QUALITY & SAFETY IN MILK PROCESSING

MILK PROCESSING MODEL: A GUIDE FOR MILK PROCESSORS

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Definition of Terms

*Calibration:* Involves checking instruments or equipment against a standard to ensure accuracy.

*Controlled process:* A process which the control chart shows no points outside control limits.

*Allergen:* A substance (usually the protein component) which, when consumed in a dairy product, causes an adverse reaction which involves the human immune system.

*CCPs decision tree:* A sequence of questions to determine whether a particular processing step or ingredient is a CCP.

*Audit:* An evaluation against a dairy plant’s written HACCP program to determine conformance. An audit may also include evaluation of compliance with dairy customer or government HACCP requirements.

*Control:* To manage the conditions of an operation to maintain compliance with established criteria.

*Control measure:* Any action or activity that can be used to prevent, eliminate, or reduce a significant hazard.

*Control point (CP):* Any step at which biological, chemical or physical factors can be controlled.

*Corrective action:* Procedures followed when a deviation occurs.

*Critical:* A deficiency or non-conformity that is likely to result in an adverse health consequence if left unmanaged.

*CCP:* Any point, step, or procedure at which control can be applied and a dairy food safety hazard can be prevented, eliminated or reduced to acceptable levels. A CCP is one that is concerned only with safety or health considerations.

*Critical limit:* A maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at CCP to prevent, eliminate or reduce the potential of a food safety hazard to an acceptable level.

*Deficiency:* An element inadequate or missing from the requirements of the written HACCP program.

*Deviation:* A failure to meet a critical limit for a CCP.

*Documentation:* Information/records available in a written, electronic or other form which can be utilized to detect trends assisting the verification and validation of the prerequisite program and HACCP plan.
**HACCP**: A systematic approach to the identification, evaluation and control of significant food safety hazards.

**HACCP plan**: The written document specific to a product and process, which identifies CCP(s), establishes critical limits, control and documents and delineates procedures to be followed to assure control on the basis of the seven principles of HACCP.

**HACCP program**: The preliminary steps, prerequisite program, good manufacturing practices (GMPs) and written HACCP plan.

**HACCP system**: The implementation of the written HACCP program.

**HACCP team**: The group of people who are responsible for developing, implementing and maintaining the HACCP system.

**Hazards**: A biological, chemical or physical agent that is of sufficient severity or is reasonably likely to cause illness or injury in the absence of its control.

**Hazard analysis**: The written and documented process of collecting and evaluating information on hazards associated with the food under consideration to decide which are severe or of sufficient likelihood to occur and must be addressed in the HACCP plan or prerequisite program.

**Non-conformity**: A failure to meet specified requirements of the HACCP prerequisite program.

**Preventive measures**: Physical, chemical or other factors that can be used to manage an identified hazard.

**Potentially hazardous food**: Food that requires time/temperature control for safety (TCS) to meet pathogenic microorganism growth or toxin formation.

**Risk**: An estimate of the likely occurrence of a hazard, i.e. usually the responsibility of governments.

**Severity**: The seriousness of a hazard.

**Validation**: The element of verification focused on collecting and evaluating scientific and technical information to determine whether the prerequisite program and HACCP plan, when properly implemented, will effectively control the hazard(s).

**Verification**: The use of methods, procedures or tests, in addition to those used in monitoring, to determine if the HACCP system has properly implemented the prerequisite program and HACCP plan and/or whether there is need for modification and revalidation.
Chapter One

Food is the basic of life. Quality or excellence in our food supply should be an important concern to all food processors. Safety and wholesomeness are the two most important attributes of food quality. The lack of quality as it relates to safety and wholesomeness can result in personal injury, sickness or death. Food-borne illness may happen, for example resulting to sickness or even death in some instances when unsafely produced food is eaten.

This milk processing model will give milk processors a useful guide on how to process milk products with consideration for quality and safety. This model highlights necessary issues related to quality control program and hazard analysis critical control points system. Its application will promote production of high quality and safe milk products.

The purpose of this guide is to assist milk processors in applying basic quality tools for continuous product and process improvement so as to assure quality targets are met. In this guide you will find information: (a) that helps to identify hazards that may potentially occur in your products, (b) that helps to identify and use methods of controlling and preventing hazards, (c) that helps to understand some key aspects of HACCP system and help you plan how you will initiate your HACCP activities. I have included information on some other important aspects of the Dairy HACCP System.

The scope of this guide addresses the development of a product flow diagram, description of product, hazard identification and evaluation, implementation of basic tools of quality control and quality management tools for problem solving as examples. The development of prerequisite program and formation of HACCP team are also discussed.

This guide is very useful to food inspectors who are responsible for inspecting processors of milk and milk products. More importantly, the guide will be used as training manual for various stakeholders who are required by law to be equipped with such knowledge. The use of this model will provide an opportunity to identify strength and weaknesses on food safety processing programs. While you are reviewing this guide, provide me with feedbacks so that I can strengthen its anticipated objectives.
Chapter Two

2.0 Quality Control

Quality control has the objective of ensuring that the quality and safety of the milk offered to consumers are met. The dairy products industry need to control the raw milk supplied by farmers and setup controls on the process and/or the end product in order to ensure the safety and quality of the product going out into the market.

2.1 Quality Control of Raw Milk

Testing raw milk is thus essential to ensure safety and quality. Raw milk is analyzed for the presence of microscopic abnormalities such as; addition of water, microbial quality, presence of milk from mastitic cows, presence of residues and composition. Microbial composition is a major issue, because pathogens can compromise product’s safety and spoilage microorganisms can limit the shelf life of the products.

2.2 Quality Control of Processed Milk

Short-shelf life milks; the limiting shelf life factor is a post-heat treatment contamination i.e. spoilage by bacteria that enter milk after the heat treatment, usually in the filling/packaging line and grow at refrigeration temperature (Tamime, 2009).

Routine determinations of total microbial count such as; coliforms, psychrotrops and other pathogens are paramount. An important source of spoilage in short life milk is the presence of heat resistant spore forming bacteria, mainly Bacillus spp. These bacteria are ubiquitous in raw milk that survive heating process and grow at refrigeration temperature (Tamime, 2009).

Long-shelf life fluid milk include; sterile and UHT milks. The major shelf life limiting factor for UHT milk is the presence of heat resistant enzymes, particularly lipase and proteases, produced by psychrotrophs during refrigerated storage of the raw milk, which cause age gelation and off-flavor (Tamime, 2009).

The microbial content, appearance and organoleptic properties are routinely tested by an accelerated shelf life test, performed by the incubation of UHT milk in a closed container for 15 days at 30°C (or for 7 days at 55°C) after being processed (Tamime, 2009).
2.3 Factors Affecting the Quality of Pasteurized Milk

The main controlled points for ensuring good quality processed milk products are:

- Raw milk quality.
- Processing conditions such as; temperature and holding time.
- Post-processing contamination.
- Storage temperature.

2.4 Factors Affecting the Quality of UHT Milk

- Growth of psychotropic bacteria in raw milk.
- Heat-resistant spore forming bacteria in raw milk.

### Table 1.0

<table>
<thead>
<tr>
<th>Microbial species</th>
<th>Associated problem</th>
<th>Main pathway, contamination source</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Bacillus cereus</em> (spores)</td>
<td>Spoilage of pasteurized dairy products</td>
<td>Environment(^a) (feeds, soil + feaces), milking equipment</td>
</tr>
<tr>
<td><em>Bacillus sporothermodurans</em> (spores)</td>
<td>Spoilage of UHT-treated dairy products</td>
<td>Environment (feeds &amp; feaces)</td>
</tr>
<tr>
<td>Butyric acid bacteria (spores)</td>
<td>Spoilage of Gouda &amp; Emmenthal cheeses</td>
<td>Environment (feeds &amp; feaces)</td>
</tr>
<tr>
<td><em>Campylobacter jejuni</em></td>
<td>Food safety (Products made of raw milk)</td>
<td>Environment (feaces)</td>
</tr>
<tr>
<td><em>Escherichia coli</em></td>
<td>Spoilage &amp; food safety (Products made of raw milk)</td>
<td>Environment (feaces &amp; bedding)</td>
</tr>
<tr>
<td><em>Mycobacterium paratuberculosis</em></td>
<td>Food safety (Products made of raw milk)</td>
<td>Environment(^a) (feaces)</td>
</tr>
<tr>
<td><em>Salmonella spp</em></td>
<td>Food safety (Products made of raw milk)</td>
<td>Environment(^a) (feaces)</td>
</tr>
<tr>
<td><em>Pseudomonas spp</em></td>
<td>Spoilage</td>
<td>Environment(^a) (bedding, soil, milking equipment)</td>
</tr>
<tr>
<td><em>Streptococcus thermophilus</em></td>
<td>Spoilage</td>
<td>Environment(^a) (feaces, bedding, soil, milking equipment)</td>
</tr>
<tr>
<td><em>Staphylococcus aureaus</em></td>
<td>Food safety (Products made of raw milk)</td>
<td>Interior of teats</td>
</tr>
<tr>
<td><em>Listeria monocytogenes</em></td>
<td>Food safety (Products made of raw milk)</td>
<td>Environment(^a) (feeds &amp; feaces)</td>
</tr>
</tbody>
</table>

Main Source of Microorganisms Occurring in Milk and Associated Spoilage and Safety Issues in Dairy Products.

