

A routine programme to verify the adequacy of cleaning should be in place.

All equipment and utensils used in processing should, as necessary, be cleaned and disinfected, rinsed with water which is safe and suitable for its intended purpose (unless the manufacturer's instructions indicate rinsing is not necessary), then drained and air dried where appropriate.

7 ESTABLISHMENT: PERSONAL HYGIENE

No specific requirements beyond those contained in the *Recommended International Code of Practice-General Principles of Food Hygiene*, CAC/RCP 1 - 1969, Rev. 4, 2003 are needed.

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*, CAC/RCP 1 - 1969, Rev. 4, 2003 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.)

8.1 REQUIREMENTS

Products covered under this Code should be transported at time/temperature combinations that will not adversely affect the safety and suitability of the product.

8.2 USE AND MAINTENANCE

In the case of refrigerated products, the vehicle product compartment should be cooled prior to loading and the product compartment should be kept at an appropriate temperature at all times, including during unloading.

9 PRODUCT INFORMATION AND CONSUMER AWARENESS

These principles and guidelines are supplemental to those contained in Section 9 of the *Recommended International Code of Practice-General Principles of Food Hygiene*, CAC/RCP 1 - 1969, Rev. 4, 2003.

9.1 LABELING

Milk products should be labelled in accordance with the *Codex General Standard for the Labelling of Prepackaged Foods* (CAC/STAN 1; 1985 (Rev. 1 – 1991)), the *Codex General Standard for the Use of Dairy Terms* (CAC/STAN 206; 1999) and the relevant labelling section of Codex commodity standards for individual milk products.

Unless the product is shelf stable at ambient temperatures, a statement regarding the need for refrigeration or freezing should be included on the label of the product.

Additional provision for raw milk products

Raw milk products should be labeled to indicate they are made from raw milk according to national requirements in the country of retail sale.

10 TRAINING

These principles and guidelines are supplemental to those contained in Section 10 of the *Recommended International Code of Practice-General Principles of Food Hygiene*, CAC/RCP 1 - 1969, Rev. 4, 2003.

10.1 TRAINING PROGRAMMES

Milk producers and personnel involved in the collection and transport and retail of milk should be trained as necessary and have appropriate skills in the areas listed below:

- health of animals and use of veterinary drugs;
- manufacturing and use of feeds (more specifically fermented feeds);
- herd management;
- hygienic milking;
- storage, handling, collection and transport of milk (cleaning of storage tanks, temperature requirements, sampling procedures, etc.);
- microbiological, chemical and physical hazards and their control measures.

ANNEX I

GUIDELINES FOR THE PRIMARY PRODUCTION OF MILK

INTRODUCTION AND OBJECTIVES

The detailed information contained in this annex should be implemented in order to reduce the likelihood of milk contamination through inadequate primary production practices. This information will enable the implementation of the principles laid down in Section 3 of the main body of the Code by providing guidelines for their application.

These measures, in combination with microbiological control measures found in Annex II, should be used to effectively control the microbiological hazards in milk products. There is a close relationship between the hygienic conditions found in primary production and the safety and suitability of processed milk products based on the control measures presented in Annex II.

SCOPE

This Annex provides details of the approaches that should be used for the primary production of milk intended for further processing of an unspecified nature. The milk should be subjected to the application of microbiological control measures described in Annex II.

The degree to which on-farm practices control the likelihood of occurrence of food safety hazard in milk will have an impact on the nature of controls needed during the subsequent processing of the milk. Under normal circumstances, milk will be subjected to control measures sufficient to address any hazards that may be present. Where the subsequent processing of milk does not involve the application of control measures necessary to address any hazards that may be present, the focus then becomes preventative in nature in order to reduce the likelihood that such hazards will occur during the primary production phase of the continuum. Likewise, in certain primary production situations, the occurrence of food safety hazards may be less avoidable, which will mandate the application of more stringent control measures during subsequent processing in order to insure the safety and suitability of the finished product.

USE OF ANNEX I

The information in Annex I is organized to correspond with the relevant sections in the main part of the Code and the *Recommended International Code of Practice-General Principles of Food Hygiene*, CAC/RCP 1 - 1969, Rev. 4, 2003. Where a particular principle has been identified in the main body of the Code, guidelines for the application of that principle will be located in the corresponding section of this Annex.

Additional Provisions for the Production of Milk Used for Raw Milk Products.

When milk is intended to be used for the manufacture of raw milk products, the hygienic conditions used at the primary production are one of the most important public health control measures, as a high level of hygiene of the milk is essential in order to obtain milk with a sufficiently low initial microbial load in order to enable the manufacturing of raw milk products that are safe and suitable for human consumption. In such situations, additional control measures may be necessary. Where applicable, these additional measures are provided at the end of each sub-section.

Compliance with these additional hygienic provisions is important, and is considered mandatory in certain circumstances (where the nature of the finished product or national legislation requires), throughout the milk production process, up to the manufacture of the particular raw milk product. In addition, increased emphasis in certain aspects of the production of milk for raw milk products (animal health, animal feeding, milk hygiene monitoring) are specified and are critical to the production of milk that is safe and suitable for the intended purpose. To reflect the greater emphasis on the compliance needed on certain provisions, the word "should" has been substituted with the word "shall" where applicable.

As is the case with the rest of this code, this section also does not mandate or specify the use of any one set of controls to be used, but leaves it up to those responsible for assuring the safety of the finished product to choose the most appropriate set of control measures for the particular situation.

There are a wide variety of raw milk products, most of which are cultured products such as cheeses. The range of moisture content, pH and salt content (among other parameters) in these products will have varying degrees of impact on any potential microbiological hazards that may be present in the milk used for their manufacture. The degree to which the inherent characteristics of the product (or process used to manufacture the product) will control the hazard should guide the extent to which these potential hazards need to be prevented or controlled during primary production.

A wide range of food safety approaches exist for the production of raw milk products. As is the case with the rest of this code, the approach taken in this section is intended to be flexible enough to take into account the different approaches used in different countries regarding the manufacture and marketing of raw milk products.

Special Provisions for the Production of Milk on Small Holder Dairy Farms

In the context of this Code, the expression “Small Holder Dairy Farm” refers to farms where the number of animals per farmer or per herd usually does not exceed 10, milking machines are not generally used, milk is not chilled at the producer’s level and/or the milk is transported in cans.

Flexibility in the application of certain requirements of the primary production of milk in small holder dairy farms can be exercised, where necessary, provided that the milk is received by dairy plants and will be subjected to a combination of microbiological control measures sufficient to obtain a safe and suitable milk product. Such flexibility is indicated throughout this annex by the use of a parenthetical statement “if used” or “if applicable” placed next to the particular provision where the flexibility is needed.

Flexibility as above may also apply to farms with larger number of animals but having similar economic constraints or limited water and/or power supplies, preventing investment in technological facilities and infrastructure.

3 PRIMARY PRODUCTION

3.1 ENVIRONMENTAL HYGIENE

When water is used for the cleaning of the udder and for cleaning equipment used for the milking and storage of milk it should be of such quality that it does not adversely affect the safety and suitability of the milk.

Precautions should be adopted to ensure that milking animals do not consume or have access to contaminated water or other environmental contaminants likely to cause diseases transmissible to humans or contaminate milk.

3.2 HYGIENIC PRODUCTION OF MILK

3.2.1 Areas and Premises for Milk Production

3.2.1.1 Animal holding areas

The design, layout and provision of holding areas should not adversely affect the health of animals. In particular, holding areas should be kept clean and maintained in a manner that minimizes the risk of animal infection or contamination of the milk.

Access to the animal holding area, including the stable and attached premises, if used, should preclude the presence of other species that would adversely affect the safety of the milk.

The holding area should, as far as practicable, be kept clean and free of accumulations of manure, mud or any other objectionable materials.

If used, stable and stalls should be designed and constructed to keep them free of accumulations of manure, feed residues, etc.

Animal holding areas should be designed such that animals with contagious diseases can be separated to prevent the transmission of disease to healthy animals.

Animal holding areas should not adversely affect the health of animals. In particular, the litter and the stabling area should be maintained in a manner that minimizes the risk of teat injuries and udder diseases.

3.2.1.2 Milking areas and related facilities

Premises where milking is performed should be situated, constructed (if applicable) and maintained in a manner that will minimize or prevent contamination of the milk.

Milking areas should be kept free of undesirable animals such as pigs, poultry and other animals whose presence may result in the contamination of milk.

Premises where milking is performed should be easy to clean, especially in areas subject to soiling or infection, e.g., they should have:

- flooring constructed to facilitate draining of liquids and adequate means of disposing of waste;
- adequate ventilation and lighting;
- an appropriate and adequate supply of water of a suitable quality for use when milking and in cleaning the udder of the animals and equipment used for milking;
- effective separation from all sources of contamination such as lavatories (if used) and manure heaps; and
- effective protection against vermin.

Additional Provisions for the Production of Milk Used for Raw Milk Products

Only potable water can be used in milking areas, product storage areas and other critical areas.

3.2.2 Animal Health

Adequate management measures should be implemented to prevent animal diseases and to control drug treatment of diseased animals or herds in an appropriate way. In particular, preventive measures should be taken to prevent disease including:

- Eradication of animal diseases or control of risk of transmission of the diseases, according to the specific zoonosis
- Management of other animals in the herd and other farmed animals present (including the segregation of diseased animals from healthy animals)
- Management of new animals in the herd

The milk should originate from herds or animals that are officially free of brucellosis and tuberculosis, as defined by the OIE International Animal Health Code. If not officially free, then milk should originate from herds or animals that are under official control and eradication programmes for brucellosis and tuberculosis. If controls for brucellosis and tuberculosis were not sufficiently implemented, it would be necessary for the milk to be subjected to subsequent microbiological control measures (e.g., heat treatment) that will assure the safety and suitability of the finished product.

Milk should be drawn from animals that:

- are identifiable to facilitate effective herd management practices;
- do not show visible impairment of the general state of health; and
- do not show any evidence of infectious diseases transferable to humans through milk including but not limited to diseases governed by the OIE International Animal Health Code.

Adequate measures should be implemented in order to prevent udder infections, especially:

- the correct use of milking equipment (e.g. daily cleaning, disinfection and disassembling of equipment);
- the hygiene of milking (e.g. udder cleaning or disinfection procedures);
- the management of the animal holding areas (e.g. cleaning procedures, design and size of areas);

- the management of dry and lactation periods (e.g., treatment for the drying off).

