

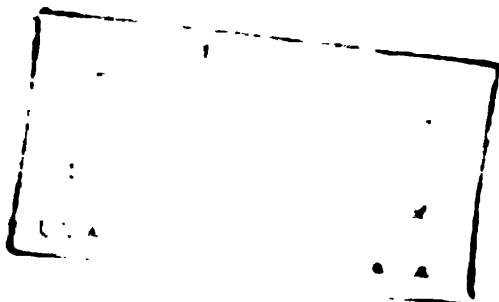
**APPLICATION OF HAZARD ANALYSIS CRITICAL
CONTROL POINT (HACCP) SYSTEM TO THE ICE CREAM
MANUFACTURING PROCESS OF
CEYLON COLD STORES LTD.**

BY

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Thesis submitted in the partial fulfilment of the requirement for the Degree of Bachelor of Science in Food Science and Technology of the faculty of Applied Sciences, Sabaragamuwa University of Sri Lanka, Buttala, Sri Lanka.

December 2000



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Declaration

The work Described in this thesis was carried out by me at Ceylon Cold Stores Ltd and Faculty of Applied Sciences under the supervision of Mrs K A Anula Perera, Mr D A M Arsecularatne and Mr M A J Wansapala

A report on this has not been submitted to any other University for another degree




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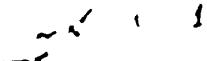


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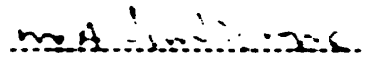
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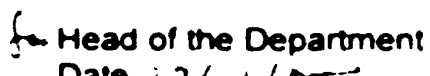
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Affectionately Dedicated to parents and Teachers

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ABSTRACT

By Application of HACCP food manufactures can assure safety of their products to the consumers. HACCP system as it applies to food safety management use the approach of controlling critical control points in food handling to prevent food safety problems. The system, which is science, based and systematic, identifies specific hazards and measures for their control.

The study was carried out to identify the critical control points and establish a HACCP system for the ice cream manufacturing process of ice cream factory of Ceylon Cold Stores Ltd. It was conducted following the systematic methods specified in HACCP system. It contained hazard analysis, determination of critical control points, determination of critical limits, establishment of monitoring and verification procedures and record keeping.

All hazards associated with the ingredients and the process steps were identified. Critical Control Points for preventive measures were identified. The measures used to control hazards carried out with the ingredients, which are added after pasteurization, were found as critical control points. The process steps mix filtration, pasteurization, aging, freezing and finished product storage was found to be the critical control points.

Supplier Quality Assurance (SQA) was the main element of controlling hazards, which are associated with raw materials, which are not subjected to treatments against these hazards during the manufacturing process of the factory.

Filters intact for mix filtration, 79°C for 25 seconds, for pasteurization, 7°C within 90 min for cooling, 7°C for temperature of Aging, and 72 hrs maximum for Aging were established as critical limits of the manufacturing process. Introduction of air filtration to ice cream freezers was suggested as a process modification to be made.

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CHAPTER 1 INTRODUCTION

Pure, safe and wholesome food is the minimum expectation of today's consumer. If a food borne hazard is communicated with a food item, it can bring damages to the consumer as well as to the manufacturer in several ways. Currently, Hazard Analyses Critical Control Point (HACCP) has been a popular way of assuring food safety. The Pillsbury Company and the US army Natick laboratories, for producing 100% safe food for astronauts, firstly developed HACCP system. HACCP system is adapted also by the International Committee for Microbiological Specifications of Food (ICMSF) and the Codex Alimentarius commission (World Health Organization and Food and Agriculture organisation). HACCP system as it applies to food safety management use the approach of controlling critical control points in food handling to prevent food safety problems. The system, which is science based and systematic, identifies specific hazards and measures for their control, to ensure the safety of the food. HACCP is based on prevention and it reduces the reliance on end product inspection and testing. It is the most accepted way of achieving food safety. But within Sri Lankan context still HACCP has not been a popular system with food manufactures. The reasons for this are the less information with food processors regarding HACCP and lesser government enforcement.

Ice cream is a food product, which is consumed by general public including high-risk groups (elder people and sick people). The product is such that it is consumed directly and the consumers apply no further treatment to it. If any hazard (Biological, Physical, and Chemical) is carried with ice cream the consumers will suffer from it. Several food-borne disease outbreaks has been reported due to contaminated ice cream in several countries. So a considerable attention should be paid for assuring food safety in the process of ice cream manufacture.

The study was carried out in the ice cream factory of Ceylon Cold Stores which is Located at Kaduwela. The factory produces about 30000 liters of ice cream per day and it contributes to 65% of ice cream production in Sri Lanka. Application of HACCP is in prime importance for the factory because of its large scale production, the sensitivity of its products (ice cream) and other operational benefits and the consumer confidence, which they can gain from it.

The objectives of the study were

- 1 Identification of the hazards associated with the ice cream manufacturing process of the factory**
- 2 Determination of critical control points for the identified hazards and establishing critical limits**
- 3 Establishment of the HACCP plan together with monitoring corrective action and record keeping procedures**

CHAPTER - 2
LITRETURE REVIEW

2.1 Food safety issues of the modern world

In modern world the desire of consumers is for foods that are safe, convenient, readily available and affordable in price. Food processors should give priority to safety out of all above because there is a potential for human suffering or even death due to unsafe food. Food may become microbiologically unsafe if a disease-causing organism (pathogen) is present and causes an infection. Alternatively a toxin may be produced causing an illness usually referred to as intoxication. Foods with infections and intoxications therefore are prevented. Complete public health facts and financial consequences cannot be determined until the outbreak ends. A full evaluation takes time and all consequences may not be known for years. Pending legal proceedings may be lengthy and sales may take time to recover to previous volume levels.

