DEVELOPMENT OF HAZARD ANALYSIS AND CRITICAL CONTROL POINTS PLAN FOR ICE CREAM MANUFACTURING PROCESS

By

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DECLARATION

The work described in this thesis was carried out by me at the Department of Food Science & Technology, Faculty of Applied Sciences, Sabaragamuwa University of Sri Lanka, under the supervision of Mr. M.C.N Jayasooriya and Mr. A.R.V. Abesinghe. The report on this has not been submitted to another university for another degree.

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Affectionately Dedicated

To
My Parents, Teachers

&
My Alma mater

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ABSTRACT

People around the world are used to consume raw, ready-to-eat and minimally processed food due to their modern life style and people are more concerned about food safety as well as food quality. To achieve this objective, Hazard Analysis and Critical Control Point (HACCP) system is identified as the most effective and efficient method to ensure the product safety and it commenced new chapter in present era. There is a growing demand in the global trade with recent approach and it is become the primary requirement to commercialize the food products. All most all the Sri Lankan food companies are expecting to implement the HACCP system; because it is the weapon that can be used to compete the market competition in the local market as well as overseas. The study was aimed at development of HACCP plan for ice cream manufacturing process of MILCO (pvt) Ltd , one of the Sri Lankan milk industry that produce natural, high nutrition and very fresh product totally depending local farmers.

Good Manufacturing Practices manual (GMP) was developed as a pre-requisite program to build solid foundation for the HACCP plan. All the potential hazards associated with each processing step from raw milk reception to dispatch of end product were identified under the categories of biological, chemical and physical hazards and selected the significant hazards among them according to the severity and risk. Then Critical Control Point were identified . CCP monitoring, corrective action and verification procedure were established and documented.

Chilled milk storage and raw milk pasteurization are the Critical Control Points (CCPs) that were identified from raw milk receiving to standardization of milk. The mix pasteurization, aging and hardening were identified as the CCPs in rest of ice cream manufacturing process.

Chilled milk storage temperature need to maintain below 4^0C and 71.7^0C for15 seconds were established as critical limits for raw milk pasteurization.

The time temperature combination for the mix pasteurization should be maintained at 65.6^0C not less than 30 minutes to destroy *Bacillus cereus* and *Listeria monocytogenes* which are the microbial hazard commonly present in ice cream. 4 C - 7^0C, at least 4- 48hours for aging and -23^0C to -26^0C for hardening were the critical limit that was established for the each CCPs from mix pasteurization to dispatch of end product respectively.

CONTENTS

LIST OF ABREVIATIONS

CCP	Critical Control Point
CL	Critical Limit
CODEX	Code Alimentarius Commission an FAO/WHO Organization
GMP	Good Manufacturing Practices
HACCP	Hazard Analysis and Critical Control Point
hrs	hours
HTST	High Temperature Short Time
KQ	Keeping Quality
MO	Micro Organisms
MSNF	Milk Solid Non Fat
s	seconds
SLS	Sri Lanka Standards
SQA	Supplier Quality Assurance

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CHAPTER 01

INTRODUCTION

1.1. Background:

Milk Industry of Lanka Company Ltd. (MILCO) is the esteem industry among the milk industry in Sri Lanka which is manufactured ice cream, yoghurt, cheese ,butter ,milk powder , sterilized milk ect. under the brand name of 'Highland'.

Ice cream is frozen sweetened product made from a heat treated mix consisting of edible fat and milk solids with or without other ingredients and permitted additives (SLS 223:1989). It is one of the main product that manufactured under the 'Highland' brand.

It is a trend over the world that consumers thoroughly concern about safety of food as well as the food quality. Because after consuming some kind of food, it may cause adverse health effects on human being directly or indirectly within a few minutes or some hours later. Therefore food safety is the main requirement of customers other than the nutrition that they expect to gain while consuming the food.

All the food companies intended to implement Hazard Analysis and Critical Control Point (HACCP) concept along the food chain, because it was already a legal requirement in a number of countries. The HACCP system which is straight forward science based program, identifies hazard associated with a food and measures for their control to ensure safety of food. A key issue for product safety is the risk of cross contamination occur during the process from the internal factory environment. It is managed through adherence to pre-requisite program such as Good Manufacturing Practices or the cordex General Principles of food hygiene and it is possible to work pre-requisite program effectively while implementing HACCP system in the company. There are seven principles belongs to HACCP system which gives a lot of benefits if it is implemented and managed very effectively within the organization. (Carol and Sara, 1998)

After identifying the present situation of the field ,MILCO is willing to implement HACCP plan for ice cream process to provide safe as well as quality product to their customers and to keep their authority within the local market farther more.

1.2. General Objectives: -

- To develop an HACCP plan to improve the quality of 'Highland' Ice cream.

1.3. Specific Objectives:-

- To develop Good Manufacturing Practices (GMP) manual for the ice cream plant.
- To identify all possible hazards associated with the 'Highland' Ice cream product.
- To determine of Critical Control Points (CCPs) for identified hazards within the Ice cream production process.

CHAPTER 02

LITERATURE REVIEW

2.1. Background on HACCP

HACCP was developed originally as a microbiological safety system in the early days of the US manned space programme, as it was vital to ensure the safety of food for the astronauts. The original system was pioneered by The Pillsbury Company working alongside NASA and the US Army laboratories at Natick. At that time, most food safety and quality systems were based on end-product testing, but it was realized that this could only fully assure safe products through testing 100% of the product, a method which obviously could not have worked as all product would have been used up. Instead it become clear that a preventative system was required which would give a high level of food safety assurance, and the HACCP system was born. (Carol and Sara 1998)

HACCP is a preventive system of food control aimed at food safety assurance. It is a documented and verifiable approach for the identification of hazard, preventive measures and critical control point and the implementation of a monitoring system.

The internationally agreed principles of HACCP can be applied to all sectors of food and drink, manufacturing, distribution, retailing, and catering. They may be applied to currently marketed and new products.

The establishment of an effective HACCP system demands improvement in three areas ,namely the infrastructure, re-training and commitment from the management.

a. Infrastructure facilities and maintenance

The selection of appropriate locations, scientifically planned construction addressing requirement of food processing factories, and maintenance based on sanitary principles are basic requirements prior to addressing HACCP issues. The location should provide an environment free of contaminants and interaction by pests. In planning of processing units high priority need to be given to liner production flow and controlled traffic to minimize cross contamination. Operational cleaning and

sanitation program need to be based on documented procedure addressing both facilities and equipment with identified responsibilities. Pest control need to be addressed through purposefully designed infrastructure and planned control activities. Documentation of the plans and regularly audited activities are expected as evidence of concerns on quality issues in a factory. (Arampath *et al.* 2005).

b. Training and education

Substantial involvement of manual activities , make education and training of the staff essential to operate processing system with proper understanding and with collective responsibility. The success of an HACCP system depends to a great extent on proper understanding of the HACCP principles by both the management and the employees. Special attention need to be provided on quality issues, role of people in ensuring safety of products, and measures to control food borne hazards in all production stages. All employees should receive documented training in personal hygiene, GMP, cleaning and sanitation procedures, personal safety, and their role in the HACCP program. Re-training of staff as they gather experience to broaden their understanding and their role on regular basis contributes much in enhancement of product quality. (Arampath *et al.* 2005).

c. Management commitment

Application of a HACCP system involves its scientific documentation component and a strong commitment to apply and maintain the documented procedure in the system honestly in an effort to reach the highest standards working towards near zero level of food safety. This need a commitment from the top management down to everybody engaged in production and marketing. Every person need to understand the benefits of a HACCP and also that it involves a worthy cost. The cost comes not only in the form of infrastructure building, but more importantly and continuously, in the form of engagement of the team with right qualifications and correct attitudes. To begin with the organization needs to establish clearly the quality policy and objectives as a major component in the policy of the organization. As success of a HACCP program involve progressive improvements of the system meeting the changing concepts and addressing new issue arising with progress in science, the management need to engage in a regular review process of the HACCP system, its weaknesses and actions

to further improve and quality of products though scientific practices meeting the changes in market demand and process parameters (Arampath *et al.* 2005).

2.2. Prerequisite Programs

Prior to the development of HACCP plans, there is a requirement for establishments to have developed, documented and implemented programs to control factors that may not be directly related to manufacturing controls but support the HACCP plans. These programmed are called prerequisite programs and need to be effectively monitored and controlled before attempting to put any HACCP plan in place.

Prerequisite programs may be defined as universal steps or procedures that control the operational conditions within a food establishment allowing for environmental conditions that are favourable to the production of safe food.

The production of safe food products requires that the HACCP system be built upon a solid foundation of prerequisite programs. Each segment of the food industry must provide the conditions necessary to protect food while it is under their control. This has traditionally been accomplished through the application of Good Manufacturing Practices (GMPs).These conditions and practices are now considered to be prerequisite to the development and implementation of effective HACCP plans. Prerequisite programs provide the basic environmental and operations that are necessary for the production of safe, wholesome food (Carol and Sara 1998).

2.2.1. Facilities

The establishment should be located, constructed and maintained according to sanitary design principles. There should be liner product flow and traffic control to minimize cross-contamination from raw to cooked materials.

2.2.2. Supplier Control

Each facility should assure that its suppliers have in place effective GMP and food safety programs. These may be the subject of continuing supplier guarantee and supplier HACCP system verification.

2.2.3. Specification

There should be written specifications for all ingredients, products and packaging materials.

2.2.4. Production Equipment

All equipment should be constructed and installed according to sanitary design principles. Preventive maintenance and calibration schedules should be established and documented.

2.2.5. Cleaning and Sanitation

All procedures for cleaning and sanitation of the equipment and the facility should be written and followed. A master sanitation schedule should be in place.

2.2.6. Personal hygiene

All employees and other persons who enter the manufacturing plant should follow the requirements for personal hygiene.

2.2.7.Training

All employees should receive documented training in personal hygiene, GMP, cleaning and sanitation procedures, personal safety, and their role in the HACCP program.

2.2.8. Chemical Control

Documented procedures must be in place to assure the segregation and proper use of non-food chemicals in the plant. These include cleaning chemicals, fumigants and pesticides or baits used in or around the plant.

2.2.9. Receiving, Storage and Shipping

All raw materials and products should be stored under sanitary conditions and the proper environmental conditions such as temperature and humidity to assure their safety and wholesomeness.

2.2.10. Traceability and Recall

All raw materials and products should be lot-coded and recall system in place so that rapid and complete traces and recalls can be done when product retrieval is necessary.

2.2.11. Pest Control

Effective pest control programs should be in place.

2.3. Developing a HACCP Plan

In the development of a HACCP plan, five preliminary tasks need to be accomplished before the application of the HACCP principles to a specific product and process.

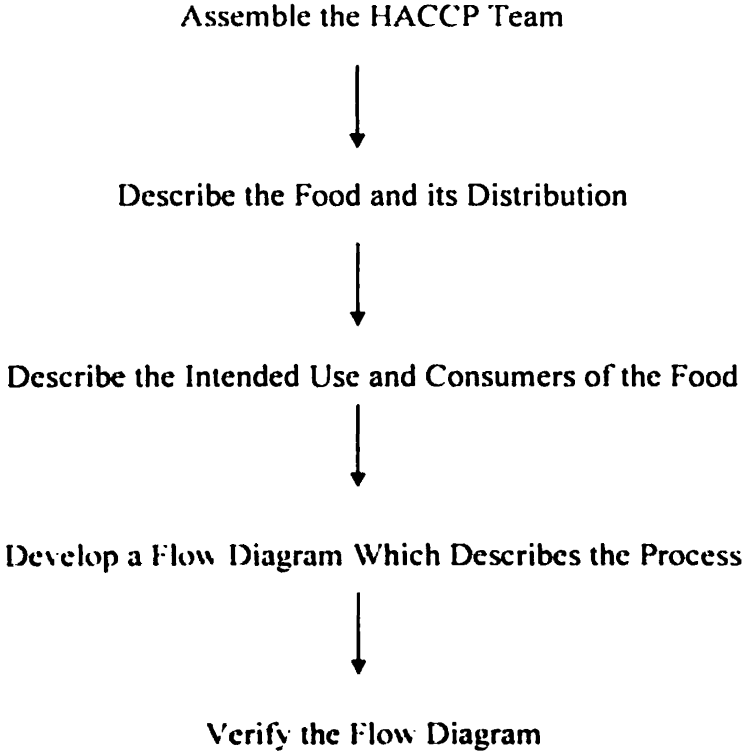


Fig.2.1. Preliminary Tasks in the Development of the HACCP Plan

2.3.1. Assemble the HACCP Team

Before beginning the study, management should inform all staff of the intended exercise. Both the company and personnel involved in the HACCP study must totally committed to its implementation.

The development of the HACCP system needs product specific knowledge and expertise. This is accomplished by assembling a multidisciplinary team (maximum 6).The team should include plant personnel from production, sanitation, quality assurance, laboratory, engineering and inspection. It is essential to assemble the right blend of expertise and experience, as the team will collect and evaluate technical data to identify hazards and critical control points. In smaller establishments, one person may fulfill several roles or even constitute the whole team. In the latter case the use of external consultants or advice from external experts may be necessary. The team should not be structured according to the company hierarchy.

