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JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD HYGIENE

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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 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, Eleventh Edition*, pages 21-22) **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 uscodex@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 **by 1 September 2000.**

BACKGROUND

The Codex Committee on Food Hygiene (CCFH), at its Twenty-Ninth Session, agreed to initiate work on a *Code of Hygienic Practice for Milk and Milk Products*¹. The Committee assigned the delegation of the United States of America to prepare a draft discussion paper and outline of the Code, with the assistance of India, France and the International Dairy Federation (IDF), for consideration at the Thirtieth Session of CCFH.

At its Thirtieth Session, the CCFH considered a discussion paper on the *Proposed Draft International Code of Hygienic Practice for Milk and Milk Products*² including an outline containing the recommended elements for the proposed Code. During the Session, the Committee

¹ ALINORM 97/13A, paragraphs 40-43.

² CX/FH 97/13.

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 Code³. Further, the Committee agreed to convert the outline into a proposed draft Code and confirmed that the drafting group would be led by the United States with the assistance of Argentina, Australia, France, India, the Netherlands, New Zealand, the United Kingdom, Uruguay, and the IDF.

At the Thirty-first 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 code⁴. 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.

The drafting partners, at a Drafting Group meeting, considered these areas and provided certain recommendations to the Committee at its 32nd Session, including the following.

- The recognition that Annexes have an appropriate role in the Code with specific functions, including for example, presenting control measures applicable to specific milk production situations including those for raw milk products and small holder dairies, and presenting specific provisions for the processing of milk products, such as annexes for preventative measures, hurdle technologies and thermal processing.
- That 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 the specific sections of the Code should follow a hierarchical format involving principles, objectives and/or explanatory narratives, and guidelines on application.
- That validation of food safety control measures is an important principle that has general application for CCFH and has specific application throughout the Code.
- That 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.
- That 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 Drafting Group prepared a revised document for consideration by the Committee at its 32nd Session.

The Committee, at its 32nd Session, considered the revised document. The Delegation of the United States, on behalf of the Drafting Group, outlined the new nature of the revised Code and pointed out that the document provided a general framework but required substantial further work, in particular to more fully develop the various sections of the Code and to also develop the annexes.

³ ALINORM 99/13, paragraphs 66-67.

⁴ ALINORM 99/13A, paragraphs 42-45.

Some Delegations noted the need to include suitability in the Code while others noted that the annexes should not be regarded as additional since they would refer to specific production considerations. The Delegation of the United States indicated that the intention was to develop a comprehensive set of annexes that would be an integral part of the Code to cover all milk and milk products. It was noted by some Delegations that the Code should be developed in the context of a risk-based approach, should refer to the acceptable level of protection and should focus first on principles specific to all dairy products.

The Committee agreed that the general approach in the framework document was appropriate for the further development of the Code. The Committee returned the Proposed Draft Code to Step 3 for redrafting, including development of specific annexes, by the United States with the assistance of a Drafting Group for consideration at the 33rd Session of the Committee.

The United States prepared a revised Code based on the discussion on the Code at the 32nd Session and on country comments received, and circulated it to all Codex Member countries via the Codex “L” list for comment prior to a meeting of the drafting group.

The drafting partners, at a meeting of the Drafting Group held in Brussels in April, 2000, considered the revised document as prepared by the United States and further developed the proposed draft Code for consideration by the Committee.

REVISED DOCUMENT

The Drafting Group, noting the earlier recommendation that the Code should follow a hierarchical format involving principles, objectives and/or explanatory narratives and guidelines for application, discussed the relationship between principles and guidelines for application. The Drafting Group noted that a principle should be a statement of outcome while guidelines should provide specific information needed to achieve the outcome. The Drafting Group recognized that, because of differences in the manner in which the primary production of milk and the processing of milk were handled in the Code (i.e., providing more specific guidance with respect to primary production practices), the actual format of the Code would have to be somewhat different in some of its sections. The Drafting Group agreed that Section 3 of the Code, dealing with primary production, would consist solely of principles and explanatory narrative with the specific implementing guidelines for the various approaches to the primary production placed in the annexes (see below), which are an integral part of the Code. The other sections, while including appropriate principles and explanatory narratives, would also contain certain guidance information.

The Drafting Group also discussed the area of suitability, recalling its earlier discussion that suitability was an appropriate element for the Code by virtue of its inclusion in the *Recommended International Code of Practice—General Principles of Food Hygiene* and the *Codex Alimentarius Procedural Manual*. The Group restated the need for the CCFH to develop a definition and guidelines for suitability that would have applicability across commodities. The Group also restated the appropriateness of including suitability in the Code and that the elements relating to suitability could be included in the Code as it is developed, based on the broader work on the issue proposed to be done by the CCFH.

The Drafting Group further discussed the area of validation of food safety control measures. The Group reiterated its previous recommendation that this was an important area with specific application throughout the Code and that the concept, since it also had applicability to many other commodities, should be further developed by CCFH.

The Drafting Group discussed whether the Code should apply to composite milk products by virtue of the title of the Code. There were differing views on this subject. Some Delegations considered such products outside the scope of the Code while other Delegations were in favour of their inclusion. Those favouring the inclusion of composite milk products noted that products such as flavoured yoghurts were fundamentally milk products while also being composite milk products, and that excluding composite milk products from the Code would result in the lack of an international hygiene Code that covered such products. The Drafting Group agreed to retain composite milk products in the Code for the present, retain the title of the Code and refer the issue to the Committee for discussion.

