Annexes to

Quality Based Milk Payment Study

Mission Report
January 12 – February 1



Prepared by:

Irwin Foreman MSc (Agric)

[Dairy Industry Consultant (UK)]

Berend De Leeuw DVM

[The Friesian (The Netherlands)]

Quality Based Milk Payment Study

Meetings Schedule

Date	Persons Met	Irwin	Berend
14.01.13	SNV staff	+	+
15.01.13	SNV staff	+	+
15.01.13	Analabs: Dr. Capstick	+	+
16.01.13	NKCC: Luke Kingu (Field Services Officer) Geoffrey Bartenge (Chief Manager Factory Operations)	+	+
17.01.13	Kinangop: Edwin Munyori (Production Manager) Dr Maiteri (Head of Extension)	+	+
18.01.13	Bio Foods:Binoy Zachariya	+	+
18.01.13	Sameer: Charles Marete (Senior Manager Procurement and Extension) Norah Yagomba (Procurement Coordinator) Sanjay Sharma (Deputy GM)	+	+
21.01.13	Kabiyet Milk Collection Center: Tahir Mahmood (Nestle) Abraham Rugut (Coop Chairman) Belinda Kosgei (MCC Manager)	+	+
22.01.13	Gerard and Catherine Oosterwijk/QA staff Happy Cow Nakuru		+
22.01.13	KDB: Machira Gichohi (MD) Dr. Cherono (Chief Technical Officer) Joyce Kiio (Technical Officer)	+	
23.01.13	KDB: Joyce Kiio (Technical Officer)	+	+
24.01.13	Nestle: Emmanuel Scharer	+	+
27.01.13	New KCC: Dr. Kipkirui Arap Lang'at (MD) Emillie Mugeni (Head of QA)	+	+
30.01.13	KDB: Machira Gichohi (MD) Dr. Cherono (Chief Technical Officer) Joyce Kiio (Technical Officer)	+	+
31.01.13	Tetra Pak: Helen Too (Marketing Director)	+	+
1.01.13	Brookside: John Gethi and Emmanuel Kabaki (Milk Procurement and Extension Services)	+	+

Annex 1

KENYA DAIRY INDUSTRY REGULATIONS

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KENYA DAIRY INDUSTRY REGULATORY REQUIREMENT - 2009.

In the pursuant of Part (III) of the Dairy Industry Act, Chapter 336 of the Laws of Kenya, sections (17, 19 and 20), Kenya Dairy Board (KDB) developed the following regulations to be applied during the production, transportation, processing and marketing of milk and milk products.

1. REGULATION 1A: TERMS, DEFINITIONS AND ABBREVIATIONS

1.1: DEFINITIONS

The following definitions shall apply in the interpretation and enforcement of this regulatory document.

a. **Abnormal Milk:** Milk that is visibly changed in colour, odour, viscosity or texture.
b. **Milk Transporter:** A person who transports milk and milk products from a farm, a milk collection point, a milk collection center, a chilled raw milk storage tank to or from a milk processing plant, receiving station or transfer station or retail milk shop.
c. **Milk Sampler:** A person who has in their possession a permit from Kenya Dairy Board or any other competent Authority to sample milk and milk products
d. **Bulk Milk Collection Tanker:** A bulk milk collection tanker is a vehicle, including the truck, tank and its accessory equipment necessary for its use, used by a milk transporter to transport bulk raw milk from a dairy farm, a milk collection center to a milk processing plant or retail milk shop.
e. **Dairy Farm:** A dairy farm is any place where or premises where one or more lactating animals are kept, and from which milk is obtained and sold or offered for sale to persons, to milk traders, to milk collection centers, to milk processing plants or to retail milk shops.
f. **Official Milk Sampler:** A person responsible for the collection of official samples. This person is an employee of the regulatory agency or is empowered by the regulatory agency, and is evaluated once every two year period by the regulatory agency.
g. **Goat Milk:** Goat milk is the normal lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy goats. Goat milk sold in retail packages shall contain not less than 7.5 percent milk solids non fat. Goat milk shall be produced according to the sanitary standards of this regulation. The word "milk" shall be interpreted to include goat milk.
h. **Dry Milk and Whey Products:** A dry milk and whey products are products which have been produced for use in pasteurized or aseptically processed milk products and which have been manufactured under the provisions of this Regulation.
i. **Milk Trader:** A milk trader is any person who offers for sale or sells to another, any milk or milk products.
j. **Milk Processing Plant:** A milk processing plant is any place, premises or establishment where milk or milk products are collected, handled, stored, processed, packaged or prepared for distribution.
k. **Primary Producer:** A milk producer is any person who produces milk for sale, but does not include persons employed for that purpose
l. **Milk Products:** Milk products include all products in which milk is an ingredient. Milk products also include those dairy foods made by modifying the products. This definition shall include milk and milk products as defined herein, which have been aseptically processed and packaged.
   This definition shall include milk and milk products that have been packaged and then processed by sterilization in a retort.
   This definition does not include dietary products or infant formula.

m. **Milk Transport Van:** A milk transport van is any vehicle prescribed to transport milk in milk cans.
n. **Milk Bar:** Is a fixed milk retail premise handling less than 1000 liters per day of processed milk and milk products and distributing directly to consumers.
o. **Milk Tank Truck and Milk Transport Van Cleaning Facility:** Any place, premises, establishment, separate from a milk processing plant, milk collection center, milk or receiving station, where a milk tank or milk churns are cleaned and sanitized.
p. **Milk Tank Truck and Milk Transport Van Driver:** A milk tank truck and milk transport van driver is any person who transports raw or pasteurized milk products to or from a milk collection center, a milk processing plant, a milk receiving station, a milk transfer station or a retail milk shop. Any transportation of milk from a milk collection center requires the milk tank or transport van driver to have responsibility for accompanying official samples.
q. **Milk Transport Tank:** A milk transport tank is a vehicle, including the truck and tank, used by a bulk milk transporter to transport bulk shipments of milk from a milk collection center, a dairy farm or farms, a processing plant to a retail milk shop, another milk collection center or a processing plant.
r. **Milk Transportation Company:** A milk transportation company is the person responsible for a milk tank truck or a milk transport van vehicle.
s. Official Laboratory: An official laboratory is a biological, chemical or physical laboratory which is accredited by Kenya National Accreditation Service (KENAS) or the equivalent to perform analyses of milk and milk products.
t. **An officially designated laboratory**: Is a laboratory accredited by KENAS and authorized to perform analyses of milk and milk products, by Kenya Dairy Board
u. Pasteurization: The terms "pasteurization", "pasteurized" shall mean the process of heating every particle of milk or milk product, in properly designed and correctly operated equipment in accordance with EAS 69:2000 Specification for pasteurized milk.
v. **Person:** The word "person" shall include any individual, plant operator, partnership, cooperative, corporation, company, firm, trustee, association or institution.
w. **Milk Collection Center or Milk Bulking Center:** A milk collection center is any place, premises or establishment where raw milk is received, collected, handled, stored or cooled and prepared for further transportation.
x. **Reconstituted or Recombined Milk and Milk Products:** Reconstituted or recombined milk and/or milk products shall mean milk or milk products which result from reconstituting or recombining milk powder or milk constituents with potable water.
y. **Potable Water:** Potable water is water that is of a quality suitable for drinking whose quality requirements complies with KS-05- 459 part1, Specification of drinking water.
z. **Sheep Milk:** Sheep milk is the natural lacteal secretion practically free from colostrum, obtained by the complete milking of one or more healthy sheep.
aa. **Camel Milk:** Camel milk is the normal lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy camels.
bb. **Cow milk:** Cow milk means the normal, clean and fresh secretions, without any addition or subtraction, extracted from the udder of a healthy cow, and free from colostrum, i.e. excluding that got during the first seven days after calving.
cc. **Transfer Station:** A transfer station is any place, premises or establishment where milk or milk products are transferred directly from a milk tank, milk, milk transport truck or transport van vehicle to another.
dd. **Regulatory Agency:** The regulatory agency shall mean the Kenya Dairy Board (KDB). The term "regulatory agency" whenever it appears in this regulation shall mean the Kenya Dairy Board and its authorized and designated officers having jurisdiction, control and responsibility for the matters embraced in this document.

ee. **Aseptic Processing:** The term "Aseptic Processing" when used in the context of a dairy process, means that the product has been subjected to a sufficient heat process and packaged aseptically in a hermetically sealed container to maintain commercial sterility of the product under normal non-refrigerated conditions.
ff. **Sanitization:** Is the application of any effective method or substance to properly cleaned surfaces for the destruction of pathogens, and other microorganisms, as far as is practicable. Such treatment shall not adversely affect the equipment, the milk or milk product, or the health of the consumers, and shall be acceptable to the regulatory agency.
gg. **VIP:** Ventilated improved pit latrine.
hh. **Single Service Articles** are any packaging materials, or other material which is intended for single use which will come into contact with milk or milk product.

1.2 ABBREVIATIONS

FDD – Flow Diversion Device
HTST – High temperature short time
KDBIs – Kenya dairy board inspectors
UHT – Ultra high temperature
CCL – Critical Control Limit
CCP – Critical Control Point
CIP – Cleaning-in-Place
FDD – Flow Diversion Device
HACCP – Hazard Analysis and Critical Control Point
HTST – High Temperature Short Time
KDB – Kenya Dairy Board
KEBS – Kenya Bureau of Standards
KENAS – Kenya national Accreditation Services

1.3 REGULATION 1B: ADULTERATED OR MISBRANDED MILK OR MILK PRODUCTS

No person shall, within the jurisdiction of the regulatory agency, provide, sell, offer or expose for sale or have in possession with intent to sell any milk or milk product which is adulterated or misbranded. This regulation shall be used in impounding milk and milk products, or preferring charges against persons who adulterate or misbrand milk or milk products or label them with misleading information or information that has not been authorized by the regulatory agency.

1.4 REGULATION 1C: LICENCES AND PERMITS

It shall be unlawful for any person who does not possess a license or permit from the regulatory agency to sell or offer to sell, or to have in storage with intent to sell raw milk, boiled milk or any processed milk or milk products. Excluded from this provision are retail shops, supermarkets and grocery shops and similar establishments selling packaged branded processed milk and milk products, restaurants where milk and milk products are served or sold.

Only a person who complies with the requirements of this document shall be entitled to receive and retain such a permit or license. Permits/ license will not be transferable with respect to persons and/or locations.

The regulatory agency shall suspend such license/permit, whenever it has reason to believe that a public health hazard exists, or whenever the permit holder has violated any of the requirements of this regulation, or whenever the permit holder has interfered with the regulatory agency in the performance of its duties. Provided, that the regulatory agency shall, in all cases except where the milk or milk product involved creates, or appears to create, an imminent hazard to the public health, or in the case of a willful refusal to permit authorized inspection, serve upon the holder a written notice of intent to suspend the permit, which notice shall specify with particularity the violation(s) in question and afford the holder such reasonable opportunity to correct such violation(s) as may be agreed to by the parties, or in the absence of agreement, fixed by the regulatory agency before making any order of suspension effective. A suspension of permit will remain in effect until the violation(s) has been corrected to the satisfaction of the regulatory agency.

Upon notification, acceptable to the regulatory agency, by any person whose permit has been suspended, or upon application within 48 hours of any person who has been served with a notice of intention to suspend, and in the latter case before suspension, the regulatory agency shall within 72 hours proceed to a hearing to ascertain the fact of such violation(s) or interference and upon evidence presented at such hearing shall affirm, modify or rescind the suspension or intention to suspend.

Upon repeated violation(s), the regulatory agency may revoke such permit following reasonable notice to the permit holder and an opportunity for a hearing. This section is not intended to preclude the institution of court action.

1.4.1 Issuance of Permits

Every milk producer selling milk directly to consumers, milk trader, milk transporter, milk collection center operator, milk processor, retail bulk raw and boiled milk shop operators shall hold a valid permit. The permit for a milk tank truck and milk van vehicle may be issued to the milk transport company.

Milk producers, who transport milk only from their own dairy farms or their employees, shall not be required to possess a bulk milk hauler's permit. Grocery stores, supermarkets, restaurants and similar establishments where milk and milk products are served and sold, but do not process, are exempt from the requirements of this section.

1.4.2 Suspension of Permits and licenses

When any requirement(s) of this regulation is violated, the permit/ license holder is subject to the suspension of his/her permit/license. The regulatory agency may forego the suspension of the permit, provided the product or products in violation are disposed of according to existing regulations.

1.4.3 Hearings

Appropriate procedures, including provision for notice, hearing officer, rules of evidence and court review shall be established by the appropriate agency.

1.4.4 Reinstatement of Permits and licenses

Any milk producer, milk trader, milk transporter, milk collection center operator, milk processor or retail bulk raw and boiled milk shop operator whose permit has been suspended may make written application for the reinstatement of his/her permit.

When the permit suspension has been due to a violation of these regulations or other dairy produce standards, the regulatory agency within one week after the receipt of the notification for reinstatement of the permit, shall issue a temporary permit after determining by an inspection of the facilities and operating methods that the conditions responsible for the violation have been corrected.

1.5 REGULATION 1D: LABELLING

All bottles, containers and packages enclosing processed milk or milk products, shall be labeled in accordance with the Kenya / EAC standards.

All bottle, containers and packages enclosing milk or milk products, except milk tank trucks, milk cans containing raw milk, storage tanks in raw and boiled milk retail sales shops, milk storage tanks in milk collection centers, shall be conspicuously marked with:

1. Identity of the plant where pasteurized or UHT treated milk was processed.
2. The words “Keep refrigerated after opening” in the case of aseptically packaged milk and milk products.
3. The word “Goat” or “Sheep” or “Camel” shall precede the name of the milk or milk product when the product is made from goat, sheep or camel milk respectively.
4. The word “reconstituted” or “recombined” if the product is made by reconstitution or recombination.
5. In the case of condensed or dry milk products the following shall also apply:
    a. The identity of the regulatory Agency issuing such permit and if distributed by another party, the name and address of the distributor shall be shown by a statement, such as “Distributed by”.
    b. A code or lot number identifying the contents with a specific date and batch of the product, and the quantity of the contents of the container.

All milk tank trucks, milk van vehicles containing or transporting milk in bulk or in milk churns shall be legibly marked with the name and address of the milk plant or milk transporter in possession of the contents. All cans of raw milk from individual dairy farms shall be identified by the name or number of each individual milk producer at the collection center or the processing plant.

Milk tank trucks, milk van vehicles transporting raw milk in bulk or in milk churns to a milk collection center or a milk processing plant or to a retail milk sales shop are required to be marked with the name of and address of the milk transporter or the milk trader. In addition each transporter will be accompanied by a delivery note containing at least the following information:

1. Date and time of collection at the farm or milk collection center.
2. Milk tanker or churn transport vehicle license.

3. Farmer's name and address or milk collection center identification.
4. Driver's name.
5. Volume of milk taken from each of the farmers or the milk collection center or the farm tank, and the respective volumes loaded in each compartment of the tanker, or into milk churns. All milk churns must be numbered and carry an ID to identify their source.
6. Name and Signature of the milk collection center manager/ or appointee, the farmer and the transport driver.