\(^a\) For species having the environment as the major source of contamination and are the microbial carries indicated between brackets. Data compiled from Fenlon (1988), Haven et al. (1996), Slaghuis et al. (1997), Stadhouders & Jørgensen (1990), Te Giffel et al. (1995) and Vaerewijck et al. (2001).
Chapter Three

3.0 Basic Tools of Quality Control

3.1 Ingredient Specifications

The quality of the finished food product after manufacturing depends entirely on the quality of the raw materials and ingredients. The basic starting point for developing ingredient specifications is the supplier. Ask for a copy of the supplier’s ingredient specification, review the information and modify the specifications to fit your needs. Then, discuss and settle the differences regarding specific specifications with the supplier. The ingredient specifications should be documented in a form consistent with the processor’s needs. This should include:

- Name of ingredient
- Internal code number
- Effective date
- Basic description of ingredient
- Specifications (categorized as critical, major and minor)
- Action and reject levels
- Ingredient statement

The ingredient statement for the raw material is a reference point to assure that the supplier has not changed the material. The final key point for ingredient specifications is for the supplier to know and agree to the content of the document.

3.2 Approved Supplier List

For each ingredient, an approved supplier list should exist and be available to individuals responsible for purchasing and quality control. A good target is three suppliers per ingredient. At times, only one acceptable supply source may be available because of special requirements. In this case, alternate sources should be listed for emergency purpose. The approved supplier list should contain the following information:

- Ingredient name and internal code
- Supplier name, address, key contact and phone number
- Trade name of ingredient
- Supplier code number
3.3 Product Formulation/Recipe

For each product, written documentation of the formula or recipe should exist and be available for use by selected production personnel. The formula should be used daily as a means of assuring consistency between batches, lots and even days of production. For highly confidential formulas, the production worker does not need all the details. A simplified recipe can be provided to assure that the secret stays a secret. The individual formula sheets can have a variety of formats.

Key aspects of any formula document are:

- Name of the product
- Internal code number
- Effective date
- Listing of ingredients
- Listing of the ingredient code
- Percentage formula
- Batch formula
- Batch yield
- Ingredient statement

3.4 Product Standards

A key tool to assure quality in a finished processed food is the product standard document. Product standards define the food by physical, chemical and microbiological characteristics. Appearance, aroma, flavor and texture can also be considered for product standards.

The milk processors should comply with the requirements of the Tanzania standards, some of them mentioned down here:

- TZS 251: 1985 Standardized and pasteurized cow's milk specification
- TZS 112: 1981 Code for hygienic conditions for production, processing, transportation and distribution of milk
- TZS 120: 1981 Microbial analysis of milk
- TZS 124: 1981 Methods for sampling milk and milk products for microbial examination
- TZS 307: 1987 Yoghurt specification
- TZS 253: 1985 Butter –methods of sampling and test
The sensory properties of a food product are keys to the consumer acceptance and it is considered as a part of the total quality control of a product. Milk is a pleasant and satisfying food when correctly produced and processed. For this reason alone, milk is analyzed for sensory analysis in the following manner:

- On-farm milk production-controls for raw milk
- Processing-effects of processing methods on the finished products (temperature of heating and time/ effect of packaging materials, inter-batch consistency.
- Marketing- assesses consumer preferences; understanding how a product performs against competitor’s products in relation to consumer perceptions or sensory characteristics.

3.5 Manufacturing Procedures

For each product, document the processing procedure to ease duplication from lot to lot, shift and day to day. Several key points to consider when identifying important processing operations are time, temperature, equipment required, order of addition for ingredients and weight. Once prepared, make manufacturing procedures or portions of the procedures available to production employees. Use the document as an employee training tool (Http://www.ces.uga.edu/pub/cd/b997-w.html).

3.6 In- Process Records

It is important to know what is happening with the product and process during manufacturing. This is the way of obtaining information, where by both quality control and production personnel should participate in maintaining a daily manufacturing log. The specific product weight, temperature, size and shape, ingredient usage, product yield, scrap or reworks are examples of measurements made during the manufacturing process. In-processing records also are means of making adjustments to the product or process and prevent substandard product (Http://www.ces.uga.edu/pub/cd/b997-w.html).

Tally charts and Statistical process control charts are continuous quality improvement tools that can be used in-process records (Http://www.leanman.hubpages.com).
3.7 Packaging and Labeling

A quality control program should include packaging and labeling. One of the first items that influence the consumer is the appearance of the package and the label. Dairy products require packaging to inhibit light penetration and excessive oxygen because of the potential for flavor defects due to oxidation, rancidity or the absorption of foreign flavor ([http://www.ces.uga.edu/pub/cd/b997-w.html](http://www.ces.uga.edu/pub/cd/b997-w.html)). It is to a food processor’s advantage to develop packaging and label specifications along the same format as ingredient specifications.

3.8 Warehousing

Warehousing involves three activities (receiving, storage and shipping) that are included in a quality control program. The receiving operation is the foundation for processing finished food products of a designated quality. Guidelines for incoming shipments are:

1. Be sure the storage space is clean and consistent with the first-in-first-out rotation principle. FIFO rotation is the removal of inventory from storage in a systematic way where earlier stock items are used first. This can be accomplished by date coding the inventory according to the date of receipt.
2. Before unloading, inspect the condition of the carrier. Measure temperature, observe and note foul odors, spills and insects. For refrigerated and frozen products, temperature is critical.
3. Observe the condition of the containers for damage which could be a source of contamination.
4. Collect random samples from the shipment and analyze or evaluate the samples in relation to specifications.

5. After unloading, inspect the condition of the carriers and notice the condition of the floors and walls. Take a note of any dirt, filth or residues and evidence of previous spills.

6. Do not accept food, ingredient or packaging shipments combined with chemicals or poisonous substances.

7. If the shipment does not meet specifications, be prepared to reject all or part of the load.

8. Minimize dock time. Move refrigerated or frozen items directly into storage.

9. Date code all incoming shipments directly on the container or pallet load for stock rotation.

Storage in an orderly manner under proper conditions of temperature and humidity is essential to quality.

Shipping is the final step in which a food business can have direct control on product quality. Ship items on First-in-first-out basis and use the same guide-lines in shipping that you followed in receiving.

3.9 Laboratory Analysis

Laboratory analysis is the phase in which a quality control program is implemented after product is produced. A sampling plan, along with an analysis frequency (time schedule defining how often analyses are made, as defined in a specific Tanzania Standards), is absolutely necessary. Perform all laboratory analyses in a room away from the processing area. Therefore, there are three ways to obtain laboratory analysis results:

- In-house lab
- Outside independent lab
- Combination of in-house and independent lab

Appoint a qualified individual to conduct analyses, report the results and manage the job of quality control. Have laboratory tests results recorded and compared to the specifications or standards. Deviations from standards should be communicated so that additional action can be taken if necessary.
3.91 Recall Plan

Product recall has to bring back product from the distribution system. The public image of businesses can be destroyed during a recall if a well organized plan is not implemented. A recall plan should be developed and communicated to appropriate individuals within the firm before an emergency arises. The plan should include:

1. An effective product coding system. Date of manufacture, date code plus shift code, lot code or various combinations are possible.
2. A record keeping system to identify and associate specific product, product code, carrier and destination.
3. A list of key personnel and their assigned responsibilities for a recall.
4. A communication system within the firm and a system into the distribution marketing/receiving channels and legal counsel.
5. Establish procedures for evaluating and correcting situations.

8D-method is a tool of QM-system for problem solving process that can be used to evaluate and correct this situation or other related situation from customers. 8D systems is methodology for finding rapid and lasting solutions to customer complaints, using a team or individual approach and ensuring that similar problem will not recur.