As noted and detailed below, the Drafting Group also discussed the nature and content of the proposed annexes, which are an integral part of the Code. The Drafting Group noted that the link between the main part of the Code and the annexes needs to be strengthened as does the link between the Primary Production Section and the Control of Operations Section of the Code.

The Drafting Group carried out a comprehensive review of the draft Code, revising its various sections and developing an approach to the nature and content of the annexes, the result of which is a revised Code for the Committee's consideration that appears as Appendix 1 of this document. The Drafting Group noted the importance of treating all products equally. The use of the annexes to provide detailed guidance on the various approaches to the production and processing of milk is important in this regard.

The Drafting Group developed an approach regarding the nature and organization of annexes which it recommends to the Committee for its consideration. The Drafting Group proposes three sets of annexes, the first dealing with the primary production of milk, the second dealing with the application and management of systems to control the processing operations for milk products, and the third containing supporting information. These annexes are as follows.

- I. Annexes relating to the primary production of milk.
 - Part A. Guidelines for the application of the "General" approach for the production of milk.
 - Part B. Guidelines for the production of milk by small holder dairy farms.
 - Part C. Guidelines for the production of milk intended for the manufacture of raw milk products.
- II. Annexes relating to the control of operations for milk and milk products.
 - Part A. Guidelines for the application and management of Hurdle Technology.
 - Part B. Guidelines for the application and management of microbiocidal treatments.
- III. Annexes on supporting information (e.g., water reuse).

Outlines for the content of each of annexes groups I and II are contained in Appendix 1 to this document.

RECOMMENDATION

The Committee is invited to review the attached *Proposed Draft Code of Hygienic Practice for Milk and Milk Products*, with a view towards its further development, particularly the elaboration of the annexes through work by the drafting partners utilising a Drafting Group.

APPENDIX 1

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR MILK AND MILK PRODUCTS

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INTRODUCTION

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. Milk and milk products are a rich and convenient source of nutrients for people in many countries, and implementing proper hygienic control is essential in ensuring the safety and suitability of these important foods. Dairy animals frequently carry human pathogens. Such pathogens present in the milk are transmissible to man as intrinsic pathogens or are responsible for food borne illness after the subsequent contamination of the milk. 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 these foods makes them good media for the outgrowth of pathogenic microorganisms. Potential also exists for the contamination of milk with residues of veterinary drugs and pesticides. Therefore, implementing the proper hygienic control of milk and milk products is essential in ensuring 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, milk products and composite milk products. It also provides guidance on how to achieve the general requirements contained in the hygiene sections of the Codex milk products standards.

2. SCOPE AND USE OF THE DOCUMENT

2.1 SCOPE

This Code applies to the production processing and handling of milk, milk products and composite milk products as defined in the *General Standard for the Use of Dairy Terms*, Codex Standard 206-1999.

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

2.2 USE OF THE DOCUMENT

This document is to be used in combination with the *Recommended International Code of Practice-General Principles of Food Hygiene*, CAC/RCP 1- 1969, Rev. 3, 1997. The HACCP principles together with their Guidelines for Application annexed to the General Principles should also be used where appropriate. Similarly, the *Principles for the Establishment and Application of Microbiological Criteria for Foods*, CAC/GL 21-1997, should be used as appropriate.

This document consists of a series of principles, explanatory narratives and guidelines on specific control measures for the hygienic production of milk and milk products. Over-arching principles that are applicable to all phases of production and processing of milk and milk products are given in Section 2.3. Specific principles and their associated explanatory narrative which are only applicable to particular aspects or sections of the Code (e.g., primary production, control of operations) are given in the appropriate section. Principles are shown in bold text, explanatory narratives are shown in italicized text and guidelines are shown in normal text.

Annexes, which are an integral part of this Code, are also employed. These annexes provide guidelines for the application of principles that have been identified for different approaches to the primary production and processing of milk and milk products. For primary production, the annexes include general guidance for milk production as well as specific guidance for milk production for raw milk products and specific guidance for milk production in small holder dairy farms. For Control of Operations, the annexes provide guidance for the implementation of various processes and technologies applied during the subsequent manufacturing of dairy products, including the use of Hurdle Technology and the application of thermal and non-thermal microbiocidal treatments. 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.

It is important to recognize that 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. The proper application of the principles and guidelines contained in this Code will insure, to the extent that it is possible, that the entire continuum of controls are adequately applied and that the finished products produced under this Code are safe and suitable for their intended use.

The user of this Code should understand that the information presented in the main body of the Code as well as that provided in the annexes is inextricably linked and therefore cannot be considered on its own, in isolation. The information presented in the various parts of this document loses its value once it is removed from the context of the Code. Thus, the code has been constructed such that where a particular principle has been identified in the main body of the Code, the guidelines necessary for its application will be located in the corresponding section of the annex and vice versa.

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

Over-arching principles applicable to all milk and milk products are the following:

- 1. From raw material production to the point of consumption, the products covered by 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.**
- 2. Hygienic practices should be applied throughout the food chain so that milk and milk products are safe and suitable for their intended use.**
- 3. Milk and milk products should be produced, handled, stored and transported under the best possible hygiene conditions.**
- 4. 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, available guidance on proper on-farm practices should be followed.

