DEVELOPMENT OF HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP) FOR FLAVORED YOGHURT MANUFACTURING PROCESS

BY

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DECLARATION

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AFFECTIONATELY DEDICATED TO
MY LOVING PARENTS
&
TEACHERS

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Abstract

In the modern world of globalization era food processing industry is achieved procedures to produce safety product. The control of physical, chemical, and biological hazards is the primary concern. Hazard Analysis Critical Control Point (HACCP) is the best system to achieve that goal. The implementation of HACCP system was carried out by the HACCP team members to assure safety in flavored yoghurt manufactured by Lucky Lanks Daries (Pvt) Limited.

Good manufacturing practices (GMP) manual was developed as a pre-requisite program for HACCP plan. The HACCP team identified the all potential hazards with the ingredients and the processing steps. Critical control points (CCPs) were identified using decision tree. At each critical control points, critical limits were established using control chart and monitoring procedures were identified. Verification procedures were applied and finally documentation was established. As a final out come of all above steps HACCP manual was developed.

Critical control points were identified for ingredients used for flavored yoghurt. This is achieved through implementation of Supplier Quality Assurence (SQA) and frequently testing of receiving ingredients as control measures.

The pasteurization process, in-line transferring of milk, filling, and cool room storage were identified as critical control points on the manufacturing process. Pasteurization at 95-97.04^{0}C, Application of 92% Nacl cleaning solution, 2-micron sieve size for filter and maintenance of cool room temperature at 0-5^{0}C were the safe boundaries or critical limits in the manufacturing process.

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Abbreviations

CAC	:	Codex Alimentarious Commission
FAO	:	Food and Agriculture Organization
FDA	:	The United State Food and Drug Administration
GMP	:	Good Manufacturing Practices
HACCP	:	Hazard Analysis Critical control Point
ICMSF	:	International Commission for Microbiological Specification for foods
ISO	:	International Organization for Standardization
LCL	:	Lower Control Limit
LSL	:	Lower Specification Limit
NACMCF	:	National Advisory Committee on Microbiological Criteria for food (USA)
PPM	:	Parts Per Million
SLS	:	Sri Lanka Standard
SLSI	:	Sri Lanka Standard Institute
SPC	:	Statistical Process Control
SQA	:	Supplier Quality Assurance
USFDAC	:	United Status Food and Drug Administration Center
UCL	:	Upper Control Limit
USL	:	Upper Specification Limit
US	:	United Status
WHO	:	World Health Organization
IPA	:	In Process Analysis
LLD	:	Lucky Lanka Dairies
SMP	:	Skimmed Milk Powder
RMA	:	Raw Milk Analysis

Chapter 1

Introduction

1.1 Introduction

In the modern of globalization quality standards are play an important role in food industry. Because it certifies safety & quality of the products to consumer. As Sri lanka standards institute,1994 in any organization the attainment of the desired levels in production or in the services provided requires the application of well planned quality systems. The objective of such a system is to achieve an d sustain the quality of product or service provided so as to meet continually the purchaser's stated or implied needs. The design and application of an appropriate system, requires a clear understanding of the principal concepts of quality.

Several standards has published by SLSI such as SLS, ISO series, HACCP etc and the international organization for standardization also has published a series of standards for the purpose of clarifying the distinction and interrelationships among principal quality concepts and providing guidelines for the selection of an appropriate system for the desired purpose. These standards are the refinement of the most practical and generally applicable principles of quality. They provide essential for putting quality management and quality assurance policies in to action.

All companies have management system such as financial management, Personnel management, production management and quality management systems. Quality management system may be simple such as the processors unwritten understanding of the processors or complex such as the ISO series. The application of HACCP is compatible with the implementation of quality management system and is the system of choice in the management of food safety within the systems. HACCP system must be considered as essential for any enterprise whether or not other organized management systems are in place, therefore HACCP system must be capable of operating independently of other quality management systems (Marine fisheries research department,1996).

The HACCP system, which is a science-based programme, identifies hazard associated with a food & measure for their control to ensure safety of foods. HACCP is a tool to assess hazards & establish control systems that focus on preventive rather than relying mainly on end product testing & inspection. Any HACCP system is capable of accommodating change, such as advances in equipment design processing procedure or technological developments. While the application of HACCP to all segments, and sectors of the food chain is possible. It is assumed that all sectors operate to Good Manufacturing practices (GMP) or the Codex general principles of food hygiene(SLSI,1998) Therefore support network is essential to implement HACCP system such as Good Manufacturing Practices (GMP), Supplier Quality Assurance (SQA), Good Laboratory practices, Statistical process control, personnel and training (Mortimore and Walace,1998).

All types of food safety hazards are considered as part of the HACCP system, biological, chemical & physical. Effective implementation of HACCP system can involve everyone in the company and each employee has a role to play. The culture that evolves through this approach makes it much simpler to progress to additional programmes such as quality improvement, productivity and cost reduction (Mortimore ,1998).

Appling a HACCP system for flavored yoghurt & fruit jelly yoghurt at Lucky Lanka Daries (pvt) Limited At matara will be the number one in yoghurt production among dairy companies and also reduce the number of waste products ,and cost of further inspection & testing of the end products (Lucky lanka daries,2005).

Several previous studies were carried out regarding application of HACCP system in dairy industry. Mr.G.D.I.P Amarasena at Faculty of Applied sciences, Sabaragamuwa University of Sri Lanka as his final year research on December 2000, the HACCP system was applied to the ice-cream manufacturing process of ceylon cold stores limited at Ranala. For Milk powder manufacturing process the HACCP system was also developed at Milco industries, Abewela on July 2003 by Mr.W.K.Jayasuriya at Faculty of Agriculture, Sabaragamuwa University of SriLanka.

The HACCP system Milk contains many essential nutrients such as carbohydrates, proteins, lipids, minerals and vitamins. Therefore milk provides an ideal medium for rapid proliferation of most microorganisms which degrade and alter its composition thus reducing its keeping quality and making it unfit for human consumption.

Consequently during the production, processing, storage and distribution (SLS872:1989).Therefore dairy products are subjected to spoilage and food poisoning. Spoilage is occurred as a result of growth or enzyme production of microorganisms and food poisoning is occurred due to pathogenic microorganisms or their toxin (ICMSF,2000). Several health hazards are recorded in Sri Lanka and all over the world regarding to milk products. *Salmonella* outbreaks, *Listeria* outbreaks and *Coliform* outbreaks are frequently associated with milk products (Gould and Lund,2000). As a milk products yoghurt were associated with above outbreaks (ICMSF,2000). Therefore potential hazard should be avoided using well organized food safety system. HACCP system is the best system to eliminate those hazards.

1.2 Objectives

1.2.1. Overall objective

- Identification of hazard and Critical Control Points (CCPs) and critical limits in flavored yoghurt manufacturing process.

1.2.1. Specific objectives

- Development of safety character in flavored yoghurt.
- Introduction of an easy way to identify safe flavored yoghurt.
- Make a solution to prevent loss of flavored yoghurt.

Chapter 2

Literature Review

2.1 Origin and concept of HACCP

The concepts underlying the Hazard analysis and Critical Control Point system originated in work done in the 1960s to help establish the risk of *Salmonella* infection in food and also in the development of quality assurance system by the National Aeronautics and space administration (NASA) and the U.S.militory Natick Laboratory. The HACCP system today took from at the 1971 national conference on food protection. Around that time hazard analysis procedures were adopted to plan critical control points designed to control the hazards in the food system. Linking the hazard analysis to critical control points gave rise to the abbreviation HACCP (Donald,1998).

The pillsbury company first used HACCP for the assurance of the safety of food intended for the U.S. space program. Pillsbury had previously concluded that standard quality methods were not reliable enough to bring close to 100% assurance that food used for the space program would be free from food borne hazards, particularly bacterial or viral hazards. The pillsbury company, led by Dr.Howard Bauman, successfully employed the HACCP system for the space program food safety and also adopted HACCP as the companywide food protection system (Donald,1998).

HACCP was used to some extent for non-canned foods during the 1970s and the early 1980s,but only in 1985 was serious consideration given to broad application of HACCP to various categories of non-canned food (Donald,1998).

The National Advisory committee on Microbiological criteria for foods (NACMCF) HACCP system evolved in part from the frustration encountered in the

food industry in a decade of trial, error, and debate on end product microbiological standards for food (Donald,1998).

On November 28,1989 the NACMSF gave final approval to its first major document "Hazard Analysis and Critical Control system". This document was forwarded to the cabinet secretaries of the Department of Agriculture, Health and Human Services, commerce and defense. The NACMCF HACCP guide was subsequently retiled HACCP principle for food production (Donald,1998).

2.2 HACCP system and food safety

HACCP is a system of food control based on prevention. In identifying where the hazards are likely to occur in the process, and have the opportunity to put in place the measures needed to prevent those hazard occurring. This will facilitate the move towards a preventative quality assurance approach within a food business, reducing the traditional reliance on end product testing. Physical, Chemical and Biological food safety hazards are considered when implementing HACCP system.

Nowadays food borne disease continues to be one of the largest public health problem worldwide. The importance of the HACCP approach as a means of preventing food borne illness has long been recognized by the world health organization and many governments worldwide.(Mortimore and Wallace,1998)

HACCP was developed as a simple method of helping manufactures assure the consumer, but many companies have only recently started to realize the full potential of the system.

An effective HACCP system is one way of preventing incidents of food hazards. It is a system where all hazards to food safety are identified and effective control mechanisms are put in place. The essential continued monitoring of these control mechanisms and maintenance of the system, ensure that any potentially unsafe situations that occur are highlighted, and this means that the company can take appropriate steps to prevent a food safety incident (Mortimore and Wallace,1998).

2.3 Food industry and worldwide evaluation

Within the food industry, the safety of products must, without question, be considered top priority. The food is 'safe' is often an unwritten requirements of many

customer specifications. Consumers expect safe food and manufactures in the food industry have a reasonability to meet their expectation.

Government's recognition of HACCP as the most effective means of managing food safety is increasing on a worldwide basis. The difficulty in focusing on specific pieces of legislation is that legislation is ever changing. In Europe one of the most powerful legal driving forces is the European community Directive 93/43 EC(1993) on the hygiene of foodstuffs. The Directive, while not using the precise wording of codex Alimentarius or NACMCF states that food business operators shall identify any step in their activities critical to ensuring food safety and ensure that adequate safety procedures are implemented, maintained and reviewed. In essence the Directive lists the first principles required to develop the system of HACCP, and can be interpreted in virtually the same way as Codex/BACMCF, with the exception of any specific reference to record keeping.

All food businesses throughout Europe are strongly recommended to use the HACCP approach, in that it will enable them to meet the requirements of the legislation. It also, means that food businesses that are certified to the international quality standard ISO 9000 will be forced to include HACCP within the scope of their quality management systems as under this standard all relevant legislation must be complied with the full.

New Zealand, the Ministry of Agriculture is in the process of making HACCP mandatory for all food producers. In the USA the HACCP techniques were used to identify the controls specified in the low acid canned food regulations. The US department of agriculture has decreed that HACCP programmes will be required for all meat and poultry-processing facilities, beginning in 1998. The US food and drug administration is considering additional HACCP regulations on an industry-by-industry basis. At the time of writing a rule for fruit-juice processing is nearing completion. The trend seems to indicate the HACCP will eventually be mandatory not only for all US food-processing facilities but also all food processors who are exporting into the US from anywhere else in the world. In Canada, manufactures of high-risk food products by the end of 1991.

The Codex Alimentarius Commission (CAC) is able to influence food regulation worldwide and utilizes the food safety best practice standards adopted by member governments in drawing up the CAC. HACCP Seven principles has been published within the Codex (1993 and 1997 update) documents. From these

documents many manufacturing companies, committees and food research associations, large and small, have taken a lead.

Nowadays international legislation is moving more and more towards making HACCP a mandatory requirement for the food industry. Key indicators include the legal requirements for use of HACCP in specific sectors of the food industry and the strong recommendation from many governments through directives and food safety reports and surveys (Mortimore and Wallace,1998).

2.4 Benefits of implementing HACCP

2.4.1 To the company

HACCP is the most effective method of maximizing product safety and also it gives evidence of safe production and handling of food products. From these evidences, promote international trade by increasing buyer's confidence (U.S. Food and Drug Administration center,2004).

Other benefits of applying HACCP include more effective use of resources, saving to the industry from reduced customer complaints and more timely response to food safety problems. HACCP enhance the responsibility of employees towards food safety and degree of control of over hazards at implemented HACCP system demands a greater involvement of food handlers during development and implementation of the system thus provides them with renewed motivation in their work (SLSI,1998). Customer requirements can be satisfied by implementation HACCP system due to undergoing quality assurance procedures when manufacturing products. The Company is moved towards a quality management system. Because the HACCP plan is a integration of GMP and quality assurance procedures (U.S. Food and Drug Administration center,2004).

2.4.2 To the customer

The application of the HACCP system can aid buying safe products without any dought.. Consumer awareness of their right to purchase food that is safe has increased. Their awareness of quality failure such as physical chemical and biological contaminants. Therefore the HACCP system provides brand consumer protection. It also help to reduce food-borne illness(Mortimore & Wallace,1998).

2.5 Drawbacks of implementing HACCP

If HACCP system not properly applied, then it may not result in an effective control system. This may be due to improperly trained or untrained personnel not following the principles correctly; it may be that the outcome of the HACCP study is not implemented within the workplace; or it may be or it may be that the implemented system fails through lack of maintenance, e.g. if a company implements a system and stops there, paying little or no heed to changes that occur in the operation, then new hazards may be missed. The effectiveness may also be lost if company carries out the hazard analysis and then tries to make its findings fit with existing controls. HACCP compatible with existing quality management systems but must be ensured that product safety is always given priority and that HACCP findings are not changed because they differ from existing operational limits.

Other problems may arise if only one person, rather than a multi-disiplinary team, or where it is done at the co-oparate level with little or no input from the processing facility carries out HACCP. Some critics may say that HACCP is too narrow in that it focuses only on food safety; others say that it should only be used for microbiological safety. HACCP was designed for food safety and safety should always came first, but the HACCP techniques are flexible and can be applied to other area such as product quality, work practices and to products outside the food industry (Mortimore & Wallace,1998).

2.6 HACCP definition and principles

HACCP is a management system which food safety is addressed through the analysis and control of biological, chemical and physical hazards from raw material production procurement and handling to manufacturing distribution and consumption of the finished product (NACMSF,1997).

HACCP is an abbreviation for Hazard Analysis and Critical Control Point and requires a team approach and the full commitment of management and employees. It is applicable to all food producers, small companies as well as multinational food corporations (U.S. Food & Drug Administration,2004).

HACCP is an alternative to the traditional, statistically insignificant end product testing, and it is internationally accepted as the most effective system for the production of safe food (Roday,1999).

The HACCP system consists of the seven principles as conduct a hazard analysis (principle 1), Determine the Critical Control Points(CCPs) (Principle 2), Establish Critical limits (principle 3), Establish system to monitor control of the CCP (principle 4), Establish corrective action (principle 5), Establish procedure for verification (principle 6) and Establish documentation (principle 7) (SLSI,1998).

2.6.1 Hazard

2.6.1.1 Definition

Hazard is a biological, chemical or physical property or condition pf , food with the potential o cause an adverse health effect.(Codex,1997)

2.6.1.2 Hazard types

Hazard can be categorized as physical hazards, Chemical hazards and biological hazards.

Physical hazards are the most common type of hazard o occur in foods, and can enter a food product at any stage in its production. There is a huge variety of physical items that can enter food as foreign material, some of which may also described as microbiological, but only a few of these are hazards to food safety. Foreign material should be carefully considered that they are likely to cause health risk to the consumer.

Any foreign material item could be a safety hazard if it has the potential to make consumer choke. This is particularly important in foods that may be consumed by children, where even pieces of paper sacks or boxes could pose a safety risk. As with macro biological hazards, it should also be noted that any foreign material item could transport microbiological hazards into the product, and this is a significant if they gain access after all processing steps that would control these hazards. The procedures for GMP and/or prerequisite programmes should ensure that these issues

are considered as part of the building environment and should prevent any physical hazard from being brought into the production area by employees.

