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CODE OF HYGIENIC PRACTICE FOR
DAIRY INDUSTRY
(First Revision)

SRI LANKA STANDARDS INSTITUTION

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SLS 872 : 2009

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SRI LANKA STANDARDS INSTITUTION
17. Victoria Place
Elvitigala Mawatha
Colombo 8
Sri Lanka.

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**CODE OF HYGIENIC PRACTICE FOR DAIRY INDUSTRY
SLS 872 : 2009**

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Sri Lanka Standard
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FOREWORD

This Sri Lanka Standard was approved by the Sectoral Committee on Agricultural and Food Products and was authorized for adoption and publication as a Sri Lanka Standard by the Council of the Sri Lanka Standards Institution on 2009-05-29.

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 cooling 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 ensure the safety and suitability of milk and milk products to protect consumers' health and to facilitate trade. It is also the purpose of this Code to prevent unhygienic practices and conditions in the production, processing and handling of milk and milk products. 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. 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.

This Code was first published in 1989 and is being revised with a view to updating it with the latest publication of Codex Alimentarius Commission/Code of Hygienic Practice for Milk and Milk Products CAC/RCP 57 – 2004.

This Code is subject to the restrictions imposed under the Food Act No. 26 of 1980 and the regulations framed thereunder, wherever applicable.

The provisions of this Code are supplemental to and should be used in conjunction with, the SLS 143 - Code of Practice for General Principles of Food Hygiene.

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 text of this Code may be met in practice.

In revising this Code, the assistance derived from the publications of the Codex Alimentarius Commission (CAC) and International Dairy Federation (IDF) is gratefully acknowledged.

1 SCOPE

1.1 This Code applies to the production, processing and handling of milk and milk products. Where milk products are referred to in the Code it is understood that this term also includes composite milk products.

1.2 This Code does not extend to the production of raw drinking milk.

1.3 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. This Code should only be used within the context of an understanding that there is a continuous system of controls that are applied from production to consumption.

2 REFERENCES

- SLS 143 Code of practice for general principles of food hygiene
SLS 614 Potable water
Part 1 : Physical and chemical requirements
Part 2 : Bacteriological requirements
SLS 467 Code of practice for labelling of prepackaged foods
SLS 1173 Guidelines for the application of Hazard Analysis Critical Control Point System
CAC/GL 030 – 1999 Principles and Guidelines for the Conduct of Microbiological Risk Assessment
CAC/GL 21 – 1997 Principles for the Establishment and Application of Microbiological Criteria for Foods

3 DEFINITIONS

For the purpose of this Code, following definitions shall apply:

3.1 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.

3.2 composite milk products : A product of which the milk, milk products or milk constituents are an essential part in terms of quality in the final product, as consumed provided that the constituents not derived from milk are not intended to take the place in part or in whole of any milk constituent.

3.3 contaminant : Any biological or chemical agent, foreign matter, or other substances not intentionally added to food which may compromise food safety or suitability.

3.4 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.

3.5 intended use : 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.

3.6 milk : Milk is the normal mammary secretion of milking animals obtained from one or more milkings without either addition to it or extraction from it, intended for consumption as liquid milk or for further processing.

3.7 milk product : A product obtained by any processing of milk, which may contain food additives, and other ingredients functionally necessary for the processing.

3.8 minimize : To reduce the likelihood of occurrence or the consequence of an unavoidable situation such as microbiological growth.

3.9 process criteria : The process control parameters (e.g. time, temperature) applied at a processing step.

3.10 raw milk : Milk which has not been heated beyond 40 °C or undergone any treatment that has an equivalent effect.

3.11 shelf life : The period during which the product maintains its microbiological safety and suitability at a specified storage temperature and, where appropriate, specified storage and handling conditions.

4 PRIMARY PRODUCTION

These guidelines are supplemental to those prescribed in Clause 4 of the **SLS 143**.

Details on specific approaches to the production of milk intended for further processing of an unspecified nature are given in Annex 1 of this Code. 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 clause should be subjected to the application of control measures described in Annex II.