1.5.1 Identity Labeling

"Identity" is defined as the name and address of the milk processing plant at which the pasteurization, UHT or other heat treatment and packaging has taken place. In cases where several processing plants are operated by one company, the common company name may be utilized on product packages. Provided, that the location of the plant at which the contents were heat treated and packaged is also shown, either directly or by a code. This requirement is necessary in order to enable the regulatory agency to identify the source of the milk or milk product.

The identity labeling requirement may be interpreted as permitting plants and persons to purchase and distribute, under their own label, milk and milk products processed and packaged at another processing plant, provided that the label reads, "Processed" at (Name and address), or that the processing and packaging plant is identified by a known code.

1.5.2 Misleading Labels

The regulatory agency shall not permit the use of any misleading marks, words or endorsements upon the label. They may permit the use of registered trade designs or similar logos on the bottle cap or label, when in their opinion, they are not misleading and are not used so as to obscure the labeling required by the regulation.

1.6 REGULATION 1E: THE EXAMINATION OF MILK AND MILK PRODUCTS

It shall be the responsibility of the milk and milk products business owner or operator, to collect a representative sample of milk or milk product in accordance with Kenya/EAC standard sampling procedure and deliver to a laboratory approved by the Regulatory Agency. The number of samples and frequency of submission shall be as outlined below:

1. **Milk Collection Centres**: During any consecutive twelve (12) months at least three (3) samples of raw milk for processing shall be collected from each milk collection centre, in at least three (3) separate months, when the sampling days will be separated by not less than sixty (60) days.
2. **Milk Processing Plants:** During any consecutive twelve (12) months, at least three (3) samples of raw milk for processing, shall be obtained by the processing plant and submitted to the regulatory agency approved laboratory for quality analysis.
3. **Milk Processing Plants:** During any consecutive twelve (12) months, at least six (6) samples of pasteurized and/or ultra-heat treated milk products, from milk processing plants offering such products for sale, shall be submitted to a laboratory approved by the regulatory agency.
4. **Milk Processing Plants:** During any consecutive twelve (12) months, at least two (2) samples of each dairy product processed in any milk processing plant, shall be submitted to a laboratory approved by the Regulatory Agency.
5. The Regulatory Agency shall obtain representative samples of milk and milk products while in the possession of the producer, milk plant or distributor at any time prior to delivery to the shop or consumer. Samples of milk and milk products from dairy retail shops, supermarkets, grocery

shops and other places where milk and milk products are sold shall be examined periodically by the Regulatory Agency and the results of such examination shall be used to determine compliance with Kenya/EAC products standards. Proprietors of such establishments shall furnish the Regulatory Agency, upon request, with names of all distributors from whom milk or milk products are obtained.

6. Whenever the results of tested samples exceed the standard for milk or milk products, the Regulatory Agency shall send a written notice thereof to the proprietors/person concerned. This notice shall be in effect as long the results of the last two (2) consecutive samples exceed the standard. An additional sample shall be taken within twenty one (21) days of the sending of such a notice.
7. Immediate suspension of permit, in accordance with regulation 1C, and/or court action shall be instituted whenever the standard is violated during third sampling and testing.
8. Whenever pasteurized milk is phosphatase test positive, the cause shall be determined. Where the cause is improper pasteurization, it shall be corrected and any milk or milk product involved shall not be offered for sale.
9. Whenever a pesticide residue test is positive, an investigation shall be made to determine the cause and the cause shall be corrected. An additional sample shall be taken and tested for pesticide residues and no milk or milk products shall be offered for sale until it is shown by a subsequent sample to be free of pesticide residues or below the actionable levels established for such residues.
10. UHT processed milk or milk product shall comply with the requirements of Kenya/EAC standards. No UHT milk product shall be sold until it can be shown that the processes, equipment and procedures used are suitable for consistent production of a commercially sterile product.
11. For retort sterilized milk and milk products all products from a lot found to contain two (2) or more non-sterile units shall be recalled and disposed of as directed by the Regulatory Agency. For continuously processed UHT milk and milk products, packaged aseptically, all product from a lot found to contain by calculation more than one half (0.5) percent of the total number of packages processed in the batch, shall not be offered for sale and if released for sale shall be recalled and disposed of as directed by the Regulatory Agency.
12. Samples shall be analysed at an officially designated laboratory. All sampling procedures required for laboratory examinations shall be in accordance with the EAC milk and milk products standards.

1.7 ENFORCEMENT PROCEDURES

Detection of all non-conforming products should be followed promptly by inspection to determine and correct the cause.

Retort-sterilized milk and milk products and UHT processed milk and milk products are exempt from the refrigerated storage requirements of this regulation. Therefore, whenever a breakdown in the processing or packaging of these products occurs, an imminent hazard to public health exists. Prompt action is needed by the Regulatory Agency. Milk processing plants processing retort-sterilized or UHT processed milk and milk products in hermetically sealed containers should be encouraged to perform bacterial and other quality tests on each lot of these products produced in order to ascertain that these products have been properly processed and have not been rendered non-sterile after processing and packaging. The Regulatory Agency may utilize industry records, of each lot of retort-sterilised or UHT processed milk and milk products, to determine when lots can be released for sale after a violation of the bacterial standards has existed.

1.8 LABORATORY TECHNIQUES

Procedures for the collection and handling of samples, the selection and preparation of apparatus and instrumental analytical equipment, media and reagents, and the analytical procedures, incubation, reading, recording and reporting of results shall be in accordance with the methods described in Kenya /EAC dairy standards.

When a warning letter has been sent, because of non-compliance with any of the preceding test results, an official inspection of the dairy farm, milk collection centre or dairy processing plant should be made by the regulatory personnel. In the case of an official inspection of a dairy farm, the visit should be made during milking time.

All methods used in the determining violation of standards shall be in accordance with Kenya/ EAC standard procedures.

1.9 SMAPLING PROCEDURES

Sampling shall be in accordance with the Kenya/ EAC Standards methods for the examination of milk and milk Products.

REGULATION 2: KENYA DAIRY INDUSTRY REGULATORS

In pursuant of part III section 17-20 of the Dairy Industry Act cap 336 of laws of Kenya, Kenya Dairy Board is mandated to regulate the dairy industry activities.
Under this Act Kenya Dairy Board Inspectors (KDBIs) or their Appointed Agents shall inspect dairy farms, milk collection centers, transporters, milk bars, cottage industries, mini dairies, milk plants, and milk retailers to determine their compliance to the requirements of this regulation and subsequent issuance of permits/license

2.1 Certification of Dairy Industry Inspectors

The purpose of certification is to have the applicants formally demonstrate their inspection ability to apply proper interpretations of this document, related documents and the Regulatory Agency's procedures. The certification and inspection process shall involve:

1) The Regulatory Agency shall certify industry inspection personnel, to carry out cooperatively the provisions of this document.
2) Reports of all inspections conducted by such personnel to determine compliance with the provisions of this document shall be maintained by the industry at a location acceptable to the Regulatory Agency.
3) The Certified Industry Inspector may perform all punitive actions and all inspections for the issuance or reinstatement of permits in consultation with the Managing Director of KDB.
4) Initial inspections and change of market inspections are required and shall be conducted by the Regulatory Agency.
5) When a producer changes market, the producer records for the preceding twenty-four (24) months shall be transferred with the producer, through the Regulatory Agency, and will continue to be a part of the producer's record.
6) The Dairy inspector shall be certified every three (3) years by the Regulatory Agency.
7) At least annually, the Certified Industry Inspector shall attend a refresher course provided by the Regulatory Agency, or equivalent training acceptable to the Regulatory Agency.

2.2 Qualification of Dairy Industry Inspectors

Prior to conducting the certification procedure, background information shall be secured on the applicant. These shall include:

1) A minimum of a two (2) years certificate course in Dairy Technology and related fields.
2) Experience in the field of dairy sanitation, and shall be an employee of a milk plant, a producer association, officially designated laboratory or shall be employed on a consulting basis.

This information shall be retained by the Regulatory Agency as part of the applicant's file, along with appropriate records of the applicant's performance during the certification examination.

2.3 Inspection reports:

A copy of the inspection report shall be filed as directed by the Regulatory Agency and retained for at least twenty-four (24) months. The results shall be entered on computer or other information retrieval system or other appropriate ledger forms may be used. Examples of field inspection forms are identified in Appendix E.

REGULATION 3: PERSONNEL IN MILK AND MILK PRODUCTS MANUFACTURE

All the personnel involved in milking, milk handling, collection, transportation, processing and distribution shall meet the following requirements:

1) Shall have medical certificates as proof of their medical fitness to handle milk. Milking shall not be performed nor shall milk be handled by persons known, or suspected to be suffering from, or to be a carrier of a contagious or infectious disease or illness which may be transferred through the milk. Such a person shall not take part in the milking until all danger thereof from the communication of the infection to the milk in the opinion of a medical officer of health has ceased and a certificate issued.
2) Shall wear clean outer protective clothing while milking or handling milk and milk products, milk containers, utensils, or equipment.
3) Shall have their hands (up to elbow) washed frequently and always following a visit to the toilet room and before initiating milking or handling of milk and milk products.
4) Shall observe the basic principles of hygiene such as keeping short finger nails, no beard, no spitting in work area, no eating, no nose picking, no drunkenness, no nail vanish, no bangles, no bracelets, no smoking or any other undesirable behaviour during milking, or handling of milk and milk products.
5) Personnel handling milk and engaged in milk transportation should be provided with basic skills in evaluating milk to determine its quality.
6) Personnel involved in milk value addition operations shall have basic professional knowledge in milk and milk products manufacture.
7) All personnel responsible for milk bars, milk collection/cooling center, cottage industry, mini-dairy or a milk processing plant, shall be qualified with a minimum of a 2 years certificate in dairy and/or food technology.

REGULATION 4: STANDARDS FOR MILK AND MILK PRODUCTS

All dairy products offered for sale in Kenya shall comply with the respective Kenya/EAC standards

No process or manipulation other than pasteurization, UHT processing, retort-sterilization, or processing methods integral therewith, and appropriate refrigeration shall be applied to milk and milk products for the purpose of removing or deactivating microorganisms.

Whey shall be from cheese made from, pasteurized milk before use. Buttermilk shall be from butter whose cream has been pasteurized prior to use in accordance with Kenya/EAC milk and milk products standards. Provided, that this requirement shall not be construed as barring any other heat treatment process which has been recognized to be equally efficient in the destruction of microorganisms and which is approved by the Regulatory Agency.

Cheese shall be made from pasteurized milk, which has been heat-treated to a temperature of at least 64°C and held continuously at that temperature for at least thirty (30) minutes or to at least 75°C and held continuously at that temperature for at least fifteen (15) seconds, in equipment meeting the pasteurization requirements complying with Kenya/EAC milk and milk products standards. Provided, that this requirement shall not be construed as barring any other heat treatment process which has been recognized and approved by the Regulatory Agency to be equally efficient in the destruction of pathogenic microorganisms.

REGULATION 5: DAIRY FARMS

5.1 Milk quality

Dairy farms shall offer only good quality milk for sale by ensuring that:

1) Lactating animals which show evidence of the secretion of milk with abnormalities in one (1) or more quarters, such as bloody, stringy, off-coloured milk, or milk that is abnormal to sight or odour, shall be so handled and disposed of as to preclude the infection of other lactating animals and the contamination of milk utensils.

2) Lactating animals secreting milk with abnormalities shall be milked last or in separate equipment, which effectively prevents the contamination of the wholesome supply.

3) Lactating animals producing contaminated milk, that is, lactating animals which have been treated with, have consumed chemical, medicinal or radioactive agents, which are capable of being secreted in the milk and which, in the judgment of the Regulatory Agency, may be deleterious to human health, shall be milked last or with separate equipment and the milk disposed of as the Regulatory Agency may direct.

4) Milking equipment used on animals with abnormalities in their milk shall be maintained clean to reduce the possibility of re-infecting or cross infection of the dairy animals.

5) Equipment, utensils and containers used for the handling of milk with abnormalities shall not be used for the handling of milk to be offered for sale, unless they are first cleaned and effectively sanitized.

5.2 Milking shade construction and cleanliness

A milking shade shall be sited and constructed in such a way as to minimize the risk of environmental contamination and shall be kept clean by ensuring that:

1) Floors are easily cleaned, graded to drain, maintained in good repair, and free of excessive breaks or worn areas that may create pools.
2) Gravity flow manure channels, if used, shall be constructed to ensure effective drainage.
3) Be provided with natural and/or artificial light, well distributed, for day and/or night milking.
4) There is sufficient air space and air circulation to prevent condensation and excessive odours.
5) Manure, fodder residues, effluent and any other wastes shall be disposed of in such a manner as to prevent breeding of pests and bacterial contamination off-flavours and abnormal odours in milk.
6) Feed shall be stored in a manner that will not increase the dust content of the air or interfere with the cleaning of the floor.
7) Auxiliary equipment associated with milking shall be kept clean and stored above the floor.
8) The bedding material, if used, does not contain more manure than has accumulated since the previous milking.
9) Control of insect vectors and rodents.
10) Have separate pens for calves and not overcrowded.
11) Other domestic and non milking animals are kept out of the milking area.
12) Toilets or pit latrines with doors shall be provided away from the milking areas and they shall not communicate directly into the milking or milk storage areas.
13) Wastewater or other effluents shall be disposed of in a drain or in such a manner as to avoid its accumulation in the milking area and the stable.

5.3 Cow yard

Dairy farms that have cow-yards shall keep them clean by ensuring that:

1) They are graded and drained and have no standing pools of water or accumulations of organic wastes.
2) Lactating animal-housing areas, lactating animal droppings and soiled bedding are removed, or clean bedding added, at sufficiently frequent intervals to prevent the soiling of the lactating animal's udder and flanks.
3) Waste feed shall not be allowed to accumulate.
4) Manure packs shall be properly drained and shall provide a reasonably firm footing.
5) Other animals are kept out of the cow-yards.

5.4 Milk storage areas

Where applicable, dairy farms with milk storage rooms shall be so sited and constructed as to avoid risk of contamination of the milk or equipment and shall have:

1) Impervious, easily cleanable floors.

2) Adequate separation between milking areas and any premises where animals are housed.

3) Suitable milk cooling rooms or refrigeration facilities when appropriate.

4) A sufficient supply of potable water for use in milking and in cleaning of equipment and instruments.

5) Be well ventilated. Where possible, windows should be placed to provide cross ventilation.

6) Have adequate natural and/or artificial light and be well ventilated.

7) Be used for no other purpose than milk storage operations.

8) No direct opening into milking shade or into a room used for domestic purposes. Provided, that a direct opening between the milk storage room and milking shade is permitted when a tight-fitting, self-closing, solid door(s) hinged to be single or double acting is provided.

9) Be equipped with adequate facilities for cleaning and sanitizing milking equipment

5.5 Water supply

Dairy farms shall have adequate and clean potable water to facilitate hygienic practices in production and handling of milk on the farm. Potable water shall be achieved by:

1) Using treated water which is appropriate for drinking by animals, cleaning and sanitation of equipment and utensils, and for all relevant processes on the farm.

2) Where potable water is unavailable, treatment of water shall be considered essential e.g. chlorination, sedimentation, filtration, and boiling.