Foreign material items are food safety hazard if the items that are sharp and could cause injury or hard and could dental damage or capable of blocking the airways and causing chocking. The main physical food safety hazards are glass, metal, stones, wood plastics, pests etc (Mortimore & Wallace,1998).

Chemical hazards are occurred due to chemical contamination of foodstuffs can happen at any stage of their production, from growing of the raw materials through to consumption of the finished product. The effect of chemical contamination on the consumer can be long term (chronic), such as for carcinogenic or accumulative chemicals (mercury) which can build up for many years, or it can short term (acute), such as the effect of allergenic foods (Mortimore & Wallace,1998).

Chemical hazards fall into two categories, naturally poisons and added poisons. Naturally occurring poisons, chemicals, or deleterious substances are those that are natural constituents of food and are not the result of environmental, agricultural, or other contamination. Example includes aflatoxins, mycotoxins, and shellfish toxins. Added poison chemicals or deleterious substances are those, which are intentionally or unintentionally added to foods at some point in growing, harvesting, storage, processing, packing or distribution. This group of chemicals can include pesticides, fungicides, insecticides, fertilizers, drug residues, and antibiotics, as well as direct and indirect food additives. This group can also include chemicals such as lubricants cleaners, paints and coatings.

To identify any chemical hazards, first need to identify any chemical residue that might still be present in the animal tissue (Donald,1998).

Biological hazards are living organisms, including micro-organisms that can put human health at risk. Biological hazard include bacteria, parasites, protozoa, viruses, and the like (Donald,1998). Most food processing operations will be at risk from one or more biological hazards, either from the raw materials or during the process and the HACCP plan will be designed to control these. Biological hazards can be either macro biological or microbiological.

Macro biological issues, such as the presence of flies or insects, while unpleasant if found rarely pose a risk themselves to product safety in its true sense. There are few exception to this, such as poisonous insects, but on the whole the appearance of macro biological hazards, simply cause revulsion. However, they may

be an indirect risk by harboring pathogenic microorganisms and introducing these to the product considering product should be free from macro biological hazards and should be considered as part of HACCP study or prerequisite programmes.

Pathogenic or disease-causing micro-organisms exert their directly or indirectly on humans. Direct effect result from an infection or invasion of boy tissues and are caused by the organism itself. Indirect effects are caused by the formation of toxins that are usually pre-formed in the food, by bacteria and moulds (Mortimore & Wallace,1998).

2.6.2 Preliminary steps of HACCP plan

In the development of a HACCP plan, five preliminary steps need to be accomplished before the application of the HACCP principles to a specific product and process. Figuer 2.1 shows the five preliminary steps of HACCP paln.

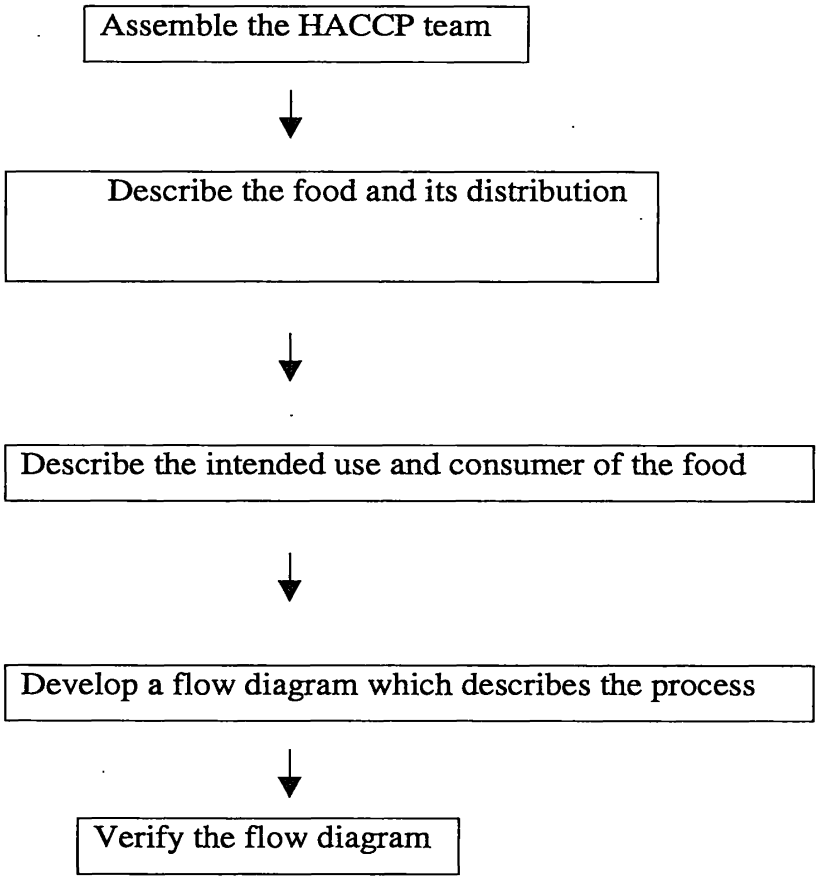


Figure 2.1 Preliminary steps in the development of he HACCP plan

2.6.2.1 Assemble the HACCP team

The first step in developing a HACCP plan is to assemble a HACCP team consisting of individuals who have specific knowledge and expertise appropriate to the product and process. It is team's responsibility to develop the HACCP plan. The team should be Multi-disciplinary and include individuals from area such as engineering, production, sanitation, quality assurance, and food microbiology. The team should also include local personnel who are involved in the operation as they are more familiar with the variability and limitation of the operation. In addition this fosters a since of ownership among those who must implement the plan. The HACCP team may need assistance from outside experts who are knowledgeable in the potential biological, chemical and/or physical hazards associated with the product and the process. However a plan which is, develop totally by outside sources may be erroneous, incomplete, and lacking in support at the local level.

Due to the technical nature of the information required for hazard analysis, it is recommended that experts who are knowledgeable in the food process should either participate in or verify the completeness of the hazard analysis and the HACCP plan. Such individual should have the knowledge and experience correctly for applying seven principles in HACCP plan (NACMSF,1997).

2.6.2.2 Describe the food and its distribution

The HACCP team first describes the food. This consists of a general description of the food ingredients, and processing methods. The method of distribution should be described along with information on whether the food is to be distributed, frozen, refrigerated, or at ambient temperature (NACMSF,1997). The product description may be constructed for two reasons. Firstly it is essential that the HACCP team is fully familiarized with the product and process technologies to be covered by the HACCP plan. Secondly the product description act as an introduction and point of historical references to the HACCP plan (Mortimore & Wallace,1998).

2.6.2.3 Describe the intended use and consumers of the process

Describe the normal expected use of the food. The intended consumers may be the general public or particular segment of the population (e.g. infants, immunocompromised individuals, the elderly etc) (NACMSF,1997).

2.6.2.4 Develop a flow diagram which describe the process

The purpose of a flow diagram is to provide a clear, simple outline of the steps involved in the process. The scope of the flow diagram must cover all the steps in the process, which are directly under the control of the establishment. In addition, the flow diagram can include steps in the food chain, which are before and after the processing that occurs in the establishment. The flow diagram needs to be as complex as engineering drawings. A block type flow diagram is sufficiently descriptive. Also a simple schematic of the facility is often useful in understanding and evaluating product and procee flow (NACMSF,1997).

2.6.2.5 Verify the flow diagram

When the process flow diagram is complete the HACCP team prior to the hazard assessment stage must verify it. This involves team members watching the process in action to make sure that what happens is the same as what is written down, and may also involve going in on the night shift or weekend shift to ensure that any alternatives are included. It is essential to establish that get it right as the hazards analysis and all decisions about CCPs are based on the data (Mortimore & Wallace,1998).

2.6.3 Secondary steps of HACCP plan

After these five preliminary steps have been completed, the seven principle of HACCP are applied.(NACMSF,1997)

2.6.3.1 Conduct a hazard analysis (principle 1)

After addressing the preliminary steps, the HACCP team conducts a hazard analysis and identifies appropriate control measures. The purpose of the hazard analysis is to develop a list of hazards, which are of such significance that they are reasonably likely to cause injury or illness if not effectively controlled. Hazards that are not reasonably likely to occur would not require further consideration within a HACCP plan. It is important to consider in the hazard analysis the ingredients and the raw materials, each steps in the process, product, storage and distribution, and the final preparation and use by the consumer. When conducting a hazard analysis, safety concerns must be differentiated from quality concerns.

If the hazard analysis is not done correctly and the hazard warranting control within the HACCP system are not identified, the plan will not be effective regardless of how well it is followed.

The hazard analysis and identification of associated control measures accomplish three objectives. Those hazards and associated control measures are identified. The analysis may identify needed modification to a process or product so that product safety is further assured or improved. The analysis provides a basis for determining CCPs in principle 2.

The process of conducting a hazard analysis involves two stages. The first hazard identification can be regarded as a brain storming session. During this stage, the HACCP team reviews the ingredients used in the product, the activities conducted at each step in the process and the equipment used. The final product and its method of storage and distribution, and the intended use and consumers of the product. Based on the review the team develops a list of potential biological, chemical or physical hazards, which may be introduced, increased or controlled at each step in the production process.

After the list of potential hazards is assembled, stage two, the hazard evaluation, is conducted. The HACCP team decides which potential hazards must be addressed in the HACCP plan. During this stage, each potential hazard is evaluated based on the severity of the potential hazard and its likely occurrence. Severity is the seriousness of the consequences of exposure to the hazard. Consideration of severity can be helpful in understanding the public health impact of the hazard. Consideration of the likely occurrence is usually based upon a combination of experience, epidemiological data,

and information in the technical literature. When conducting the hazard evaluation, it is helpful to consider the likelihood of exposure and the severity of the potential consequences if the hazards are not properly controlled. However, there may be differences of opinion in HACCP team even among experts, as to the occurrences and severity of a hazard. The HACCP team may have to rely upon the opinion of experts who assist in the development of the HACCP plan (NACMSF,1997).

2.6.3.2 Determine the Critical Control Points (CCPs) (principle 2)

A Critical Control Point is defined as a step at which control can b applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level. The potential hazards that are reasonably likely to cause illness or injury in the absence of their control must be applied addressed in determining CCPs.

Complete and accurate identification of CCPs is fundamental to controlling food safety hazards. The information developed during the hazard analysis is essential for the HACCP team in identifying which step in the process are CCPs. One strategy to facilitate the identification of each CCP is the use of a CCP decision tree.(Appendix A) Although application of the CCP decision tree can be useful in determining if a particular step is a CCP for a previously identified hazard, it is merely a tool and not a mandatory element of HACCP. A CCP decision tree is not a substitute for expert knowledge.

Critical control points are located at any steps where hazards can be either prevented, eliminated or reduced to acceptable levels. In addition there must be used only for purposes of product safety. Different facilities preparing similar food items can differ in the hazard identified and the steps which are CCPs. This can be due to differences in each facility's layout, equipment ,selection of ingredients, process employed, etc.(NACMSF,1997)

2.6.3.3 Establish critical limits (principle 3)

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

is used to distinguish between safe and unsafe operating condition at a CCP. Critical limit should not be confused with operational limits, which are established for reasons other than food safety.

Each CCP will have one or more control measures to assure that the identified hazards are prevented, eliminated or reduced to acceptable levels. Each control measure has one or more associated critical limits. Critical limit may be based upon factors such as: temperature, time, physical dimensions, humidity, moisture level, water activity (a_w), pH, titrable acidity, salt concentration, available chlorine, viscosity, preservatives, or sensory information such as aroma and visual appearance. Critical limit must be scientifically based. For each CCP, there is at least one criteria on for food safety that is to be met (NACMSF,1997).

2.6.3.4 Establish monitoring procedure (principle 4)

Monitoring is a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification. Monitoring serves three main purposes. First monitoring is essential to food safety management in that it facilitates tracking of the operation. If monitoring indicates that there is a trend towards lost of control, then action can be taken to bring the process back into control before a deviation from a critical limit occurs. Second, monitoring is used to determine when there is loss of control and deviation occurs at a CCP. When a deviation occurs, an appropriate action must be taken. Third, it provides written documentation for use in verification.

An unsafe food may result if a process is not properly controlled and a deviation occurs. Because of the potentially serious consequences of a critical limit deviation, monitoring procedures must be effective. Ideally monitoring should be continuous, which is possible with many types of physical and chemical methods.

Assignment of the responsibility for monitoring is an important consideration for each CCP. Specific assignment will depend on the number of CCPs and control measures and the complexity of monitoring. Personnel who monitor CCPs are often associated with production and, as required, quality control personnel. Those individuals must be trained in the monitoring technique for which they are

responsible, fully understand and purpose and importance of monitoring, be unbiased in monitoring and reporting, and accurately report the results of monitoring. In addition employees should be trained in procedures to follow when there is a trend towards loss of control so that adjustment can be made in a timely manner to assure that the process remains under control. The person responsible for monitoring must also immediately report a process or product that does not meet critical limits.

All records and documents associated with CCP monitoring should be dated and signed by the person doing the monitoring. When it is possible to monitor a CCP on a continuous basis. It is necessary to establish a monitoring frequency and procedure that will be reliable enough to indicate that the CCP is under control. Statistically designed data collection or sampling systems lend themselves to this purpose.

Microbiological test are seldom effective for monitoring due to their time consuming and problems with assuring detection of contaminants (NACMSF,1997).

2.6.3.5 Establish corrective action

Corrective action are defined as any action to be taken when the results of monitoring at the CCP indicate a loss of control or in other words deviation from critical limits (SLSI,1998). However the HACCP system for food safety management is designed to identify health hazards and to establish strategies to prevent , eliminate, or reduce their occurrences. Ideal circumstances do not always prevail and deviation from established processes may occur. An important purpose of corrective actions is to prevent foods, which may be hazardous from reaching consumers. Where there is a deviation from established critical limits, corrective actions are necessary. Therefore corrective actions should include the following elements: (a) determine the correct the cause of non-compliance, (b) determine the disposition of non-compliant product and (c) record the corrective actions that have been taken. Specific corrective action 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 maintain of the action taken, Individuals who have a thorough understanding of the process, product and HACCP plan should be assigned the responsibility for oversight of corrective action. As appropriate, expert may be

consulted to review the information available and to assist in determining disposition of non- compliant product (NACMSF,1997).

2.6.3.6 Establish verification procedure (principle 6)

Verification is defined as those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan. The NAS (1985) pointed out that the major infusion of science in a HACCP system centers on proper identification of the hazards, critical control points, critical limits, and instituting proper verification procedures. These processes should take place during the development and implementation of the HACCP plan and maintenance of the system.

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 if 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 hazard have been identified and that if the HACCP plan is properly implemented these hazards will be effectively controlled information needed to validate the HACCP plan often include, expert advice and scientific studies and in plant observations, measurements, and evaluations. Subsequent validations are performed and documented by a HACCP team or an independent expert as needed.

In addition, an unbiased, independent authority should conduct a periodic comprehensive verification of the HACCP system. Such authorities can be internal or external to the food operation. This should include a technical evaluation of the hazard analysis and each element of the HACCP plan as well as on-site review of all flow diagrams and appropriate records from operation of the plan. A comprehensive verification is independent of other verification procedures and must be performed to ensure that the HACCP plan is resulting in the control of the hazards. If the result of the comprehensive verification identifies deficiencies, the HACCP team modifies the HACCP plan as necessary.

Verification activities are carried out by individuals within a company, third party experts, and regulatory agencies (NACMSF,1997).

2.6.3.7 Establish documentation and record keeping (principle 7)

Documentation and record keeping should be kept as apart of HACCP plan and it may be in any form such as processing chart, written record and computerized record. The importance of records to the HACCP system cannot be over emphasized. It is imperative the produce maintain complete current, properly filed and accurate records. Four types of record should be kept such as support documentation for developing the HACCP plan, record generated by the HACCP system, documentation of methods and procedures use, and records of employee training programmes.