The report given to a customer after eight stages of decision by following this rule 1-2-14, therefore the written statement will be given to customer within one day, two days up to fourteen days. The last statement contains; root cause analysis, implemented and the planed corrective action, after immediate containment actions whereby all customers protected from further complaints.
Table 2.0

<table>
<thead>
<tr>
<th>8D - report</th>
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<table>
<thead>
<tr>
<th>Company :</th>
<th>reference-no. :</th>
<th>date :</th>
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<th>unconformancy :</th>
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<tr>
<td>part :</td>
</tr>
</tbody>
</table>

1. Team name, department

2. problem description:

3. sudden activity: effect in % : Start date:

4. definition of cause: % -rate on problem:

5. planned corrective actions: Evaluation of efficiency : effect in % :

6. realized corrective actions: Start date:

7. preventive actions: Start date:

8. continuous control : responsibility : Finishing date : author :

An example of 8D report.
3.92 Good Manufacturing Practices and Sanitation

Good manufacturing practices are an integral part of quality control. It is the responsibility of milk processors to know, practice, communicate and ensure that GMP is carried out by employees. An overview of GMP is as follows:

- Individual with communicable diseases cannot work in areas where food contamination is possible. This includes individuals with boils, sores or infected wounds.
- Food handlers must follow good personal hygiene practices.
  - Wear protective clothing.
  - Clean and sanitize hands and gloves.
  - No jewelry.
  - Use gloves (non-absorbent) when the job requires hand covering.
  - Use effective hair restraints and covering.
  - Eat, drink or smoke only in designated areas.
- Train employees effectively in hygiene, sanitation and pest control.

Along GMPs, a cleaning and sanitizing program is essential. Cleaning and sanitizing should address three basic areas:

- Exterior facility and grounds.
- Internal facility including floors, walls, ceilings and ventilation system.
- Equipment and all food contact areas.

A cleaning and sanitizing program prevents the buildup of dirt and debris, maintains equipment in good repair, prevents growth and contamination from microorganisms and prevents the entry and harboring of insects and other pests. The quality program should: outline specific activities to be performed, any corrective measures, and schedules for cleaning and sanitizing, identify approved cleaning compounds, sanitzers and define a standard. Keep and maintain proper records.
Chapter Four

4.0 Management Quality Tools

One of the requirements of business survival is continuous quality improvement of both your products and services, the quality tools can help you make this improvement. Milk processors should understand and implement quality tools, for chasing your competitors and problems. Failure to continually improve your processes, service and product quality will at some point result in the demise of your livelihood. Quality tools that you could use are:

4.1 Tally Chart

A tally chart is probably the simplest and oldest way to record data, it is merely a table of how often a specific occurrence happens, normally put together when the event occurs. It can be used to record defects against categories as a machine works, the number of requests made of department each hour and so on.

4.2 Pareto Chart

It is a column chart for the graphical analysis of problem causes in the order of severity. This analysis allows us to focus our resources on the critical few to gain the maximum benefit. Use the 80:20 Rule to identify the vital few areas to tackle.

![Pareto Chart](image.png)

*Figure 2.0* Pareto chart
4.3 Histogram

Is a simple method to graphically represent collected data and allow analysis of frequency of data which are collected in group or classes. The histogram will quickly and clearly tell you how good your process is at meeting the required tolerances as well as pointing out any unusual situations.

**Frequency**

![Histogram](image)

*Figure 3.0* Histogram

4.4 Brainstorming

Method for an easy collection of lots of ideas and the selection of preferred activities. It stimulates creative thinking, either to discover potential causes of a problem or potential solutions. Through brainstorming approach the data can be organized and analyzed in a different ways such as in a fishbone diagram.

4.5 Cause and Effect Diagram (Ishikawa, Fishbone)

It is a way to represent cause and effect, the effect forming the head of the fishbone and the potential causes forming the skeleton behind. It is a structured way to represent the results of a brainstorm in specific categories that contribute to problems that are Man, Machine, Material, Method and Mother Nature.

4.6 Statistical Process Control Chart

Is a graphical tool (form or IT) based statistics to monitor a continuous production flow. Goal is to react very early on beginning deviations which will lead to an error. If the process is running in a normal fashion then the plots on the chart will fall randomly
within the limits defined on the chart, otherwise they act in a non random manner and the operator is warned of a problem in a process, often before the rejects are produced.

\[ 
\begin{array}{c}
\text{UCL} \\
\hline \\
\text{LCL} \\
\end{array} 
\]

Figure 4.0 Structure of SPC chart

4.7 The 5 Whys

The 5 why is a simple discipline to keep asking why of the potential cause until you can think of no more causes of your cause, often asking 5 whys will get you to the true root cause.

Example of the 5 whys

Problem: Our pasteurized milk fails to meet minimum shelf life.

**WHY?** Because of bacterial contamination.

**WHY?** Because of poor hygienic practices.

**WHY?** Because of lack of hygienic training to personnel.

**WHY?** Because of lack of training program in our company.

**WHY?** Because the funds have not been approved for training.

“Ask whys at least five times for each cause”.

Chapter Five

5.0 HACCP in Milk Processing

The use of the Hazard analysis critical control point (HACCP) system has become a mature food safety system used widely in the International dairy processing industry. HACCP is a logical, effective, scientifically based and highly structured system of food safety management designed to assist plant HACCP teams in producing a program to minimize, manage or control hazards.

One of the key advantages of the HACCP concept is to enable a dairy food manufacturing companies to move away from a philosophy of control based on testing (i.e. testing for failure) to a preventive approach, whereby potential hazards are identified and controlled in the manufacturing environment (i.e. prevention of product failure).

The success of an HACCP system mandates educating and training management and production personnel in the importance of their role in manufacturing safe dairy foods. This training should also include information for the control of food borne hazards related to all stages of food chain.

5.1 General Aspects of the Benefits of HACCP System

Food safety is the primary concern in a dairy product HACCP system. However, the wholesomeness and quality of the product may also be enhanced by proper implementation of HACCP and associated prerequisite programs. The overall and specific benefits of an HACCP system include:-

i. Focus on prevention
ii. Utilizes science – based food safety data and principles.
iii. Provides a high level of assurance of dairy product safety.
iv. Focus appropriate technical resources and control on critical points in the production process.
v. Lessens emphasis on end product testing.
vi. Places the primary responsibility for food safety on processors, where it belongs.

vii. Meets customer needs and expectations.
viii. Assured brand integrity.
ix. Decreased numbers of consumer complaints.
x. Reduced incidence of product holds and or recalls.
xi. Increased sales opportunities.
5.2 Implementation and Maintenance of HACCP Program

5.21 Commitment from Top Management

It is necessary in order to support the need for additional resources for start-up, initiation and implementation. It is recommended that plant management agree to:

- Commit short term resources to support development, training and implementation of an HACCP program.
- Provide long term commitment of support and resources.
- Create an environment to encourage a change in culture.
- Establish a tracking system to measure the progress and benefits of the HACCP program.

Table 3.0

Date:

To: Name
Title
Address

As part of our continuing efforts to manufacture food under the safety possible conditions that meet or exceed customer, company and government standards, the ................................................................. has adopted the HACCP principles for food safety.

Periodic update of program will be necessary to maintain its effectiveness.

Approved by:............................
Plant Manager: ................................. Date:
Corporate Production Manager: .................................. Date:
President: ................................. Date:

Example of management letter of endorsement.
5.22 Establish a Plan

That describes the individuals responsible for developing, implementing and maintaining the HACCP system. Select HACCP team and coordinator, provide training.

There must be representatives from all major plant operational areas.

- Different product teams can be appointed to develop the HACCP program for specific products. Upon completion of the HACCP program, operation procedures, forms and procedures for monitoring and corrective actions are developed.
- Production personnel, who will be responsible for monitoring and documenting, need to be trained.

Prior to the developing an HACCP plan, there is a requirement for dairy plants to have developed, documented and implemented programs to control factors that may not be directly related to product safety, but serve as a foundation of an HACCP system. These programs together are known as the “Prerequisite program”.

The prerequisite program is the universal procedure used to control the plant environment and operating conditions that contribute to the production of safe, wholesome dairy products.

Eight mandatory prerequisites:

- Safety of water that comes into contact with food or food contact surfaces.
- Condition and cleanliness of the food contact surface
- Prevention of cross contamination between food, food-pack material, food contact surfaces and unsanitary objects, this include contact between raw and processed products.
- Maintenance of the hand washing and toilet facilities.
- Protection from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agent, condensate and other chemical, physical or biological compounds.
- Proper labeling, storage and use of toxic compound
- Control of employee health conditions.
- Exclusion of pests.
5.3 HACCP Implementation

The preliminary tasks in the development of an HACCP plan include the following:

a) Assemble the HACCP Team.

b) Describe the food and its distribution.

c) Describe the intended use and consumers.

d) Develop a flow diagram which describes the process.

e) Verify the flow diagram.

5.31 HACCP Team

The team consists of individuals who have specific knowledge and expertise appropriate to the dairy product and process.