- 5. Hygienic practices should be validated as effective for achieving the appropriate level of public health protection for specified products.**
- [6. Risk assessment based on Codex principles and methodologies should be used wherever possible as the basis for:**
 - validation of selected control measures**
 - evaluation of new technologies, processes and product formulations to ensure that they are consistent with production of milk and milk products that are safe and suitable for the intended purpose**
 - claims relating to the equivalence of different sanitary measures applied by different countries.]**

2.4 Relative roles of milk producers, manufacturers and control authorities

Milk producers play a key role in helping to ensure the safety and suitability of milk. The implementation of management systems such as the application of good agricultural practices may be helpful. In this regard as far as product safety and suitability is concerned it is important to consider maintaining adequate record keeping with respect to:

- animal illnesses
- use of veterinary drugs
- nature and source of feeds and fertilisers.*

[Need to consider the placing of record keeping at farm level.]

Similarly, the manufacturer also has a key role in helping to ensure that milk and milk products are safe and suitable. In this regard they should apply the hygienic practices presented in this code.

Clear communications by control authorities to both producers and manufacturers of their respective responsibilities to ensure safe and suitable products is important and should be emphasised.

2.5 DEFINITIONS (TO BE FURTHER DEVELOPED)

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.

[Equivalent Sanitary Measure - Different sanitary measures which, when properly applied, result in end products which meet the same [Food Safety Objective] level of public health protection.]

[Food Safety Objective] - To be developed.

Hurdle – [A factor or a process that limits, retards or prevents microbial growth, and/or reduces the microbial load, but which by itself cannot keep microbiological hazards under control] [Factor(s) that limit, retard or prevent microbial growth.]

Hurdle Technology – [The use of a combination of hurdles with or without application of microbiocidal processing steps which when validated can keep hazards under control so as to achieve a safe end product.] [The use of a combination of control factors to limit, retard or prevent microbial growth.]

[Microbiocidal Step] – [A single processing step that reduces the number of micro-organism including pathogens to a level that does not compromise food safety or suitability.]

Raw Milk Product – To be developed

Suitability – To be developed by CCFH

Validation – To be developed by CCFH

3. PRIMARY PRODUCTION

These principles and guidelines are supplemental to those set forth in Section 3 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. Details on specific approaches to the production of milk are given in the Annexes to this Code; these annexes are an integral part of the Code and are intended to be used in conjunction with information presented in this Section.

PRINCIPLES APPLYING TO THE PRIMARY PRODUCTION OF MILK

The raw milk should be as clean as possible.

Contamination of raw milk from intrinsic (animal) and extrinsic (environmental) sources during primary production should be minimized to the greatest extent practicable.

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” (International Code of Practice – General Principles of Food Hygiene).

Any contamination of raw milk with hazards to human health should not be at a level that when milk and milk products are presented to the consumer, achievement of the appropriate level of public health protection is jeopardized.

Although hygienic practices should be based on HACCP principles wherever practicable, it is recognized that this may not be possible in some situations at the primary production level.

Milk and milk products provide an ideal medium for maintenance and growth of a number of food-borne pathogens and other undesirable microorganisms. Because of the important influence of primary production activities on the safety and suitability of milk and 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 are maintained. Further, lack of good agricultural, animal feeding and veterinary practices and inadequate general hygiene during milking may lead to unacceptable levels of contamination with chemical residues and other contaminants during primary production.

Hazard analysis and design of a HACCP plan by the processor so that milk and milk products are safe and suitable for their intended purpose may identify the need for additional measures to be taken for hazard control at the primary production level.

USE OF THIS SECTION

Provisions contained in Annex I are an integral part of this Code and are intended to be used in conjunction with the information presented in this Section. Details provided in Annex I relate to specific approaches to primary production of milk. Where the annexes provide specific guidelines to a particular principle, cross reference will be made to where the guidelines necessary for its application are located.

A wide range of systems can be used for primary production as long as the hygienic practices that are applied, in combination with manufacturing controls, can be shown to achieve the appropriate level of public health protection.

In general, the provisions contained in Annex I, Part A should be implemented in order to reduce the likelihood of milk contamination due to inadequate primary production practices.

For small holder dairy farms in developing countries where the milk will be subjected to adequate public health control measures during subsequent processing, the provisions contained in Annex I, Part B should be implemented in order to reduce the likelihood of milk contamination due to inadequate primary production practices.

When the milk will be used in the manufacture of raw milk products where primary production conditions serve as the principal public health control measure, the provisions contained in Annex I, Part C should be implemented in order to minimize or prevent the presence of human pathogens in the milk due to inadequate primary production practices.

3.1 ENVIRONMENTAL HYGIENE

Water and other environmental factors should not be a source or a vehicle for transmission, directly or indirectly, of hazards into the milk.

[Explanatory narrative to be developed]

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 and maintained in a manner that will minimize the introduction of hazards to the 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 should be managed in a manner that minimizes the introduction of hazards to the milk.

Milk from diseased animals should not be used for human consumption when, considering the end use, such milk presents a risk to human health or can adversely affect suitability.

Milk from certain diseased animals has been known to be not safe nor suitable for human consumption.

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

3.2.3 General Hygienic Practice (supplemental to the GPFH)

3.2.3.1 Feeding

With consideration given to the end use of the milk, forage, and feed for lactating animals should not present a risk of introducing, directly or indirectly microbiological or chemical hazards to the milk in amounts that present a health risk to the consumer.

It has been shown that improper handling of animal feed can result in the introduction of pathogens to milking animals and the introduction of chemical hazards such as pesticide residues, mycotoxins and other potentially hazardous agents used or introduced into the production of feedstuffs which can affect the safety of milk.

When the milk will be used in the manufacture of raw milk products where primary production conditions serve as the principal public health control measure, the provisions contained in Annex I, Part C, Section 3.2.3.1 should be implemented in order to minimize or prevent the presence of human pathogens in the milk due contaminated feed.