The HACCP plan support document include information and support data used to establish the HACCP plan such as the hazard analysis and record documenting the scientific basis for establishing the CCPs and critical limits. Records regarding to HACCP team responsibilities and information, product description and intended use, flow diagram also belongs to this.

HACCP system records are kept to demonstrate adherence of the HACCP system with the HACCP plan. These records are used to demonstrate control at CCPs in the food process. By tracking records generated by the HACCP system, an operator or manager can become aware that a process is approaching its critical limit. Review of records can be instrumental in identifying trends and in making operational adjustments. Timely corrective action can be taken in if a critical limit is violated. All records pertinent to CCPs shall be documented in the relevant column of the HACCP plan. Failure to record at a CCP is a critical departure from HACCP plan and is a critical non-conformity. However all HACCP monitoring records, deviation and corrective action records, and verification records should be included.

The procedure shall document the methods and producers used in the HACCP system including description of the monitoring system for critical limits at of each CCP, methods and equipment used for monitoring, plans for corrective actions for critical limit violations, description of record keeping procedures, description of verification and validation procedures, and HACCP training records (SLSI,1998).

2.7 Good manufacturing Practices (GMP)

Gmp is the essential pre-requisite programme when applying HACCP plan to a industry. Gmp is a key issue for product safety is the risk of cross-contamination occurring the process from the internal factory environment. Cross-contamination could arise from wide range of sources the inherent risks in a particular processing area must be understood. Most of these issues are managed through adherence to Good manufacturing Practices (GMP). Some of the main sources of potential cross-contamination are as follows:

Layout:

The facility layout should be considered to minimize the cross-contamination risks. This should indicate adequate segregation of raw material and finished products. Availability of the required services and facilities for manufacture of the product should be also considered including availability of portable water, and adequate cleaning facilities for plant, equipment and environment, along with the connection of all required in the correct area. The number of holding stages associated time should also be considered. The pattern of movement of staff and equipment should also be assessed here, with the provision of adequate hygiene facilities.

Building:

The fabric of the building itself could pose a hazard or safety risk to the product, through harborage of pests and other contamination, or other physical contamination due to poor design and maintenance. Surface should be non-porous and easy to clean, with all cracks filled and sealed. All building should be maintained to prevent physical hazards falling to the product, and drains should be designed and serviced so that the flow is always away from the production areas. Adequate pest and proofing and cleaning schedules should be drawn up for all facility buildings.

Equipment should be designed to minimize any cross-contamination risk. This could arise through parts of the equipment breaking off and gaining entry to the product and as physical hazards. If the equipment has ant dead-leg areas, is difficult to clean or is poorly cleaned, microbiological build-up could contaminate the product.

Chemical contamination could arise through lubricants or cleaning residues remaining on the equipment food-contact surfaces.

People:

Food handlers and other personnel with access to the food processing area could cross-contaminate the product with microbiological, chemical, and physical hazards. The process layout and movement patterns should be considered in order to minimize this risk, along with the appropriate training programmes. All personnel in a food plant should be trained in Good Hygiene Practice.

Cleaning:

There must be sufficient facilities for the cleaning of equipment, people, plant and buildings, and these should be situated to enable their convenient use. Cleaning areas should not cause a cross-contamination risk to the process. Cleaning schedule should be prepared for all areas and staff must be adequately trained to carry and cleaning activities effectively.

Chemicals:

Storage facilities must be provided for any chemicals that are required for use in the manufacturing area. These must prevent the risk of product contamination. All chemical must be properly labeled and must not be decanted into food containers. All personnel handling chemicals must be trained in their safe use.

Raw materials:

Raw material can act as cross-contaminants if they gain access to the wrong product, or if they are added in excess quantities. This can have serious consequences in the case of allergenic raw materials entering a product where they are not labeled. Handling areas for raw materials must be carefully planned, and areas used for more than one type of ingredients may require through cleaning between use.

Storage:

Storage areas must be properly planned to minimize damage and cross-contamination issues. Adequate segregation, temperature, humidity control, and pest proofing should be considered. All materials must be stored off the floor and in sealed

bags or containers. Part-used container must be resealed after each use and strict stock rotation should be employed.

Products:

Residues of other can also cause a serious hazard if allergenic material is present or if they affect the intrinsic nature of the product that is contaminated. Production lines should be spatially separated to prevent cross-contamination, and handling and cleaning procedures should be planned appropriately.

Packaging:

Packaging areas and handling practices should be managed and controlled to prevent any cross-contamination risk. The packaging itself could be a major hazard such as material fragments, or could introduce microorganism to the product. Packaging should not be damaged during product storage and distribution. (Mortimore and Wallace,1998).

2.8 Yoghurt and food safety issues

Yoghurt is a fermented milk product, with custard like consistency, flavored or non-flavored, whose semi-solid characteristics differentiate the product from the fermented milk It is slightly acidic, semisolid, cultured milk food which is made from homogenized, pastured milk to which two cultures of bacteria *Streptococcus thermophillus* and *Lactobacillus bulgaricus* have been added. It is a vitamin rich and digestive drink available in variety of flavors. It is more nutrious than other fermented milk products because of its higher milk solid contents. In addition to this yoghurt is well know to have antibiotic properties and is widely consumed for controlling intestinal disorders.

Nowadays several type of yoghurt can be seen in the market such s Natural yoghurt, Flavored yoghurt, Fruit yoghurt, and vegetable yoghurt. Flavors and colors are not added to natural yoghurt and it is fermented by culture. Sugar and flavors (Strawberry, Vanilla, Cherry) are added to natural yoghurt and prepared Flavored yoghurt. Fruit yoghurt is consisted with fruit pieces (Papaya, pineapple, Mango) and after fermentation fruit pieces are distributed in yoghurt. Vegetable pieces (Carrot,

Beet, Saldiri) are added to natural yoghurt and called Vegetable yoghurt.(Premanath,1999)

Yoghurt can be made from whole/ skim milk available either fresh or powder form. Sugar, Gelatine, Flavors and Colors, Culture are other raw material in manufacturing of flavored yoghurt. In the case of fruit yoghurt tooty fruity , plump and preservatives are added except above the raw material (Tamine and Robinson,1985).

Several contamination types are associated with yoghurt industry, such as physical contamination, chemical contamination and biological contamination. Among of them biological contamination is the most abundant contamination type. *Salmonella* outbreaks, *Listeria monocytogenes* outbreaks, *Escherichia coli* outbreaks, *Yersinia enterocolitica* outbreaks, *Camphylobacter jejuni* outbreaks, and *Staphylococcus aureus* outbreaks are the familiar outbreaks with yoghurt industry, due to bacteria contamination. As fungal contamination yeast and moulds yoghurt spoilage also associated. Chemical and physical contaminations are associated due to bad sanitary conditions in yoghurt industry (ICMSF,2000).

2.8.1 Ingredients used in Flavored yoghurt process

- Whole milk
- Skimmed milk powder (smp)
- Sugar
- Stabilizer
- Yoghurt culture
- Permitted food colors and food flavors

Whole milk:

Milk is the major raw material in yoghurt production. Quality of the yoghurt can be vary due to fat content of milk and high percentage of fat produces a "rich" and "creamy" yoghurt with an excellent mouthfeel. The lactose in milk provides the energy sources for the yoghurt started organisms. But the proteins play an important role in the formation of the coagulum and hence the consistency of the product is directly proportional to the level of protein present.(Tamine and Robinson,1985)

Skimmed milk powder:

Skimmed milk powder is widely used in the food industry to fortify liquid milk for the manufacture of a thick smooth yoghurt. The rate of addition to the basic mix may range from as little as 1% to as higher as 6%, but the recommended level is 3-4%. Since the addition of higher levels of milk powder may lead to a "powdery" taste in the yoghurt (Tamine and Robinson,1985).

Sugar:

Sugar plays an important role in yoghurt production as a sweetening agent. The main object of the adding sweetening agents to yoghurt is to tone down the acidity of the product and the level of incorporation is depend on, consumer preference, possible inhibitory effects on the yoghurt starter organism and legal aspects. The recommended level is 5% to the basic mix of yoghurt.

Sugar is consisted with disaccharides called 'sucrose' and refined carbohydrate is obtained commercially from sugarcane. Sugar is mostly used in yoghurt industry as granulated form. This type requires more agitation for complete dissolution when added to liquid milk. The addition of sugar before the heat treatment of the milk is highly desirable, since it ensures the destruction of any vegetative contaminants, e.g. Osmophilic yeast and moulds and possibly some spores as well (Tamine and Robinson,1985).

Stabilizer:

The primary aim of adding stabilizer to the basic mix is to enhance and maintain the desirable characteristic in yoghurt such as body texture, viscosity, appearance, and mouth feel. Gelatine is the widely used stabilizer in yoghurt manufacturing. It refined to as hydrocolloids and their mode of action in yoghurt includes two basic functions; firstly, the binding of water and secondly, promotion of an increase in viscosity. Thus the molecules of gelatine are capable of forming a network of linkages between the milk constituent(s) and themselves due to the presence of a negatively charged group. These negative groups are concentrated at the interfacial areas and the gelatine achieves the binding of water into the basic mix (Tamine and Robinson,1985).

Yoghurt culture:

Culture is consisted with two types of bacteria, *Streptococcus thermophillus* and *Lactobacillus bulgaricus*. Incubation step in yoghurt manufacturing give an ideal condition to growth of them. Because these orgarnisms were thermophillic lactic acid bacteria, capable of growing at 40-45^{0}C, and fail, to grow at 10^{0}C. The metabolic activity of an organism is indicative, to some extent, of its growth rate, and one of the most popular tests for monitoring starter culture is the development of acidity in the growth medium (Tamine and Robinson,1985).

Lactose in milk is converted to Lactic acid by organisms in culture and increases the acidity and decreases the pH value. As a result of that yoghurt became gel state (Premanath,1999).

Permitted food colors:

The addition of food color to fruit/flavored yoghurt is aimed at making the products more attractive, and the active agents may be natural origin or synthetic organic dyes. The FAO/WHO (1976) have offered some guidance as to which color compound should be permitted and at what concentration in yoghurt, assuming that the agents come entirely from the fruit/flavored ingredients. Tartazine, Sunset yellow, Erythrosine BS are some of examples for recommended food colors (Tamine and Robinson,1985)

Permitted food flavors:

Heat treatment of manufacturing steps can result in a reduction in their flavor intensity, and hence it is the practice to add flavoring agents to compensate such losses. Flavoring agents are divided into three categories depending on there source such as natural flavor, nature identical flavor, and synthetic flavor (Tamine and Robinson,1985).

Preservatives:

Different types of preservatives are used in the food industry, including the processing fruits, where they are effective growth inhibitors against yeast and moulds. The addition of such fruits to yoghurt result in the carry-over of some of these compounds such as Sulphur dioxide(60ppm), Benzoic acid(120ppm), Methyl 4-hydroxybenzoate(120ppm), Sorbic acid(300ppm) etc, are permitted in fruit yoghurt,

but not in natural yoghurt. Because presence of such compound(s) in the milk may affect the growth of starter culture (Tamine and Robinson,1985).

2.8.2 Process step used in the manufacturing flavored yoghurt

Reception:

Milk reception is carried out at a dairy plant and collection centers at Baddegama, Horana, Pannegamuwa, Badagirita, Adala. When milk reception quality of milk is checked by testing lactometer reading(LR), fat percentage. Alcohol test is carried out to test whether milk is spoilage or not. Milk reception in cans done in the morning (8.00-10.00a.m.) at plant and collection centers. Milk is transported by bowser from collection center to plant (Lucky Lanka daries pvt Limited,2005).

Filtration:

The objective of milk filtration is to remove visible particles and dirt present in milk, which find entry into milk during milking and subsequent handling. By filtration of milk its overall quality improves. It also indicates sanitation and hygiene adopted in the production of milk. Filtration of milk is carried out mostly at room temperature.(ideal temperature is 32-42^{0}C) (Khan and Salooja,1998).

Chilling:

Efficient cooling after reception is the best way to prevent bacterial growth (Gosta,1995).Because of their number increases during subsequent handling specially under unsanitary conditions at village level. Chilling should be carried out between 0-4^{0}C (SLS872:1989). Chilling tanks are used to chill milk then pumped to pre-heating vat.

Pre-heating:

Before homogenization, pre-heating is carried out at 50^{0}C. Because when homogenization, fat globules are broken down and it helps to react lipase enzyme in fat globule membrane, with lipids in fat globules. Rancid flavor can be associated in final product as a result of that. When pre-heating lipase enzyme is destroyed and prevent formation of rancid flavor (Floyd,1993).

Standardization:

Standardization is defined as keeping the one or more of milk constituents to a stipulated level. The fat and SNF contents of milk received at the dairy dock may vary almost daily due to many factors. Standardization provides a more uniform product and effectuated economics in production. Standardization is done by smp and water, according to Pearson's square formula (Khan and Salooja,1998).

Homogenitation:

Homogenization refers to the process of forcing the milk through a homogenizer with the objective of sub-dividing the fat globules are broken down to the size of less than two microns. The process of homogenization result in non-formation of cream layer. The appearance become more brighter and soft curd is formed. Two stage homogenizer is operated. Generally, 175-210kg/cm^2 (2500PSI) pressure in the first stage and 35kg/cm^2 (500PSI) in the second stage is maintained. The second stage is breaks up any clump and produces better dispersion of the fat in the milk (Khan and Salooja,1998).

Pasturization:

Milk is pasteurized to make it safe for human consumption by destroying pathogenic micro-organisms present in raw milk The process involves heat treatment designed to suitable time-temperature combination to kill pathogens. Batch pasteurizer is carried out in yoghurt production. It consists of an inner vessel made of stainless steel surrounded by an insulated outer casing. Milk is heated by circulating hot water or steam through the jacket where located between inner vessel and outer casing). Milk is continuously agitated (Khan and Salooja,1998). The exceeding time-temperature combination at 95^{0}C for 20 minutes. (Lucky Lanka daries pvt Limited,2005).

Cooling:

Prior to addition of culture milk should be cooled to 43^{0}C. Otherwise starter culture organisms can be destructed. Cooling is carried out in cooling vats. Cooled water is supplied to remove heat of milk and hot water is removed immediately. Cooling temperature should be carefully inspected when mixing step (Floyd,1993).

Mixing:

Culture, colors and flavors are mixed to milk when mixing. Quality of each ingredient is tested before addition. Stock culture is prepared and part of it is used for yoghurt production daily which called working mother culture (Premanath,1999).

Filling:

Filling machine-1 is used to fill milk mixture to cups. Temperature of mixture is maintained at 43^0C (Lucky Lanka daries pvt Limited,2005).

Sealing:

Aluminium foil is fixed to cup when sealing. Sealing is carried out also filling machine-1. Proper sealing is reduce the growth of undesirable micro-organisms (Floyd,1993).

Incubation:

Fermentation process is exceeded in incubation. Time-temperature combination may vary from culture to culture. At 43^0C, 3-4 hours is carried out when incubation. Biochemical reactions are associated in incubation and as a result of that gel is formed. The formation of the yoghurt gel is the result of biological and physical action of milk. Yoghurt starter culture utilizes the lactose in milk and produces the lactic acid. The gradual development of lactic acid starts to destabilize casein micelle by solubilization of the calcium phosphate. The individual micells are aggregated and partially coalesce as the pH approaches the iso-electric point (pH4.6-4.7). It is most likely that alpha lactalbumin/ beta lactoglobulin interaction with the capa casein partially protects the micelles against complete destabilization and gel network of a regular structure which entraps within it all the other constituents of the basic mix, including the water phase (Tamine and Robinson,1985).