Table 4.0

<table>
<thead>
<tr>
<th>Name</th>
<th>Job title &amp; role</th>
<th>Experience</th>
<th>HACCP program development responsibilities</th>
<th>Task completion date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allein Smith</td>
<td>QC Supervisor/</td>
<td>Bsc..... 12 years in</td>
<td>Oversee development &amp; maintenance of plant</td>
<td>June 2007</td>
</tr>
<tr>
<td></td>
<td>HACCP team Leader</td>
<td>various Dairy plants</td>
<td>HACCP program develop &amp; finalize written verification &amp; validation program</td>
<td></td>
</tr>
</tbody>
</table>

Name of drafter:

Date of document:

Plant HACCP Team summary.
HACCP team needs be multi-disciplinary with knowledge and experience in the following areas:-

a) Quality assurance  
b) Engineering  
c) Production  
d) Sanitation  
e) Microbiology and  
f) Outside experts (if necessary)

These individuals should have the knowledge and experience to correctly:

- Conduct a hazard analysis.  
- Identify potential hazards.  
- Evaluate potential hazards and how they will be managed.  
- Recommend controls critical limits and procedures for monitoring and verification.  
- Recommend appropriate corrective actions when a deviation occurs.  
- Recommend research.  
- Verify and validate the HACCP program.

Responsibility of HACCP team;

- Select a trained HACCP coordinator.  
- Prepare a statement of intent.  
- Develop action plan.  
- Identify resources needs.  
- Establish a timetable for completion of written documents, implementation and oversight.

5.32 Description of Products and its Distribution

First the HACCP team describes each dairy products manufactured. This consists of a general description of the dairy product, ingredients and processing methods as well as other pertinent information.

The use of food maybe for direct consumption, as an ingredient in another food or for non-food uses.
Example of a form of product description

<table>
<thead>
<tr>
<th>Plant name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street address:</td>
</tr>
<tr>
<td>State/Country:</td>
</tr>
<tr>
<td>Zip/Area code:</td>
</tr>
</tbody>
</table>

Formal product name: e.g. Cheddar cheese

Food safety characteristics: Ph 4.9-5.4

Ingredients:

Packaging used:

Labeling requirement: Keep refrigerated

Storage & distribution:

Intended consumers: All ages

Intended use: Ready to serve product

Shelf life: 3-12 months

Approved by:

Date:

5.33 Identify Intended Use and Consumers of the Food

The intended use should be based on the expected uses of the product by the end user or consumers. In specific cases, vulnerable groups of the population e.g. infants, elderly, institutional feeding, may have to be considered. The use of the food maybe for direct consumption, as an ingredient in another food or for non-food uses.
5.34 Develop a Flow Diagram of Process

The purpose of a flow diagram is to provide a clear, simple outlines of the steps involved in the manufacturing process. The scope of flow diagram must cover all the steps in the process, which are directly under the control of establishment. In addition, the flow diagram can include steps in the process, which are before and after the processing that occurs in the HACCP plan. Point to consider;

- All process steps where raw materials/ingredients and packaging are used.
- All raw materials/ingredients.
- All process steps in production.
- Product recycle/rework loops.
- Storage and distribution.
- Gases and water used in contact with products.

![Figure 5.0 Typical HACCP of pasteurized milk flow diagram](image)
5.35 Verification of Flow Diagram

The HACCP team should perform an on-site review of the operation to verify the accuracy and completeness of the flow diagram. The flow diagram should be reviewed periodically, modified, updated and documented, as necessary. It is recommended to take the diagram out to the production floor and walk through the steps to ensure the diagram's accuracy.

5.4 Hazard Components

Hazards to be considered in the hazard analysis are those reasonably likely to occur in a dairy-processing facility that is developing a written HACCP program. Careful consideration must be given to all ingredients, every step in the process and the finished product packaging and storage. Remember, hazards, as defined within HACCP relate to *product safety*. In brief, the different hazards within an HACCP program are as follows.

5.41 Biological Hazards

Biological hazards for dairy processors might include pathogenic bacteria, viruses or parasites/protozoa. Specific pathogenic bacteria that have been linked to food borne illness outbreaks associated with dairy products include *Escherichia coli*, *Listeria monocytogenes*, *Salmonella* spp. *Campylobacter* spp. and *Staphylococcus aureus*. Table 6.0 illustrates the potential biological hazards found in foods; however, it might be more useful to group organisms by characteristics necessary for growth and destruction. For example, most microorganisms in the vegetative state are easily destroyed by pasteurization temperatures (e.g. 72°C for 15 sec); however, higher heat treatment(s) may trigger outgrowth of certain spore-forming organisms. The outgrowth of the spores from spore-forming microorganisms is generally inhibited by lower pH. Toxin producing organisms usually require mesophilic growth conditions to achieve large enough populations to produce toxins.

### Table 5.0

<table>
<thead>
<tr>
<th>Severe</th>
<th>Moderate with potentially Extensive spread</th>
<th>Moderate with limited spread</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Brucella</em> ssp.</td>
<td><em>Salmonella</em> ssp.</td>
<td><em>Bacillus cereaus</em></td>
</tr>
<tr>
<td><em>Clostridium botulinum</em></td>
<td><em>Enterotoxigenic Escherichia coli</em></td>
<td><em>Clostridium perfringens</em></td>
</tr>
<tr>
<td><em>Listeria monocytogenes</em></td>
<td><em>Enteroinvasive Escherichia coli</em></td>
<td><em>Staphylococcus aureus</em></td>
</tr>
<tr>
<td><em>Salmonella typhi, paratyphi</em></td>
<td><em>Shigella</em> spp.</td>
<td><em>Campylobacter jejuni and other species</em></td>
</tr>
<tr>
<td><em>Shigella dysenteriae</em></td>
<td><em>Viruses</em></td>
<td><em>Aeromonas</em> spp.</td>
</tr>
<tr>
<td><em>Hepatitis A and E</em></td>
<td><em>Protozoa (Cryptosporidium spp.)</em></td>
<td><em>Yersinia enterocolitica</em></td>
</tr>
<tr>
<td><em>Escherichia coli</em> 0157:H7</td>
<td><em>Protozoa (Giardia spp.)</em></td>
<td><em>Parasites</em></td>
</tr>
</tbody>
</table>

Some examples of biological hazards.
5.42 Chemical Hazards

Chemical hazards that might be considered in a dairy plant hazard analysis are listed in a Table no.7.0, because they have the potential to cause illness in susceptible individuals, if not properly addressed.

Table 6.0

<table>
<thead>
<tr>
<th>Chemical compound</th>
<th>Chemical hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Natural toxins</td>
<td>Mycotoxins</td>
</tr>
<tr>
<td></td>
<td>Acute (e.g. ochratoxin, trichothecene, zearalenone or aflatoxin), chronic (e.g.</td>
</tr>
<tr>
<td></td>
<td>aflatoxin, sterigmatocystin or patulin), other natural toxins (e.g. thyro-toxicosis)</td>
</tr>
<tr>
<td>• Metals</td>
<td>Copper, cadmium, mercury and lead</td>
</tr>
<tr>
<td>• Drug residues</td>
<td>β-Lactams, Sulphonamides, Tetracyclines, Macrolides, others</td>
</tr>
<tr>
<td>• Cleaner/ Sanitizer residues</td>
<td>Nitrates, phosphates, chlorinated organic, Iodophors</td>
</tr>
<tr>
<td>• Pesticide residues</td>
<td>Organo-phosphates, fumigants, others</td>
</tr>
<tr>
<td>• Allergens and Sensitivities</td>
<td>Egg and egg products, milk and milk products, peanuts and peanuts product,</td>
</tr>
<tr>
<td></td>
<td>sea food/shellfish, seeds, soy and soy products, tree nuts, wheat and wheat</td>
</tr>
<tr>
<td></td>
<td>product, sulphites</td>
</tr>
<tr>
<td>• Food additives</td>
<td>Vitamins, colors, Aspartame</td>
</tr>
<tr>
<td>• Inadvertent or toxic chemicals</td>
<td>Equipments, cleaning chemicals, lubricants, boiler additives, water treatment</td>
</tr>
<tr>
<td></td>
<td>additives, others</td>
</tr>
</tbody>
</table>

Main examples of potential chemical hazards.

5.43 Physical Hazards

Physical hazards are those materials that are likely to cause injury or choking and must also be evaluated within each dairy plant. Employee practices might also influence the types of physical hazards to be considered in the processing facility.
Table 7.0

<table>
<thead>
<tr>
<th>Glass fragments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wood fragments</td>
</tr>
<tr>
<td>Plastic fragment, such as pieces, shavings</td>
</tr>
<tr>
<td>Metal fragments, such as bolts, nuts, bag clips/locks</td>
</tr>
<tr>
<td>Personal effects, such as jewellery, earrings, buttons, pens</td>
</tr>
<tr>
<td>Other extraneous materials (e.g. nut shells, fruits pits (cherry, peach), fruit material (stems, caps, seeds)</td>
</tr>
</tbody>
</table>

Some examples of potential physical hazards.