3) Carefully locating and constructing the wells or boreholes to prevent the draining of surface water into the supply.

4) Taking precautions to ensure that dairy animals do not consume or have access to contaminated water likely to cause disease or contaminate milk.

5.6 Toilet and waste disposal facilities

Dairy farms shall be provided with one (1) or more toilets; conveniently located; properly constructed, operated, and maintained in a sanitary manner. The waste shall not pollute the soil surface or contaminate any water supply by ensuring that:

1) Manure and other organic wastes are removed from the milking shade and milk storage rooms and disposed of in a sanitary manner on land or by properly controlled composting and storage.
2) Wastewater or other effluents shall be disposed of in a drain or in such a manner as to avoid its accumulation in the milking area.

3) Human waste shall not be deposited within the milking areas or grazing grounds.

4) Toilets or pit latrines with doors shall be provided away from the milking areas and they shall not communicate directly into the milking or milk storage areas. They shall comply with the relevant regulatory requirements.

5) Dust in the immediate surroundings of milk production shall be controlled not to contaminate the milk.

5.7 Milking equipment

Dairy farms with milking equipment shall ensure that they operate efficiently and are maintained in a sanitary condition by observing the following sanitary practices:

1) New milking equipment shall be installed and tested in accordance with appropriate technical standards.
2) Machine milking installations, when used, shall undergo periodic inspections to verify that they are in good working condition to provide appropriate service. Repairs and adjustments ordered during the inspection shall be implemented. The machines shall be maintained on a regular basis, between inspections.
3) Equipment and instruments or their surfaces which are intended to come into contact with milk (utensils, containers, tanks, etc. intended for milking) shall 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 humans.

5.8 Milk storage equipment

Milk handling and storage equipment shall be approved for milk storage use, including tanks and cans shall be so designed and constructed to avoid any contamination of the milk by ensuring that:

1) There is complete drainage when being emptied.

2) Surfaces of milk storage tanks, cans and associated equipment intended to come in contact with milk shall 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 humans.

3) Milk storage tanks and cans are used to store milk only.

4) Immediately after milking, the milk shall be stored in a clean place, which is equipped to avoid adverse effects on the milk. If the milk is not collected within two hours of milking, it shall be cooled to a maximum temperature of 7^{o}C.

5.9 Cleaning and sanitization of milking and milk storage equipment

Milking equipment shall be cleaned and disinfected using appropriate cleaning agents after each milking. Storage tanks and cans should be cleaned and sanitized / disinfected after each emptying, and remain fully drained between uses. The equipment shall be rinsed with potable water and drained before use, unless it is shown that the disinfectants, when used in accordance with manufacturers' instructions, will not present a health risk to the consumer.

5.10 Hygienic milking practice

Milking methods must be geared to permit the efficient withdrawal of milk without contaminating milk or causing injury to the udder. Milking shall be carried out under hygienic conditions, including:

1) Prior to milking, checking the milk from each teat for visible defects to ensure that the milk is free from infectious diseases and if the milk is abnormal, the milk is not be used for human consumption.

2) Observing strict personal hygiene practices by cleaning udders, teats, groins, thighs and abdomens of the animal.

3) Cleaning and disinfecting or sanitized milking equipment.

4) Avoidance of any damage to the tissue of the udder.

5) Segregating animals showing clinical symptoms of diseases transferable to humans through the milk and milking it last, or milking using separate milking equipment or by hand.

5.11 Machine milking

When using milking machine, proper milking procedure shall be followed as required by the technical requirements including:

1) Before the milking unit is applied to the udder, the operator takes thirty (30) seconds to prepare the lactating animal in the recommended manner to obtain milk letdown, and the milking machine should be applied immediately thereafter.
2) Attaching the teat cups in a manner that limits the volume of air drawn into the system.
3) Positioning the teat cups as low on the teats as practicable.
4) The operator staying near the machine and, at the end point of milk removal, the claw is briefly pulled down to open the teat cavity and remove the strippings. Stripping by machine should not extend over a period of more than fifteen to twenty (15-20) seconds avoid prolonging stripping which can be injurious to the udder.
5) Before removing the machine, the vacuum to the teat cups is broken and the cups removed in a gentle manner; and
6) Avoid over-milking, by the operator limiting the number of machines in use. Two (2) bucket-type units, two (2) movable pipeline units or three (3) fixed units, in a walk-through barn, usually represent maximum workloads with conventional milking systems.

5.**12 Drug and chemical control**

Use of drugs and chemicals on the farm shall be under strict control by taking the following measures:

1) Cleaners and sanitizers shall be stored in properly identified, dedicated end-use containers.

2) Animal drugs and drug administration equipment shall be stored in such a way that milk, milking equipment, wash vats and hand sinks are not subject to contamination.

3) Animal drugs shall be properly segregated, lactating from non-lactating.

4) Unapproved drugs shall not be used.

5.13 Raw milk cooling

Where applicable raw shall be preserved after milking by ensuring that: It is cooled to 10°C or less within two (2) hours if it is not processed immediately.

5.14 Drug residue avoidance control measures

Animal identification and record keeping are critical for avoiding milk drug residues. Producers shall establish systems to ensure that animal drugs are used properly and be able to provide evidence that adequate control over the administration of drugs to prevent residues in milk has been implemented. These control systems shall include the following measures:

1) Identifying lactating animals treated with medicinal agents.
2) Segregating milk from treated animals not offering for sale.

    a. Keeping records of the following information:
    b. Identity of the animal(s) treated;
    c. Date(s) of treatment;
    d. Drug (s) or other chemicals administered;
    e. Dosage administered;
    f. Milk discard time; and
    g. Withdrawal time prior to milking

5.15 Insect and rodent control

1) The milk producer shall control insect and rodents by ensuring that:
2) They employ only those insecticides and rodenticides that are recommended by competent authority for the insect and rodent problems they seek to overcome and shall follow implicitly the manufacturer's label directions for their use.
3) Effective measures shall be taken to prevent the contamination of milk, containers, utensils and equipment by insects and rodents and by chemicals used to control such vermin.
4) Milk storage rooms are free of insects and rodents.
5) Surroundings are kept neat, clean and free of conditions, which might harbor or be conducive to the breeding of insects and rodents.
6) Feed shall be stored in such a manner that it will not attract rodents or insects.

REGULATION 6: MILK COLLECTION CENTERS

6.1 Location and surrounding area cleanliness

Milk collection centers shall be located in areas that do not pose any threat to milk safety and shall be protected from environmental pollution.

6.1.1 Construction of facilities

The premises for milk collection centers shall meet the following requirements:

1) The premises of the collection centers shall be of sufficient area to carry out work under sanitary/hygienic condition.
2) Structure and design shall be able to allow for layout of equipment in such a way that does not impede milk and personnel flow.
3) Material used in construction shall be non-toxic to human.
4) The walls inside shall be smooth and cleanable.

5) The design of floor shall be in such a way that it allows for liquid flow towards the waste drainage.
6) The floor shall be made of water proof material and resistant to chemical actions by acid and alkalis.
7) Drainage shall be adequate and sufficient to drain away waste water/liquids.
8) There shall be adequate bright light either of natural or artificial sources.
9) There shall be adequate ventilation to provide sufficient air circulation

6.1.2 Milk collection points

Milk collection points shall ensure that the following sanitary practices are observed:

1) **Shall have some shade to protect the milk cans from direct sunlight.**
2) **Shall have raised platforms for holding milk cans to avoid contamination from dust, soil or mud and earth.**
3) **Shall carry out basic quality tests such as organoleptic to isolate obvious poor quality milk**
4) **Shall carry out accurate weighing and recording of the milk received before bulking, where applicable.**

6.1.3 Equipment construction and cleanliness

The construction and repair of containers and equipment for milk collection centers shall meet the following requirements:

1) Equipment and containers coming in contact with milk shall be designed and constructed to ensure that they can be adequately cleaned, sanitized and maintained to avoid contamination
2) All equipment surfaces that come into contact with milk shall be of food grade (non-toxic, inert to milk, non-absorbent and affected by cleaning chemicals) preferable stainless steel, aluminium.
3) Equipment shall be kept in appropriate state of repair and condition to facilitate cleaning and sanitation to prevent possible contamination of milk.

6.1.4 Milk storage tanks cleanliness and sanitization

The cleaning and sanitizing of equipment at milk collection centers shall meet the following requirement:

1) Milk storage tanks shall be so designed and constructed as to avoid any contamination of the milk and to ensure complete drainage. Surfaces of milk storage tanks and associated equipment intended to come in contact with milk shall 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 humans.
2) Milk Storage tanks shall be cleaned and sanitized using appropriate cleaning agents after each emptying and remain fully drained between uses.
3) Milk storage tanks shall be used to store milk only.

6.1.5 Water supply

The milk collection centers shall maintain sanitary requirements by ensuring that they shall have:

1) Adequate and clean potable water to facilitate cleaning and sanitation of equipment and utensils
2) Where potable water is unavailable, treatment of water shall be done e.g. chlorination, sedimentation, filtration, and boiling.

6.1.6 Toilet and waste disposal facilities

The milk collection centers shall have toilet and waste disposal facilities that meet the following requirements:

1) Have adequate and appropriate means of disposing of wastes.
2) Have an adequate drainage system to drain off waste water and liquids and soak pits where applicable.
3) Have adequate and suitable bins in which to collect solid wastes and be located in areas that do not pose a risk of contamination of the milk.
4) Toilets or pit latrines with doors shall be provided away from the milking collection areas and shall not communicate directly into the milking collection or milk storage areas.

6.1.7 Milk collection

The milk collection centers shall ensure that:

1) The centers are designed and operated in such a manner that minimizes or prevents the contamination of milk.
2) Milk is checked for quality before it is received by subjecting it to the basic raw milk quality tests such as organoleptic, alcohol, and lactometer to confirm its quality. If the milk shows any indication of spoilage it shall not be received.
3) Milk shall be collected under hygienic conditions to avoid contamination.
4) The milk is weighed accurately and the quantity received recorded.

REGULATION 7: MILK TRANSPORTATION

7.1 Milk sampling procedures

Milk sampling, hauling, and transport are integral parts of a modern dairy industry. Hauling, sampling and transport can be categorized into three (3) separate functions: Dairy or Industry Plant Samplers, Bulk Milk Hauling and Sampling and Milk Transport from one (1) milk handing facility to another. Appropriate sampling procedure shall be followed to obtain a representative sample from the source whether from cans or tankers. The milk shall be sampled in accordance with the Kenya/EAC standard procedures.

The sampling procedure shall ensure that samples are representative of the batches they were obtained from by observing the following procedures:

1) Pick-up and handling practices are conducted to prevent contamination of milk contact surfaces.
2) The milk must be agitated for a sufficient time to obtain a homogeneous blend.
3) While the tank is being agitated, bring the sample container, dipper, dipper container and sanitizing agent for the outlet valve or single-service sampling tubes into the milk-house aseptically. Remove the cap from the tank outlet valve and examine for milk deposits or

foreign matter and then sanitize if necessary. Protect the hose cap from contamination when removing it from the transfer hose and during storage.

4) The sample may only be collected after the milk has been properly agitated. Remove the dipper or sampling device from the sanitizing solution or sterile container and rinse at least twice in the milk.

5) Collect a representative sample or samples from the bulk tank. When transferring milk from the sampling equipment, caution should be used to assure that no milk is spilled back into the tank. Do not fill the sampling container more than ¾ full. Close the cover on the sample container.

6) The sample dipper shall be rinsed free of milk and placed in its carrying container.

7) Close the cover or lid of the bulk tank.

8) The sample must be identified with the producer's number at the point of collection.

9) A temperature control sample must be taken at the first stop of each load. This sample must be labeled with time, date, temperature and producer and bulk milk hauler/sampler identification.

10) Place the sample or samples immediately into the sample storage case.

11) All sample containers and single-service sampling tubes used for sampling shall be in accordance with the Kenya/EAC .standards. Samples shall be cooled to and held between 0°C and 4°C during transit to the laboratory.

7.2 Can transport containers

The milk transported in cans shall meet the following requirements:

1) Cans shall be made of food grade materials (aluminium or stainless steel)
2) Cans shall be designed such that they can be effectively cleaned and sanitized.
3) Cans shall be designed and constructed to ensure complete drainage.
4) Cans and other equipment containing milk shall be properly covered during transportation.
5) Milk cans should exclusively be used to transport milk.
6) Lorries, trucks or other vehicles which carry the tank or cans should be cleaned whenever necessary
7) Vehicles used to transport milk in cans from the dairy farm to the milk plant, receiving station or transfer station shall be constructed and operated to protect their contents from sun and contamination.
8) Vehicles shall have bodies with ventilation and a roof cover.
9) Vehicles shall be kept clean, inside and out.

7.3 Tanker transport containers

The milk transported in tankers shall meet the following requirements:

1) Surfaces of milk transport tankers, intended to come into contact with milk shall 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 consumers.
2) The tankers shall be designed such that they can effectively be cleaned and disinfected.
3) The tankers shall be designed and constructed to ensure complete drainage
4) The tankers shall be used exclusively for milk.
5) The tankers shall be washed and sanitized at the permitted milk plant, receiving station, or transfer station receiving the milk, or at a permitted milk tanker cleaning facility.
6) The tankers shall be effectively agitated in order to collect a representative sample.

7) The tankers shall be parked on a self-draining concrete or equally impervious surface during filling and storage.
8) Sanitized product-contact surfaces, including tanker openings and outlets shall be protected against contact with unsanitized utensils and equipment, hands, clothing, splash, condensation and other sources of contamination.
9) Any sanitized product-contact surface, which has been otherwise exposed to contamination, shall be cleaned and sanitized again before being used.
10) Vehicles used to transport milk from the dairy farm to the milk plant, receiving station or transfer station shall be constructed and operated to protect their contents from sun, and contamination.

REGULATION 8: MILK BARS

8.1 Location and surrounding area cleanliness

Milk bars shall be located in areas that do not pose any threat to milk safety and shall be protected from environmental pollution.

8.2 Floors: Construction

The buildings for milk bars shall meet the following requirements:

1) The floors of all rooms in which milk or milk products are handled, processed, packaged, or stored, or in which milk containers, utensils, and/or equipment are washed, shall be constructed of good quality concrete, or equally impervious tile or brick laid closely with impervious joint material, or metal surfacing with impervious joints, or other material which is the equivalent of good quality concrete. The floors of storage rooms for dry ingredients and/or packaging material may be constructed of tightly joined wood.
2) The floor surface shall be smooth and sloped, so that there are no pools of standing water after flushing, and the joints between the floor and the walls are impervious.

8.3 Walls and ceilings: Construction

The walls and ceiling of the milk bar buildings shall meet the following requirements:

1) Walls shall be tiled to a height of not less than one and half (11/2) meters and ceilings shall have smooth, washable, light-colored impervious materials.
2) Walls, partitions and ceilings shall be kept in good repair.

8.4 Doors and windows

The doors and windows of the milk bars shall have all outer openings that are rodent-proofed to the extent necessary to prevent the entry of rodents.