Cooling:

Yoghurt production is a biological process and cooling is the method used to control the metabolic activity of the starter culture and its enzymes. Cooling of the coagulum commences directly after the product reaches the desired acidity around pH 4.6 or 0.9& lactic acid. The cooling stage take place in cold store where the "coolish" yoghurt less to ,10^0C. The final cooling of yoghurt takes place, therefore in the retail

container, and as the coagulum is left undistributed the viscosity of the yoghurt improves after 1-3 days storage (Tamine and Robinson,1985).

2.8.3 pathogens associated with yoghurt

2.8.3.1 *Salmonellae*

Salmonella are gram negative, facultatively anaerobic, non-spore forming rod-shaped bacteria. Most are motile (Mortimore and Wallace,1998). Sources of salmonella are human beings, poultry and animals, either directly or indirectly contaminate the food. Cats, dogs, swine, cattle and rodents proliferate salmonella in their faecal matter. Eggs from hens, the flesh of beef, and pastured milk are prone source of salmonellae. Riches and flies and dropping from rats or mice may spread the bacteria (Minor,1983).

Salmonellae invade lumen of the small intestine and multiply. To cause human illness over 125,000 .*Salmonellae* control includes avoidance of contamination of the food with bacteria either from vectors or from infected foods; cooking or pasteurizing to destroy the organism, especially in held over the foods. Adequate refrigeration to inhibit the growth and good food handling procedures. Salmonella are readily destroyed at 82^0C. Recontamination should not be permitted to occur from work surfaces or utensils used for raw product preparation (Minor,1983).

2.8.3.4 Staphyloccus aureus

Staphyloccus aureus is one of the principal causative agents in food-borne illnesses. They are on the hands and skin proliferate when the skin breaks dye to cuts, boils, and burns. The bacteria is heat sensitive and can be controlled or destroyed by heat. But a heat stable toxin develops which persist long after the cells have been destroyed (Minor,1983).

Staphyloccus aureus is gram negative, catalase positive,anaerobic, and exhibit facultative anaerobic metabolism. They forms a wide variety of aggress inns, exotoxins and enterotoxins. Enterotoxin cause vomiting response by stimulatimg the sympathetic nervous system. 0.1 microgram per kilogram of toxin will cause a toxin illness to human. Normally 2-4 hours after ingestion of food containing the

enterotoxin. Symptoms include nausea, abdominal cramps and diarrhoea. Recovery is usually in 2 days.

Optimum temperature is 37^0C, pH 6.0-7.0, and water activity 0.98. *Staphyloccus aureus* is controlled by protecting product from contamination and avoid conditions that will favor growth. If production of product involves temperatures where *Staphyloccus aureus* and grow , then control of the raw materials is very important as well as strict control of the fermentation and maturation stage. The enterotoxins are made under a variety of conditions and are very heat resistant and survive cooking and some sterilization processes (Mortimore and Wallace,1998).

2.8.3.3 Escherichia coli

Escherichia coli are gram positive, catalase positive, oxidase negative, facultative anaerobic short rods. *Escherichia coli* are subdivided into four pathogenic groups by the main mechanisms causing illness such as Enterohaemorragic E. coli (E. coli 0157:H7), enterotoxigenic E. coli (ETEC), Enteroinvasive E. coli (EIEC), Enteropathogenic E. coli (EPEC). However E. coli 0157:H7 has been in the number of outbreaks, and those are linked mainly to raw milk, undercooked ground beef, and contaminated water. Symptoms are haemorrhagic colitis: grossly bloody diarrhoea, sever abdorminal pain, vomiting. Optimum temperature range for E. coli 0157:H7 is lies between 35-40^0C, pH6-7, water activity 0.995. They can be controlled under avoid contamination via faecal material during milking. Therefore control must come from proper pasteurization of milk. (Mortimore and Wallace,1998).

2.8.3.4 *Listeria monocytogenes*

Listeria monocytogenes is gram positive ,short none-spore-forming, catalase positive and facultatively anaerobic rod. They are motile at 25°C and non-motile at 35^0C.This bacteria can be found in soil, silage, sewage, food processing environment and the faeces of healthy human and animals. Infection in cattle can lead to *Listeria monocytogenes* being found in milk. Wet surfaces in food facilities may harbour and their ability to multiply at low temperatures allows food to be a major vector in human illness.

Listeria monocytogenes is a haemolytic pathogens. Three servars account for nearly all human listeriosis. A high infection dose of >100 viable cells is needed and infection occurs via intestine. A third of cases involve pregnant women and the other two-thirds affect those with an impaired immune system, and also can be resulted fatal for the foetus. The other case meningitis with a small percentage having focal lesions.

Optimum temperature for Listeria monocytogenes is 37^0C, pH 7.0, water activity 0.998. The bacteria can not be eliminated from the diet. But the risk of foodborne listerotitis should be managed via HACCP from farm to consumer. Multification can be minimized by proper heating during processing, and prevent recontamination of processed foods (Mortimore and Wallace,1998).

2.8.3.5 *Camphylobacter*

Camphylobacter is a microaerophilic gram negative, small vibroid cells that moves rapidly. The bacteria is harbored in the intestinal track of domesticated animal and can infect human via directly or indirectly. Raw or inadequately pastureized milk is the most common route of infection, and also untreated drinking water. The bacteria is very sensitive to drying, air, and heat.

Illness is by infection of the intestinal track and can be caused by 500 cells in milk. Diarrhoea may be caused by producing enterotoxin. It is a heat liabile enterotoxin. Optimum temperature for that bacteria is 42-43^0C, pH6.5-7.5, and water activity 0.997.

To control the bacteria, proper chlorination of drinking water, and avoiding raw food contamination can be applied (Mortimore and Wallace,1998).

Chapter 3

Methodology

3.1 Identification of scope of the HACCP study

The Scope was identified regarding to HACCP application for flavored yoghurt.

3.2 Setting up the HACCP team

The HACCP team was assembled with multi-disciplinary personnel including Quality assurance manager, Production director, Engineer and additional experts which regards to the field of SQA, Research and development, Distribution, Purchasing, Microbiology, Toxicology, HACCP.

3.3 Identification of products and their intended use

Each and every selected flavored yoghurt products and their intended use were described under product specification and packaging materials. SLS regulations and product specification records were used.

3.4 Development of a flow diagram and onsite confirmation

Before developing the flow diagram the production line was inspected. Then process flow diagram was drawn including all steps of processing line.

3.5 Development of at the GMP manual

After visiting the production line, HACCP team was discussed to develop GMP manual as a pre-requisite program of HACCP system.

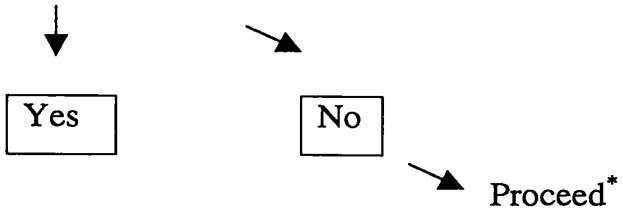
3.6 Identification of hazards and hazard analysis

All potential hazards were identified and listed out individually regarding to every ingredients and process steps. Preventive measures were applied for each potential hazards using GMP manual. Under the hazard evaluation hazard severity was justified for all potential hazards.

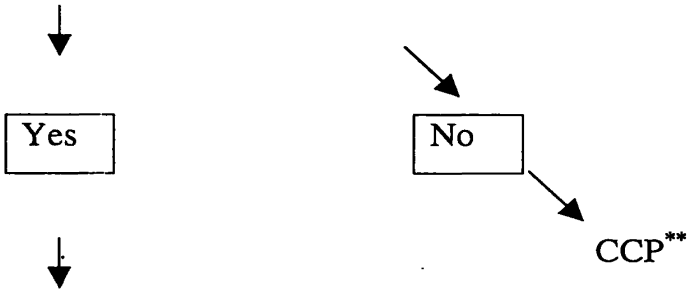
3.7 Determine the Critical control Points

Critical control Points were determined by application of the raw material decision tree Figure 3.1 shows the decision tree which was applied to determine critical control points for raw material.

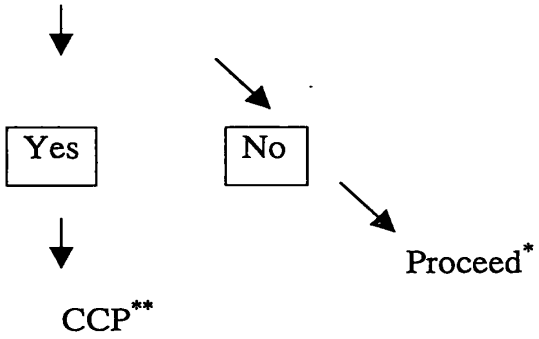
Q1. Is there a hazard associated with this raw material?



Q2. Are you or the consumer going to process this hazard out of the product?



Q3. Is there a cross –contamination risk to the facility or to other products which will not be controlled?

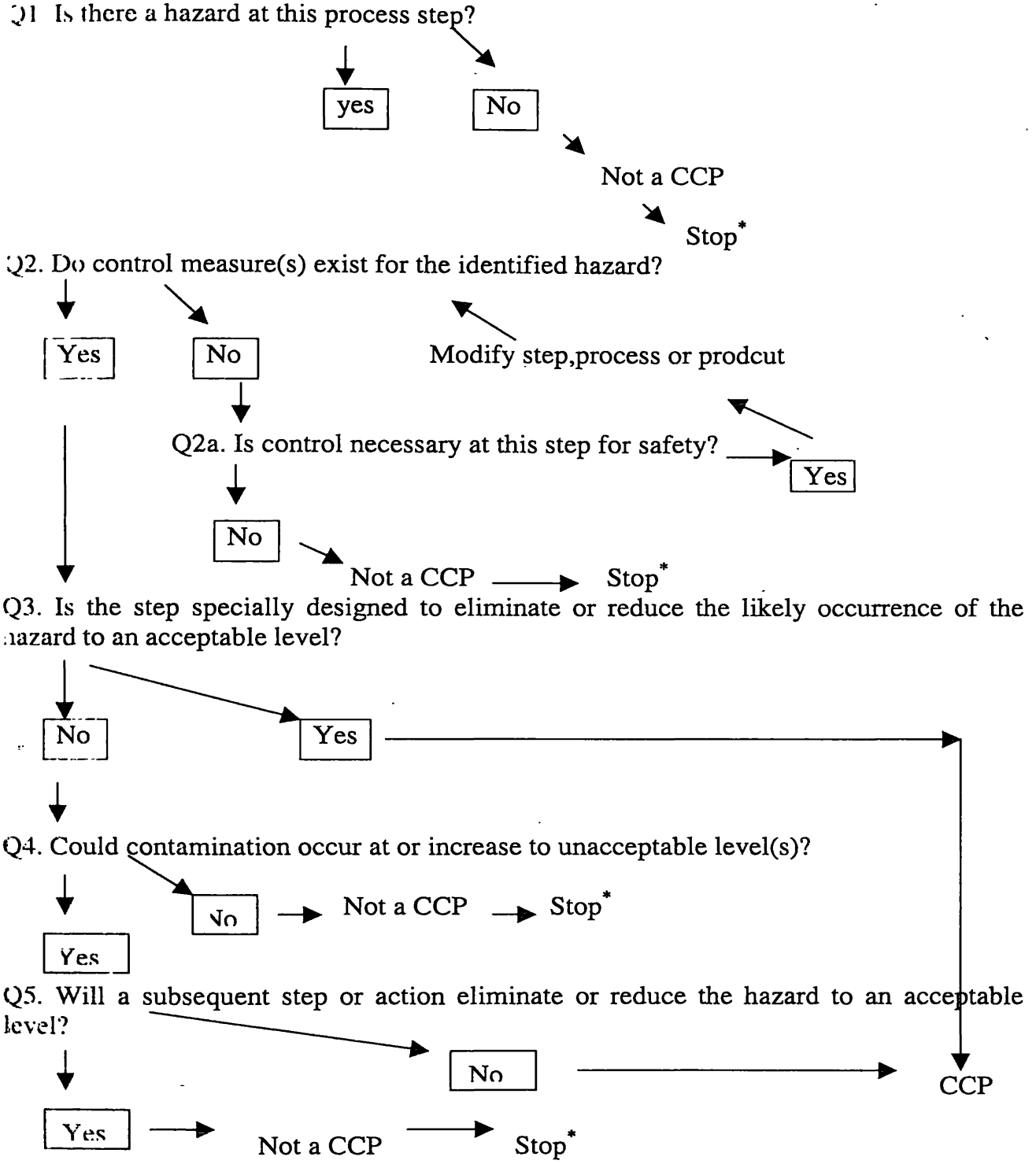


*proceed to your next raw material

**Following the hazard analysis, you are likely to find that this raw material must be managed as a CCP

Figure 3.1 Raw Material Control Decision Tree

Figure3.2 shows the decision tree which was applied to determine critical control points for process step.



* Stop and proceed with the next hazard at the current step or the next step in the described process

Figure 3.2 A CCP Decision Tree (Codex,1997)

3.8 Determine the critical limits using control charts

Critical limits was established using scientific publication, regulatory requirements and guidelines of SLS. After that control charts were established by using pasteurization temperature data.(See Appendix A)

The temperature of batch pasteurizer was checked using three samples at one time and twice a day for a month. Then average temperature was calculated and average chart was plotted by using MINITAB package. Then the range was calculated and range charts was plotted.

3.9 Establish a monitoring system

Monitoring procedure was established for each critical limit. How to monitor, Who is the responsible person and frequency of monitoring were included in this column.

3.10 Establish a corrective action procedure

Corrective action procedures were established for each CCP when deviation of critical limits are taken place.

3.11 Establishment of verification procedures

Verification procedures and the responsible person of the verification were established for each CCP.

3.12 Establish record keeping and documentation procedure

Critical limit establishment record, log sheets, CCP determination forms, all hazard identification forms were named and documented.

Chapter 4

Results and Discussion

4.1 Results

4.1.1. Scope of HACCP study

This HACCP study was considered physical, chemical, biological hazards for all ingredients and throughout the entire process of flavoured yoghurt.
Biological hazards included vegetative pathogens such as *Escherichia, Listeria* and toxin formers such as *Staphylococcus aureus.* Chemical hazards could be associated with the raw materials such as pesticides, antibiotics, peroxide, urea or with contamination during process. Physical hazards were also associated with raw materials and processing steps. It should be identified to prevent choking on large items when consumption.

4.1.2. Setting up HACCP team

Table 4.1 HACCP team table

Post of the member	Name of the member
1) Quality Assurance	Miss.Kanchana Fernando
2) Production specialist	Mrs.Namalee Gunawardena
3) Engineering	Mr.Keerthi Ganawardena Mr.L.W.Aruna
4) Additional experts: a) Supplier Quality Assurance (SQA)	Mr.Janaka Danasekara Miss.Kanchana Fernando
b) Research & Development	Mr.Achala Godavita
c) Distribution	Mr.Kamal Senewiratna
d) Purchasing	Mr.Rohan Lokugama
e) Microbiologist	Miss.Rasika
f) Toxicologist	Miss.Kanchana Fernando
g) HACCP Experts/Chairperson	Mr.Priyantha Perera

Source: (NACMCF,1997)

4.1.3. Product description

For flavored yoghurt:

Flavored yoghurt is cooled ready-to-eat products containing both pasteurized and unpasteurized components.

The sugar, skim milk powder, gelatine and water were pasteurized while the flavoring and colouring were added without further heat processing. Culture was also added into the product after cooling.

4.1.3.1 Name: Flavoured yoghurt

4.1.3.2 Composition/raw materials:

- Whole milk, sugar, skim milk powder, water
- Stabilizer eg.Gelatine
- Yoghurt culture
- Permitted food colour(E102)
- Permitted food flavors (Vanilla, Strawberry, etc)

4.1.3.3 Volume/weight:

- Volume: 86mililiters
- Weight: 90gram

4.1.3.4 Functional information:

- PH: 4.20-4.50
- Fat: Greater than 3.1
- Titrabale acidity:0.8-1.25
- Solid Non-Fat: .20-.24

4.1.3.5 Labeling instructions:

- Brand name
- Ingredients
- Nutrition information

- Manufactured company, address, telephone number, web address
- Weight
- Storage condition
- Expiry date
- Manufacture date
- Prize
- Batch number
- Operational instruction
- Halal mark
- Message for environmental cleaning

4.1.3.6 Storage conditions:

Store in refrigeration(0-5^{0}C)

4.1.3.6 Shelf life:

35 days

4.1.3.8 Distribution condition:

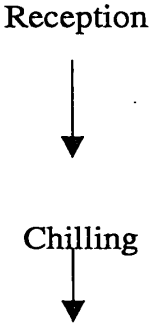
Refrigeration conditions(0-5^{0}C)

4.1.4 Describe the intended use

General public is the suitable group for this product in Sri Lanka.