2.3.2. Scope

One of the first tasks of the HACCP team is to identify the scope of the HACCP plan. That is:

-Limit the study to a specific product or product category and associated processes as at a time.

-Define the type(s) of hazards to be included (e.g. biological, chemical, physical) in the plan

-Define the part of the food chain to be studied under the project.

2.3.3. Describe the Food and its Distribution

A broad overview of the ingredients, processing condition, final product characteristics and the instruction for use will help the HACCP team to have a complete understanding of the product from receipt of ingredients to possible use by the consumer.

Information Required:

- Name of the product common name
- Ingredients raw materials
- Composition of the final product
- Potential to support microbial growth such as aw, pH of the final product

- How the product will be used by consumers (ie. Ready-to-eat) further processing required, heated prior to consumption
- Type of packaging and packaging material used
- Storage and shelf life of the product including storage conditions
- Labeling instruction (ie. Handling and usage information)
- Special distribution control (ie. Shipping conditions)

2.3.4. Describe the Intended Use and Consumers of the Food

Describe the normal expected use of the food. The intended consumers may be the general public or a particular segment of the population (e.g., infants, immunocompromised individuals, the elderly, etc.) and determine if sensitive populations are included. If the product is unsuitable for some sensitive group that ensure appropriate labeling or change the product or process to ensure suitability.

2.3.5. Develop a Flow Diagram Which Describes the Process

Describe the process from ingredients to processing, distribution, retail, consumer handling in accordance with the scope of the study. The process should be outlined in sequence in the flow diagram with sufficient technical data at each process step where appropriate.

2.3.6. Verify the Flow Diagram

The HACCP team should perform an on-site review of the operation to verify the accuracy and completeness of the flow diagram. Modification should be made to the flow diagram as necessary and documented.

After these five preliminary tasks have been completed, the seven principles of HACCP are applied.

2.4. Principles of the HACCP system

The HACCP system consists of seven principles which outline how to establish, implement and maintain a HACCP plan for the operation under study. The HACCP

principles have international acceptance and details of this approach have been published by the Cordex Alimentarius commition(1993/1997)

2.4.1. Principle 1

Identify the all potential hazard(s) associated with food production at all stages, i.e.- primary production, processing, storage and distribution and consumption. Assess the likelihood of occurrence of the hazard(s) and identify the measures for their control.

In this stage the HACCP team must perform the hazard analysis. In practice, hazard analysis is one of the most difficult steps in the HACCP procedure because appropriate identification of potential hazards and assessment of their risk is complex requiring much technological knowledge and information. The result of this step is a list of significant hazards, which must be controlled in the process.

Hazard analysis consists of hazard identification, hazard evaluation and listing of relevant preventive measures. In hazard identification a list containing all potential hazards that are reasonably likely to cause illness, if not properly controlled, must be composed (Arampath *et al.* 2005)

2.4.1.1. Hazard

A hazard is a biological, chemical or physical agent or factor with the potential to cause an adverse health effect.

The HACCP team should list all of the hazards that may be reasonably expected to occur at each step from primary production, processing, manufacture and distribution until the point of consumption.

Biological hazards which include pathogenic microbes (parasites, bacteria, viruses), toxigenic plants and animals and products of decomposition (histamine)

Chemical hazards which include, among others, natural toxins, pesticides, cleaning compounds, veterinary drug residues (antibiotics), heavy metals and unapproved food and colour additives.

Physical hazards which include objects-such as bones, metal fragments, glass and stones-that may cut the mouth, break teeth, cause choking or perforate the alimentary tract.

2.4.1.2. Conduct A Hazard Analysis

The HACCP team should next conduct a hazard analysis to determine which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food.

In conducting the hazard analysis the following should be included:

- The likely occurrence of hazards and severity of their health effect
- The qualitative and/or quantitative of the presence of hazards
- Survival or multiplication of microorganism of concern
- Production or persistence in foods of toxins, chemicals or physical agents; and
- Condition leading to the above situation

Hazard Analysis consists of asking a series of questions which are appropriate to the specific food process and establishment. The hazard analysis must consider factors which may be beyond the immediate control of the processer. During the hazard analysis, the potential significance of each hazard should be assessed by considering its risk and severity. Risk is an estimate of the likely occurrence of a hazard. The estimate of risk is usually based upon a combination of experience, epidemiological data and information in the technical literature. Severity is the seriousness of a hazard. The HACCP team has the responsibility to decide which hazards are significant and must be addressed in the HACCP plan.

2.4.1.3. Identification of Control Measures

Control measures are action and activities that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level. More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure.

Biological Hazards: Time/temperature control, thermal processing, cooking and freezing, fermentation and/or pH control, addition of salt or other preservatives, drying, source control(eg: obtaining raw materials from non-contaminated sources), hygienic practices

Chemical Hazards: Source control (vendor certification and raw materials testing), production control (proper use and application of food additives, etc.)

Physical Hazard: Source control, production control (use of metal detectors, etc.)

2.4.2. Principle 2

Determine the Critical Control Points (CCPs)

Determine the points, procedures or operational steps that can be controlled in-order to eliminate the hazard(s), minimize its (their) likelihood of occurrence or prevent the hazard entering into the food.

The determination of a CCPs in the HACCP system can be facilitated by the application of a decision tree, which indicates a logic reasoning approach. The use of a decision tree should be used for guidance, but its application should be flexible, given the nature of the operation. While this model has been found to be useful to explain the logic and depth of understanding needed to determine CCPs, it is not specific to all food operations (eg. Slaughter) and therefore it should be used in conjunction with professional judgment, and modified in some cases. Training in the application of the decision tree is recommended.

2.4.3. Principle 3

Establish Critical Limit(s)

Establish critical limit(s) which must be met to keep the CCPs under control. The critical limits describe the difference between safe and unsafe product at the CCPs.

A critical limit must be specified for each control measure at each CCP, in some cases, more than one critical limit will be specified at a particular CCP. The critical

limits and criteria for food safety may be derived from sources such as regulatory standards and guidelines, literature surveys, experimental results and experts.

2.4.4. Principle 4

Establish a system to monitor control of the CCP

Establish a system to monitor control of the CCP by scheduled testing or observations.

Monitoring is the "act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control". These observations/measurements are done relative to critical limits.

Monitoring at CCPs can be done on a "continuous basis" (100% check) or periodically. As continuous monitoring is reliable, it is preformed wherever possible. If periodical checks are to be done gap between two checks shall be sufficient to detect deviations to assure safety.

In establishing a monitoring system consideration shall be given to "time taken to achieve a result". Monitoring procedures, ideally shall be rapid, because in continuous production process lengthy analytical testing are not practical. As such physical and chemical measurements or visual observations are mostly employed. Microbiological tests are not often used due to time constrains. All monitoring equipment's at CCPs shall be calibrated for accuracy. Monitoring records at all CCPs shall be reviewed by a designated person having knowledge and authority to correct the process.

A monitoring procedure shall include following information:

- What to monitor
- How to monitor
- Frequency of monitoring
- Who will monitoring

2.4.5. Principle 5

Establish corrective action

Corrective actions are define as "any action to be taken when monitoring at the CCP indicate a loss of control" or in other words deviation from critical limits. Such action shall be pre-determined and documented.

Corrective actions should include the following elements:

- Determine and correct the cause of non-compliance
- Determine the disposition of non-compliant product and
- Record the corrective actions that have been taken

Specific corrective actions should be developed in advance for each CCP and included in the HACCP plan. As a minimum, the HACCP plan should specify what is done when a deviation occurs, who is responsible for implementing the corrective actions, and that a record will be developed and maintained of the actions taken. Individuals who have a thorough understanding of the process, product and HACCP plan should be assigned the responsibility for oversight of corrective actions. As appropriate, experts may be consulted to review the information available and to assist in determining disposition of non-compliant product.

2.4.6. Principle 6

Establish procedure for verification

Establish procedure for verification to confirm that the HACCP system is working effectively.

Verification is "the application of method, procedures, tools and other evaluations, in addition to monitoring to determine compliance with HACCP plan" or effectiveness of the HACCP plan.

One aspect of verification is evaluating whether the facility's HACCP system is functioning according to the HACCP plan. An effective HACCP system requires little end product testing, since sufficient validated safeguards are built in early in the

process. Therefore, rather than relying on end-product testing, firms should rely on frequent reviews of their HACCP plan, verification that the HACCP plan is being correctly followed, and review of CCP monitoring and corrective action records.

Another important aspect of verification is the initial validation of the HACCP plan to determine that the plan is scientifically and technically sound, that all hazards have been identified and that if the HACCP plan is properly implemented these hazards will be effectively controlled.

Verification activities are carried out by individuals within a company, third party experts, and regulatory agencies. It is important the individuals doing verification have appropriate technical experts to perform this function.

2.4.7. Principle 7

Establish documentation and record keeping

Establish documentation concerning all procedures and records appropriate to these principles and their application.

Four types of records should be kept as part of the HACCP plan

- Support documentation for developing the HACCP plan
- Records generated by the HACCP system
- Documentation of methods and procedures use
- Records of employee training programmes

2.5. Milk

Milk is the lacteal secretion practically free from colostrum, obtained by the complete milking of one or more healthy cows, which contains not less than 8 ¼ % of milk solids not-fat and not less than 3 ¼ % of milk fat. Average gross composition of cow's milk would be as follows. Water 8.7% ; fat 3.5-3.7% ; lactose 4.9%; protein 3.5% and ash(minerals) 0.7%.(Arnold *et al*, 1978)

There are a lot of milk based product in the market such as Ice cream ,yogurt, milk powder, Cheese ,Butter so on These are vary according to the method that are used to

produced the product. Within these, Ice cream is the renewed milk based historical product which is a palatable ,nutritious ,healthy and relatively inexpensive food

2.6. Historical Background

The history of Ice cream is described differently depending on source. It is likely that ice cream was not invented, but rather came to be over years of similar efforts.

Ice cream had its origins in Europe and was introduced later in all over the world. It is widely believed that ice cream evolved from iced and beverages and water ices that were popular in the medieval period. It is known that wines and fruit juices were cooled with ice and snow brought from mountains to the court of the Roman Emperor Nero in the first century. In the 13th century, Macro Polo returned to Italy from his famous journey to the Orient and brought recipes for water ices said to have been used in Asia for thousands of years. The art of making these products then moved to France, Germany and England during the next few centuries. The development of condensed and dry milk, the introduction of the pasteurizer and homogenizer, improved freezers and other preserving equipments accompanied a slow growth in the industry only after 1900. (Vivek 2001)

2.7. Definition

A frozen sweetened product made from a heat treated mix consisting of edible fat and milk-solids with or without other ingredients and permitted additives. (SLS 223:1989)

2.8. Nutritional Value

Ice cream is an excellent source of energy. It provides all the nutrients of protein, carbohydrates, fat, vitamin as well as minerals in different amount that is required to human being.

The nutritional value of ice cream depends on the food of the ingredients from which it is made. Ice cream is an excellent source of food energy and it contains about four times as much carbohydrate, three or four times as much fat and about12-16% more protein than does milk. Fruits, nuts and eggs, when added, contribute significantly to its nutritive value. However, like milk, ice cream is not a good source of iron and vitamin C. (Vivek 2001)

The total caloric value of ice cream depends on

i. the percentage of protein including milk protein or any other source of protein that is present in nuts, eggs, or stabilizers.
ii. the percentage of carbohydrates including lactose, added sweeteners and sugars that is present in fruit or flavouring , and
iii. the percentage of fat from any source including emulsifier,egg,cocoa,nuts,etc.,that is present in the mix.

2.8.1. Protein Content of Ice Cream

The milk proteins in ice cream have high biological value. They contain all the essential amino acids.

Amino acids	Cow's milk
Isoleucine	47
Leucine	95
Lysine	78
Methionine and Cystine	33
Phenylalanine and tyrosine	102
Threonine	44
Tryptophan	14
Valine	64

Table 2.1. Content of Essential Amino Acids in Protein (mg Amino Acid/g Protein) **(Source:** Goff 2009)

The assimilation of milk protein is 5-6% higher than that of other proteins. Ice cream has a high concentration of milk solid not fat, which represents 34-36% milk protein.

2.8.2. Milk Fat Content of Ice Cream

Milk fats have both saponifiable and non-saponifiable matters.The saponifiable fraction include the glycerides (mainly triglycerides),phospholipids and other esters such as those cholesterol and minor acids components. The non-saponifiable fraction includes cholesterol and related sterol, the fat soluble vitamins,A,D,E,and K and traces of other minor components.

Carbohydrates

The sugars most commonly used in Ice cream are sucrose, corn sugar(contains predominantly glucose or maltose and fructose) and invert sugar which is a mixture of equal amounts of fructose and glucose. The sugar from fruits added to ice cream are sucrose and fructose. Lactose ,milk sugar, constitutes about 20% of the total carbohydrate in ice cream.

