

**MINISTRY OF AGRICULTURE,
LIVESTOCK & FISHERIES**



SMALLHOLDER DAIRY COMMERCIALIZATION PROGRAMME

MODULE VI



**QUALITY ASSURANCE GUIDE
FOR MILK PROCESSORS**



This guide is intended to assist milk processors to process and market quality milk and milk products that comply with regulatory and market requirements through the application of Quality Assurance Systems in milk production.

Like any other business, milk processors should aim at meeting or surpassing their customers' expectations by providing high quality and safe milk and milk products.

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The programme covers nine counties namely Nakuru, Trans Nzoia, Uasin Gishu, Bomet, Nandi, Bungoma, Kakamega, Nyamira and Kisii. The goal of the programme is to increase the income of poor rural households that depend substantially on production and trade of dairy products for their livelihoods by

- Improving the financial returns of market oriented production and trade activities by small-scale operators, through improved information on market opportunities, increased productivity, cost reduction, value adding and more reliable trade relations
- Enabling more rural households to create employment through, and benefit from, expanded opportunities for market-oriented dairy activities, as a result of strengthened farmer organizations.

Through the facilitation of SDCP, Kenya Dairy Board (KDB), a statutory organization established by an Act of Parliament, the Dairy Industry Act Cap 336, and in partnership with the Kenya Industrial Research and Development Institute (KIRDI) and Dairy Training Institute (DTI) developed this guide to assist milk bulking and cooling centers to establish and benefit from a Quality Assurance System.

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PREFACE

The dairy industry in Kenya is an important socio-economic enterprise. With an estimated production of 5.2 billion litres of milk per annum, the industry supports the livelihoods of an estimated 1.5 smallholder dairy farmers. The industry provides raw material for large, medium and small scale milk processing enterprises. The industry contributes approximately 14% and 4.5% of the country's agricultural and National Gross Domestic Products (GDP) respectively.

The volume of processed milk has grown over time to reach 649 million litres in 2016. The milk is processed into a variety of products including pasteurized milk, long life milk, milk powder, cream, ice cream, cheese, butter and ghee among others. Processing is undertaken at various levels by 40 processing plants and 148 mini dairies (Kenya Dairy Board 2017).

The processing plants serve both the local and export markets. However, most of the products are consumed locally. The advent of the milk dispensing technology and school milk programs has created new markets for Kenyan milk processors. A large number of the well-established milk processors have either adopted or implemented quality and food safety management systems such as ISO 9001, ISO 22000 and HACCP.

The challenges faced by milk processors are diverse and include seasonality of milk production which affects throughput and utilization of capacity, competition from the informal sector, high cost of milk production and processing and compliance to milk quality and safety requirements.

Adoption and implementation of Good Manufacturing Practices (GMP) and Quality Assurances Systems (QAS) in milk processing is

required to enhance compliance to milk quality and safety requirements and meet consumers expectations. This is especially so for the small to medium milk processing enterprises which are often constrained by several challenges including limited market penetration of their products.

The Government of Kenya has provided an enabling environment to support the development of the Kenyan dairy industry and investment by the private sector in milk production, bulking, cooling, processing and marketing.

The goodwill and support from our development partners including IFAD has immensely contributed to make the Kenyan dairy industry a fast growing enterprise that supports and nourishes many Kenyans.

We hope that this guide will be of value to milk processors and other stakeholders in adopting best practices and QAS that will lead to improvement in the quality and safety of milk and milk products.

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ABBREVIATIONS

DTI	Dairy Training Institute
GDP	Gross Domestic Product
GOK	Government of Kenya
GMP	Good Manufacturing Practices
IFAD	International Fund for Agricultural Development
KDB	Kenya Dairy Board
KIRDI	Kenya Industrial Research and Development Institute
MODE	Market Oriented Dairy Development
QA	Quality Assurance
QAM	Quality Assurance Manual
QAS	Quality Assurance System
SDCP	Smallholder Dairy Commercialization Programme
SOP	Standard Operating Procedures

Table of Contents

ACKNOWLEDGEMENTS	I
PREFACE	III
ABBREVIATIONS	V
CHAPTER 1: INTRODUCTION	1
1.1 Purpose	1
1.2 Objectives.....	1
1.3 Scope	2
1.4 Structure.....	2
CHAPTER TWO: INTRODUCTION TO QUALITY ASSURANCE SYSTEMS IN MILK PROCESSING	4
2.1 What is quality?	4
2.2 What is Quality Assurance?	4
2.3 What is Quality Assurance System?	5
2.4 Components of a quality assurance system	6
2.5 Steps in implementation of Quality Assurance Systems.....	6
2.6 Documentation requirements in a Quality Assurance System	7
2.7 Importance of QA systems in milk processing.....	10
CHAPTER THREE: QUALITY AND SAFETY REQUIREMENTS IN MILK PROCESSING	11
3.1 Quality and safety objectives in milk processing.....	11
3.2 Regulatory requirements for milk processing.....	12
CHAPTER FOUR: IMPLEMENTATION OF QUALITY ASSURANCE IN MILK PROCESSING	18
4.1 Background.....	18
4.2 Preparatory stage	19
4.3 Sourcing and procuring of raw materials	24

4.4 Processing, packaging and storage	27
4.5 Distribution and marketing of dairy produce	30
CHAPTER FIVE: SELF-ASSESSMENT GUIDELINES FOR MILK PROCESSORS.....	32
ANNEX 1: SAMPLE RECORDS.....	37
REFERENCES.....	38

CHAPTER 1: INTRODUCTION

1.1 Purpose

The purpose of this guide is to assist milk processors to source, procure, process, distribute and market quality and safe milk and milk products that comply to regulatory and market requirements. These requirements include the physical, chemical and microbiological specifications as provided by the relevant Kenyan standards for milk and milk products.

