codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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

ALINORM 03/13A

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-fifth Session
Rome, 30 June - 05 July 2003

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

Orlando, Florida, United States of America, 27 January - 1 February 2003

NOTE: *This report includes Codex Circular Letter CL 2003/5-FH*

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CX 4/20.2 CL 2003/5 - FH

TO: Codex Contact Points
Interested International Organizations

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

SUBJECT: **Distribution of the Report of the Thirty-fifth Session of the Codex Committee on Food Hygiene (ALINORM 03/13A)**

The report of the Thirty-fifth Session of the Codex Committee on Food Hygiene (CCFH) is attached. It will be considered by the Twenty-fifth Session of the Codex Alimentarius Commission, Rome, 2003.

A. MATTERS FOR ADOPTION BY THE CODEX ALIMENTARIUS COMMISSION:

1. Draft Revised Guidelines for the Application of HACCP System at Step 8 (ALINORM 03/13A, Appendix II). See also paras 22 through 30 of this report.

Governments wishing to propose amendments to or 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*, Eleventh Edition, page 23). Comments or proposed amendments should be sent to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy preferably by e-mail: codex@fao.org or fax: +39 (06) 570.54593 **before 1 May 2003**.

2. Proposed Draft Code of Hygienic Practice for Milk and Milk Products at Step 5 (ALINORM 03/13A, Appendix III). See also paras 111 through 150 of this report.

Governments and interested international organizations are invited to comment on the above cited Guidelines and should do so in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts at Step 5 (*Procedural Manual of the Codex Alimentarius Commission*, Eleventh Edition, page 22). Comments should be sent to Dr F. Edward Scarbrough, U.S. Manager for Codex, Attn. Mr S. Amjad Ali, Room 4861 - South Bldg., Food Safety and Inspection Service, U.S. 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, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, by fax: +39 (06) 570.54593 or e-mail: Codex@fao.org **before 1 May 2003**.

B. REQUEST FOR COMMENTS AND INFORMATION:

Risk Profile for Enterohemorragic *E. Coli,* Including the Identification of the Commodities of Concern, Including Sprouts, Ground Beef and Pork. See also paras 60 through 64 of this report.

Wile considering the Risk Profile for Enterohemorragic *E. Coli,* Including the Identification of the Commodities of Concern, Including Sprouts, Ground Beef and Pork the Committee agreed to solicit comments on the top five serotypes of human Enterohemorragic *E. Coli* isolates and the top five commodities of concern as well as the scope of animal husbandry practices which should be included in the risk profile.

Governments and interested international organizations are invited to provide their information and comments on the above subject matter. Comments should be forwarded to Dr F. Edward Scarbrough, U.S. Manager for Codex, Attn. Mr S. Amjad Ali, Room 4861 - South Bldg., Food Safety and Inspection Service, U.S. 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, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, by Fax: +39 (06) 570.54593 or E-mail: Codex@fao.org **before 1 June 2003.**

CONTENTS

SUMMARY AND CONCLUSIONS

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

MATTERS FOR ADOPTION BY THE 26TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION:

AT STEP 8:

Draft Revised Guidelines for the Application of HACCP System (ALINORM 03/13A, paras 22-30 and Appendix II).

AT STEP 5:

- Proposed Draft Code of Hygienic Practice for Milk and Milk Products (ALINORM 03/13A, Appendix III (paras 111 - 150).

MATTERS OF INTEREST OF THE CODEX ALIMENTARIUS COMMISSION:

The Committee:

- Concluded that the current restrictions excluding the use of the lactoperoxidase system for products intended for international trade should continue to be applied and therefore, there was no need for the revision of the existing Guidelines in the framework of Codex. In view of this decision, the Committee noted that a JECFA review was not requested (para.12);
- Requested FAO and WHO to convene an expert consultation on the *Enterobacter* genus, including *Enterobacter sakazakii*, and *Clostridium botulinum*, at the earliest opportunity, subject to the provision of adequate funding (para. 173);
- Endorsed the Hygiene Provisions of the draft Code of Practice for Fish and Fishery Products and the Draft Standard for Boiled Dried Salted Anchovies as amended during the Session (paras 14 – 21);
- Accepted the offer of FAO and WHO Representatives to elaborate a document on "Obstacles to the Application of HACCP, Particularly in Small and Less Developed Businesses, and Approaches to Overcome Them" (para. 33);
- Agreed that Discussion Papers on Risk Management Strategies for *Salmonella* spp. in Poultry and on Risk Management Strategies for *Campylobacter* spp. in Broiler Chickens, and discussions on this matter at the Committee would be forwarded to the Committee on Meat and Poultry Hygiene for possible consideration in their continued elaboration of the proposed draft Code of Hygienic Practice for Fresh Meat (paras 47 and 54);
- Decided to suspend the further elaboration of the Discussion Paper on Risk Management Strategies for *Vibrio* spp. for the time being, pending the outcome of discussions in the CCFFP and the completion of the risk assessment (para. 59);
- Agreed to solicit comments on the top five serotypes of human EHEC isolates and the top five commodities of concern as well as the scope of animal husbandry practices which should be included in the risk profile and to update the risk profile for presentation at the next session of the CCFH (para. 64)
- Decided to split the elaboration of the proposed draft Guidelines for the Control of *Listeria monocytogenes* in Foods into two documents namely, one with immediate commence of work on the proposed draft Guidelines on the Application of General Principles of Food Hygiene to the [Management] of *Listeria monocytogenes* in Foods and another on the specific microbiological criteria for *Listeria* in foods elaboration of which could be considered at future meeting (paras 99-110).

MATTERS OF INTEREST TO OTHER COMMITTEES:

CODEX COMMITTEE FOR FISH AND FISHERIES (CCFFP)

Hygiene Provisions of the Codex Code of Practice for Fish and Fishery Product

- The Committee endorsed the food hygiene provisions of the Codex Code of Practice for Fish and Fishery Products and the Codex Standard for Anchovies, with amendments during the session (paras 55-59) and understanding that provisions on the unloading of fish, shellfish and other invertebrates would be developed by the CCFFP; and forwarded to the CCFFP the discussion paper on the Risk Management Strategies for *Vibrio* spp. for their consideration.

CODEX COMMITTEE FOR MEAT AND POULTRY HYGIENE (CCMPH)

- Agreed that Discussion Papers on Risk Management Strategies for *Salmonella* spp. in Poultry and on Risk Management Strategies for *Campylobacter* spp. in Broiler Chickens, and discussions on this matter at the Committee would be forwarded to the Committee on Meat and Poultry Hygiene for possible consideration in their continued elaboration of the proposed draft Code of Hygienic Practice for Fresh Meat (paras 39 through 54).

LIST OF ABBREVIATIONS USED IN THIS REPORT

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
EUC	Commission of the European Community
FAO	Food and Agriculture Organization of the United Nations
HACCP	Hazard Analysis and Critical Control Point System
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 THIRTY-FITH SESSION OF THE COMMITTEE ON FOOD HYGIENE

INTRODUCTION

1. The Codex Committee on Food Hygiene (CCFH) held its Thirty-fifth Session in Orlando, Florida, United States of America, from 27 January to 1 February 2003, 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 the Vice-Chairperson. The Session was attended by 170 participants from 43 Member countries and 14 international organizations. A complete list of participants is given in Appendix I to this report.

OPENING OF THE SESSION

2. The session was officially opened by Dr Garry McKee, Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture. Dr McKee welcomed the delegates to the United States and noted the importance of the work of the Codex Committee on Food Hygiene, especially since food safety problems were changing and international trade in foods was becoming ever more global. Dr McKee commended the CCFH for its groundbreaking work in developing new risk management and assessment thinking and tools, and emphasized the importance of continuing this work in the future.

3. Dr Karen Hulebak emphasized the importance of the primary role of the CCFH in protecting the health of consumers, as well as the Committee's responsibility in ensuring that the results of its work were practical and suitable for ensuring fair practices in international trade. Dr Hulebak indicated that she would keep the Committee focused on its primary goals, in accordance with its terms of reference, and emphasized that she would strive to ensure effective and efficient discussions and debate that was inclusive of all points of view, including the consideration of all written comments submitted. In view of the Committee's extensive agenda, Dr Hulebak stressed the need to keep discussions brief and succinct so as to enable the committee to manage its work in an effective and efficient manner.

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

4. The Committee recalled that the document on Risk Application in the Elaboration of Codex Standards prepared by India (CRD 13) had not been considered at the 34th Session of the CCFH and therefore, it was rescheduled for consideration at the current meeting. However, the Delegation of India informed the Committee that the matter had been further discussed by the 17th Session of the Codex Committee on General Principles (April 2002) and that several proposals contained in the above document had been incorporated into the proposed draft Working Principles for Risk Analysis under development by the CCGP (ALINORM 03/33, paras 15-66). In recognition that the remaining issues raised by the delegation of India could be discussed and addressed under different agenda items, the Committee agreed to discontinue the specific consideration of this subject under agenda item 11.

5. The Committee agreed to consider the risk profile of *Enterobacter sakazakii* in Powdered Infant Formula and communication between committees on risk management procedures under Other Business and Future Work.

6. At the suggestion of the Chairperson, the Committee agreed to discuss new approaches to managing the work of the CCFH, including the development of a clearer sense of strategic prioritization of its work plan and priorities, and interactions with other Codex committees, under Other Business and Future Work.

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1 CX/FH 03/1

7. The Committee adopted the Provisional Agenda as the Agenda for the Session with the above modifications.

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES (Agenda Item 2)[2]

8. The Committee noted a number of matters arising from the 50th Session of the Executive Committee and Other Codex Committees and had specific discussions on these matters, as follows:

LACTOPEROXIDASE

9. The Committee noted that the Codex Committee on Milk and Milk Products had considered the request from the FAO Global Lactoperoxidase Group of Experts to reconsider the provisions of the Codex Guidelines for the Preservation of Raw Milk by Use of the Lactoperoxidase System (CAC/GL 13-1991), and requested the Executive Committee to provide advice on whether and how to proceed with a revision of the Guidelines in the framework of Codex (ALINORM 03/11, para. 13). The 50th Session of the Executive Committee requested the CCFH to consider whether the provisions restricting the use of the lactoperoxidase system in international trade should be retained and whether the current Guidelines should be revised.

10. The Committee also noted that this matter had been considered at the Regional Coordinating Committees and despite the fact that the system was currently used in some countries, there was little support for its use for products intended for international trade.

11. Most delegations were of the view that this system should continue to be restricted to use in countries where appropriate refrigeration facilities were not available and did not support the use of the system for international trade purposes. In addition, the microbiological data were not clear in order to determine how effective this system was for the control of food borne pathogens and what the microbiological consequences would be of its long use.

12. The Committee concluded that the current restrictions excluding the use of the lactoperoxidase system for products intended for international trade should continue to be applied and therefore, there was no need for the revision of the existing Guidelines in the framework of Codex. In view of this decision, the Committee noted that a JECFA review was not requested.

ANTIMICROBIAL RESISTANT BACTERIA IN FOOD

13. The Committee thanked Consumers International for their information paper prepared on the Presence of Antimicrobial Resistant Pathogens in Chicken Sold at Retail: A Report on Tests by CI Members in Australia and the United States[3]. Consumers International recommended that that risk assessments by FAO/WHO and risk management work by the Committee consider the additional risk issues raised by the presence of antimicrobial resistant bacteria, especially salmonella and campylobacter in poultry. The Committee noted that further action would depend on the results of the scientific advice provided by the FAO/WHO and OIE expert consultations.

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2 CX/FH 03/2, CRD 17 (comments from Cuba).

3 This paper and other CRDs are available at the request from the Codex Secretariat.

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

DRAFT CODE OF PRACTICE FOR FISH AND FISHERY PRODUCTS[4]

DRAFT STANDARD FOR BOILED DRIED SALTED ANCHOVIES[5]

14. In accordance with the provisions of the Codex Alimentarius Commission Procedural Manual and in consideration of the terms of reference of the Codex Committee on Food Hygiene, the Committee was invited to endorse the hygiene provisions of the draft Codex Code of Practice for Fish and Fishery Products, including the section on frozen surimi, and the draft Standard for Boiled Dried Salted Anchovies.

15. The Delegation of India noted that the term "vessels" was not properly defined although it was included in the definition and requirements for fishing vessels. It was noted that in India most of the vessels engaged in fish harvesting operations were small fishing boats which were only used for the capture and transportation of fish but not for processing and therefore, there was no need for the requirements stipulated in sections 3.1.2, 3.1.3 and 3.1.4.