To be placed in the annex - reference to the Codex Code of Practice for Good Animal Feeding (to be developed by the Codex Task Force on Animal Feeding).

3.2.3.2 Treatment for Pests

Pests should be controlled and in a way that does not result in 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

Milk from animals that have been treated with antibiotics or other veterinary drugs should not contain residues at unacceptable levels.

Milk from animals which have been treated with antibiotics or other veterinary drugs which can be transferred to the milk should not be used until the withdrawal period specified for the drug in question has been achieved.

Diseased animals must only be treated with authorized veterinary drugs and in a manner that may not adversely impact on the safety and suitability of the milk, including adherence to the withdrawal period specified. Milk exceeding MRLs established for such drugs should not be used.

[Note: Reference will be made to appropriate CCRVDF documents, including those for antibiotic residues in milk. Reference will also be made to appropriate provisions of the *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods*.]

The improper use of veterinary drugs has been shown to result in potentially harmful residues in milk.

3.2.4 Hygienic milking

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

Effective hygienic practice during milking is essential to ensuring that milk and milk products presented to the consumer will be safe and suitable for their intended purpose. 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.

Minimising contamination of raw milk during milking requires that effective hygienic practices are 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.

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 minimize or prevent the contamination and/or increase the microbiological load of milk.

Proper handling, storage and transport of milk is essential to ensuring that milk and milk products presented to the consumer will be safe and suitable for their intended purpose. Temperature abuse, introduction of foreign materials and contact with unsanitary equipment are known causes of milk contamination.

For small holder dairy farms in developing countries where the milk will be subjected to adequate public health control measures during subsequent processing, the provisions contained in Annex I, Part B, Section 3.3 should be implemented in order to reduce the likelihood of milk contamination due to inadequate primary production practices.

3.3.1 Milking equipment

Milking equipment should be designed constructed and maintained in a manner that will minimize the introduction of hazards into milk.

3.3.2 Storage Equipment

Milk storage tanks and cans should be designed, constructed, used and maintained in a manner that will [minimize] the introduction of hazards to milk.

3.3.3 Premises for, and storage of, raw milk and milking-related equipment

Premises for the storage of milk should be situated, designed, constructed and maintained in a manner that would make it possible to avoid the introduction of contaminants into milk.

Whenever milk is stored it should be stored in a manner that prevents, the introduction of contaminants into milk and in a manner that [minimizes] the growth of micro-organisms.

When the milk will be used in the manufacture of raw milk products where primary production conditions serve as the principal public health control measure, the provisions contained in Annex I, Part C, Section 3.3.3 should be implemented in order to minimize the presence of human pathogens in the milk.

3.3.4 Delivery and Collection Procedures

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

This section covers on-farm transport only or delivery from the farm to collection centers. Transport from the farm or collection center to any other location is covered in Section 3.3.6.

3.3.5 Transport equipment

Milk transport tankers and cans should be designed, constructed and maintained in a manner that will [minimize] the introduction of contaminants into milk

3.3.6 Transport Procedures

Milk should be transported without undue delay, and in a manner that [minimizes] the introduction of contaminants to the milk and [minimizes] the growth of micro-organisms into milk.

This section covers delivery from the farm or collection center to the manufacturing facility as well as transport between manufacturing facilities.

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

4 ESTABLISHMENT: DESIGN AND FACILITIES

These principles and guidelines are supplemental to those set forth 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.

4.4 EQUIPMENT

Equipment should be designed and installed such that dead ends or dead spots in sanitary piping do not occur.

5 CONTROL OF OPERATION

These principles and guidelines are supplemental to those set forth in Section 5 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.

PRINCIPLES APPLICABLE TO CONTROL OF OPERATION

The use of control measures and control measure combinations should be based on HACCP principles, wherever practicable.

Milk and milk products provide an ideal medium for maintenance and growth of a number of food-borne pathogens. Because of the important influence of manufacturing activities on the safety and suitability of milk and milk products, potential microbiological contamination from all sources should be minimized to the greatest extent practicable at the manufacturing phase.

Hazard analysis and design of a HACCP plan by the processor so that milk and milk products are safe and suitable for their intended purpose may identify the need for additional measures to be taken for hazard control at the primary production level.

A wide range of control measures or control measure combinations can be used for the processing and manufacture of milk and milk products as long as the control measures or control measure combinations that are applied can be shown to achieve the appropriate level of public health protection.

Contamination during processing operations should be avoided to the greatest extent practicable.

The objective of this principle is to avoid contamination of finished products from sources within the processing environment (e.g., contaminated product contact surfaces) as well as from sources outside the processing environment (e.g., contaminated incoming raw materials).

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” (International Code of Practice – General Principles of Food Hygiene).

USE OF THIS SECTION

Provisions contained in Annex II are an integral part of this Code and are intended to be used in conjunction with the information presented in this Section. Details provided in Annex II relate to specific approaches to the control of food hazards, including microbiocidal treatments and Hurdle Technology. Where the annexes provide specific guidelines to a particular principle, cross reference will be made to where the guidelines necessary for its application are located.

Where appropriate control measures or control measure combinations are chosen to control hazards that are reasonably likely to occur, the detailed procedures contained in the appropriate annexes

should be implemented in order to minimize or prevent the likelihood of a health risk to the consumer.

5.1 CONTROL OF FOOD HAZARDS

The guidance presented in the *International Recommended Code of Practice: General Principles of Food Hygiene (GPFH)* is essential to the manufacture of safe and suitable milk and milk products.