Milk processors provide a useful link between dairy farmers and the milk market. They support dairy farmers, through provision of extension and other embedded services, to produce quality and safe raw milk which is converted into a variety of dairy produce to meet the diverse needs of consumers.

The Quality Assurance Framework provided in this guide will assist milk processors to implement good practices in milk sourcing, procurement, processing and marketing, identify and establish preventive and control mechanisms, undertake self-assessment of their operational systems and maintain proper quality records in their milk businesses. This will especially be of value to small and medium milk processors who may have limited capacity to invest in an elaborate Quality Management System (QMS). The guide will support extension and advisory services in line with the overall objective of achieving the quality assurance goals.

1.2 Objectives

The guide will assist milk processors to source, procure, process, distribute and market quality and safe dairy produce. It seeks to build the capacity of milk processors to:

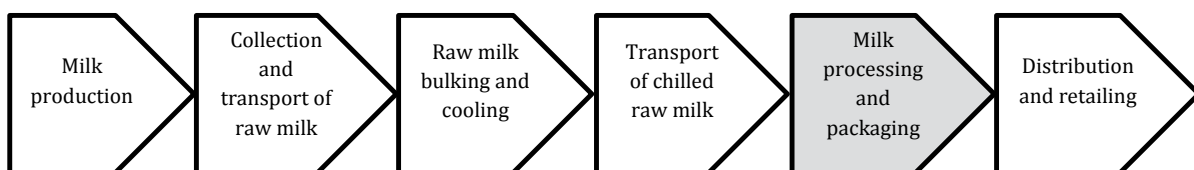
- (a) Identify quality and safety requirements in milk processing

- (b) Identify and address causes of poor quality milk and milk products
- (c) Establish raw material specifications and identify appropriate suppliers
- (d) Adopt best practices in milk processing
- (e) Determine and implement preventive and corrective actions for quality management
- (f) Establish and administer quality assurance self-assessment mechanisms
- (g) Undertake proper documentation

1.3 Scope

This guide covers quality assurance practices in milk processing including sourcing, procurement, processing, distribution and marketing of quality and safe milk and milk products. Aspects related to good milk handling practices, personnel, equipment, containers, vessels, vehicles and records requirements are addressed where relevant to the quality and safety of milk and milk products.

Figure 1: The Dairy value chain



1.4 Structure

This guide is presented in four chapters covering the following quality assurance practices in milk processing:

- (a) Introduction to Quality Assurance Systems
- (b) Quality and safety requirements in milk processing
- (c) Application of Quality Assurance in milk processing

- (d) Self-assessment guidelines to evaluate Quality Assurance practices in milk processing.

CHAPTER TWO: INTRODUCTION TO QUALITY ASSURANCE SYSTEMS IN MILK PROCESSING

2.1 What is quality?

Quality is the totality of features and characteristics of a product or service to satisfy the stipulated needs and requirements of the users.

Milk processing is the quality oriented activity of processing and packaging of dairy based products on the basis of heat treatment or other approved methods. It involves a series of inter-twined activities ranging from sourcing of raw milk and other processing aids, procurement and delivery of bulk raw milk to the plant, actual processing and packaging of products and distribution to the market. Quality Assurance is a requirement throughout the entire process.

Raw milk is primarily intended for processing into dairy products which meet specified standards. Therefore, raw milk should be harvested and handled under hygienic conditions to meet this purpose. The immediate cooling of raw milk to four degrees centigrade after milking maintains the physical and chemical properties of the milk. Good handling practices to minimize contamination of the milk are required and should be implemented.

Processing of milk should be undertaken under conditions established to achieve stated quality and safety objectives of the end products.

2.2 What is Quality Assurance?

Quality assurance (QA) is a management method that is defined as “all those planned and systematic actions needed to provide

adequate confidence that a product, service or result will satisfy given requirements for quality and be fit for use” (ISO 1994).

In milk processing QA entails identification, implementation and documentation of relevant activities that will lead to sourcing, procurement, processing, distribution and marketing of quality and safe milk and milk products.

2.3 What is Quality Assurance System?

Quality Assurance System is a tool to help enterprises to operate more effectively and efficiently and comply with product or service specifications and requirements. They help to ensure that at every step of operation a minimum standard of defined quality and safety is met for a product or service.

Quality Assurance Systems in milk processing will provide and document relevant controls that will lead to delivery of quality and safe milk and milk products to consumers.

In practice, there are several types of QAS that are applicable in milk bulking and cooling such as:

- ISO 9001 Quality Management System
- ISO 22000 Food Safety Management System
- Hazard Analysis Critical Control Points (HACCP)
- Good Agricultural Practises (GAP)
- Total Quality Management (TQM)

These systems have basic principles of Quality Assurance which include:

- Design and scope of the system
- Management commitment and responsibility
- Systematic analysis and systematic action
- Process approach
- Customer focus

- Record keeping and documentation
- Continuous improvement

This guide has adopted these principles to present a simple QAS that can be adopted and implemented in the bulking and cooling of raw milk.

2.4 Components of a quality assurance system

The components of a QA system in milk processing can be grouped into three levels, namely;

- (a) The top level commitment by management of milk processing companies to meet product quality and safety requirements.
- (b) The operational level which involves establishing, implementing and documenting methods and practices for processing and marketing of quality and safe milk and milk products.
- (c) The assessment stage where the effectiveness of the QA system in meeting the desired goals is evaluated and remedial actions to improve the system instituted.