Principles Applying to the Primary Production of Milk

Milk shall 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 shall be minimized.

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

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

4.1 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.

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

4.2 Hygienic production of milk

4.2.1 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.

4.2.2 Animal health

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

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

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

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

4.2.3 General hygienic practice

4.2.3.1 Feeding

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

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

4.2.3.2 Pest control

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

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

4.2.3.3 Veterinary drugs

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

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

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

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

4.2.4 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.

4.3 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.

4.3.1 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 shall meet recognized design and construction standards. Recognized guidelines also exist for the proper use, cleaning and maintenance of milking equipment; such guidelines should be followed to avoid transfer of disease between animals through milking equipment and to help ensure obtaining milk that is safe and suitable.

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

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

4.3.2 Milk storage equipment

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

4.3.3 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.

4.3.4 Collection, transport and delivery procedures and equipment

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.

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

4.4 Documentation and record keeping

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

5 ESTABLISHMENT : DESIGN AND FACILITIES

These guidelines are supplemental to those prescribed in Clause 5 of the SLS 143.

5.1 Equipment

Equipment should be designed and installed such that as far as possible dead ends or dead spots in milk pipelines do not occur. Where dead ends or dead spots occur, special procedures should ensure they are effectively cleaned or otherwise do not permit a safety hazard to occur.

6 CONTROL OF OPERATION

These guidelines are supplemental to those prescribed in Clause **6** of the **SLS 143**.

This Clause contains principles for the control of operation that are intended to be applied in such a manner as to result in meeting acceptable levels of relevant hazards specified as Food Safety Objectives and/or related objectives and criteria, or end product criteria that have been established to express the level of protection for the specific situation. Guidelines for applying the principles with respect to physical, chemical and microbiological hazards are provided in this Clause 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 Clause, milk should be produced in accordance with Clause **4** and Annex I of this Code.

6.1 Control of food hazards

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

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

Where appropriate control measures and/or control measure combinations are chosen to control hazards that are reasonably likely to occur, the procedures described in Clauses **6.1.1** to **6.1.3** 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.

6.1.1 Hazard identification and evaluation

All potential hazards should be identified.

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

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

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

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

6.1.2 Control measure selection

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

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

6.1.3 Establishment of process criteria

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

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

6.2 Key aspects of hygiene control systems

6.2.1 Temperature and time controls

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

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

6.2.1.1 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.

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

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

6.2.1.2 Distribution of finished products

Milk and milk products should 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 nonperishable 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.

6.2.1.3 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.

6.2.2 *Specific process steps*

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

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

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

6.2.3 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.

6.2.3.1 Incoming Milk

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

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

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

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

6.2.3.2 Microbiological criteria

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

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

6.2.4 Microbiological cross contamination

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

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

6.2.5 Physical and chemical contamination

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

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

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

6.3 Incoming material (other than milk) requirements

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

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

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.

6.4 Water

Dairy processing establishments should have potable water, conforming to the **SLS 614**.

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

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

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

*These criteria depend upon the origin and the intended use of the water. For example, reuse water intended for incorporation into a food product should at least meet the microbiological requirements of potable water (see **SLS 614 Part 2**).*

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.

7 ESTABLISHMENT: MAINTENANCE AND SANITATION

These guidelines are supplemental to those prescribed in Clause **7** of the **SLS 143**.

7.1 Maintenance and cleaning

Processing areas should be kept as dry as possible.

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

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

7.2 Cleaning programmes

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

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

8 ESTABLISHMENT: PERSONAL HYGIENE

No specific requirements beyond those prescribed in Clause **8** of the **SLS 143** are needed.

9 TRANSPORTATION

These guidelines are supplemental to those prescribed in Clause **9** of the **SLS 143**.

9.1 Requirements

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

9.2 Use and maintenance

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

10 PRODUCT INFORMATION AND CONSUMER AWARENESS

These guidelines are supplemental to those prescribed in Clause **10** of the **SLS 143**.