**Figure 6.0** An illustration of an HACCP pyramid.

5.5 Prerequisite Program

Prior to the developing an HACCP plan, there is requirement for dairy plants to have developed, documented and implemented programs to control factors that may not be directly related to product safety, but save as foundation of an HACCP system. These programs together known as the ‘Prerequisite program’. A prerequisite program should be written, effectively checked, documented and managed before attempting to develop the HACCP plan. The prerequisite program is the universal procedure used to control the plant environment and operating conditions that contribute to the production of safe, wholesome dairy products. They represent the sum of programs, practices and procedures that must be applied to design, produce and distribute safe products in a clean, sanitary environment.
An outline for the development and documentation of a prerequisite program include the following:

- Identify mandatory or key prerequisites
- Write brief description (see Tables 8.0, 9.0 and 10.0)
- Identify hazards reduced or eliminated
- Identify records maintained to verify reduced or eliminated hazards
- Identify staff responsible for maintaining records
- Written brief description of corrections

A prerequisite program should address common public health concerns, which may be slightly different depending on the specific region of the world and specific dairy product. One example of government-based mandatory prerequisite or SSOP programs in the USA.

**Table 8.0**

<table>
<thead>
<tr>
<th>PP # 1</th>
<th>Deep South Milk Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety of water that comes into contact with food or food contact surfaces (including steam and ice)</td>
<td>Page 1 of 1, 15 February 2008</td>
</tr>
<tr>
<td>Goals:</td>
<td>Approved by:</td>
</tr>
<tr>
<td>- Water for milk plant purposes, including re-circulated cooling water, shall be from a system that is properly constructed, protected and operated, and shall be accessible, adequate and of a safe sanitary quality.</td>
<td></td>
</tr>
<tr>
<td>- Whenever steam is used in contact with milk or milk products, it shall be of culinary quality.</td>
<td></td>
</tr>
<tr>
<td>- Ice is produced from municipal portable water.</td>
<td></td>
</tr>
<tr>
<td>Procedures:</td>
<td></td>
</tr>
<tr>
<td>- Test well water and re-circulated cooling water for coliforms semi-annually, for example (a) monitoring- water sample log (laboratory) and (b) other documentation-water sampling reports.</td>
<td></td>
</tr>
<tr>
<td>- Use only approved boiler water and re-circulated cooling water additives, for example (a) monitoring- boiler chemical addition log and (b) other documentation-additives with supplier’s certifications.</td>
<td></td>
</tr>
<tr>
<td>- Construction requirement for wells, the plant water distribution systems, the re-circulated cooling system and the steam generation system will be evaluated upon installation and after major changes to the system.</td>
<td></td>
</tr>
<tr>
<td>Summary of required monitoring documentation:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Monitor</th>
<th>Frequency</th>
<th>Document</th>
<th>Verification</th>
<th>Retention</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Role</td>
<td>Frequency</td>
<td>Requirement</td>
<td>Frequency</td>
<td></td>
</tr>
<tr>
<td>-------------------------------</td>
<td>------------</td>
<td>--------------</td>
<td>------------</td>
<td></td>
</tr>
<tr>
<td>Laboratory manager</td>
<td>Semi-annual</td>
<td>1.1.a. Water and re-circulated cooling water sampling reports file</td>
<td>Quality Manager</td>
<td>Laboratory-3 years</td>
</tr>
<tr>
<td>Boiler maintenance Engineer</td>
<td>Semi-annual</td>
<td>1.2.a. Boiler chemical addition log</td>
<td>Laboratory manager</td>
<td>Laboratory-1 year</td>
</tr>
<tr>
<td>Laboratory manager</td>
<td>Semi-annual</td>
<td>1.1.a. Additives Supplier's Certification file</td>
<td>File only</td>
<td>Laboratory – 3 year</td>
</tr>
</tbody>
</table>

Sampling should be considered if the water system has been breached by construction.

**Corrections:**

- Corrections will be taken as needed at each step and noted on the monitoring form.
- Any correction that cannot be accomplished immediately will be reported to the appropriate supervisor to assess whether the non-conformity presents a significant weakness or has a potential impact on the ability to produce a safe product. In addition, the supervisor will assess whether immediate short-term measures are needed to minimize the effect of the problem on our product or operation.

Corrections that cannot be addressed immediately will be given a timeline for correction in the scheduled correction log and will be reassessed on a weekly basis.

Summary of the required monitoring documentation when preparing prerequisite program (PP#1).
Table 9.0

<table>
<thead>
<tr>
<th>Monitor</th>
<th>Frequency</th>
<th>Document</th>
<th>Verification</th>
<th>Retention</th>
</tr>
</thead>
<tbody>
<tr>
<td>2nd shift sanitation employee</td>
<td>Daily</td>
<td>Sanitation checklist PS#11355</td>
<td>3rd shift sanitation supervisor, daily</td>
<td>QC PP verification files</td>
</tr>
<tr>
<td>Supervisor team different each month</td>
<td>Monthly</td>
<td>Sanitation checklist PS#11355</td>
<td>QC supervisor, weekly</td>
<td>QC PP verification files</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Monthly supervisory checklist-facilities</td>
<td>Plant manager, monthly</td>
<td>QC PP verification files</td>
</tr>
<tr>
<td></td>
<td></td>
<td>inspection section: assess repair, general</td>
<td></td>
<td>QC PP verification files</td>
</tr>
<tr>
<td></td>
<td></td>
<td>construction and maintenance of hand-washing</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>and toilet facility.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HACCP team</td>
<td>Annually</td>
<td>Annual Verification Report</td>
<td>HACCP team leader</td>
<td>QC plant verification files</td>
</tr>
</tbody>
</table>

Goals:

- Toilet rooms shall not open directly into any room in which milk/milk product processed. Toilet rooms shall be completely enclosed and shall have tight-fitting, self closed doors. Dressing rooms, toilet rooms and fixtures shall be kept in a clean condition, in good repair and shall be well ventilated and well lighted. Sewage and other liquid wastes shall be disposed of in a sanitary manner.
- Convenient hand-washing facilities shall be provided, including hot and cold running water and or warm water, soap and individual sanitary towels. Hand-washing facilities shall be kept clean and in good repair.

Procedures:

- Restroom facilities and hand-washing areas will be inspected and maintained by the last powder packer of the shift, at the close of each shift.
- A contract cleaning service will clean and perform scheduled maintenance on restrooms weekly.
- Monthly plant audits will assess repair, ventilation and lighting.
- Annual verification will assess adequacy and convenience of hand washing facilities.

Summary of the required monitoring documentation
Corrections:

- Corrections will be taken as needed at each monitoring step and noted on the monitoring form.
- Any correction that cannot be accomplished immediately will be reported to the appropriate supervisor to assess whether the non-conformity presents a hazard, a potential impact on our ability to produce a quality product or a legal violation. In addition, the supervisor will assess whether temporary measure are needed to minimize the effect of the non-conformity on our product or operation.
- Corrections that cannot be addressed immediately will be given a timeline for correction in the 'Scheduled Correction Log' and will be reassessed at weekly supervisor's meeting until corrected.

Note: All corrections cannot be accomplished immediately, and some corrections have higher urgency than others. No identified non-conformance should be noted without a carefully considered correction plan and a timeline to get it accomplished. Have a procedure to reassess the timeline regularly and adjust as necessary to make sure the due date does not pass without some action, if only to extend the timeline as necessary.

Date:................................................................. Signature:........................................
Supersedes: 10 June 2007

Summary of the required monitoring documentation when preparing the prerequisite program (PP #4).

Figure 7.0 Prerequisite check of condition and cleanliness of processing equipment.
Temperature control program

Goals: To have adequate mean of establishing, maintaining and monitoring temperatures
- Raw materials/ingredients used in production.
- Finished product to ensure safe storage of the food.
- Distributed products.

Procedures:
- Raw materials/ingredients temperature control, for example (a) monitoring-silo storage temperature recording charts and (b) monitoring- incoming milk temperature log.
- Finished product temperature control, for example (a) monitoring-finished product temperature recording charts, (b) monitoring – pasteurization recording charts and (c) other documentation-daily temperature checks.
- Pre-shipment transport requirements, e.g. monitoring-truck inspection/refrigeration checks.

<table>
<thead>
<tr>
<th>Monitor</th>
<th>Frequency</th>
<th>Document</th>
<th>Verification</th>
<th>Retention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Production supervisor</td>
<td>Daily</td>
<td>1.1.a. Silo, temperature charts</td>
<td>Production manager-weekly</td>
<td>Production department-1 year</td>
</tr>
<tr>
<td>Milk receiver</td>
<td>Daily</td>
<td>1.b Milk receiving temperature log</td>
<td>Production manager-weekly</td>
<td>Production department-1 year</td>
</tr>
<tr>
<td>Warehouse supervisor</td>
<td>Weekly</td>
<td>2.a Finished product temperature charts</td>
<td>Warehouse manager-weekly</td>
<td>Warehouse department-1 year</td>
</tr>
<tr>
<td>Production supervisor</td>
<td>Daily</td>
<td>2.b Pasteurization temperature charts</td>
<td>Production manager-weekly</td>
<td>Production department-1 year</td>
</tr>
<tr>
<td>Warehouse supervisor</td>
<td>Daily</td>
<td>2.c Daily temperature charts</td>
<td>Warehouse manager-weekly</td>
<td>Warehouse department-1 year</td>
</tr>
<tr>
<td>Warehouse supervisor</td>
<td>Daily</td>
<td>3.a Transport inspection log</td>
<td>Warehouse manager-weekly</td>
<td>Warehouse department-1 year</td>
</tr>
</tbody>
</table>

Corrections:
- Corrections will be taken as needed at each step and noted on the monitoring form.
- Any correction that cannot be accomplished immediately will be reported to the appropriate supervisor to assess whether the non-conformity presents a significant weakness or has a potential impact on the ability to produce a safe product. In addition, the supervisor will assess whether immediate short-term measures are needed to minimize the effect of the problem on our product or operation.
- Corrections that cannot be addressed immediately will be given a timeline for correction in the ‘Scheduled Correction Log’ and will be reassessed on a weekly basis.