2.5 Steps in implementation of Quality Assurance Systems

Generally, the implementation of a QA system in the food industry would entail the following steps

- (a) Identification of the quality and safety goals of a product
- (b) Identification of the activities required to produce and meet the stated quality and safety goals of the product
- (c) Identification of the most likely problems that may occur and which may affect the quality and safety of the product
- (d) Establishment of control mechanisms to reduce the likelihood of the problem occurring

- (e) Identification and implementation of remedial actions to manage the problems if they occur
- (f) Establishment of documentation and records requirements
- (g) Identification and implementation of the assessment and feedback mechanism

2.6 Documentation requirements in a Quality Assurance System

Documentation is any written text document used to explain some attributes of an object, procedure or process. Documentation is an essential part of the QAS system. It provides the control measures and actions that need to be implemented and also documents the various activities undertaken in the production of a good or service, their inter-relationship, characteristics and operating parameters.

The documents required in a QAS are summarized in figure 1 below

Figure 2: Documents required in a QAS



(a) The Quality Assurance Manual (QAM):

Is the first level of documentation in a Quality Assurance System. The QAM clearly identifies the product being provided under the QAS and provides an understanding of the processes affecting quality of the product.

The manual also describes:

- The organization
- The scope of the QAS
- The organization's quality policies which shows that the organization is committed to processing and marketing of quality products
- The product and its specifications
- The processes involved in the production of the product

The QAM for a milk processor will among other things document a brief profile of the organization, the products handled, the product quality objectives and the processes involved in sourcing, procuring, processing, distributing and marketing of the products.

(b) Quality Assurance Procedures:

Quality Assurance Procedures (QAP) is vital in Quality Management System. They establish processes that identify the activity, establish what to look for in that activity based on a certain reference, acceptance criteria and the records to keep. They are simplified step-by-step sequence of activities or course of action that must be followed in the same order to correctly perform a task

In milk processing, Quality Assurance Procedures are required for the following actions among others;

- Sourcing of raw materials
- Sampling and testing of raw materials for acceptance
- Product processing
- Product storage
- Distribution and marketing

- Cleaning and sanitization programs
- Control of non-conforming products
- Control of records

(c) Standard Operating Procedure (SOP):

Are step-by-step instructions compiled to help workers carry out routine operations. SOPs aim to achieve efficiency, quality output and uniformity of performance. SOP's in a milk processing facility ensure personnel follow the correct procedures in sourcing, procurement, processing, distribution and marketing of milk and milk products and cover the following activities among others

- Milk reception
- Milk sampling and testing
- Operation of equipments
- Handling and storage of products
- Cleaning of equipments

(d) Quality Records:

Are the documented evidences that processes are executed according to the QA plan and requirements. Such records in milk processing include:

- Test results for raw materials and finished products
- Cleaning and sanitization records
- Customer complaints
- Product recalls
- Approved supplier records
- Pest management records
- Staff training records
- Equipment maintenance and calibration records
- Building maintenance records
- Health records for milk handlers

Figure 3: Benefits of record keeping in milk processing



Records in milk processing are important for the following reasons

- Accountability of operations
- Compliance with legislative requirements
- Quality improvement
- Management planning and decision making
- Communication to stakeholders

2.7 Importance of QA systems in milk processing

A well designed and implemented QA system in milk processing will have the following benefits:

- (a) Increase confidence of customers on the quality and safety of the products
- (b) Establish reliable and premium markets for milk and milk products
- (c) Protect consumers from possible harm or risks associated with poor quality and unsafe milk and milk products.
- (d) Demonstrates management commitment to market quality and safe milk and milk products that meets market requirements
- (h) Reduces post-harvest losses of dairy produce resulting from spoilage and rejections from the market
- (i) Establish traceability and recall mechanism for the product where necessary
- (j) Overall contribute to increased operational efficiency and profitability of the enterprise

CHAPTER THREE: QUALITY AND SAFETY REQUIREMENTS IN MILK PROCESSING

3.1 Quality and safety objectives in milk processing

The primary objective of a milk processor is to procure high quality and safe raw milk that can be converted through processing into high quality and safe milk and milk products.

The operations of a milk processor can be complex depending on the level of operation and geographical coverage. Milk procurement can be spread out over vast distances and therefore appropriate milk procurement infrastructure need to be established including building strong partnerships with dairy farmers, dairy producer groups and other service providers. The same applies to milk marketing where products are distributed over wide geographical areas. The premise, technology, equipments, personnel and among others must be carefully considered in order to achieve the quality and safety goals of the dairy produce.

Milk processors handle raw milk, a variety of finished milk products and other forms of raw materials and processing aids. All of these must comply with the product specifications as provided by the relevant Kenyan standards.

Raw milk is the base material in milk processing. Raw milk must be obtained from healthy and well-kept animals; subsequently it should be handled, bulked and cooled under hygienic conditions. It should be transported to the processing plant in a manner that avoids the introduction of contaminants and minimizes the growth of micro-organisms in the milk.