4.1.5 Develop Process flow diagram

Figure 4.1 shows the process flow diagram for flavored yoghurt.



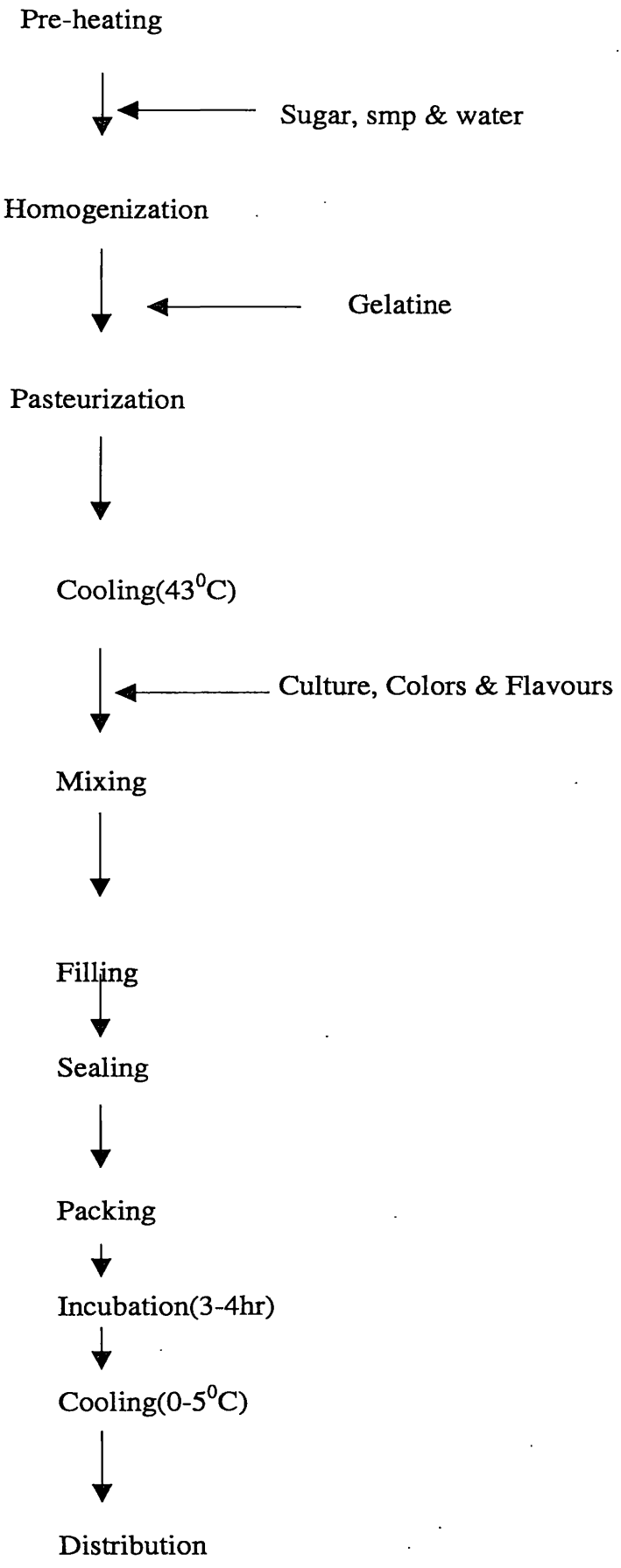


Figure 4.1 Process flow diagram for flavored yoghurt

4.1.6 Develop GMP manual

The GMP manual was developed (Appendix A) as a pre-requisite program for the HACCP system. Most of GMP were applied and some needed GMP were missed when visiting the process flow diagram. After applying GMP completely the HACCP system began to apply.

4.1.7 Conduct hazard analysis (principle 1)

4.1.7.1 Determination of hazard for ingredient-flavored yoghurt

Since flavored yoghurt is a milk based product pathogenic microorganisms can be presented as a biological hazard. By applying GMP it was prevented to some extent. As potential chemical hazard, presence of cleaning chemical residues was identified.

Foreign material was identified as the major physical hazard mainly due to bad storage condition. Visual inspection, sieving, and SQA were the major control measure to control physical hazard. Table 4.2 shows identified hazard for ingredients.

Table 4.2 Hazard analysis chart for ingredients

Ingredients	Hazard	Control measure(s)
1)Raw milk	Physical	
	Metal	GMP-1,3-a
	Wood	GMP-1,3-a
	Pests	GMP-1,3-a
	Glass	GMP-1,3-a
	Chemical	
	Antibiotics	GMP-3-c
	Peroxides	GMP-3-c
	Pesticide	GMP-1
	Radio active element	GMP-1
	Cleaning chemical	GMP-1
	Urea	GMP-3-c
	Formalin	GMP-1
	Boric acid	GMP-1
	Biological	
	Bacteria, Yeast, Mold	GMP-29-a
	Viruses	GMP-29-a
	Protozoa	GMP-29-a

	Mycotoxin	GMP-1
2)Sugar	Physical	
	Stones	GMP-1,32-a
	Glass	GMP-1,32-a
	Wood	GMP-1,32-a
	Pests	GMP-1,32-a
	Chemical	
	Pesticides	GMP-1
	Toxic metals	GMP-1
	Biological	
	Pests	GMP-1,29-a
	Mold	GMP-1,29-a
3)Gelatin	Physical	
	Wood	GMP-1,32-a
	Pests	GMP-1,32-a
	Chemical	
	Cleaning chemical	GMP-1
	Toxic metals	GMP-1
	Biological	
	Pests	GMP-1,29-a
	Bacteria, Yeast, Mold	GMP-1,29-a
4)Smp	Physical	
	Foreign material	GMP-1,32-a
	Chemical	
	Cleaning chemical	GMP-1
	Toxic metals	GMP-1
	Antibiotics	GMP-1
	Biological	
	Vegetative pathogens	GMP-1,29-a
5)Water	Physical	
	Foreign material	GMP-1,32-a
	Chemical	

	Pesticides	GMP-1
	Antibiotics	GMP-1
	Cleaning chemical	GMP-1
	Toxic metal	GMP-1
	Biological	
	Vegetative pathogens	GMP-1,29-a
6)Yoghurt culture	Physical	
	Foreign material	GMP-1,32-a
	Chemical	
	Chemical reaction	GMP-1,16-a
	Biological	
	Bacteriophage	GMP-1,16-a
7)Food colors and flavors	Physical	
	No hazards were identified	-
	Chemical	
	Chemical reaction	GMP-1,32-p,q
	Biological	
	Vegetative pathogens	GMP-1,29-a

Source:(SLSI,1998)

4.1.7.2 Determination of hazard for process step

In the process steps of flavored yoghurt, hygienic conditions were applied according to the GMP. However vegetative pathogens were identified as the major biological hazard. As the chemical hazard cleaning residues was identified, and foreign material play an important role as the major physical hazard. Most of the hazards were controlled by applying GMP. Table 4.2 shows identified hazards for process step of flavored yoghurt.

Table 4.3 Hazard analysis chart for process step-flavored yoghurt

Process step	Hazards	Preventive/ Control measure(s)
1.Receiption /Purchasing of milk	Physical	
	Presence of foreign material	GMP-3-b
	Chemical	
	No hazard identified	-
	Biological	
	Presence of vegetative pathogens	GMP-3-b
2.Transferring to chilling tanks	Physical	
	Presence of insect due to uncovered area of chilling tanks	GMP-6-a
	Chemical	
	Cleaning chemical residues due to washing improperly bowser/container	GMP-27-d
	Biological	
	Vegetative pathogens due to unsanitary condition	GMP-29-a
3.Filtering	Physical	
	No hazard identified	-
	Chemical	
	Cleaning chemical residues due to washing improperly filter	GMP-27-d

	Biological	
	Vegetative pathogens due to washing improperly filter	GMP-29-a,5-a
4.Chilling	Physical	
	Presence of foreign material (wood. Glass , insect, metal) due to uncovered area of chilling tanks	GMP-6
	Chemical	
	Cleaning chemical residues due to washing improperly chilling tanks	GMP-27-d
	Presence of peroxide due to power failure	GMP-10
	Biological	
	Vegetative pathogens due to temperature fluctuation	GMP-29-a,6-b
5.Pumping to pre-heating vat	Physical	
	No hazards were identified	-
	Chemical	
	Cleaning chemical residues due to washing improperly lines	GMP-27-d
	Biological	
	Vegetative pathogens due to washing improperly vat	GMP-29-a
6.Pre-heating	Physical	
	Presence of Foreign material due to uncovered corroted motor, vat & Broken ceiling	GMP-32-b,31-a,20-a
	Chemical	
	Cleaning chemical residues due to washing improperly vat	GMP-27-d
	Chemical reaction due to bad quality ingredient	GMP-1-a

	Biological	
	Vegetative pathogens due to open vat & bad personnel hygiene	GMP-32-c,21
7.Mixing Smp, Sugar & water	Physical	
	Presence of Foreign material due to uncovered corroted motor & vat	GMP-32-b,31-a,20-a
	Chemical	
	Cleaning chemical residues due to washing improperly vat	GMP-27-d
	Chemical reaction due to bad quality ingredient	GMP-1
	Biological	
	Vegetative pathogens due to open vat & bad personnel hygiene	GMP-29-a
8.Filtering to small vat-1	Physical	
	Presence of foreign matter due to insufficient area of filter	GMP-11-a
	Chemical	
	Cleaning chemical residues due to washing improperly vat	GMP-27-d
	Biological	
	Vegetative pathogens due to open vat & bad personnel hygiene	GMP-32-c,21
9.Homogenization	Physical	
	No hazards were identified	-
	Chemical	
	Cleaning chemical residues due to rinsing improperly homogenizer	GMP-27-d

	Chemical reaction due to high pressure	GMP-12-a
	Biological Vegetative pathogens due to bad cleaning & bad tile condition around homogenizer	GMP-27-c,20-a
10.Pumping & storing to holding tank	Physical	
	Presence of foreign matter due to a hole presence of ceiling & open vat	GMP-20-a,-32-c
	Chemical	
	Cleaning chemical residues due to washing improperly tank	GMP-27-d
	Chemical reaction due to high pressure of connecting pipe	GMP-31-a
	Biological	
	Vegetative pathogens due to open vat & bad personnel ygiene	GMP-32-c,21
11.Pumping to batch pasteurizer-1	Physical	
	No hazards were identified	
	Chemical	
	Cleaning chemical due to improper washing of pipes	GMP-30-a,27-d
	Biological	
	Vegetative pathogens due to pipe leakage	GMP-30-a-b-c,21
12.Mixing gelatine	Physical	
	Present of wood & pest due to unsanitary	GMP-32-q,-

	condition	1
	Chemical	
	Cleaning chemical due to manufacturing failure	GMP-1
	Biological	
	Vegetative pathogens due to bad storage	GMP-32-q
13.Pasterization	Physical	
	Presence of foreign material (metal, insect, wood) due to malpractices	GMP-32-b,31-a
	Chemical	
	Cleaning chemical due to improper washing of vat	GMP-27-d
	Chemical reaction due to adding of milk in high pressure	GMP-15-b
	Biological	
	Survival of vegetative pathogens	GMP-15-a
14.Pumping to cooling vats	Physical	
	No hazards were identified	-
	Chemical	
	Cleaning chemical due to improper washing of pipes	GMP-27-d
	Biological	
	Vegetative pathogens due to pipe leakage & replacing pipes	GMP-30-a-b-c
15.Cooling	Physical	
	Presence of foreign material (metal, insect, wood) due to malpractices	GMP-32-b,31-a,20
	Chemical	
	Cleaning chemical due to improper washing of vats	GMP-27-d
	Chemical reaction due to adding bad quality milk	GMP-1

	Biological	
	Vegetative pathogens due to open vats	GMP-32-c,21
16.Pumping to mixing vat	Physical	
	No hazards were identified	-
	Chemical	
	Cleaning chemical due to improper washing of pipes	GMP-30-a-c
	Biological	
	Vegetative pathogens due to pipe leakage & replacing pipes	GMP-30-a-b-c
17.mixing culture	Physical	
	Presence of plastizer due to mixing container migration	GMP-16-c
	Chemical	
	Cleaning chemical due to improper washing of vats & basket	GMP-27-d
	Chemical reaction due to bad transport & storage condition	GMP-1
	Biological	
	Vegetative pathogens due to bad transport & storage condition	GMP-32-c,21
18.Pumping to filling machine-1	Physical	
	No hazards were identified	-
	Chemical	
	Cleaning chemical due to improper washing of pipes	GMP-27-d
	Biological	
	Vegetative pathogens due to bad washing pipes & manual filing	GMP-27-d,-31-a

19.Adding & travelling of cups	Physical	
	Presence of foreign material (metal, insect, wood, hair) due to bad inspection	GMP-1,32-d
	Chemical	
	Plastizer & paint leakage by cups	GMP-1,32-d
	Chemical reaction due to high temperature of plant	GMP-20-b
	Biological	
	Vegetative pathogens due to open cups	GMP-32-e,20
20.Filling the mixer	Physical	
	Presence of foreign material (metal, insect, wood, hair) due to bad maintenance of filling machine	GMP-32-f,32-d,31-a,32-g
	Chemical	
	Cleaning chemical due to improper washing of machine	GMP-27-d
	Plastizer migration due to uncovered wires of machine	GMP-31-b
	Toxic metal by machine	GMP-31-a
	Oil leakage by pistons	GMP-31-b
	Biological	
	Vegetative pathogens by remaining leaked milk drops between cup lines	GMP-31-c
21.Sealing	Physical	
	Aluminum flakes by foil	GMP-1
	Chemical	
	Toxic metal by foil flakes	GMP-1
	Chemical reaction due to high heat of sealer	GMP-31-a
	Plastizer migration due to high pressure	GMP-32-d
	Link leakage by damaged cups	GMP-1
	Biological	

	Vegetative pathogens due to bad storage of foil	GMP-32q,21
22.Flowing sealed cups to conveyor	Physical	
	No Hazards were identified	-
	Chemical	
	Cleaning chemical due to improper washing of machine frames	GMP-27-d
	Toxic metal by machine	GMP-31-a,32-i
	Biological	
	Vegetative pathogens due to trapping of cups	GMP-21,32-h
23.Visual inspection of sealing	Physical	
	No Hazards were identified	-
	Chemical	
	Link leakage by foil	GMP-32-j
	Biological	
	Vegetative pathogens by touching hand	GMP-21,32-j
24.Printing	Physical	
	No Hazards were identified	-
	Chemical	
	Link mixing by printer	GMP-1
	Biological	
	No Hazards were identified	-
25.Packing	Physical	
	Foreign material migration by cartons	GMP-1,32-p-q

	Chemical	
	Carton flakes by container	GMP-1
	Biological	
	Vegetative pathogens by bad storage of carton	GMP-32-p-q
26.Putting to trollies	Physical	
	No Hazards were identified	-
	Chemical	
	Cleaning chemical due to grounded cups	GMP-32-k
	Biological	
	Vegetative pathogens entering by trollies	GMP-32-p-q
27.Incubation	Physical	
	No Hazards were identified	-
	Chemical	
	Chemical reaction due to temperature fluctuation	GMP-32-r
	Biological	
	Vegetative pathogens due to temperature fluctuation	GMP-32-r
28.Cooling in room temperature	Physical	
	No Hazards were identified	
	Chemical	-
	Chemical reaction due to keeping long	
	time in room temperature	GMP-17-a
	Biological	
	Vegetative pathogens due to keeping long time in room temperature	GMP-17-a,21
	Physical	

29.Cooling (0-5^{0}C)	No Hazards were identified	
	Chemical	-
	Chemical reaction due to temperature fluctuation	GMP-18-a
	Biological	
	Vegetative pathogens due to temperature fluctuation	GMP-18-a
30.Loading	Physical	
	No Hazards were identified	-
	Chemical	
	Chemical reaction due to keeping long time in room temperature	GMP-32-p
	Biological	
	Vegetative pathogens due to keeping long time in room temperature & loading balance	GMP-32-p
34.Distribution	Physical	
	No Hazards were identified	-
	Chemical	
	Chemical reaction due to temperature fluctuation	GMP-32-p
	Biological	
	Vegetative pathogens due to temperature fluctuation	GMP-32-p

Source:(SLSI,1998)

4.1.7.3 Justification of hazard severity for ingredient-flavored yoghurt

After listing of all potential hazards, hazard evaluation was conducted. According to references I.P.A .2005 presence of foreign material could be applied in HACCP plan as a physical hazard for raw milk and water. Raw milk can be contaminated by foreign material during transportation and use of opened vats as container for milk. Water can be contaminated by foreign material due to pipe leckage and during pumping.