10.1 Labelling

Milk products should be labelled in accordance with the **SLS 467** and the relevant labelling requirements specified in product 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.

11 TRAINING

These guidelines are supplemental to those prescribed in Clause **11** of the **SLS 143**.

11.1 Training programmes

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

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

ANNEX I

GUIDELINES FOR THE PRIMARY PRODUCTION OF MILK

INTRODUCTION AND OBJECTIVES

The detailed information prescribed 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 Clause 4 of the text of the Code by providing guidelines for their application.

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

SCOPE

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

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

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-clause.

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.

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.

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

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

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

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

4 PRIMARY PRODUCTION

4.1 Environmental hygiene

When water is used for the cleaning of the udder and for cleaning equipment used for the milking and storage of milk, should be potable water, conforming to the **SLS 614**.

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.

4.2 Hygienic production of milk

4.2.1 *Areas and premises for milk production*

4.2.1.1 Animal holding areas

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

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

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

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

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

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

4.2.1.2 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, conforming to **SLS 614**, should be used in milking areas, product storage areas and other critical areas.

4.2.2 Animal health

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

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

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

Milk should be drawn from animals that:

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

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

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

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

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

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

In addition, it is necessary that the milk also be checked for other relevant aspects in accordance with Clause **6.2.3** (microbiological and other specifications) which can have an impact on the safety and suitability of raw milk products; these results may provide information regarding the health status of the animals.

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

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

4.2.3 General hygienic practice

4.2.3.1 Feeding

The relevant practices on Good Animal Feeding should be applied to minimize or prevent the introduction of contaminants through feed or feeding practices.

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

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

- the design of silos;
- good production practices of silage;
- regular check of the quality of the fermented feed (organoleptic inspection or pH).

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

4.2.3.2 Pest control

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

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

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

If it is necessary to resort to chemical pest control measures, such products should be approved officially for use in food premises and used in accordance with the manufacturer's instructions.

Any pest control chemicals should be stored in a manner that will not contaminate the milking environment. Such chemicals should not be stored in wet areas or close to feed stores. It is preferable to use solid baits, wherever possible.

No pesticides should be applied during milking.

4.2.3.3 Veterinary drugs

The relevant procedures on the Control of veterinary drug residues in milk and milk products should be applied to minimize or prevent the introduction of drug residues in milk or milk products.

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

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

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

The veterinarian and/or the livestock owner or the collection centre should keep a record of the products used, including the quantity, the date of administration and the identity of animals. Appropriate sampling schemes and testing protocols should be used to verify the effectiveness of on-farm controls of veterinary drug use and in meeting established MRLs.

4.2.4 *Hygienic milking*

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

Milking should be carried out under hygienic conditions, including:

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

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

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

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

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

4.2.4.1 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.

4.2.4.2 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.

4.2.4.3 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 conform to the **SLS 614**, so 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, conforming to the **SLS 614**, should be used in contact with milking equipment and other milk contact surfaces.

4.2.4.4 Health and personal hygiene of milking personnel

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

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

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

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

4.3 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.

4.3.1 Milking equipment

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

Milking equipment should be installed and tested (if applicable) in accordance with manufacturer's instructions and in accordance with any available technical standards that have been established by appropriate technical standards setting organizations for such equipment (e.g., IDF, ISO) 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.

4.3.2 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) 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 should be used only to store milk and milk products.

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

4.3.3 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 potable water conforming to the **SLS 614**, for use in milking and in cleaning of equipment and instruments;
- protection against vermin;
- easily cleanable floors, if applicable; and
- adequate separation between milking areas and any premises where animals are housed in order to prevent contamination of milk by animals. Where separation is not possible, adequate measures should be taken to ensure that the milk is not contaminated.

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

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

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

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

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

Deviations from those temperatures may be acceptable if those deviations will not result in an increased risk of microbiological hazards, have been approved by the manufacturer receiving the milk, have been approved by the competent authority, and the end product will still meet the microbiological criteria established in accordance with **6.2.3.2**.