16. The Secretariat clarified that the definitions were thoroughly discussed at several sessions of the Committee on Fish and Fishery Products and in order to practically apply this Code to all countries, and governments might need to make adjustments in the application of the Code in order to take account of local conditions and fishing practices.

17. The Observer of the EC and the delegation of France noted that some sections of the Code were still under development and that some steps were missing in Section 3 related to prerequisite programmes, and also that there were no provisions regarding the unloading and wholesaling of fish, shellfish and other vertebrates. The Observer was of the view that "factory vessels" should be considered as fish processing facilities and that this should be expressed more precisely in the Code. The Observer also noted that histamine levels were higher in the Community legislation for Dried Salted Anchovies which were subjected to enzymatic ripening. However, in acknowledging the tremendous work of the Committee on Fish and Fishery Products in combining different fish codes, he supported the endorsement of the food hygiene provisions.

18. The Committee agreed to the proposal of the United States and recommended to the Commission to amend the last sentence of Section 1.1.2 in Annex I to delete the phrase "and produce heat resistant toxins" to read "Certain strains of *Vibrio parahaemolyticus* can be pathogenic" as there were no heat resistant toxins produced by these bacteria.

19. The Committee also agreed to the proposal of the delegation of France and included an amendment in the last sentence in Section 1.1.2 in Annex I that *Staphylococcus aureus* might produce the heat resistant toxins.

20. The Delegation of Indonesia proposed to clarify the Scope of the Code in order to expand it and accommodate other sea products, however the Committee was of the view that this was not within the mandate of CCFH.

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4 Draft Code of Practice for Fish and Fishery Products (ALINORM 03/18, Appendix II) and comments submitted in response to CL 2002/43-FH on the Hygiene Provisions of the Proposed Draft Code of Practice from USA (CX/FH 03/3) and India and Indonesia (CRD 1).

5 CX/FH 03/3-Add.1.

Status of the Endorsement of the Hygiene Provisions of the Draft Code of Practice for Fish and Fishery Products and the Draft Standard for Boiled Dried Salted Anchovies

21. The Committee endorsed the food hygiene provisions of the Draft Code of Practice for Fish and Fishery Products, including the Section of the Frozen Surimi, and the Standard for Boiled Dried Salted Anchovies as amended above and with the understanding that the above discussions would be considered by the CCFFP at a future meeting.

DRAFT REVISED GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM (Agenda Item 4a)[6]

22. The 34th Session of the Codex Committee on Food Hygiene forwarded the proposed draft Revised Guidelines for the Application of the HACCP System for adoption at Step 5 by the 50th Session of Executive Committee.[7] The 50th Session (June 2002) of the Executive Committee adopted the proposed draft Guidelines at Step 5, and requested that the Guidelines should take account of concerns and particular needs of specific sectors of small and/or less developed businesses.[8] The delegation of the Netherlands introduced the document and pointed out that major problems in revising the HACCP Guidelines and the use of the document on "Obstacles to the Application of the HACCP Particularly in Small and less Developed Businesses and Approaches to Overcome Them" were mainly solved during elaboration procedure.

GENERAL COMMENTS

23. The Committee agreed with the opinion of the Executive Committee that the draft Guidelines should be revised to take account of the needs of specific sectors of small and less developed businesses (SLDBs) and agreed with the draft Guidelines as proposed, with the following changes.

INTRODUCTION

24. The Committee revised the first sentence of the first paragraph to read that "Prior to the application of HACCP to any sector of the food chain, that sector should have in place prerequisite programs such as good hygienic practices according to the" in order to clarify the meaning of the last sentence in the paragraph. The Committee also changed the term "legislation" to "requirements" in this sentence in order to reflect the fact that not all countries legislated the use of HACCP.

25. The Committee reordered the sentences in paragraph 6 and specified that it was recognized "by governments and businesses" that there were obstacles hindering the effective application of the HACCP principles by individual businesses. The paragraph was also clarified to state that although all seven principles must be applied in the HACCP system, a flexible approach was appropriate depending on the business to which HACCP was applied.

26. The Committee decided to incorporate a reference in paragraph 7 to a document to be jointly developed by FAO and WHO with information on the obstacles in implementing HACCP, particularly in reference to SLDBs, including recommendations for resolving these obstacles (also see agenda item 4b, below). The Committee also changed the phrase "Expertly developed HACCP guidance" to "HACCP guidance developed by experts" in paragraph 7 and as a subsequent change throughout the text.

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6 ALINORM 03/13, Appendix III and comments submitted in response to CL 2002/36-FH from Argentina, Cuba, India, Paraguay, Peru, South Africa, Thailand, Uruguay, United States (CX/FH 03/4) and India (CRD 2).

7 ALINORM 03/13, para. 150 and Appendix III.

8 ALINORM 03/3A, para. 72 and Appendix II.

APPLICATION

ASSEMBLE HACCP TEAM

27. The Committee moved the last sentence of this section to follow immediately after the third sentence for clarity.

ESTABLISH VERIFICATION PROCEDURES

28. The Committee modified the first paragraph of this section to indicate that qualified third parties should perform verification of certain activities that could not be performed in house. The Committee also agreed to ensure the correct the use of the terms "plan" and "system" throughout the text.

ESTABLISH DOCUMENTATION AND RECORD KEEPING

29. The Committee deleted the last bullet in this section as it was already adequately addressed in the penultimate bullet.

Status of the Draft Revised Guidelines for the Application of the HACCP System

30. The Committee forwarded the draft Revised Guidelines for the Application of the HACCP System (see Appendix II) to the 26th Session of the Codex Alimentarius Commission for final adoption at Step 8.

CONSIDERATION OF OBSTACLES TO THE APPLICATION OF THE HACCP, PARTICULARLY IN SMALL AND LESS DEVELOPED BUSINESSES AND APPROACHES TO OVERCOME THEM (Agenda Item 4b)[9]

31. The 34th Session of the CCFH agreed to request comments on Annex II of document CX/FH 01/10 (Obstacles to the Application of HACCP, Particularly in Small and Less Developed Businesses (SLDBs) and Approaches to Overcome Them) for forwarding to the Netherlands so that an updated version of the paper could be prepared for consideration at its current Session.[10]

32. The Committee noted that general concerns related to the application of HACCP in developing countries, particularly in small and less developed businesses, had already been incorporated into the draft Revised Guidelines for the Application of the HACCP System (see agenda item 4a, above) forwarded to the Commission for final adoption at Step 8.

33. However, in recognition that the Guidelines for the Application of the HACCP System might benefit from a complementary text which took account of the needs of SLDBs, the Committee accepted the offer of the FAO/WHO Representatives, with the assistance of WHO, to elaborate a document on "Obstacles to the Application of HACCP, Particularly in Small and Less Developed Businesses, and Approaches to Overcome Them" as a guidance paper.

REPORTS OF THE *AD HOC* EXPERT CONSULTATIONS ON RISK ASSESSMENT OF MICROBIOLOGICAL HAZARDS IN FOOD AND RELATED MATTERS (Agenda Item 5)[11]

34. The representatives of FAO and WHO informed the committee about progress made to date on the various activities jointly undertaken by the two Organizations on risk assessment of microbiological

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9 CX/FH 03/4-Add. 1 and comments submitted in response to CL 2001/32-FH from India and Indonesia (CRD 3).

10 ALINORM 03/13, para. 151.

11 CX/FH 03/5 and comments submitted by New Zealand (CRD 19).

hazards in foods. Four risk assessments (RA) were currently in various states of completion. The RA on Salmonella in eggs and poultry had been finalized and published. In addition to the main technical document, an interpretative summary aimed mainly at managers had also been developed and published.

35. The RA on Listeria in ready-to-eat foods was in the final stage and will be published in a few months. The interpretative summary was distributed to CCFH prior to this meeting. The RAs on *Campylobacter* spp. in broiler chickens and *Vibrio* spp. in seafood were further developed this year and the work had been evaluated during a Joint FAO/WHO Expert Consultation held in Bangkok, Thailand in August 2002. The report of this consultation was available in English, French and Spanish. These two RAs were expected to be finalized this year. These RAs aim to meet the needs of CCFH and FAO and WHO member countries with regard to providing assistance for managing the risks posed by these microorganisms in specific food products. The representatives of FAO and WHO emphasized that the outcomes of the RAs present CCFH with a very valuable resource for use in the elaboration of risk management tools and represent a significant improvement in the available scientific advice for the management of the risk posed by specific hazards in foods.

36. The representatives of FAO and WHO also referred to the document of the report of the *Ad Hoc* expert consultations on risk assessment of microbiological hazards in food (JEMRA) in which details were given on the other guidelines document under preparation. These are the FAO/WHO guidelines on hazard characterization of microbiological hazards in food and water; the FAO/WHO guidelines on Exposure Assessment of Microbiological hazards in food and water; the guidelines for incorporating microbiological risk assessment in the development of food standards; the Expert Consultation on developing a strategy for global surveillance for food-borne diseases and risk analysis; and the WHO expert consultation on methods of food-borne disease surveillance in selected sites. These Guidelines could assist the CCFH in the development of some of its guideline document under consideration under the present agenda.

37. The representatives of FAO and WHO finally reiterated the need for guidance from CCFH on several aspect of each of the risk assessments under development to further assist FAO and WHO in delivering useful risk assessment meeting the needs of the Committee. They further suggested that a thorough consideration of the important issues presented in the risk assessments should be undertaken noting that these are outcome of CCFH initiatives to base risk management considerations on risk assessment.

38. The Committee decided to comment and provide guidance on these risk assessments during the subsequent deliberations on the management discussion papers on each pathogen.

GENERAL CONSIDERATIONS OF RISK MANAGEMENT PAPERS

39. The Chairperson suggested that the major task facing the Committee was the utilization of the risk assessments performed by FAO and WHO to develop risk management options and strategies particular to each pathogen/commodity combination under consideration, i.e., *Salmonella* spp. in Poultry (agenda item 5a), *Campylobacter* spp. in Poultry (agenda item 5b), *Vibrio* spp. (agenda item 5c), Enterohemorragic *E. coli* (agenda item 5d) and *Listeria monocytogenes* (agenda item 7). It was stressed that a necessary step in developing risk management strategies in each case was to firstly examine the adequacy of previous or ongoing work being undertaken by the CCFH, as well as work undertaken by other relevant committees (e.g., Fish and Fishery Products, Meat and Poultry Hygiene), before proceeding further. It was noted that communication with and between other Codex committees working in areas related to food hygiene was of paramount importance in this regard.

40. It was noted that in general the development of risk management strategy should begin with a risk profile. It was also noted that preferably a risk profile, and options for interactions with other Codex committees and questions directed back to the risk assessors should be included in the development of a risk management strategy. It was stated that communication with other Codex committees could

involve the sharing of information only, a request for information to further the work within the CCFH or a request through the Codex Alimentarius Commission for the work to be undertaken by the other Codex committees. In any case, it was stressed that communications with other Codex committees should provide clear guidance as to what was needed or required by the CCFH to further elaborate their work.

41. The Codex Secretariat clarified that work being undertaken by the CCFH which was related to ongoing work in other Codex committees would be raised as a matter of information in these committees in order to facilitate information exchange in the development of such texts. It was further noted that in developing such texts, it was also the responsibility of individual countries to ensure that all views from their various national ministries and departments were taken into account. It was stated that the Codex procedure encouraged the submission of comments from all Codex Member governments and that the endorsement of any text related to food hygiene was under the ultimate responsibility of the CCFH unless the Commission decided otherwise.

DISCUSSION PAPER ON RISK MANAGEMENT STRATEGIES FOR *SALMONELLA* SPP. IN POULTRY (Agenda Item 5a)[12]

42. The 34th Session of the CCFH noted that there was currently no work underway on *Salmonella* spp. in poultry and therefore, agreed that a drafting group led by Sweden would develop a Discussion Paper on Risk Management Strategies for *Salmonella* spp. in Poultry for consideration at its current meeting with a view towards developing risk management strategies for *Salmonella* spp. in poultry.[13]

43. In presenting the document on *Salmonella* spp. in poultry, the delegation of Sweden noted that in view of the risk assessment provided by FAO and WHO, a further risk profile might not be required. It was stated that in any case, it was the responsibility of the CCFH to determine whether existing Codex texts provided adequate guidance in this regard or alternatively, whether additional risk management activities were required.