Summary of the required monitoring documentation when preparing the prerequisite program (PP # 10).
There are eight mandatory prerequisites, which are addressed within the associated general prerequisite as follows:

- Safety of water that comes into with food or food-contact surfaces, including ice.
- Condition and cleanliness of the food contact surface.
- Prevention of cross-contamination between food, food-packaging material, food-contact surfaces and unsanitary objects; this includes contact between raw and processed product (includes allergen prevention program).
- Maintenance of the hand washing and toilet facilities (see Table 9.0).
- Protection from adulteration with lubricants, fuel, pesticides, cleaning compound, sanitizing agents, condensate and other chemical, physical or biological compounds.
- Proper labeling, storage and use of toxic compounds.
- Control of employee health conditions.
- Exclusion of pests.

The intent of this section is to provide guidance to plant management and the HACCP team in evaluating the plant areas falling under the mandatory prerequisite program (see above list) or identifying hazards that need to be addressed by new prerequisite program. The importance of prerequisite program cannot be overstated; it is the foundation of a comprehensive HACCP system and must be effective. In summary, comprehensive, effective prerequisite programs will simplify HACCP plans, and will ensure that the integrity and comprehensiveness of the HACCP program is maintained and that the manufactured product is safe.

This section outlines examples of prerequisite areas including key environmental and operational areas. A dairy plant's prerequisite program may include some or all of the areas listed below, depending on the plant, product and hazard analysis.

*Premises*-They include (a) outside property, (b) building and personnel traffic patterns and (c) sanitary facilities (mandatory PP#4- see Table 9.0).

*Water/steam/ice safety* (mandatory PP#1-see Table 8.0) includes the following: (a) portable water supply, (b) steam supply, (c) ice supply, (d) cooling water and (e) reclaimed water.

*Receiving/storage/transportation* consists of (a) supply control, (b) receiving of raw materials, ingredients and packaging materials (i.e. specifications and storage conditions) (mandatory PP#6), (c) temperature control program and (d) transportation program.

*Equipment performance and maintenance program* include (a) general equipment design, (b) equipment installation and (c) equipment maintenance and calibration.
Personnel training program and employee hygiene involves (a) training, (b) hygienic practices (mandatory PP#7), (c) infectious disease policy (mandatory PP#7), (d) injury/open wound policy (mandatory PP#7), (e) controlled access policy (mandatory PP#7) and (f) personnel safety program (mandatory PP#7).

Environmental and processing equipment hygiene program involves manufacturing controls.

Cleaning and sanitation program (mandatory PP#2) takes into account (a) interior facility cleaning, (b) processing equipment cleaning and sanitation and (c) pest control (mandatory PP#8).

Recall program involves (a) product traceability and (b) product recall system.

Cross-contamination prevention program include the following: (a) allergens (mandatory PP#5), (b) general adulteration (mandatory PP#5) and (c) cross-contamination (mandatory PP#3).

5.6 The Principle of an HACCP Plan

There are seven principles in establishing an effective HACCP plan, which is used in conjunction with the prerequisite program and other associated parts of the entire HACCP program; these principles are

- Conduct a hazard analysis
- Determine CCPs
- Establish critical limits
- Establish monitoring procedures
- Establish corrective actions
- Establish verification procedures
- Establish record-keeping and documentation procedures

5.61 Principle 1 - Conduct a Hazard Analysis

The HACCP team conducts a hazard analysis and identifies appropriate control measures using two separate but related steps “hazard identification and hazard evaluation”.

The hazard identification and hazard evaluation accomplish three objectives:

- The hazards are identified at each processing step and for each ingredient and material used.
- The hazards are evaluated to determine their severity and likelihood of occurrence.
- The hazard analysis provides a basis for determining management or control measures, such as prerequisite program or critical control point in principal 2.

### 5.611 Hazard Identification

The purpose of this step is to develop a list of potential hazards, based on historical operations, HACCP team experience, scientific literature and governmental requirements. The HACCP team develops a list of potential biological, chemical or physical hazards, which may be introduced, increased or controlled at each step in the production process and for each ingredient and packaging type.

### 5.612 Hazard Evaluation

In this step, the HACCP team needs to decide which potential hazards must be addressed in the HACCP plan. Each potential hazard is evaluated on the basis of the severity of the potential hazard and its likelihood of occurrence. Severity is the seriousness of the consequence of exposure to the hazard. During the evaluation of each potential hazard, the food, its method of preparation, transportation, storage and persons likely to consume the product should be considered to determine how each of these factors may influence the likely occurrence and severity of the hazard being controlled. The team must consider the influence of likely procedures for manufacturing and storage and whether the intended consumers are susceptible to a potential hazard.
<table>
<thead>
<tr>
<th>Stage</th>
<th>Hazard analysis</th>
<th>Incoming raw milk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 1- hazard identification</td>
<td>Determine potential hazards associated with product</td>
<td>Enteric pathogens (i.e. <em>Escherichia coli</em> 0157: H7 and <em>Salmonella spp.</em>)</td>
</tr>
<tr>
<td>Stage 2- hazard evaluation</td>
<td>Assess severity of health consequences if potential hazard is not properly controlled</td>
<td>Epidemiological evidence indicates that these pathogens cause severe health effects among children and elderly. Un-pasteurized milk has been linked to disease from these pathogens</td>
</tr>
<tr>
<td></td>
<td>Determine likelihood of occurrence of potential hazard if not properly controlled</td>
<td>Using information above, determine if this potential hazard is to be addressed in the HACCP plan</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Escherichia coli 0157: H7 is both likely to occur in raw milk as well as other enteric pathogens</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The HACCP team decides that enteric pathogens are hazards for this product. Sanitation and temperature control will not destroy these pathogens. The microbiological hazard must be controlled in the plan</td>
</tr>
</tbody>
</table>

Examples of how the stages of hazard analysis are used to identify and evaluate hazards.

Note: For illustration purposes only. The potential hazard identified may not be the only hazards associated with the products listed; however, the responses may be different establishments.

5.62 Principle 2- Determine Critical Control Points

A CCP is defined as a step at which control can be applied, and is essential to prevent, eliminate or reduce a food safety hazard to an acceptable level. Identification of each CCP can be facilitated by the use of the hazard analysis decision tree. Although application of the hazard analysis decision tree can be useful in determining if a particular step is a CCP for a previously identified hazard, it is merely a tool and not a mandatory element of HACCP. If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or late stage, to include a control measure.
Different facilities preparing the same dairy product can differ in their hazards and the points, steps, or procedures, at which are CCPs. This can be due to differences in each facility layout, equipment, selection of ingredients (including raw versus pasteurized milk) or the process that employed.

**Figure 8.0** Codex decision tree to identify Critical Control Points
5.63 Principle 3- Establishments of Critical Limits

A critical limit is a maximum and/or minimum (i.e. scientifically based) numerical value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard. A critical limit is used to distinguish between safe and unsafe operating conditions at a CCP. Critical limits should not be confused with operational limits, which are established for reasons other than food safety. Critical limits must be met to ensure the safety of the dairy product, and may be derived from different sources, such as regulatory standards and guidelines, scientific literature searches, experimental studies and experts. Critical limits are parameters, which may be established as control measures and include:

- Temperature
- Time
- Water activity
- pH
- Titratable acidity
- Safe or tolerance levels of drug residues

Example of a very common CCP in the dairy industry is pasteurization; ‘time’ and ‘temperature’ are the critical limits in pasteurization (see Table no12.0).

5.64 Principle 4- Establish Monitoring Procedures

Monitoring is a planned sequence of observations or measurements used to assess whether a CCP is under control, and an accurate record exists for future use in verification. Monitoring serves three purposes:

- Monitoring is essential to dairy product food safety management in that it tracks the systems operation.
- Monitoring is used to determine when there is loss of control and deviation occurs at CCP (i.e. exceeding the critical limit); corrective action must be taken.
- Monitoring provides written documentation for use in verification of the HACCP plan.