A hazard analysis approach should be used to identify hazards that are likely to occur in milk and milk products.

Control measures and control measure combinations including Hurdle Technology and/or microbiocidal treatments should effectively control the hazards in milk and milk products that are identified by the hazard analysis.

Control measures and control measure combinations for milk and milk products should be validated.

HACCP provides a suitable framework for the identification and management of measures that are appropriate for the control of hazards in milk and milk products.

Note: If it is not possible to use HACCP, a “hazard analysis approach” should be considered.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.1 Temperature Control

Raw milk, intermediate products and end products should be stored at appropriate temperatures and for appropriate times that will [*prevent] the development of a food safety hazard or will not adversely affect suitability.

Because milk and many milk products have a sufficient moisture content to support the growth of pathogens, temperature control represents an important way in which such growth can be controlled throughout the manufacturing process.

[*prevent to be further considered]

5.2.2 Manufacturing Process Controls

Validated control measures should be selected and implemented for the manufacturing of products covered by this code which will prevent, eliminate or reduce to acceptable levels, hazards that are reasonably likely to occur.

A wide range of processing control measures can be used during the manufacturing phase that, when validated, can be effective in producing safe and suitable products. Examples of control measure combinations are provided in the annexes to illustrate how such combinations can be selected when establishing a manufacturing process.

Guidance to validation of food safety control measures is given in *Guidelines for the Validation of Food Safety Control Measures* [document in preparation].

Details to enable the effective implementation and management of specific control measure and control measure combinations once they have been selected and validated are provided in the annexes. These are provided through examples of established processes and can be used to

demonstrate how the delivery of such processes are effectively managed in the context of dairy product manufacturing

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 *Draft Revised 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* (ALINORM 99/13A, Appendix II).

5.2.3.1 Raw milk

The raw 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.) may be used to detect unacceptable conditions.

Depending upon the end use of the milk, particularly for milk used in the production of raw milk products, certain specific incoming raw milk microbiological criteria may be necessary to ensure the product does not present an unacceptable health risk to the consumer.

5.2.3.2 Microbiological end product specifications

Depending upon the hazards identified and the control measures used in the manufacture of dairy 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.

5.2.4 Microbiological cross contamination

Effective measures should be taken to prevent contamination of products and intermediates from the processing environments or contact with materials from an earlier stage of the process.

The following basic models should be used to assist in the prevention of microbiological cross contamination of milk and milk products:

- the flow-forward-in-time-and-space model: - the flow of the product and of the ingredients should maintain a forward progression from raw material receipt to finished product packaging;
- the absence-of-crossing model: - the flow of contaminating materials should not cross the flow of materials that should not be contaminated. For example, the flow of the following elements: water, air, effluents, and raw milk, should be carefully evaluated for suitability. The same principle should be strictly applied to personnel flow;
- the partition model: - there should be adequate separation of areas with different levels of contamination risk.

Returned milk products 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.

Information contained in Sections 4 and 6 of this Code and Sections 4 and 6 of the *International Recommended Code of Practice: General Principles of Good Hygiene* should be reviewed for its applicability in preventing cross contamination within the processing environment.

5.3 INCOMING MATERIAL REQUIREMENTS

NO ADDITIONAL PROVISIONS REQUIRED BEYOND THOSE NOTED IN THE GPFDH.

5.4 PACKAGING

Operations involving packaging of milk and milk products should be done following sanitary practices and should not result in contamination of the product.

5.5 WATER

The reuse of water (including reclaimed and recycled water) should follow the recommendations presented in the *Guidelines for the Hygienic Reuse of Processing Water in Food Plants* [document in preparation].

[To be included in Annex III: specific details on water reuse applicable to manufacture of milk and milk products.]

6. ESTABLISHMENT: MAINTENANCE AND SANITATION

These principles and guidelines are supplemental to those set forth in Section 6 of the *Recommended International Code of Practice-General Principles of Food Hygiene, CAC/RCP 1 - 1969, Rev. 3, 1997*.

6.1 MAINTENANCE AND CLEANING

Processing areas should be kept as dry as possible.

Whenever possible, wet cleaning should not be used during the processing of milk products in areas in which product is exposed and can be contaminated by aerosols.

Care should be taken to adequately clean all product contact surfaces in sanitary piping and equipment, including difficult to clean areas such as by-pass valves, sample cocks, and overflow siphons in fillers.

6.2 CLEANING PROGRAMS

All equipment and utensils used in processing should, as necessary, be cleaned and disinfected, rinsed with potable water (unless the manufacturer's instructions indicate rinsing is not necessary), then drained and dried where appropriate.

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

7. ESTABLISHMENT: PERSONAL HYGIENE

No specific requirements beyond those made 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*.

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 set forth 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

[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.] ***This section to be redrafted taking into consideration the General Standard for the Labeling of Prepackaged Foods (GSLPF) and the need for additional requirements for dairy products as long as they don't conflict with the GSLPF***

10. TRAINING

These principles and guidelines are supplemental to those set forth in Section 9 of the *Recommended International Code of Practice-General Principles of Food Hygiene*, CAC/RCP 1 - 1969, Rev. 3, 1997.