Additional Provisions for the Production of Milk Used for Raw Milk Products

The milk cannot carry unacceptable levels of zoonotic agents. Therefore, the milk shall originate from individual animals:

- that are identifiable such that the health status of each animal can be followed. To this effect:
 - the herd shall be declared to the competent authorities and registered;
 - each animal shall be identified with a steadfast device and registered by the competent authorities.
- that do not show visible impairment of the general state of health and which are not suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or recognizable inflammation of the udder;
- that do not show any evidence (signs or analytical results) of infectious diseases caused by human pathogens (e.g., Listeriosis) that are transferable to humans through milk including but not limited to such diseases governed by the OIE International Animal Health Code;
- that, in relation to brucellosis and tuberculosis, shall comply with the following criteria:
 - Cows milk shall be obtained from animals belonging to herds that are officially free of tuberculosis and brucellosis in accordance with the relevant chapters of the OIE International Animal Health Code;
 - Sheep or goat milk shall be obtained from animals belonging to sheep or goat herds that are officially free or free of brucellosis as per the OIE International Animal Health Code;
 - when a farm has a herd comprised of more than one species, each species shall comply with sanitary conditions that are mandatory for each particular species ;
 - if goats are in the same environment with cows, goats shall be monitored for tuberculosis.

In addition, it is necessary that the milk also be checked for other relevant aspects in accordance with point 5.2.3.1. (microbiological and other specifications) which can have an impact on the safety and suitability of raw milk products; these results may provide information regarding the health status of the animals.

In particular, preventive measures are needed to prevent disease including:

- animals of unknown health status shall be separated, before being introduced in the herd, until such time that their health status has been established. During that separation period, milk from those animals shall not be used for the production of milk for the manufacture of raw milk products;
- the owner shall keep a record of relevant information, e.g., results of tests carried out to establish the status of an animal just being introduced, and the identity for each animal either coming or leaving the herd.

3.2.3 General Hygienic Practice

3.2.3.1 Feeding

The relevant aspects of the Codex Code of Practice on Good Animal Feeding (under development) should be applied to minimize or prevent the introduction of contaminants through feed or feeding practices.

Additional Provisions for the Production of Milk Used for Raw Milk Products

When using fermented feed, it is necessary that the feed be prepared, stored and used in a manner that will minimize microbial contamination. Particular attention shall be given to compliance with good practices concerning the following aspects:

- the design of silos;
- good production practices of silage;

- regular check of the quality of the fermented feed (organoleptic inspection or pH).

The owner shall keep a record of relevant information concerning feed.

3.2.3.2 Pest control

Before pesticides or rodenticides are used, all efforts should be made to minimize the presence of insects, rats and mice. Although stables and milking parlours (if used) attract such pests, good preventive measures such as proper building construction and maintenance (if applicable), cleaning, and removal of faecal waste can minimize pests.

Accumulations of manure should not be allowed to develop close to milking areas.

Mice and rats are also attracted to animal feed stores. Hence, any such feed stores should be located at a suitable place and feed kept in containers that provide adequate protection against such pests.

If it is necessary to resort to chemical pest control measures, such products should be approved officially 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 milking environment. Such chemicals should not be stored in wet areas or close to feed stores. It is preferable to use solid baits, wherever possible.

No pesticides should be applied during milking.

3.2.3.3 Veterinary Drugs⁶

The relevant aspects of the Guidelines on the Control of Veterinary Drug Residues in Milk and Milk Products (under development) should be applied to minimize or prevent the introduction of drug residues in milk or milk products.

Good husbandry procedures should be used to reduce the likelihood of animal disease and thus reduce the use of veterinary drugs.

Only those medicinal products and medicinal premixes that have been authorized by competent authority for inclusion in animal feed should be used.

Milk from animals that have been treated with veterinary drugs that can be transferred to milk should be discarded until the withdrawal period specified for the particular veterinary drug has been achieved. Established MRLs for residues of veterinary drugs in milk may serve as a reference for such verification.

The veterinarian and/or the livestock owner or the collection centre should keep a record of the products used, including the quantity, the date of administration and the identity of animals. 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.

3.2.4 Hygienic Milking

Minimizing contamination during milking requires that effective hygienic practices be applied in respect of the skin of the animal, the milking equipment (whenever used), the handler and the general environment e.g. faecal sources of contamination.

Milking should be carried out under hygienic conditions, including:

- good personal hygiene of the milking personnel;
- clean udders, teats, groins, flanks and abdomens of the animal;
- clean and disinfected milking vessels/equipment; and
- avoidance of any damage to the tissue of the teat/udder.

⁶ Treatment with veterinary drugs should be consistent with the Code of Practice to Minimize and Contain Antimicrobial Resistance (under development by the Codex Committee on Residues of Veterinary Drugs in Foods).

In particular, during any milking, consideration should be given to minimizing and/or preventing contamination from the milk production environment and maintaining personal hygiene.

Animals showing clinical symptoms of disease should be segregated and/or milked last, or milked by using separate milking equipment or by hand, and such milk should not be used for human consumption.

Operations such as feeding the animals or placement/removal of litter should be avoided prior to milking in order to reduce the likelihood of contamination of the milking equipment and the milking environment from manure or dust.

The milking animals should be maintained in an as clean state as possible. Prior to any milking, teats should be clean. The milker should monitor by appropriate means that the milk appears normal, for example by careful observation of the condition of milking animals, by checking the milk of each animal for organoleptic or physicochemical indicators, and by using records and identification of treated animals. If the milk does not appear normal, the milk should not be used for human consumption. The producer should take appropriate precautions to minimize the risk of infections to teats and udders, including the avoidance of damage to tissue. Foremilk (initially drawn small quantity of milk) from each teat should be discarded or collected separately and not used for human consumption unless it can be shown that it does not affect the safety and suitability of the milk.

3.2.4.1 Environmental contamination

Milking operations should minimize the introduction of food-borne pathogens and foreign matter from the skin and general milking environment as well as chemical residues from cleaning and disinfection routines.

3.2.4.2 Milking equipment design

Milking equipment, utensils and storage tanks should be designed, constructed and maintained in such a way that they can be adequately cleaned and do not constitute a significant source of contamination of milk.

Milking equipment should be designed such that it does not damage teats and udders during normal operation.

3.2.4.3 Milking equipment cleaning and disinfection

Milking equipment and storage tanks (and other vessels) should be thoroughly cleaned and disinfected following each milking, and dried when appropriate.

Rinsing of equipment and storage tanks following cleaning and disinfection should remove all detergents and disinfectants, except in those circumstances where the manufacturer instructions indicate that rinsing is not required.

Water used for cleaning and rinsing should be appropriate for the purpose, such that it will not result in contamination of the milk.

Additional Provisions for the Production of Milk Used for Raw Milk Products

Only potable water can be used in contact with milking equipment and other milk contact surfaces.

3.2.4.4 Health and personal hygiene of Milking Personnel

Milking personnel should be in good health. Individuals known, or suspected to be suffering from, or to be a carrier of, a disease likely to be transmitted to the milk, should not enter milk handling areas if there is a likelihood of their contaminating the milk. Medical examination of a milk handler should be carried out if clinically or epidemiologically indicated.

Hands and forearms (up to elbow) should be washed frequently and always washed before initiating milking or handling of milk.

Milking should not be performed by persons having exposed abrasions or cuts on their hands or forearms. Any injury on hands or forearms must be covered with a water-resistant bandage.

Suitable clothing should be worn during milking and should be clean at the commencement of each milking period.

3.3 HANDLING, STORAGE AND TRANSPORT OF MILK

Time and temperature control is important during storage and transport of milk and depends highly on the type and effectiveness of the control measures applied during and after processing. Therefore, the needs for time/temperature control at farm level should be clearly communicated by the manufacturer of the milk products.

3.3.1 Milking Equipment

The design of milking equipment, where used, and cans, should ensure there are no crevices or recesses that can interfere with proper cleaning.

Milking equipment should be installed and tested (if applicable) in accordance with manufacturer's instructions and in accordance with any available technical standards that have been established by appropriate technical standards setting organizations for such equipment (e.g., IDF, ISO, 3A) in order to assist in assuring that the equipment is functioning properly.

Milking equipment and cans should be cleaned and disinfected regularly and with sufficient frequency to minimize or prevent contamination of milk.

There should be a periodic verification process to ensure that milking equipment is in good working condition.

Milking equipment and utensils which are intended to come into contact with milk (e.g., containers, tanks, etc.) should be easy to clean and disinfect, corrosion resistant and not capable of transferring substances to milk in such quantities as to present a health risk to the consumer.

Between inspections, milking equipment should be maintained in proper working condition.

3.3.2 Milk Storage Equipment

Milk storage tanks and cans should be so designed to ensure complete drainage and constructed to avoid contamination of the milk when it is stored.

Milk storage equipment should be properly installed, maintained and tested in accordance with manufacturer's instructions and in accordance with any available technical standards that have been established by appropriate technical standards setting organizations for such equipment (e.g., IDF, ISO, 3A) in order to assist in assuring that the equipment is functioning properly.

Surfaces of milk storage tanks, cans and associated equipment intended to come into contact with milk should be easy to clean and disinfect, corrosion resistant and not capable of transferring substances to milk in quantities that will present a health risk to the consumer.

Milk tanks and cans should not be used to store any harmful substance that may subsequently contaminate milk. If milk storage tanks and cans are used to store foods other than milk, precautions should be taken to prevent any subsequent milk contamination.

Storage tanks and cans should be cleaned and disinfected regularly and with sufficient frequency to minimize or prevent contamination of milk.

Storage tanks or portions of storage tanks that are outdoors should be adequately protected or designed such that they prevent access of insects, rodents and dust in order to prevent contamination of milk.

There should be a periodic verification process to ensure that milk storage equipment is properly maintained and in good working condition.

Additional Provisions for the Production of Milk Used for Raw Milk Products

Milk tanks and cans can be used only to store milk and milk products.

It is necessary to verify, at least once a year, that milk storage equipment is maintained and in good working order.

3.3.3 Premises for, and Storage of, Milk and Milking-Related Equipment

Premises for the storage of milk should be situated and constructed to avoid risk of contamination of milk or equipment.

Premises for the storage of milk should have:

- suitable milk refrigeration equipment, when appropriate;
- a sufficient supply of water of a suitable quality of for use in milking and in cleaning of equipment and instruments;
- protection against vermin;
- easily cleanable floors, if applicable; and
- adequate separation between milking areas and any premises where animals are housed in order to prevent contamination of milk by animals. Where separation is not possible, adequate measures should be taken to ensure that the milk is not contaminated.

Immediately after milking, the milk should be stored in properly designed and maintained tanks or cans in a clean place.

Storage temperatures and times should be such that minimizes any detrimental effect on the safety and suitability of milk. The time and temperature conditions for milk storage at the farm should be established taking into account the effectiveness of the control system in place during and after processing, the hygienic condition of the milk and the intended duration of storage. In situations where the milk cannot be chilled on the farm, collection and delivery of this milk to a collection centre or processing facility within certain time limits may be required. These conditions may be specified in legislation, in Codes of Practice, or by the manufacturer receiving the milk in collaboration with the milk producer and the competent authority.