8.5 Lighting and ventilation

The lighting and ventilation of the milk bars shall meet the following prescribed requirement:

1) Adequate light sources shall be provided (natural, artificial or a combination of both) which furnish at least.
2) Ventilation in all rooms shall be sufficient to keep them reasonably free of odors and excessive condensation on equipment, walls and ceilings.

8.6 Separate rooms

The milk bars shall meet the following layout requirements:

There shall be separate rooms for:

1) The handling and processing of milk and milk products.
2) Cleaning and sanitizing of milk and milk products equipment.
3) Designated for the receiving, handling and storage of returned packaged milk and milk products.

8.7 Toilet-and waste disposal facilities

The milk bars shall have toilet and sewage facilities that meet the following requirements:

1) Shall be clean and sanitary.
2) Toilet rooms shall not open directly into any room in which milk and/or milk products are handled, processed and stored.
3) Toilet rooms and fixtures shall be kept in a clean condition, in good repair and shall be well ventilated and well lit.
4) Toilet tissue and easily cleanable covered waste receptacles shall be provided in toilet rooms.
5) Sewage and other liquid wastes shall be disposed of in a sanitary manner.
6) There shall be adequate and suitable bins in which to collect solid wastes.
7) The bins shall be located in areas that do not pose a risk of contamination of the milk and milk products.
8) There shall be adequate and sufficient drainage to drain off wastewater and liquids.

8.8 Water supply

The milk bars shall have water supply system that meets the following requirements:

1) Shall be of adequate supply, properly located, protected and operated. It shall be easily accessible and of a safe, sanitary quality.
2) The water supply that is approved as safe by the Local Authority and, in the case of individual water systems, complying with Kenya/ EAC Specification for drinking water.
3) There shall be no cross-connection between the safe water supply and any unsafe or questionable water supply, or any source of pollution through which the safe water supply might become contaminated.
4) Where potable water is unavailable, treatment of water shall be done e.g. chlorination, sedimentation, filtration, and boiling.

8.9 Hand washing facilities

The milk bars shall have convenient hand-washing facilities including hot and cold and/or warm water, soap and individual sanitary paper towels. They shall be kept in clean conditions and in good repair.

8.10 Milk bars cleanliness

The cleanliness in milk bars rooms shall meet the following prescribed requirements:

1) Only equipment directly related to milk and milk products handling, shall be kept in milk product storage rooms.
2) Floors, walls, ceilings, shelves, tables and the non-product-contact surfaces of other facilities and equipment shall be kept clean.
3) No trash, solid waste or waste dry product shall be stored within the milk and milk products handling rooms.
4) All rooms in which milk and milk products are handled, processed or stored; or in which containers, utensils, and/or equipment are washed or stored, shall be kept clean, neat and free of evidence of insects and rodents.

8.11 Cleaning and sanitizing of containers and equipment

The cleaning and sanitizing of equipment in the milk bars shall meet the following requirement:

1) All multi-use containers and utensils shall be thoroughly cleaned and sanitized after each use preferably using hot water.

8.12 Storage of cleaned and sanitized containers and equipment

After cleaning, and sanitizing, all the containers and equipment shall be stored on racks made of impervious food grade materials, or in clean shelves elevated above the floor. Containers shall be stored inverted, on racks or in cases constructed of relatively nonabsorbent, impervious, food-grade, corrosion-resistant, non-toxic materials, or otherwise protected from contamination.

8.13 Storage of single-service containers, utensils and materials

To achieve the desired sanitary requirements the storage of single-service bottle caps, packaging paper, containers, bags and other single-service articles for use in contact with milk and milk products:

1) Shall be stored in sanitary wrappings or cartons.
2) Shall be kept in a clean, dry place until used, and shall be handled in a sanitary manner.

8.14 Milk reception

The milk bars shall have:

1) The capacity to assess the quality of milk they use or receive from suppliers.
2) Milk collected under hygienic conditions to avoid contamination of milk.
3) Records of the quality tests results for the milk they receive and use
.

8.15 Milk storage

Milk bars shall handle and store milk and milk products in the following ways:

1) All processed milk and milk products, except those to be cultured, shall be cooled immediately prior to packaging, in approved equipment, to a temperature of 7°C
2) Cooling facilities shall be maintained in good repair.
3) Each storage tank shall be equipped with an indicating thermometer.

8.16 Cleaning and sanitizing of milk handling and storage equipment

Storage tanks and cans shall be cleaned and sanitized using appropriate cleaning and sanitizing agents after each emptying, and remain fully drained between uses. The equipment shall be rinsed with potable water and drained before use, unless it is shown that the disinfectants, when used in accordance with manufacturers' instructions, will not present a health risk to the consumer.

8.17 Milk processing

Milk bars shall process milk and milk products in accordance with the respective Kenya/ EAC standards. They shall ensure that milk and milk products are processed under sanitary conditions by observing the following. Milk bars with batch pasteurization systems shall comply with the following requirements/

1) All indicating and recording thermometers used in connection with the batch pasteurization of milk or milk products shall comply with the applicable specifications. The pasteurizer shall be so designed that the simultaneous temperature difference between the milk or milk product, at the center of the coldest milk or milk product in the vat, will not exceed 0.5°C at any time during the holding period.

2) The vat shall be provided with adequate agitation, operating throughout the holding period and no batch of milk or milk product shall be pasteurized unless it covers a sufficient area of the agitator to insure adequate agitation.

3) Each batch pasteurizer shall be equipped with an indicating and a recording thermometer or manual recording by the operator.

4) The thermometers shall not read less than the required pasteurization temperature throughout the required holding period.

5) The recording thermometer if present shall not read higher than the indicating thermometer.

6) No batch of milk or milk product shall be pasteurized unless it is sufficient to cover the bulbs of both the indicating and the recording thermometer.

7) Batch pasteurizers shall be so operated that every particle of milk or milk product will be held at not less than the minimum pasteurization temperature continuously for at least thirty (30) minutes.

8) No milk or milk product shall be added to the batch pasteurizer after the start of the holding period.

REGULATION 9: DAIRY PLANTS (COTTAGE INDUSTRY, MINI DAIRY AND MILK PLANTS)

9.1 Location and surrounding area cleanliness

The dairy plants shall be located in areas that do not pose any threat to milk and milk products safety and shall be protected from environmental pollution. The dairy plants surroundings shall be kept neat, clean and free from conditions which might attract or harbor flies, other insects and rodents or which otherwise constitute a nuisance by observing the following requirements:

1) There shall be no accumulation of trash, garbage or similar waste in areas adjacent to the milk plant. Waste material stored in suitable covered containers shall be considered in compliance.

2) Driveways, lanes and areas serving milk plant vehicle traffic shall be graded, drained and free from pools of standing water.

3) Outdoor areas for milk tank truck unloading shall be constructed of smooth concrete or equally impervious material, properly sloped to drain and equipped with trapped drains of sufficient size.

4) Only insecticides and rodenticides approved for use by the relevant authority shall be used for insect and rodent control.

5) Rooftops shall be kept clean of dry milk or milk products, which may accumulate and contribute to unsanitary conditions.

9.2 Floors

The floor construction of dairy plants buildings shall meet the following requirements:

1) The floors of all rooms in which milk or milk products are handled, processed, packaged, or stored, or in which milk containers, utensils, and/or equipment are washed, shall be constructed of good quality concrete, or equally impervious tile or brick laid closely with impervious joint material, or metal surfacing with impervious joints, or other material which is the equivalent of good quality concrete.
2) The floor surface shall be smooth and sloped, provided with trapped drains and kept in good repair so that there are no pools of standing water after flushing, and the joints between the floor and the walls are impervious. Provided, that cold-storage rooms used for storing milk and milk products need not be provided with floor drains when the floors are sloped to drain to one (1) or more exits.

9.3 Walls and ceilings

The walls and ceiling of rooms of the dairy plants in which milk or milk products are handled, processed, packaged, or stored; or in which milk containers, utensils and/or equipment are washed, shall meet the following requirements:

1) Walls shall tiled one and half metres from the floor and ceilings shall have a smooth, washable, light-colored surface of impervious materials.
2) Walls, partitions and ceilings shall be kept in good repair.

9.4 Doors and windows

The doors and windows of dairy plants shall meet the following requirements:

1) All outer openings shall be rodent-proofed to the extent necessary to prevent the entry of rodents.
2) The sills should be sloping to prevent it from being used for storage of items.

9.5 Lighting and ventilation

All rooms of dairy plants in which milk or milk products are handled, processed, packaged, or stored, or in which milk containers, utensils and/or equipment are washed shall meet the following requirements:

1) Have adequate natural lighting/ and artificial lights that is not be coloured.
2) Sufficient ventilation to keep them free of odours and build-up of excessive condensation on equipment, walls and ceilings.
3) The bulbs for artificial lighting shall be shatter proof or suitably protected.
4) Pressurized venting, or air conditioners if used shall have a filtered air intake.
5) For milk plants that condense and/or dry milk or milk products, ventilating systems in packaging rooms, where used be separate and where possible have the ducts installed in a vertical position.

9.6 Separate rooms

The dairy plants shall have separate sections for:

1) Milk reception, processing and packaging.
2) The cleaning of milk cans and containers, bottles, cases and dry milk or milk product containers.
3) The fabrication of containers and closures for milk and milk products.
4) Cleaning and sanitizing facilities for milk tankers in milk plants receiving milk.
5) Receiving cans of milk and milk products in milk plants receiving such cans.
6) Designated areas or rooms for receiving, handling and storage of returned packaged milk and milk products.

9.7 Toilet and waste disposal facilities

The dairy plants shall have toilet and sewage facilities that meet the following requirements:

1) Clean and sanitary toilet facilities.
2) Toilet rooms shall not open directly into any room in which milk and/or milk products are handled, processed and stored.
3) Toilet rooms and fixtures that are kept in good repair, well ventilated and well lit.
4) Toilet tissue and easily cleanable covered waste receptacles are provided in toilet rooms.
5) Pit latrines shall not be allowed in milk plants.
6) Sewage and other liquid wastes are disposed of in a sanitary manner.

7) There shall be adequate and suitable bins in which to collect solid wastes.
8) The bins shall be located in areas that do not pose a risk of contamination of the milk and milk products.
9) There shall be drainage adequate and sufficient to drain off liquid waste and sewage in a sanitary manner.

9.8 Water supply

The dairy plants shall have water supply system that meets the following requirements:

1) Adequate supply, properly located, protected, and of a safe sanitary quality.
2) The water supply that is approved as safe by the Local Authority and, in the case of individual water systems, complying with Kenya/ EAC Specification for drinking water.
3) There is no cross-connection between the safe water supply and any unsafe or questionable water supply, or any source of pollution through which the safe water supply might become contaminated.
4) Where potable water is unavailable, treatment of water shall be done e.g. chlorination, sedimentation, filtration, and boiling.
5) Water for different purposes shall be clearly distinguished by colour coding in accordance with the code of hygienic practice in the dairy industry.

9.9 Hand washing facilities

The dairy plants shall have convenient hand-washing facilities that meet the following requirements:

1) Are provided with hot and cold and/or warm water, soap and individual sanitary paper towels.
2) Kept in clean condition and in good repair.
3) The tap shall be non-hand operated in the toilets and milk handling areas.

9.10 Dairy plant cleanliness

The cleanliness in dairy plants shall meet the following requirements:

1) All rooms in which milk and milk products are handled, processed or stored; or in which containers, utensils and/or equipment are washed or stored, shall be kept clean, neat and free of evidence of insects and rodents.
2) Only equipment directly related to processing operations or the handling of containers, utensils and equipment shall be permitted in the processing, cooling, condensing, drying, packaging, and bulk milk or milk product storage rooms.

3) Floors, walls, ceilings, shelves, tables and the non-product-contact surfaces of other facilities and equipment shall be kept clean.

4) All sanitary piping, fittings and connections which are exposed to milk and milk products shall consist of smooth, impervious, corrosion-resistant, non-toxic, easily cleanable material, which is approved for milk product-contact surfaces.

5) All piping shall be in good repair.

6) No trash, solid waste or waste dry product shall be stored within the milk and milk products handling rooms.

7) Pasteurized milk and milk products shall be conducted from one piece of equipment to another only through sanitary piping.

9.11 Construction and repair of containers and equipment

The construction and repair of dairy plants containers and equipment shall meet the following requirements:

1) All multi-use containers and equipment that milk and milk products come into contact with shall be of smooth, impervious, corrosion-resistant, non-toxic material.

2) Shall be constructed for ease of cleaning; and shall be kept in good repair.

3) All single-service containers, closures, gaskets and other articles that milk and milk products come in contact with shall be food grade, non-toxic and shall have been manufactured, packaged, transported and handled in a sanitary manner.

4) Articles intended for single-service use shall not be reused.

9.12 Cleaning and sanitizing of containers and equipment

The cleaning and sanitizing of equipment in the dairy plants shall meet the following requirements:

1) The product-contact surfaces of all multi-use containers, utensils and equipment used in the transportation, processing, condensing, drying, packaging, handling, and storage of milk or milk products shall be effectively cleaned and sanitized before each use. Provided that cloth-collector systems used on dryers shall be cleaned and sanitized or purged at intervals and by methods recommended by the manufacturer. Provided further, that piping, equipment and containers used to process, conduct or package aseptically processed milk and milk products, beyond the final heat treatment process, shall be sterilized before any aseptically processed milk or milk product is packaged and shall be re-sterilized whenever any non sterile product has contaminated it.

2) Storage tanks shall be cleaned when emptied and shall be emptied at least every seventy-two (72) hours. Records must be available to verify that milk storage in these tanks does not exceed seventy-two (72) hours. These records shall be available for at least the previous three (3) months or from the time of the last regulatory inspection, whichever is longer.

3) In the case of pasteurized storage tanks, which are mechanically cleaned at intervals of less than seventy-two (72) hours, the mechanical cleaning records shall be available.

4) Storage tanks, which are used to store raw milk or milk products or heat-treated milk products longer than twenty-four (24) hours and silo tanks used for the storage of raw milk or milk products or heat-treated milk products shall be equipped with a seven (7) day temperature recording device complying with the manufacturer's specifications or manual system of recording with a documented frequency of a maximum of three hours.

5) Evaporators shall be cleaned at the end of a continuous operation, not to exceed forty-four (44) hours, and records must be available to verify that the operation time does not exceed forty-four (44) hours.

6) Drying equipment, cloth-collector systems, packaging equipment and multi-use dry milk products and dry whey storage containers shall be cleaned at intervals and by methods recommended by the manufacturer. Such methods may include cleaning without water by use of vacuum cleaners, brushes, or scrapers. After cleaning, such equipment shall be sanitized by methods recommended by the manufacturer.

7) Cloth collector systems and all dry product-contact surfaces downstream from the dryer shall be sanitized or purged at intervals and by methods recommended by the manufacturer.

8) Storage bins used to transport dry milk or milk products shall be dry cleaned after each usage and washed and sanitized at regular intervals.

9) Pipelines and/or equipment designed for mechanical cleaning shall meet the following requirements:

   i) An effective cleaning and sanitizing regime for each separate cleaning circuit.

   ii) A temperature recording device, complying with the manufacturer's specifications or a recording device which provides sufficient information to adequately evaluate the cleaning and sanitizing regime and shall be installed in the return solution line or other appropriate area to record the temperature and time which the line or equipment is exposed to cleaning and sanitizing solutions.

   iii) Cleaning charts and electronically stored records shall be identified, dated and retained for a minimum of two (2) years for long life products.

   iv) During each official inspection, the Regulatory Agency shall examine charts and records to verify the cleaning regimes.

