

# codex alimentarius commission



FOOD AND AGRICULTURE  
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**Agenda Item 8**

**CX/FH 03/9  
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## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD HYGIENE**

**Thirty-fifth Session  
Orlando, Florida, USA, January 27 – February 1, 2003**

### **PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR MILK AND MILK PRODUCTS (At Step 3 of the Procedure)**

*Prepared by the United States of America with assistance of Argentina, Australia, Canada, France, Germany, India, Netherlands, New Zealand, Switzerland, United Kingdom, Uruguay, and the International Dairy Federation (IDF)*

Governments and interested international organizations are invited to submit comments or information on the attached Draft Code at Step 3 (see Appendix) and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission, Twelfth Edition*, pages 19-20) to: Mr S. Amjad Ali, Staff Officer, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 4861, 1400 Independence Avenue, SW, Washington, D.C. 20250, USA, FAX +1-202-720-3157, or email [syed.ali@fsis.usda.gov](mailto:syed.ali@fsis.usda.gov) with a copy to: Secretary, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, by FAX +39-06-5705-4593 or email [codex@fao.org](mailto:codex@fao.org) **by November 15, 2002.**

## **BACKGROUND**

The Codex Committee on Food Hygiene (CCFH), at its 29<sup>th</sup> Session (1997), agreed to initiate work on a *Code of Hygienic Practice for Milk and Milk Products*<sup>1</sup>. The Committee assigned the preparation of a draft discussion paper and outline of the Code to the Delegation of the United States, with the assistance of India, France and the International Dairy Federation (IDF), for consideration at the Thirtieth Session of CCFH. Subsequently, the following countries also agreed to assist in the development of the Code: Argentina, Australia, Canada, Germany, Netherlands, New Zealand, Switzerland, and the United Kingdom. These countries (including the original three countries) and IDF comprise the current drafting Group.

<sup>1</sup> ALINORM 97/13A, paragraphs 40-43.

At its 30<sup>th</sup> Session, the CCFH considered a discussion paper on the *Proposed Draft International Code of Hygienic Practice for Milk and Milk Products*<sup>2</sup> including an outline containing the recommended elements for the proposed Code. During the Session, the Committee agreed with the recommendation of the United States (which was supported by other delegations including France) to discontinue development of the *Proposed Draft Code of Hygienic Practice for the Manufacture of Uncured/Unripened and Ripened Soft Cheeses* as an independent Code with the understanding that the work would continue as a part of the elaboration of this Code<sup>3</sup>.

At the 31<sup>st</sup> Session of CCFH, the United States, on behalf of its drafting partners, presented the *Proposed Draft International Code of Hygienic Practice for Milk and Milk Products* in which the previous outline had been converted into a draft code<sup>4</sup>. The Delegation of the United States, at the request of the Committee, highlighted some of the essential issues that would need to be addressed in order to provide a basis for further development of the Code.

At the 32<sup>nd</sup> Session, the Committee agreed to certain key aspects regarding the framework of the Code as follows:

- The main body of the text should focus on principles for the hygienic production of milk and milk products rather than prescriptive material, and that detailed information on the production and processing of milk and milk products should be contained in Annexes
- Annexes are an integral part of the Code.
- Validation of food safety control measures is an important principle that has general application for CCFH and has specific application throughout the Code.
- Suitability is already included for the dairy sector by virtue of the definition of food hygiene in the *Recommended International Code of Practice—General Principles of Food Hygiene* (GPFH) and the Codex Alimentarius Commission's (CAC) *Procedural Manual* and therefore it is appropriate to be within the scope of the Code.
- Shelf life could be included in the Code under certain specified conditions with respect to it being a part of the hazard analysis for a product(s).

The Committee agreed that the general approach in the framework document was appropriate for the further development of the Code and requested the United States, with the assistance of its drafting partners, to continue development of the Code.

The Committee, at its 33<sup>rd</sup> Session<sup>5</sup>, considered the revised Code. The Committee recalled that the Codex Committee on Milk and Milk Products had referred the Heat Treatment Definitions to CCFH and noted that definitions would be incorporated into the Annex dealing with microbiocidal treatments. The Committee considered the area of suitability, including a Discussion Paper on the subject prepared by New Zealand; while recognizing the generic nature of the subject, the Committee agreed that the issue should be considered within the framework of the Milk Code. The Committee recognized that, while substantial progress had been made on developing the code, significant additional work remained, in particular the development of the Annexes. The Committee

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<sup>2</sup> CX/FH 97/13.

<sup>3</sup> ALINORM 99/13, paragraphs 66-67.

<sup>4</sup> ALINORM 99/13A, paragraphs 42-45.