Additional Provisions for the Production of Milk Used for Raw Milk Products

When milk for further processing is not collected or used within 2 hours after milking, it shall be cooled:

- to a temperature equal to or below 6°C when collected on a daily basis; or
- to a temperature equal to or below 4°C when not collected every day.

Deviations from those temperatures may be acceptable if those deviations will not result in an increased risk of microbiological hazards, have been approved by the manufacturer receiving the milk, have been approved by the competent authority, and the end product will still meet the microbiological criteria established in accordance with 5.2.3.2.

3.3.4 Collection, Transport and Delivery Procedures and Equipment

3.3.4.1 Collection, Transport and Delivery Procedures

Personnel and vehicular access to the place of collection should be adequate for the suitable hygienic handling of milk. In particular, access to the place of collection should be clear of manure, silage, etc.

Prior to collection, the milk hauler or collection/chilling centre operator should check the individual producer's milk to ensure that the milk does not present obvious indications of spoilage and deterioration. If the milk shows indications of spoilage and deterioration, it should not be collected.

Collection and chilling centres, if employed, should be designed and operated in such a manner that minimizes or prevents the contamination of milk.

Milk should be collected under hygienic conditions to avoid contamination of milk. In particular, the milk hauler or collection centre operator should, where appropriate, take samples in such a way to avoid contamination of the milk and should ensure that the milk has the adequate storage/in-take temperature prior to collection.

The milk hauler should receive adequate training in the hygienic handling of raw milk.

Milk haulers should wear clean clothing.

Milk hauling operations should not be performed by persons at risk of transferring pathogens to milk. Appropriate medical follow-up should be done in the case of an infected worker.

Milk haulers should perform their duties in a hygienic manner so that their activities will not result in contamination of milk.

The driver should not enter the stables or other places where animals are kept, or places where there is manure.

Should driver clothing and footwear be contaminated with manure, the soiled clothes and footwear should be changed or cleaned before work is continued.

The tanker driver should not enter the processing areas of the dairy plant. Conditions should be arranged to allow necessary communication with the staff of the dairy, delivery of milk samples, dressing, rest breaks, etc. without direct contact taking place with the dairy processing areas or with staff members involved with processing milk and milk products.

Additional Provisions for the Production of Milk Used for Raw Milk Products

Milk to be used for the manufacture of raw milk products shall be collected separately. Mixing, or cross-contamination with milk which does not comply with the quality (including microbiological) expected for the processing of raw milk products shall not be allowed.

For example:

- organize collection pick-ups in such a way that milk for the manufacture of raw milk products be collected separately ; or
- use milk transport tankers with compartments that will allow the separation of the milk for raw milk products from milk to be heat processed combined with the pick-up of milk for raw-milk products before milk for other products.

3.3.4.2 Collection, Transport and Delivery Equipment

Guidance on the bulk transport of foods is given in the Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food (CAC/RCP 47-2001).

Milk transport tankers and cans should be designed and constructed such that they can be effectively cleaned and disinfected.

Milk transport tankers and cans should be designed and constructed to ensure complete drainage.

Milk transport tankers and cans should not be used to transport any harmful substance. If milk transport tanks and cans are used to transport foods other than milk, precautions such as the implementation of adequate cleaning protocols should be taken to prevent any subsequent milk contamination.

Surfaces of milk transport tankers, cans and associated equipment intended to come into contact with milk should be easy to clean and disinfect, corrosion resistant and not capable of transferring substances to the milk in such quantities as to present a health risk to the consumer.

Milk cans and transport tankers (including the milk discharge area, valves, etc.) should be cleaned and disinfected with sufficient frequency in order to minimize or prevent contamination of milk.

After disinfection, tankers and cans should be drained.

Lorries, trucks or other vehicles which carry the tank or cans should be cleaned whenever necessary.

3.3.4.3 Transport Time and Temperature

Transport temperature and time should be such that milk is transported to the dairy or to the collection/chilling centre in a manner that minimizes any detrimental effect on the safety and suitability of milk.

The time and temperature conditions for the collection and transport of milk from the farm should be established taking into account the effectiveness of the control system in place during and after processing, the hygienic condition of the milk and the intended duration of storage. In situations where the milk cannot be chilled on the farm, collection and delivery of this milk to a collection centre or processing facility within certain time limits may be required. These conditions may be specified in legislation, in Codes of Practice, or by the manufacturer receiving the milk in collaboration with the milk producer, collector and transporter and the competent authority.

Additional Provisions for the Production of Milk Used for Raw Milk Products

The temperature of the milk to be used for the manufacture of raw-milk products shall not exceed 8°C, unless the milk has been collected within 2 hours after milking.

Deviations from this temperature may be acceptable if these deviations will not result in an increased risk of microbiological hazards, have been approved by the manufacturer receiving the milk, have been approved by the competent authority and the end product will still meet the microbiological criteria established in accordance with 5.2.3.2.

3.4 DOCUMENTATION AND RECORDKEEPING

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

- Prevention and control of animal diseases with an impact on public health;
- Identification and movement of animals;
- Regular control of udder health;
- Use of veterinary drugs and pest control chemicals;
- Nature and source of feed;
- Milk storage temperatures;
- Use of agricultural chemicals;
- Equipment cleaning.

ANNEX II

GUIDELINES FOR THE MANAGEMENT OF CONTROL MEASURES DURING AND AFTER PROCESSING

INTRODUCTION AND OBJECTIVES

The detailed information contained in this annex should be implemented in order to prevent, eliminate or reduce hazards associated with incoming materials to acceptable levels and to reduce the likelihood of milk contamination resulting from inadequate control of manufacturing operations. This information will enable the implementation of the principles laid down in Section 5 of the main body of the Code by providing guidelines for their application.

These measures should be used in combination with guidelines on primary production found in Annex I in order to effectively control the microbiological hazards in milk products. There is a close relationship between the control of manufacturing operations and the safety and suitability of processed milk products based on the control measures presented in Annex II.

SCOPE

The provisions in this Annex reinforce and supplement the principles and guidelines specified in Section 5 of the Code (Control of Operation), in particular Section 5.1, and should apply to the manufacture of any milk product. The principles in Section 5, Control of Operation, as well as the hazard identification provisions of this annex apply not only to the control of microbial hazards but also to the control of chemical and physical hazards.

The most common microbiological control measures are addressed in further detail in Part A (microbiostatic control measures) and Part B (microbiocidal control measures), respectively. However, this does not preclude in any way the use of additional and/or alternative microbiological control measures, provided that the general guidance provided in this Annex is followed.

USE OF ANNEX II

The information in Annex II is organized to correspond with the relevant sections in the main part of the Code and the *Recommended International Code of Practice-General Principles of Food Hygiene*, CAC/RCP 1 - 1969, Rev. 4, 2003. Where a particular principle has been identified in the main body of the Code, guidelines for the application of that principle will be located in the corresponding section of this part of the Annex.

These guidelines are supplemental to those contained in Section 5 of the *Recommended International Code of Practice-General Principles of Food Hygiene*, CAC/RCP 1 - 1969, Rev. 4, 2003 (including the Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application Annex) and to the overarching principles presented in Section 2.3 of the base document.

The guidelines presented in this annex are intended to enhance and supplement those aspects of the *Recommended International Code of Practice-General Principles of Food Hygiene* HACCP Annex which are critical to the successful design of a system of food safety controls. The users of this document are encouraged to implement the guidelines contained in the HACCP Annex when designing a HACCP system and to refer to those Annex II guidelines for further details on the hazard analysis, control measure selection and critical limit determination.

DEFINITIONS

The definitions below apply for the purpose of this Annex, and in addition to those definitions contained in Section 2.5 of the main body of this Code.

Microbiocidal treatments are control measures that substantially reduce or practically eliminate the number of microorganism present in a food.

Microbiostatic treatments are control measures that minimize or prevent the growth of microorganisms present in a food.

Pasteurization is a microbiocidal heat treatment aimed at reducing the number of any pathogenic microorganisms in milk and liquid milk products, if present, to a level at which they do not constitute a significant health hazard. Pasteurization conditions are designed to effectively destroy the organisms *Mycobacterium tuberculosis* and *Coxiella burnettii*.

UHT (ultra-high temperature) **treatment** of milk and liquid milk products is the application of heat to a continuously flowing product using such high temperatures for such time that renders the product commercially sterile at the time of processing. When the UHT treatment is combined with aseptic packaging, it results in a commercially sterile product.⁷

5 CONTROL OF OPERATIONS

5.1 CONTROL OF FOOD HAZARDS

It is important that control measures are applied during both primary production and processing to minimize or prevent the microbiological, chemical or physical contamination of milk. In addition, special attention should be given during the processing of different milk products so that inadvertent cross-contamination does not occur, including with respect to ingredients that may contain allergenic substances. *Note: A distinction can be drawn between the types of control measures used for microbiological hazards and those used for chemical and physical hazards. The control measures used for chemical and physical hazards in food are generally preventive in nature, i.e., they focus on avoiding the contamination of food with chemical or physical hazards in the first place rather than on reducing or eliminating such hazards once they have been introduced into the product. It should be noted however that there are some exceptions to this type of distinction, e.g., the use of filters, screens and metal detectors to remove certain physical hazards.*

Microbiological food hazards are controlled by appropriate selection of control measures applied during primary production in combination with control measures applied during and after processing. The result of applying any microbiocidal control measure depends significantly on the microbial load (including the concentration of microbiological hazards) in the material subjected to it. It is therefore important that preventive measures are applied in primary production to reduce the initial load of pathogenic microorganisms as well as during processing to avoid contamination within the processing environment. The initial microbial load significantly impacts the performance needed for the microbiological control measures applied during and after processing as well as the performance required for suitability. The safety and suitability of the end product depends not only on the initial microbiological load and the efficiency of the process, but also on any post-process growth of surviving organisms and post-process contamination.

Individual control measures should be selected and applied in such combination as to achieve a sufficient performance as to result in end products with acceptable levels of hazards.

Acceptable levels of contaminants in the end product should be identified and be based upon:

- Food safety objectives, end product criteria and similar regulatory requirements, as applicable;
- Acceptable levels derived from the purchaser constituting the subsequent link of the food chain; and/or
- The maximum levels found acceptable by the manufacturer, taking into account acceptable levels agreed with the customer and/or regulatory measures established by public health authorities.

The guidelines contained in sections 5.1.1 to 5.1.3 are intended to be supplemental to the *Recommended International Code of Practice-General Principles of Food Hygiene* HACCP Annex.

⁷ The concepts of aseptic packaging and commercially sterile can be found in the Codex documents on Low Acid and Acidified Canned Foods (CAC/RCP 23-1979, Rev. 2 (1993) and Aseptic Processing (CAC/RCP 40-1993).

5.1.1 Hazard Identification and Evaluation

Hazard identification can be separated into two distinctly different parts, the identification of all potential hazards and the evaluation of the identified potential hazards to determine which are considered to have severe adverse health effects and/or are reasonably likely to occur and therefore need to be controlled through the implementation of effective control measures.