44. Some delegations were of the opinion that the risk management strategies presented in the document should be revised to take account of the farm to table approach. It was further stated that although the proposed draft Code of Hygienic Practice for Fresh Meat under development by the Codex Committee on Meat and Poultry Hygiene (CCMPH) did not contain specific provisions related to *Salmonella* spp. in poultry, the text under development by the CCFH should nonetheless be forwarded to the CCMPH for their use and in order to determine if modifications to the CCFH document were required.

45. Other delegations were of the opinion that in order to incorporate a farm to table approach, new data and information were required, and governments were encouraged to submit data in this regard. It was noted that in any case, such a step did not preclude further work on the discussion paper within the CCFH.

46. Various delegations recommended that the following questions should be considered by the Drafting Group:

- Refine and prioritize possible interventions throughout the food chain with potential for risk reduction, with a view of formulating questions to risk assessors to be dealt with in modeling risk;
- Encourage input from experts on aspects throughout the food chain and scientific expertise;
- Risk management/risk assessment should be further developed.

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12 CX/FH 03/5-Add. 1 and comments submitted by India (CRD 4) and Thailand (CRD 18).

13 ALINORM 03/13, para. 73.

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

47. The Committee decided that the drafting group led by Sweden, with the assistance of Australia, Canada, China, Czech Republic, Denmark, France, Germany, Netherlands, New Zealand, Thailand, USA and the EC and ALA, would revise the Discussion Paper on Risk Management Strategies for *Salmonella* spp. in Poultry for consideration at its next Session. The Committee agreed that the risk management strategies proposed should consider a farm to table approach.

48. The Committee also agreed that the above discussions, as well as document CX/FH 03/5-Add.1, would be forwarded to the CCMPH for information and possible consideration in their continued elaboration of the proposed draft Code of Hygienic Practice for Fresh Meat.

DISCUSSION PAPER ON RISK MANAGEMENT STRATEGIES FOR *CAMPYLOBACTER* SPP. IN POULTRY (BROILER CHICKEN) (Agenda Item 5b)[14]

49. The 34th Session of the CCFH agreed that a drafting group led by the Netherlands would develop a Discussion Paper on Risk Management Strategies for *Campylobacter* spp. in broiler chickens for consideration at its current meeting and in order to provide further guidance to FAO and WHO in their risk assessment of *Campylobacter* spp. in broiler chickens.[15]

50. In presenting the document on *Campylobacter* spp. in broiler chickens, the delegation of the Netherlands noted that the drafting group had followed the instructions of the 34th Session of the CCFH and had formulated specific questions for the risk assessors as well as elaborating a format for the risk profile. The delegation noted that although the document recommended the development of a code of practice, such a step should take account of the feasibility and cost effectiveness of initiating such a proposal.

51. The Committee was informed that several questions presented in the discussion paper had been adequately responded to by the risk assessors but that others could not be answered and would require further consideration. In view of this information, it was noted that the elaboration of a code of practice might be premature, especially in consideration that additional data would need to be submitted in order to perform a complete risk assessment.

52. Various delegations recommended that the following questions should be considered by the Drafting Group:

- Refine and prioritize possible interventions throughout the food chain with potential for risk reduction, with a view of formulating questions to risk assessors to be dealt with in modeling risk;
- Encourage input from experts on aspects throughout the food chain and scientific expertise;
- Risk management/risk assessment should be further developed.

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

53. The Committee decided that the drafting group led by the Netherlands, with the assistance of Australia, Belgium, Canada, China, Denmark, Finland, Japan, New Zealand, Norway, Philippines, Thailand, the United Kingdom, USA and the EC and ALA, would revise the Discussion Paper on Risk Management Strategies for *Campylobacter* spp. in broiler chickens for consideration at its next Session. The Committee agreed that the results of further FAO and WHO work on risk assessment should be

[14] CX/FH 03/5-Add. 2 and comments submitted by Australia (CRD 4).
[15] ALINORM 03/13, para. 79.

taken into account, and that a decision on the possible elaboration of a code of practice would be deferred for the time being.

54. The Committee also agreed that the above discussions, as well as document CX/FH 03/5-Add.2, would be forwarded to the CCMPH for information and possible consideration in their continued elaboration of the proposed draft Code of Hygienic Practice for Fresh Meat asking specific questions to be answered.

DISCUSSION PAPER ON RISK MANAGEMENT STRATEGIES FOR *VIBRIO* SPP. (Agenda Item 5c)[16]

55. The 34th Session of the CCFH agreed that a drafting group led by the United States would develop a Discussion Paper on Risk Management Strategies for *Vibrio* spp. in seafood for consideration at its current meeting and with a view towards defining specific questions to be addressed in the risk assessment. The Committee also suggested that the paper could provide guidance to FAO and WHO in their risk assessment of *Vibrio* spp. in seafood.[17]

56. In presenting the document on *Vibrio* spp., the delegation of the United States noted that the drafting group had followed the instructions of the 34th Session of the CCFH and had focussed on *Vibrio parahaemolyticus* and formulated specific questions for the risk assessors as well as reviewing existing Codex texts for completeness. The delegation noted the need for the consideration of additional data, including input from the Codex Committee on Fish and Fishery Products (CCFFP), if necessary.

57. The representative of FAO noted ongoing related work in the CCFFP, namely, the proposed draft Standard for Molluscan Shellfish and the revised Code of Practice for Fish and Fishery Products, in particular the section related to the Processing of Molluscan Shellfish. It was noted that the CCFFP would be informed of CCFH work related to risk management strategies for *Vibrio parahaemolyticus* . as well as the results of the Joint FAO/WHO Expert Consultation on Risk Assessment of *Vibrio* spp. in Seafood. The representative of WHO noted several questions posed by the risk assessors to the CCFH as to the scope, approach and preliminary results of the expert consultation, especially as to how it related to ongoing work within the CCFH.

58. It was suggested that further elaboration of the discussion paper should be suspended until the CCFFP had an opportunity to consider the document and pending the completion of the risk assessment. It was noted that future revisions to the document should focus on risk management strategies. It was also suggested that risk assessments should include adequate data related to the pathogenicity of different *Vibrio* species.

Status of the Discussion Paper on Risk Management Strategies for *Vibrio* spp.

59. The Committee decided to suspend the further elaboration of the Discussion Paper on Risk Management Strategies for *Vibrio* spp. for the time being, pending the outcome of discussions in the CCFFP and the completion of the risk assessment.

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16 CX/FH 03/5-Add. 3.

17 ALINORM 03/13, para. 79.

RISK PROFILE FOR ENTEROHEMORRAGIC *E. COLI*, INCLUDING THE IDENTIFICATION OF THE COMMODITIES OF CONCERN, INCLUDING SPROUTS, GROUND BEEF AND PORK (Agenda Item 5d)[18]

60. The 34th Session of the CCFH agreed that a drafting group led by the United States would prepare a risk profile for enterohemorrhagic *E. coli,* including the identification of the commodities of concern (sprouts, ground beef and pork) for consideration at its current meeting. The Committee also agreed that the paper should take account of the recently completed Code of Hygienic Practice for Fresh Fruits as related to sprouts[19].

61. In presenting the risk profile for enterohemorrhagic *E. coli,* the delegation of the United States indicated that the document provided an overview of the completed risk profile, existing international guidelines and codes of practice that were likely to mitigate the occurrence of infection and suggested risk management activities for consideration by the CCFH.

62. It was noted that the risk profile focused on intensive beef raising practices and that other approaches to beef raising practices, such as pastoral or range practices, should be taken into account. This included the expansion of the section dealing with on-farm mitigation strategies.

63. The Committee noted that since this was its first effort in developing a new process to assist the CCFH in developing risk management strategies, the clarification of the exact scope of the risk assessment required, including the commodities (i.e., vegetables or meat) and serotypes of concern and the scope of the risk profile, needed to be more clearly defined. It was also noted that a risk profile was not only meant to define the commodities of concern, but also the need for a risk assessment or other appropriate measures (e.g., codes of practice) and the exact questions for consideration by the risk assessors.

Status of the Risk Profile for Enterohemorragic *E. Coli*, Including the Identification of the Commodities of Concern, Including Sprouts, Ground Beef and Pork

64. The Committee agreed to solicit comments by Circular Letter to this report on the top five serotypes of human EHEC isolates and the top five commodities of concern as well as the scope of animal husbandry practices which should be included in the risk profile. It was further agreed that the drafting group led by the United States, and with the assistance of Austria, Australia, Canada, China, France, Germany, Japan, New Zealand and the EC, would update the risk profile for presentation at the next session of the CCFH based on the information submitted in response to the circular letter, the above discussions and written comments considered at the current meeting.

PROPOSED DRAFT PROCESS BY WHICH THE CODEX COMMITTEE ON FOOD HYGIENE COULD UNDERTAKE ITS WORK IN MICROBIOLOGICAL RISK ASSESSMENT/RISK MANAGEMENT (Agenda Item 5e)[20]

65. The 34th Session of the CCFH requested the United States to revise its proposal (CX/FH 01/5-Add.2) concerning CCFH work related to risk management so that the document took account of the risk profile template provided by FAO and WHO (CX/FH 01/5-Add.3) and that the process be as simple, short and flexible as possible. It was agreed that the paper would be circulated for comments and further consideration at the current meeting and that depending on the outcome of these discussions, might eventually be considered for inclusion in the Codex Alimentarius Procedural Manual[21].

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18 CX/FH 03/5-Add. 4 and comments submitted by Cuba and Poland (CRD 4).

19 ALINORM 03/13, para. 86.

20 CX/FH 03/6 and comments submitted in response to CL 2002/43-FH from Canada, Brazil, Mexico, Consumers International (CX/FH 03/6-Add.1), India, Iran (CRD 5) and the EC (CRD 15).

21 ALINORM 03/13, para. 82.

66. In introducing the process paper, the delegation of the United States noted that it proposed a general procedure for the integration of risk assessment and management into the work of the CCFH in a logical manner, including steps to be taken in evaluating the consideration of new work and the elaboration of discussion papers for background information. The delegation stated that the process paper also included elements necessary for a risk profile so that the Committee could decide whether a full risk assessment or other alternative measures would be required. In view of the fact that the paper was drafted prior to the Kiel consultation[22], it was noted that the results of the Consultation as well as the insertion of additional elements related to risk communication need to be considered.

GENERAL COMMENTS

67. The Committee generally supported the approach taken in the process document, but did not consider the written comments in detail. It was suggested that it was important to clarify its relationship to CCFH work on the proposed draft Principles and Guidelines for the Conduct of Microbiological Risk Management (see agenda item 6), especially in overlapping areas related to risk management and elements required for risk profiles. It was agreed that the results of the Kiel Consultation would need to taken into account, especially as related to the decision chart on risk profiles and their relation to risk management decisions. It was also noted that ongoing work in the Codex Committee on General Principles related to the development of the proposed draft Working Principles for Risk Analysis could also provide useful guidance to the CCFH.

68. The Codex Secretariat clarified that Codex texts were either directed to provide specific guidance to Codex committees or alternatively, specific guidance to Codex Member governments and that the former guidance was to be included in the Codex Alimentarius Commission Procedural Manual, while the latter guidance was to be included in the Codex Alimentarius itself. The Committee noted that the process document was intended for eventual inclusion in the Procedural Manual for guidance to the CCFH and other related Codex committees while the document on proposed draft Principles and Guidelines for the Conduct of Microbiological Risk Management was intended for application by governments.

69. The Committee discussed the process paper point by point, with delegations providing specific points to be considered by the Drafting Group and noted the following comments:

PROPOSED PROCESS

70. In response to an observation that the undertaking of a risk assessment by FAO and WHO should be a mandatory requirement (bullet three), it was noted that the undertaking of such an assessment was dependent on the results of the risk profile and therefore, might not always be required. The Committee however agreed that if it was decided that a risk assessment should be undertaken, it should be conducted by the Joint FAO/WHO Expert Group on Microbiological Risk Assessment (JEMRA). Furthermore it was suggested that a risk profile to be considered as an explicit step in the process.

SECTION 1 - PROPOSAL FOR WORK

71. The Committee noted that the criteria for proposed new work in section 1.2 should be structured but at the same time flexible in that not all criteria might need to be addressed. In this regard, it was noted that the issues related to the undertaking of a microbiological risk assessment would not necessarily be based on the identification of a problem in both developed and developing countries (bullet 2) and that in any case, it was felt that the third bullet covered the situation adequately. It was also suggested that the relationship between sections 1.2 and 1.3 should be clarified and that section 1.3 should take into account global data, including data from developing countries.