4.3.4 Collection, transport and delivery procedures and equipment

4.3.4.1 Collection, transport and delivery procedures

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

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

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

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

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

Milk haulers should wear clean clothing.

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

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

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

When driver's clothing and footwear 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.

4.3.4.2 Collection, transport and delivery equipment

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.

4.3.4.3 Transport time and temperature

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

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

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

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

Deviations from this temperature may be acceptable if these deviations will not result in an increased risk of microbiological hazards, have been approved by the manufacturer receiving the milk, have been approved by the competent authority and the end product will still meet the microbiological criteria established in accordance with 6.2.3.2.

4.4 Documentation and recordkeeping

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

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

ANNEX II GUIDELINES FOR THE MANAGEMENT OF CONTROL MEASURES DURING AND AFTER PROCESSING

INTRODUCTION AND OBJECTIVES

The detailed information contained in this annex should be implemented in order to prevent, eliminate or reduce hazards associated with incoming materials to acceptable levels and to reduce the likelihood of milk contamination resulting from inadequate control of manufacturing operations. This information will enable the implementation of the principles prescribed in Clause 6 of the text of the Code by providing guidelines for their application.

These measures should be used in combination with guidelines on primary production stated 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 guidelines specified in Clause 6 of the Code (Control of Operation), in particular Clause 6.1 and should apply to the manufacture of any milk product. The principles in Clause 6, 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.

DEFINITIONS

The definitions below apply for the purpose of this Annex, and in addition to those definitions stated in Clause 3 of the text of this Code.

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

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

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

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

6 CONTROL OF OPERATIONS

6.1 Control of food hazards

It is important that control measures are applied during both primary production and processing to minimize or prevent the microbiological, chemical or physical contamination of milk. In addition, special attention should be given during the processing of different milk products so that inadvertent cross-contamination does not occur, including with respect to ingredients that may contain allergenic substances.

Note: A distinction can be drawn between the types of control measures used for microbiological hazards and those used for chemical and physical hazards. The control measures used for chemical and physical hazards in food are generally preventive in nature, i.e., they focus on avoiding the contamination of food with chemical or physical hazards in the first place rather than on reducing or eliminating such hazards once they have been introduced into the product. It should be noted however that there are some exceptions to this type of distinction, e.g., the use of filters, screens and metal detectors to remove certain physical hazards.

Microbiological food hazards are controlled by appropriate selection of control measures applied during primary production in combination with control measures applied during and after processing. The result of applying any microbiocidal control measure depends significantly on the microbial load (including the concentration of microbiological hazards) in the material subjected to it. It is therefore important that preventive measures are applied in primary production to reduce the initial load of pathogenic microorganisms as well as during processing

to avoid contamination within the processing environment. The initial microbial load significantly impacts the performance needed for the microbiological control measures applied during and after processing as well as the performance required for suitability. The safety and suitability of the end product depends not only on the initial microbiological load and the efficiency of the process, but also on any post-process growth of surviving organisms and post-process contamination.

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

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

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

6.1.1 *Hazard identification and evaluation*

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

The hazard identification should be based on the initial descriptions developed during preliminary steps contained in the SLS 143, SLS 1173 and on experience, external information, as well as epidemiological and other historical data that have been associated with the type of food under consideration, the type of raw materials and ingredients used, and that may be introduced during the processing distribution. To insure a comprehensive approach, the various step(s) in the manufacturing process, from material selection through processing and distribution, where a hazard may occur or be introduced should be identified.

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

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

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

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

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

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

6.1.2 Control measure selection

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

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

Selection of individual Control measures

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

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

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

Combination of microbiological control measures

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

The combination of control measures has two main objectives:

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

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

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

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

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

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

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

6.1.3 Establishment of process criteria

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

The performance of control measures and control measure combinations selected should be validated. 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 6.2.3.1 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.

6.2 Key aspects of hygiene control systems

6.2.1 *Time and temperature control*

6.2.1.1 Distribution of finished products

Perishable products:

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

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

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

Particular attention should be paid throughout storage and distribution to:

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

Products stable at ambient temperatures:

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

6.2.1.2 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.