Because of the potentially serious consequences of a deviation, monitoring procedures must be effective. Continuous monitoring is possible with many types of physical and chemical methods, for example, the time and temperature of pasteurization. Monitoring equipment must be carefully calibrated for accuracy (verification activity). When it is not possible to monitor a critical limit on a continuous basis, it is necessary to establish
the monitoring interval, which will be reliable enough to indicate the hazard is under control.

Assignment of the responsibility for monitoring is an important consideration for each CCP. Specific assignments will depend on the number of CCPs, their critical limits and the complexity of monitoring. Those individuals monitoring CCPs must

- Be trained in the technique used to monitor each critical limit
- Fully understand the purpose and importance of monitoring
- Have ready access to the monitoring activity
- Accurately report the monitoring activity

The person responsible for monitoring must also inform management when a process or a product does not meet critical limits so that immediate corrective action can be taken. Most monitoring procedures for CCPs will need to be done rapidly because they relate to online processes, and there will not be time for lengthy analytical testing. Microbiological testing is seldom, if ever, effective for monitoring CCPs due to the time required to conduct tests. Therefore, physical and chemical measurements are preferred because they may be conducted rapidly and can indicate the conditions of microbiological control in the process.

The following areas must be addressed when considering monitoring/inspection:

Monitoring control- Need to know correct control points (critical) before establishing monitoring programs; designed to measure if the CCP is in or out of control.

Frequency-Will vary depending on likelihood and severity of the identified hazard. Continuous monitoring and recording are preferred in most situations.

Responsibility, i.e. position title assigned and work station.

5.65 Principle 5- Establish Corrective Actions

Corrective actions are procedures to be followed when a deviation occurs. Because of variations in CCPs for different dairy products and the diversity of possible deviations, specific corrective action plans must be developed for each CCP. Corrective actions must demonstrate the CCP has been brought under control, i.e. within critical limits.

Written corrective action plans may include:

- Elimination of actions or potential hazards created by deviation.
- Specific corrective actions for each CCP, i.e. hold production of the product, isolate the affected product, return process to control and determine the disposition of the product.
- Disposition of the dairy product involved.
• Methods to demonstrate that the CCP is brought under control, i.e. determination of the cause of the deviation.

Another approach to establishing corrective action plans in advance is to utilize the five steps when an HACCP deviation occurs. These steps are widely recognized as being adequate for the HACCP team to use in documenting a deviation, and they are:

• Segregate and hold the affected product.
• Perform or obtain a review to determine the acceptability of the affected product for distribution.
• Take corrective action, when necessary, with respect to the affected product to ensure that no injurious or adulterated product enters commerce.
• Correct the cause of the deviation.
• Perform or obtain timely validation as required by a qualified individual(s), to determine whether modification of the HACCP plan is required to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.

When the critical limit has been exceeded, decisions must be made on the basis of whether there are indications that

• Evidence or existence of a direct health hazard.
• Evidence that a direct health hazard could develop.
• Indications that a dairy product was not produced under conditions assuring safety.
• Evidence that a CCP is not under control.

Once the corrective actions have been established should be transferred to column 8 on the HACCP plan summary (see Table 12.0).

5.66 Principle 6- Establish Verification Procedure

Verification is addressed in two ways in the HACCP plan. First, establishing verification on the HACCP plan summary (Table 12.0), and second, establishing internal verification monitoring. In both situations, documentation is critical.

Verification is an activity designed to ensure that the monitoring program is operating according to the requirements of the HACCP program. Once the verification has been established, the internal verification monitoring program can be developed.

Verification report should include:

a) Status of records associated with CCP monitoring.

b) Direct monitoring data of the CCP while in operation.
c) Calibration and testing of monitoring equipment.
d) Deviations and corrective actions.
e) Training and knowledge of individual responsible for monitoring CCPs and
f) A check of chart to show the records have been verified.

Internal verification monitoring can be utilized to ensure that the HACCP plan is
functioning effectively rather than relying on end product sampling. Firms must rely on
frequent reviews of their HACCP plan for effectiveness, and examples of internal
verification monitoring may include

- Establishing of appropriate verification monitoring schedules.
- Review of the CCP monitoring records at specified frequency.
- Visual verification of operations to observe if the CCPs are under control.
- Verify that changes have been implemented correctly after an HACCP plan has
  been modified.
- Review of consumer feedback records.

5.661 HACCP System Audits

As part of verification, audits are performed to compare the actual practices and
procedures of the HACCP system with those written in the HACCP plan. Audits may be
performed for individual CCPs and/or for the overall plan.

5.662 Calibration

Calibration should be documented and the records should be available for review
during verification. Calibration of appropriate equipment and instruments used in the
development and implementation of the HACCP plan should be carried out during
monitoring and/or verification:

- At a frequency sufficient to assure continuous accuracy
- According to procedures established in the HACCP plan (which can be based on
  instrument or equipment manufacturer specifications)
- By checking accuracy against a recognized standard
- Under conditions similar or identical to those under which the instrument or
  equipment will be used

5.663 Targeted Samples Collection and Testing

Verification may also include targeted sampling and testing and other periodic
activities. Targeted sampling and testing involves taking product samples periodically
and testing them to ensure that critical limits are appropriate for product safety. When
critical limits are set for equipment operation, product samples may be taken to ensure
that the equipment settings are appropriate to provide product safety.
Verification of the HACCP program should occur at least annually. At this point, if internal verification monitoring is not acceptable to resolve the issues, the HACCP team may have to validate the HACCP plan as described in the next section. One possible verification plan recording form is shown in Table 13.0.

**Table 13.0 An example of verification Plan recording form**

<table>
<thead>
<tr>
<th>Specify activity</th>
<th>Classification of activity</th>
<th>Responsible verifier</th>
<th>Frequency</th>
<th>Outcome</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i.e. CCP records,</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corrective actions,</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment calibration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>and/or other aspects)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**5.664 Validating the HACCP Plans**

The HACCP team should conduct a validation of the HACCP plan annually or at any time when the process or product formulation is altered. In addition, the validation process may need to be conducted if the verification process does not correct and address the hazard.

The validation basis by reviewing the following items:

- The effectiveness of the process.
- The accuracy of the flow diagram.
- The soundness of the hazard analysis.
- The completeness of the HACCP plan.
- The appropriateness of the CCPs.
- The scientific justification for the critical limits.
- The comprehensiveness of the corrective actions.
- The effectiveness of the monitoring program, and the record keeping.

In addition to the annual validation, some situations that require validations are

- New potential hazard for that dairy food, e.g. new pathogens and/ new CCPs.
- New scientific data available.
- Recall of dairy products.
• Response to new dairy product development, for example (a) raw materials change, (b) preparation and processing change, (c) formulation change, (d) packaging change and (e) new uses of dairy product by consumers.

• Response to manufacturing change, i.e. changes in dairy product flow in plant and/or equipment change.

Table 13.1 Example of validation Plan recording form

<table>
<thead>
<tr>
<th>Specific Activity</th>
<th>Narrative of specific activity</th>
<th>Name of Validator</th>
<th>Date of Validation</th>
<th>Outcome and actions items</th>
</tr>
</thead>
</table>

5.67 Principle 7- Records

Records that are being used to monitor control points should be placed in column 10 on the HACCP plan summary (see Table 9.0). Records utilized in the total HACCP system may include the following, and they all must be documented. It is strongly recommended that an inventory (see example illustrated in subsequent section) of all HACCP records be made as soon at the HACCP written program has been completed. This inventory summary is very useful in evaluating the HACCP program to make sure all identified records have actually been created and utilized in the HACCP system.

The HACCP plan may include the following:

• Listing of the HACCP team and assigned responsibilities
• Statement of intent
• Description of the dairy manufacturing process indicating CCPs
• Monitoring system
• Corrective action plans for deviations from critical limits
• Procedures for verification of HACCP system
• Records for all CCPs
• Hazard analysis
• Procedures for validation

The following records must be available for review:

• Training- documentation showing that all individuals have been properly trained in their role in monitoring CCP(s) identified in the HACCP plan summary (Table 9.0).
• Processing- records showing that the monitoring for the CCP is in place.
• Deviation or corrective action log- documentation to be completed in the event of a deviation from a critical limit for a CCP; a centralized deviation/corrective action log is strongly recommended.
- Verification and Validation records - these include (a) records showing that validation has occurred a minimum of annually or as necessary and (b) records showing routine verification of control charts.

- Records to show any major changes to the HACCP plan.

In order to provide the HACCP team with an overall view of all records utilized and referenced to document the written HACCP program, it is strongly recommended that each HACCP program contain a centralized list of HACCP program records (see Table 11). The purpose of Table 11.0 is to assist the plant HACCP team in demonstrating that

Table 14.0

<table>
<thead>
<tr>
<th>Centralized list of HACCP program records</th>
<th>Issue date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plant name</td>
<td>Supersedes</td>
</tr>
<tr>
<td>Address</td>
<td>Page</td>
</tr>
<tr>
<td>Record</td>
<td>Available (√= yes)</td>
</tr>
</tbody>
</table>

Required HACCP documents including forms are dated or identified with current version number. Each page is marked with a new date or version number whenever that page is updated. Most current versions used.