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[22] Report of a Joint FAO/WHO Consultation on Principles and Guidelines for Incorporating Microbiological Risk Assessment in the Development of Food Safety Standards, Guidelines and Related Texts; Kiel, Germany; 18-22 March 2002.

72. It was noted that a risk profile should be required in the development of any proposal for new work (section 1.2), and that such proposals should in all cases be provided to the Committee in written form (section 1.4). While recognizing the risk management responsibilities of the CCFH, it was also suggested that a process might be incorporated into section 1.5 (also see section 4, below) to allow for such work to be undertaken between sessions of the Committee. It was also stated that the undertaking of risk assessment activities by JEMRA should only be requested on the basis of a through discussion in the CCFH, including the consideration of a risk profile (section 1.7).

Section 2.0 – Development of a Discussion Paper, Including a Risk Profile and Agreement to Proceed with the Work

73. In the interest of facilitating the efficient consideration of new work, it was suggested that section 2.1 be strengthened to indicate that it was preferable for discussion papers to also include a risk profile.

SECTION 4 – INTERACTIVE PROCESS BETWEEN THE CCFH AND THE JOINT FAO/WHO EXPERT GROUP ON MICROBIOLOGICAL RISK ASSESSMENT

74. It was suggested that elements related to interactions with other Codex committees should be included in this section, and that provisions for the undertaking of risk management work between sessions of the CCFH be considered (see section 1.5, above), with the understanding that the relevance of such work to the full plenary session was important in this regard.

SECTION 5 – DEVELOPMENT OF CCFH OUTPUT DOCUMENT(S)

75. It was suggested that the risk management options should be specifically indicated in this section on the basis of the results of the Kiel consultation. In this regard, it was noted that the risk management options, including the scope of such options.

ANNEX 1

76. It was suggested that the elements in risk profile in Annex could be omitted and replaced by a reference to the ongoing CCFH work on the proposed draft Principles and Guidelines for the Conduct of Microbiological Risk Management (agenda item 6) and could also include Figure 1 (page A III – 4) of the report of the Kiel Consultation. It was also felt that the text should be clarified to indicate that it was the responsibility of countries to identify their sources of information when submitting proposed risk profiles. In any case, it was stressed that elements related to the risk profile needed to be clearly indicated considering the Kiel consultation.

Status of the Proposed Draft Process by Which the Codex Committee on Food Hygiene Could Undertake its Work in Microbiological Risk Assessment/Risk Management

77. The Committee agreed that a drafting group led by the United States, and with the assistance of Australia, Canada, India, Ireland, France, Germany, Japan, New Zealand, the Netherlands, Sweden, the United Kingdom, EC, FAO and WHO, would revise the process document for circulation, comment and further consideration at its next Session. It was decided that the document should be revised on the basis of the above discussions, written comments submitted at the current meeting, the results of the Kiel Consultation, discussions in other Codex committees and in consideration of the proposed draft Principles and Guidelines for the Conduct of Microbiological Risk Management (agenda item 6).

PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT (Agenda Item 6)[23]

78. The 34th Session of the CCFH requested the drafting group led by France to revise the proposed draft Principles and Guidelines for the Conduct of Microbiological Risk Management based on the Committee's discussions and written comments submitted for circulation, additional comment and further consideration at its current meeting[24].

79. In presenting the proposed draft Guidelines, the delegation of France noted that three main issues considered by the drafting group included the definition of appropriate level of protection (ALOP), the definition for food safety objectives (FSOs) and the establishment of performance criteria. It was noted that the last meeting of the working group (Paris, France, 27-29 May 2002) specifically separated sections regarding the application of microbiological risk management with respect to Codex and with respect to countries; the relationship between the ALOP, an FSO and performance criteria; and the implementation of microbiological risk management decisions and the monitoring and review of these decisions with a complete revision of sections 6 and 7. It was noted that the work was further based on the results of the Kiel Consultation.

80. The delegation of France requested the Committee to focus its discussions on the ALOP taking into account its definition in the SPS Agreement; the definition and elements required in the consideration of FSOs; the application of risk management principles in Codex Member countries as opposed to the responsibilities of national governments; and, the consideration of traceability, especially as related to ongoing work in other Codex committees.

81. The Committee did not discuss the written comments in detail and discussed the proposed draft Principles and Guidelines point by point, with delegations providing specific points to be considered by the Drafting Group and noted the following comments:

GENERAL COMMENTS

82. It was suggested that further work was required in the Scope and other sections of the document to clearly differentiate between specific recommendations applying to Codex and those applying to national governments. For instance, it was noted that the definition for ALOP, which was already established under the SPS Agreement, should be clearly designated as a responsibility of national governments. In this regard, it was suggested that the document should focus on the application of risk management as opposed to an evaluation of hazards.

83. It was also noted that the concept, connotation and definition of FSOs, including its application and the designation of performance criteria at points within or at the end of the food chain (i.e., at the point of consumption), needed to be discussed further. It was noted that the consideration of ongoing work in other Codex committees related to the determination of FSOs, including in the Codex Committee on Meat and Poultry Hygiene (CCMPH), should be taken into account. The role of the CCFH and the CCMPH in the elaboration of the definition and concepts related to FSOs was also discussed and it was noted that CCFH had a leadership role.

84. The relationship between risk assessment and risk management was also felt to be an important aspect of the Principles requiring further attention. In regard to the consideration of precaution, it was noted that the Commission had already reached a compromise position on a definition that needed to be taken into account. It was further noted by one delegation that non-safety related issues should not be considered in carrying out risk management decisions.

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[23] CX/FH 03/7 and comments submitted by Argentina, USA, EC, CI, ICGMA, IDF (CX/FH 03/7-Add. 1), Canada, India (CRD 6), Denmark, Sweden (CRD 11) and New Zealand (CRD 20).

[24] ALINORM 03/13, para. 128.

85. It was noted that the current document overlapped in many areas with the proposed draft Process paper previously discussed under agenda item 5(e) and that inconsistencies between the documents should be avoided wherever possible.

SCOPE

86. It was suggested by one delegation that contrary to what was implied in this Section, the risk profile should not define the scope and purpose of a risk assessment, but that this should be done after risk profile had been carried out. It was also stated that the notion of directing recommendations to countries as opposed to recommendations for use within Codex should be deleted from the third paragraph of this section.

DEFINITIONS

87. The Committee noted that most of the terms and definitions within this section had been long established in Codex and therefore, were not subject to discussion or change. In this regard, it was suggested that the list of terms and definitions should be restricted and should take account of work in other Codex committees. It was stated that the Committee could better focus its efforts on the application of concepts within the guidelines.

88. In discussing the current proposed definition for an FSO and its application at the point of consumption, various opinions were expressed. A simplified definition of "A performance parameter at the point of consumption" was also proposed. It was also suggested that the example of an FSO under the proposed definition was misleading and could lead to an erroneous conclusion and therefore, should be deleted.

89. Some delegations were of the opinion that the FSO should be applied at the point of consumption and that performance criteria or parameters at various points along the food chain would ensure that the FSO was met. In any case, the Committee agreed that the definition needed to be considered further by the drafting group.

90. In regard to the term ALOP, the Committee reaffirmed that the definition was clearly established under the SPS Agreement and therefore, changes to the definition were not within the mandate of Codex. However, it was noted that the application of the term within the remainder of the text was under the responsibility of the CCFH.

91. In regard to the proposed definition for product tracing/traceability, the Committee noted that ongoing discussions within other Codex committees, including the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) and the Codex Committee on General Principles (CCGP), should be taken into account before proceeding further.

GENERAL PRINCIPLES

92. The Committee noted an opinion that questioned the need for general principles within the document as they were not directly related to microbiological risk management and were already under consideration by the CCGP in its consideration of the proposed draft Working Principles for Risk Analysis in the Framework of the Codex Alimentarius and the Consideration of the Development of Working Principles for Risk Analysis to be Applied by Governments and that in any case, the list of principles should be kept at a minimum. It was further suggested that the principles should take account of the situation in developing countries, including the consideration of traditional and cultural differences.

PRELIMINARY RISK MANAGEMENT ACTIVITIES

93. It was noted that certain relevant steps were missing from the list of general steps in microbiological risk management in sections 5.1.1 to 5.1.4, for example the preparation of the risk profile as well as the assessment and selection of risk management options. It was also noted that the roles of risk assessors and risk managers needed to be clearly identified and defined, as in some situations the same person may carry out both roles.

94. In section 5.1.7, it was suggested by a delegation that the composition and selection of experts for risk assessment bodies and consultations should take account of all regions, including developing countries, and that the conclusions of such risk assessments should be available before any risk management decisions were taken.

ASSESSMENT OF RISK MANAGEMENT OPTIONS

95. In section 5.2.1 it was suggested that scientific justifications related to ALOPs was not required and therefore, should be removed from the fourth paragraph. It was also stated that assistance in the application of ALOPs was available through the FAO and WHO and that in any case, further CCFH work in this area was required. It was also noted by one delegation that the statement in section 5.2.2.2 that FSOs are not applicable to food safety problems associated with raw commodities, was incorrect.

GUIDELINES FOR IMPLEMENTATION OF MICROBIOLOGICAL RISK MANAGEMENT DECISIONS

96. It was suggested that the section should be expanded to include other methods of control in relation to food control emergency situations and that the concept of traceability/product tracing was under the purview of other Codex committees. It was noted however that traceability was a risk management tool that might more logically be included in section 5.2.2.

MONITORING AND REVIEW

97. It was suggested that this section should include guidelines concerning the effectiveness of regulatory control programs and should be broadened to include the effectiveness of a wide variety of interventions.

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

98. The Committee agreed that a drafting group led by France, and with the assistance of Argentina, Australia, Belgium, Canada, Denmark, Finland, Germany, Hungary, India, Italy, the Netherlands, New Zealand, Norway, Singapore, Sweden, the United Kingdom, the United States, CI, EC, ICGMA, ICMSF, IDF, would revise the proposed draft principles and guidelines at Step 2 for circulation, comment and further consideration at its next Session. It was decided that the document should be revised on the basis of the above discussions and discussions under agenda item 5e, written comments submitted at the current meeting, the results of the Kiel Consultation and discussions in other Codex committees.

PROPOSED DRAFT GUIDELINES FOR THE CONTROL OF *LISTERIA MONOCYTOGENES* IN FOODȘ AT STEP 3 (Agenda Item 7)[25]

99. The 34th Session of the CCFH agreed that the drafting group led by Germany would revise the proposed draft Guidelines on the basis of written comments submitted and the results of the risk assessment for circulation, additional comment and further consideration at its current meeting[26].

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[25] CX/FH 03/8 and comments submitted by Argentina, Australia, Egypt, USA, CI, EC, FAO/WHO, IDF (CX/FH 03/8-Add.1) and India (CRD 7); Report of the Drafting Group (CRD 23).

100. In introducing the proposed draft Guidelines, the delegation of Germany noted that the paper was revised on the basis of document CX/FH 01/6 and the outcome of the last meeting of the working group that was held in Berlin, Germany from 12-14 June 2002. It was noted that the scope of the Guidelines was clarified, the latest risk assessment results were incorporated, and precise chapters on risk management options and a separate chapter on guidelines for managing Listeria in food production were added. On the basis of previous discussions (see paras 39-41), it was also proposed to split the guidelines into two new documents, namely, one document that contained general guidance for managing *Listeria monocytogenes* in foods and another document on the specific microbiological criteria on *Listeria monocytogenes* for foods in international trade.

101. It was suggested that if two separate papers were elaborated, the scope of each paper needed to be clearly defined. Some delegations were of the view that in order to ensure the consistent elaboration of guidelines for *Listeria monocytogenes* and other pathogens, it was necessary to agree on the general risk management framework before proceeding with the elaboration of specific advice in this area.

102. Some delegations were of the view that in order to progress with the development of a general guideline document, careful consideration should be given to its scope and format. Some delegations suggested that the scope should be limited to ready-to-eat products that supported the growth of Listeria and which presented the highest risk of listeriosis for consumers.

103. It was pointed out that the best approach for the development of the general applicability guideline document to manage Listeria in foods was to follow the structure of the Recommended International Code of Practice-General Principles of Food Hygiene and to only elaborate provisions that were specific to this microorganism.