[Text concerning training of haulers and loaders etc to be developed here. The milk hauler is the tanker driver or individual responsible for transporting milk. Issues to be covered in such training include:

- The milk hauler should receive adequate training in the hygienic handling of raw milk.
- Milk haulers should wear clean clothing and not have infectious or contagious diseases that would present a risk of contaminating milk.
- Milk haulers should perform their duties in a sanitary manner so that their activities will not result in contamination of milk]

ANNEXES

PROVIDING GUIDELINES FOR THE APPLICATION OF THE DIFFERENT APPROACHES TO THE PRIMARY PRODUCTION AND PROCESSING OF MILK AND MILK PRODUCTS

The following annexes are an integral part of this Code. These annexes provide guidelines for the application of principles that have been identified for different approaches to the primary production and processing of milk and milk products. These annexes must be used with the main body of this Code and the *International Recommended Code of Practices: General Principles of Food Hygiene* (CAC/RCP 1- 1969, Rev. 3, 1997) to obtain complete guidance on the hygienic production of milk and milk products. The section numbering of Annex I is consistent with the section numbering of the main body of this code.

The following individual Annexes are given below.

- I. Annexes relating to the primary production of milk.
 - Part A. Guidelines for the application of the “General” approach to primary production.
 - Part B. Guidelines for the production of milk by small holder dairy farms.
 - Part C. Guidelines for the production of milk intended for the manufacture of raw milk products.
- II. Annexes relating to the control of operations for milk and milk products.
 - Part A. Guidelines for the application and management of Hurdle Technology.
 - Part B. Guidelines for the application and management of microbiocidal treatments.
- III. Annexes providing support information.

NOTE: Annexes are presented only in outline form and will be more fully developed .

ANNEX I, PART A

GUIDELINES FOR THE APPLICATION OF THE 'GENERAL' APPROACH TO PRIMARY PRODUCTION

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.

Scope and Use of Annex

This annex provides details of the approach that should be used for the production of milk intended for general use, covering the implementation of on-farm practices for the production of milk used in the manufacture of dairy products in international trade. Additionally, specific approaches are described in Parts B and C of this annex which are only intended for use in those specific situations. With these approaches, reference will be made to certain provisions of this annex..

The information in this annex is organized to correspond with the relevant sections in the main part of the Code and the 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 the annex.

3. PRIMARY PRODUCTION

- 3.1 ENVIRONMENTAL HYGIENE
- 3.2 HYGIENIC PRODUCTION OF RAW MILK
 - 3.2.1 Areas and Premises for Milk Production
 - 3.2.1.1 *Animal holding areas*
 - 3.2.1.2 *Milking areas and related facilities*
 - 3.2.2 Animal health
 - 3.2.3 General hygienic practice
 - 3.2.3.1 *Feeding*
 - 3.2.3.2 *Treatment for pests*
 - 3.2.3.3 *Veterinary Drugs*
 - 3.2.4 Hygienic milking
 - 3.2.4.1 *Environmental contamination*
 - 3.2.4.2 *Milking equipment design*
 - 3.2.4.3 *Milking equipment sanitation*
 - 3.2.4.4 *Health of Milking Personnel*

- 3.3 HANDLING, STORAGE AND TRANSPORT OF MILK
- 3.3.1 Milking equipment
- 3.3.2 Storage equipment
- 3.3.3 Premises for, and storage of, raw milk and milking-related equipment
- 3.3.4 Collection procedures
- 3.3.5 Transport equipment
- 3.3.6 Transport procedures

ANNEX 1, PART B**GUIDELINES FOR THE PRODUCTION OF MILK BY SMALL HOLDER DAIRY FARMS****Introduction and objectives.**

The provisions of this annex are to be applied to milk produced by small holder dairy farms [definition of small holder dairy farms to be developed]. This annex contains information on the special characteristics of the primary production of milk by small holder dairy farms. While these primary production provisions may be implemented in the case of small holder dairy farms, the level of public health protection of the milk or milk products must meet the stated appropriate level of public health protection

Scope and Use of the Annex

This annex presents guidelines for the primary production of milk produced by small holder dairy farms. The guidelines must be used in conjunction with the GPFH, the main body of the Code and also Annex 1, Part A, *Guidelines for the Application of the “General” Approach to Primary Production*.

The information in this annex is organised to correspond with the relevant sections in the main body of the Code and the GPFH.

3. PRIMARY PRODUCTION**3.1 ENVIRONMENTAL HYGIENE****3.2 HYGIENIC PRODUCTION OF MILK****3.2.1 Areas and Premises of Milk Production***3.2.1.1 Animal Holding Areas**3.2.1.2 Milking Areas, Premises and Related Facilities***3.2.2 Animal Health****3.2.3 General Hygienic Practice***3.2.3.1 Feeding**3.2.3.2 Treatment for Pests**3.2.3.3 Veterinary Drugs***3.2.4 Hygienic Milking***3.2.4.1 Milking Equipment/Vessel Design*

3.2.4.2 *Milking Equipment/Vessel Sanitation*

3.2.5 Movement of Milk from Producer to Collection Centre

3.3 HANDLING, STORAGE AND TRANSPORT OF MILK (COLLECTION CENTRE/TRANSPORT TO PROCESSING PLANT)

3.3.1 Milk Collection Equipment

3.3.2 Storage Equipment

3.3.3 Premises for Collection and Storage of Raw Milk

3.3.4 Collection and Delivery Procedures

3.3.5 Transport Equipment

3.3.6 Transport Procedures

3.3.7 Milk Hauler (tanker driver or individual responsible for transport)

ANNEX 1 PART C**GUIDELINES FOR THE PRODUCTION OF MILK INTENDED FOR THE
MANUFACTURE OF RAW MILK PRODUCTS****Introduction and objectives.**

The information contained in this annex is to be applied to milk intended to be supplied unprocessed directly to consumers and for manufacturing raw-milk products. This information concerns both the provisions that apply when the milk is used directly at the production site or when it is stored and transported to a processing establishment.