<sup>5</sup> ALINORM 01/13A, paragraphs 96-102.

returned the Proposed Draft Code to Step 3 for continued redrafting by the United States with the assistance of a drafting group.

At the 34<sup>th</sup> Session<sup>6</sup>, the Committee considered a revised Code that contained three separate and complete primary production annexes relating to; a general approach to primary production; the production of milk for raw milk products; and, the production of milk by small holder dairies. The Code also contained a comprehensive annex on the processing of milk and milk products. While the Committee continued to agree with the general direction and content of the Code, many delegations expressed concern with the duplication presented in the three primary production annexes and also indicated that simplification of the processing annex was needed. The Committee returned the Code to Step 3 with the request for revision by the Drafting Group.

## **REVISED DOCUMENT**

The Drafting Group met May 13-17, 2002 to revise the document based on discussions at the 34<sup>th</sup> Session and comments submitted to the Session.

Key changes made to the Code are presented below. For a more complete discussion on the results of the meeting, refer to the Drafting Group Chairman's Notes as presented in CX/FH 03/9, Add.1.

The Drafting Group:

- Agreed to retain the basic formatting of the document in which the base code contains principles and explanatory narrative relating to the production, processing, labeling of milk and milk products and related areas with detailed guidelines for the application of the principles in annexes.
- 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 dairies into a single annex. Also agreed to a definition for small-holder dairies (see Annex 1 of the Code).
- Substantially revised the text of Annex II, primarily reordering and supplying text but also adding text to more fully explain the application of HACCP to milk and milk products
- Recognized that food hygiene as applied to milk and milk products included chemical and physical hazards as well as microbiological hazards and agreed to incorporate provisions with respect to these hazards, as appropriate, throughout the document.
- Agreed that the Milk Code applied to all milk and milk products obtained from all milking animals, not just bovine species, and incorporated a footnote in this regard.
- Strengthened provisions relating to animal health including reference to pertinent provisions developed by the Office International des Epizooties (OIE).
- Discussed extensively the areas of validation and determining the performance of food hygiene control measures and agreed to incorporate the definition for validation currently proposed in the *Codex Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures*.

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<sup>6</sup> ALINORM 03/13, paragraphs 129-134

- Recognized that control measures were broad in scope, incorporating both preventative measures as well as microbiocidal and microbiostatic measures, and extending from primary production through processing to storage, distribution and retail sale.
- Agreed to delete the definition for raw milk product and to incorporate a definition for raw milk, noting the difficulty in appropriately defining the broad range of raw milk products. Also agreed to incorporate into Annex I under “Special Provisions for the Production of Raw Milk Used for Raw Milk Products”, a discussion of the nature and scope of raw milk products.
- Discussed at length the need to include text relating to determining the performance of control measures and agreed that this subject was very important but that it was a cross-cutting one and should more properly be considered in the context of the *Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures*.
- Included specific principles relating to water reuse.
- Agreed that mention should be made in Section 9 of the Base Code to Section 4.2.1.4 of the *Codex General Standard for the Labelling of Prepackaged Food* relating to the need for mandatory declaration in the food product ingredient statement of foods known to cause hypersensitivity.
- Agreed to insert as an additional special provision relating to raw milk products that such products should be labeled to indicate they are made from raw milk.
- Agreed to include a provision in Section 9.4, Consumer Education, that “vulnerable populations should be informed of the risk associated with certain products”.

Importantly the Drafting Group prepared a document that contains no square bracketed text other than references to Food Safety Objectives (FSO), the definition of validation and certain temperature provisions. The Drafting Group recognized that the definition for an FSO is under discussion in the context of the *Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management*, currently under development by CCFH.

## **REQUEST FOR REVIEW**

The Committee is invited to comprehensively review the Proposed Draft Code, submitted by the Drafting Group to the Committee for its’ consideration, to ensure the Code’s appropriateness and adequacy with a view towards progressing the document, as appropriate, in the Codex Step Procedure.

## APPENDIX 1

**PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR MILK AND MILK  
PRODUCTS at Step 3 of the Procedure**

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## 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. 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*<sup>7</sup>(Codex Standard 206-1999). Where milk products are referred to in the code it is understood that this term also includes composite milk products.

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

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<sup>7</sup> This code applies to the milk and milk products obtained from all milking animals.

## 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.<sup>8</sup>

**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 40°C or undergone any treatment that has an equivalent effect.

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

## 2.6 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.

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<sup>8</sup> 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.