The hazard identification should be based on the initial descriptions developed during preliminary steps contained in the *Recommended International Code of Practice-General Principles of Food Hygiene*, CAC/RCP 1 - 1969, Rev. 4, 2003, HACCP Annex and on experience, external information, as well as epidemiological and other historical data that have been associated with the type of food under consideration, the type of raw materials and ingredients used, and that may be introduced during the processing distribution. To insure a comprehensive approach, the various step(s) in the manufacturing process, from material selection through processing and distribution, where a hazard may occur or be introduced should be identified.

The potential hazards for such consideration should be listed in relation to the identified acceptable levels, including established FSO(s), where available.

For microbiological hazards, the likelihood of occurrence will depend on the actual prevalence in the milk and raw materials used. Factors influencing the prevalence are climatic conditions, animal species, prevalence of animal disease (sub-clinically or clinically) caused by the organism, prevalence of mastitis including the relative distribution of causing organisms, the adequacy of primary production practices including the potential of environmental contamination (feeding practices, water quality, milking hygiene level), and the potential for human contamination. Consultation of the competent authorities having jurisdiction in relation to the herds is appropriate.

When evaluating potential microbiological hazards, consideration should be given to which of the organisms are likely to be present in the milk. For instance, microbiological hazards that are not relevant in the geographical area of concern (e.g. because the prevalence is insignificant or zero) can be ruled out at an early stage. Also, where it can be verified that specific sanitary measures are successfully applied during primary production to prevent or significantly reduce introduction of a pathogen into the herd, including efficient eradication programmes, the pathogen in question may be ruled out. The manufacturer or other appropriate party is responsible for documenting the conditions that support such a determination. This can be accomplished by documenting the OIE status (e.g. disease-free area), the effectiveness of national programmes, the effectiveness of individual producer screening programmes, on the basis of documented historical evidence, and through the development of epidemiological evidence.

Regular analysis of the milk (including but not restricted to microbiological analyses) received at the manufacturing establishment producing milk products can be used to verify the implementation of control measures affecting the likelihood of occurrence of a hazard, depending upon the technology used and the kind of milk product being made.

Hazard identification should take into consideration the allergenic nature of some foods. Milk products may contain ingredients such as nuts, eggs and cereal grains that are known to be allergens

Further, any additional hazards that can be introduced into the milk product during and after processing (e.g. environmental contamination, human contamination) should also be considered. During such considerations, the effectiveness of preventive measures taking place in the manufacturing environment (e.g., environmental and equipment sanitation programmes, employee practices, pest control programmes, etc.) should be evaluated to determine the likelihood of occurrence of potential hazards.

5.1.2 Control Measure Selection

Note: *While the following guidelines are focused on the control of microbiological hazards, the concepts presented herein can be applied as well to the control of chemical and physical hazards.*

The next step in the hazard analysis process is to select control measures that will be effective in controlling those hazards. A number of such control measures are further described in Appendices A and B of Annex II.

Selection of individual Control measures

Individual microbiological control measures can be grouped according to primary function as follows:

- *Microbiocidal control measures* that reduce the microbial load, for instance by killing, inactivation or removal. These may be applied during processing as processing steps (e.g. microfiltration, thermization, pasteurization) or after the processing as intrinsic factors (e.g. ageing).
- *Microbiostatic control measures* that prevent, limit or retard the growth of microorganisms by chemical or physical means. These are used to stabilize the product against activity of pathogens and spoilage organisms and may apply after milk production, during processing (e.g. in between processing steps) and after processing. Microbiostatic control measures still imply some probability of growth. Microbiostatic control measures that are efficient after processing may be applied towards the product (e.g. temperature/time control) as extrinsic factors or be built into the product as intrinsic factors (e.g. preservatives, pH).
- *Microbiostatic control measures that prevent direct contamination* of product, for instance by closed circuits or by appropriate packaging to protect the product. These are used to physically prevent contamination, in particular, during packaging and/or after processing.

The use of a single processing step may have subsequent microbiological effects (e.g. reduction of pH, water content), while other microbiological control measures only reduce the number of microorganisms at the point in the manufacturing process, where it is applied.

Combination of microbiological control measures

More than one microbiological control measure is usually needed to control microbial content, to retard or prevent spoilage and to help prevent food borne diseases. Suitable combinations can be devised in order that specific organisms of concern can be reduced in number and/or no longer grow/survive in the product. Such suitable combinations are sometimes referred to by the dairy industry as “hurdle technology”.

The combination of control measures has two main objectives:

- During processing: Providing assurance that the levels of the pathogens (and/or spoilage organisms) of concern, where present, are kept at or reduced to acceptable levels.
- After processing (packaging, distribution and storage): Providing assurance that the acceptable levels of the pathogens (and/or spoilage organisms) of concern that have been achieved during processing are kept under control throughout shelf life.

It may be necessary to ensure that growth of microorganisms is kept to a minimum prior to processing, in between different processing steps, and after processing. The microbiostatic control measures used should be adapted to the need of the particular product in the particular situation. The resulting outcome in terms of the safety and suitability of the end product does not depend only on the initial microbial load and the effectiveness of the process, but also on any post-process growth of surviving organisms and post-process contamination. Therefore, all microbiological control measure combinations should be supported by appropriate preventive measures prior to and after the process, as deemed necessary.

Depending on the source and possible routes of contamination, the hazard(s) may be kept under control by preventive measures implemented at primary production level and/or in processing environments. When evaluating microbiological preventive measures, it is particularly important to know which of the hazards are affected by the preventive measure and to what extent the measure reduces the probability of the hazard contaminating the milk product during milking, processing and/or distribution. Those microbiological hazards that are not managed adequately by preventive and microbiostatic control measures need to be managed and controlled by adequate microbiocidal control measures with sufficient combined performance.

Microbiological control measures having effect only at the point of application must be applied in appropriate combinations with other microbiological control measures.

The combination of microbiological control measures is most efficient when it is *multi-targeted*, that is, when various individual measures are selected so that different factors effecting microbial survival are targeted, e.g., pH, A_w , availability of nutrients, etc. In many cases, a multi-targeted combination using microbiological control measures with low intensity may be more effective than one single measure with high intensity. The presence of a number of microbiological control measures inhibiting or reducing the number of microorganisms may be *synergistic*, that is that interaction occurs between two or more measures so that their combined effect is greater than the sum of their individual effects. Therefore, the utilization of synergistic effects can allow for combining microbiological control measures of less intensity than would be otherwise expected from each measure individually.

Where flexibility from provisions in Annex I is granted for small holder dairy farms, particular attention should be paid to the nature of the granted deviations and their potential consequences in terms of hazard levels in the milk.

Attention should be paid to the application of microbiocidal control measures with such performance that they effectively eliminate any risks associated with the transfer of additional zoonotic hazards to the milk. Similarly, where certain animal diseases are present in herds producing the milk, particular attention should be drawn to the recommendations in the OIE International Animal Health Code, as specific microbiocidal control measures or performances thereof may be necessary to eliminate the animal health risks associated with these diseases.

5.1.3 Establishment of Process Criteria

From the performance required, the corresponding process criterion or criteria (as appropriate to the nature of the microbiological control measure) should be established. They are intended for the appropriate implementation (set-up) of a processing step and for application in practical process control (e.g. filter size, pH, concentration of preservative, time/temperature combinations). In the context of HACCP, process criteria may or may not constitute critical limits.

The performance of control measures and control measure combinations selected should be validated using procedures outlined in the *Guidelines for the Validation of Food Hygiene Control Measures* (in preparation). The validation of control measures or control measure combinations is especially important when establishing the effectiveness of new or developing technologies. validation may not be necessary in situations where well established control measures or technologies are considered to be acceptable.

If the performance required cannot be achieved by the control measure(s) or if it is estimated and/or monitoring shows that the hazards are not under sufficient control by the selected combination of microbiological control measures, modification of the control system design is necessary.

Examples of some of the modifications that can be made until the hazard of concern is considered under control include:

- Increase of the intensities of the microbiological control measure(s) applied.
- Identification of additional microbiological control measure(s) that target the hazard of concern.
- Implementation of more stringent on-farm control measures
- Introduction of specifically targeted measures at farm level that reduce the prevalence of the hazard of concern in the milk used
- Reduction of the intended shelf life and/or amendments of the intended storage conditions

Additional Provisions for the Manufacture of Raw Milk Products

It is critical for a dairy farm, when producing milk intended for the manufacturing of raw milk product, to comply with the provisions (including the identified additional provisions) detailed in Annex I and in section 5.2.3.1 of this Annex, and these activities should be frequently monitored and evaluated for their effective implementation. This evaluation may lead to the identification of needed improvements at the primary production level (practices, equipment, environment, etc.) or in the classification of dairy farms according to their ability to provide milk for the processing of raw milk products.

Any non-compliance detected either at the farm level or at the milk reception of a manufacturing plant should result in immediate action that may affect the farm, the manufacturing establishment or both. For this reason, there should be clear communication between the manufacturer and the farm and, if necessary, technical assistance should be provided to the primary producer by the manufacturer.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.1 Time and Temperature Control

5.2.1.2 Distribution of Finished Products

Perishable products:

The storage temperature should be sufficient to maintain product safety and suitability throughout the intended shelf life. If the temperature of the product is the principal means of preservation, it is essential that the product be maintained at the appropriate temperature. Validation of the selected temperature should be carried out except in situations where well established storage temperatures are considered acceptable.

Regular and effective monitoring of temperatures of storage areas, transport vehicles and store display cases should be carried out where:

- the product is stored, and
- the product is being transported, within the product load, which could be done by using temperature indicating and recording systems;
- the product is being presented for retail sale.

Particular attention should be paid throughout storage and distribution to:

- periods of defrosting of refrigeration units;
- temperature abuse; and
- overloading the cold storage facility.

Products stable at ambient temperatures:

Products that can be stored at ambient temperatures, should be protected against external agents and contamination, e.g., direct sun radiation, excessive heating, moisture, external contaminants, etc. from rapid temperature changes which could adversely affect the integrity of the product container or the safety and suitability of the product.

5.2.1.3 Establishment of Shelf Life

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

- Applied microbiological control measures, including storage temperatures;
- Cooling methods applied to product;
- Type of packaging (e.g., hermetically sealed or not, Modified Atmosphere Packaging);
- Likelihood of post-process contamination and type of potential contamination.

The shelf life of milk products may be limited by microbial changes (e.g., deterioration and growth of pathogenic and spoilage microorganisms to unacceptable levels).

When establishing product shelf life, it is the responsibility of the manufacturer to assure and, as necessary, to demonstrate, that the safety and suitability of the milk product can be retained throughout the maximum period specified, taking into consideration the potential for reasonably anticipated temperature abuse during manufacture, storage, distribution, sale and handling by the consumer.