Raw milk should be;

- (a) Wholesome, has no added water, preservatives, or other added substances, nor should any proportion of a natural constituent be removed
- (b) Free from extraneous matters like dust, dirt, flies and manure.
- (c) Has a normal composition, possesses a natural milk sensory attributes such as flavor and color
- (d) Is low in bacteria counts
- (e) Is free from hazardous residues such as toxins and veterinary drugs and chemical contaminants
- (f) Has a high keeping quality
- (g) Has a high commercial value

3.2 Regulatory requirements for milk processing

The requirements for milk processing are stipulated in various Kenyan food legislations which include:

i. Laws and regulations

- (a) Public Health Act Cap 242
- (b) Dairy industry Act Cap 336
- (c) Food, Drugs and Chemical Substances Act Cap 254
- (d) Standards Act Cap 496

ii. Standards and codes of practice

Milk processors deal with a variety of dairy produce which are subject to several standards. The standards include;

- (a) Raw cow milk specifications - KS EAS 67:2007
- (b) Pasteurized milk specifications – KS EAS 69:2007
- (c) Specification for yoghurt – KS EAS 33:2007
- (d) Specifications for cultured milk – KS 941:1993

- (e) Specification for butter – KS EAS 22:2007
- (f) Specification for dried whole milk powder and skimmed milk powder – KS EAS 49:2007
- (g) Specification for cheese – KS 28-1: 2015
- (h) Specification for UHT milk – KS EAS 27:2007
- (i) Specification for dairy milk ices and dairy ice creams – KS EAS 70: 2007
- (j) Specifications for cow ghee – KS 2684:2017
- (k) Specification for flavored milk – KS 1756:2017
- (l) Labelling standard – KS EAS 38:2014
- (m) Standard specifications for drinking (potable water) - KS EAS 12:2014
- (n) Code of hygienic practice for milk and milk products - KS 1552: 2015
- (o) Relevant international standards such as the ones developed by the Codex Alimentarius Commission

In general, the above laws, regulations and standards require milk processors to observe or comply with the following requirements:

(a) Hygienic milk handling and processing

Milk should be produced, handled, processed and marketed under conditions that minimize contamination from the environment, personnel, vehicle, equipment and containers and among others.

(b) Certification of milk handlers

Milk handling personnel should observe good personal hygiene that minimizes the likelihood of contaminating the milk. They should be free from communicable diseases and medically certified. The milk handlers should undergo some basic training on hygiene milk handling.

Figure 4: Diseases that can be transmitted through milk



Dairy animals and milk handlers can contaminate milk with pathogenic micro-organisms which cause the following diseases in humans

- Typhoid fever
- Brucellosis
- Tuberculosis
- Diarrhea
- infectious hepatitis

(c) Compliance to product specifications

Milk processors deal with a variety of dairy produce which are subject to several standards. Some of the dairy produce standards are summarized below (it should be noted that standards are dynamic and may change from time to time. Milk dealers are advised to keep abreast with revisions of the relevant standards).

- i. **Raw cow milk:** Raw milk is the normal, clean and fresh secretion extracted from the udder of a healthy cow, properly fed and kept, but excluding that got during the first seven days after calving. It shall not contain added water, preservatives, or other added substances, nor shall any proportion of a natural constituent be removed.

Raw cow milk shall comply with the following among others

- Minimum of 3.25 % milk fat and 8.50 % milk solids not fat.
- Density at 20 °C shall be within the range of 1.028 g/ml – 1.036 g/ml
- Low bacterial counts not exceeding 2,000,000 CFU/ml
- Low coliform counts not exceeding 50,000 cfu/ml
- Low somatic cell count not exceeding 300 000 per ml

- Be free from pesticides and veterinary drugs residues
- Be free from toxins e.g. aflatoxin M1

In addition, the raw milk should:

- Have a characteristic creamy white color, free from off flavors and taints
- Be free of objectionable matter
- Test negative to the alcohol test
- Test negative for presence of hydrogen peroxide

ii. **Pasteurized milk:** Pasteurization is a heat treatment process applied to milk with the objective of eliminating possible health hazards arising from pathogenic micro-organisms which is consistent with minimal chemical, physical and organoleptic changes in the milk. Pasteurization is a temperature-time combination process. The heat treatment can either be batch at 65 °C for 30 minutes or High Temperature Short Term (HTST) at 73 °C for 16 seconds as provided in the relevant Kenyan standards.

Pasteurized milk shall comply with the following specifications among others

- Density at 20 °C shall be within the range of 1.028 g/ml – 1.036 g/ml
- Low bacterial counts not exceeding 30,000 CFU/ml
- Low coliform counts not exceeding 10 cfu/ml
- Be free from pesticides and veterinary drugs residues
- Be free from toxins e.g. aflatoxin M1
- Shall test negative for alkaline phosphatase enzyme

iii. **Yoghurt and cultured milk:** Yoghurt and cultured milk (mala) are fermented milk products obtained by lactic acid fermentation using selected strains of lactic acid bacteria. Yoghurt is attained

through fermentation process of lactobacillus bulgaricus and streptococcus thermophilus while cultured milk is derived from the fermentative action of mesophilic starter cultures.

Yoghurt and cultured milk should comply to the following specifications among others

- Free of pathogenic micro-organisms such as Escherichia Coli, Salmonella and staphylococcus aureus
- Low counts of molds and yeasts not exceeding 10 per ml
- Be free from toxins e.g. aflatoxin M1
- Use of approved food grade additives at the recommended levels. These include colors, flavors, emulsifiers and stabilizers

(d) Labelling of dairy produce

The Kenyan standards on labelling require that processed dairy products are labelled. The information to be provided includes:

- Name and address of manufacturer
- Name of the product
- Batch or lot number
- List of ingredients
- Batch or code number
- Date of manufacture
- Date of expiry
- Nutritional composition
- Net content
- Instruction for storage and use

(e) Certification of milk and milk products

Milk processors are required to have standardization mark from the Kenya Bureau of Standards. This is issued subject to compliance of the product to the requirements of the relevant dairy standards.