Antibiotics and peroxide could be addressed to HACCP plan as chemical hazard. Raw milk can be contaminated by antibiotics by injecting antibiotics to diseased cow and milking within 10 days (ICMSF,2000). Water can be contaminated also by antibiotics by medicinal garbage (Ekanayaka,2005). Antibiotics can be migrated to Skimmed milk powder from milk which is used to manufacture Skimmed milk powder (Tamine & Robinson,1985).Vegetative pathogens and pest were addressed to HACCP plan as biological hazards. As raw milk is a highly nutrious food for microorganisms, vegetative pathogens also grow in milk and cause disease to human when consumption milk and milk products (ICMSF,2000) and Skimmed milk powder also contaminated by pathogenic microorganism during transportation and storage(Tamine & Robinson,1985). Sugar can be contaminated by osmoplilic microorganism due to bad storage condition(Kapoor,1999). Pathogenic microorganism can be presented in gelatine due to gelatine is rich in protein (Tamine & Robinson,1985). Water also highly contaminate with vegetative pathogens due to contact with wastes (Peris,2004). Food colors and flavors can be contaminated due to bad storage condition (Tamine & Robinson,1985).

Table 4.4 shows the hazard severity for ingredient in manufacturing of flavored yoghurt.

Table 4.4 Hazard analysis summary table for ingredients

Ingredients	Hazard	Justification	Hazard to be address in plan? Y/N	Control measure(s)
1)Raw/Whole milk	Physical			
	Metal	Outbreaks were associated(LLD,2004)	Y	GMP-1,3-a
	Wood	Outbreaks were associated(LLD,2004)	Y	GMP-1,3-a
	Pest	Outbreaks were associated(LLD,2004)	Y	GMP-1,3-a
	Chemical			
	Antibiotics	Outbreaks were associated(ICMSF,2000)	Y	GMP-3-c
	Peroxides	Outbreaks were associated(ICMSF,2000)	Y	GMP-3-c
	Pesticide	Outbreaks were not associated	N	GMP-1
	Radio active Element	Outbreaks were not associated	N	GMP-1
	Cleaning chemical	Outbreaks were not associated	N	GMP-1
	Urea	Outbreaks were not associated	N	GMP-3-c

	Formalin	Outbreaks were not associated	N	GMP-1
	Boric acid	Outbreaks were not associated	N	GMP-1
	Biological			
	Bacteria ,Yeast, Mold	Mastitis disease outbreaks are reported. *Stapyloccus aureus, Escherechia coli, Listeria monocytogenes* can be present in milk (ICMSF,2000) *Salmonella* (Barrelf,1996) *Clostridium botulinum* (Floyd,1993) have been associated with outbreaks of food borne illness from raw milk. *Yersinia* outbreaks were also associated(Barrelf,1996) Yeast & mold outbreaks were associated(LLD,2004)	Y	GMP-29-a
	Viruses	Associated with foot & mouth disease(ICMSF,2000)	Y	GMP-29-a
	Protozoa	Outbreaks were not associated	N	GMP-29-a
	Mycotoxin	Outbreaks were not associated(Barrelf,1996)	N	GMP-1

2)Sugar	Physical			
	Stones	Outbreaks were not associated	N	GMP-1-32-a
	Glass	Outbreaks were not associated	N	GMP-1-32-a
	Wood	Outbreaks were not associated	N	GMP-1-32-a
	Pests	Outbreaks were not associated	N	GMP-1-32-a
	Chemical			
	Pesticides	Outbreaks were not associated	N	GMP-1
	Toxic metals	Outbreaks were not associated	N	GMP-1
	Biological			
	Pests	Outbreaks were not associated	N	GMP-1,29-a
	Mold	Outbreaks were not associated but microbiology tests were not carried out	N	GMP-1,29-a
	Pathogenic microorganisms	Outbreaks were associated(Kapoor,1999)	Y	GMP-1,29-a
3)Gelatine	Physical			
	Wood	Outbreaks were not associated	N	GMP-1-32-a
	Pests	Outbreaks were not associated	N	GMP-1-32-a
	Chemical			
	Cleanng hemical	Outbreaks were not associated	N	GMP-1

	Toxic metals	Outbreaks were not associated	N	GMP-1
	Biological			
	Pests	Outbreaks were not associated	N	GMP-1,29-a
	Bacteria, Yeast, mold	Outbreaks were not associated but microbiology tests were not carried out	Y	GMP-1,29-a
4)Smp	Physical			
	Foreign material	Outbreaks were not associated	N	GMP-1-32-a
	Chemical			
	Cleanng hemical	Outbreaks were not associated	N	GMP-1
	Toxic metals	Outbreaks were not associated	N	GMP-1
	Antibiotics	Outbreaks were associated(ICMSF,2000)	Y	GMP-1
	Biological			
	Vegetative pathogens	Outbreaks were not associated but microbiology tests were not carried out	Y	GMP-1,29-a
5)Water	Physical			
	Foreign material	Some inciedent were observed(LLD,2004)	Y	GMP-1-32-a
	Chemical			
	Pesticides	Outbreaks were not associated	N	GMP-1
	Antibiotics	Outbreaks were associated(Perera,2003)	Y	GMP-1

	Cleaning chamical	Outbreaks were not associated	N	GMP-1
	Toxic metal	Outbreaks were not associated	N	GMP-1
	Biological			
	Vegetative pathogens	Outbreaks were not associated but microbiology tests were not carried out	Y	GMP-1,29-a
6)Yoghurt culture	Physical			
	Foreign material	Outbreaks were not associated	N	GMP-1-32-a
	Chemical			
	Chemical reaction	Outbreaks were associated(Gunawardena,2004)	Y	GMP-1,16-a
	Biological			
	Bacteriophage	Outbreaks were not associated	N	GMP-1,16-a
7)Food colors and flavors	Physical			
	No hazards were idetified	-	-	-
	Chemical			
	Chemical reaction	Outbreaks were not associated	N	GMP-1,32-p,q

	Biological			
	Vegetative pathogens	Outbreaks were not associated but microbiology tests were not carried out	Y	GMP-1,29-a

Source: (NACMCF,1997)

4.1.7.4 Justification of hazard severity for process steps-flavored yoghurt

According to the following table, hazards were addressed to HACCP plan regarding to hazard severity. Presence of foreign material was the major physical hazard after the justification. Cleaning residues was the major the major chemical hazard by justification. As the main biological hazard vegetative pathogens was shown high severity according to the references. Table 4.4 shows hazard severity according to references.

Table 4.5 Hazard analysis summary table for process steps

Process step	Hazards	Justification	Hazard to be addressed in plan? Y/N	Preventive/ Control measure(s)
1.Receiption/Purchasing of milk	Physical			
	Presence of foreign material	Outbreaks were associated(LLD,2004)	Y	GMP-3-b
	Chemical			
	No hazard identified	-	-	-
	Biological			
	Presence of vegetative pathogens	Outbreaks were associated(ICMSF,2000)	-	GMP-3-b
2.Transferring to chilling tanks	Physical			

	Presence of insect due to uncovered	Outbreaks were associated(LLD,2004)		
	area of chilling tanks		Y	GMP-6-a
	Chemical			
	Cleaning chemical residues due to washing improperly bowser/container	Outbreaks were associated(LLD,2004)	Y	GMP-27-d
	Biological			
	Vegetative pathogens due to unsanitary condition	Outbreaks were associated(LLD,2004)	Y	GMP-29-a
3.Filtering	Physical			
	No hazard identified	-	-	-
	Chemical			
	Cleaning chemical residues due to washing improperly filter	Outbreaks were not associated	N	GMP-27-d
	Biological			
	Vegetative pathogens due to washing improperly filter	Outbreaks were not associated but microbiology tests were not carried out	Y	GMP-29-a,5-a
4.Chilling	Physical			

	Presence of foreign material (wood, .glass, insect, metal) due to uncovered area of chilling tanks	Outbreaks were associated(LLD,2004)	Y	GMP-6
	Chemical			
	Cleaning chemical residues due to washing improperly chilling tanks	Outbreaks were associated(LLD,2004)	Y	GMP-27-d
	Presence of peroxide due to power failure	Outbreaks were not associated	N	GMP-10
	Biological			
	Vegetative pathogens due to temperature fluctuation	Outbreaks were associated(ICMSF,2000)	Y	GMP-29-a,6-b
5.Pumping to pre-heating vat	Physical			
	No hazards were identified	-	-	
	Chemical			
	Cleaning chemical residues due to washing improperly lines	Outbreaks were not associated	N	GMP-27-d
	Biological			
	Vegetative pathogens due to washing improperly vat	Outbreaks were associated(LLD,2004)	Y	GMP-29-a

6.Pre-heating	Physical			
	Presence of Foreign material due to uncovered corroted motor,vat	Outbreaks were associated(LLD,2004)	Y	GMP-32-b,31-a,20-a
	Chemical			
	Cleaning chemical residues due to washing improperly vat	Outbreaks were not associated	N	GMP-27-d
	Chemical reaction due to bad quality ingredient	Outbreaks were associated(Floyd,1993)	Y	GMP-1-a
	Biological			
	Vegetative pathogens due to open vat & bad personnel hygiene			GMP-32-c,21
7.Mixing Smp,Sugar & water	Physical			
	Presence of Foreign material due to uncovered corroted motor & vat	Outbreaks were associated(LLD,2004)	Y	GMP-32-b,31-a,20-a
	Chemical			
	Cleaning chemical residues due to washing improperly vat	Outbreaks were not associated	N	GMP-27-d

	Chemical reaction due to bad quality ingredient	Outbreaks were associated(Floyd,1993)	Y	GMP-1
	Biological			
	Vegetative pathogens due to open vat & bad personnel hygiene	Outbreaks were associated(LLD,2004)	Y	GMP-29-a
8.Filtering to small vat-1	Physical			
	Presence of foreign matter due to insufficient area of filter	Outbreaks were associated(LLD,2004)	Y	GMP-11-a
	Chemical			
	Cleaning chemical residues due to washing improperly vat	Outbreaks were associated(LLD,2004)	Y	GMP-27-d
	Biological			
	Vegetative pathogens due to open vat & personnel hygiene	Outbreaks were not associated but microbiology tests were not carried out	Y	GMP-32-c,21
9-.Homogenization	Physical			
	No hazards were identified	-	-	
	Chemical			

	Cleaning chemical residues due to rinsing improperly homogenizer	Outbreaks were not associated	N	GMP-27-d
	Chemical reaction due to high pressure	Outbreaks were associated(Gosta,1985)	Y	GMP-12-a
	Biological			
	Vegetative pathogens due to bad cleaning	Outbreaks were associated(Floyd,1993)	Y	GMP-27-c,20-a
10.Pumping & storing to holding tank	Physical			
	Presence of foreign matter due to a hole presence of ceiling & open vat	Outbreaks were associated(LLD,2004)	Y	GMP-20-a,-32-c
	Chemical			
	Cleaning chemical residues due to washing improperly tank	Outbreaks were not associated	N	GMP-27-d
	Chemical reaction due to high pressure of connecting pipe	Outbreaks were not associated	N	GMP-31-a
	Biological			

	Vegetative pathogens due to open vat &	Outbreaks were not associated	N	GMP-32-
	bad personnel hygiene			c,21
11.Pumping to batch pasteurizer-1	Physical			
	No hazards were identified	-	-	-
	Chemical			
	Cleaning chemical due to improper washing of pipes	Any incident was not associated	N	GMP-30-a,27-d
	Biological			
	Vegetative pathogens due to pipe leakage	Outbreaks were associated(Tamine & Robinson,1985)	Y	GMP-30-a-b-c,21
12.Mixing gelatine	Physical			
	Present of wood & pest due to unsanitary condition	Any incident was not associated	N	GMP-32-q,-1

	Chemical			
	Cleaning chemical due to manufacturing failure	Any incident was not associated	N	GMP-1
	Biological			
	Vegetative pathogens due to bad storage	Any incident was not associated. But microbiology testing are not carried out	Y	GMP-32-q
13.Pasterization	Physical			
	Presence of foreign material (metal, insect, wood) due to malpractices	Some incident was observed	Y	GMP-32-b,31-a
	Chemical			
	Cleaning chemical due to improper washing of vat	Any incident was not associated	N	GMP-27-d
	Chemical reaction due to adding of milk in high pressure	Any incident was not associated	N	GMP-15-b
	Biological			
	Survival of vegetative pathogens	*Salmonella* (Moris,1985), *Staphyloccus aureus*	Y	GMP-15-a

		(Gosta,1995)outbreaks are associated		
14.Pumping to cooling vats	Physical			
	No hazards were identified	-	-	-
	Chemical			
	Cleaning chemical due to improper washing of pipes	Any incident was not associated	N	GMP-27-d
	Biological			
	Vegetative pathogens due to pipe leakage & replacing pipes	Any incident was not associated. But microbiology testing are not carried out	Y	GMP-30-a-b-c
15.Cooling	Physical			
	Presence of foreign material (metal, insect, wood) due to malpractices	Some incident was recorded(I.P.A.,2004)	Y	GMP-32-b,31-a,20
	Chemical			
	Cleaning chemical due to improper washing of vats	Any incident was not associated	N	GMP-27-d

	Chemical reaction due to adding bad quality milk	Some incident was recorded(I.P.A.,2004)	Y	GMP-1
	Biological			
	Vegetative pathogens due to open vats	Any incident was not associated. But microbiology testing are not carried out	Y	GMP-32-c,21
16.Pumping to mixing vat	Physical			
	No hazards were identified	-	-	-
	Chemical			
	Cleaning chemical due to improper washing of pipes	outbreaks were not associated	N	GMP-30-a-c
	Biological			
	Vegetative pathogens due to pipe leakage & replacing pipes	Any incident was not associated. But microbiology testing are not carried out	Y	GMP-30-a-b-c
17.mixing culture	Physical			

	Presence of plastizer due to mixing container	Any incident was not associated	N	GMP-16-c
	Chemical			
	Cleaning chemical due to improper washing of vats & basket	outbreaks were not associated	N	GMP-27-d
	Chemical reaction due to bad transport & storage condition	Some incident was recorded(I.P.A.,2004)	Y	GMP-1
	Biological			
	Vegetative pathogens due to bad transport & storage condition	Any incident was not associated. But microbiology testing are not carried out	Y	GMP-32-c,21
18.Pumping to filling machine-1	Physical			
	No hazards were identified	-	-	-
	Chemical			
	Cleaning chemical due to improper washing of pipes	outbreaks were not associated	N	GMP-27-d