9.13 Storage of cleaned containers and equipment

Dairy plants shall ensure that cleaned and sanitized containers and equipment are:

1) Transported and stored to assure complete drainage.

2) Protected from contamination before use.

3) Single-service caps, cap stock, parchment paper, containers, gaskets, liners, bags and other single-service articles for use in contact with milk and milk products are purchased and stored in sanitary tubes, wrappings or carton, kept in a clean, dry place until used; and shall be handled in a sanitary manner.

9.14 Protection from contamination

Milk and milk products in dairy plants shall be protected from contamination by observing the following requirements:

1) Milk plant operations, equipment and facilities shall be located and conducted to prevent any contamination of milk or milk products, ingredients, containers, utensils and equipment.
2) All milk or milk products or ingredients that have been spilled, overflowed or leaked shall be discarded.
3) The processing or handling of products other than quality assured processed milk or milk products in the milk plant shall be performed to preclude the contamination of such quality assured milk and milk products.
4) The storage, handling and use of poisonous or toxic materials shall be performed to preclude the contamination of milk and milk products, or ingredients of such milk and milk products, or the product-contact surfaces of all containers, utensils and equipment.
5) Only insecticides and rodenticides approved by the relevant authority shall be used for insect and rodent control. Such insecticides and rodenticides shall be used only in accordance with the manufacturer's label directions and shall be prevented from contaminating milk and milk products, containers, utensils and equipment.
6) All insecticides and rodenticides shall be stored in a lockable poisons cabinet.

9.15 Pasteurization and aseptic processing

Dairy processing plants shall process milk and milk products in accordance with the respective Kenya/ EAC standards.

1) Pasteurization and aseptic processing of milk shall be performed in accordance with the Kenya/EAC standards
2) Pasteurization of raw milk or milk product shall be performed before the raw milk or milk product enters the reverse osmosis (RO), ultra-filtration (UF), evaporator or condensing equipment and shall be performed in the milk plant where the processing is done.
3) All condensed milk and milk products transported to a dairy plant for drying shall be re-pasteurized at the milk plant at which it is dried.
4) Milk tank trucks, dedicated to hauling pasteurized product, shall be used to transport the condensed, partially crystallized whey and shall be washed and sanitized immediately prior to filling and then sealed after filling until unloading.
5) Separate unloading pumps and pipelines shall be provided and used only for the unloading of the condensed, partially crystallized whey. Such pumps and pipelines shall be cleaned and sanitized as a separate cleaning circuit.

9.16 Batch pasteurization of milk and milk products

Dairy plants with batch pasteurization systems shall comply with the following requirements:

1) All indicating and recording thermometers used in connection with the batch pasteurization of milk or milk products shall comply with the applicable specifications. The pasteurizer shall be so designed that the simultaneous temperature difference between the milk or milk product, at the center of the coldest milk or milk product in the vat, will not exceed 0.5°C at any time during the holding period.
2) The vat shall be provided with adequate agitation, operating throughout the holding period and no batch of milk or milk product shall be pasteurized unless it covers a sufficient area of the agitator to insure adequate agitation.

3) Each batch pasteurizer shall be equipped with an indicating and a recording thermometer or manual recording by the operator.
4) The thermometers shall not read less than the required pasteurization temperature throughout the required holding period.
5) The recording thermometer if present shall not read higher than the indicating thermometer.
6) No batch of milk or milk product shall be pasteurized unless it is sufficient to cover the bulbs of both the indicating and the recording thermometer.
7) Batch pasteurizers shall be so operated that every particle of milk or milk product will be held at not less than the minimum pasteurization temperature continuously for at least thirty (30) minutes.
8) No milk or milk product shall be added to the batch pasteurizer after the start of the holding period.

9.17 High temperature short time (HTST) Continuous flow-pasteurization of milk and milk products

Dairy plants with continuous flow-pasteurization systems shall comply with the following requirements:

9.17.1 HTST control equipment

All indicating thermometers and recorder/controller instruments and devices used in connection with the HTST, continuous-flow pasteurization of milk or milk products shall comply with the applicable specifications.

1) Each HTST, continuous-flow pasteurization system shall be equipped with an automatic milk-flow control of the diversion type.
2) Milk or milk product-flow controls shall be of the flow-diversion type, which automatically cause the diversion of the milk or milk product in response to a sub-legal pasteurization temperature which complies with applicable regulations.
3) All Flow Diversion Devices (FDDs) used in continuous pasteurizers shall comply with the following or equally satisfactory specifications:

    i) The forward-flow of milk or milk product below the minimum pasteurization temperature shall be prevented by requiring the timing pump to be de-energized when the milk or milk product is below the pasteurization temperature and the valve is not in the fully diverted position; or by any other equally satisfactory means.

    ii) When a packing gland is used to prevent leakage around the actuating stem, it shall be impossible to tighten the stem-packing nut to such an extent as to prevent the valve from assuming the fully diverted position.

    iii) A leak-escape shall be installed on the forward-flow side of the valve seat. However, when backpressure is exerted on the forward-flow side of the valve seat, while the milk or milk product-flow is being diverted, the leak-escape should lie between two valve seats or between two portions of the same seat, one upstream and the other downstream from the leak-escape. The leak-escape shall be designed and installed to discharge all leakage to the outside, or to the constant-level tank through a line separate from the diversion line

iv) The FDD shall be so designed and installed that failure of the primary motivating power shall automatically divert the flow of milk or milk product.

v) The FDD shall be located downstream from the holder. The flow-control sensor shall be located in the milk or milk product line not more than 46 centimeters (18 inches) upstream from the FDD.

vi) The HTST Milk or Milk Product-Flow Controller Instrumentation shall meet the following requirements with respect to the instrumentation of the milk or milk product-flow controller.

vii) The thermal-limit-controller shall be set and sealed so that forward-flow of milk or milk product cannot start unless the temperature at the controller sensor is above the required pasteurization temperature as defined in this document for the milk or milk product, and the process used, nor continue during descending temperatures when the temperature is below the required pasteurization temperature. The system shall be so designed that no milk or milk product can be bypassed around the controller sensor that shall not be removed from its proper position during the pasteurization process. The cut-in and cut-out milk or milk product temperatures, as shown by the indicating thermometer, shall be determined at the beginning of each day's operation and entered upon the recorder chart daily by the milk plant operator.

viii) In the case of pasteurization systems, with the FDD located downstream from the regenerator and/or cooler section, additional temperature controllers and timers shall be inter-wired with the thermal-limit-controller, and the control system shall be set so that forward-flow of milk or milk product cannot start until all product-contact surfaces between the holding tube and FDD have been held at or above the required pasteurization temperature, continuously and simultaneously for at least the required pasteurization time as defined in this document. The control system shall also be set and sealed so that forward-flow cannot continue when the temperature of the milk or milk product in the holding tube is below the required pasteurization temperature.

ix) Manual switches for the control of pumps, homogenizers or other devices, which produce flow through the holder, shall be wired so that the circuit is completed only when milk or milk product is above the required pasteurization temperature as defined in this document for the milk or milk product and the process used, or when the FDD is in the fully-diverted position.

4) The holding tubes in the HTST system shall comply with the following requirements:

i) Holding tubes shall be designed to provide for the holding of every particle of the milk or milk product for at least the time required in accordance with the standard for the milk or milk product and the process used.

ii) No device shall be permitted for short-circuiting a portion of the holding tube to compensate for changes in rate of milk or milk product-flow. Holding tubes shall be installed so that sections of pipe cannot be left out, resulting in a shortened holding time.

iii) Supports for holding tubes shall be provided to maintain all parts of the holding tubes in a fixed position, free from any lateral or vertical movement.

5) The HTST indicating and recording thermometers shall meet the following requirements:

i) An indicating thermometer shall be located as near as practicable to the temperature sensor of the recorder/controller, but may be located a short distance upstream from the latter where milk or milk product between the two thermometers does not differ significantly in temperature.

ii) The temperature shown by the recorder/controller shall be checked daily by the milk plant operator against the temperature shown by the indicating thermometer. Readings shall be recorded on the chart. The recorder/controller shall be adjusted to read no higher than the indicating thermometer.

iii) The recorder/controller charts shall comply with the applicable provisions.

6) The HTST Flow-Promoting Devices shall meet the following requirements:

i) The pump or pumps and other equipment which may produce flow through the holding tube shall be located upstream from the holding tube, provided that pumps and other flow-promoting devices may be located downstream from the holding tube, if means are provided to eliminate negative pressure between the holding tube and the inlet to such equipment. When vacuum equipment is located downstream from the holding tube, an effective vacuum breaker, plus an automatic means of preventing a negative pressure in the line between the FDD and the vacuum chamber, shall be acceptable.

ii) The speed of pumps or other flow-promoting devices, governing the rate of flow through the holding tube, shall be so controlled as to ensure the holding of every particle of milk or milk product for at least the time required as defined in this document for the milk or milk product and the process used. In all cases, the motor shall be connected to the timing pump by means of a common drive shaft, or by means of gears, pulleys, or a variable-speed drive, with the gear box. The pulley box or the setting of the variable speed shall be protected. Variable speed drives, used in connection with the timing pump, shall be so constructed that wearing or stretching of the belt results in a slowdown, rather than a speedup, of the pump.

iii) The metering or timing pump shall be of the positive-displacement type or shall comply with the specifications for magnetic flow meter based timing systems. Timing pumps and homogenizers, when used as a timing pump, shall not have by-pass lines connected from their outlet pipelines to their inlet pipelines during processing if an additional flow-promoting or vacuum producing device is located within the system.

7) When a homogenizer is used in conjunction with a timing pump:

i) The holding time shall be taken to mean the flow time of the fastest particle of milk or milk product at or above the required pasteurization temperature as defined in this document for the milk or milk product and the process used, throughout the holding tube section; i.e., that portion of the system that is outside of the influence of the heating medium, slopes continuously upward in the downstream direction and is located upstream from the FDD.

ii) Tests for the holding time shall be made when all equipment and devices are operated and adjusted to provide for maximum flow.

iii) When a homogenizer is located upstream from the holding tube, the holding time shall be determined with the homogenizer in operation with no pressure on the homogenizer valves.

iv) For those systems which do not homogenize all milk or milk products and utilize by-pass lines as outlined above, the holding time shall be tested in both flow patterns and the fastest time used. The holding time shall be tested during both forward and diverted-flow. If it is necessary to lengthen the holding time during diverted-flow, an identifiable restriction may be placed in the vertical portion of the diversion pipeline.
v) When vacuum equipment is located downstream from the holding tube, the holding time shall be tested with the timing pump operating at maximum flow and the vacuum equipment adjusted to provide for the maximum vacuum. The holding time shall be tested in both forward and diverted-flow upon installation semiannually; after any alteration or replacement that may affect the holding time and records on such tests kept as evidence.

9.18 Aseptic processing systems

Dairy plants using aseptic processing systems shall meet the following requirements:

1) The design and operation of aseptic processing systems shall comply with the applicable specifications and operational procedures.
2) All indicating thermometers, recorder/controller instruments and devices, used in connection with aseptic processing systems, used for the aseptic processing of milk or milk products shall comply with the applicable specifications.

Each aseptic processing system shall be equipped with at least one (1) alcohol thermometer or an equivalent temperature-indicating device.

a. An accurate temperature recorder/controller shall be installed in the milk or milk product at the holding tube outlet and before the inlet to the cooler or regenerator. The following requirements shall be met with respect to the instrumentation of the temperature recorder/controller:

b. The temperature recorder/controller shall be set so that during milk or milk product processing the forward-flow of milk or milk product cannot start unless the temperature at the controller sensor is above the required temperature for the milk or milk product and the process used, nor continue during descending temperatures when the temperature is below the required temperature. The system shall be so designed that no milk or milk product can be bypassed around the controller sensor, which shall not be removed from its proper position during the processing of aseptic milk and milk products.

c. Additional temperature-controllers and timers shall be inter-wired with the thermal-limit controller, and the control system shall be set so that forward-flow of milk or milk product cannot start until all product-contact surfaces between the holding tube and FDD have been held at or above the required sterilization temperature, continuously and simultaneously for at least the required sterilization time. The control system shall also be set so that forward-flow cannot continue when the temperature of the milk or milk product in the holding tube is below the required temperature. The system shall be so designed that no milk or milk product can be bypassed around the control sensors, which shall not be removed from their proper position during the processing of aseptic milk and milk products.

d. The timing pump in aseptic processing system shall meet the following requirements:

e. A timing pump shall be located upstream from the holding tube and shall be operated to maintain the required rate of milk or milk product flow. The motor shall be connected to the

timing pump by means of a common drive shaft, or by means of gears, pulleys or a variable-speed drive, with the gear box, the pulley box or the setting of the variable speed protected in such a manner that the hold time cannot be shortened. Variable speed drives, used in connection with the timing pump, shall be so constructed that wearing or stretching of the belt results in a slowdown, rather than a speedup, of the pump. The metering or timing pump shall be of the positive-displacement type or shall comply with the specifications for magnetic flow meter based timing systems.

f. The holding time shall be taken to mean the flow time of the fastest particle of milk or milk product throughout the holding tube section, i.e., that portion of the system that is outside of the influence of the heating medium; and slopes continuously upward in the downstream direction; and is located upstream from the FDD.

g. The milk or milk product holding tube for aseptic processing system shall meet the following requirements:

h. The holding period shall be tested and demonstrated that it lasts for the required time. Records for such tests shall be made available to the Regulatory Agency.

i. For new equipment, the holding tube shall be designed to give continuous holding of every particle of milk or milk product for at least the minimum holding time specified in the scheduled process. The holding tube shall be designed, so that no portion of the holding tube between the milk or milk product inlet and the milk or milk product outlet can be heated. In addition, it must be sloped upward at least 2.1 centimeters per meter. Supports for holding tubes shall be provided to maintain all parts of the holding tubes in a fixed position, free from any lateral or vertical movement.

j. No device shall be permitted for short-circuiting a portion of the holding tube to compensate for changes in rate of milk or milk product flow. Holding tubes shall be installed so that sections of pipe cannot be left out, resulting in a shortened holding time.

k. The holding tube length must be such that the fastest flowing particle of any milk or milk product will not traverse the holding tube in less than the required holding time

l. An aseptic processing system which can operate with milk or milk product in forward-flow mode, with less than 518 kPa (75 psig) pressure in the holding tube shall be equipped with a pressure limit indicator/pressure switch in the holding tube to assure that the heated milk or milk product remains in the liquid phase. In systems that do not have a vacuum chamber between the holding tube and the aseptic milk or milk product side of the regenerator, this can be established by verifying that the aseptic processing equipment cannot operate in forward-flow with less than 518 kPa (75 psig) pressure on the aseptically processed side of the regenerator. The pressure limit indicator/pressure switch must be inter-wired so that the FDD, milk or milk product divert system, milk or milk product divert valve or other acceptable control system will move to the divert position, if the milk or milk product pressure falls below a prescribed value. The instrument must be set at a pressure 69 kPa (10 psi) above the boiling pressure of the milk or milk product at its maximum temperature in the holding tube. If this pressure is too low, the resultant vaporization in the holding tube will substantially reduce residence times. The instrument must have a differential pressure switch so that the FDD will move to the divert position if the pressure drop across the injector falls below 69 kPa (10 psi).