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

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

Shelf life determination can be carried out at the plant level by testing products subjected to the storage conditions specified or by predicting microbial growth in the product under the specified storage conditions. Reasonable anticipated temperature abuse can be integrated into the study or be taken into account by applying an appropriate safety factor (e.g., by shortening the maximum durability specified in the labelling or by requiring lower storage temperatures).

6.2.2 Microbiological and other specifications

6.2.2.1 Milk

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

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

Any non-compliance with the above mentioned criteria, and in particular with regards to pathogens, should result in immediate corrective actions at the farm level and in the manufacturing establishment, for example: rejection of the milk for the processing of raw milk products; corrective actions on the milking procedure (cleaning and sanitation procedures of the milking equipment, cleaning or sanitation procedures of the udder, etc.); quality of feed; the

hygienic quality of the water supply; practices in animal holding areas; individual check of animals to find the animal(s) that may be the carrier; isolation of that animal from the herd as necessary. Corrective actions should be identified and implemented, and specific assistance to the dairy farm may need to be provided.

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

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

APPENDIX A : MICROBIOSTATIC CONTROL MEASURES

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

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

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

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

Note : 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.

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 (CO₂) : The addition and/or formation of carbonic acid to obtain a multiple inhibitory effect, including the creation of anaerobic conditions by replacing oxygen, reducing pH, inhibiting certain intracellular enzymes (decarboxylation), and inhibiting the transport of water-soluble nutrients across the membrane (by dehydrating the cellular membrane). The

efficiency depends mainly on the point of application. In ripened cheese, the emission of carbon dioxide from the cheese to the outside environment is often utilized to provide (almost) anaerobic conditions in the headspace of cheese packaging.

Coatings : The introduction of a physical barrier against contamination, with or without antimicrobial substances implemented into it (immobilized) to obtain a slow migration of these from the surface.

Freezing : The lowering of temperature below the freezing point of the product combined with a reduction of the water activity. Freezing has microbiostatic as well as microbicidal effects.

Lactoferrins : Retardation through the utilization of naturally present glycoproteins (highest concentration in colostrum) to prolong the lag phases of bacteria for 12-14 hours, by binding iron in the presence of bicarbonates.

Modified atmosphere: The establishing of a gaseous environment (either low in oxygen and/or high in carbon dioxide or nitrogen) to limit growth of aerobic microorganisms by impairing biochemical pathways. Modified atmosphere packaging (MAP) means that a modification of the gas atmosphere in the packaging is created. Establishing anaerobic environment to limit growth of aerobic microorganisms may proliferate certain anaerobic pathogenic microorganisms.

Packaging: Packaging provides a physical barrier that protects against access of microorganisms from the surroundings.

pH reduction: The creation of extra-cellular acid conditions that enables hydrogen ions to be imported into the cytoplasm of microorganisms, thus disturbing the homeostasis mechanism of the intracellular pH responsible for maintaining functionality of key cell components vital for continuing growth and viability. Low pH values are obtained by fermentation or addition of acids (inorganic or organic). The pH value for preventing growth depends on the pathogen, but lies typically between pH 4.0-5.0. Microorganisms become more sensitive to other microbiological control measures at lower pH. Synergy occurs with salt, water activity, organic acids and antimicrobial substances.

(Use of) Preservatives: The addition of certain additives to enhance keeping quality and stability through direct or indirect antimicrobial and/or fungicidal activity. Most preservatives are rather specific and have effect only on certain microorganisms.

Redox potential control: The redox potential (Eh) is a measure of the oxidizing or reducing potential of food systems that determines whether aerobic or anaerobic microorganisms are able to grow. Eh is influenced by removal of oxygen and/or addition of reducing substances (e.g. ascorbic acid, sucrose, etc.).

Refrigeration: The lowering of product temperature to limit microbial activity.

Time: The practice of applying very short collection/storage periods, limiting the shelf life of products, or immediate processing of raw milk to ensure that all microorganisms present are in the lag phase, and therefore not active and more susceptible to other microbiological control measures.