104. Some delegations were of the view that the general guideline document and the microbiological criteria should be elaborated at the same time, while others indicated that until an agreement on FSOs and other related definitions was reached the elaboration of microbiological specifications for Listeria in foods was premature. However, it was noted that the Committee's earlier discussion to develop microbiological specifications for Listeria in foods moving in international trade was the basis for the risk assessment conducted for Listeria in ready–to-eat foods.

105. On the basis of the above discussions, an informal in-session working group was convened in order to provide advice on the development of general document for management of Listeria in foods, specifically as related to the scope and structure of such Guidelines. The Committee considered the report[27] of the in-session working group led by Germany, and agreed to the proposed scope and structure of the guidelines on the basis of their report.

106. The Committee amended the title of the Guidelines to read "Proposed Draft Guidelines for the Application of Food Hygiene Principles to the [Management] of *Listeria monocytogenes* in Foods". However, some delegations were of the view that the document should be oriented as a code of hygienic practice for control of Listeria in foods, while other delegations indicated that it should focus on the management of risks. In view of the different opinions expressed on the use of the term "management" as opposed to the term "control", the Committee concluded that further clarification of the title was necessary and therefore referred this matter for future consideration by the drafting group.

107. Some delegations were of the view that the results of FAO/WHO risk assessment for *Listeria monocytogenes* in ready-to-eat foods should be taken into account in the development of the Guidelines, while other delegations indicated that the present risk assessment was not intended to examine different control strategies and therefore, could not provide much advice in this regard.

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[26] ALINORM 03/13, para. 98.

[27] Report of the Ad Hoc Working Group on *Listeria monocytogenes* (CRD 23).

108. The Committee noted that there was no consensus on the parallel development of both the Guidelines and the document on specific microbiological criteria for Listeria in foods and concluded that the development of a document on specific microbiological criteria could be considered at a future meeting.

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

109. The Committee agreed that the drafting group led by Germany, and with the assistance of Austria, Canada, China, Denmark, France, Greece, Hungary, Italy, Japan, Norway, the United Kingdom, Uruguay, USA, EC, ICMFS, IDF and IFT would revise the proposed draft guidelines at Step 2 for circulation, comment and further consideration at its next Session.

110. It was decided that the document should be redrafted on the basis of the above discussions, written comments submitted at the current meeting and the report of the informal working group that met during the current session (CRD 23). It was also agreed that the results of the Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in *Listeria monocytogenes* in Ready-to-Eat Foods be taken into account, especially in the development of additional questions for consideration by the risk assessors.

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR MILK AND MILK PRODUCTS (AGENDA ITEM 8)[28]

111. The 34th Session of the CCFH returned the proposed draft Code 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[29].

112. The delegation of the United States introduced the proposed draft Code and informed the Committee about major discussions and numerous changes that had taken place in the drafting group in Brussels (13-17 May 2002). It was noted that the drafting group agreed to the retain the basic formatting of the document in which the base code contained principles and explanatory narrative relating to the production, processing and labelling of milk and milk products and related areas with detailed guidelines for the application of the principles in the annexes. It was also agreed to combine the various approaches to primary production, including information relating to the production of milk used for raw milk products and small-holder dairy farms, into a single annex. Special provisions specifically relating to the production of milk used for raw milk products and small-holder dairy farms were clearly identified.

113. Annex I was reworked by combining various approaches to primary production originally contained in three separate annexes and the text of Annex II had been substantially revised, primarily by reordering and revising the text but also to more fully explain the application of HACCP to milk and milk products, including the hazard analysis and the design of the control system.

114. The Committee discussed the proposed draft Code section by section and in addition to minor editorial changes throughout the text, agreed to the following revisions:

INTRODUCTION

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[28] CX/FH 03/9 and comments from Argentina, Brazil, Canada, Egypt, Mexico, New Zealand, Switzerland, the USA, CI, IDF, (CX/FH 03/9-Add.1and corrections), India, Indonesia (CRD 8), EC (CRD 14) and Cuba (CRD 17).

[29] ALINORM 03/13, para. 134.

115. The Committee added wording in the second paragraph of this section to stress the importance of milk and milk products in the diets of certain population groups, such as infants, children and pregnant and lactating women.

SECTION 3 PRIMARY PRODUCTION

116. The third principle was modified to stress that the microbiological load of milk should be as low as achievable, while taking into account technological requirements for subsequent processing steps.

117. Wording was added to the end of the text in Sections 3.3.2 and 3.3.4 to clarify that the design and construction of storage tanks and cans should minimize the growth of microorganisms in milk.

SECTION 5.1.1 HAZARD IDENTIFICATION

118. The wording related to the declaration of allergens was deleted from the third paragraph as this requirement was already adequately covered by requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev. 1-1991). The remaining first sentence of the paragraph was moved to Annex II before the last paragraph of Section 5.5.1.1 on Hazard Identification.

SECTION 5.1.3 ESTABLISHMENT OF PROCESS CRITERIA (CRITICAL LIMIT DETERMINATION)

119. As it was noted that this section did not address critical limits, the title of this section was amended by deleting the wording in brackets, with a consequential change made to the title in section 5.1.3 in Annex II.

SECTION 5.2.3.2 MICROBIOLOGICAL END PRODUCT SPECIFICATIONS

120. The title of this section was simplified to read ”Microbiological criteria”. In order to cover different steps of production, the principle was modified to read ”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” with subsequent amendments of the explanatory text which followed.

SECTION 5.2.4 MICROBIOLOGICAL CROSS CONTAMINATION

121. The first principle was amended by incorporating a reference to cross contamination and therefore, the second principle was deleted.

SECTION 5.3 INCOMING MATERIAL (OTHER THAN MILK) REQUIREMENTS

122. The timing and nature of verification of compliance of ingredients specifications was clarified by inserting additional wording and by deleting provisions which only restricted verification prior to the use of ingredients.

SECTION 5.5 WATER

123. The first principle in this section was modified to indicate that potable water used in dairy “processing” establishments should be regularly monitored in order to be consistent with the General Principles of Food Hygiene.

124. The second principle regarding the reuse of water was replaced by wording contained in Section 5.5.1 of the General Principles of Food Hygiene.

125. The first and second sentences of the explanatory text were combined into a single paragraph and both sentences were amended for clarification.

SECTION 9.3 LABELLING

126. In order to be consistent with the previous decision regarding the labelling of allergens (see para 118 above), the third paragraph was deleted.

127. Provisions for the labelling of raw milk products were clarified in order to take into account the national requirements in the country of retail sale.

SECTION 9.4 CONSUMER EDUCATION

128. This section was deleted in that it was already adequately covered by the General Principles of Food Hygiene. The Observer of Consumers International strongly supported retaining the statement that vulnerable populations should be informed of the risk associated with certain products.

SECTION 10.2 TRAINING PROGRAMMES

129. The last bullet regarding hazards was amended in order to accommodate their control measures.

ANNEX I GUIDELINES FOR THE PRIMARY PRODUCTION OF MILK

SPECIAL PROVISIONS FOR THE PRODUCTION OF MILK ON SMALL HOLDER DAIRY FARMS

130. The expression of “Small Holder Dairy Farm” in the first paragraph was amended by inserting wording “or per herd” to take account of small sized dairy producers. In this regard, the Committee noted the availability of FAO guidelines and publications related to small sized dairy farms.

SECTION 3.2.1.1 ANIMAL HOLDING AREAS

131. The third paragraph was amended to indicate that animal holding areas should be kept clean and free of objectionable materials “as far as practicable”. In addition, the heading stating “Additional provisions for the production of milk used for raw milk products” was deleted as provisions of this section were of general applicability.

SECTION 3.2.2 ANIMAL HEALTH

132. The last paragraph from the section entitled “Additional provisions for the production of milk used for raw milk products” was moved to the end of general paragraphs in section 3.2.2 as having more general applicability. It was also clarified that “competent” should replace “sanitary” throughout the text when used in conjunction with animal health control.

ADDITIONAL PROVISIONS FOR THE PRODUCTION OF MILK USED FOR RAW MILK PRODUCTS

133. The first bullet of the third set of bullets of this section was amended to clarify that separation was required for animals of “unknown health status”.

SECTION 3.2.3.2 TREATMENT FOR PESTS

134. The title of the section was renamed to “Pest control” with consequential changes in Appendices.

SECTION 3.2.3.3 VETERINARY DRUGS

135. The third paragraph of section was amended to read that "Only those medicinal products and medicinal premixes that have been authorised by the competent authority for inclusion in animal feeds should be used".

SECTION 3.2.4 HYGIENIC MILKING

136. The second sentence of the last paragraph referring to the normal appearance of milk was felt to be too prescriptive and therefore, was modified on the basis of written comments submitted.

SECTION 3.2.4.4 HEALTH AND PERSONAL HYGIENE OF MILKING PERSONNEL

137. The Committee had a lengthy debate regarding the medical examination of milk handlers. Some delegations were of the view that that the current provisions requiring medical examination of individuals suspected or infected with diseases transmittable to milk were too restrictive, while others pointed out the significance of this provision to public health protection.

138. As a compromise solution, the Committee agreed to delete the sentence referring to the necessity of immediately reporting to management illnesses and diseases as it was not practically achievable in all situations. In view of this decision, the last sentence of this paragraph was aligned with the last sentence in Section 7.1 of the General Principles of Food Hygiene.

SECTION 3.3.1 MILKING EQUIPMENT

139. The first sentence of this section was amended to indicate that milking equipment, if used, and cans should be designed to allow for adequate cleaning.

SECTION 3.3.2 MILKING STORAGE EQUIPMENT

ADDITIONAL PROVISIONS FOR THE PRODUCTION OF MILK USED FOR RAW MILK PRODUCTS

140. The first sentence of this section was amended in order clarify that milk cans could also be used to store whey, provided that cross contamination was avoided.

SECTION 3.3.3 PREMISES FOR, AND STORAGE OF, MILK AND MILKING-RELATED EQUIPMENT

141. The second paragraph of the section *Additional provisions for the production of milk used for raw milk products* was amended in recognition of the fact that the competent authority did not always know the intended use of the milk produced on the farm, and that manufacturers, which had ultimate responsibility for end product safety, could deviate from the temperatures if necessary. In view of this decision, the square brackets were deleted from the temperatures specified.

SECTION 3.3.4.3 TRANSPORT TIME AND TEMPERATURE

SPECIAL PROVISIONS FOR THE PRODUCTION OF MILK USED FOR RAW MILK PRODUCTS

142. The amended paragraph of section 3.3.3 (see para. above) was inserted at the end of the section on *Special provisions for the production of milk used for raw milk products* in section 3.3.4.3 and the square brackets were deleted from the temperature specification.

SECTION 3.4 RECORD KEEPING

143. The first bullet point was amended to emphasize the focus on the prevention and control of animal diseases that had an "impact on public health" and an additional bullet point regarding use of agricultural chemicals was added.

ANNEX II

DEFINITIONS

PASTEURISATION

144. The last sentence of this definition was deleted and the accompanying footnote 9 regarding different levels of alkaline phosphatase in milks from different species of milking animals was moved as a reference to the term "alkaline phosphatase" in Section B.1.2 - Verification of process, in Appendix B.

SECTION 5.1.2 CONTROL MEASURE SELECTION

COMBINATION OF MICROBIOLOGICAL CONTROL MEASURES

145. The last paragraph was split into two separate paragraphs and the new second paragraph was amended to ensure that attention was focussed on the potential consequences of deviations granted from the application of microbiocidal control measures.

APPENDIX A: MICROBIOSTATIC CONTROL MEASURES

146. The introductory notes of Appendices A and B were clarified to indicate that the control measures described were to be used as examples which required validation with respect to their effectiveness and safe use.

APPENDIX B: MICROBIOCIDAL CONTROL MEASURES

147. In view of ongoing deliberations in the Codex Committee on Food Additives and Contaminants on Codex texts related to food irradiation, this control measure was put in square brackets pending the results of these discussions.

SECTION B.2.2 PROCESS MANAGEMENT

148. The wording "viable" was inserted to clarify the nature of microorganisms and the provision regarding 12 log reductions of *C. botullinum* was put in square brackets.

PROCESS CRITERIA

149. It was clarified that the minimum thermal process should be established in consultation with the "official or officially recognized" thermal processing authority throughout the text.

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

150. The Committee forwarded the proposed draft Code of Hygienic Practice for Milk and Milk Products (see Appendix III) to the 26th Session of the Codex Alimentarius Commission for preliminary adoption at Step 5.