These temperature abuses may allow the growth of pathogenic microorganisms, if present, unless appropriate intrinsic factors are applied to prevent such growth.

Explanatory note: Reasonably anticipated temperature abuse takes into account the normal period of transporting of purchased products to appropriate consumer storage facilities and normal patterns of handling during consumption, for instance, the number and length of periods in which the product is removed from the refrigerator and subjected to ambient temperatures until the whole package has been consumed.

The possible reactivation of pathogens with time should be taken into account when determining the shelf life.

Shelf life determination can be carried out 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. Reasonable anticipated temperature abuse can 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 labelling or by requiring lower storage temperatures).

5.2.2 Microbiological and Other Specifications

5.2.2.1 Milk

The milk used for the manufacture of products covered by this Code should be evaluated based on sampling of milk from individual farms or milk collection centres.

Upon receiving, the milk should be subject to olfactory and visual inspection. Other criteria (e.g., temperature, titratable acidity, microbiological and chemical criteria) should be used to detect unacceptable conditions.

Any non-compliance with the above mentioned criteria, and in particular with regards to pathogens, should result in immediate corrective actions at the farm level and in the manufacturing establishment, for example: rejection of the milk for the processing of raw milk products; corrective actions on the milking procedure (cleaning and sanitation procedures of the milking equipment, cleaning or sanitation procedures of the udder, etc.); quality of feed; the hygienic quality of the water supply; practices in animal holding areas; individual check of animals to find the animal(s) that may be the carrier; isolation of that animal from the herd as necessary. Corrective actions should be identified and implemented, and specific assistance to the dairy farm may need to be provided.

In some cases, where more comprehensive control measures are put into place to ensure the safety and suitability of milk, as may be the case for raw milk intended to be used in the production of raw milk products, it may be necessary to classify farms into two categories: those acceptable for use in raw milk products and those that are not.

Additional Provisions for Milk used in the Manufacture of Raw Milk Products

Depending on the hazard analysis performed by the manufacturer and the combination of microbiological control measures applied during and after processing of milk products, specific microbiological criteria regarding pathogens (for example: *Salmonella* spp., *Listeria monocytogenes*) may need to be established.

APPENDIX A: MICROBIOSTATIC CONTROL MEASURES

Note: The control measures described in this appendix are presented as descriptive examples only and require validation prior to use with respect to their effectiveness and safe use.

Microbial growth is dependent upon many conditions in the organism's environment such as: ingredients, nutrients, water activity, pH, presence of preservatives, competitive microorganisms, gas atmosphere, redox-potential, storage temperature and time. Control of these conditions can therefore be used to limit, retard, or prevent microbial growth.

Such microbiological control measures as well as microbiological control measures protecting the product against direct microbial contamination from the surroundings have microbiostatic functions.

Many microbiostatic control measures act by interfering with the homeostasis⁸ mechanisms that microorganisms have evolved in order to survive environmental stresses.

Maintaining a constant internal environment requires significant energy and material resources of the microorganism, and when a microbiological control measure disturbs the homeostasis there will be less energy left for the microorganism to multiply. Consequently, the organisms will remain in the lag phase and some may even die out before the homeostasis is re-established.

Examples of typical microbiostatic control measures include the following:

Carbon dioxide (CO ₂):	The addition and/or formation of carbonic acid to obtain a multiple inhibitory effect, including the creation of anaerobic conditions by replacing oxygen, reducing pH, inhibiting certain intracellular enzymes (decarboxylation), and inhibiting the transport of water-soluble nutrients across the membrane (by dehydrating the cellular membrane). The efficiency depends mainly on the point of application. In ripened cheese, the emission of carbon dioxide from the cheese to the outside environment is often utilized to provide (almost) anaerobic conditions in the headspace of cheese packaging
Coatings:	The introduction of a physical barrier against contamination, with or without antimicrobial substances implemented into it (immobilized) to obtain a slow migration of these from the surface.
Freezing:	The lowering of temperature below the freezing point of the product combined with a reduction of the water activity. Freezing has microbiostatic as well as microbiocidal effects.
Lactoferrins:	Retardation through the utilization of naturally present glycoproteins (highest concentration in colostrum) to prolong the lag phases of bacteria for 12-14 hours, by binding iron in the presence of bicarbonates.
Lactoperoxidase system ⁹ :	The activation of the lactoperoxidase/thiocyanate/hydrogen peroxide system (indigenous system in milk) to inactivate several vital metabolic bacterial enzymes, consequently blocking their metabolism and ability to multiply. Guidance for application is provided in the Codex Guidelines for Preservation of Raw Milk by the Use of the Lactoperoxidase System (CAC/GL 13-1991).

⁸ Homeostasis is the constant tendency of microorganisms to keep their internal environment stable and balanced. For instance, microorganisms spend considerable efforts keeping their internal pH and osmotic pressure within narrow limits.

⁹ These microbiostatic control measures should only be used as a last resort in countries where infrastructure does not permit cooling of milk at farm level or at collection centres. Whenever used, chemical methods should never replace nor delay implementing good hygienic practices in milk production.

Modified atmosphere:	The establishing of a gaseous environment (either low in oxygen and/or high in carbon dioxide or nitrogen) to limit growth of aerobic microorganisms by impairing biochemical pathways. Modified atmosphere packaging (MAP) means that a modification of the gas atmosphere in the packaging is created. Establishing anaerobic environment to limit growth of aerobic microorganisms may proliferate certain anaerobic pathogenic microorganisms.
Packaging:	Packaging provides a physical barrier that protects against access of microorganisms from the surroundings.
pH reduction:	The creation of extra-cellular acid conditions that enables hydrogen ions to be imported into the cytoplasm of microorganisms, thus disturbing the homeostasis mechanism of the intracellular pH responsible for maintaining functionality of key cell components vital for continuing growth and viability. Low pH values are obtained by fermentation or addition of acids (inorganic or organic). The pH value for preventing growth depends on the pathogen, but lies typically between pH 4.0-5.0. Microorganisms become more sensitive to other microbiological control measures at lower pH. Synergy occurs with salt, water activity, organic acids, the LP-system, and antimicrobial substances.
(Use of) Preservatives:	The addition of certain additives to enhance keeping quality and stability through direct or indirect antimicrobial and/or fungicidal activity. Most preservatives are rather specific and have effect only on certain microorganisms.
Redox potential control:	The redox potential (Eh) is a measure of the oxidizing or reducing potential of food systems that determines whether aerobic or anaerobic microorganisms are able to grow. Eh is influenced by removal of oxygen and/or addition of reducing substances (e.g. ascorbic acid, sucrose, etc.).
Refrigeration:	The lowering of product temperature to limit microbial activity
Time:	The practice of applying very short collection/storage periods, limiting the shelf life of products, or immediate processing of raw milk to ensure that all microorganisms present are in the lag phase, and therefore not active and more susceptible to other microbiological control measures.
Water activity control:	<p>The control of the water activity (a_w) in the product (the accessibility of water for microorganisms, not the water content in the food), expressed as the ratio of water vapour pressure of the food to that of pure water. The a_w value for preventing growth depends on the pathogen, but lies typically between 0.90 and 0.96. Water activity can be controlled by:</p> <ul style="list-style-type: none">• concentration, evaporation and drying, which also increase the buffering capacity of milk (synergy);• salting (addition of sodium chloride), which also reduces the cell resistance against carbon dioxide and in the solubility of oxygen (synergy); and• sweetening (addition of sugars), which at a_w below 0.90-0.95 also results in an antimicrobial effect, depending on the type of sugar (synergy).

APPENDIX B: MICROBIOCIDAL CONTROL MEASURES

Note: the control measures described in this appendix are presented as descriptive examples only and require validation prior to use with respect to their effectiveness and safe use.

Microbiocidal or practical elimination control measures act by reducing the microbial load, for instance through killing, inactivation or removal.

Many microbiological control measures have multiple functions. Some microbiostatic control measures also have microbiocidal effects, the degree often depending upon the intensity at which they are applied (e.g. pH reduction, refrigeration, freezing, preservatives and indigenous antimicrobial systems).

Pasteurization and other heat treatments of milk that have at least an equivalent efficiency are applied at such intensities (sufficient time/temperature combinations) that they practically eliminate specific pathogens. They have therefore been traditionally used as key microbiocidal control measures in the manufacture of milk products. Non-thermal microbiocidal control measures with similar efficiencies are not yet applied at such intensities that will render the milk product safe at the point of application.

Examples of typical microbiocidal control measures include the following:

Centrifugation:	The removal of microbial cells of high density from milk using high centrifugal forces. Most efficient against microbial cells of high density, notably bacterial spores and somatic cells
Commercial sterilization:	The application of heat at high temperatures for a time sufficient to render milk or milk products commercially sterile, thus resulting in products that are safe and microbiological stable at room temperature.
Competitive microflora:	The reduction of the number of undesirable microorganisms by lowering the pH, consumption of nutrients, and production of bacterial antimicrobial substances (such as nisin, other bacteriocins and hydrogen peroxide). Usually, this microbiological control measure is applied by choice of starter cultures. The efficiency is determined by many factors, including the speed and level of pH-reduction and variations in the pH level.
“Cooking” of cheese curd:	The application of heat to cheese curd, mainly for technical purposes. The heat treatment has a lower intensity than thermization but stresses microorganisms to become more susceptible to other microbiological control measures.
Electromagnetic energy treatment:	Electromagnetic energy results from high voltage electrical fields, which alternate their frequency millions of times per second ($< 10^8$ MHz). Examples are microwave energy (thermal effect), radio-frequency energy (non-thermal effects) or high electric field pulses (10 - 50 kV/cm, non-thermal effects). The treatment destroys cells by establishing pores in the cell walls due to the build up of electrical charges at the cell membrane.
High-pressure treatment:	Application of high hydrostatic pressures to irreversibly damage the membranes of vegetative cells.
Microfiltration:	Removal of microbial cells, clumps and somatic cells by recirculation over a microfilter. Normally, a pore size of ~ 0.6 - 1.4 μm is sufficient to separate most bacteria. Synergy in combination with heat treatment.
Pasteurization:	The application of heat to milk and liquid milk products aimed at reducing the number of any pathogenic microorganisms to a level at which they do not constitute a significant health hazard.