(f) Licensing of milk processing plants

Milk processing plants are required to obtain licenses and permits from the relevant authorities before commencement of business. These include the licenses issued by Kenya Dairy Board and County Governments.

Persons in charge of milk processing plants should have the relevant qualifications and experience. They should also obtain a Dairy Managers' license from Kenya Dairy Board.

Figure 5: Importance of licensing of milk processing plants



Why registration and licensing of milk processing plants?

- For compliance
- Facilitates periodic inspection of production facility
- For traceability of products
- For certification of products
- Builds consumer confidence in product

CHAPTER FOUR: IMPLEMENTATION OF QUALITY ASSURANCE IN MILK PROCESSING

4.1 Background

The quality and safety of dairy produce is influenced by many factors including environment, temperature, time, personnel, equipment, containers and utensils, cleaning and sanitization processes among others. It is important for the milk processors to adhere to Quality Assurance Guidelines in order to produce and deliver quality and safe milk and milk products. A QAS recognizes the need for putting in place an elaborate mechanism that defines the requirements at each stage and sets acceptable limits within which milk and milk products would be considered appropriate for human use or further processing.

Quality Assurance System establishes procedures and/or guidelines that require to be followed at every stage of the production process. Training of personnel involved in milk handling is key in developing the necessary skills to support the implementation of such a system. Records generated from every stage of the production process are a crucial component in assuring the end users of the integrity of the QAS.

Assessment of the QAS can be conducted through physical inspection of premises, equipment, personnel, raw materials and finished goods among others. Broadly defined, physical inspection is an organized examination using the senses of sight, touch and smell and also the use of tools to measure or determine certain attributes or characteristics of an object or activity. It may also involve examination of records and other relevant documents.

Adoption of a robust Quality Assurance System will therefore focus on all stages of milk sourcing, procuring, processing, distribution and marketing which can be categorized into four broad stages:

- (a) Preparatory stage
- (b) Sourcing and procuring
- (c) Processing, packaging and storage
- (d) Distribution and marketing

In each of the five stages, the following Quality Assurance Practices are recommended.

4.2 Preparatory stage

Processing of milk requires adequate preparation of required facilities including premises, equipments, utilities, personnel and raw materials. Records relating to this preparation should be maintained. It is important that the processing and milk testing equipment are calibrated as required and reagents standardized for accuracy of test results.

The personnel involved in milk handling should be trained and equipped with the appropriate work attire and sanitary facilities to minimize chances of contaminating the milk. Milk handlers should abide by appropriate behavior that does not predispose the milk to contamination. Some of the inappropriate behaviors in a milk handling and processing environment include;

- Chewing
- Smoking
- Spitting
- Eating
- Picking of nose, ears etc.
- Sneezing
- Coughing

The water used to clean equipments, containers and facilities should be adequate and meet the requirements for potable water. The choice of the cleaning and sanitizing agent and the cleaning program should be well considered to eliminate possibility of residues which may contaminate the product and render it unwholesome. Other utilities required in milk processing such as steam, compressed air and chilled water should be sanitary and adequate to meet the processing needs.

Milk processing plants should comply with basic hygienic requirements including:

Figure 6: Requirements for milk processing plants



Milk processing plants should be:

- Located away from potential sources of contamination
- Have adequate lighting and ventilation
- Have separated areas for different milk handling activities to prevent cross contamination of milk and milk products.
- Properly designed and layout of equipment
- Be provided with clean and adequate sanitary facilities
- Floors and walls should be impervious and easy to clean and disinfect
- Proper drainage and waste management system
- Control of insects, flies, rodents and birds

Table 1: Recommended QA practices in preparatory stage of milk processing

Factors to consider	Risk element	Requirements	Monitoring mechanism	Remedial action if requirements are not met	Records
1. Environment	Contamination of milk	Premise should be located away from sources of contamination	Physical inspection	Take appropriate action to manage the source of contamination Identify suitable premises before operation Relocate the premise	
	Contamination of the milk by pests and rodents	Environment and processing facilities should be free of pests and rodents	Physical inspection	Implement a pest and rodent control programme	Pest and rodent control records
2. Premise	Contamination of milk	Premise should be designed to prevent cross contamination of milk	Physical inspection	Control of human movement Separation of high risk areas	
		The floors, walls and ceilings should be impervious, easy to clean and sanitize	Physical inspection	Renovate as required	Cleaning records
		The premise has adequate and protected lighting and ventilation	Physical inspection	Provide adequate lighting and ventilation Renovate as required	
		Premise has adequate hand washing and sanitization facilities	Physical inspection	Installation of required amenities Provide consumables such as soap	Records for replenishment of soap and disinfectants

Factors to consider	Risk element	Requirements	Monitoring mechanism	Remedial action if requirements are not met	Records
				and sanitizers	
		Adequate and clean toilet and sanitary facilities provided	Physical inspection	Provide adequate facilities as required	Cleaning schedule
		Footbaths and appropriate disinfectant is provided at the entrance of the processing facility	Physical inspection	Provide adequate facilities as required	Records for replenishment of disinfectants
3. Equipment and containers	Contamination of the milk	Surfaces of milk equipment and containers intended to come into contact with milk should be easy to clean and disinfect, corrosion resistant and not capable of transferring harmful substances to the milk	Physical inspection Rinse and swab tests for product contact surfaces	Repair or replace affected containers and vessels	Maintenance records Rinse and swab test results
		The layout of the equipment should allow for adequate cleaning and prevent cross contamination	Physical inspection	Re-work on the layout	Installation and commissioning records
3. Cleaning and sanitization programs	Contamination of the milk	The cleaning and disinfecting agents should be effective, safe and easily rinsed.	Physical inspection Rinse and swab tests of cleaned surfaces	Replace detergents and sanitizers Review cleaning and sanitization program	Cleaning schedule Rinse and swab test results
		Immediate cleaning and disinfection of the equipment and containers after use	Physical inspection	Develop Standard Operating Procedures for cleaning of equipments and containers Provide cleaning and disinfection facilities	Standard Operating Procedures for cleaning of equipments and containers Cleaning schedule
4. Personnel	Contagious diseases	Milk handlers should be free of contagious or	Physical inspection of	Relieve infected milk handlers	Valid medical certificate