9.18.1 Prevention of adulteration with added water

The following measures shall be taken to prevent milk or milk product adulteration with added water:

1) When culinary steam is introduced directly into the milk or milk product, automatic means, i.e., stand-alone and/or PLC-based ratio control system, shall be provided to maintain a proper temperature differential between incoming and outgoing milk or milk products to preclude dilution with water.

2) Where a water feed line is connected to a vacuum condenser and the vacuum condenser is not separated from the vacuum chamber by a physical barrier, means shall be provided to preclude the back-up and overflow of water from the vacuum condenser into the vacuum chamber. This provision may be satisfied by the use of a safety shutoff valve, located on the water feed line to the vacuum condenser that is automatically actuated by a control that shuts off the in-flowing water. This valve may be actuated by water, air or electricity and shall be so designed that failure of the primary motivating power will automatically stop the flow of water into the vacuum condenser.

9.19 Flow Diversion devices

All Flow Diversion Devices (FDDs) used in continuous aseptic process systems shall comply with approved specifications.

9.20 Regeneration heating in pasteurizers and aseptic processing

Regeneration heating in pasteurizers and aseptic processing shall meet the following requirements:

9.20.1 Pasteurizers and aseptic processing systems employing milk or milk product-to-milk or milk product regenerative heating with both sides closed to the atmosphere.

The heating system with this design shall comply with the following or equally satisfactory specifications:

1) Regenerators shall be constructed, installed and operated so that pasteurized or aseptic milk or milk product in the regenerator will automatically be under greater pressure than raw milk or milk product in the regenerator at all times.
2) The pasteurized or aseptic milk or milk product, between its outlet from the regenerator and the nearest point downstream open to the atmosphere, shall rise to a vertical elevation of 30.5 centimeters (12 inches) above the highest raw milk or milk product level, downstream from the balance tank, and shall be open to the atmosphere at this or a higher elevation.

3) The overflow of the top rim of the constant-level tank shall always be lower than the lowest milk or milk product level in the regenerator.

4) No pump shall be located between the raw milk or milk product inlet to the regenerator and the balance tank, unless it is designed and installed to operate only when milk or milk product is flowing through the pasteurized or aseptic milk or milk product side of the regenerator and when the pressure of the pasteurized or aseptic milk or milk product is higher than the maximum pressure produced by the pump. This may be accomplished by wiring the booster pump so that it cannot operate unless:

a) The timing pump is in operation.

b) The FDD is in forward-flow position.

c) The pasteurized or aseptic milk or milk product pressure exceeds, by at least 6.9 kPa (1 psi), the maximum pressure developed by the booster pump. Pressure gauges shall be installed at the raw milk or milk product inlet to the regenerator and the pasteurized or aseptic milk or milk product outlet of the regenerator or the outlet of the cooler. The accuracy of these required pressure gauges shall be checked, by the Regulatory Agency, on installation; quarterly thereafter; and following repair or adjustment.

d) The motor, casing and impeller of the booster pump shall be identified for those systems that rely on a pressure switch, located only on the pasteurized side, and such records maintained.

e) All electric wiring interconnections for the booster pump should be in permanent conduit, except that rubber covered cable may be used for final connections, with no electrical connections to defeat the purpose of any provisions of these regulations.

f) All raw milk or milk product in the regenerator will drain freely back into the balance tank when the raw milk or milk product pump(s) are shut down and the raw milk or milk product outlet from the regenerator is disconnected.

g) When vacuum equipment is located downstream from the FDD, means shall be provided to prevent the lowering of the pasteurized or aseptic milk or milk product level in the regenerator during periods of diverted-flow or shutdown. An effective vacuum breaker, plus an automatic means of preventing a negative pressure, shall be installed in the line between the vacuum chamber and the pasteurized or aseptic milk or milk product inlet to the regenerator.

h) In the case of pasteurization systems, with the FDD located downstream from the regenerator and/or cooler section, the requirements above may be eliminated. Provided, that a differential pressure controller is used to monitor the highest pressure in the raw milk or milk product side of the regenerator and the lowest pressure in the pasteurized side of the regenerator, and the controller is interlocked with the FDD and is set so that whenever improper pressures occur in the regenerator, forward-flow of milk or milk product is automatically prevented and will not start again until all milk or milk product-contact surfaces between the holding tube and FDD have been held at or above the required pasteurization temperature, continuously and simultaneously for at least the required pasteurization time as defined in this regulation.

i) In the case of aseptic processing systems used for producing aseptic milk and milk products, there shall be an accurate differential pressure recorder-controller installed on the regenerator. The scale divisions shall not exceed 13.8 kPa (2 psi) on the working scale of not more than 138 kPa (20 psi) per 2.54 centimeters (1 inch). The controller shall be tested for accuracy against a known accurate standard pressure indicator upon installation; at least once every three (3) months of operation thereafter; or more frequently if necessary, to ensure its accuracy. One (1) pressure sensor shall be installed at the aseptic milk or milk product regenerator outlet and the other pressure sensor shall be installed at the raw milk or milk product regenerator inlet.

j) When culinary steam is introduced directly into milk or milk product to achieve pasteurization or aseptic processing temperature, and vacuum equipment is located downstream from the holding tube, the requirement that a vacuum breaker be installed at the inlet to the pasteurized or aseptic side of the regenerator may be eliminated. Provided, that the differential pressure controller is installed and wired to control the FDD.

k) When the differential pressure controller is installed and wired to control the FDD the raw milk or milk product booster pump may be permitted to run at all times. Provided, that the timing pump is in operation.

9.20.2 Milk or milk product-to-water-to-milk or milk product regenerative heating

Option 1. Milk or milk product-to-water-to-milk or milk product regenerators, with both the milk or milk product and the heat-transfer water in the raw milk or milk product section, closed to the atmosphere, shall comply with the following or equally satisfactory specifications:

1) Regenerators of this type shall be so designed, installed and operated that the heat-transfer-medium side of the regenerator, in the raw milk or milk product section, will automatically be under greater pressure than the raw milk or milk product side at all times.
2) The heat-transfer water shall be safe water and the heat-transfer water shall be in a covered tank, which is open to the atmosphere at an elevation higher, by at least 30.5 centimeters (12 inches), than any raw milk or milk product level downstream from the constant-level tank. The heat-transfer water between its outlet from the regenerator and the nearest point downstream open to the atmosphere shall rise to a vertical elevation of at least 30.5 centimeters (12 inches) above any raw milk or milk product in the system and shall be open to the atmosphere at this or a higher elevation.
3) The heat-transfer water circuit shall be full of water at the beginning of the run and all loss of water from the circuit shall be automatically and immediately replenished whenever raw milk or milk product is present in the regenerator.

4) The overflow of the top rim of the balance tank shall always be lower than the lowest milk or milk product level in the raw milk or milk product section of the regenerator. The regenerator shall be designed and installed so that all raw milk or milk product shall drain freely back to the upstream supply tank when the raw milk or milk product pumps are shut down and the raw milk or milk product line is disconnected from the regenerator outlet.

5) No pump shall be located between the raw milk or milk product inlet to the regenerator and the balance tank, unless it is designed and installed to operate only when water is flowing through the heat-transfer section of the regenerator and when the pressure of the heat-transfer water is higher than the pressure of the raw milk or milk product. This may be accomplished by wiring the booster pump so that it cannot operate unless:

a) The heat-transfer water pump is in operation; and

b) The heat-transfer water pressure exceeds, by at least 6.9 kPa (1 psi), the raw milk or milk product pressure in the regenerator. A differential pressure-controller shall be installed at the raw milk or milk product inlet and the heat-transfer water outlet of the regenerator. The raw milk or milk product booster pump must be wired so that it cannot operate unless the differential pressure is met. The accuracy of the required differential pressure-controller shall be checked on installation; quarterly thereafter; and following repair or replacement. Records for such checks should be kept as evidence.

Option 2. Milk or milk product-to-water-to-milk or milk product regenerators may also be constructed, installed and operated such that the pasteurized or aseptic milk or milk product in the regenerator will be under greater pressure than the heat-transfer-medium in the pasteurized or aseptic milk or milk product side of the regenerator:

1) A differential pressure controller shall be used to monitor pressures of the pasteurized milk or milk product and the heat-transfer-medium.

2) In the case of aseptic processing systems, a differential pressure-recorder shall be used to monitor pressures of the aseptic milk or milk product and the heat-transfer-medium.

3) In either case, one pressure sensor shall be installed at the pasteurized or aseptic milk or milk product outlet of the regenerator and the other pressure sensor shall be installed at the heat-transfer-medium inlet of the pasteurized or aseptic milk or milk product side of the regenerator. This controller or recorder-controller shall divert the FDD whenever the lowest pressure of pasteurized or aseptic milk or milk product in the regenerator fails to exceed the highest pressure of the heat-transfer-medium in the pasteurized or aseptic milk or milk product side of the regenerator by at least 6.9 kPa (1 psi). Forward-flow of milk or milk product shall be automatically prevented until all milk or milk product-contact surfaces between the holding tube and the FDD have been held at or above the required pasteurization or sterilization temperature continuously and simultaneously for at least the pasteurization or sterilization time.

4) The heat-transfer-medium pump shall be wired so that it cannot operate unless the timing pump is in operation.

9.21 Pasteurization and aseptic processing records, equipment tests and examinations

9.21.1 Pasteurization and aseptic processing systems shall keep the following records:

1) All temperature and flow rate pasteurization recording charts or alternative records in place of charts shall be preserved for a period of two years provided, that all records and recording charts for aseptic milk and milk product systems shall be retained for a period of three (3) years. The use of such charts shall not exceed the time limit for which they are designed. Overlapping of recorded data shall be a violation of this regulation.
2) The following information shall be entered on the charts or other records in place of charts as applicable:

9.21.1.1 Batch Pasteurizers:

1. Date
2. Number or location of recording thermometer when more than one is used where applicable
3. A continuous record of the product temperature
4. Extent of holding period, including filling and emptying times when required
5. Reading of indicating thermometer, at the start of the holding period, at a given time or reference point as indicated on the chart
6. Quarterly, the initials of the Regulatory Agency
7. Quarterly, the time accuracy of the recording thermometer as determined by the Regulatory Agency.
8. Volume and name of the pasteurized milk or milk product, represented by each batch or run on the chart
9. Record of unusual occurrences
10. Signature or initials of the operator
11. Name of the milk plant

9.21.1.2 HTST Pasteurizers

Recording thermometer charts shall contain all the specified information above, except (4), and in addition, shall include the following:

1. A record of the time during which the FDD is in the forward-flow position
2. The cut-in and cut-out milk or milk product temperatures, recorded daily by the operator, at the beginning of the run
3. Number (5) from above shall also be recorded immediately after a chart has been changed.

9.21.1.3 Continuous-Flow Pasteurizers or Aseptic Processing Equipment with Magnetic Flow Meter Based Timing Systems:

Flow rate recording charts shall be capable of continuously recording flow at the flow alarm set point and at least 19 liters (5 gallons) per minute higher than the high flow alarm setting. Flow rate recording charts shall contain all the specified information above, except (3), (4), (5), (6), and (7) and in addition shall include the following:

1. A continuous record of the status of the high and low-flow/loss of signal alarms; and
2. A continuous record of the flow rate.

9.21.1.4 Aseptic Processing Systems:

Recording thermometer charts shall contain all the specified information above, except (4). In addition these records shall include the following if applicable:

1. A continuous record of the time during which the FDD, valve or system is in the forward-flow position;
2. A continuous record of applicable regenerator pressures;
3. Not later than one (1) working day after the actual process, and before release for distribution, a representative of the milk plant management, who is qualified by suitable training or experience, shall review all processing and production records for completeness and to ensure that the milk or milk product received the scheduled process. The records, including the recording thermometer chart(s), shall be signed or initialed and dated by the reviewer; and
4. Number (4) Number (6) from above shall also be recorded immediately after a chart has been changed.

9.22 Equipment tests and examinations:

The processing plant shall perform the following tests as indicated in Appendix D on instruments and devices initially on installation; and at least once each twelve (12) months, including the remaining days of the month in which the equipment tests are due; and whenever any alteration or replacement is made which may affect the proper operation of the instrument or device. Provided, that the holding time test shall be conducted at least every twenty four (24) months, including the remaining days of the month in which the equipment check is due.

Test results for Pasteurization and Aseptic Processing Equipment Testing shall be recorded by all milk plants.

Industry personnel conducting the Pasteurization and UHT Processing Equipment Testing must be adequately trained and must be able to demonstrate an acceptable understanding and ability to conduct these tests to the Regulatory Agency.

Industry must physically demonstrate to the Regulatory Agency that they understand and can perform the required equipment tests according to the requirements of this regulation.

The Regulatory Agency shall accept a field practical exercise, a written exam, formal classroom training, on-the-job training or any combination of these except that, if industry personnel do not physically demonstrate the appropriate capability to perform the tests to the satisfaction of the Regulatory Agency, they are not acceptable for conducting such tests.

Continued training such as, but not limited to, on-the-job training with supervision or an acceptable pasteuriser training course should be completed before they reapply for pasteuriser equipment testing approval.

Pasteurization and UHT Processing Equipment Tests shall be conducted at a frequency not less than the requirements of this regulation. Industry shall have responsibility for the performance of all required tests. At least each twenty four (24) months the Regulatory Agency shall physically supervise these tests. Regulatory supervised tests shall include the annual HTST tests. These twelve (12) month tests should be performed at a time that is mutually convenient to all parties. The industry is responsible for conducting these tests even in the absence of the regulatory official, with appropriate supporting report documentation.

Upon initial installation or extensive modification of any pasteurization and aseptic processing equipment, tests shall be physically supervised by the Regulatory Agency.

During an audit, the auditor may conduct any or all of the Pasteurization or Aseptic Processing Equipment Tests. The auditor should, through a combination of physical examination of the equipment and a records review, satisfy themselves that the equipment is properly installed and operated.

9.23 Handling and storage of milk and milk products

Dairy plants shall handle and store milk and milks in the following way:

1) All pasteurized milk and milk products, except those to be cultured, shall be cooled immediately prior to filling or packaging, in approved equipment, to a temperature of 7°C or less, unless drying is commenced immediately after condensing. All condensed whey and whey products shall be cooled during the crystallization process to 7°C or less within 48 hours of condensing, including the filling and emptying time, unless filling occurs above 57°C, in which case, the 48 hour time period begins when cooling is started. Aseptically processed milk and milk products to be packaged in hermetically sealed containers shall be exempt from the cooling requirements.
2) Each refrigerated room in which milk and milk products are stored, except aseptically processed milk and milk products, shall be equipped with an accurate indicating thermometer that complies with the specification. Such thermometer shall be located in the warmest zone of the refrigerated room.