Pulsed high-intensity light:	The application of (on e.g. packaging material, equipment and water) high intensity broadband light pulses of wavelengths in the ultraviolet, visible and infrared spectrum (~20,000 times sunlight) to destroy microorganisms. Due to the inability to penetrate in-transparent substances, the technology is only effective against surfaces, for instance, in the removal of biofilm and can therefore prevent cross contamination
Ripening (ageing):	The holding for such time, at such temperature, and under such conditions as will result in the necessary biochemical and physical changes characterizing the cheese in question. When applied as a microbiocidal control measure, the multifactoral, complex system developing in cheese (pH, antagonistic flora, decreased water activity, metabolism of bacteriocins and organic acids) is utilized to influence the microenvironment in and on the food and consequently the composition of the microflora present.
Thermization:	The application to milk of a heat treatment of a lower intensity than pasteurization that aims at reducing the number of microorganisms. A general reduction of log 3-4 can be expected. Microorganisms surviving will be heat-stressed and become more vulnerable to subsequent microbiological control measures.
Ultrasonication:	The application of high intensity ultrasound (18-500 MHz) that cause cycles of compression and expansion as well as cavitation in microbial cells. Implosion of microscopic bubbles generates spots with very high pressures and temperatures able to destroy cells. More effective when applied in combination with other microbiological control measures. When applied at higher temperatures, the treatment is often referred to as “thermosonication”.
Warm sealed packaging:	The application of heat (80 to 95 °C) to a solid end product in connection with the packaging process, for instance to maintain the product at a viscosity suitable for packaging. Such process can be done in a continuous flow system or in batch processes. The product is sealed at the packaging temperature and chilled for storage/distribution purposes afterwards. When combined with low pH in the product, e.g. below 4.6, the warm sealed product may be commercially sterile as any surviving microorganisms may not be able to grow. A supplementary microbiostatic control measures is to ensure adequate cooling rates of packaged products to minimize potential for <i>B. cereus</i> growth.

1 PASTEURIZATION OF MILK AND FLUID MILK PRODUCTS

1.1 Description of Process

Pasteurization can either be carried out as a batch operation (“batch pasteurization” or “LTLT-pasteurization” (Low Temperature, Long Time)), with the product heated and held in an enclosed tank, or as a continuous operation (“HTST-pasteurization” (High Temperature, Short Time)) with the product heated in a heat exchanger and then held in a holding tube for the required time.

Currently, the most common method of pasteurization is by means of heat exchangers designed for the HTST process (High Temperature Short Time). This process involves heating of the milk to a certain temperature, holding at that temperature under continuous turbulent flow conditions for a sufficiently long time, to ensure the destruction and/or inhibition of any hazardous microorganisms that may be present. An additional outcome is the delay of the onset of microbiological deterioration, extending the shelf life of milk.

To save energy, heat is regenerated, i.e. the chilled milk feeding the exchangers is heated by the pasteurized milk leaving the pasteurization unit. The effect of this pre-heating is cumulative, and should be taken into account when simulating pasteurization conditions at laboratory scale.

Pasteurization carried out in a batch-process involves the heating of milk placed in a container to a certain temperature for sufficiently long time to achieve equivalent effects as in the case of the HTST process. The heat can be supplied externally or internally in heat exchangers or within a pasteurizer. Due to the non-continuous flow conditions, heating and cooling takes longer and will add to the effect (cumulative).

1.2 Process Management

Performance criteria

As *C. burnettii* is the most heat-resistant non-sporulating pathogen likely to be present in milk, pasteurization is designed to achieve at least a 5 log reduction of *C. burnettii* in whole milk (4% milkfat).

Process criteria

According to validations carried out on whole milk, the minimum pasteurization conditions are those having bactericidal effects equivalent to heating every particle of the milk to 72 °C for 15 seconds (continuous flow pasteurization) or 63 °C for 30 minutes (batch pasteurization). Similar conditions can be obtained by joining the line connecting these points on a log time versus temperature graph.¹⁰

Processing times necessary rapidly decrease with minimal increase in temperature. Extrapolation to temperatures outside the range of 63 to 72 °C, in particular, processing at temperatures above 72°C must be treated with the utmost caution as the ability for them to be scientifically [validated] is beyond current experimental techniques.

For example, it would be extremely difficult if not impossible to determine pasteurization efficiency at 80 °C given the extrapolated processing time would be around 0.22 seconds to achieve at least a 5 log reduction.

To ensure that each particle is sufficiently heated, the milk flow in heat exchangers should be turbulent, i.e. the Reynolds number should be sufficiently high.

When changes in the composition, processing and use of the product are proposed, the necessary changes to the scheduled heat treatment should be established and a qualified person should evaluate the efficiency of the heat treatment.

For instance, the fat content of cream makes it necessary to apply minimum conditions greater than for milk, minimum 75 °C for 15 seconds.

Formulated liquid milk products with high sugar content or high viscosity also require pasteurization conditions in excess of the minimum conditions defined for milk.

Verification of process

The products subjected to pasteurization should show a negative alkaline phosphatase reaction immediately after the heat treatment as determined by an acceptable method. Other methods could also be used to demonstrate that the appropriate heat treatment has been applied.

¹⁰ Note: The time/temperature combinations for HTST pasteurization were established many years ago on the basis of the hygiene status at that time (quality of raw milk and of hygiene management levels). With time, the hygiene status has increased considerably. However, the tradition to specify the minimum time/temperature combinations in regulatory texts has not enabled the elevation of the hygiene status to be converted into the application of microbiocidal control measures of less intensity. Instead, it has been (and still is) converted into extension of the product shelf life.

Alkaline phosphatase¹¹ can be reactivated in many milk products (cream, cheese, etc.). Also, microorganisms used in the manufacture may produce microbial phosphatase and other substances that may interfere with tests for residual phosphatase. Therefore, this particular verification method must be performed immediately after the heat treatment in order to produce valid results. *Note: Low residual alkaline phosphatase levels in heat-treated milk (below 10 µg p-nitro-phenol equivalent/ml) are taken as assurance that the milk has been correctly pasteurized and that it has not been contaminated by raw milk. However, although this measure is still considered as being the most appropriate method of verification, the factors listed below influence the residual levels and should be taken into account when interpreting the results:*

Initial concentration in milk: the “pool” of alkaline phosphatase present in milk varies widely between different species and within species. Typically, raw cow’s milk shows an activity much higher than goats milk. As pasteurization results in a log reduction of the initial level, the post-pasteurization residual level will vary with the initial level in the raw milk. Consequently, different interpretation according to origin of the milk is necessary and in some cases, the use of alkaline phosphatase testing to verify pasteurization may not be appropriate.

Fat content of the milk: Phosphatase is readily absorbed on fat globules, thus the fat content in the product subjected to pasteurization influence the result (typical concentrations in cows milk: skim 400 µg/ml; whole 800 µg/ml, and 40% cream 3500 µg/ml).

Application of pre-heating: The level of alkaline phosphatase is decreased with heat, such as at temperatures typically applied in separation and in thermization.

1.3 Application of Pasteurization

Numerous manuals recognized by competent authorities exist for the correct layout, designs and constructions of suitable pasteurizing equipment as well as for practical operation and monitoring. Such manuals should be available and consulted whenever necessary.

2 COMMERCIAL STERILIZATION OF MILK AND MILK PRODUCTS

Details on the establishment of thermal processes designed to render milk or milk products commercially sterile can be found in the Codex document on Low-Acid Canned Foods (CAC/RCP 23-1979, Rev. 2 - 1993) and the Codex document on Aseptic processing (CAC/RCP 40 – 1993).

2.1 Description of Process

Commercial sterilization is a microbiocidal control measure that can be obtained by various heat treatments, the most common and [validated] methods being UHT (Ultra High Temperature) processing in combination with aseptic packaging or In-container Sterilization.

UHT treatment is a continuous operation that can either be carried out by direct mixing of steam with the product to be sterilized, or by indirect heating by means of a heat exchanging surface, followed by further aseptic processing (eventual) and aseptic packaging/filling. Thus the UHT plant are constituted by heating equipment in conjunction with appropriate packaging equipment and, eventually, additional treatment equipment (e.g. homogenization).

In-container sterilization may be a batch or continuous process.

¹¹ Milk from different species of milking animals normally contains different levels of alkaline phosphatase. These differences should be taken into account when establishing criteria for phosphatase analysis and when establishing the effectiveness of alkaline phosphatase testing as a means to verify that pasteurization conditions have been properly applied.

2.2 Process Management

Performance criteria

Thermal processes necessary to obtain commercially sterile products are designed to result in the absence of viable microorganisms and their spores capable of growing in the treated product when kept in a closed container at normal non-refrigerated conditions at which the food is likely to be held during manufacture, distribution and storage.

Process criteria

For products at risk of contamination with *Clostridium botulinum* such as certain composite milk products (as identified as likely to occur by a hazard analysis), the minimum thermal process should be established in consultation with an official or officially recognized authority. Where the risk of contamination with *Clostridium botulinum* is lower, alternative thermal processes may be established by an official or officially recognized authority, provided that the end products are microbiologically shelf stable and verified.

The combined effects of two or more treatments may be considered additive provided they comprise a single continuous process.

UHT treatment

UHT treatment is normally in the range of 135 to 150 °C in combination with appropriate holding times necessary to achieve commercial sterility. Other equivalent conditions can be established through consultation with an official or officially recognized authority.

Validation of milk flow and holding time is critical prior to operation.

See CAC/RCP 40 – 1993 for aspects of aseptic processing and packaging not already covered by this code.

Verification of process

The products subjected to commercial sterilization must be microbiologically stable at room temperature, either measured after storage until end of shelf life or incubated at 55 °C for 7 days (or at 30 °C for 15 days) in accordance with appropriate standards. Other methods could also be used to demonstrate that the appropriate heat treatment has been applied.

2.3 Application of Commercial Sterilization

Numerous manuals exist for the establishment of thermal processes needed to achieve commercial sterility, for the proper layout, designs and constructions of suitable sterilization equipment and for practical operation and monitoring of thermal processing equipment. Such manuals should be available and consulted whenever necessary.

Also, see CAC/RCP 23-1979, Rev. 2 (1993) for aspects of in-container sterilization not already covered by this code.

Appendix III

DEFINITIONS TO BE INCLUDED IN THE PROCEDUAL MANUAL

(for endorsement by the Codex Committee on General Principles)

Food Safety Objective (FSO): 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).

Performance Objective (PO): 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.

Performance Criterion (PC): 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.

Appendix IV**Discussion Paper on the Management of the Work of the Committee****Prepared by****Australia, New Zealand, and United States of America****Background**

The Codex Committee on Food Hygiene (CCFH) is moving towards a broad risk management-based approach to developing recommendations on ensuring consumer protection and facilitating fair practices in food trade. This broad risk-management approach may employ microbiological risk assessment and may utilize a spectrum of risk management or risk communication work products including guidance documents, codes of hygienic practice, food safety objectives and microbiological criteria.

The Codex Alimentarius Commission recognized this change in the Committee's operation by adopting, at its 24th Session, two additional Terms of Reference for the Committee. Specifically, these are:

- To suggest and prioritize areas where there is a need for microbiological risk assessment at the international level and to develop questions to be addressed by the risk assessor.
- To consider microbiological risk management matters in relation to food hygiene and in relation to the microbiological risk assessment activities of FAO and WHO.