Factors to consider	Risk element	Requirements	Monitoring mechanism	Remedial action if requirements are not met	Records
		infectious diseases which may be transferred through the milk or affect the quality and safety of the milk	milk handlers Medical examination by a certified medical examiner	from milk handling duties	Health declaration records
	Contamination of milk	Milk handling personnel should observe personal hygiene, wear suitable protective attire and avoid undesirable behavior during milk handling	Physical inspection of milk handling personnel	Develop and implement personal hygiene rules for milk handlers Relieve affected milk handlers from milk handling duties Train and sensitize milk handlers on hygiene Provide adequate and appropriate attire and sanitary facilities	Personal hygiene rules for milk handlers Training records
5. Water	Contamination of the milk	Provide potable water for cleaning and processing	Physical inspection of water sources Testing water for quality	Procure water from certified sources Water treatment Protect sources of water and distribution systems from possible contamination Code water conduits according to quality and intended usage	Water procurement records Water treatment records Results of water quality tests
6. Waste	Contamination	Liquid and solid waste	Physical	Comply with	Waste

Factors to consider	Risk element	Requirements	Monitoring mechanism	Remedial action if requirements are not met	Records
management	of milk and milk products and spread of contagious and infectious diseases	should be disposed in accordance with the relevant regulations	inspection	the relevant regulations	treatment and disposal records
		Ensure solid and liquid waste does not harbor flies, insects and other rodents	Physical inspection	Provide solid waste disposal facilities	

Figure 7: Requirements for milk handling personnel



Milk handlers must take all reasonable measures not to compromise the safety and suitability of milk. They should;

- Report if suffering or suspecting to be suffering from foodborne disease(s)
- Not engage in milk handling if suffering or suspecting to be suffering from food borne disease(s)
- Ensure clothing is of a level of cleanliness that is appropriate for the handling of milk
- Not sneeze, blow or cough over unprotected milk or surfaces likely to come into contact with milk
- Not to spit, smoke or use tobacco or similar preparations in areas in which milk is handled
- Wash hands always before handling milk

4.3 Sourcing and procuring of raw materials

In a milk processing plant, the quality of raw materials significantly affect the quality of the final products. Careful identification and selection of suppliers of raw materials is an important step in

Quality Assurance. The commonly used raw materials in a milk processing plant include raw milk, packaging material, ingredients and additives and other processed dairy products.

Milk processors should be adequately equipped to test for the quality of all raw materials. Raw material acceptance criteria should be established and documented at all stages.

The raw material acceptance criteria should be based on the following;

- Relevant product specifications and standards
- Legal and statutory requirements
- Market requirements
- Internal standards and Quality Assurance objectives
- Internationally recognized standards and norms

However, it should be noted that the acceptance criteria adopted should be in conformity with the relevant product specifications and legal requirements.

Raw material procurement should then be conducted in conformity with the acceptance criteria. The required procurement, transport and storage infrastructure should be established and maintained to ensure the integrity of the raw materials. Procurement and quality records should be maintained to support the QAS.

Good stock and inventory management practices should be implemented in procurement and storage of raw materials. It involves managing the physical stock for purpose of:

- Accurate pre-planning of processing requirements
- Allows monitoring and control of stock levels to avoid overstocking or understocking
- Identification and proper organization of raw materials to facilitate First in First out (FIFO) principle of stock

management. This is consistent with Good Quality Assurance Practices

- Lowers inventory procurement and management costs
- Contributes to customer satisfaction by meeting their needs as and when they arise

Table 2: Recommended QA practices at sourcing and procurement of raw materials

Factors to consider	Risk element	Requirements	Monitoring mechanism	Remedial action if requirement is not met	Records
1 Sourcing and procurement of raw materials	Poor quality and unsafe raw materials	Procure raw materials that conform to specifications	Testing raw materials against specifications	Establish raw material specifications Periodically review raw material specifications Identify and select appropriate suppliers of raw materials Reject low quality raw materials Develop supplier feedback mechanisms	Raw material specifications Raw material test results List of approved suppliers Supplier audit records
2 Storage and utilization of raw materials	Contamination and spoilage	Raw materials should be stored under specified conditions	Physical inspection Temperature and time controls Raw material quality tests during storage	Dispose poor quality and unsafe raw material Modify storage conditions	Temperature and time control records Raw material test results
		Practice First in First Out (FIFO) principle	Physical inspection of inventory management records	Improve inventory management practices	Inventory management records

4.4 Processing, packaging and storage

Once the raw materials have been procured, the next stage is utilization of the materials in processing of milk and milk products. The quality of the raw materials should be verified before utilization.

Proper planning of the production schedules and raw material and utility requirements is an important consideration in milk processing. Appropriate production and quality control records should be maintained throughout the production process. Cleaning and sanitization schedules of processing equipment and facilities should be adhered to. The cleanliness of the processing environment should be maintained throughout the production process.

The processing requirements depending on the type of dairy product should be followed. Constant monitoring of process and product safety controls during the production process should be undertaken. The integrity of the product should be maintained through the production process.