Scope and Use of the Annex

This annex presents guidelines that should be applied for milk which is intended to be supplied unprocessed directly to consumers and for the manufacturing of raw milk products. It is necessary that the information contained in this annex be used in conjunction with the GPFH and with information appearing in the main body of the Code and in Annex 1, Part A, *Guidelines for the Application of the “General Approach” to Primary Production*.

The information in this annex is organised to correspond with the relevant sections in the main body of the Code and the GPFH.

3. PRIMARY PRODUCTION

A high level of hygiene of the milk is essential in order to obtain a raw-milk product that is safe and suitable for human consumption. Compliance with the hygiene provisions is therefore important throughout the milk production process, up to and including the manufacturing of the raw-milk product.

3.2 HYGIENIC PRODUCTION OF MILK**3.2.1 Premises for milk production****3.2.1.1 *Animal holding areas*****3.2.1.2 *Milking areas and related facilities*****3.2.2 Animal health****3.2.3 General hygienic practice****3.2.3.1 *Feeding*****3.2.4. Hygienic milking****3.2.4.4 *Health of milking personnel*****3.3 HANDLING, STORAGE AND TRANSPORT OF RAW MILK**

3.3.1 Milking equipment

3.3.2 Storage equipment

3.3.3 Premises for the storage of raw milk and milking-related equipment

3.3.6 Transport time and temperature

5. CONTROL OF OPERATION

5.2.3 Microbiological and other specifications

5.2.3.1 Raw milk

5.2.3.2 Microbiological end product specifications

5.2 PACKAGING

ANNEX II, PART A**GUIDELINES FOR THE APPLICATION AND MANAGEMENT OF HURDLE TECHNOLOGY*****INTENDED APPROACH (not part of the annex)***

The annex will be developed with a focus on the management (validation, use, implementation and verification) of hurdles (understood as being individual steps, factors, conditions, treatments that limit, retard or prevent microbial growth and/or reduce the microbiological load, but which individually do not achieve a safe and suitable end product as a result), and which have to be used in combination within the context of Hurdle Technology in order for the product to be safe and suitable.

Hurdle Technology is among the possible control measures that, in combination with other control measures applied at the primary production level during manufacture and during distribution, may be used to achieve an acceptable level of protection.

The guidance provided herein is an integral part of the Code and will therefore apply to the extent the safety and suitability of end products depending on the use of Hurdle Technology to meet the principles established in the main body of the Code, including the HACCP based approach, where appropriate.

Guidance will also be provided with respect to providing adequate follow-up on the provisions provided for in the annexes addressing primary production (small holder dairy farms and raw milk products).

The Annex will address the most commonly used hurdles, focus on their combined use within the concept of Hurdle Technology, and provide examples accordingly. Explanatory narratives will be provided, as necessary.

In certain cases, similar technologies can be used both as a hurdle and as a Microbiocidal Treatment depending on the application of the technology.

INTRODUCTION AND OBJECTIVES

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. Some specific treatments reduce the number of micro-organisms and target pathogens.

To the extent such treatments do not result in safe products as a result of such a single processing step they are regarded as Hurdles (e.g. heat treatments with less effect than pasteurization). When they do result in a safe product as an outcome of a single treatment, they are regarded as Microbiocidal Treatments (see Annex II).

The intention of using hurdles is to prevent or restrict the growth and/or reduce the microbiological load, including target pathogen(s) in milk products. *Most milk products need the use of hurdles to become safe and suitable or retain such quality.*

To ensure the safety and suitability and/or to extend the shelf life of milk products, generally more than one hurdle is used to control microbial growth, to inhibit spoilage and to help prevent foodborne diseases. Suitable combinations of hurdles can be devised so that the organisms of concern can no longer grow/survive in the product. Such suitable combinations are called **“Hurdle Technology”**.

The presence of a number of hurdles inhibiting or reducing the number of microorganisms may be synergistic. Some hurdles rely on a change of the physiological status of microorganisms, which leads to stress. Consequently, other subsequent hurdles can become more efficient. Therefore, it may require less of each hurdle to control growth than would be expected from considering the effect of each individual hurdle.

When Hurdle Technology is applied as the key control mechanism to obtain and/or retain a safe end product, its effectiveness should be validated taking into consideration the characteristics of the individual microorganism(s) of concern.

When Microbiocidal Treatments are not applied, the safety and suitability of the end product will depend on the selection and effective application of Hurdle Technology in combination with control measures enforced at farm level. If the use of hurdles is not sufficient, the application of adequate microbiocidal processing step(s) may be necessary.

When using Hurdle Technology for product development, the effect of a hurdle(s) on product safety and shelf life should be considered thoroughly within the context of the application of the HACCP principles, where appropriate.

When establishing product shelflife, and noting that shelflife is an inherent control measures, it is the responsibility of the manufacturer to ensure that the milk product produced is safe and suitable throughout its shelf life, taking into consideration the potential for 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 hurdles are built into the product to prevent such growth.

SCOPE AND USE OF THE ANNEX

The provisions in this Annex provide guidance on how to manage (validate, use, implement and verify) hygienic control systems based upon the use of Hurdle Technology to control microbiological hazards and suitability in the manufacture of milk and milk products.

These provisions apply in conjunction with relevant sections of the principles and guidelines contained in the main body of this Code as well as relevant sections of the other Annexes to this Code and should apply whenever Hurdle Technology is used.

When employing the treatments described in this Annex, expert advice and consultation are necessary to ensure that effective implementation is executed.