2.8.3. Minerals

Ice cream is a very rich source of essential minerals, especially calcium and phosphorus. The Calcium conten of milk and ice cream are 0.118 and 0.132g/100g,respectively;the corresponding phosphorus content are 0.093 and 0.105 g/100g,respectively.

2.8.4. Vitamin

Ice cream contains water soluble and fat soluble vitamins which are required in small amounts by the body for its metabolism and cannot be synthesized in sufficient quantities by the body.

Product	Weight (g)	Fat (g)	Protein (g)	Carbohydrates (g)	Total Solids (g)	Calories
Vanilla	100	12	4.0	20.7	38.3	204
Chocolate	100	13.1	3.6	21.8	42.1	221
Strawberry	100	8	3.6	25.8	40.8	194
Mango	100	10	3.5	21.2	36.3	188
Diabetic ice cream	100	9.0	4.3	13.2	28.6	152
Chocolate coated ice cream bar	60	10.4	1.8	10.7	23.1	142

Table 2.2. Nutritional Value of Commercial Ice Cream and Related Products(**Source:** Vivek 2001)

2.9. Basic Raw materials

Ice cream is composed of a mixture of food materials. The selection of good ingredients that used to manufacture high quality product is the most important factor in the successful ice cream process. Milk products, sweetening materials, stabilizers,

flavours or egg products are the unfrozen blend of the ice cream ingredients with the exception of air. The composition of ice cream is usually expressed as percentage of its constituents and its composition varies in different markets.

- Milk fat: >10% - 16%
- Milk solids-not-fat (snf): 9% - 12%
- Sucrose: 10% - 14%
- Stabilizers: 0% - 0.4%
- Emulsifiers: 0% - 0.25%
- Water: 55% - 64%

2.9.1. Milk Fat

The fat content of a good average ice cream is considered to be 12%.The best source of milk fat is fresh cream and other source are frozen cream, plastic cream, butter, butter oil and condensed milk blends. Vegetable (non-dairy) fats are used extensively as fat sources in ice cream in some countries. (Professor H. Douglas Goff, 2008) It contributes a rich flavour to ice cream. Milk fat does not lower the freezing point and tends to retard the rate of whipping. It is essential to use the correct percentage of milk fat to balance the mix properly as also to satisfy legal standards.. (Vivek 2001)

2.9.2. Milk Solid Not Fat (MSNF)

MSNF is the solid of skim milk contain the protein, the milk sugar lactose and the mineral matter. It is approximately 36.7% protein,55.5% lactose and 7.8% minerals. Vivek, 2001). In expensive source of MSNF are provided a lot of benefits such as improve the texture of ice cream, capable of allowing a higher overrun without the characteristic snowy or flaky textures associated with high overrun, due to the protein functionality, help to give body and chew resistance to the finished product . The limitations on their use include off flavours which may arise from some of the products, and an excess of lactose which can lead to the defect of sandiness prevalent when the lactose crystallizes out of solution. Excessive concentrations of lactose in the serum phase may also lower the freezing point of the finished product to an unacceptable level. (Goff 2008)

2.9.3. Sweetener Solids

A sweet ice cream is usually desired by the consumer. As a result, sweetening agents are added to ice cream mix at a rate of usually 12 - 16% by weight. Sweeteners improve the texture, handling properties, palatability and enhance flavors of the ice cream. (Professor H. Douglas Goff, 2008) The most common sweetener used in ice cream is cane sugar (sucrose) and it can be used in liquid or dry form. Lack of sweetness produces a flat taste while too much sugar tends to mask desirable flavous. Sugar increase the viscosity and the total solids concentration of the mix. This improves the body and texture characteristics provided the total solids content does not exceed 40%,or the sugar content does not exceed 16%.Beyond these limits the ice cream tend to become soggy and sticky. The sugar, being in solution ,depress the freezing point of the mix. This results in slower freeing and requires a lower temperature for proper hardening. (Vivek 2001).

2.9.4. Stabilizers

The stabilizers are a group of compounds, usually polysaccharide food gums, that are responsible for many functional benefits. Generally, stabilizers are added at the rate of 0.2 to 0.3% of the mix to prevent the formation of objectionable large ice crystals in ice cream. They have high water holding capacity which is effective in giving smooth body and texture to the product. It gives uniformity of product, give desired resistance to melting and improve handling properties. (Goff 2009)

2.9.5. Emulsifiers

Emulsifiers are used to produce ice cream with a smoother body and texture ,to impart dryness and to improve whipping ability of the mix. Emulsifiers extensively used are monoglycerides or diglycerides, sorbitan ester and polyoxyethylene sorbitan esters(polysorbates) and are added at the rate of 0.1 to 0.4% of the finished product. Egg yolk solids are also used as emulsifiers. Excessive amounts of emulsifiers result in ice cream having slow melting characteristics and body and texture defects.(Goff 2009)

2.9.6. Flavour and Colour

flavour is generally considered the most important characteristic of ice cream. The kind of flavouring material to be added is influenced by the quality of the ice cream mix since slight off-flavour in it can obscure the delicate flavor of the flavouring material to be added. Natural and synthetic flavor substances are available for the flavouring of ice cream.

Ice cream should have a delicate, attractive colour which can be readily associated with the flavor. Most colours are of chemical origin and available in liquid or powder form. Most ice cream manufactures prefer to purchase dry colours since these are more economical and can be dissolved in boiling water as needed. (Goff 2009)

2.10. The basic steps in the manufacturing of Ice Cream

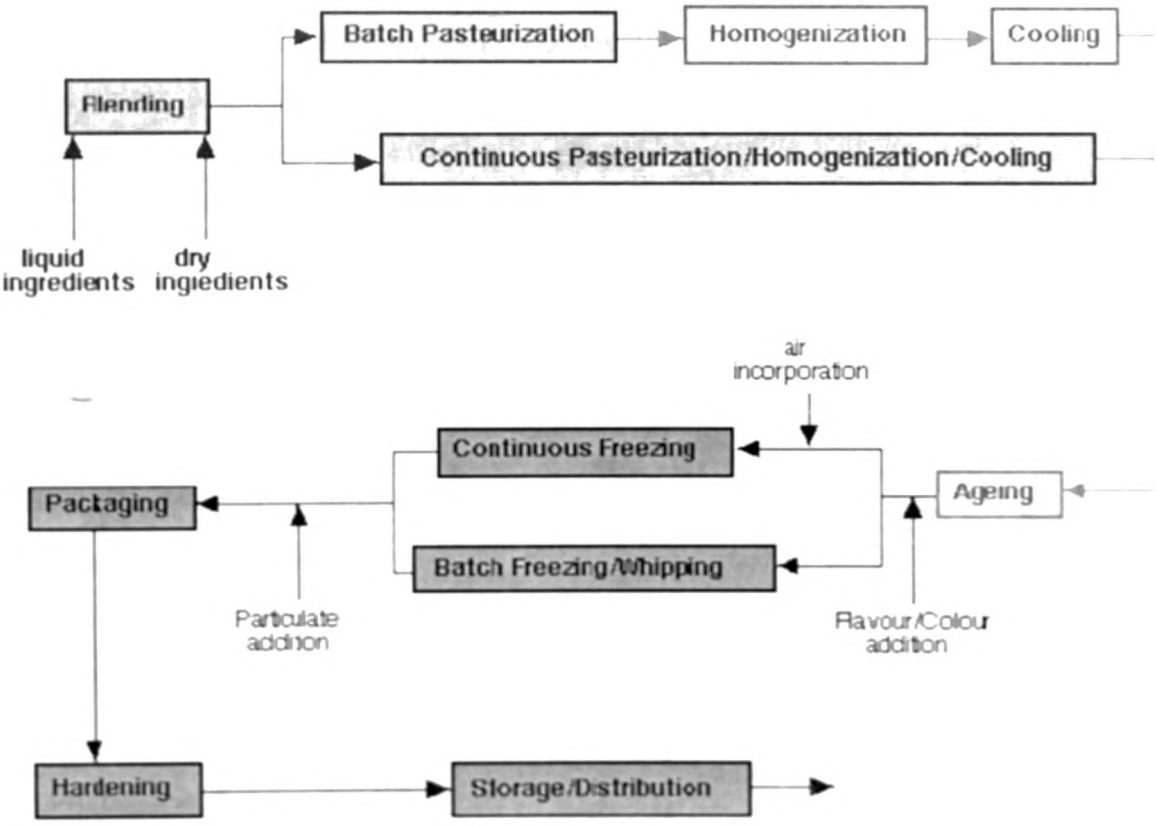


Fig. 2.2 Process flow diagram for ice cream manufacture (Goff 2008)

2.10.1. Blending of the mix ingredients

First the ingredients are selected based on the desired formulation and the calculation of the recipe from the formulation and the ingredients chosen, then the ingredients are weighed and blended together to produce what is known as the "ice cream mix". Blending requires rapid agitation to incorporate powders, and often high speed blenders are used.(Goff 2008)

All the liquid ingredients (cream, milk, condensed milk, syrup, etc)are placed in the vat, and the agitation and heating started at once. The dry ingredients, including skim milk powder, sugar, stabilizer and dried eggs(when used)are added, while the liquid material is agitated and before the temperature reaches 50^0C .In order to obtain proper suspension without lump formation, the dry material is mixed thoroughly with part of sugar before slowly adding it to the liquid, or sifting, or otherwise slowly adding these substances to the liquid. Skim milk powder, cocoa and similar products should be sifted on top of the liquid. This is always done while the agitated liquid is still cool (under 30^0C).Stabilizers are added after thoroughly mixing with an equal volume of sugar and before the liquid reaches50^0C or ,it can be sprinkled on the surface of the cold liquid and allowed to soak ,before the mixture is heated. When butter, plastic cream, frozen cream or other frozen products are used ,they should be cut into small pieces and added in time to allow complete melting before the pasteurizing temperature is reached. (Vivek 2001)

2.10.2. Pasteurization of the mix

Pasteurization of mixes is essential because this process destroys all pathogenic bacteria, thereby safeguarding the health of the consumer. In addition to this very important function, pasteurization also reduces the number of spoilage organisms such as psychrotrophs, and helps to hydrate some of the components (proteins, stabilizers).

Pasteurization consists in rapidly heating to a definite temperature, holding at that temperature for a definite minimum of time, and then rapidly cooling to below 5°C by using Both batch pasteurizers and continuous (HTST) methods.

Method	Temperature ^{0}C	Time
Batch method	68	For not less than 30 minutes.
High temperature short time	79	For not less than 25 seconds

Table 2.3. Pasteurization Time and Temperature for Ice Cream Mixes (Source: Vivek 2001)

Batch pasteurizers lead to more whey protein denaturation, which some people feel gives a better body to the ice cream. In a batch pasteurization system, blending of the proper ingredient amounts is done in large jacketed vats equipped with some means of heating, usually steam or hot water. The product is then heated in the vat to at least 69 ^{0}C ($155^{0}F$) and held for 30 minutes to satisfy legal requirements for pasteurization, necessary for the destruction of pathogenic bacteria. Various time temperature combinations can be used. The heat treatment must be severe enough to ensure destruction of pathogens and to reduce the bacterial count to a maximum of 100,000 per gram. (Vivek 2001).

Continuous pasteurization is usually performed in a high temperature short time (HTST) heat exchanger following blending of ingredients in a large, insulated feed tank. Some preheating, to 30 to 40 ^{0}C, is necessary for solubilization of the components. The HTST system is equipped with a heating section, a cooling section, and a regeneration section. Cooling sections of ice cream mix HTST presses are usually larger than milk HTST presses. Due to the preheating of the mix, regeneration is lost and mix entering the cooling section is still quite warm. (Goff 2008)

2.10.3. Homogenizing the Mix

The main purpose of homogenizing is to make a permanent and uniform suspension of the fat by reducing the size of the fat droplets to a very small diameter, preferably, not more than two microns. Thus ,when a mix is properly homogenized, the fat will not rise and form a cream layer. Other advantages derived are ,a more uniform ice cream with a smoother texture, improved whipping ability, a shorter ageing period, prevention of churning in the freezer and the use of slightly less stabilizer. It is essential to homogenize the mix when plastic cream, frozen cream, butter and butter oil and oil from vegetable sources are used (Vivek 2001)

2.10.3.1. Homogenizing Temperature

The mix is homogenized at temperature from 63^{0}C to 76^{0}C because at low temperatures (50-55^{0}C) homogenization increase the formation of clumps of fat globules, increases the viscosity ,and increase the freezing time in batch freezers. When high pasteurizing temperatures are employed in the batch system, the mix may be cooled to 65^{0}C for homogenization to reduce the intensity of the cooked flavour, especially when homogenization is not likely to be completed within 30 min. If homogenization precedes pasteurization, the minimum temperature recommended for homogenization is 60^{0}C in order to inactivate lipase enzyme, thereby ensuring lipolysis will not take place as the protective membrane is stripped from the fat globules during homogenization. (Vivek 2001)

2.10.3.2. Pressure for Homogenization

The pressure for homogenization depends upon the composition of the mix, desired viscosity, stability of the mix, temperature used and construction of the homogenizer. On homogenization, there is a tremendous increase in surface area of the fat globules. There is not enough membrane material to form membranes round all the new fat globules. The formation of new membranes takes some time , during which many of the fat globules are unprotected. Therefore, mix having a higher fat content should be homogenized at a lower pressure, because the distance between globules in a high fat mix will be very small and recoalescence of the fat globules will tend to occur. Lower pressures are also used when mixes contain butter, plastic cream etc., as the only source of fat or mixes having concentrated products as the only source of MSNF. Vivek 2001).