PROPOSED DRAFT REVISION OF THE CODE OF HYGIENIC PRACTICE FOR EGG PRODUCTS (CAC/RCP 15-1976) (Agenda Item 9)[30].

151. The 34th Session of the CCFH agreed that the drafting group led by Australia would revise the proposed draft Code of Hygienic Practice for Egg Products for circulation, additional comments and

[30] CX/FH 03/10 and comments submitted by Argentina, Denmark, Iran, Mexico, New Zealand, Poland, USA (CX/FH 03/10-Add. 1), Egypt (CX/FH 03/10-Add. 2), India (CRD 9) and the EC (CRD 16).

further consideration at its current meeting.[31] The Committee noted that the document was drafted in a working group meeting that met in Brussels from 23-25 April 2002 at the kind invitation of the European Commission.

152. In presenting the document, the delegation of Australia noted that the proposed draft revised Code included eggs in shell and egg products but that substantial further work was needed in the inclusion of guidance text for the implementation of its principles, consideration of the layout and hierarchy of the Code and further elaboration of a number of sections, including definitions.

153. The Committee generally supported the initiative to revise the current Code, especially in view of the large volume of international trade and potential problems related to the transmission of diseases through egg products. However, in view of the extensive revisions required, the Committee decided not to discuss the proposed draft Code in detail and focused its discussions on matters to be considered by the drafting group so as to provide general guidance.

154. It was suggested that in addition to general requirements, the Code should be expanded and clearly divided into provisions related to hygienic practices for in-shell eggs and other egg products, possibly through the use of separate annexes. In view of this suggestion, the Committee agreed that the Title of the Code should read as "Proposed Draft Revised Code of Hygienic Practice for Eggs and Egg Products"

155. It was also noted that the Code should be expanded to take account of small-scale (e.g. free-range) farming practices, including organic egg production, in addition to large scale or intensive production methods. In this regard, it was also noted that provisions within the Code should be divided between egg laying facilities and other facilities used for the production of egg products.

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

156. The Committee agreed that the drafting group led by the Australia, and with the assistance of Belgium, Brazil, Canada, India, the Netherlands, New Zealand, Spain, the United Kingdom, the USA, ALA and the EC, would revise the Code of Practice for circulation, additional comment and further consideration at its next session. 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 would also take account of the Joint FAO WHO Expert Consultation on Risk Assessment of *Salmonella* spp. in Eggs and Boiler Chickens. The Committee also noted the gracious offer of the representative of the European Commission to host the meeting of the working group in Brussels to undertake this work.

PROPOSED DRAFT GUIDELINES FOR THE VALIDATION OF FOOD HYGIENE CONTROL MEASURES (Agenda Item 10)[32]

157. The 34th Session of the CCFH requested the drafting group led by the United States to elaborate proposed draft Guidelines for the Validation of Food Hygiene Control Measures for eventual inclusion as an Annex to the International Code of Practice – General Principles of Food Hygiene. The Committee agreed to circulate the proposed draft Guidelines for comment and further consideration at its current meeting, pending the approval of the initiative as new work.[33] The 50th Session (June 2002) of the Executive Committee approved the elaboration of the Guidelines as new work, and with the understanding that newly elaborated validation provisions should be consistent with the texts elaborated by the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS).[34]

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31 ALINORM 03/13, para. 157.

32 CX/FH 03/11 and comments submitted by Argentina, Canada, Egypt, Peru, Poland, Mexico, New Zealand, USA, EC, IDF (CX/FH 03/11-Add. 1), Australia (CRD 10), Thailand (CRD 21) and Brazil (CRD 22).

33 ALINORM 03/13, para. 167.

34 ALINORM 03/3A, para. 65 and Appendix III.

158. In presenting the proposed draft Guidelines, the delegation of the United States noted that the Guidelines were intended to meet the need for assurances that a single point of or the entire food safety control system met their objectives. It was noted that the Guidelines should be consistent with a risk analysis framework, including the verification of the public health outcome.

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

160. It was noted that there was some overlap within the document, especially in regard to Section VII, and that the document should be simplified to focus on key issues related to food hygiene control measures that were not already addressed in other Codex texts. It was also stated that too much emphasis was placed on situations where the validation of one control measure was used to verify all control measures.

161. It was also noted that the difficulties experienced by small businesses in meeting validation and verification control measures should be taken into account. It was also stressed that microbiological criteria needed to address both concepts as separate but related approaches to food control. It was further noted that the title of the document might need to be revised to more accurately reflect the scope, i.e., as addressing the validation of systems.

162. Although it was suggested that the much broader International Organization for Standardization definition for validation might be taken into account in order to avoid confusion within the industry, the Committee agreed that the current Codex definition for validation contained in the HACCP Guidelines was a long-standing specific definition related to the food safety. However, it was also noted that validation was not limited to the evaluation of control measures within the HACCP system and that the document might need to be expanded to address the evaluation of other food hygiene control measures. Some delegations were of the view that practicability of validation procedures should be taken into account.

163. In view of this discussion, the Committee agreed that the scope of the Guidelines, as well as the definition for validation, might need to be expanded to any control systems related to food hygiene control measures.

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

164. The Committee agreed that a drafting group led by the United States, and with the assistance of Australia, Canada, France, Germany, Italy, the Netherlands, New Zealand, Norway, Spain, Sweden, Thailand, Uruguay, ICGMA, ICMSF and IDF, would revise the proposed draft Guidelines at Step 2 for circulation, comment and further consideration at its next Session. It was decided that the document should be revised on the basis of the above discussions and written comments submitted.

RISK APPLICATION IN THE ELABORATION OF CODEX STANDARDS (Agenda Item 11)[35]

165. The Committee recalled that the document on Risk Application in the Elaboration of Codex Standards prepared by India (CRD 13) had not been considered at the 34th Session of the CCFH[36].

166. The Committee noted that concerns of developing countries were taken into account by the 17th Session of the Codex Committee on General Principles (April 2002) while developing the proposed draft Working Principles for Risk Analysis (ALINORM 03/33, paras 15-66) and that the remaining issues were addressed by the current meeting of the CCFH, when considering different agenda items.

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35 CX/FH 03/12 (not issued)

36 ALINORM 03/13, para. 172.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 12)

RISK PROFILE OF *ENTEROBACTER SAKAZAKII* IN POWDERED INFANT FORMULA[37]

167. The 24th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) requested the CCFH to revise the Recommended International Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979) in order to address concerns with pathogens that may be present in infant formula, including *E. sakazakii* infections[38].

168. In introducing the document CX/FH 03/13, the delegation of the United States noted that *Enterobacter sakazakii* had been associated with a variety of severe and life-threatening conditions, including meningitis, bacteremia, and necrotizing enterocolitis, especially in neonates and infants. It was suggested that the CCFH should focus on the recommended risk management actions contained in the document when discussing this matter.

169. Some delegations were of the opinion that before proceeding with the elaboration of a code of practice, the risk profile needed to be revised on the basis of additional information from industry and other sources and on the basis of the results of a FAO/WHO expert consultation. It was also noted that there were other pathogens of concern that may be present in powdered infant formula, including *Clostridium botulinum*, *S. aureus* and other types of *Enterobacter* and that any new work needed t considered in the context of other Committee's priorities.

170. Other delegations, while recognizing the usefulness of the present risk profile, noted that guidelines were critically needed for the preparation of infant formula, especially in hospital settings. It was also stated that the revision of the existing Code of Practice should be undertaken by the drafting group.

171. The representative of WHO noted that they had initiated a review of the scientific literature available on *E. sakazakii* and of the outbreaks that have in recent years been linked to its presence in powdered infant formula. It was further stated that very little was known about populations at risk, infectious doses and *E. sakazakii* ability to resist thermal processing, and other physico-chemical parameters in food and its ability to grow in different foods. It was stated by the Representative of WHO that before proceeding with a Consultation, the Committee should firstly decide on the revision to the Code since in WHO's opinion the risk profile provided enough information to take such a decision.

172. The Committee accepted the offer of the United States to update the risk profile on *E. sakazakii*. The Committee also agreed that a drafting group under the direction of Canada, and with assistance provided by Finland, France, Germany, the Netherlands, Switzerland, the United Kingdom, the United States, ICMSF and ISDI would initiate work towards revision of the proposed draft Revised Recommended International Code of Hygienic Practice for Foods for Infants and Children particularly for dried infant formula for circulation, comment and further consideration at its next Session.

173. The Committee also requested FAO and WHO to convene an expert consultation on the *Enterobacter* genus, including *E. sakazakii,* and *Clostridium botulinum*, at the earliest opportunity, subject to the provision of adequate funding.

DEVELOPMENT OF PROCESS, PROCEDURES AND CRITERIA TO ESTABLISH PRIORITIES FOR THE WORK OF THE CODEX COMMITTEE ON FOOD HYGIENE[39]

174. In presenting CRD 24, the delegation of New Zealand noted that the document was based in part on previous discussions on the prioritization of CCFH work at its 33rd Session (CX/FH 00/14). The

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37 CX/FH 03/13 and comments submitted by ISDI (CRD 12) and FAO/WHO (CRD 13).

38 ALINORM 03/26A, paras 132-134.

39 CRD 24.

current document indicated the need for the committee to clearly identify its priorities in three main areas, namely, the codes of hygienic practice that require revision; the items currently on the CCFH agenda; and, other matters that may need to be added to the agenda, taking into account the current state of activity and thinking on risk analysis and risk management in particular.

175. On the basis of its discussions, the Committee agreed that a drafting group led by New Zealand, and with the assistance of Australia, Austria, Brazil, Canada, Denmark, Finland, France, Japan, Malaysia, Norway, UK and the United States, would develop a discussion paper for circulation, comment and further consideration at its next meeting based on the following tasks:

a) To revise the list of existing codes of practice that need review, taking into account document CX/FH 00/14 and the written comments submitted at the 33rd CCFH;

b) To review and propose a priority list for the work currently on the CCFH work program, and;

c) Propose how CCFH might:

- Identify emerging areas/topics for attention
- Deal with matters that require urgent attention
- Deal with matters of less urgency but with wide impact
- Deal with general matters (i.e., matters referred, codes sent for endorsement requiring extensive CCFH work, etc.)

d) Propose a mechanism that would allow CCFH to prioritize its work program (related to items listed in a, b and c above) on an ongoing basis.

176. It was further agreed that when considering tasks c and d above, the drafting group would need to consider the criteria proposed in CX/FH 03/6, the requirements set out in the Codex Alimentarius Procedural Manual, the Codex Strategic Framework and the Medium-Term Plan 2003-2007.

DEVELOPMENT OF OPTIONS FOR A CROSS-COMMITTEE INTERACTION PROCESS[40]

177. In presenting CRD 25, the delegation of Australia noted that much of the work under consideration by the CCFH might also be applicable to ongoing work in other Codex committees (and vice-versa), and that it was advisable that the necessary expertise and advice was shared across these committees to facilitate a more efficient and effective completion of its work. The document highlighted communication processes already in place, elements that could be incorporated into a proposed process of information exchange and recommendations for consideration by the Committee.

178. Although it was suggested that the communication process might be better accommodated in the work assigned to the drafting group examining the work priorities of the CCFH (see immediately above) or under the process for work undertaken on microbiological risk management (agenda item 5e), it was noted that the proposed development of cross committee communication processes was directed to a related but specific aspect of the Committee's work.

179. The Codex Secretariat informed the Committee that although such a process could facilitate the work of the CCFH, it was important to consider relevant advice in the Codex Alimentarius Procedural Manual, including the section on Relations between Commodity Committees and General Subject Committees. In any case, it was noted that the Codex Alimentarius Commission had the ultimate responsibility for designating and assigning work to its subsidiary bodies. It was also noted that cross-communication was facilitated through discussions between Codex committee chairpersons.

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40 CRD 25.

180. On the basis of its discussions, the Committee agreed that a drafting group led by Australia, and with the assistance of France, Norway New Zealand, the United States and the EC, would develop a discussion paper on a process for communication with other Codex committees for circulation, comment and further consideration at its next meeting. The Committee noted that the group should base the document on current related provisions within the Codex Alimentarius Procedural Manual, ongoing work in the Joint FAO/WHO Evaluation of the Codex Alimentarius and other FAO and WHO Work on Food Standards and in liaison with the drafting group working on the priorities discussion paper.