3) Each storage tank shall be equipped with an indicating thermometer, the sensor of which shall be located to permit the registering of the temperature of the contents when the tank contains no more than twenty percent (20%) of its calibrated capacity. Such thermometer shall comply with the applicable specifications.

4) Milk delivery vehicles should be refrigerated.

5) All surface coolers shall comply with the following specifications:

   a. The sections of open-surface coolers shall be so installed as to leave a gap of at least 6.4 millimeters (0.25 inches) between the header sections to permit easy cleaning.

   b. Where header ends are not completely enclosed within the cooler covers, condensation or leakage from the headers shall be prevented from entering the milk or milk product by so shaping the exposed header faces, above and below all gaps, that condensation is directed away from the tubes, and by using deflectors at the bottom of the headers; or by shortening the bottom of the headers; or by shortening the bottom trough; or by some other approved method.

   c. The location of supports of cooler sections shall prevent condensation and leakage from entering the milk or milk product.

   d. All open-surface coolers shall be provided with tight-fitting shields that protect the milk and milk product from contamination by insects, dust, drip, splash or manual contact.

9.24 Bottling, packaging and container filling

Bottling, packaging and container filling of milk and milk products in dairy plants shall meet the following requirements:

1) All milk and milk products, including concentrated (condensed) milk and milk products, shall be bottled and packaged at the milk plant where final pasteurization is performed. Such bottling and packaging shall be done without undue delay following final pasteurization.

2) All bottling or packaging shall be done on mechanical equipment/s which has been approved by the regulatory agency. The term "approved mechanical equipment" shall not be interpreted to exclude manually operated machinery, but is interpreted to exclude methods in which the bottling and capping devices are not integral within the same system.

3) All pipes, connections, de-foaming devices and similar appurtenances shall comply with Items 10 and 11 below. Milk and milk products from continuous de-foamers shall not be returned directly to the filler bowl.

4) Bottling or packaging machine supply tanks and bowls shall be equipped with covers that are constructed to prevent any contamination from reaching the inside of the filler tank or bowl. All covers shall be in place during operation.

5) A drip deflector is installed on each filler valve. Drip deflectors shall be designed and adjusted to divert condensation away from the open container.

6) Container in-feed conveyors to automatic bottling or packaging machines have overhead shields to protect the bottles or packages from contamination. These shields shall extend from the bottle washer discharge to the bottle feed-star, or in the case of single-service packaging

machines, from the forming unit discharge to the filling unit and from the filling unit to the closure unit. Overhead shields shall be required on can in-feed conveyors when the cans are fed to the filler with the covers off.

7) Container coding/dating devices are designed, installed and operated such that the coding/dating operations are performed in a manner that open containers are not subjected to contamination. Shielding shall be properly designed and installed to preclude the contamination of open containers.

8) Container fabricating materials, such as paper stock, foil, wax, plastic, etc., are handled in a sanitary manner and protected against undue exposure during the package assembly operation.

9) Bottling and packaging machine floats shall be designed to be adjustable without removing the cover.

10) The filler pipe of all bottling and packaging machines shall have a diversion apron or other acceptable device, as close to the filler bowl as possible, to prevent condensation from entering the inside of the filler bowl.

11) Filling cylinders on packaging machines shall be protected from contamination by overhead shields. When lubricants are used on filler pistons, cylinders or other milk or milk product-contact surfaces, the lubricant shall be food-grade and applied in a sanitary manner.

12) In the case of aseptic processing systems, the milk and milk product shall be aseptically filled into sterilized containers and hermetically sealed in conformance with the standard.

For milk plants that condense and/or dry milk or milk products, the following shall apply:

1) The filling of condensed and dry milk product containers is done by mechanical equipment. The term "mechanical equipment" shall not be interpreted to exclude manually operated equipment.

2) All pipes and connections comply with Items 10 and 11.

3) Filling devices are constructed so as to prevent any contamination from reaching the product. Covers of filling devices, if used, shall be in place during operation.

4) Packaged dry milk and milk products are stored and arranged so as to be easily accessible for inspection and to permit cleaning of the storage room.

5) All condensed and dry milk product containers are filled in a sanitary manner by methods which:

6) Protect the product from airborne contamination;

7) Prevent manual contact with condensed and dry milk product-contact surfaces; and

8) Minimize manual contact with the product.

9) All final containers for dry milk products shall be new and of the single-service type and sufficiently substantial to protect the contents from impairment of quality with respect to sanitation, contamination and moisture, under customary conditions of handling, transportation, and storage.

10) If portable storage bins are used, they comply with the applicable provisions of Items 10 &11.

11) Containers are closed immediately after being filled.

For milk plants that dry milk products, these dry milk products shall be packaged in new containers, which protect the contents from contamination, and after packaging, shall be stored in a sanitary manner.

For milk plants that condense and/or dry milk or milk products, these condensed and dry milk products may be transported in sealed containers in a sanitary manner from one (1) milk plant to another for further processing and/or packaging.

Condensed and dry milk product packaging containers shall be stored in a sanitary manner.

9.25 Capping, container closure and sealing and dry milk product storage

The capping, closing or sealing of milk and milk product containers in dairy plants shall meet the following requirements:

1) The capping, closing or sealing of milk and milk product containers shall be done in a sanitary manner on approved mechanical capping, closing and/or sealing equipment. The term "approved mechanical capping, closing and/or sealing equipment" shall not exclude manually operated machinery. Hand capping shall be done under hygienic conditions that will be approved by the Regulatory authority. Provided, that suitable mechanical equipment, for the capping or closing of containers is not available, other methods which eliminate all possibility of contamination may be approved by the Regulatory Agency.

2) All mechanical capping, closing or sealing mechanisms shall be designed to minimize the need for adjustment during operation.

3) Bottles and packages that have been imperfectly capped or closed shall be emptied immediately into approved sanitary containers. Such milk or milk products shall be protected from contamination, maintained at 7° C or less, except dry milk products, and subsequently re-pasteurized or discarded.

4) All caps and closures shall be designed and applied in such a manner that the pouring lip is protected to at least its largest diameter and, with respect to fluid milk and milk product containers, removal cannot be made without detection. Single-service containers shall be so constructed that the product and the pouring and opening areas are protected from contamination during handling, storage and when the containers are initially opened.

5) All caps and closures shall be handled in a sanitary manner. The first cap from each tube, the first lap(s) from each roll of cap or cover stock and the first sheet of parchment or cover paper shall be discarded. The subsequent use of loose caps that are left in the cappers at the end of an operating period, after removal from the cap tubes, shall be a violation of this requirements provided, that loose plastic caps and closures supplied by the manufacturer in plastic bags may be returned to storage in a protective wrap if removed from a hopper/descrambler immediately after a production run. Plastic caps and closures remaining in the chute between the hopper and the capping device shall be discarded.

6) All dry milk products shall be stored in a sanitary manner.

9.26 Vehicles

Vehicles in the dairy plants used for the transportation of pasteurized milk and milk products shall meet the following requirements:

1) All vehicles shall be kept clean.

2) Materials that are capable of contaminating milk or milk products shall not be transported with milk or milk products.

3) Milk and milk products, except dry and long life milk products, shall be maintained at 7°C or less.

4) The operation of milk tank cars and shipping bins shall comply with the following provisions:

a) Milk and milk products shall be conducted to and from tank cars or shipping bins only through sanitary conveying equipment. Such equipment shall be capped or otherwise protected when not in use.

b) Inlets and outlets of shipping bins shall be provided with tight-fitting dust caps or covers.

c) Facilities shall be provided for the adequate washing and sanitizing of shipping bins, piping, and accessories at all milk plants receiving or shipping milk or milk products in shipping bins.

d) Shipping bins shall be cleaned at the receiving milk plant immediately after being emptied. The clean shipping bins shall be sanitized at the shipping milk plant before loading. Milk tank trucks, which must make more than one trip while unloading a tank car, need not be cleaned and sanitized after each time they are emptied.

e) Piping connections and pumps used with shipping bins shall be cleaned and sanitized after each use.

f) The doors of tank cars and covers of shipping bins shall be sealed with a metal seal immediately after loading. The seal shall remain unbroken until the contents are delivered to the consignee. Contents of the tank car or shipping bin shall be labeled in accordance with the standard.

g) Vehicles shall have fully enclosed bodies with well-fitted, solid doors.

REGULATION 10: CALIBRATION OF EQUIPMENT AND APPARATUS

The following list of dairy equipment shall be tested for operational functionality and / or calibrated according to the existing regulations.

a. Thermometers (including Indicating, Recording)
b. Pressure Gauges
c. pH meters
d. Electrical Conductivity measuring devices
e. Time/ Frequency equipment
f. Flow Diversion Device (FDD) assembly and function
g. Pressure switches
h. Differential pressure controller

i. Milk or milk product flow controls and temperature cut – in cut –out
j. Continuous flow holding tube – Time
k. Continuous flow Holding tube and alarm

REGULATION 11: ENFORCEMENT

These regulations shall be enforced by the Regulatory Agency in accordance with the Kenya Dairy Industry Act cap 336.

REGULATION 12: PENALTIES

Any person who shall violate any of the provisions of this regulation shall be guilty of a misdemeanor and upon conviction thereof shall be punished by a fine of not more than Ksh. 1,000,000 and/or such persons may be enjoined from continuing such violation(s). Each day upon such a violation(s) occurs shall constitute a separate violation.

Annex 2

Method for the Determination of Specific Gravity of Milk (Lactometer Method)

1. **Scope:** This standard describes a method for determination of the density (specific gravity) of milk.

2. **References:** National British Standard BS 718-1979 Specification for density hydrometers.

3. **Principle of Method:** Determination by use of a pyconometer or a hydrometer (lactometer)

4. **Definitions**

4.1 Density: the weight of a unit volume at a temperature of 20° Celsius (gm per ml).

4.2 Specific Gravity: the ratio of the weight of the unit volume to the weight of the same volume of water (water at 4°C). Specific gravity has no unit of measurement.

5. **Method**

5.1 Preparation of sample: While gently stirring, warm the milk sample to approximately 40° Celsius and retain the temperature for 5 minutes. Stir the sample carefully to prevent incorporation of air bubbles. Cool the sample in a water bath and adjust the temperature to 20±2° Celsius.

5.2 Method: Determine the density (specific gravity) by means of a pyconometer or a hydrometer calibrated to a temperature of 15° Celsius or 20° Celsius.
For the determination use a measuring cylinder whose diameter is such that a space of 3 mm exists between the hydrometer and the wall of the measuring cylinder. Gently pour the milk to be examined into the measuring cylinder down the wall, taking care to prevent the formation of air bubbles or foam. Fill the measuring cylinder to almost the top and then place the hydrometer into the milk causing a displacement of a part of the milk, which is allowed to pour over the rim of the measuring cylinder. Depress the hydrometer slightly into the milk, and release. Allow the hydrometer to float freely and come to rest in the milk.
Read the hydrometer scale at the upper point of the meniscus formed by the milk.

6. **Corrections**

If at the time of measurement, the milk temperature is not equal to the hydrometer calibration temperature, add an appropriate correction, the value A. as given in Table 1. Table 1 applies to hydrometers calibrated for a temperature of 20° Celsius.

Table 1

Measurement Temperature (Degrees Celsius)	A
22	+0.0005
21.5	+0.0004
21	+0.0003
20.5	+0.0001
20	+0
19.5	–0.0001
19	–0.0003
18.5	–0.0004
18	–0.0005

6.2 When using a hydrometer that is calibrated for a density (specific gravity) different from that defined in Paragraph 4.2, corrections should be applied as follows:

6.2.1 Hydrometers calibrated for relative density at 20/4° Celsius
Correct the hydrometer reading by adding on the value A as obtained from Table 1, for the specific temperature.

6.2.2 Hydrometers calibrated for relative density at 20/20º Celsius
(a) Multiply the hydrometer reading by the factor 0.99823 (density of water at 20ºC).
(b) To the result obtained from (a), add the value given in Table 1 for the specific temperature.

6.2.3 Hydrometers calibrated for relative density 15/4° Celsius or for density (specific gravity) for temperature 15° Celsius
Correct the hydrometer reading by the addition of value B given in Table 2, for the specific temperature.

Annex 3

QUALITY BASED MILK PAYMENT SYSTEM STUDY – MEETING OF PROCESSORS	
DATE	20th November2012
VENUE	SNV SRP Office

Agenda of meeting

AGENDA OF THE MEETING	➢ Experience Sharing on Quality Based Milk Payment systems ➢ Potential for a pilot in Kenya. ➢ Way forward
EXPECTED OUTPUT OF THE MEETING	➢ Views from Processors on how to design a QBMPS ➢ Input for the Term of Reference for the QBMPS study

Discussions and actions to be taken

Discussion point	Main discussions and conclusions
Experience Sharing on Quality Based Milk Payment systems	<u>PURE and SURE was a QBMPS that was implemented in Vietman, Indonesia, Serbia and China. It's about milk quantity, quality and cost effectiveness.</u> • The consultant (Mr.Berend from The Friesian) shared experiences from Vietnam, Indonesia and Serbia. • In Vietman they were able to achieve a TPC of below 500,000, while in Serbia it was less that 100,000 the milk was collected at village level. • A functional farmer audit was done periodically to main the standards, PURE and SURE made efforts to avail training and extension to farmers. • The factory employed own quality assurance personnel and Vet doctors who would visit farmers. • The farmer's diagnosis was free but the farmers had to pay for drugs. • The guiding principle for such a system is that farmers would be paid for the quality of milk supplied and not necessarily that the processor will pay more. • Realization that some quality parameters are not externally influenced e.g. Fat and Protein contents is mainly a factor of genetics of the cow. • The basic starting point is for every Processor to set own parameters with available resources (equipment and skills) and improve with time ; "Perform Zero Setting". • QBMP System should be an incentive to the farmers. <u>BIO FOODS</u> • Bio Foods company has been implementing QBMPS in Kenya. • They have 20 years' experience in Kenya • The biggest incentive according to them for suppliers is payment on time and consistency in price.(Leah cited inconsistent and late payments by processors as one of the disincentives to the farmers as far as improving milk quality goes) • Feedback and education to the farmer on milk quality results very important

Potential for Pilot in Kenya	<u>Parameters to consider in QBMPS</u> The consultant facilitated a session to find out what the Kenya processors would be willing to pay for. The results were as follows: (Parameter and No. of processors willing to pay) - Freshness – 8 - Solids Not Fat (SNF) - 6 - Fats and Proteins - 4 - Total solids – 4 - Absence of Antibiotics- 4 - Added water 2 - Microtoxins e.g. Aflatoxins <u>Challenges of the QBMPS</u> Majority of processors were willing to pilot such a system but sited some challenges in Kenya that would be a hindrance: - Processors in Kenya are their "own enemies"; milk rejected by one processor is accepted by the other, this sends wrong signal to the supplier. (The consultant challenged the processors to "fight each other in the market, not on the farm") - Adulteration occurs along the whole supply chain, including some staff members of the processors. - Lack of price incentive makes farmers add water for more volume, a practice by most farmers in collusion with staff of processors – income is shared in this case. - Lack of support by the regulatory body; this includes inadequate supervision and the fact that a large market share (70%) has been taken by raw milk market. Licensing of such milk traders sets a bad precedence by Regulatory authority. - Due to seasonality; lack of consistency in carrying out tests e.g. changing density calibration depending on seasonality. - Generally the QBMPS is not easy because farmers expect more money - Poor milk testing equipments in Kenya and equipment-handling cited as challenges <u>Implications for farmers/CBEs</u> - Right attitude of the CBE to the farmer - Farmer relations with the CBE/processor very critical - CBEs got to have quality assurance staff at the cooling plant - Rewarding good quality milk - Penalties for poor quality - Investment in clean milk production and good quality feeds - Invest in small lab at the CBE level - Ensure 100% quality check at the collection points by use of rapid quality check methods. - While rejecting milk, educate farmers why milk has been rejected at the same time

	Implication for processors - Build loyalty by consistent and regular payment e.g Bio - Compete at the end markets (for consumers) and not for suppliers). - Have a budget for training and extension
Way forward	How Partners and SNV can support (What support SNV can offer in a QBMP pilot) - Training and Extension (skills development for quality clerks, farmers) - Modern Equipment for quality –testing equipment s and milk cans- create linkages with suppliers - Maintenance skills of equipment and training - Design a long term program (start small and increase investments)- farmers/CBE ownership and sustainability key.(The processors noted that similar QBMP initiatives have been initiated before by other development partners but they did not last-cited lack of funds for maintenance.)