2.10.4. Cooling the mix

Mix should be cooled immediately after homogenization to 0-5 ^{0}C. Slow cooling of the mix from 30-400C down to 50C imparts increased viscosity to the mix and also results in ice cream that does not melt smoothly. Also temperatures below 5 ^{0}C retard the growth of bacteria. Cooling of mixes to 0-2 ^{0}C increases the capacity of freezers

2.10.5. Ageing the Mix

The mix is aged for at least four hours for continuous freezers and for the batch-type freezers, which have limited whipping mechanisms, a longer ageing period is necessary. Also for high fat mixes. which have been homogenized at very low pressures,24hr of ageing produce good results. The ageing temperature should not exceed 5^0C.At temperatures lower than 5^0C the bacterial count will not increase during ageing.

The changes which occur during ageing are: the fat is solidified due to increased adsorption of the emulsifier on the fat globules, stabilizers, especially gelatin swell and combine with water and increased adsorption and hydration of the milk proteins. In the presence of the emulsifier protein displacement from the fat globules also occur (on cooling the emulsifier becomes more surface active and displaces protein from the interface),though this is a slower process. The combined effect of all these changes is an increase in viscosity during ageing. (Goff 2008)

2.10.6. Freezing

Ice-cream mix is frozen in single-batch machines or in continuous freezers. In general, both machines utilize a cylindrical chamber with double wall which acts as a jacket to contain the refrigerant. On the axis of the cylinder, a rotating dasher and scraper keep the mix thoroughly agitated and remove the ice from the refrigerated walls.

Kind of Freezer	Freezing Time to 90% Overrun (Approx)	Drawing Temperature (^{0}C)
Batch freezer	7min	-3.3 to -4.4 ^{0}C
Continuous freezer	24 sec	-5.5 to -6 ^{0}C
Low temperature Continuous freezer	26-36 sec	-8 to -9 ^{0}C
Soft-serve freezer	3 min	-6.6 to -8 ^{0}C
Counter freezer	10 min	-3.3 ^{0}C

Table 2.4. Freezing Time and Drawing Temperature (**Source:** Goff 2009)

The function of the freezing process is to freeze a portion of the water of the mix, and to incorporate air into the mix. When the mix is put into the freezer its temperature

drops very rapidly, while the sensible heat is being removed and before any ice crystals are formed. This process should take less than 1-2 min. At the same time ,the rapid agitation reduces the viscosity by partly destroying the gel-like structure and by breaking up the fat globule clusters.

Fast freezing ensure the production of small ice crystals. Therefore ,fast freezing is essential for a smooth product because ice crystals that are formed quickly ,are smaller than those formed slowly. Hence, it becomes necessary to freeze and draw from the freezer in as short a time as possible. This is achieved in a continuous freezer in a few seconds ,while batch freezers take 6 - 10 min. (Goff 2009)

2.10.7. Hardening

When ice cream drawn from the freezer and put into the container to be placed in the hardening room, it has a semi-fluid consistency and not stiff enough to hold its shape. Therefore, the freezing process is continued without agitation until the temperature of the ice cream reaches -18 ^{0}C or lower, preferably -26^{0}C .It is desirable to get quick freezing or quick hardening, since slow hardening favours large ice crystals and coarseness. The time required for hardening has been assumed to be the time necessary for the temperature at the center of the packaged to drop to -18^{0}C.

Factors affecting the hardening time are size and shape of package, Temperature of air , Air - Circulation ,Temperature of Ice cream Drawn from the freezer , section of the hardening room , Composition of the mix and Percent overrun. (Goff 2009)

CHAPTER 03

MATERIALS AND METHODOLOGY

3.1 Identification of the scope of HACCP study

Scope of HACCP study was identified at the commencement of the study in MILCO (pvt) Ltd at Digana.

3.2 Identification of HACCP team

The expertise such as a quality assurance (QA) specialist, production specialist, engineer, production supervisor, microbiologist and production assistant were selected as personnel to assembling the multidisciplinary HACCP .

3.3 Product description and intended use of Ice Cream product

Full description of the product such as ingredients, product characteristic, packaging, storage condition for shelf life, labeling and instruction its distribution channel and intended uses of consumers were described.

3.4 Construction of Process Flow Diagram

The two practiced flow diagram were developed to provide a clear, simple outline of the major steps involved in the Ice Cream process from raw milk receiving to dispatch of the final product.

First flow diagram was pointed out the steps from raw milk receiving to pasteurization of the milk and the second diagram was explained rest of processing steps from mix pasteurization to dispatch of final product.

3.5 Develop pre-requisite programme

3.5.1. Development of GMP manual

The GMP manual was developed as a pre-requisite programme. It was developed according to the legal requirements for after reviewing existing practices and programmes in the factory. The key areas address through the GMP manual is

included design and facilities, control of operation, maintenance and sanitation, pest control systems, personal hygiene ect.

3.6 Implementation of principles of HACCP

3.6.1 Conduct the hazard analysis

Hazard analysis was done through the hazard identification, hazard evaluation and listing of relevant preventive measures. In hazard identification, all potential hazards that are reasonably likely to cause illness were categorized as biological, chemical and physical agents. Significant hazards were identified in hazard evaluation step by using risk assessment matrix.

A risk assessment matrix is computed by classifying risks into four levels based on their severity on the following basis.

Risk level	Control measures
1	Informal control -No formal registration required
2	Basic prerequisites - Hygiene and GMP training of personnel - Personnel hygiene measures - Pest control
3	Most stringent prerequisites needing a formal control - Cleaning and sanitation
4	Physical control required - Parameters such a temperatures of processing, pH, metal contaminants to be monitored - Sealing integrity

Risk Assessment Matrix

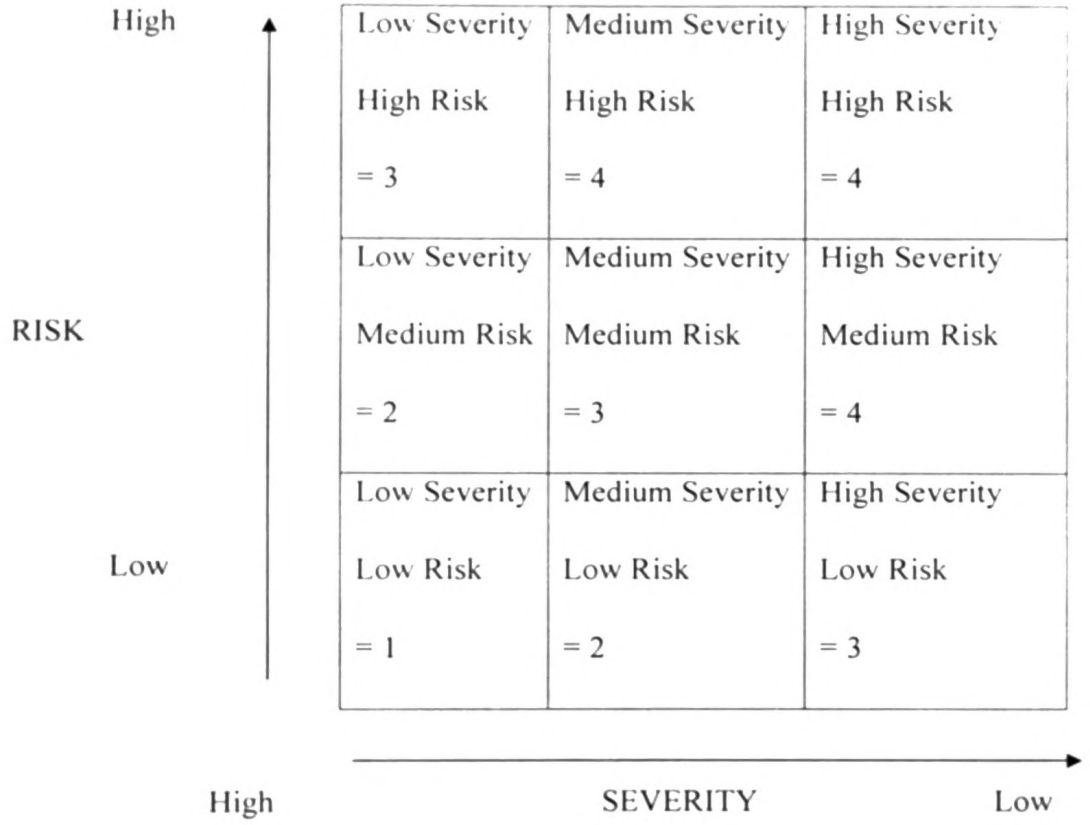


Fig. 3.1. Risk assessment matrix (Arampath *et al.* 2005)

Control measures were distinguished respectively for each significant hazards. When evaluating control measures it was considered what already have in place and what new measures may need to be put in place.

3.6.2 Determination of Critical Control Points

CCPs were determined separately by applying the CODEX CCP decision tree for each step of the process and all the ingredients that use for manufacturing Ice Cream.