	Biological			
	Vegetative pathogens due to bad washing pipes & manual filing	Any incident was not associated. But microbiology testing are not carried out	Y	GMP-27-d,-31-a
19.Adding & travelling of cups	Physical			
	Presence of foreign material (metal, insect, wood, hair) due to bad inspection	Some incidents were observed	Y	GMP-1,32-d
	Chemical			
	Plastizer & paint leakage by cups	Some incident was recorded(R.M.A.,2004)	Y	GMP-1,32-d
	Chemical reaction due to high temperature of plant	outbreaks were not associated	N	GMP-20-b
	Biological			
	Vegetative pathogens due to open cups	Some incident was associated. By lowering pH.(I.F.P.,2005)But microbiology testing are not carried out	Y	GMP-32-e,20

20.Filling the mixer	Physical			
	Presence of foreign material (metal, insect, wood, hair) due to bad maintenance of filling machine	Some incidents were observed	Y	GMP-32-f,32-d,31-a,32-g
	Chemical			
	Cleaning chemical due to improper washing of machine	Any outbreak was not associated	N	GMP-27-d
	Plastizer migration due to uncovered wires of machine	Any outbreak was not associated	N	GMP-31-b
	Toxic metal by machine	Any outbreak was not associated	N	GMP-31-a
	Oil leakage by pistons	Any outbreak was not associated		GMP-31-b
	Biological			
	Vegetative pathogens by remaining leaked milk drops between cup lines	Any incident was not associated. But microbiology testing are not carried out	Y	GMP-31-c
21.Sealing	Physical			
	Aluminium flakes by foil	Any incident was not associated	N	GMP-1

	Chemical			
	Toxic metal by foil flakes	Any incident was not associated	N	GMP-1
	Chemical reaction due to high heat of sealer	Some incidents were recorded(I.F.P.,2005)	Y	GMP-31-a
	Plastizer migration due to high pressure	Any incident was not associated	N	GMP-32-d
	Link leakage by damaged cups	Any incident was not associated		
			N	GMP-1
	Biological			
	Vegetative pathogens due to bad storage of foil	Some incidents were recorded by lowering pH(I.F.P.,2005)	Y	GMP-32q,21
22.Flowing sealed cups to conveyor	Physical			
	No Hazards were identified	-	-	-
	Chemical			
	Cleaning chemical due to improper washing of machine frames	Any incident was not associated	N	GMP-27-d
	Toxic metal by machine	Any incident was not associated	N	GMP-31-a,32-i

	Biological			
	Vegetative pathogens due to trapping of cups	Some incidents were recorded by lowering pH(I.F.P.,2005)	Y	GMP-21,32-h
23.Visual inspection of sealing	Physical			
	No Hazards were identified		-	-
	Chemical			
	Link leakage by foil	Any incident was not associated	N	GMP-32-j
	Biological			
	Vegetative pathogens by touching hand	Some incidents were recorded by lowering pH(I.F.P.,2005)	Y	GMP-21,32-j
24.Printing	Physical			
	No Hazards were identified	-	-	-
	Chemical			
	Link mixing by printer	Any incident was not associated	N	GMP-1

	Biological			
	No Hazards were identified	-	-	-
25.Packing	Physical			
	Foreign material migration by cartons	Any incident was not associated	N	GMP-1,32-p-q
	Chemical			
	Carton flakes by container	Any incident was not associated	N	GMP-1
	Biological			
	Vegetative pathogens by bad storage of carton	Some incidents were recorded by lowering pH(I.F.P.,2005)	Y	GMP-32-p-q
26.Putting to trollies	Physical			
	No Hazards were identified			
	Chemical			
	Cleaning chemical due to grounded cups	Any incident was not associated	N	GMP-32-k
	Biological			
	Vegetative pathogens entering by trollies	Some incidents were recorded by lowering pH(I.F.P.,2005)	Y	GMP-32-p-q

27.Incubation	Physical			
	No hazards were identified	-	-	-
	Chemical			
	Chemical reaction due to temperature fluctuation	Some inciedents were recorded by changing color & upset setting(I.F.P.,2005)	Y	GMP-32-r
	Biological			
	Vegetative pathogens due to temperature fluctuation	Some incidents were recorded by lowering Ph & upset setting(I.F.P.,2005)	Y	GMP-32-r
28.Cooling in room temperature	Physical			
	No Hazards were identified	-	-	-
	Chemical			
	Chemical reaction due to keeping long time in room temperature	Some incidents were recorded by changing colour(I.F.P.,2005)	Y	GMP-17-a
	Biological			
	Vegetative pathogens due to keeping long time in room temperature	Some incidents were recorded by lowering pH(I.F.P.,2005)	Y	GMP-17-a,21

29.Cooling (0-5^{0}C)	Physical			
	No Hazards were identified	-	-	-
	Chemical			
	Chemical reaction due to temperature fluctuation	Some incidents were recorded by changing colour(I.F.P.,2005)	Y	GMP-18-a
	Biological			
	Vegetative pathogens due to temperature fluctuation	Some incidents were recorded by lowering pH(I.F.P.,2005)	Y	GMP-18-a
30.Loading	Physical			
	No Hazards were identified	-	-	-
	Chemical			
	Chemical reaction due to keeping long time in room temperature	Some incidents were recorded by changing colour(I.F.P.,2005)	Y	GMP-32-p
	Biological			
	Vegetative pathogens due to keeping long time in room temperature & loading balance	Some incidents were recorded by lowering pH(I.F.P.,2005)	Y	GMP-32-p

31. Distribution	Physical			
	No Hazards were identified	-	-	-
	Chemical			
	Chemical reaction due to temperature fluctuation	Some incidents were recorded by changing colour(I.F.P.,2005)	Y	GMP-32-p
	Biological			
	Vegetative pathogens due to temperature fluctuation	Some incidents were recorded by lowering pH(I.F.P.,2005)	Y	GMP-32-p

Source: (NACMCF,1997)

4.1.8 The Critical Control Points in ingredients

Table 4.6 shows identified Critical Control Points for ingredients in manufacturing of flavored yoghurt.

Table 4.6 Critical control point determination form for ingredients- Flavored yoghurt

Ingredients	Q1	Q2	Q3	CCP
1. Whole milk				
P- Foreign material(metal, Wood, Pest)	Y	Y	N	Not a CCP
C- Antibiotics, Peroxide, Urea	Y	N	-	Not a CCP
B-*Listeria, Salmonella, E.coli, Yersinia*	Y	Y	N	Not a CCP
2.Smp				
P- Foreign material(metal, Wood, Pest)	Y	Y	N	Not a CCP
C- Antibiotics	Y	N	N	Not a CCP
B- Pathogenic micro-organism	Y	Y	N	Not a CCP
3. Water				
P- Foreign material(metal, Wood, Pest)	Y	Y	N	Not a CCP
C- Antibiotics, Peroxide, Urea, Pesticide	Y	Y	N	Not a CCP
B- *E.coli, Campylobacter,* Protozoa	Y	Y	N	Not a CCP
3. Gelatine				
P- Foreign material(metal, Wood, Pest)	Y	Y	N	Not a CCP
B- Pathogenic micro-organism	Y	Y	N	Not a CCP
4.Yoghurt culture				
P- Foreign material(metal, Wood, Pest)	Y	Y	N	Not a CCP
C- Chemical reaction	Y	Y	N	Not a CCP
5. Sugar				
P- Foreign material(metal, Wood, Pest)	Y	Y	N	Not a CCP
B- Pathogenic micro-organism	Y	Y	N	Not a CCP

P-Physical C – Chemical B- Biological

4.1.9 The Critical Control Points in process steps

Table 4.7 shows Critical Control Point (CCP) for process step in manufacturing flavored yoghurt.

Table 4.7 Critical control point determination form for process step- flavored yoghurt

Process step	Q1	Q2	Q3	Q4	Q5	CCP
1. Reception of milk						
P-Foreign material	Y	Y	N	Y	Y	Not a CCP
C- Chemical reaction	Y	Y	N	Y	Y	Not a CCP
B- Vegetative pathogens	Y	Y	N	Y	Y	Not a CCP
2. Transferring to chilling tanks						
P-Foreign material	Y	Y	N	Y	Y	Not a CCP
C- Chemical reaction	Y	Y	N	Y	Y	Not a CCP
B- Vegetative pathogens	Y	Y	N	Y	Y	Not a CCP
3.Filtering						
B- Vegetative pathogens	Y	Y	N	Y	Y	Not a CCP
4. Chilling						
P-Foreign material	Y	Y	N	Y	Y	Not a CCP
C- Cleaning chemicals	Y	Y	N	Y	Y	Not a CCP
B- Vegetative pathogens	Y	Y	N	Y	Y	Not a CCP
5.Pumping to pre-heating vat						
B- Vegetative pathogens	Y	Y	N	Y	Y	Not a CCP
6. Pre-heating						
P-Foreign material	Y	Y	N	Y	Y	Not a CCP
C- Chemical reaction	Y	Y	N	Y	Y	Not a CCP
7. Mixing Smp, Sugar, Water						
C- Chemical reaction	Y	Y	N	Y	Y	Not a CCP
B- Vegetative pathogens	Y	Y	N	Y	Y	Not a CCP
8. Filtering to small vat-1						
P-Foreign material	Y	Y	N	Y	Y	Not a CCP
C- Chemical reaction	Y	Y	N	Y	Y	Not a CCP

B- Vegetative pathogens	Y	Y	N	Y	Y	Not a CCP
9.Homogenization						
P-Foreign material	Y	Y	N	Y	Y	Not a CCP
C- Chemical reaction	Y	Y	N	Y	Y	Not a CCP
B- Vegetative pathogens	Y	Y	N	Y	Y	Not a CCP
10.Pumping & storing in holding tank						
P-Foreign material	Y	Y	N	Y	Y	Not a CCP
11. Pumping to Batch pasturizer-1						
B- Vegetative pathogens	Y	Y	N	Y	Y	Not a CCP
12. Mixing gelatine						
B- Vegetative pathogens	Y	Y	N	Y	Y	Not a CCP
13. Pasteurization						
P-Foreign material	Y	Y	N	Y	Y	Not a CCP
B- Vegetative pathogens	Y	Y	Y	-	-	CCP(1-B)
14. Pumping to cooling vat						
B- Vegetative pathogens	Y	Y	N	Y	Y	Not a CCP
15. Cooling(43^0C)						
P-Foreign material	Y	Y	N	Y	Y	Not a CCP
C- Chemical reaction	Y	Y	N	Y	Y	Not a CCP
B- Vegetative pathogens	Y	Y	N	Y	Y	Not a CCP
16. Pumping to mixing vat*						
B- Vegetative pathogens	Y	Y	N	Y	N	CCP(2-B)
17.Mixing culture						
C- Chemical reaction	Y	Y	N	Y	Y	Not a CCP
18. Pumping to Filling machine-1*						
B- Vegetative pathogens	Y	Y	N	Y	N	CCP(2-B)
19.Adding & traveling of cups						
P-Foreign material	Y	Y	N	N	-	Not a CCP
C- Chemical reaction	Y	Y	N	Y	Y	Not a CCP
B- Vegetative pathogens	Y	Y	N	Y	Y	Not a CCP
20. Filling the mixer						
P-Foreign material	Y	Y	N	Y	N	CCP(3-P)

B- Vegetative pathogens	Y	Y	N	Y	Y	Not a CCP
21. Sealing						
C- Chemical reaction	Y	Y	N	Y	Y	Not a CCP
B- Vegetative pathogens	Y	Y	N	N	-	Not a CCP
22. Flowing sealed cup on conveyor						
B- Vegetative pathogens	Y	Y	N	Y	Y	Not a CCP
23.Visual inspection of sealing						
B- Vegetative pathogens	Y	Y	N	N	-	Not a CCP
24. packing						
B- Vegetative pathogens	Y	Y	N	Y	Y	Not a CCP
25.Putting to trollies						
B- Vegetative pathogens	Y	Y	N	N	-	Not a CCP
26. Incubation						
C- Chemical reaction	Y	Y	N	N	-	Not a CCP
B- Vegetative pathogens	Y	Y	N	N	-	Not a CCP
27.Cooling in room temperature						
C- Chemical reaction	Y	Y	N	N	-	Not a CCP
B- Vegetative pathogens	Y	Y	N	N	-	Not a CCP
28. Cooling(0-5^{0}C)						
C- Chemical reaction	Y	Y	N	N	-	Not a CCP
B- Vegetative pathogens	Y	Y	Y	-	-	CCP(4-B)
29.Loading						
C- Chemical reaction	Y	Y	N	N	-	Not a CCP
B- Vegetative pathogens	Y	Y	N	N	-	Not a CCP
30. Distribution						
C- Chemical reaction	Y	Y	N	Y	Y	Not a CCP
B- Vegetative pathogens	Y	Y	N	Y	Y	Not a CCP

* No 16 and 18 were taken as in-line transferring

P- Physical C- Chemical B- Biological

Source: (NACMCF,1997)

4.1.10 Critical limit validation levels for flavored yoghurt production

Table 4.4 shows justification of each CCP and validation for critical limit

Table 4.8 Critical limit validation form for flavored yoghurt

CCP	Jutification	Validation for critical limit
1.Pasteurization in batch-pasteurizer	When decrease the temperature it will form pathogenic micro-organism	95^0C at least 20 minutes(Tamine & Robinson,1985)
2.In-line transferring	Listeria monocytogenes can be cross contaminated and it will form Listeriosis to consumer	92% Nacl cleaning solution at 30^0C(Gould,Lund, Parker,2000)
3. Filling	When presence of foreign matter it will cause chocking during consumption	Sieve size of filter less than 2 micron of filter(Tamine & Robinson,1985)
4. Cooling(0-5^0C)	When decrease the temperature it will form parhogenic micro-organisms	Less than 5^0C until consumption(Tamine & Robinson,1985

Source: (SLSI,1998)

4.1.11 HACCP control charts

Monitoring is different from control and involves conducting tests or observation to confirm that the process remain, in control. The monitoring requirements have been defined within the HACCP control chart. Practicalities of implementation within the workplace should be considered. A method such may be useful to some organizations when setting up monitoring and verification system is Statistical Process Control(SPC) Statistical profile which has been built up from the capability study can be used to produce a process control chart for the control of a process and its parameters in two respects means and range which measure the accuracy and the precision of the process, respectively. The control chart may have upper and lower warning bands. And it also help to adjust the process to maintain control before the CCP actually deviates from its critical limit.(Mortimore and Wallace,1998) Regarding to following graph the upper control limit is 97.04^{0}C. The critical limit for pasteurization process is 90^{0}C in 20 minutes for yoghurt manufacturing.(Tamine and Robinson,1985) The process parameter must be apply at 97.04^{0}C for 20 minutes as the Upper control limit to certify that deviation does not occur. Pasteurization temperature should be lies between 97.04^{0}C and 90^{0}C, it is possible to maintain the critical limit when operating system to target levels should ensure that a deviation from the critical limit. Figure 4.2 shows Xbar/R chart for pasteurization process.

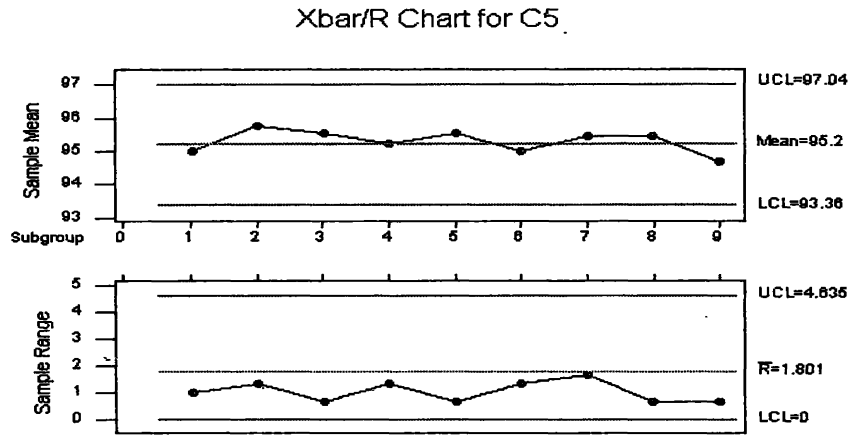


Figure 4.2 HACCP control charts

4.1.12 Process capability analysis

As part of the HACCP plan the critical limit for each CCP within the process has been established. These limit may sometimes only be a minimum value , such as time and temperature combination for the pasteurization process, or the limit may be soley a maximum value, such as cool room temperature. Other CCPs may require a process to be contained between a minimum and maximum limit where the minimum level controls microbiological safety but the maximum level is necessary to ensure chemical safety. It may also be necessary to have a minimum limit in terms of food safety, but also have a maximum limit in terms of product quality. For each CCP will be need to verify that, under normal operating conditions, the process can be realistically and consistently maintained within these defined limit. One way of assessing whether process is capable to use statistical analysis. The statistical verification of a process in order to establish the probability of its ability stay within specified limit is known as establishing the process capability. Figure 4.3 shows process capability analysis graph for pasteurization process.