The Committee recognized that the process of initiating work, preparing a microbiological risk assessment and developing a risk management strategy is a complex process, involving CCFH, the FAO/WHO Joint Expert Group on Microbiological Risk Assessment (JEMRA) and specific member countries. The Committee also recognized that a structured, yet flexible process was needed to initiate and carry out this work in a timely, orderly and complete fashion. The Committee, at its 34th Session, considered a Document (CX/FH 01/5 – Add.2) on a "*Proposal for a Process by which the Codex Committee on Food Hygiene Could Undertake Its' Work in Microbiological Risk Assessment/Risk Management*" originally submitted by the United States as a Conference Room Document at the 33rd Session of CCFH.

The Committee agreed that establishing a process in regards to undertaking its work on microbiological risk management was beneficial and invited the United States to prepare a Discussion Paper on the subject for the Committee's consideration at its 35th Session.

During the 35th Session, CCFH requested the United States to revise the described process concerning work related to risk management so that it was simple, short, and flexible as possible. It was agreed that the revised document should be circulated for further consideration and pending the outcome of the discussions be considered for inclusion in the Codex Alimentarius Procedural Manual. A drafting group consisting of the United States of America in collaboration with Australia, Canada, India, Ireland, France, Germany, Japan, New Zealand, the Netherlands, Sweden, the United Kingdom, the Commission of the European Community, Food and Agriculture Organization, and World Health Organization was established to assist in the revision of the document.

During the 35th Session, CCFH also concluded that because of increasing work load there was a need to develop a transparent procedure with established criteria for prioritizing its work. Furthermore, since much of the work undertaken by CCFH impacts other Codex committees, the Committee also recognized the efficiency at which it achieves its work could be enhanced by fostering improved communications with other Codex committees. Two working groups were established to develop discussion papers to address these needs: "*Discussion Paper on the Development of Process, Procedures, and Criteria to Establish Priorities for the Work of the Codex Committee on Food Hygiene*" which was led by New Zealand with the assistance of Australia, Austria, Brazil, Canada, Denmark, Finland, France, Japan, Malaysia, Norway, UK and the United States, and "*Discussion Paper on the Development of Options for Cross-Committee Communication Process*" led by Australia with the assistance of France, Norway, New Zealand, the United States and the European Commission.

During discussions among the three working groups, it was evident that there is substantial overlap in areas being addressed, and that it would be more effective to consolidate the three documents. During the opening session of the 36th Session of the CCFH, the leads of the three working groups recommended to the Committee the consolidation of the work items.

- *Proposed Draft Process by which the Committee on Food Hygiene Could Undertake Its Work in Microbiological Risk Assessment/Risk Management.* (Agenda Item 5(a), CX/FH 04/5).
- *Development of Process, Procedures and Criteria to Establish Priorities for the Work of the Codex Committee on Food Hygiene* (Agenda Item 5(b), CX/FH 04/5-Add.2. (Discussion Paper)
- *The Development of Options for a Cross-Committee Interaction Process* (Agenda Item 5(c), CX/FH 04/5, Add.3). (Discussion Paper)

In recommending to the Committee the consolidation of the three documents, the three working groups were cognizant of the “Codex Strategic Framework 2003-2007” and the activities of the Codex Committee on General Principles (CCGP) related to their review of the Codex *Procedural Manual* in response to Codex Evaluation. In particular, the working groups considered the draft changes related to “Criteria for the Establishment of Work Priorities” and the draft text on guidelines for the establishment and functioning of work groups, both physical and electronic. The following document is intended to be consistent with and further elucidate how CCFH will implement and augment the general approach being developed by CCGP.

The Process by which the Codex Committee on Food Hygiene Will Prioritize and Undertake Its Work

Purpose

The following guidelines are established to assist the CCFH to:

- Identify, prioritize and efficiently carry out its work; and,
- Interact with other Codex committees and task forces as the need arises.

Scope

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 implementing new work; and means for fostering and guiding the interaction of CCFH with other Codex committees and/or task forces on items of mutual interest.

Guidelines for Undertaking New Work

As specified in the *Codex Procedural Manual*, work undertaken by the Codex Committee on Food Hygiene should fall within its Terms of Reference¹ and meet the *Codex Criteria for the Establishment of Work Priorities*². Furthermore, new work should be consistent with the strategic plan established by the Commission and the general procedures established by the Codex Committee on General Principles. As a means of assisting it in meeting these goals, the Committee will use the following procedures to consider, accept and prioritize proposals for new work.

Criteria for new work:

- The proposal for new work should address a known or emerging public health issue or problem.
- Public health issues or problems that impact on international trade.
- Public health issues or problems that do not impact international trade but are of interest to a substantial number of member countries.
- There is sufficient scientific knowledge available to provide scientifically sound guidance.

Process for Considering New Work

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

1. A proposal for new work shall be developed. New work may be proposed by the Codex Alimentarius Commission, by the Committee on its own initiative, by another Codex subsidiary body upon referral to CCFH, by an individual country or countries, or by a recognized international intergovernmental organization.

The proposal shall be consistent with, and include the specified elements of the project document required for approval of new work by the Codex Alimentarius Commission³.

The proposal should indicate the specific nature of the new work that is being proposed (e.g., new or revised code of hygienic practice, risk management guidance document).

New or revised codes of hygienic practice should be consistent with the framework of the *Recommended International Code of Practice: General Principles of Food Hygiene*, (CAC/RCP 1-1969, Rev. 4 (2003)).

Risk management guidance documents, other than specific codes of hygienic practice may also be developed to provide risk management guidance. Two possible formats for the development of such risk management guidance documents are presented in Annex I.

¹ *Codex Procedural Manual*, 13th Edition, p. 111.

² *Codex Procedural Manual*, 13th Edition, p. 69.

³ Specifications for project document under development by the Codex Committee on General Principles for adoption by the Codex Alimentarius Commission. Specific *Codex Procedural Manual* reference to be provided.

The proposal for work should be provided in written form that is consistent with the required Codex “project document,” preferably in sufficient time to be included in the formal agenda of the CCFH meeting at which the nominator wishes to have the proposal considered.

To facilitate decision-making, when undertaking new work in the management of foodborne microbial hazards, the proposal should include a risk profile. A risk profile is an abbreviated discussion paper that lays out the key elements of a microbiological risk management concern in order to facilitate decision-making on the part of the Committee in relation to the need and scope of the newly proposed work. The Risk Profile should provide the Purpose, Scope and Rational, and a Recommendation regarding the microbiological risk management concern and the proposed work and should, to the extent possible, provide information on the following elements:

- Pathogen(s) and food(s) combination(s) of concern;
- Description of the public health problem;
- Food production, processing, distribution and consumption;
- Other risk profile elements (e.g., extent of international trade of the food commodity, potential public health and economic consequence of establishing Codex risk management guidance; public perceptions of the problem and the risk; existence of regional/international trade agreements and how they impact the public health with respect to the hazard/commodity combination);
- Risk assessment needs and questions for the risk assessors;
- Available information and major knowledge gaps.

2. The proposal, including, as appropriate, the Risk Profile and the scientific issues underlying the new work, will be reviewed by the Committee.

3. The proposal will be accepted, submitted for revision or denied. If accepted: a) the priority of the new work will be established using the criteria and procedures presented below; b) a project document will be developed and submitted to the Codex Alimentarius Commission (CAC) with a request for approval of the proposed new work. The project document should contain the following elements:

- The purposes and scope of the standard;
- Its relevance and timeliness;
- The main aspects to be covered;
- An assessment against the *Criteria for the Establishment of Work Priorities*;
- Relevance to the Codex strategic objectives
- Information on the relation between the proposal and other existing Codex documents;
- Identification of any requirement for and availability of expert scientific advice;
- Identification of any need for technical input to the standard from external bodies so that this can be planned for;
- The proposed time-line for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years.

Criteria and Process for Prioritization of Work

The Committee will annually review, evaluate and prioritize its work. This will be carried out by the Committee through a “Working Group for the Establishment of CCFH Work Priorities.” This working group will provide recommendations for review and approval by the Committee. The recommendations will present a proposed prioritization of potential new work.

In establishing priorities for its work, the Committee will use the criteria for new work outlined above. The Committee will also use the following additional criteria.

1. There is a need for urgent action to address an identified public health problem or issue.
2. The work affects the ability of Codex to fulfill its mandate; that is, other work within CCFH or other committees cannot progress until the issue is addressed.
3. New work is needed to facilitate risk analysis activities, e.g., establishment or revision of general principles or guidance.
4. The need to revise existing CCFH texts to reflect current knowledge and/or consistency with the *Recommended International Code of Practice: General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003).
5. The total resource capacity available to CCFH would dictate the total workload that could be undertaken by CCFH at any one time.

The “Working Group for the Establishment of CCFH Work Priorities” should also assess the need for cross-committee interactions (see below).

If the proposed new work will benefit from the acquisition of additional expert scientific advice such as an international risk assessment to be conducted by the FAO/WHO Joint Expert Committee on Microbiological Risk Assessment (JEMRA), this should also be considered in prioritizing work.

A flow diagram for the categorization/prioritization of new and existing work for CCFH is given in flow chart.

Process for Conduct of Work within CCFH

1. Upon approval of the project document by the CAC, the new 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”*.
2. An electronic or physical working group may be established to assist the Committee to undertake the new work. Working groups established by the Committee will follow the criteria established by Codex Alimentarius Commission.⁴
3. In certain instances, CCFH work will require a risk assessment of other expert scientific advice. This will be sought from FAO/WHO using the procedure outlined below.
4. Upon completion of work the Committee will submit the final draft text to the Codex Alimentarius Commission at Step 8 of the Codex Step Procedure.

Acquiring Scientific Advice

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 sought through FAO/WHO Joint Expert Committee on Microbiological Risk Assessment (JEMRA) or through one or more FAO/WHO Joint Expert Consultations or Workshops. In such instances the Committee shall serve as the risk managers and the FAO/WHO Joint Expert Committee on Microbiological Risk Assessment shall serve as the risk assessors. 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*⁵.

In seeking an international risk assessment to be conducted by the FAO/WHO Joint Expert Committee on Microbiological Risk Assessment (JEMRA), CCFH should consider and seek advice on:

1. The availability of sufficient scientific knowledge and data to conduct the needed risk assessment. (An initial evaluation of available knowledge and data will typically be provided within the Risk Profile.)

⁴ Criteria under development. See ALINORM 04/33, paras. 104-119, and CX/GP 03/19/7.

⁵ Codex *Procedural Manual*, 13th edition, pp. 42-48.

2. 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.
3. The availability of risk assessments performed at the regional, national and multinational levels that can facilitate the conduct of an international risk assessment.

If the Committee decides to request that a microbiological risk assessment be developed, the Committee will forward a specific request to FAO/WHO and will provide the JEMRA with the risk profile document, a clear statement of the purpose and scope of the risk assessment, any time constraints facing the Committee that could impact the risk assessment, and the specific risk management questions to be addressed by the risk assessors. The Committee will, as appropriate, also provide the risk assessors information relating to the risk assessment policy for the specific risk assessment work to be undertaken⁶. FAO/WHO will inform the Committee of its agreement to carry out such work and will provide a scope of work for the Expert Consultation. 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).