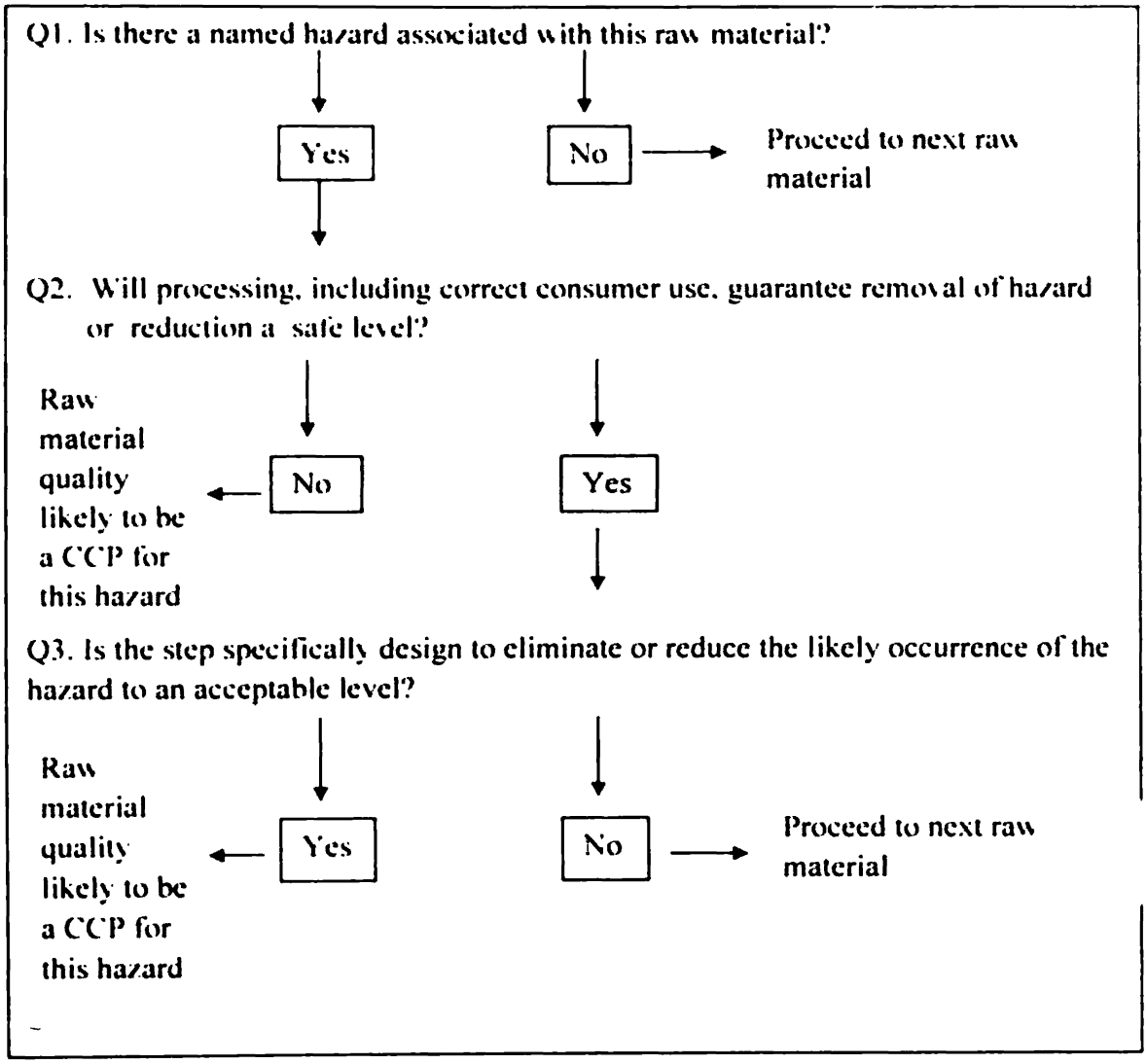


Fig 3.2. -Critical Control Point decision tree as applied to the raw material

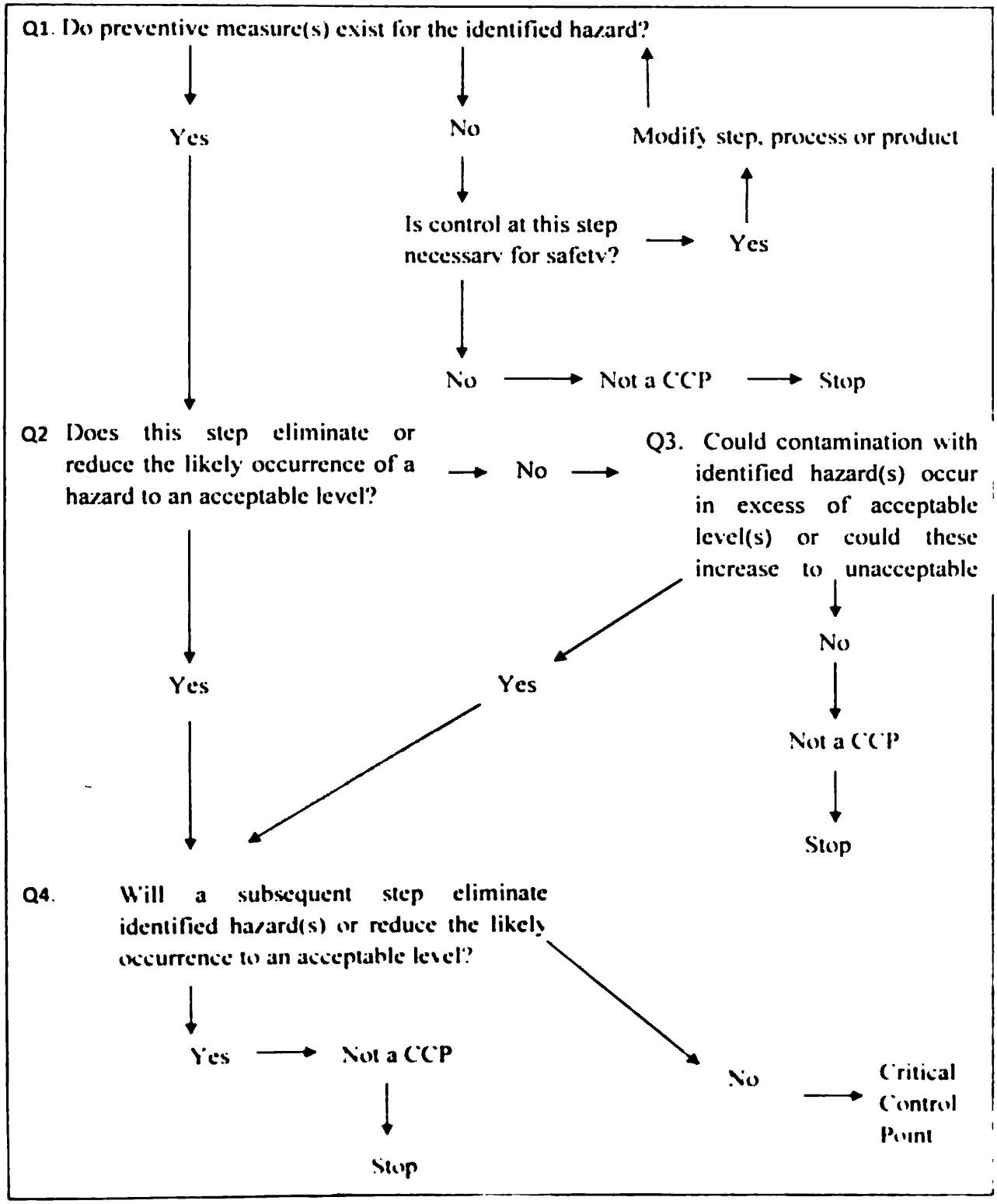


Fig 3.3. -Critical Control Point decision tree as applied to the production process steps

3.6.3 Establishment of Critical Limits for each CCP

The appropriate Critical Limits were established after getting fully understands the criteria governing safety at each CCP. Critical limits were set base on legal and other requirements of hazard analysis information and quantitative risk assessment.

3.6.4 Establishment of a monitoring system for each CCP

Monitoring procedure was established to assess if the CCP is operating within the critical limits and to provide written documentation for verification. The monitoring procedure for each CCP was mentioned what, how, when and who will monitor the system.

3.6.5 Establishment of a corrective action plan

Corrective action was established to prevent the problem when the monitoring results show a deviation from the critical limit(s) at a CCP. This procedure was specified on the HACCP control chart to minimize any confusion or disagreements which might otherwise have occurred when the action needs to be taken.

3.6.6 Establishment of verification procedure

Guidance and importance of verification procedure was identified to determine validity of HACCP plan.

3.6.7 Establish record keeping and documentation

All hazards identification note, process flow charts, critical limits establish records, corrective action, CCP determination chart, GMP manual were recorded.

CHAPTER 04

RESULTS AND DISCUSSION

4.1 Results

4.1.1 Scope of HACCP study

The HACCP manual was developed to prevent, eliminate or reduced hazards related to Ice Cream production from milk receiving to dispatch of final products.

4.1.2 HACCP team

HACCP team that were selected to cover the main areas in food industry were not exceed six members and their ranks title are slightly difference when comparing with other companies in Sri Lanka.

Position of members	**Name**
Assistant Manager Production	A.R.V.Abeyasinghe
Office Quality Assurance	K.E.Udayathilake
Assistant Subordinate Production	R.T.Thalewela
Microbiologist	Ms.M.P.W.Pathirana
Officer Engineering	Chaminda Silva
Production Assistant	Anura Jayarathna

4.1.3 Product description and Intended use of Ice Cream product

1. Product name(s)	Ice Cream Vanilla, Chocolate, Strawberry, Banana, Mango flavoured and Fruit and Nut Ice Cream varieties are produced under the brand name 'Highland'.
2. Ingredients	Full cream milk, full cream milk powder, sugar, cream, pulsgard (stabilizer and emulsifiers) glucose syrup, colours, flavours

Chocolate powder, plums, cashew nut, ginger preserve, pumpkin preserve, tooty fruity

3. Important product Characteristic of end product

fat% standard tolerance

Vanilla	Chocolate
11.5	11.2
11.0-12.0	10.7-11.7

Total solids% standard tolerance

Vanilla	Chocolate
40.60	41.9
39.6-41.6	40.9-42.9

Acidity	0.20 maximum
Total count	50,000 maximum
E.coli	Nil
Coliform	Nil
Yeast	Nil
Moulds	Nil

4. Packaging

The products are packed in containers of 4.0liter(l), 2.0 l, 1.0 l, 500ml and 80ml single serve size by manually

5. Shelf life

6 month (If it store < -18° C)

6. Where the product will be sold

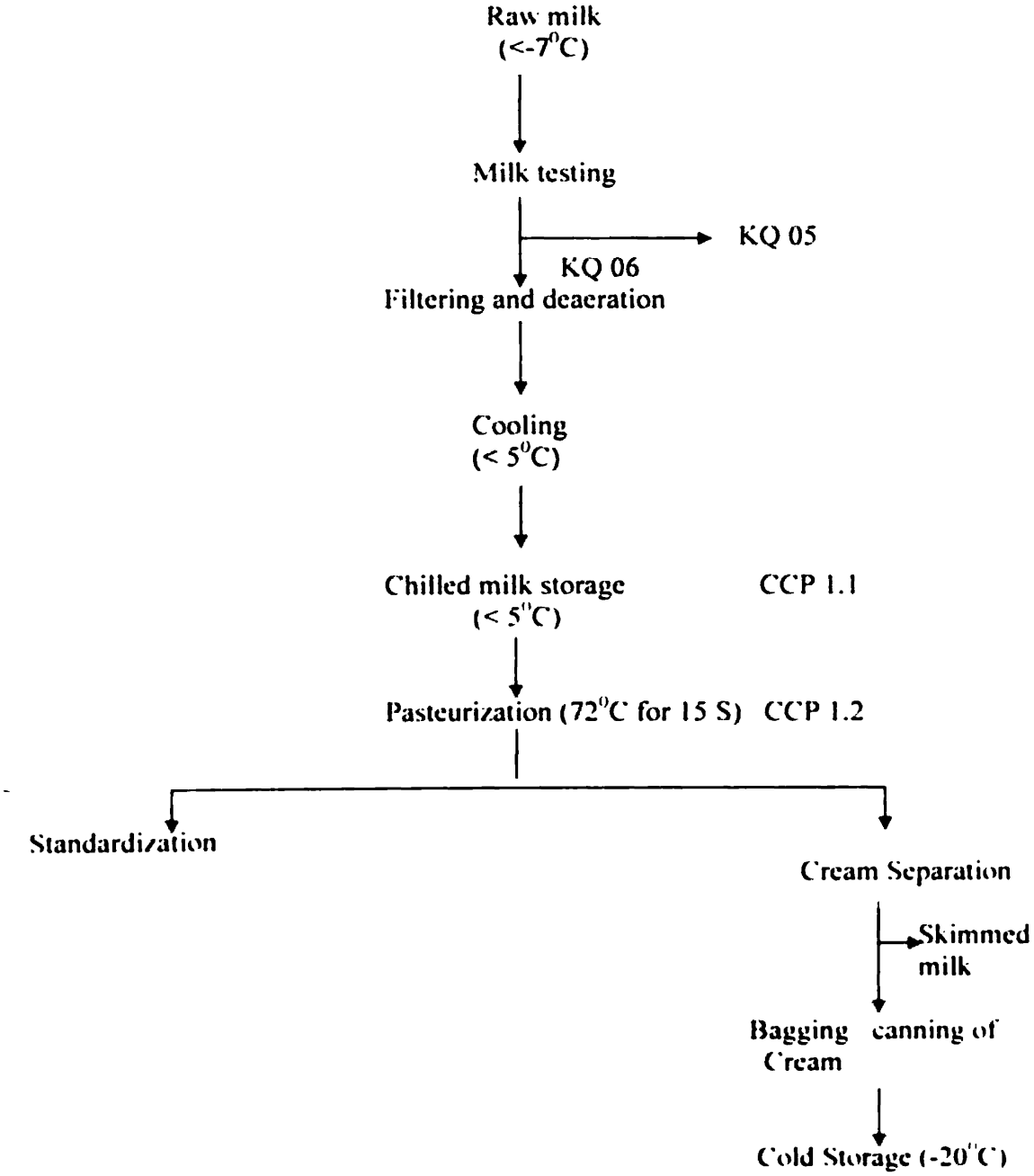
- Through agents appointed by the company
- Welfare outlet at Digana plant
- At regional sales center to distributors appointed by the company

7. Labeling Instruction	Manufacturing date, Expire date, Batch number, Ingredients, Storage condition, volume and price
8. Special distribution control	Store < -18^{0}C
9. Intended use	The products will be consumed without further processing by the general population
10. How the product is to be used	These are frozen, ready-to-eat product