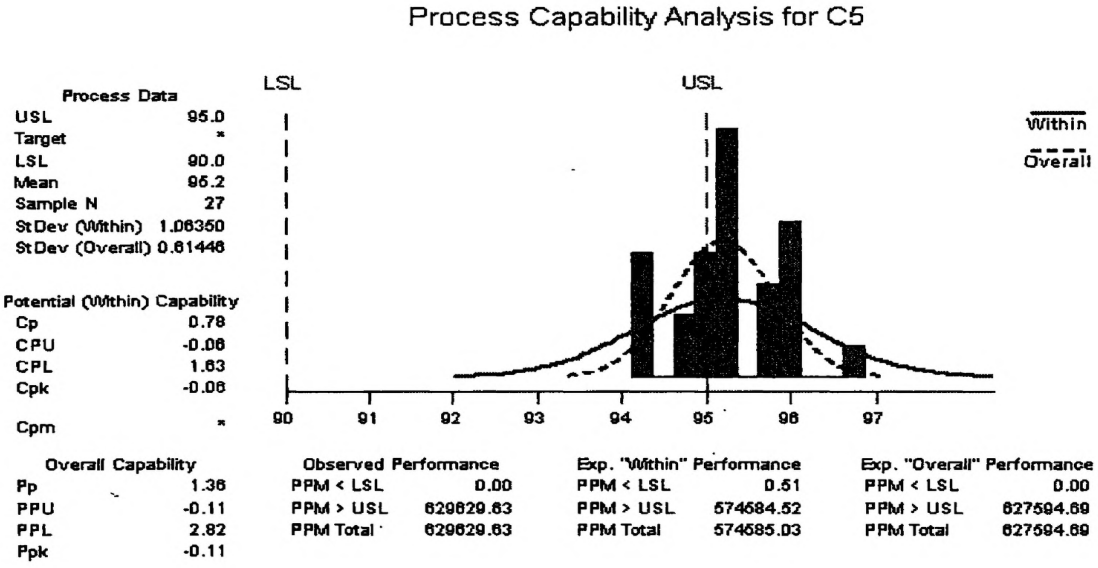


Figure 4.3 Process capability analysis

4.1.13 Establish critical limit for flavored yoghurt

Table 4.5 shows identified CCP and critical limits for each CCP.

Table 4.9 Critical limit for flavored yoghurt

Hazard	CCP	Critical limit
1. Pathogenic micro-organism	Pasteurization	95^0C at least 20 minutes(Tamine & Robinson,1985)
2. Pathogenic micro-organism	In-line transfering	92% Nacl cleaning solution at 30^0C(Gould,Lund, & Parker,2000)
3.Foreign material	Filling	Sieve size of filter less than 2 micron of filter(Tamine & Robinson,1985)
4. Pathogenic micro-organism	Cooling(0-5^0C)	Less than 5^0C until consumption(Tamine & Robinson,1985)

Source: (SLSI,1998)

4.1.14 HACCP plan for flavored yoghurt(Principal 4,5,6,7)

Table 4.10 shows the summary of the HACCP plan.

Table 4.10 HACCP plan for flavored yoghurt production

Process step	Identified hazard	Identified CCP	Critical limit	Monitoring procedure Who/What/When/How	Corrective action	HACCP records	Verification procedure
1.Pasteurization	Biological hazard (pathogenic micro-organism)	CCP-1B	Heat the milk in 90^0C for 20 minutes	Production manager will measure the temperature in pasteurizer using a thermometer in each batch & measure the time using electric watch.	Continue the pasteurization until the temperature reach 90^0C	1.Pasteurization record sheet 2.Corrective action log 3.Thermometer calibration log	1. QAM will check the Pasteurization record for each batch 2. Thermometer will be calibrated once a month
2.In-line transferring in pumping to	Biological hazard (pathogenic	CCP-2B	Clean the transferri	QAM will check the cleaning solution concentration before	Ingredient should be measured	1. Cleaning solution preparation	1. QAM will check the cleaning solution

mixing vat & filling machine1	micro-organism		ng line using 92% Nacl at 30^0C	cleaning line in every day by titration	when preparing cleaning solution	record 2. Cleaning records	for every cleaning step 2. Electric balance & burrets will be calibrated once per month
3. Filling	Physical hazard (Foreign material)	CCP-3P	Keep the filter in size 2 microns when filling	Production manager will audit the filter in filling machine for each operation by visual inspection	Repaired/changed the filter when it is in malfunction	1. Filling machine records 2. Filter functioning records	1. Production manager will audit the filter for each operation of filling machine
4. Cooling ($0\text{-}5^0$C)	Biological hazard (pathogenic micro-organism	CCP-3B	Cool the product in $0\text{-}5^0$C until consumption	QAM will measure the temperature the temperature of product in every 3 hours using thermometer	Keep the product in cold room until core temperature get 5^0C	1.Cold-room log sheet 2.Process analysis records 3.Thermometer calibration	1.QAM will audit the accuracy of cold room temperature for each batch 2.Thermometer

						log 4. Corrective action log sheet	will be calibrated once a month

Source: (SLSI,1998)

4.1.15 Validation of HACCP plan

After completing HACCP plan and highlighting all CCPs on process flow diagram then the HACCP plan is complete. However before going on to the implement the plan it is important to know that is correct and valid-a final check. This should be carried out soon after the plan is completed so that implementation can follow without delay.(Mortimore and Wallace,1998) However HACCP plan validation is the act of assessing the HACCP plan of a particular product/process to ensure that all significant food hazards are correctly identified and "controlled or reduced" to acceptable levels. Thus HACCP plan validation includes:

- Reviewing of hazard analysis
- Reviewing of CCP determination
- Justification for critical limits based on current scientific information and regulatory limits
- Determination of adequacy of monitoring activities, corrective action, record keeping
- Reviewing of audit repots
- Reviewing of changes made to HACCP plan and reasons for such changes
- Reviewing of deviation and corrective action reports
- Reviewing of consumer complaints
- Reviewing of GMP practices (SLSI,1998)

4.1.16 Discussion

The major hazard identified with ingredients such as in whole milk is biological hazard. *Escherichia coli, salmonella, Listeria* are the major pathogens found in dairy products including fermented products such as yoghurt. Regarding to SLS regulations and other references above mentioned micro-organism can be killed by proper pasteurization, which is applied 95^0 C for 20 minutes (Tamine and Robinson,1985). Applying exact temperature point is not a practicable. Use of temperature range can be applied as a solution for it. The plotted data regarding to pasteurization temperature in batch pasteurizer, control chart revealed the accurate time temperature range on 97.04^0 C -95^0 C. As a solution for biological hazard above mentioned temperature can be applied.

The lowest amount of cleaning solution that can be applied is 92% of NaCl (Gould,Lund and Parker,2000). When Nacl level is decrease below 92% Nacl, it will form a biological hazard, *Listeria monocytogenes* and other pathogenic organism will be destroyed due to high concentration of NaCl level. Otherwise *Listeria monacytogenes* will cause listerosis to consumer.

If foreign material presence of final product of yoghurt it will cause to choking consumer. Therefore filtering system should be applied prior to filling and sieve size should be 2-micron (Tamine and Robinson,1985).

Another CCP is identified in cool room. Because, due to fluctuation of cool room temperature pathogenic microorganism can grow. The critical limit which are recommended range between 0-5^0C (Tamine and Robinson,1985).

After implementing critical limit with monitoring procedure safety character in flavored yoghurt can be developed. As a result of that HACCP certification can be obtained and it can be used to identify safe yoghurt.

The loss of flavored yoghurt in production line and in final inspection can be reduced due to application of critical limit, monitoring procedure and corrective action.

Chapter 5

Conclusion and Recommendation

5.1 Conclusion

After considering the observations and results from start to end of the research period, the final conclusions can express as follows.

- No CCPs regarding to ingredients for Flavored yoghurt.
- By applying the Decision tree, it concluded that pasteurization, In-line transferring for mixing vat and filling machine-1, filling, and cooling(0-5^{0}C) found to be the critical control points in the manufacturing process.
- Referring to scientific evidences the time-temperature combination of pasteurization should be 90-97.04^0 C for 20 minutes, filling machine-1 filter size is 2micron, 92% NaCl concentration of cleaning solution for pipe line cleaning, and cooling temperature of 0-5^{0}C in cool room should be established as critical limit.
- Verification activities can be concluded as auditing pasteurization records, cleaning records, filling machine records, cool room records and thermometer calibration, burette calibration and scale calibration.

5.2 Recommendation

- Introduction of air filtering system to processing area, and aseptic packaging as control measures.
- Introduction of metal detector for finished flavored yoghurt.
- Introduction of microfilteration system when filling yoghurt mixture to cup.

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Appendix i

GOOD PRACTICES MANUFATURING (GMP) MANNUAL

No 1) Suppler certification for all Ingredients and all raw material.

No 2) Water should be chlorinated when using well water and should be applied filtering system when using tap water.

No 3) Reception of milk

a) After purchasing raw milk , raw milk should be filtered

b) The milk sample which used for testing, it should be thrown instead of adding original sample

c) Delvo test or Culture activity test (for Antibiotics) & peroxide test should be carried out for every milk container.

No 4) Transferring to chilling tank

a) Milk should be pumped instead of manual filling.

No 5) Filtering

a) Filter touching with floor should be prevented.

No 6) Chilling

a) Chilling tanks should be separated from outside environment.

b) Chilling temperature should be maintained below +4°C .

No 10) Milk transportation

a) Raw milk transportation should be carried out within 2-3 hours.

No 11) Filtering to small vat

a)Surface area of filter should be increased.

No 12) Homogenization

a) Pressure should be maintained around 1500 psi (can be changed regarding to fat content) to prevent rancid flavour.

b) Proper rinsing should be carried out after adding Sodium hydroxide.

No 13) Pumping to holding tank

a) The length should be increased of connecting pump to prevent mixing with air.

No 15) Pasteurization

a) Correct time & temperature should be maintained. (At 90°C for 20minutes).

b) Milk should be added slowly when pumping.

No 16) Preparing culture

a) Culture transportation & storage should be prevented from high temperature.

b) Separated room should be used in culture preparation & it should be in good hygienic condition.

c) Stainless steel utensils should be used for culture preparation & Transferring to vat.

No 17) Incubation

a) Incubation should be carried out at 45°C at 4 hours (time vary according to culture).

No 18) Cooling

a) Cooling should be carried between 0-5°C & at least 48 hours.

b) Damaged yoghurt contained baskets & lids should close jelly baskets.

c) Opened sample should not be kept in cool room after checking pH.

No 19) Loading

a) Returned yoghurt should be checked before loading.

No 20) Plant designing

(According to SLS 872:1989,4.2 the plant should be designed.)

a) Building should be repaired & bulb should be covered.

b) Ventilation system should be added to reduce temperature.

No 21) Personel hygiene

(According to SLS 872:1989,4.2)

a) Full uniform should be submitted with mask & gloves.

c) Foot operated tap & electrically operated dreiers should be submitted to hand washing with nail brushers.

No 27) Cleaning & disinfections

(According to SLS 872:1989,4.2)

Cleaning & disinfections facilities should be carried out for every process Steps.

a) Baskets should be cleaned before transferring milk to churner.

b) Touching of pumping wire with floor should be prevented.

c) All the machines & containers should be cleaned before using.

d) Proper rinsing should be carried out after rinsing with sanitizers.

e) All chemicals should be storage properly.

No 28) Pest control

(According to SLS 872:1989,4.2)

a) Electrical traps should be located on ceiling at entrances to processing line.

No 29) Microbiology testing

(According to SLS 872:1989,4.2)

a)) Microbiology testing should be carried out at necessary steps even for air samples.

No 30) Pumping system

a) Direct pumping system should be applied with CIP (Clean In Place) system instead of changing pump system.

b) Touching pump with floor should be prevented.

c) Pump leakage should be repaired frequently.

No 31) Machine & Equipment

(According to SLS 872:1989,4.2)

a) All the machines & Equipment in the plant should be maintained.

b) The spaces between cup lines in filling machine should be thourally cleaned & wires should be covered & windows should be closed when process operating.

c) Milk dropping should be prevented when filling.

d) Trollies should be painted.

N0 32) Processing line

a) Ingredients (sugar, smp, gelatine) sieved before adding to vats

b) Motor should be covered to prevent metal particles & foreign materials.

c) Vat should be completely closed after adding ingredients.

d) Visual inspection should be carried out when cup flowing in filling machine. (Remove damaged cups, foreign matter 7 link leackaged cups) In jell filling, tooty fruity adding & in cool room)

e) Cup adding area should be covered with glass & action should be taken to prevent contamination of microorganism.

f) Metal detector should be applied to detect metal particles.

g) Filtering system should be applied before filling.

h) All the steps should be taken to prevent grounded of cups &lids (Fixed belt under the area of conveyor belt.)

i) Frame width should be maintained to prevent grounded cups.

j) Camera sensor or self-rejected sensor should be used in visually checking.

k) Sealed cups should be packed in carton boxes to prevent grounded cups.

l) Jell filling area should be covered & separated from flavoured yoghurt processed area.

m) Milk drops of putter surface area should be cleaned after adding liquid jell.

n) Immediate cooling should be taken after dissolving jell.

o) Gas cylinder should be separated from process line & repair leakage of gas wires.

Appendix ii

Pasteurization temperature data sheet

Date	Time	Sub group no	Temperature			Average	Range
			1^0 C	2^0 C	3^0 C		
2005.04.30	8.30	1	96	95	95	95.3333	1
	12.30	2	97	95	95	95.3333	2
2005.05.01	9.30	3	93	94	95	94.3333	2
	1.30	4	95	95	96	95.3333	1
2005.05.02	8.30	5	93	96	97	95.3333	4
	12.30	6	98	98	94	96.6667	4
2005.05.03	9.30	7	96	97	95	96.0000	2
	1.30	8	97	94	95	95.3333	3
2005.05.04	8.30	9	95	96	95	95.3333	1
	12.30	10	93	95	96	94.6667	3
2005.05.05	9.30	11	95	95	98	96.0000	3
	1.30	12	94	94	97	95.0000	3
2005.05.08	8.30	13	95	96	97	96.0000	2
	12.30	14	96	95	95	95.0000	1
2005.05.09	9.30	15	95	98	93	96.0000	5
	1.30	16	94	94	95	95.3333	1
2005.05.10	8.30	17	95	96	94	95.3333	2
	12.30	18	95	97	95	94.3333	2
2005.05.11	9.30	19	95	93	95	95.0000	2
	1.30	20	97	95	96	95.6667	2
2005.05.12	8.30	21	97	96	95	94.3333	2
	12.30	22	95	98	94	96.0000	4
2005.05.15	9.30	23	93	97	95	96.0000	4
	1.30	24	95	97	95	95.6667	2
2005.05.16	8.30	25	95	95	95	95.0000	0
	12.30	26	94	97	95	94.6667	3
2005.05.17	9.30	27	95	93	94	94.3333	2
	1.30	28	96	95	94	95.0000	2

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