- 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* 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).*

**Milk should have a microbial load as low as possible.**

*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 Treatment for Pests**

**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 any 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.**

#### **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.**

### **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.

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; if this is the case, these allergenic ingredients must be declared on the product's label (see Section 9.3). Milk proteins themselves may be allergenic for some individuals and, if they are used as ingredients in foods other than dairy products, these ingredients must be declared on the product's label. **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 (Critical Limit Determination)**

**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 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 refers 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 refers 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 end product specifications

**Depending upon the hazards identified and the control measures used in the manufacture of milk products, particularly for some raw milk products, microbiological criteria may be necessary to help verify that the finished product does not present an unacceptable health risk to the consumer.**

*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 finished product criteria 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.**

**The flow of contaminating materials should not cross the flow of material that should not be contaminated.**

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 should be verified prior to use.**

*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 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.**

**Water should, prior to any reuse, be reconditioned by appropriate treatment(s) according to its intended use so as to ensure the safety and suitability of the food manufactured.**

*Proper maintenance of water conditioning systems is critical to avoid having the systems become sources of contamination.*

*For example, filter systems can become sources of bacteria and their metabolites if bacteria are allowed to grow on the entrained organic materials removed from the incoming water.*

**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 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.

Milk products that contain known allergens (e.g., nuts, eggs) should always declare these ingredients, as provided for in Section 4.2.1.4 of the *Codex General Standard for the Labelling of Prepackaged Foods* (foods and food ingredients known to cause hypersensitivity).

#### **Additional provision for raw milk products**

**Raw milk products should be labeled to indicate they are made from raw milk.**

### 9.4 Consumer Education

Vulnerable populations should be informed of the risk associated with certain products.

## 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.

## **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 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**

Water used for the cleaning of the udder and for cleaning equipment used for the milking and storage of milk 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 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

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

Animal holding areas shall not adversely affect the health of animals. In particular, the litter and the stabling area shall 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;

#### **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 sanitary authorities and registered;
  - each animal shall be identified with a steadfast device and registered by the sanitary 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 shall be isolated, before being introduced in the herd, until such time that their health status has been established. During that isolation 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, i.e., 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.

Adequate measures shall 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).

### **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 (visual inspection or pH).

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

#### **3.2.3.2 Treatment for pests**

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.

The national authority should authorize the use of all medicinal products and medicinal premixes for inclusion in animal feeds.

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 initial milk should be monitored by direct or indirect means to verify that the milk appears normal. 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. Any person so affected should immediately report illness or symptoms of illness to the management. Medical examination of a milk handler should be carried out if it is suspected that the individual is infected with a disease that can be transmitted to the milk.

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 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.

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.

Those temperatures can be exceeded, when necessary for manufacturing requirements, if those deviations will not result in an increase risk of microbiological hazards, have been approved by the authority having jurisdiction (and communicated to the manufacturer), and the end product will still

meet the microbiological specifications as defined under 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.

### **3.4 Recordkeeping**

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

- Prevention and control of animal diseases;
- 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;

## **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*. Pasteurization of milk and liquid milk products normally results in a negative alkaline phosphatase<sup>9</sup> reaction immediately after the treatment.

**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.<sup>10</sup>

## 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

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<sup>9</sup> 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.

<sup>10</sup> 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).

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

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

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

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

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

### **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 animal health 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.

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 also be paid to the application of microbiocidal control measures with such performance that they effectively eliminate any additional risks associated with the transfer of additional zoonotic hazards to the milk as well as any likelihood of higher levels of microbiological hazards. 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 (Critical Limit Determination)**

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 typically 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 have not been [validated].*

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<sup>11</sup> 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 <sub>2</sub> ):	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

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<sup>11</sup> 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<sup>12</sup>:

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 cytoplasm of microorganisms, thus disturbing the homeostasis mechanism of the intracellular pH responsible for maintaining functionality of key cell components vital for continuing growth and viability. Low pH values are obtained by fermentation or addition of acids (inorganic or organic). The 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

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<sup>12</sup> 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:	<p>The control of the water activity (<math>a_w</math>) 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 <math>a_w</math> value for preventing growth depends on the pathogen, but lies typically between 0.93 and 0.96. Water activity can be controlled by:</p> <ul style="list-style-type: none"><li>• Concentration, evaporation and drying, which also increase the buffering capacity of milk (synergy).</li><li>• Salting (addition of sodium chloride), which also reduces the cell resistance against carbon dioxide and in the solubility of oxygen (synergy)</li><li>• Sweetening (addition of sugars), which at <math>a_w</math> below 0.90-0.95 also results in an antimicrobial effect, depending on the type of sugar (synergy).</li></ul>

## APPENDIX B: MICROBIOCIDAL CONTROL MEASURES

*Note: the control measures described in this appendix are presented as descriptive examples only and have not been [validated].*

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  $\mu\text{m}$  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.<sup>13</sup>

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<sup>13</sup> 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 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 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.*

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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.

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 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 thermal processing authority. Where the risk of contamination with *Clostridium botulinum* is lower,

alternative thermal processes may be established by a 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 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.