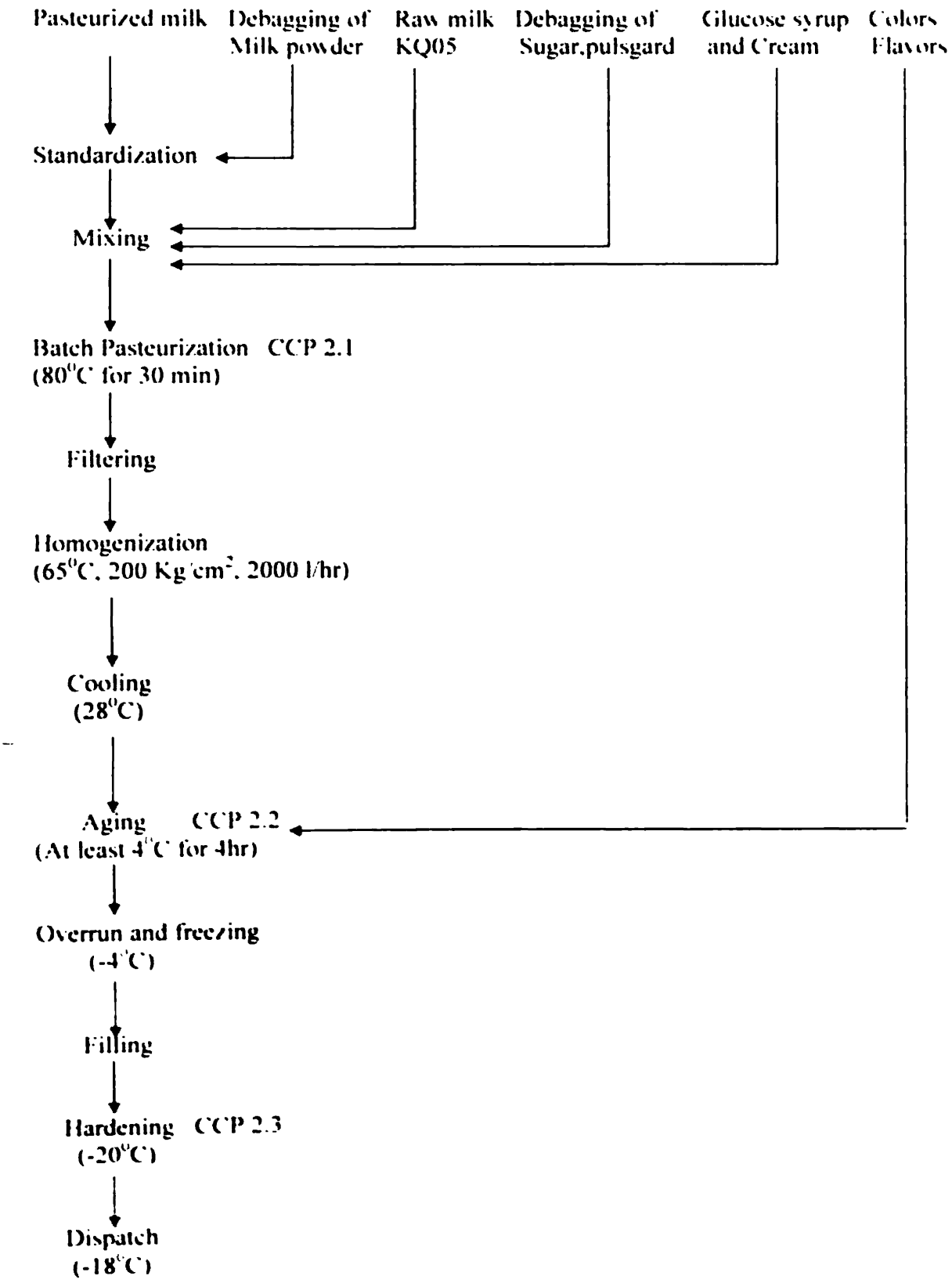
4.1.4 Development of process flow diagram

All the milk samples that are taken from bousers or cans are tested before taking to the production. These samples are ranked as an excellent (KQ06),very good (KQ05), good (KQ04),poor (KQ03),bad (KQ02) and worst (KQ01) according to the keeping quality (KQ)of milk and they use KQ 06 milk for Ice Cream production . Very rarely KQ 05 milk is used directly to mix pasteurization due to low keeping quality.

4.1.4.1 Development of process flow diagram from raw milk reception to raw milk pasteurization



4.1.4.2 Development of process flow diagram from standardization to dispatch of final product



4.1.5 Develop pre-requisite programme

4.1.5.1 Development of GMP manual

Existing Situation of the Factory:

Floor

-Floor has constructed with slope to adequate drainage of water after cleaning the floor.

-There is not smooth cement surface on the floor.

-There are some cracks and small holes on the floor .Therefore, water remain in there.

-Drainage system is not closed

Walls

-There is not smooth surface of wall in some places.

-Pores, cracks and dust can be seen on the wall.

-It is difficult to clean the edges between wall-wall and wall-floor junction.

-Services (current wire)are not properly sealed.

-Epoxy paint is used in dry surface.

Windows

-Window are fixed in very lower position in the wall.

-Windows are not covered by mesh.

- There are windows in production section which never opened.

-Wall panes have not slope. Labors are used to keep colouring bottles, fittings on there.

Door

-There is open entrance for production line.

-Doors are made from wood.

Lighting facilities

-Bulbs are hanged on thee roof and bulbs in production are not covered.

-It is evenly distributed and maintain properly

Hand washing facilities

-There are manually operating taps at the entrance of the production area.

-Tipol is used to wash hands and it is placed in the entrance of production area.

-There is no any dryers or papers to dry out the hand before entering to the production.

Ventilation

- There are 'natural convention excusing fan' on the roof to ventilation

-There are fans and open windows in Ice Cream filling area.

Waste water disposal system

-There are two draining system

Outer draining system- drain out rain water

Inner draining system drain out waste water

- Waste milk is throw away along with waste water.
- There is still not proper waste water disposal system.
- Currently ,waste water is collected in to tank and keep to sedimentation and water is pumped in to ground and sludge is bedded.
- There is a propose waste water treatment plant and it is still under construction.

Solid waste disposal system

-Polythene bags and paper bag that accumulate after debagging are removed from production area as soon as possible.

-These bags are collected separately and sold to out side.

-Sometimes it is incinerated in out side(open area)

-Spoil products are just throw out to open yard.

Control of Operation

Cooler

Mostly receiving milk temperature is nearly 10 C.It is reduced to 8 C by passing through cooler.

Plate heat exchanger

-Chilled milk (8°C) temperature is reduced to 5 C temperature

Vat

-Pasteurized milk just stored in chilled milk storage around 5^{0}C.After pasteurization of milk(mostly in the evening) is tested to measure temperature, fat, SNF, acidity, alcohol and KQ by laboratory analyst.

Mix tank

Ice Cream mix is heated to 80^{0}C for 30min in batch pasteurization tank.

Ageing tank

4^{0}C temperature is controlled and tank has subjected to cooling .

Freezer

-4^{0}C temperature is controlled in freezer.

Hardening temperature

-There is maintain -25^{0}C for Ice Cream.

-There are two filters at the beginning (near to deaerater) and before the homogenizer.

Calibration of equipment

-Thermometer, Butrometer are calibrated by using thermometer and butrometer which were calibrated by Sri Lanka Standard Institute.

-Mix tank are calibrated by work engineer.

-Equipments in the factory are not calibrated periodically by third party.

-Only milk can weighing machine is calibrated periodically by involving third party.

Cleaning and disinfection

-There is a properly functioning cleaning procedure

-All the equipment and tube are cleaned at the end of the each production process and end of the day.

-Fumigation is done by per week.

Personal hygiene

-Labors wear uniform and hats

-They do not were jewelleries

-Some times gloves and mask are used.

-Boost are kept inside the production area and not wear them all the time that they work in production.

-Labors go outside wearing uniform.

-labors wash their hand when entering to the production area and going out.

- Medicinal facilities are providing for labors every day on free.

Pest Control

- Pest control is done twice a week by third party.
- Liquid, powder ,pellets ,glue etc. are used according to the place and pest .
- The traps in the draining system were removed by labors.

Water Quality Monitoring

- Chlorine test, coliform and Total count are tested perweek.
- Hardness in water is tested.

Storage

-Raw material, chemicals, packaging material are stored separately.

-All are kept elevated.

-There is not ceiling and birds can come in to the stores.

-Followed the first in first out method.

Factory environment

-Garden is maintaining properly.

-There are some plants such as flowers ,fruits etc. very close to factory premises.

Training

- Company is provided internal and external training facilities for staff periodically
- It is scheduled by head office in Colombo.

4.1.6. Development of HACCP principles

4.1.6.1. Conduct hazard analysis.

4.1.6.1.1 Hazard analysis chart- from raw material to raw milk pasteurization

Table 4.1 Hazard Analysis chart- Ingredients

Ingredients	Hazard category	Hazard	Risk	Severity	Significant (s)/ Non Significant(NS)	Control measures
1.Raw milk	P	Presence of foreign maters such as sand, hair, dust etc.	3	1	NS	GMP
	B	Presence of MOs* Presence of insects *Pseudomonas spp.* *Flavobacterium spp.* *Lactobacillus Spp.* Coliform *Micrococcus spp.* etc	3	3	S	Supplier Quality Assurance(SQA) Laboratory test
	C	Presence of H_2O_2, antibiotics	3	2	NS	SQA
2. Milk powder	P	Presence of foreign matters	1	1	NS	Effective SQA
	B	Presence of MOs,	2	3	S	SQA GMP
	C	Antibiotic residues	1	3	NS	SQA

P : Physical B : Biological C : Chemical *MOs : Microorganisms

Ingredients	Hazard category	Hazard	Risk	Severity	Significant (S)/ Non Significant(NS)	Control measures
3.Chocolate powder	P	Presence of foreign matters such as packaging material fragments	1	1	NS	GMP SQA
	B	Presence of yeast, moulds and bacteria	1	2	NS	SQA GMP
	C					
4. Colurs	P	Presence of foreign matters	1	1	NS	SQA
	B	Presence of yeast and moulds	1	2	NS	SQA GMP
	C					
5.Flavours	P	Presence of foreign matters	1	1	NS	SQA GMP
	B					
	C					
6.Glucose Syrup	P					
	B	Presence of yeast	1	2	NS	SQA
	C					

Ingredients	Hazard category	Hazard	Risk	Severity	Significant (s)/ Non Significant(NS)	Control measures
7.Sugar	P	Presence of foreign matters	3	5	NS	SQA GMP
	B	Presence of yeast	1	2	NS	SQA GMP
	C					
8.Tooty fruity	P	Presence of foreign matters	1	1	NS	SQA GMP
	B	Presence of fungus	2	3	NS	SQA GMP
	C					
9. Cashew nuts	P					
	B	Presence of moulds and yeast	1	3	NS	SQA GMP
	C	Presence of off flavours	1	2	NS	SQA GMP
10. Pumpkin Preserve	P					
	B	Presence fungus and insects	2	2	NS	SQA GMP
	C					

Ingredients	Hazard category	Hazard	Risk	Severity	Significant (s)/ Non Significant(NS)	Control measures
11.Ginger Preserve	P					
	B	Presence of yeast and moulds	1	2	NS	SQA GMP
	C					
12.Emulsifiers and stabilizers	P	Presence of foreign matter such as packaging material fragments	1	1	NS	SQA GMP
	B					
	C					
13.Cream	P	Presence of foreign matters	2	1	NS	GMP
	B	Presence of MOs	2	3	S	GMP
	C					
14.Plums	P	Presence of foreign matters such as stones	2	3	NS	SQA GMP
	B	Presence of insects and warms	2	3	NS	SQA GMP
	C					

Table 4.2 Hazard Analysis chart –Raw milk process steps

Number	Process Steps	Hazard category	Hazard	Risk	Severity	Significant (s)/ Non Significant(NS)	Control measures
1	Filtering	P	Presence of foreign matters such as hair, dust, sand	2	2	NS	GMP
		B					
		C					
2	Deaeration	P					
		B					
		C					
3	Cooling	P					
		B	Survival of spores and vegetative pathogens Cross contamination with pathogens	2	3	S	Correct temperature maintenance Correct pressure set up
		C					
4	Chilled Milk Storage	P					
		B	Outgrowth of spores	2	3	S	GMP
		C	Heat stable enzymes produced by bacteria Protease and lipase	2	3	S	GMP

Number	Process Steps	Hazard category	Hazard	Risk	Severity	Significant (s)/ Non Significant(NS)	Control measures
5	Pasteurization	P					
		B	Survival of vegetative pathogens and spores *Bacillus Spp*	2	3	S	Correct heat treatment (time and temperature) process
		C					
6	Standardization	P					
		B					
		C					
7	Manual de-bagging into feed hopper	P	Presence of foreign matter such as string from bag, packaging material fragments, dust	3	1	NS	GMP In line sieving
		B	Introduction of flying insects	3	1	NS	GMP
		C					

Number	Process Steps	Hazard category	Hazard	Risk	Severity	Significant (s)/ Non Significant(NS)	Control measures
1	Cream Separation	P					
		B					
		C					
2	Bagging/canning of cream	P	Introduction of foreign matter such as dust, packaging material fragments	2	1	NS	GMP
		B	Introduce MOs and insects	2	3	S	GMP
		C					
3	Cold Storage	P					
		B	Survival of MOs	2	3	S	Effective temperature control
		C					

4.1.6.1.2 Hazard analysis chart- from standardization to dispatch of final product

All the potential hazards were analysis according to the considering process chart, process flows and activities associated with the production of Ice Cream process.