DEFINITIONS

Hurdle

Hurdle Technology

Shelf Life

(Additional definitions to be included, as necessary)

INDIVIDUAL HURDLES

Hurdles that reduce microbiological load (destroying/removing)

“Bactofugation”

Centrifugation

High-pressure treatment*

Microfiltration*

Pulsed electric field (PEF) technology*

Pulsed high-intensity light*

Sonication*

Thermization

*) These technologies may, depending on their intensity, also be applied as Microbiocidal Treatments.

Hurdles that limit and/or prevent growth

Competitive microflora

Freezing

Modified atmosphere

pH control

Refrigeration

Ripening (ageing)

Use of Preservatives

Water activity control

ESTABLISHING THE DESIGN OF THE HURDLE TECHNOLOGY SYSTEM INCLUDING THE SELECTION OF HURDLES

Objectives

Procedures

Combination of Hurdles

(Additional sections to be considered)

APPLICATION OF HURDLE TECHNOLOGY IN HYGIENE MANAGEMENT SYSTEMS

Performance criteria of Hurdle Technology

Temperature/time control

Specific processing requirements

Combinations of hurdles

Process control

Prevention of post-process contamination

Determination of product shelf life

Management of Hurdle Technology in a HACCP system

ANNEX II, PART B**GUIDELINES FOR THE APPLICATION AND MANAGEMENT OF MICROBIOCIDAL TREATMENTS****INTENDED APPROACH (NOT PART OF THE ANNEX)**

The annex will be developed with focus on the management (validation, use, implementation and verification) of Microbiocidal Treatments, understood as being individual processing steps that by themselves achieve a safe and suitable (intermediate) product as a result of the treatment.

Microbiocidal Treatments are among the possible control measures that, in combination with other control measures applied at primary production level, during manufacture and during distribution, may be used to achieve an acceptable level of protection.

The guidance provided herein is an integral part of the Code and will therefore apply whenever such treatments are used in the manufacture of milk and milk products to meet the principles established in the main body of the Code, including the HACCP based approach, where appropriate.

Guidance will also be provided with respect to providing adequate follow-up on the provisions provided for the annex addressing primary production (small holder dairy farms).

The thermal Microbiocidal Treatments addressed are the most commonly used. This should not preclude the application of other thermal treatments with at least equivalent effect:

- (i) Pasteurization*
- (ii) Commercial sterilization,*
- (iii) Warm packaging and*
- (iv) Melting cheese and milk products into processed cheese.*

In general, non-thermal Microbiocidal Treatments are currently used only on a limited basis, as the technologies are still under development. In certain cases, similar technologies can be used both as a hurdle and as a Microbiocidal Treatment depending on its application; when applied with sufficient intensity they may be suitable as Microbiocidal Treatments.

Explanatory narratives will be provided, as necessary.

INTRODUCTION AND OBJECTIVES

Pasteurization and other heat treatments of milk that have at least an equivalent effect, applied by an appropriate time/temperature combination, are traditionally used as a key treatment step in the manufacture of milk and milk products to result in a safe product. Non-thermal Microbiocidal Treatments exist, such as irradiation, and new techniques are currently being developed.

The alternative provisions implemented in small holder dairy farms (see Annex IC) may require particular attention to Microbiocidal Treatments at the plant level, in some cases, to ensure the safety of the product.

A Microbiocidal Treatment only reduces the number of micro-organisms at the point in the manufacturing process where it is applied and its effectiveness in terms of the safety and suitability of the end product depends on the initial microbiological load, the effect of the process, and any post-treatment contamination. Therefore, Microbiocidal Treatments can normally not be applied as a single control measure but must be applied in appropriate combinations with other control measures as deemed necessary by the hazard analysis.

SCOPE AND USE OF ANNEX

The provisions in this Annex provide guidance on how to manage (validate, use, implement and verify) hygienic control systems based upon the use of Microbiocidal Treatments to control microbiological hazards and suitability in the manufacture of milk and milk products.

These provisions apply in conjunction with relevant sections of the principles and guidelines contained in the main body of this Code as well as relevant sections of the other Annexes to this Code and should apply whenever Microbiocidal Treatments are.

When employing the treatments described in this Annex, expert advice and consultation are necessary to ensure that effective implementation is executed.

DEFINITIONS

Aseptic packaging

Commercial sterilization

Hermetically sealed container

In container sterilization

Pasteurization

UHT (ultra high temperature) treatment

ESTABLISHING THE EFFECTIVENESS OF MICROBIOCIDAL TREATMENTS

Objective

Procedures

(Additional sections to be considered)

THERMAL MICROBIOCIDAL TREATMENTS

Descriptions of processes

Pasteurization

Commercial sterilization

Warm packaging

Melting of cheese and other products into processed cheese

Performance criteria for other processes

Specific equipment requirements

Application of Thermal Microbiocidal Treatments

NON-THERMAL MICROBIOCIDAL TREATMENTS

Descriptions

High-pressure treatment

Irradiation

Pulsed electric field (PEF) technology

Sonication

Performance criteria of process

Specific equipment requirements

Application of Non-Thermal Microbiocidal Treatments

APPLICATION OF MICROBIOCIDAL TREATMENTS IN HYGIENE MANAGEMENT SYSTEMS

General guidelines

Process control

Temperature/time control

Lay-out/design of the process flow

Prevention of post-treatment contamination

Determination of product shelf life

Management of Microbiocidal Treatments in a HACCP system

ANNEX III

[To be developed. To contain annexes providing support information (e.g., water reuse.)].