Batching and coding of products should be done as required by the labelling and product standards. This should be constantly checked and documented.

Processed and packaged milk products should be stacked as recommended and stored under recommended time and temperature conditions. Good inventory management practices should be implemented in storage and dispatch of processed milk and milk products.

Table 3: Recommended QA practices at milk processing, packaging and storage

Factors to consider	Risk element	Requirements	Monitoring mechanism	Remedial action if requirement is not met	Records
1. Processing of milk and milk products	Contamination from poor quality raw materials	Raw materials for processing should comply to specifications	Testing of raw materials	Reject poor quality raw materials	Raw material test records
	Survival of disease causing microorganisms in the product	Dairy products should be subjected to recommended processing regimes including temperature and time combinations	<p>Testing of dairy produce for efficiency of the heat treatment process</p> <p>Monitoring of temperature and time combinations during processing</p> <p>Monitoring of process and product safety controls</p>	<p>Reject under processed milk and milk products</p> <p>Reprocess under processed milk and milk products where applicable</p> <p>Hold affected products for assessment</p> <p>Calibration of temperature and time recording devices</p> <p>Maintenance of processing equipment and process control devices</p> <p>Replace faulty equipment and process control devices</p>	<p>Heat treatment efficiency test results</p> <p>Temperature and time records</p> <p>Calibration records</p> <p>Equipment and process control maintenance records</p> <p>Product holding records</p>
	Spoilage of dairy products	Dairy products should comply to the recommended shelf life	Monitoring of product shelf life	Reject and dispose the affected products	Product rejection records Market

Factors to consider	Risk element	Requirements	Monitoring mechanism	Remedial action if requirement is not met	Records
				Reprocess the affected products where practical Review the product processing and storage conditions.	return records Product test records
	Contamination of milk and milk products	Surfaces of milk processing equipment should not contaminate the milk	Physical inspection Rinse and swab tests of product contact surfaces for cleanliness Testing of processed dairy produce	Reject contaminated dairy produce Repair or replace affected processing equipment Adequate cleaning and sanitization of processing equipments and accessories	Maintenance records for equipments Rinse and swab test results Cleaning and sanitization schedules Product test records
		Raw materials used as processing aids should not contaminate the dairy produce	Raw material test results Physical inspection	Rejection of contaminated raw materials and dairy produce Storage of materials under recommended conditions	Raw material and dairy produce rejection records Raw material test results
2. Storage	Contamination and spoilage of dairy products	Dairy products should be stored under recommended conditions	Physical inspection Monitor product storage conditions	Dispose contaminated dairy products Practice First in First Out	Dairy produce storage and disposal records

Factors to consider	Risk element	Requirements	Monitoring mechanism	Remedial action if requirement is not met	Records
			Testing the quality of stored dairy products	(FIFO) principle in dispatch of products Modify storage conditions as required Control rodents, insects and other vermin	Dairy products quality test results Pest control records

4.5 Distribution and marketing of dairy produce

The final step in milk processing is distribution and marketing of products. Distribution, which is an element of marketing, is the process of making milk and milk products available to consumers in the most direct and cost effective manner. The distribution decision should be informed by:

- Market requirements
- Product characteristics
- Infrastructure and logistics
- Geographical coverage
- Legal requirements
- Global trends

The distribution process takes care of transportation, warehousing, storage and inventory management of the dairy product.

During the marketing process, milk processors should where practical build the capacity of retailers on how to store and handle dairy produce. Provision of necessary infrastructure such as refrigeration facilities, agency support and merchandizing requirements is an added advantage. This will ensure that the

integrity of the finished product is maintained during retailing and eventual consumption.

Table 4: Recommended QA practices during distribution and marketing of dairy produce

Factors to consider	Risk element	Requirements	Monitoring mechanism	Remedial action if requirement is not met	Records
1. Transportation	Contamination and spoilage of dairy products	Dairy products should be transported under recommended conditions	Physical inspection of transportation conditions	Dispose contaminated and spoilt dairy products Modify transport conditions	Dairy products distribution and disposal records
2. Warehousing and storage	Contamination and spoilage of dairy produce	Dairy produce should be stored under recommended conditions	Physical inspection Monitor storage conditions Testing of stored dairy products for quality	Dispose contaminated dairy produce Practice First in First Out (FIFO) principle in dispatch of products Modify warehousing conditions	Dairy produce disposal records Dairy products quality test results Preventive and maintenance records
3. Merchandizing and retailing	Contamination and spoilage of dairy produce	Dairy produce should be retailed under recommended conditions	Physical inspection	Train retailers on product handling and storage Provide product retailing facilities and support where applicable	Training records of retailers

CHAPTER FIVE: SELF-ASSESSMENT GUIDELINES FOR MILK PROCESSORS

In order to evaluate whether the milk processing Quality Assurance System is effectively in place and working as desired, it is critical to routinely conduct a self-assessment.

Self-assessment is a rapid tool for internal appraisal that can give reliable results on the level of achievement of the quality assurance system in place. This evaluation will also provide a framework and input to regulatory surveillance and support. It also provides a mechanism for continuous improvement of the quality assurance system.

The tool promotes confidence build up for market access and elevates the profile of the milk processor as a reliable source of quality and safe milk and milk products.

This can be done using a simple checklist as recommended below.