Table 4.3 Hazard Analysis chart – from standardization to dispatch of final product

Number	Process Steps	Hazard category	Hazard	Risk	Severity	Significant (s)/ Non Significant(NS)	Control measures
8	Mix pasteurization	P	Introduce foreign matters such as dust, packaging material fragments etc	3	1	NS	GMP
		B	Survival of spores Such as *Bacillus cereus*	2	3	S	Correct heat process achieved
		C					
9	Homogenization	P					
		B	Introduce MOs	2	3	S	GMP
		C					
10	Filtering	P	Introduce foreign matters such as dust	2	1	NS	Effective filtration GMP
		B					
		C					
11	Cooling	P					
		B	Presence of pathogen	2	3	S	GMP Correct pressure set up
		C					

Number	Process Steps	Hazard category	Hazard	Risk	Severity	Significant (s)/ Non Significant(NS)	Control measures
12	Aging	P					
		B	Outgrowth of spores *Bacillus cereus*	2	3	S	Effective temperature control Effective stock rotation
		C					
13	Freezing and overrun	P					
		B	Introduction of pathogen	3	2	S	Effective filtration
		C					
14	Filling	P	Introduction of foreign matter such as dust, packaging material fragments	3	1	NS	GMP
		B	Introduce MOs and insects	2	3	S	GMP
		C					
15	Hardening	P					
		B	Survival of MOs	2	3	S	GMP Effective temperature control
		C					

Number	Process Steps	Hazard category	Hazard	Risk	Severity	Significant (s)/ Non Significant(NS)	Control measures
16	Dispatching	P					
		B	Cross contamination with pathogen	2	3	S	GMP Correct temperature control
		C					

Number	Process Steps	Hazard category	Hazard	Risk	Severity	Significant (s)/ Non Significant(NS)	Control measures
1	Toasting of cashew nut	P					
		B	Survival of mould and yeast	1	3	NS	GMP Correct temperature control
		C					
2	Grinding of cashew nut	P	Introduction of foreign matter such as dust	2	1	NS	GMP
		B	Introduce of MOs	1	3	NS	GMP
3	Fruit and nut Filling into top of the Ice cream	P	Introduced of foreign matters such as dust	3	1	NS	GMP
		B	Introduce of MOs	3	3	S	GMP
		C					

Number	Process Steps	Hazard category	Hazard	Risk	Severity	Significant (s)/ Non Significant(NS)	Control measures
1	Cleaning process	P					
		B					
		C	Remain of chemicals that used to clean equipment and tubes and valves	1	3	NS	GMP

4.1.6.2 Determination of Critical Control Point

4.1.6.2.1 Identification of CCP- Ingredients

Number	Process Steps	Hazard	Q1	Q2	Q3	CCP	Note
1	Raw milk	B	Y	Y	N	No	MOs are controlled during heat processing and SQA.
2	Milk Powder	B	Y	Y	N	No	MOs growth is controlled because this ingredient will undergo a heat process which is lethal to vegetative pathogens.
13	Cream	B	Y	Y	N	No	This hazard is most likely to occur through post-process contamination and it can be controlled during heat process.

Table 4.4 Identification of CCP- Ingredients

4.1.6.2.2 Identification of CCP- Raw milk receiving to pasteurization

Number	Process Steps	Hazard	Q1	Q2	Q3	Q4	CCP	Note
3	Cooling	B	Y	Y		Y	No	Cooling is caused to reduce MOs in raw milk to an acceptable level until pasteurization.
4	Chilled Milk Storage	B	Y	N	Y	Y	No	MOs growth is controlled.
		C	Y	N	Y	N	CCP 1.1	Heat stable enzymes may carry through to the final product and will not remove by any other steps.

5	Pasteurization	B	Y	Y		N	CCP 1.2	Pasteurization is specifically designed to kill vegetative pathogens.

Table 4.5 Identification of CCP- Raw milk receiving to pasteurization

4.1.6.2.3 Identification of CCP –Standardization to dispatch of final product

Number	Process Steps	Hazard	Q1	Q2	Q3	Q4	CCP	Note
8	Mix pasteurization	B	Y	Y		N	CCP 2.1	Pasteurization is specifically designed to kill vegetative pathogens
9	Homogenization	B	N Y				No	This process should be modified to prevent MOs cross contamination.
10	Cooling	B	Y	Y		Y	No	Cooling is caused to reduce MOs to an acceptable level
11	Aging	B	Y	Y		Y	CCP 2.2	Temperature control is critical in prohibiting spore germination and outgrowth
12	Freezing	B	N Y				No	This process should be modified to prevent introduced of MOs by air.

13	Filling	B	N Y				No	This step should be modified to prevent introduced of MOs by manual filling.
14	Hardening	B	Y	N	N		CCP 2.3	Temperature control is critical in prohibiting spore germination and outgrowth

Table 4.6 Identification of CCP- Standardization to dispatch of final product

4.1.6.3 Establishment of Critical Limits for each CCP

CCP	Process Step	Hazard	Critical limits (What)
1.1	Chilled Milk Storage	Heat stable enzymes produced by bacteria	Temperature control below 4^0C
1.2	Raw milk pasteurization	Survival of vegetative pathogens and spores	71.7^0C for 15S Effectively working of Flow diversion valve
2.1	Mix pasteurization	Survival of vegetative pathogens and spores	65.6^0C for not less than 30 min
2.2	Aging	Outgrowth of spores	7^0C maximum (4^0C-7^0C) 48 hrs Maximum (at least 4 hrs-48hrs)
2.3	Hardening	Presence of MOs	-23^0C to -26^0C

Table 4.7 Establishment of Critical Limits for each CCP

4.1.6.4 Establishment of a monitoring system for each CCP

CCP	Process Step	Hazard	Critical limits (What)	Monitoring Procedure		
				How	When	Who
1.1	Chilled Milk Storage	Heat stable enzymes produced by bacteria	Temperature control < 4^0C	Check temperature in stores	Every Batch	Production assistant Laboratory analyst (LA)
1.2	Raw milk pasteurization	Survival of vegetative pathogens and spores	71.7^{0}C for 15S Effectively working of Flow diversion valve	Check temperature ; visual inspection and sign off Check automatic divert operation	Every Batch Twice daily	Production assistant Production assistant
2.1	Mix pasteurization	Survival of vegetative pathogens and spores	65.6^{0}C for not less than 30 min	Check temperature;	Every Batch	Production assistant LA
2.2	Aging	Outgrowth of spores	7^{0}C maximum (4^0C-7^{0}C)	Check temperature sensor against traceable calibrated thermometer Check temperature	Every Batch Every shift	Production assistant LA Production assistant

			48 hrs Maximum (at least 4 hrs-48hrs)	sensor; visual inspection and sign off Record date and time ,in and out aging tank	Daily	Assistant subordinate production Production assistant LA
2.3	**Hardening**	Presence of MOs	-23^{0}C to -26^{0}C	Check temperature sensor against traceable calibrated thermometer Check temperature sensor; visual inspection and sign off	Daily Every shift	Production assistant Production assistant Assistant subordinate production

Table4.8 Establishment of a monitoring system for each CCP

4.1.6.5 Establishment of a corrective action plan

CCP	Process Step	Corrective action	
		How	Who
1.1	Chilled milk storage	If any deviation occurred in temperature; -report to Asst.PM -Contact QA and discussed	PM and QA
1.2	Pasteurization	If time/temperature combination is varied; -report to PM -contact QA and discuss -hold production until correct the heat process verified, -take suitable correction and corrective action	PM QA Engineer
2.1	Mix Pasteurization	If time/temperature combination is varied; -report to PM -contact QA and discuss -hold production until correct the heat process verified, dump if not -take suitable correction and corrective action	PM QA Engineer
2.2	Ageing	If any deviation occurred in temperature; -quarantine product - discuss with QA and take corrective action	QA Assistant production subordinate Production assistant

2.3	Hardening	If any deviation occurred in temperature; -discuss with QA -take correction and corrective action	QA Assistant production subordinate Production assistant

Table 4.9 Corrective action Procedure for each Critical Control Points

4.1.6.6 Establishment of verification procedure

Activity	Frequency	Responsibility	Reviewer
Verification Activities Scheduling	Yearly or Upon HACCP System Change	HACCP coordinator	Production manager
Initial Validation of HACCP Plan	Prior to and during Initial Implementation of Plan	Independent Expert(s)	HACCP Team
Subsequent validation of HACCP Plan	When Critical Limits Changed, Significant Changes in Process, Equipment Changed, after System Failure, etc.	Independent Expert(s)	HACCP Team
Verification of CCP Monitoring as Described in the Plan (eg Mix pasteurization temperature.)	According to HACCP Plan (eg Every Batch)	According to HACCP plan (eg. Production assistant)	According to HACCP Plan(eg. Quality Assurance)
Review of Monitoring ,Corrective Action Records to Show Compliance with the Plan	Monthly	Quality Assurance	HACCP Team
Comprehensive HACCP System Verification	Yearly	Independent Expert(s)	Production Manager

Table 4.10 HACCP Verification Schedule

4.2 Discussion

Ice Cream is frozen ready-to-eat product containing both pasteurized and unpasteurized components. The heat stable liquids, powders, cream and sugars are pasteurized, while the flavouring and particulates are added without further heat treatment. Air is also whipped into the product at freezing.

Milk is received from several collecting centers such as Kundasale, Digana farm, Galaha, Rikillagaskada, Gampola, Karalliyadda and Yatinuwara to Diagana factory. Keeping Quality (KQ) is checked each and every milk bousers and canes before taking to the process. KQ 06 is the excellent milk that can be taken to process after storing in chilled milk storage. KQ 05 is very good milk and that should be taken to process as soon as possible ;because it is increased microbial count after delaying the process and have to discard if it is get late.

Milk bousers are used to transport raw milk from collecting centers under 4^0C temperature. Globally it is accepted as most suitable temperature to avoid proliferation of common micro organisms that present in milk. It is increased the temperature around 10^0C during transportation .Milk cans are used to transport milk from collecting centers or farm which are very close to the factory.

Raw milk is cooled immediately and held at refrigeration temperatures. *Pseudomonas spp.*, *Flavobacterium spp.* and *Alcaligenes spp* as well as some of the *coliform* bacteria tend to be the predominant psychrotrophic bacteria of raw milk in storage. These bacteria if allowed to grow to large numbers can cause bitter, fruity, rancid and unclean flavours that persist through out further processing. Some gram negative psychrotrophic bacteria particularly Pseudomonas spp are also capable of producing heat -stable enzymes (proteases and lipases) in raw milk that can cause defects in the final product.

Raw milk pasteurization is Critical Control Point due to affects most of the micro organisms mentioned earlier. 71.7^0C for 15 second is the internationally recommended time temperature standard for High Temperature Short Time

pasteurization and should be cooled to 7^0C or below immediately after pasteurization to get effective results.

Mix pasteurization is the most significant step in Ice Cream manufacturing process. After this step there will be no more step able to efficiently reduce the amount of micro-organisms; therefore it will be crucial for quality. Used of good quality raw material is very important in this step to reduce the cross contamination from micro-organisms.

According to the Sri Lanka Standard(SLS 223:1989), it should be 65.6^0C (66^0C) not less than 30 minutes for batch pasteurization and 79 ^{0}C not less than 15 seconds for continues pasteurization. After heat treatment, the temperature of the mixture should be reduced to 7^0C or below within 90 minutes. In industry, 80^0C for 30 minutes heat treatment is used for mix pasteurization and mixture is cooled in tank up to 65^0C to pass through the homogenizer.

It is essential to recirculation the mix, if it is not heated beyond critical limits temperature of 68^0C.Recoding the temperature in mix tank has to be done.
Rapid chilling of the Ice cream mixture and keeping it at the correct temperature during the aging step is important, to create the unfavorable conditions to growth of microbes.

Even if the pasteurization works fine, organisms are present in this steps due to the heat resistant spores of *Bacillus cereus* and may also be due to inefficient cleaning and disinfection in the equipment and tubes after pasteurization. The temperature will be a way to prevent the microbial hazard. The critical limit will be set at 4^0C and maximum temperature for aging is 7^0C. At least 4 hrs is requires to aging and batch should be rotated or taken to process within 48 hrs. The critical limit will be monitored using temperature sensor. Batch rotation and temperature in the tank should be recorded.

Freezing is not an efficient way to decrease number of bacteria. Though, freezing is the most successful technique for the long term preservation since the product is largely unchanged. A modification should be done in this step by fitting effective air

filter to the freezer machine; because continuous freezer machine has air filter and batch freezer machine has not an air filter.

The hardening step is cold enough for halting microbial growth sufficiently. Although survival cannot be prevented, growth of micro-organisms is stooped at temperature below -20^{0}C.The temperature monitoring and recoded in every shift is important.

Good Manufacturing Practices are very important to get high quality product and reduce introduction of hazard to the process. Well planed GMP should be followed due to currently practices are not enough for the Ice Cream manufacturing process.

Propose modification for Ice Cream production process.

- Currently ,pasteurized milk mixture is passed through the homogenizer due to lack of facilities in the company.
  The modification should be done by changing the position of the homogenizers before to mix pasteurization. It is significant to reduce introduction of pathogen to pasteurized mix after passing through the homogenizer.

- The mixture is passed through the cooler before entering to the aging tank. It is reduced temperature up to 25^{0}C and pasteurized mixture not rapid cooling.
  A modification should be done by increasing plate number of cooler to reduce temperature rapidly within few minutes.

- The filling process is done by manually within the company .There is a risk of contamination of product in this steps through following poor hygienic practices by labors.
  Use of filling machineries for filling of Ice Cream is better to reduce the cross contamination of final product.

- There is mention all the negative and positive practices currently followed up by company. (4.1.5.1.)
  All the negative practices should be corrected when implementing GMP manual within the organization.

CHAPTER 05

CONCLUSION AND RECOMMENDATION

5.1 Conclusion

- GMP manual was developed for the current processing steps and it should be maintained continuously.

- Several biological, chemical and physical hazard were identified which are associated with the Ice Cream process.

- Biological hazard is most risky group.

- Chilled milk storage, raw milk pasteurization were the identified CCP for raw milk receiving to pasteurization of milk.