DATE AND PLACE OF NEXT SESSION (AGENDA ITEM 13)

181. The Committee noted that the 36th Session of the Codex Committee on Food Hygiene was tentatively scheduled to be held in early 2004 in Washington DC, subject to further discussions between the Codex and U.S. Secretariats including the timing of the meeting.

182. The host government also agreed to consider the request of the delegation of Tanzania to host the 37th Session of the CCFH in a developing country.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by:	Reference in ALINORM 03/13A
Draft Revised Guidelines for the Application of HACCP System	8	**Governments**, 26th Session of the CAC	paras 22 - 30 and Appendix II
Proposed Draft Code of Hygienic Practice for Milk and Milk Products	5	**Governments,** 26th CAC**,** 36th CCFH	paras 111 - 150
Proposed Draft Guidelines for the Control of *Listeria monocytogenes* in Foods	2	**Germany**, 36th CCFH	paras 99 - 111
Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management	2	**France**, 35th CCFH	paras 78-98 and Appendix III
Proposed Draft Revision of the Code of Hygienic Practice for Egg Products (CAC/RCP 30-1983)	2	**Australia**, 36th CCFH	paras 151-156
Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures	2	**US,** 36th CCFH	paras 157 - 164
Discussion Paper on Risk Management Strategies for *Salmonella* spp. in Poultry		**CCMPH**, Sweden, 36th CCFH	paras 42 - 44
Discussion Paper on Risk Management Strategies for *Campylobacter* spp. in Broiler Chickens		**CCMPH,** Netherlands, 36th CCFH	paras 49 - 54
Discussion Paper on Risk Management Strategies for *Vibrio* spp.		Temporary suspension of work	paras 55 - 59
Risk Profile for Enterohemorragic *E. Coli*, Including the Identification of the Commodities of Concern, Including Sprouts, Ground Beef and Pork		**Governments,** US, 36th CCFH	paras 60 - 64
Proposed Draft Process by Which the Committee on Food Hygiene Could Undertake its Work in Microbiological Risk Assessment/Risk Management		**US,** 36th CCFH	paras 65 - 77
Discussion Paper on the Proposed Draft Revision of the Recommended International Code of Practice for Foods for Infants and Children		**Canada,** 36th CCFH	paras 167 – 173
Discussion Paper on Development of Process, Procedures and Criteria to Establish Priorities for the Work of the Codex Committee on Food Hygiene		**New Zealand,** 36th CCFH	paras 174 - 176
Discussion paper on the Development of Options for a Cross-Committee Interaction Process		**Australia,** 36th CCFH	paras 177 - 180

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Appendix II

DRAFT REVISED GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM

(At Step 8 of the Procedure)

INTRODUCTION

Prior to application of HACCP to any sector of the food chain, that sector should have in place prerequisite programs such as good hygienic practices according to the Codex General Principles of Food Hygiene, the appropriate Codex Codes of Practice, and appropriate food safety requirements. These prerequisite programs to HACCP, including training, should be well established, fully operational and verified in order to facilitate the successful application and implementation of the HACCP system.

For all types of food business, management awareness and commitment is necessary for implementation of an effective HACCP system. The effectiveness will also rely upon management and employees having the appropriate HACCP knowledge and skills.

During hazard identification, evaluation, and subsequent operations in designing and applying HACCP systems, consideration must be given to the impact of raw materials, ingredients, food manufacturing practices, role of manufacturing processes to control hazards, likely end-use of the product, categories of consumers of concern, and epidemiological evidence relative to food safety.

The intent of the HACCP system is to focus control at Critical Control Points (CCPs). Redesign of the operation should be considered if a hazard which must be controlled is identified but no CCPs are found.

HACCP should be applied to each specific operation separately. CCPs identified in any given example in any Codex Code of Hygienic Practice might not be the only ones identified for a specific application or might be of a different nature. The HACCP application should be reviewed and necessary changes made when any modification is made in the product, process, or any step.

The application of the HACCP principles should be the responsibility of each individual businesses. However, it is recognised by governments and businesses that there may be obstacles that hinder the effective application of the HACCP principles by individual business. This is particularly relevant in small and/or less developed businesses. While it is recognized that when applying HACCP, flexibility appropriate to the business is important, all seven principles must be applied in the HACCP system. This flexibility should take into account the nature and size of the operation, including the human and financial resources, infrastructure, processes, knowledge and practical constraints.

Small and/or less developed businesses do not always have the resources and the necessary expertise on site for the development and implementation of an effective HACCP plan. In such situations, expert advice should be obtained from other sources, which may include: trade and industry associations, independent experts and regulatory authorities. HACCP literature and especially sector-specific HACCP guides can be valuable. HACCP guidance developed by experts relevant to the process or type of operation may provide a useful tool for businesses in designing and implementing the HACCP plan. Where businesses are using expertly developed HACCP guidance, it is essential that it is specific to the foods and/or processes under consideration. More detailed information on the obstacles in implementing HACCP, particularly in reference to SLDBs, and recommendations in resolving these obstacles, can be found in “Obstacles to the Application of HACCP, Particularly in

Small and Less Developed Businesses, and Approaches to Overcome Them" (document in preparation by FAO/WHO).

The efficacy of any HACCP system will nevertheless rely on management and employees having the appropriate HACCP knowledge and skills, therefore ongoing training is necessary for all levels of employees and managers, as appropriate.

APPLICATION

The application of HACCP principles consists of the following tasks as identified in the Logic Sequence for Application of HACCP (Diagram 1).

1. Assemble HACCP team

The food operation should assure that the appropriate product specific knowledge and expertise is available for the development of an effective HACCP plan. Optimally, this may be accomplished by assembling a multidisciplinary team. Where such expertise is not available on site, expert advice should be obtained from other sources, such as, trade and industry associations, independent experts, regulatory authorities, HACCP literature and HACCP guidance (including sector-specific HACCP guides). It may be possible that a well-trained individual with access to such guidance is able to implement HACCP in-house.The scope of the HACCP plan should be identified. The scope should describe which segment of the food chain is involved and the general classes of hazards to be addressed (e.g. does it cover all classes of hazards or only selected classes).

2. Describe product

A full description of the product should be drawn up, including relevant safety information such as: composition, physical/chemical structure (including A_w, pH, etc), microcidal/static treatments (heat-treatment, freezing, brining, smoking, etc), packaging, durability and storage conditions and method of distribution. Within businesses with multiple products, for example, catering operations, it may be effective to group products with similar characteristics or processing steps, for the purpose of development of the HACCP plan.

3. Identify intended use

The intended use should be based on the expected uses of the product by the end user or consumer. In specific cases, vulnerable groups of the population, e.g. institutional feeding, may have to be considered.

4. Construct flow diagram

The flow diagram should be constructed by the HACCP team (see also paragraph 1 above). The flow diagram should cover all steps in the operation for a specific product. The same flow diagram may be used for a number of products that are manufactured using similar processing steps. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation.

5. On-site confirmation of flow diagram

Steps must be taken to confirm the processing operation against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate. The confirmation of the

flow diagram should be performed by a person or persons with sufficient knowledge of the processing operation.

6. List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards

(SEE PRINCIPLE 1)

The HACCP team (see "assemble HACCP team" above) should list all of the hazards that may be reasonably expected to occur at each step according to the scope from primary production, processing, manufacture, and distribution until the point of consumption.

The HACCP team (see "assemble HACCP team") should next conduct a hazard analysis to identify for the HACCP plan, which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food.

In conducting the hazard analysis, wherever possible the following should be included:

- the likely occurrence of hazards and severity of their adverse health effects;
- the qualitative and/or quantitative evaluation of the presence of hazards;
- survival or multiplication of micro-organisms of concern;
- production or persistence in foods of toxins, chemicals or physical agents; and,
- conditions leading to the above.

Consideration should be given to what control measures, if any exist, can be applied to each hazard.

More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure.

7. Determine Critical Control Points

(SEE PRINCIPLE 2)[1]

There may be more than one CCP at which control is applied to address the same hazard. The determination of a CCP in the HACCP system can be facilitated by the application of a decision tree (e.g., Diagram 2), which indicates a logic reasoning approach. Application of a decision tree should be flexible, given whether the operation is for production, slaughter, processing, storage, distribution or other. It should be used for guidance when determining CCPs. This example of a decision tree may not be applicable to all situations. Other approaches may be used. Training in the application of the decision tree is recommended.

If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a control measure.

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[1] Since the publication of the decision tree by Codex, its use has been implemented many times for training purposes. In many instances, while this tree has been useful to explain the logic and depth of understanding needed to determine CCPs, it is not specific to all food operations, e.g., slaughter, and therefore it should be used in conjunction with professional judgement, and modified in some cases.

8. Establish critical limits for each CCP

(SEE PRINCIPLE 3)

Critical limits must be specified and validated for each Critical Control Point. In some cases more than one critical limit will be elaborated at a particular step. Criteria often used include measurements of temperature, time, moisture level, pH, A_w, available chlorine, and sensory parameters such as visual appearance and texture.

Where HACCP guidance developed by experts has been used to establish the critical limits, care should be taken to ensure that these limits fully apply to the specific operation, product or groups of products under consideration. These critical limits should be measurable.

9. Establish a monitoring system for each CCP

(SEE PRINCIPLE 4)

Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. Further, monitoring should ideally provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits. Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs. Data derived from monitoring must be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP is in control. Most monitoring procedures for CCPs will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing. Physical and chemical measurements are often preferred to microbiological testing because they may be done rapidly and can often indicate the microbiological control of the product.

All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company.

10. Establish corrective actions

(SEE PRINCIPLE 5)

Specific corrective actions must be developed for each CCP in the HACCP system in order to deal with deviations when they occur.

The actions must ensure that the CCP has been brought under control. Actions taken must also include proper disposition of the affected product. Deviation and product disposition procedures must be documented in the HACCP record keeping.

11. Establish verification procedures

(SEE PRINCIPLE 6)

Establish procedures for verification. Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively.

Verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions. Where certain verification activities cannot be performed in house, verification should be performed on behalf of the business by external experts or qualified third parties.

Examples of verification activities include:

- Review of the HACCP system and and plan and its records;
- Review of deviations and product dispositions;
- Confirmation that CCPs are kept under control.

Where possible, validation activities should include actions to confirm the efficacy of all elements of the HACCP system.

12. Establish Documentation and Record K eeping

(SEE PRINCIPLE 7)

Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP controls are in place and being maintained. Expertly developed HACCP guidance materials (e.g. sector-specific HACCP guides) may be utilised as part of the documentation, provided that those materials reflect the specific food operations of the business.

Documentation examples are:

Hazard analysis;

CCP determination;

Critical limit determination.

Record examples are:

- CCP monitoring activities;
- Deviations and associated corrective actions;
- Verification procedures performed;
- Modifications to the HACCP plan;

An example of a HACCP worksheet for the development of a HACCP plan is attached as Diagram 3.

A simple record-keeping system can be effective and easily communicated to employees. It may be integrated into existing operations and may use existing paperwork, such as delivery invoices and checklists to record, for example, product temperatures.