Table 4: Self-assessment guideline for milk processors

Consideration	Requirements	Assessment criteria	Requirements met?	
			Yes	No
1. Preparatory stage of milk processing				
(a) Environment	Premise is located away from sources of contamination	Physical inspection		
	Environment and processing facilities are free of pests and rodents	Physical inspection		
(b) Premise	Premise design and layout to prevents cross contamination of milk	Physical inspection		
	High risk areas are segregated to prevent contamination of milk	Physical inspection		
	Floors, walls and ceilings are impervious, easy to clean and sanitize	Physical inspection		
	The premise has adequate and protected	Physical		

Consideration	Requirements	Assessment criteria	Requirements met?	
			Yes	No
	lighting and ventilation	inspection		
	Premise has adequate hand washing and sanitization facilities	Physical inspection		
	Adequate, clean and properly located toilet and sanitary facilities are provided	Physical inspection		
	Footbaths and appropriate disinfectant are provided at the entrance of the processing facility	Physical inspection		
(c) Equipment	Surfaces of milk equipment and containers are easy to clean and disinfect, corrosion resistant and do not transfer harmful substances to the milk	Physical inspection		
		Rinse and swab tests		
	The layout of the equipment allows for adequate cleaning and prevents cross contamination of milk	Physical inspection		
(d) Cleaning and sanitation programme	The cleaning and disinfecting agents are effective, safe and easily rinsed.	Physical inspection		
		Rinse and swab tests are routinely conducted		
		Cleaning efficiency tests are routinely conducted		
	Equipment and containers are cleaned and disinfected immediately after use	Physical inspection		
(e) Personnel	Milk handlers are free of contagious or infectious diseases which may be transferred to or affect the quality and safety of the milk	Physical inspection		
		Medical examination is routinely conducted		
	Milk handling personnel observe personal hygiene, wear suitable protective attire and avoid undesirable behavior	Physical inspection		

Consideration	Requirements	Assessment criteria	Requirements met?	
			Yes	No
(f) Water	Adequate and potable water is provided for cleaning and processing	Physical inspection		
		Testing water for quality is routinely conducted		
(g) Waste management	Liquid and solid waste are disposed as per relevant regulations	Physical inspection		
		Inspection of waste disposal records		
	Solid and liquid waste does not harbor flies, insects and other rodents	Physical inspection		
2. Sourcing and procurement stage				
(a) Sourcing and procurement of raw materials	Specifications for raw material have been established	Raw material specifications are in place		
	Appropriate suppliers have been identified and selected	List of approved suppliers is in place		
	Raw materials that conform to specifications are procured	Raw materials are tested for quality		
(b) Storage and utilization of raw materials	Raw materials are stored under specified conditions	Physical inspection		
		Temperature and time control records are maintained		
	First in First Out (FIFO) principle is practiced	Physical inspection		
		Procurement and inventory records are maintained		
3. Milk processing, packaging and storage				
(a) Processing	Raw materials for processing comply to specifications	Raw materials are tested for		

Consideration	Requirements	Assessment criteria	Requirements met?		
			Yes	No	
		quality			
		Physical inspection			
	Dairy produce is subjected to recommended processing regimes	Product safety controls are monitored			
		Testing of dairy produce for efficiency of the heat treatment process are conducted			
	Dairy produce comply to the recommended shelf life	Monitoring of product shelf life is conducted			
	Surfaces of milk processing equipment do not contaminate the milk	Physical 1 inspection			
		Rinse and swab tests are conducted			
		Testing of processed dairy produce is conducted			
	(b) Storage	Dairy produce is stored under recommended conditions	Physical inspection		
			Testing of stored dairy produce is conducted		
4. Distribution and marketing					
(a) Transportation	Dairy produce is transported under recommended conditions	Physical inspection			
(b) Warehousing and storage	Dairy produce is stored under recommended conditions	Physical inspection			
		Testing of stored dairy produce is conducted			

Consideration	Requirements	Assessment criteria	Requirements met?	
			Yes	No
		Monitor storage conditions		
(c) Merchandising and retailing	Dairy produce is retailed under recommended conditions	Physical inspection		
5. Customer feedback				
Handling of customer feedback and complaints	There is a mechanism to receive and respond to customer complaints or feedback	Physical verification		
	Customer complaints are addressed on time	Physical verification		

ANNEX 1: SAMPLE RECORDS

Equipment maintenance schedule

Name of the farm _____ Date: _____ Prepared by: _____ Submitted by: _____ Approved by: _____							
Equipment No.	Task description	Task duration	Due date	Target date	Resource name	Person responsible	Predecessor

Cleaning schedule

Section	Frequency	Mon	Tue	Wed	Thu	Fri	Sat	Sun	Responsible	Remarks

REFERENCES

- i) Public Health Act Cap 242, laws of Kenya
- ii) Food, Drugs and Chemical Substances Act Cap 254, laws of Kenya
- iii) Dairy Industry Act Cap 336, laws of Kenya
- iv) Draft Dairy Regulations 2017
- v) Standards Act Cap 496, laws of Kenya
- vi) Kenyan Specifications for raw cow milk, KS EAS 67:2007
- vii) Code of hygienic practice for milk and milk products
- viii) FAO and IDF, 2011. Guide to good dairy farming practice
- ix) Ministry of Livestock Development, 2012. Dairy Farmers Training Manual
- x) FAO. Milk processing Guide Series, Volume 2
- xi) Tetra Pak, 1995 : Dairy Processing Handbook

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Ministry of Agriculture
Livestock and Fisheries



Investing in rural people



Smallholder Dairy Commercialization Programme (SDCP) is a jointly funded programme by the Government of the Republic of Kenya (GOK) and the International Fund for Agricultural Development (IFAD) and beneficiary communities.

The Overall goal of the programme is to increase the income of poor rural households that depend substantially on production and trade of dairy products for their livelihood.