The Committee 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). The iterative process is described in Annex II.

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 the JEMRA. As needed, the FAO/WHO will provide scientific expertise at Committee session or working groups to provide guidance on the appropriate interpretation of the risk assessment.

Unless jointly agreed upon otherwise, microbiological risk assessments carried out by the 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 Prioritize and Conduct CCFH Work

In many instances, the work of the Codex Committee is interconnected with the work of other Codex committees and task forces. In such instances, it may be appropriate for cross-committee interaction to occur that is more extensive than that which would occur under the standing agenda item relating to “matters referred by the Codex Alimentarius Commission and/or Other Codex Committees to the Food Hygiene.” In such situations, the following approach shall normally be used.

- The Chair of CCFH will annually meet with the Chairs of other appropriate committees for the purpose of identifying (1) potential work that should be undertaken by CCFH and (2) work currently underway or planned by other committees that will require or benefit from consideration by CCFH.
- The “Working Group for the Establishment of CCFH Work Priorities” work should consider as part of their deliberations the potential need for cross-committee interaction. They should include an assessment of specific needs for cross-committee interactions(s) for each work project currently underway or being considered by CCFH. Once a new project has been approved for work by CCFH, the lead country for the projects’ working group should, with the assistance of the CCFH Chair, establish the needed cross-committee interaction(s). This will typically be communicated in writing to the Chair of the appropriate Codex committee(s) with a request for the matter to be considered by the committee and the results communicated back to CCFH.
- As appropriate, when establishing working groups on items for which a cross-committee interaction has been identified, a request will be made to include representatives of that committee on the CCFH working group.

⁶ Codex *Procedural Manual, 13th Edition*, p. 52 (definition of risk assessment policy) and pp. 43-44 (working principles relating to risk assessment policy).

- As appropriate, the Chair of CCFH and the Chair(s) of the other appropriate committee(s), or their designated representatives, will be invited to attend each other Sessions.

Annex I

SUGGESTED FORMATS FOR MICROBIOLOGICAL RISK MANAGEMENT GUIDANCE DOCUMENTS

Risk management guidance traditionally provided by the Codex Committee on Food Hygiene (CCFH) has primarily been accomplished through the development of the *Recommended International Code of Practice: General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4 (2003)) and commodity specific codes of hygienic practice. This risk management guidance has focused on the control of hazards generally in a given commodity type, both microbial and chemical (e.g., pesticide residues, heavy metal contaminants).

More recently the need has arisen for the development of microbial pathogen specific risk management guidance; that is, guidance to control a specific microbial pathogen (e.g., *Listeria monocytogenes*) in one or more foods.

Alternative formats for the presentation of microbial pathogen specific guidance are possible. Two possible formats are the following.

Recommended International Code of Practice: General Principles of Food Hygiene Format

Similar to the development of a commodity code of hygienic practice, a risk management document specific for the control for a microbial pathogen in a commodity(ies) can be developed in which the section and sub-section headings of the *Recommended International Code of Practice: General Principles of Food Hygiene* are followed. When this format is used, only hygiene provisions needed to control the hazard that are supplemental to those provided the *General Principles of Food Hygiene* are given. The advantages of using such a format are that it provides a succinct means of providing specific risk management guidance in a format that is well understood by users of CCFH risk management guidance.

Format to Present Risk Profile, Risk Mitigation Strategy, Monitoring and Review Information

An alternative format may be helpful when it desirable to present optional risk mitigation strategies or when it is helpful to present microbiological risk profile and/or risk assessment information or information on monitoring and review programs. In this regard, a risk management document incorporating the following sections, as appropriate, may be appropriate.

Introduction and Background: This section should include an initial statement of the food safety problem. This section should also include the rationale and justification for the work and the Committee's previous consideration and work on the subject. Included in this section can be summary information on the pathogen/commodity of concern, the effected populations and related information.

Scope: A short statement on the microbiological pathogen(s)/commodity (commodities) to which the risk management guidance applies.

Risk Profile: A description and evaluation of the food safety problem associated with the pathogen(s)/commodity combination(s). This section should summarize the information presented in the risk profile provided to the Committee (see Attachment 2).

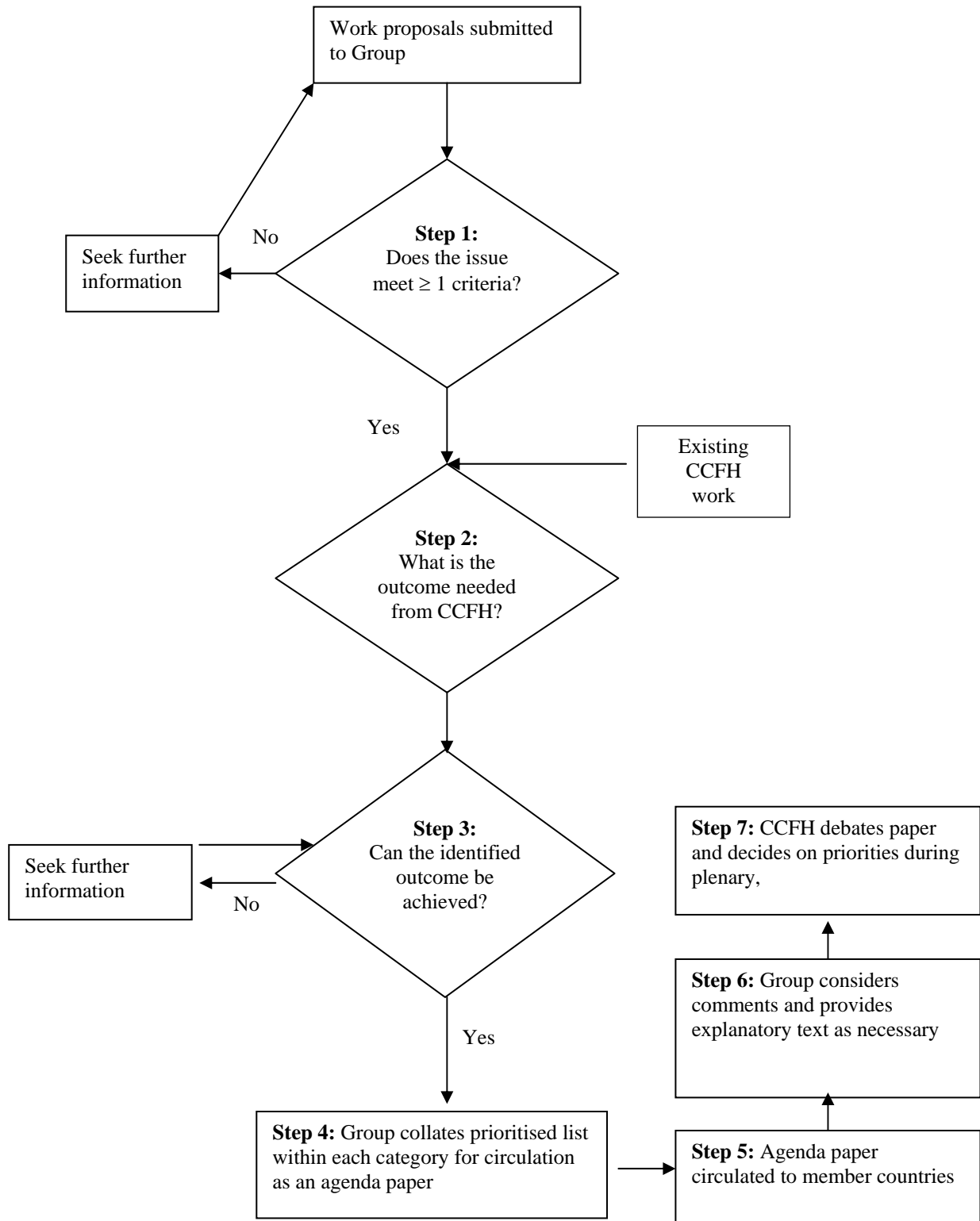
Consideration of the Risk Assessment: Consideration and interpretation of the results of a risk assessment carried out by FAO/WHO JEMRA at the request the Committee. Additional risk assessments conducted at a national level may also be considered in this section.

Risk Management Options: This section should present “best practices” options available for managing the risk from the pathogen/commodity combinations(s) over the entire food chain, including good hygienic practices and HACCP. Member countries can then use this guidance to develop specific risk management options that consist of one or more control measures (e.g., guidance for primary production, processing requirements, handling requirements during distribution and marketing, consumer education programs), instituted to control the microbiological food safety hazard, that are consistent with their specific conditions and requirements. Broad information on the types of risk management options can be found in the Codex *Principles and Guidelines for the Conduct of Microbiological Risk Management* (under development). Information should be presented in sufficient detail to enable development and implementation of food safety programs that adequately control the risk arising from the microbiological pathogen/commodity. Whenever possible, multiple risk management options that achieve the desired level of risk mitigation should be identified as a means of providing flexibility in foods safety control strategies. The use of annexes is recommended to present detailed commodity related risk management control options. If appropriate, Food Safety Objectives, performance criteria and microbiological criteria may be included in this section. The evaluation of risk management options should consider the specific needs and capabilities of developing countries.

Implementation: Implementation of microbiological risk management options is the responsibility of national governments and industry. As appropriate, specific recommendations for the implementation of risk management options may be provided, particularly in relation to international trade.

Monitoring and Review: This section provides guidance on potential strategies for validating and verifying the effectiveness of risk mitigation strategies including the identification of potential metrics that can be used to assess successful, continuing implementation. Information specific and pertinent to the monitoring and review of the specific pathogen/commodity combinations(s) addressed in the guidance document should be provided. Whenever possible, multiple strategies for effective monitoring and review should be provided so that member countries can identify strategies most pertinent to their requirements and conditions. If there are no specific recommendations unique to the pathogen/commodity combination(s), only a reference to the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (under development) is needed. Where possible, monitoring and review should include guidance on potential metrics that can be used to assess the impact of the food control measures on public health.

PROCESS OF CATEGORIZATION AND PRIORITIZATION OF NEW AND EXISTING WORK FOR CCFH THAT WILL BE USED BY THE “WORKING GROUP FOR THE ESTABLISHMENT OF CCFH WORK PRIORITIES”



Annex II**ITERATIVE PROCESS BETWEEN THE CODEX COMMITTEE ON FOOD HYGIENE AND THE
FAO/WHO JOINT EXPERT GROUP ON MICROBIOLOGICAL RISK ASSESSMENT (JEMRA)
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 understood and addressed appropriately. 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 communication. 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 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 the 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) that completion of an adequate risk assessment is not feasible; or
- 2) it is not possible to provide appropriate risk management options.