Table of contents
- Centralized list of HACCP program records
- Document change log
- Process flow diagram(s)
- Product description(s)
- Written hazard analysis(s) for each product
- CCP, HACCP plan summary(s) for each product
- CCP monitoring documents
- Centralized deviation log
- HACCP system verification documentation (including calibration of CCP monitoring equipment (i.e. pasteurization equipment checks); review of CCP monitoring records, corrective action records and calibration records; and plant signatures and date on these records)
- HACCP system validation documentation (annually or when changes are made in raw materials or source of raw materials; product formulation; processing methods or system, including computers and their software; packaging; finished product distribution systems; or the intended use or intended consumers of the finished product and consumer complaints)

Prerequisite program # 1 - Safety of water
- Monitoring records related to this PP (list records by name)
- Nonconformity correction records related to this PP

Prerequisite program # 2 - Condition and cleanliness of food contact surfaces
- Monitoring records related to this PP
- Nonconformity correction records related to this PP

Prerequisite program # 3 - Prevention of cross-contamination
- Monitoring records related to this PP
- Nonconformity correction records related to this PP

Prerequisite program # 4 - Maintenance of hand-washing and sanitizing and toilet facilities
- Monitoring records related to this PP
- Nonconformity correction records related to this PP
- Monitoring records related to this PP
- Nonconformity correction records related to this PP
Prerequisite program #5 - protection from adulteration
- Monitoring records related to this PP
- Nonconformity correction records related to this PP
Prerequisite program #6 - proper labeling, storage and use of toxic compounds
- Monitoring records related to this PP
- Nonconformity correction records related to this PP
Prerequisite program #7 - control of employee health condition
- Monitoring records related to this PP
- Nonconformity correction records related to this PP
Prerequisite program #8 - exclusion of pests
- Monitoring records related to this PP
- Nonconformity correction records related to this PP

Other prerequisite programs that are relied upon in the hazard analysis to reduce the likelihood of a potential hazard (list each separately, add rows as needed)
- Monitoring records related to this PP
- Nonconformity correction records related to this PP

Other applicable NCIMS requirements - Appendix K (list each separately, add rows as needed)
- Monitoring records related to this PP
- Nonconformity correction records related to this PP

An example of centralized HACCP record list.

PP, prerequisite program; NCIMS, US National Conference on Milk Shipments

Those records normally required. This checklist may also serve as a tool for internal and external HACCP auditors.

5.7 Internal and External Auditing in the HACCP Process

The audit process is a planned, independent, documented assessment that determines whether requirements for food safety are being achieved. An effective audit program will assess compliance, system effectiveness and identify opportunities for continuous improvement. There are three types of audit necessary to support the HACCP system, and they are

- Partial or complete HACCP program audits made by internal groups or the HACCP team.
- Partial or complete HACCP program audits made by outside third parties or government employees.
- HACCP verification and/or validation audit performed by internal groups or the HACCP team.

Fundamental to the audit process is the belief that they benefit management, are performed by qualified individuals, are based on standards (dairy plant’s written HACCP program) and conclusions are only drawn from the facts based on direct observations.
Floor supervisors, lead individuals or internal auditors can perform production floor audits. These individuals must be familiar with basic audit techniques and have process/system knowledge. Methods include record review, observation, sampling and use of short check-lists. Results should be reported internally and used to develop corrective action plans if deficiencies are noted. The audit frequency will vary depending on results.

The plant HACCP team or internal auditing group can perform HACCP program audits. Like the production floor audit, this is not an independent assessment of the HACCP system, but does provide a more in-depth verification of effectiveness. Training requirements for the HACCP team include intermediate auditing techniques and knowledge of the facility’s internal management structure, HACCP program and processing system. Methods include review of records, sampling and testing results, observation, interviews and checklists. These audits should be conducted at least quarterly with the results reported internally using formal documentation. This process can also be used to verify corrective actions have been successfully implemented.

A corporate team or external party performs HACCP verification and validation audit. Training for these individuals includes advanced audit techniques, process/system knowledge and food safety expertise. Methods include reviewing records, management controls, observation and interviews of operators, supervisors and management, sampling and testing, and comprehensive checklists. This independent audit is formally documented for distribution to plant management and the HACCP team and should be conducted annually.

Audits are used to assess HACCP team health and identify opportunities for improvement. If gaps are noted in a facility’s HACCP system, the root cause of the deficiency must be determined and corrections actions identified. The three levels of auditing discussed can be used to enhance the effectiveness of the facility’s corrective action program.
<table>
<thead>
<tr>
<th>Section and subsections</th>
<th>Page number</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Introduction</strong></td>
<td></td>
</tr>
<tr>
<td>a. Letter of management commitment</td>
<td>4</td>
</tr>
<tr>
<td>b. Principles of HACCP</td>
<td>5</td>
</tr>
<tr>
<td>c. Background documents including page on company history including current products covered under the HACCP program- news stories</td>
<td>6</td>
</tr>
<tr>
<td>d. Staff organizational chart for the plant operation</td>
<td>8</td>
</tr>
<tr>
<td>e. Front plant view plus overhead view of the plant (floor layout)</td>
<td>9</td>
</tr>
<tr>
<td>f. Product floor diagram</td>
<td>10</td>
</tr>
<tr>
<td>g. Company policy on hold and release, and returned product disposition</td>
<td>11</td>
</tr>
<tr>
<td>h. Name of each HACCP team member with a brief bio for each. Include a log of team meetings, who attended, date and time and agenda of meeting</td>
<td>12</td>
</tr>
<tr>
<td><strong>2. Plant GMPs and prerequisite program (PP)</strong></td>
<td></td>
</tr>
<tr>
<td>a. Written summary of ice cream plant GMPs</td>
<td>14</td>
</tr>
<tr>
<td>b. Written description of ice cream plant prerequisites including a brief Statement on document control (will provide some examples):</td>
<td></td>
</tr>
<tr>
<td>i. Water safety</td>
<td>31</td>
</tr>
<tr>
<td>ii. Condition and cleanliness of processing equipment -address pre-operation start-up inspection, master sanitation schedule and limited inclusion of preventive maintenance to specific processing equipment preventive maintenance</td>
<td>32</td>
</tr>
<tr>
<td>iii. Cross-contamination-micro-based hazards, raw to pasteurized product</td>
<td>35</td>
</tr>
</tbody>
</table>
| iv. Adulteration  
1. Chemical- based micro hazards, allergens  
2. Cleaning chemical and toxic compound labeling, use and storage | 37         |
| v. Temperature control-identify target temperatures for receipt of ingredients, storage of ingredients, storage of final product (s) and distribution of final product(s) | 39         |
| vi. Personal training, employee, visitor and contractor hygiene- see PMO Section 13 and 14 for suggested items to be included in a company employee manual or policy on this subject. Identify training frequency as part of documentation supporting this prerequisite | 40         |
| vii. Receiving/storage/transport-address ingredient and package receiving, specification, storage and distribution of final product(s) | 42         |
| viii. Product tracing and market withdrawals-include section on customer feedback summary information and mock recall procedures | 44         |
| ix. Pest control- include floor diagram and location of all pest stations, electrocutors, or bait stations. Address frequency of review for outside contractor’s records | 49         |
| x. Maintenance of hand-washing, employee break- room and bathroom facilities | 53         |
| xi. Facility maintenance-includes grounds and outside maintenance (buildings, fence and everything between) and inside processing | 54         |
Table of contents for USA HACCP Program.

5.8 Overview and Summary

At this point, the dairy plant’s HACCP team should have covered all important points in development of a written HACCP program. In order to organize all the information and forms developed by the HACCP team, an example of a written HACCP program table of contents is shown in Table 15.0, which contains all the important information that should be included in any dairy plant’s written HACCP program.
6.0 References

   [Http://www.ces.uga.edu/pubcd/b997-w.html](Http://www.ces.uga.edu/pubcd/b997-w.html) (Visited on 04/05/2012)
   [Http://www.leanman.hubpages.com](Http://www.leanman.hubpages.com) (Visited on 13/06/2012)
7.0 Biography

Amina Yasin Kitindi is a food scientist and technologist and also a certified quality manager. She is working as Quality Assurance regional officer in charge by the bureau of standards. She has also working experience with two German dairy industries that are Kaeserei and Molkerei companies.

She studied Food science and Technology at Sokoine University of agriculture and Quality Management Systems at university of applied science Saarbrucken. She worked in a project focuses on the improvement of quality and safety of milk products. The project outcome was a documented milk processing model as a training material. She has seen there is a need to build capacity of local small and medium sized dairy enterprises to enable them produce desirable quality and volume for export.

She lives in Tanga with her husband and she can be reached at minaj372002@yahoo.com.