- Mix pasteurization, aging and hardening were the identified hazard for rest of Ice Cream production process.

- Critical Limits were established.

  Chilled milk storage temperature need to maintain below 4^0C to avoid the rapid proliferation of bacterial count.

  Critical Limits for HTST pasteurization is 72^0C for 15s.

  Mix pasteurization should be maintained at 65.6^0C not less than 30 minutes.

  4^0C -7^0C is the critical limit for temperature and at least 4- 48hours is necessary time period for aging.

  -23^0C to -26^0C is the critical limit for hardening.

- Monitoring procedure, verification procedure were developed and documented.

5.2 Recommendation

- GMP practices should be followed to successful implementation of HACCP plan and should be provide training facilities about GMP for all the labors.

- Some steps of currently practices need to be modified.

- All the equipment that used in the processing plant and laboratory should be calibrated

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APPENDIX I

GMP manual

No. (01) **Raw material reception**

(a). Suppler certification is required for all ingredient and all raw material.

(b). Water should be chlorinated & dechlorinated, that is taken from the out side sources.

(c). Water should be treated with relevant chemicals to remove excess hardness to be found with the water.

(d). Society milk should be bring to the factory within 3 hours of milking & immediately chill after the platform tests and recording the weights of the milk.

e) Peroxide test should be carried out for every sample.

No. (02) **Milk reception**

(a). Once finish the routine tests to the raw milk, it should be filtered with appropriate mesh sized filter.

(b). The milk sample, which used for testing should be discarded, instead of adding back to the processes.

(d). Milk that taken in to the laboratory should not be re-collected to the process.

(e). Milk carrying persons should not take part in the weighting or milk filling process in to the chilling tank and factory worker should where protective clothiers.

(f). The milk puncher and the milk sample collecting cups should not keep on the ground and all the equipments should be cleaned at the end of the milk collection.

No. (03) **Chiller**

(a). Chiller should be clean according to the given documented instructions using cleaning chemicals at the beginning and the end of the collecting process.

(b). Raw milk should be processed within 36 hours from acceptance if the milk has been kept at not more than 6 C^0.

(c). Raw milk must be processed within 48 hours from acceptance if the milk has been kept at 4 C°

(d). Raw milk which has not been refrigerated must be processed as soon as possible after acceptance at the processing establishment.

No. (04) **Chilled milk storage tank**

(a). Cleaning should be done at the beginning and at the end of the processing according to the cleaning manual.

(b) It should be closed all the time.

No. (05) **Plate Heat Exchangers**

(a). CIP cleaning should be done according to the given cleaning manual.

(b). Replacing of plates, manual cleaning of plates, inspections need to be carried out according to the given instructions.

(C) Before start the production should be checked flow diversion valve is work properly.

No. (06) **Batch Pasteurizer**

(a). Manual cleaning should be done at the beginning and end of the operation. (Necessary chemicals should be supplied according to the required concentration.

(b) Polythene, cardboard, Bag stings or any other foreign material should not drop into the mix tank/mixer.

(b). Correct time & temperature should be maintained all the time.

(c). Digital sensor should be fixed to measure temperature automatically.

(e) Mixing tanks door should be closed all the time except ingredient adding occasions

No. (07) **Homogenizer**

(a). CIP cleaning should be done at the beginning and at the end of the process.

(b). Any leakage should be avoided.

No. (08) **Cream Separate**

(a). Manual cleaning should be done at the beginning and end of the operation.

(b). Cream collection should be done in to suitable vessels and cream should be use in a other processes (Manufacturing of ice cream) or discard appropriately.

No.(09) **Cooler**

(a) CIP cleaning should be done at the beginning and at the end of the process

(b) Plate should be increased to immediate cooling of Ice Cream mix.

No. (10) **Aging tank**

(a) Manual cleaning should be done at the beginning and end of the operation.

(b) The tank should be closed all the time

(c) Correct time & temperature should be maintained all the time

No.(11) **Freezer**

(a) CIP cleaning should be done at the beginning and at the end of the process.

(b) Correct temperature should be maintained all the time.

(c) Air filter should be fixed to machine.

No.(12) **Filling**

(a) Filling process should be automated.

(b) All the action should be taken to prevent the cross contamination.

No.(13) **Hardening room**

(a) Correct time & temperature should be maintained all the time

No. (14) **Dispatching and loading**

(a). Ice Cream should be dispatch only from the dispatch area.

(b). Finish product should not store or transport throw raw material storage area or any other pathways.

(c). All the action should be taken to prevent the cross contamination.

(d). Carefully larding need to be done to avoid any physical damages to the finished product.

No. (15) **Cleaning and disinfections**

(a). Cleaning and disinfections should be carried out foe every process step.

(b). Milk suppliers and milk societies has to given fully instruction about cleaning and safe handling of milk.

(c). All the machineries and equipment should be clean at the beginning and at the end of the each operation according to cleaning manuals. Occasional manual cleaning and disinfections of machinery need to be carried out to pre-determined machinery.

(d). Cleaning manual should consist of all the instructions about cleaning processes including CIP systems, COP systems and chemical concentrations and preparation instructions, rinsing cycles, use of chlorinated water, use of de-chlorinated water, use of hot and cold water, use of anti-bacterial agents, use of steam and relevant other information about safety dandling of such compounds and activities.

No. (16) **Pest control**

(a). Electrical fly traps should be located on ceiling at suitable entrances.

(b). Pest control activities/ fumigation should be carried out according to pre determined time periods.

No. (18) **Machine and equipment**

(a) Appropriate calibrations, checking and installations (new/re) should be done according to the relevant instructions.

(b) All the machine and equipments in the plant should be maintained properly

(c) Machine should be fixed by keeping distance from wall and it should be elevated from floor.

No. (19) **Personal hygiene and sanitation**

(a) All persons that are work in the factory should be wear protective clothier, need to wear boots or shoes, hair protectors or head covers, etc

(b) Jewelry should be removed before enter in to the working area. Hand bands, strings, etc should be removed.

(c) Any sick or disease persons should not enter in to the working areas.

(d) All persons should wash their hands by brushing with recommended sanitizer and brush.

(e) They should not smoke, eat and spit inside the processing and storage areas.

No.(20) **Waste disposal**

(a) The garbage quickly removed and dumped in a covered container

(b) The methods should be used in waste collection in the processing areas do not contribute towards product contamination.

(c) The waste disposals methods on the premises do not cause objectionable conditions or contribute toward product contamination?

(d) There should be well drainage system .

APPENDIX II

Ice Cream Process Inspection Check list

	Yes	No	Remarks
A. Employee			
1.The employees are in proper condition to handle process. 1.1 Are they wearing proper uniform ? 1.2 Are their uniforms clean ? 1.3 Are they wearing head coverings that properly cover their hair ? 1.4 Are hands clean, nails trimmed and fingers without jewels, bandages and sighs of injuries and infection (boils, cuts, open sores) which can contaminate food? 1.5 Are the employees not suffering from any contagious diseases such as colds, fever, tuberculosis, loose bowel movement, sore eyes etc. They should be required to submit medical certificate prior to employment?			
2. Do the employees wash and sanitize their hands before the start work, after going to the toilet and whenever necessary. They should not dip their hands in sanitizing solutions without first washing them with soap and water? 3. Do the employees change shoes before entering the processing area? 4. Do the employees maintain clean personal habits. They should keep their hands away from the hair ,mouth and body surface which are loaded with bacteria and from dirty equipment and waste materials? 5. Do the employees observe proper hygienic practices inside the plant.? They should not smoke, eat and spit inside the processing and storage areas. 6. Do the employees handle the product properly to maintain quality? 7. Do the employees well trained in what they do and they perform the processing steps as required? 8. Is there a worker's training program provided by the employers to uplift worker's skill. e.g. Seminar on GMP?			
B. Processing areas and surroundings/grounds			
1. Surroundings/Grounds Are there swamps, rivers, dumpsites etc. in the nearby neighborhood? These are contribute to rodent or insect problems. Are there improperly stored equipment, litter, waste, uncut weeds and grass within the immediate vicinity of the processing building? There are potential breeding places or harborages for rodents, insects and other pest. Are there excessively dusty roads/yards of parking lots that may be a source of contamination in an area of processed?			

	Are there inadequately drained areas that may contaminate food through seepage or food borne filth and by providing a breeding place for insects and other micro-organisms?			
2.	Plant Construction, Design and Maintenance Is the size, construction and design of the building housing the plant suitable to facilitate maintenance and sanitary operations?			
2.1.1	Do windows and doors sealed tightly to ward off pest and other contaminants?			
2.1.2	Do windows and doors have fine mesh screen to keep out insects?			
2.1.3	Are the walls and floors free or holes or cracks which can provide hiding places or entry points of pests?			
2.1.4	Will a pencil will pass under the door? That is all the space required for a rodent to enter.			
2.1.5	Are there flies, cockroaches, ants, vermin and rats and other pests entry the processing storage areas.			
2.1.6	Is the floor sloped 1:90 or 1:100 to prevent water standing?			
2.1.7	Are there necessary partitions in areas that should be separated.? e.g. washing room from raw material and production preparation room.			
2.1.8	Is there no leaks on the roof which can cause product contamination?			
2.1.9	Are there no leaky plumbing? faucets and sinks.?			
2.1.10	Is the main outlet of the drainage canal screened to avoid entry of rodents and other pests?			
2.1.11	Are the hand washing facilities furnished with running water and soap? Are they strategically situated?			
2.1.12	Are the provisions for the instructional signs such as "No Smoking" ,"Keep Door Closed", "Wash hands before retuning to work", etc. These are strategically located?			
2.1.13	Are the overhead light covered with shields to prevent contamination of products with broken glass in case the lamp durst?			
2.2	Are there provisions for worker's use. i.e. restrooms/toilet facilities, locker rooms, eating places, hand washing facilities ?			
2.2.1	Are these provisions for worker's use clean and with adequate supply of soap and water?			
2.2.2	Are the number of urinals and toilet bowls enough for the number of workers in the plant?			
2.3	Are There programs for cleaning and sanitation?			
2.3.1	Dose the plant smell clean?			
2.3.2	Are The floors and walls cleaned and disinfected before and after processing or as often as			

necessary? 2.3.3 Are the gutters are kept clean constantly and they free from solid waste and other particles? 2.3.4 Is the food spilled on the floor cleaned up quickly so as not to attract pests or breed bacteria? 2.3.5 Are the sanitizers are being used suitable in a Ice Cream processing plant. These are being used correctly? 2.3.6 Is the sewage properly disposed of? 2.3.7 Are the sinks and floor free of water hoses left dangling?			
C. Waste Disposal			
1. Is there a regular pest control program? 2. Is the garbage quickly removed and dumped in a covered container? 3. Are the methods used in waste collection in the processing areas do not contribute towards product contamination.? 4. Are the waste disposals methods on the premises do not cause objectionable conditions or contribute toward product contamination? 5. Is There a program for disposition of waste material unfit for human consumption?			
D. Equipment and Utensils			
By arriving before processing begins, the inspector is able to evaluate conditions and practices (not otherwise observable) including adequacy of clean-up, where and how equipment is stored while not in use, how hand sanitizing solutions and tea batches are prepared and whether personnel sanitize their hands and equipment before beginning work. 1. Are all equipment and utensils which come in contact with milk cleaned and sanitized before and after processing or as often as necessary to prevent contamination of the product? 2. Is There no build up of cleaning solvent and lubricant on the equipment which can contaminate Ice Cream mix? 3. Are the utensils and handling materials stacked and kept in a clean and dry area? 4. Is the equipment hard to disassemble for cleaning and inspection? 5. Are the equipment constructed or covered to protect contents from dust and environmental contamination? 6. Are the residual materials and pockets of residual building up in comers and undersides of the equipment prevented? 7. Are the processing utensils used during processing or on surface in contact with the product being processed are cleaned, sterilized and stored properly? 8. Are mercury switches, mercury thermometers or electric bulbs properly shielded and located?			

E. Warehouse-keeping and storage.			
1. Is the storage area clean ? 2. Is the storage area not overcrowded? 3. Are The raw materials contained in boxes properly stacked? 4. Are the raw materials and finished products stored on a first-in first-out basis to reduce the possibility of contamination through spoilage.? 5. Is there no overstocking of raw materials and finished products? 6. Are the storage areas intended for room temperature subject to extremes of temperature either hot or cold? (This can damage the food products.) 7. Are all products spoiled or damaged by insects, rodents or other causes stored in separate area away from the good stock? 8. Are the damaged products disposed off quickly to prevent development of pest breeding places? 9. Are the cleaning and disinfecting materials and chemicals stored away from the raw materials that used to produce Ice Cream.? 10. Are the ingredients properly labeled?			
F. Production and Process Control			
1. Are all the ice Cream processing activities including packaging and storage conducted under conditions necessary to minimize microbiological, toxin formation, deterioration of food? 2. Are there defects observed on Ice Cream when produced under GMP within specified levels? 3. Are materials which subjected to progressive decomposition left are exposed for too longer a time? 4. Is raw material quality acceptable? 5. Is raw material infected?			

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