People Present

Name	Company/Organization	Contact
1. Dr. J.K.Maiteri	Kinangop Dairies	jkmateri@yahoo.com 0723-884802
2. Dr. Nathaniel Makoni	ABS	nmakoni@yahoo.com 0722-700355
3. Emmanuel Kabaki	Brookside	emmanuel.kabaki@brookeside.co.ke 0722-243152
4. Charles Marete	Sameer	cmarete@sall.co.ke 0722-377678
5. Norah Vagomba	Sameer	norah@sall.co.ke 0716 828878
6. Tahir Mahmood	Nestle Foods	Tahir.Mahmood@ke.nestle.com 0775-553034
7. Lea Gasser Khimani	BIO Foods	lea@biofoods.co.ke 0722-736006
8. Gerard Oosterwijk	Happy Cow	g.oosterwijk@happycowkenya.com 0723-335900
9. John Muturi	Verdict Systems (Cold Chain Monitoring)	john@vea.co.ke 0721-892384
10. Berend de Leeuw	DVM – the Friesian	
11. Zipporah Kiruthu	Dairy Consultant-TOPS Mgt Consultants	znkiruthu@tops.co.ke 0722-701320
12. Karel Fentsahm	CRV Holland Genetics	Karel.fentsahm@crvuall.com
13. Bob Van Der	Netherlands Africa Business Council	b.vanderbijh@NABC.NL
14. Geoffrey Bartenge	NKCC	Geoffrey.bartenge@newkcc.co.ke
15. Nico Maat	Van den Heuvel Dairy and Food Equipment	Nico@heuvelzuivelmachines.nl
16. Herjan Bekamp	PTC+	H.Bekamp@ptcplus.com +31(0) 615494492
17. Samwel Muiruri	Githunguri Dairy	smuiruri@fresha.co.ke

Annex 4

KENYA DAIRY BOARD

MILK QUALITY BASED PAYMENT SYSTEM CONCEPT

1.0 Introduction

The value of raw milk to the dairy industry is a function of its composition and the aggregate profit of the product mix manufactured from the milk. Therefore, the value of manufacturing milk except liquid milk is directly dependent on its solids composition rather than the volume of milk. The primary objective of any milk pricing scheme should be that the price paid for milk reflect as accurately as possible the amount and value of products that can be made from it as well as the transport and processing costs incurred *(*Breen, James 2001).

The logic of paying more for high-quality product and less for low-quality resonates. It is also practiced in other industries within the agricultural sector such as sugar, horticulture amongst others. In sugar industry, payment systems are designed to create incentives to improve milling performance, cane yield and quality.

The practice of quality based payment system is more common in the developed dairy industries. This includes Australia, New Zealand and Europe amongst others. No information was obtained regarding the milk payment system in South Africa. There is however an ongoing study on a quality based payment in Ethiopia (**Greiling, 2011)**

While existing milk quality based payment systems have been based on composition being fat, protein and lactose (Hillers, Nielsen, Freeman, Dommerholt, and Deiter, 1980), the scenario in developing countries may be slightly different with density, fat and hygiene requirements taking priority. Protein composition is also important as cheese production continues to increase.

2.0 Guiding principles for a quality based payment system

2.1 Incentive

The milk payment system has a pivotal role in signaling market values of individual milk components to the producer and encourages improvements in milk quality and safety. It provides opportunities for producers to enhance profitability through the production of more valuable milk while the processors gets more value based on the product mix.

2.2 Transparency

Irrespective of the considerations made in developing a milk quality based payment system, the pricing should be transparent for milk suppliers to easily understand how their milk price has been determined.

2.3 Equity

The pricing system should be equitable in the sense that the price paid for milk reflect as accurately as possible the market returns that can be obtained from that milk in terms of

processed products and their quality. The basic principle for a payment scheme is that those suppliers with above average solids levels in their milk will generate a higher return from the marketplace and, in strict equity terms, should be entitled to a higher price per gallon/litre.

3.0 Kenyan Milk quality situation

3.1 Bacteriological quality

While Kenyan Dairy Standards require that bacterial load in raw milk quality falls in the range of < 200,000 – 2000,000 cfu for grades I –III, existing data shows Total Plate Count for raw milk in Kenya ranges from <50,000 cfu - > 300, 000,000 cfu. The high bacteria counts are however prevalent during the rainy seasons when it takes long to deliver milk to the processing plants. Even though a lot of the milk being delivered to the processing plants does not meet the set standards, it has however been observed that a group of farmers would deliver milk with a TPC of 70, million cfu in one day, and less than 1 million in another day. This implies that the standards are not out of reach for Kenyan dairy farmers and that a premium based payment would provide an incentive to the farmers to comply.

3.3 Milk density

According to Kenya Standards, the minimum requirement raw milk density is 1.028 kg/litre. Milk density is critical for milk processors because it directly impacts on the yields of other value added products other than liquid milk. Processed milk is also expected to meet the milk density requirements in both the local and export markets. However seasonal fluctuations in raw milk density and malpractices such as water adulteration impact on the density and output of final products.

3.4 Milk Fat

Minimum raw milk butterfat according to the Kenya standards is 3.5%. Because of the cross breed dairy herd in Kenya, achieving this butterfat has not been a challenge to Kenyan dairy farmers with most of the farmers supplying milk with 3.8% fat and above.

3.5 Drug residues

The Kenya standards and indeed the international standards require that contaminants such as antibiotics, pesticides and other toxins should be absent in milk and milk products. To ensure that this requirement is met, there should be a mechanism to check out for drug residues in milk delivered to the processing plants. Currently, testing for drug residues is not common practice in the dairy industry and hence a threat to compliance to food safety requirements.

4.0 Objectives of the proposed quality based payment system

1. *To Increase the yield of dairy products*

The yield of milk products will depend on the amount of total solids present, e.g. the greater the amount of solids in milk the greater the yield of cheese, butter, Milk powder.

2. *To improve the safety and hygienic quality of the milk*

This is a challenge in the industry and hence a payment system based on hygienic quality may be introduced.

3. *To avoid adulteration and contaminants in milk*

To discourage farmers from adding water or other substances to the milk or from supplying milk with antibiotics, then a payment system should be designed accordingly.

4. *To ensure fair payments to each milk producer*

This system will ensure that farmers who supply high quality raw milk are adequately compensated.

5.0 Literature Review on Quality based milk payment

Milk quality based payment scheme has been successfully practiced in the developed countries such as New Zealand, Netherlands among others and in some developing countries such as India and South Africa and Zambia amongst others. Kenya can therefore learn from existing models in the formulation of a quality based payment model that best suits the country.

5.1 Multiple Components Pricing (MCP)

According to the milk pricing structure adopted in the developed countries, milk solids constituents have positive values while the value of water (volume) is generally negative

+ Value of butterfat
+ Value of protein
+ Value of other solids (lactose and minerals)
- Cost of handling/removing fluid carrier (water)

This comprehensive MCP model is referred to as a 'plus/plus/plus/minus' scheme accurately assigning the positive values of milk solids as well as the cost associated with the fluid carrier or water (Breen et al, 2001).

5.2 Milk pricing system for Kenya

The current milk payment system in Kenya is based on quantity and not quality. This is a simple and easily understood method to calculate the milk price and no expensive testing is needed. However, it provides no incentive to improve quality or composition of milk and does not discourage malpractices such as adulteration and non adherence to withdrawal periods (Draaiyer, Dugdill, Bennett, Mounsey 2009).

A MCP model for Kenya based on existing testing methods, quality challenges and value of the various milk components could be modified as follows;

+ Solids Not Fat (SNF)
+ For high density milk
+ For Level of bacteria load (affects the quality and shelf life of final products)

0 payments for antimicrobial residues

5.3 Other factors that can be considered

1. Seasonality
2. Volumes

5.4 MCP in other countries

Denmark

The Danish milk pricing system is comprised of a number of components: a value for fat based on the intervention price for butter minus manufacturing costs, a value for protein based on the intervention price for skim milk powder minus manufacturing costs, and a number of deductions and bonuses (Keane, 2000) cited in Breen et al (2001).

The Netherlands

The Dutch payment for milk is based on an A+B-C system. Under this system there is an initial high valuation for fat and protein with a fixed deduction for milk handling and other costs as well as a number of additional premiums (Keane, 2000) cited in Breen et al (2001). Both systems included supplementary payments based on company performance as part of the final price paid to producers.

New Zealand

The New Zealand system for payment of milk is essentially based on kg of fat multiplied by cents per kg plus kg of protein multiplied by cents per kg. The protein to fat value ratio is approximately 70:30 under the New Zealand system Breen et al (2001)

6.0 Approach and Methodology

6.1 Concept development

Kenya Dairy Boards approach was first to develop the concept paper. This was developed after consultations with KDSCP experts in quality based payment, researching on quality based practices in other countries, identifying the specific issues that would be addressed by a quality based payment which informed the specific test which will be carried out during the survey. This activity has already been undertaken. Subsequent steps will be as follows.

6.2 Sharing the concept with Processors

The second step will be to share the concept with the milk processors who would be the implementers of a quality based system. So far, the concept has been presented to the Kenya Dairy Processors Association (KDPA) where it has received approval. The target will be to get at least three processors who would commit to pilot the programme. The selection of the participating processors will be based on willingness to pay premium raw milk prices to farmers who delivered good quality milk.

6.3 Identification participating farmer groups

There will be two categories of groups. Group one will be for farmer groups. This includes milk cooperatives or other group of famers who market milk to the processors as a group. A composite sample would be used to gauge the milk quality. Proposed groups include Olkalou, Kabiyet, Muthiru, Siongoroi, Sot, Oleguruone. Three groups will be picked for purposes of the pilot testing.

The second category will consist of individual farmers, traders, or groups that deliver milk directly to the processor. Sampling will be done at the collection center. Proposed centres include Abadere Milk collection plant among others. Two collection centres will be targeted.

Meetings will be held with identified farmers to create awareness. Every participating milk collection center will be required to acquire a freezer for storage of samples and the Ice boxes. The pilot targets five milk collection centers. However, about seven centers may be visited before selecting the participating centers.

6.4 Training of milk Samplers

Milk samplers from participating milk collection centers will be trained by the laboratory. The trained analysts will collect samples and therefore forward to the laboratory instead of the laboratory going to the field to collect samples. This will help to cut on costs.

6.4 Baseline survey

To determine the basis of payment for quality, a baseline line survey will be conducted. This will also help to identify challenges that may arise when the pilot starts and address them. Results of the survey will be shared with both farmers and farmer groups together with the processors. Consensus will therefore be sought on basis of paying for quality including specific quality parameters and price.

6.5 Testing and Farmer training

A composite sample will be drawn from milk delivered by the various milk supply categories including individual farmers, Traders, farmer groups and transports once a week and analyzed for the target parameters. The results will be shared with the farmers so that they can make improvements on the quality of raw milk. The weekly sampling will be done on random days to ensure that a representative sample for the week is drawn. The monthly quality results will be the average quality generated from the 4 weeks results.

This will be combined with weekly briefing to the processors and farmers on milk quality and propose interventions. Monthly, a training or farmer field day will be scheduled for participating groups. At least one training per month will be scheduled for each center.

6.5.1 Period of testing

The pilot testing will run for a period of three months.

6.6 Monitoring and evaluation

Data analysis will be undertaken to determine whether there was any improvement in milk quality and whether farmers who improved the quality of their milk were able to earn better under the quality based payment system that would be the case under the volume based payment. Challenges encountered during the piloting period will be shared.

6.7 Stakeholders workshop

A stakeholder's workshop will be held in which results of the pilot will be shared. This will include feedback on quality improvement, farmer payment and modalities of implementing the quality payment system. The report will also propose practical approaches to implementing the quality based payment system.

A survey of laboratory capacity to carry out the tests reliably will be undertaken. Each processors will then be advised to acquire the equipment that are necessary to ensure that the plant is able to

run the tests instead of depending on the external laboratory. This will ensure that the payment for quality system continues even after the pilot testing with KDB.

7.0 Expected outputs

1. Increased compositional quality of Kenyan dairy products.
2. Improved quality microbiological quality of raw milk and hence dairy products
3. Elimination of drug residues in milk
4. Improved payments to farmers supplying high quality milk

8.0 Activities and Budget

References

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Annex 5

Parmalat Raw Milk Specifications

Percentages quoted on volume per volume base

Milk	Genuine cow milk from authorised farms certified Tuberculosis and Brucellosis free. Parmalat will not collect milk from collection points where the milk was produced by cows that was treated by BsT.
Age	< 3 days
Temperature	≤ 4^{o} C at farm
Butterfat	≥ 3.20 %
Non fat solids (SNF)	≥ 8.30
Alcohol / Alizarol stability (indicates sour milk and mastitis milk)	Stability at 80 % alcohol
Freezing point (indicates added water)	-0.512^{o} C max - -0.530^{0} C min
Added water	None
Sediment	No sediment physically observed
Foreign materials	None
Powdered milk added	None
Other milk based products added	None
Odour & Taste	Typical. No taints and odours
Pasteurised milk	None
Total Bacterial Count at 30^{0} C	≤ 200 000 per ml
Inhibitants & anti-microbial residues	None
Preservatives, disinfectants & detergents	None
Pesticides, heavy metals & aflatoxins	Within legal limits

Milk that does not conform to the above specifications will not be loaded or received at the relevant milk intake centre. If milk was loaded or received and later confirmed to be out of specifications, the milk will not be paid for, except if the specifications not met are milk solids (butterfat and non-fat solids), total bacterial count (TBC) and added water. In this instance certain disciplinary procedures are applicable (Annexure C).

Milk that was loaded or received and does not conform to the above specifications, which results in a tanker load or a tanker compartment being contaminated and therefore rejected at the factory, could cause a claim against the guilty producer for the financial loss to Parmalat. The guilty producer will also be liable for a dumping fee of ZKW 1,000,000.