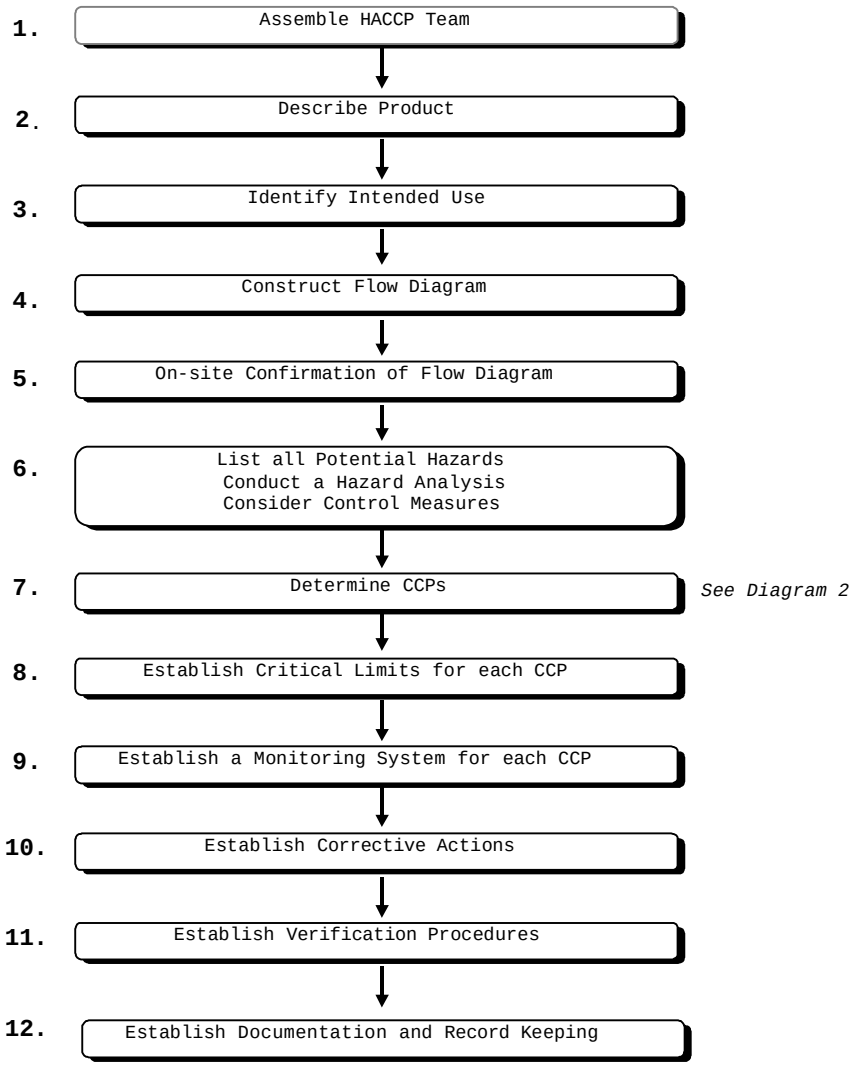
TRAINING

Training of personnel in industry, government and academia in HACCP principles and applications and increasing awareness of consumers are essential elements for the effective implementation of HACCP. As an aid in developing specific training to support a HACCP plan, working instructions

and procedures should be developed which define the tasks of the operating personnel to be stationed at each Critical Control Point.

Cooperation between primary producer, industry, trade groups, consumer organisations, and responsible authorities is of vital important. Opportunities should be provided for the joint training of industry and control authorities to encourage and maintain a continuous dialogue and create a climate of understanding in the practical application of HACCP.

DIAGRAM 1



LOGIC SEQUENCE FOR THE APPLICATION OF HACCP

DIAGRAM 2
EXAMPLE OF DECISION TREE TO IDENTIFY CCPS
(answer questions in sequence)

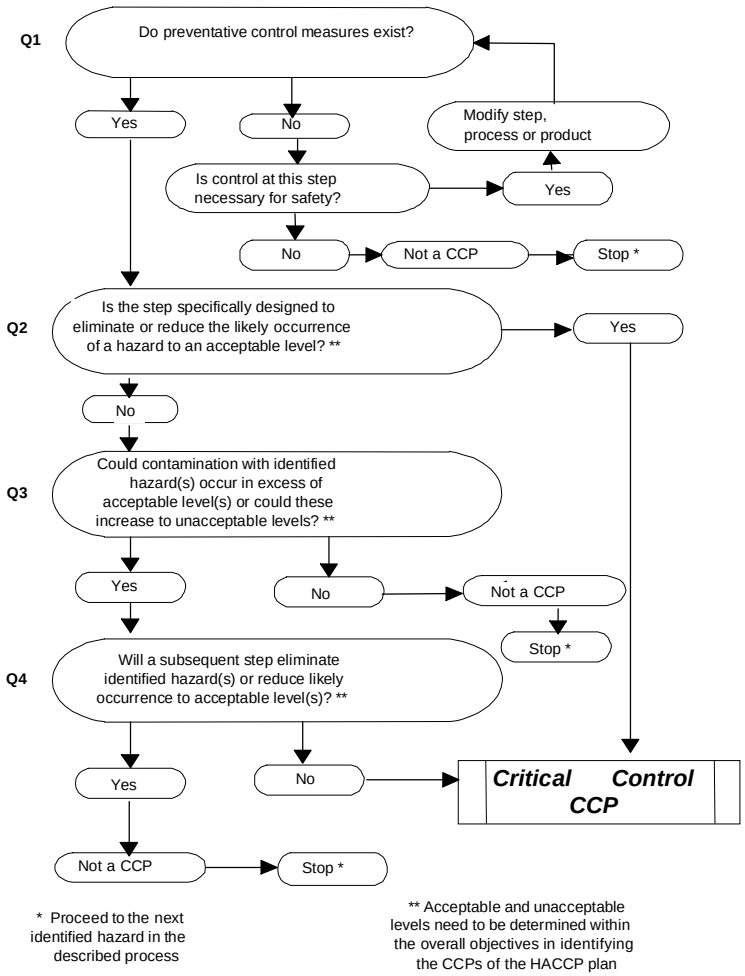


DIAGRAM 3

EXAMPLE OF A HACCP WORKSHEET

1. Describe Product

2. Diagram Process Flow

3. List

Step	Hazard(s)	Control Measure(s)	CCPs	Critical Limit(s)	Monitoring Procedure(s)	Corrective Action(s)	Record(s)

4. Verification

APPENDIX III

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR MILK AND MILK PRODUCTS
At Step 5 of the Procedure

TABLE OF CONTENTS

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. 3, 1997. 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](Codex Standard 206-1999). Where milk products are referred to in the code it is understood that this term also includes composite milk products.

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

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. 3, 1997.

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 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]. 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 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 and the distributor. 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 and transporters 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].

It is important that clear communications and interactions exist between all parties to help assure that best 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* (Codex Standard 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 Objective – [The maximum frequency and/or concentration of a [microbiological] hazard in a food at the time of consumption that provides the appropriate level of health protection.]
Minimize – To reduce the likelihood of occurrence or the consequence of an unavoidable situation such as microbiological growth.

Raw milk – milk (as defined in Codex General Standard for the Use of Dairy Terms) which has not been heated beyond 40ºC 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 conditions.

Validation – [The obtaining of evidence that food hygiene control measures selected to control a specific hazard(s) in a specific food(s) are consistently capable of controlling the hazard to the level specified.]

[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.

2.6 Suitability

Food Suitability as defined in the *Recommended International Code of Practice-General Principles of Food Hygiene,* CAC/RCP 1 - 1969, Rev. 3, 1997 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. 3, 1997 and specified in detail in this Code. The use of a management system such as HACCP 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 perished 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. 3, 1997 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:

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 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 effectiveness 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 feces.

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, microbiological or chemical 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 permitted 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. 3, 1997 and to the general principles presented in Section 2.3 above.

4.2 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. 3, 1997 (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] 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)].

Where appropriate control measures 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. These 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

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.

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Each potential hazard should be evaluated to determine its severity and likelihood of occurrence.

Potential hazards that are determined to be severe or reasonably likely to occur should be subject to control by the system of control measures.

5.1.2 Control Measure Selection

Control measures and control measure combinations should be selected that will control the hazards identified as severe and/or likely to occur.

Once severe hazards and/or hazards reasonably likely to occur have been identified, 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.

Control measures selected should be sufficient to assure that, at the point of application, the hazard has been prevented, eliminated or reduced to acceptable levels.

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 in preparation).

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 effected.

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] 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 takes 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

Preventative 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 programs, personnel, monitoring of ingredients and processing operations.

Preventative 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 Packaging

No additional provisions required beyond those noted in the *Recommended International Code of Practice- General Principles of Food Hygiene,* CAC/RCP 1-1969, Rev. 3, 1997.

5.5 Water

Dairy processing establishments should have a supply of potable water, 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.

5.6 Documentation and records

No additional provisions required beyond those noted in the *Recommended International Code of Practice- General Principles of Food Hygiene,* CAC/RCP 1-1969, Rev. 3, 1997, including the HACCP Annex.

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. 3, 1997.

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 programs

A routine program 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. 3, 1997 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. 3, 1997 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.)

8.2 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.

8.3 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. 3, 1997.

9.3 Labelling

Milk products should be labeled in accordance with the Codex *General Standard for the Labelling of Prepackaged Foods* (Codex Standard 1-1985 (Rev. 1 – 1991)), the Codex General Standard for the Use of Dairy Terms (Codex Standard 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. 3, 1997.

10.2 Training programs

Milk producers and personnel involved in the collection and transport 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 scope of this code does not extend to the production of raw drinking milk.

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 that 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. 3, 1997 (GPFH). 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.

This code does not contain provisions for the production of raw drinking milk.

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, preventative 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 programs 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 diarrhea 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 International Animal Health Code (OIE);
  - 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, preventative 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 Proposed Draft Codex Code of Practice on Good Animal Feeding (in preparation – currently contained in CL 2000/30-AF) 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 parlors (if used) attract such pests, good preventive measures such as proper building construction and maintenance (if applicable), cleaning, and removal of fecal 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 Drugs

The relevant aspects of the Proposed Draft 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 center 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. fecal 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.

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 initial milk, and by using record and identification of treated animals. The producer should take appropriate precautions to minimize the risk of infections to teats and udders, including the avoidance of damage to tissue.

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 ifclinically 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, etc) 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, etc) 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 whey.

Verification that milk storage equipment is maintained and in good working order is necessary at least once a year.

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 center 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 center 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 centers, 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 center 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 (ALINORM 01/13, Appendix III – update reference when available).

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 center 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 center 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.

Special 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 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.

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. 3, 1997 (GPFH). 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. 3, 1997 (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 harmful 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*.

Process criteria are the process control parameters (e.g. time, temperature) applied at a processing step.

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.[3]

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 preventative 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

[3] 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).

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.

5.1.1 Hazard Identification

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 be severe and/or 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. 3, 1997, 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 programs, the pathogen in question may be

ruled out. The manufacturer or other appropriate party is responsible for verifying the conditions that support such a determination. This can be accomplished by documenting the OIE status (e.g. disease-free area), verifying the effectiveness of national programs, verifying the effectiveness of individual producer screening programs, 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 factors 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 preventative measures taking place in the manufacturing environment (e.g., environmental and equipment sanitation programs, employee practices, pest control programs, 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.

Once severe and/or hazards reasonably likely to occur have been identified, 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 Appendixes 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 growth of microorganism 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 the 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 Animal Health Code established by the World Animal Health Organization (the OIE), 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. In any case, [validation] of the selected temperature should be carried out.

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.

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 an applying an appropriate safety factor (e.g., by shortening the maximum durability specified in the labeling or by requiring lower storage temperatures).

5.2.3 Microbiological and Other specifications

5.2.3.1 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 centers.

Upon receiving, the milk should be subject to olfactory and visual inspection. Other criteria (e.g., temperature, titratable acidity, microbiological and chemical criteria, etc.) 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 homeostasis[4] 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 slowly 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

[4] *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.*

for 12-14 hours, by binding iron in the presence of bicarbonates.

Lactoperoxidase system[5]:

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).

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 cytoplasma 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 minimum 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.

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

[5] 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 centers. Whenever used, chemical methods should never replace nor delay implementing good hygienic practices in milk production.

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:	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 vapor pressure of the food to that of pure water. The minimum a_w value for preventing growth depends on the pathogen, but lies typically between 0.93 and 0.96.Water activity can be controlled by: • 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) • 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, with the exception of irradiation, 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:

"Bactofugation®":	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.
[Irradiation:	The submission of beams of photons/electrons to destroy viable microorganisms. Guidance for application is provided by the Codex General Standard for Irradiated Foods (CODEX STAN 106-1983 - under revision) and Codex Code of Practice for the operation of Irradiation Facilities Used for the Treatment of Foods (CAC/RCP 19-1979 (Rev. 1))]
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 harmful microorganisms to a level at which they do not constitute a significant health hazard.
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 *B. cereus* growth.

B.1 Pasteurization of milk and fluid milk products

B.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 microbiological 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).

B.1.2 Process management

Process performance

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 [validation]s 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.[6]

[6] 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

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.

Alkaline phosphatase[7] 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:*

1. *Initial concentration in milk: the "pool" of alkaline phosphatase present in milk varies widely between different species and within species. Typically, raw cows milk shows an activity much higher than goats milk. As pasteurization results in a log*

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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.

[7] 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.

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.

2. *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).*

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

B.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.

B.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).

B.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.

B.2.2 Process management

Process performance Thermal processes necessary to obtain commercially sterile products are designed to result in [12 log reductions of *C. botulinum* and 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 a official or officially recognized thermal processing authority. Where the risk of contamination with *Clostridium botulinum* is lower, alternative thermal processes may be established by a official or officially recognized thermal processing 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 a official or officially recognized thermal processing 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 such as **[**IDF Standard 48:1969 (under review)**]**.

B.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.