Water activity control: The control of the water activity (a_w) in the product (the accessibility of water for microorganisms, not the water content in the food), expressed as the ratio of water vapour pressure of the food to that of pure water. The a_w value for preventing growth depends on the pathogen, but lies typically between 0.90 and 0.96. Water activity can be controlled by:

- concentration, evaporation and drying, which also increase the buffering capacity of milk (synergy);
- salting (addition of sodium chloride), which also reduces the cell resistance against carbon dioxide and in the solubility of oxygen (synergy); and
- sweetening (addition of sugars), which at a_w below 0.90-0.95 also results in an antimicrobial effect, depending on the type of sugar (synergy).

APPENDIX B: MICROBIOCIDAL CONTROL MEASURES

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

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

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

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

Examples of typical microbiocidal control measures include the following:

Centrifugation: The removal of microbial cells of high density from milk using high centrifugal forces. Most efficient against microbial cells of high density, notably bacterial spores and somatic cells.

Commercial sterilization : The application of heat at high temperatures for a time sufficient to render milk or milk products commercially sterile, thus resulting in products that are safe and microbiological stable at room temperature.

Competitive microflora : The reduction of the number of undesirable microorganisms by lowering the pH, consumption of nutrients, and production of bacterial antimicrobial substances (such as nisin, other bacteriocins and hydrogen peroxide). Usually, this microbiological control measure is applied by choice of starter cultures. The efficiency is determined by many factors, including the speed and level of pH-reduction and variations in the pH level.

“Cooking” of cheese curd : The application of heat to cheese curd, mainly for technical purposes. The heat treatment has a lower intensity than thermization but stresses microorganisms to become more susceptible to other microbiological control measures.

Electromagnetic energy treatment : Electromagnetic energy results from high voltage electrical fields, which alternate their frequency millions of times per second ($< 10^8$ MHz). Examples are microwave energy (thermal effect), radio-frequency energy (non-thermal effects) or high electric field pulses (10 - 50 kV/cm, non-thermal effects). The treatment destroys cells by establishing pores in the cell walls due to the build up of electrical charges at the cell membrane.

High-pressure treatment : Application of high hydrostatic pressures to irreversibly damage the membranes of vegetative cells.

Microfiltration : Removal of microbial cells, clumps and somatic cells by recirculation over a microfilter. Normally, a pore size of ~ 0.6 - $1.4 \mu\text{m}$ 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 pathogenic microorganisms to a level at which they do not constitute a significant health hazard.

Pulsed high-intensity light: The application of (on e.g. packaging material, equipment and water) high intensity broadband light pulses of wavelengths in the ultraviolet, visible and infrared spectrum ($\sim 20,000$ times sunlight) to destroy microorganisms. Due to the inability to penetrate in-transparent substances, the technology is only effective against surfaces, for instance, in the removal of biofilm and can therefore prevent cross contamination.

Ripening (ageing) : The holding for such time, at such temperature, and under such conditions as will result in the necessary biochemical and physical changes characterizing the cheese in question. When applied as a microbiocidal control measure, the multifactorial, 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.

1 PASTEURIZATION OF MILK AND FLUID MILK PRODUCTS

1.1 Description of process

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

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

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

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

1.2 Process management

Performance criteria

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

Process criteria

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

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.

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

Verification of process

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

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.

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.

Note: Low residual alkaline phosphatase levels in heat-treated milk (below 10 µg p-nitro-phenol equivalent/ml) are taken as assurance that the milk has been correctly pasteurized and that it has not been contaminated by raw milk. However, although this measure is still considered as being the most appropriate method of verification, the factors listed below influence the residual levels and should be taken into account when interpreting the results.

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

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

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

2 COMMERCIAL STERILIZATION OF MILK AND MILK PRODUCTS

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

2.1 Description of process

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

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

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

2.2 Process management

Performance criteria

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

Process criteria

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

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

UHT treatment

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

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

Verification of process

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

2.3 Application of commercial sterilization

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

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