Table 2.1 Examples of public health and financial consequences of food borne illnesses, over five-year period

Incident	Year	Country	Food involved	Organism	Number of Cases	Cost in US \$
1	1982	UK	Chocolate bar	<i>Salmonella napoli</i>	245	26800
2	1984	Canada	Cheddar cheese	<i>Salmonella typhimurium</i>	2700	10 million
3	1985	USA	Pasteurized milk	<i>Salmonella typhimurium</i>	16000 & 2 deaths	Over 30million paid settlements Dairy bankrupted.
4	1985	USA	Mexican Style Cheese	<i>Listera monocytogens</i>	142: 47 deaths	Lawsuit of 800 million
5	1985	UK	Instant dried milk	<i>Salmonella ealing</i>	76 48 infants	37 million
6	1986	UK	Pasteurized Milk	<i>Salmonella branderup</i>	54	285000
7	1987	Switzerland	Vachenn Mont d'Or cheese	<i>Listera monocytogenes</i>	30-60 deaths	1500000

source : Shapton & Shapton (1991)

As far as the food industry is concerned traditional quality control methods, such as periodic monitoring of storage conditions and manufacturing process and the testing of a small number of finished products, are simply not adequate for achieving food safety. For achieving food safety HACCP is the best ever tool which the food industry can use.

2.2. Hazard analysis and the critical control point

2.2.1. Origin of HACCP

Hazard analysis and the critical control point (HACCP) is a joint effort within the US space program, the Pillsbury company, the National Aeronautics and Space Administration and the US Army Natick Laboratories to apply a zero defect philosophy to food production for astronauts. It is based on the Engineering system, the failure mode analysis Scheme, which consist of examining the product and all the components and the process used to make the product and asking what can go wrong within the system. (Mortimore and Wallace 1994)

2.2.3. Worldwide Acceptance to the HACCP system

It was realized that the system has wider applications than the space program, and following its presentation in the first national conference for food protection in US in 1971. It was adopted in 1973 by the food and drug administration of USA in relation to the inspection of the low acid canned food. Then in 1980, the World Health Organization (WHO) produced a report, which was prepared in collaboration with the International Commission for Microbiological Specifications of Food (ICMSF). This report concluded 'the HACCP concept is a desirable alternative to traditional control points. To other approaches as it is based upon a more systematic and logical approach to the avoidance of food hazards' WHO saw application in both developed and developing countries. ICMSF, the US national advisory committee on microbiological criteria for food and other countries have endorsed the HACCP system. (Jay 1992).

2.2.4. HACCP Definitions

The terms used in HACCP system need to be defined before consideration is given to the way the system is applied.

Following terms are frequently used in HACCP systems and they are defined as follows.

1. **Control point:** Any point in a specific food system where loss of control does not lead to an unacceptable health risk

2. **Critical Control point (CCP):** Any point or procedure in a food system where control can be exercised and a hazard can be minimized or prevented.
3. **Critical Limit:** One or more prescribed tolerances that must be met to ensure that a CCP effectively controls a microbiological health hazard.
4. **Deviation:** Failure to meet a required limit for a CCP.
5. **Hazard:** Any biological physical or chemical property of food that may cause an unacceptable consumer health risk.
6. **Monitoring:** A planned sequence of observations or measurements of critical limits at critical control points.
7. **Risk Category:** One of six categories prioritizing risk based on food hazards.
8. **Verification:** Methods procedures and tests used up to determine the HACCP system is in compliance with the HACCP plan. (Codex 1997)

2.2.5. Principles of HACCP

Although interpreted variously, the ICMSF and NAMCF view HACCP as a natural and systematic approach to food safety and as consisting of the following seven principles.

1. Access the hazards and the risks associated with the growing, harvesting raw materials, ingredients, processing, manufacturing, distribution, marketing, preparation and the consumption of the food in question.
2. Determine Critical Control Points required to control the identified hazards.
3. Determine the Critical Limits that must be met to at each identified CCP
4. Establish procedures to monitor the Critical control Points.
5. Establish corrective actions to be taken when there is a deviation identified by monitoring a given CCP
6. Establish effective record keeping systems that document the HACCP plan
7. Establish procedures for verification that the HACCP system is working correctly

2.2.5.1. Principal 1: Assess Hazards and Risks. Hazards and risks may be assessed for individual food ingredient from the flow diagram or by ranking the finished food product by assessing to it a hazard rating from A through F.

- (A) A special class of foods that consist of non sterile product designated and intended for consumption by individuals at risk, including infants, the aged, infirmed, and immunoincompetents.
- (B) Product contains "sensitive" ingredients relative to microbiological hazards. (Milk, fresh meats)
- (C) There is no controlled processing step, (such as heat pasteurization) which effectively destroys harmful microorganisms.
- (D) The product is subjected to recontamination after processing but before packaging. (Pasteunzed bulk and then pack separately).
- (E) Substantial potential for abusive handling exists in distribution and/ or by consumers that could render the product harmful when consumed.
- (F) There is no terminal heat process after packaging or when cooked in the home.

Subsequently the formulated product should be assigned to one of six hazard categories.

- VI A special category that applies to non-sterile products designated and intended for individuals in hazard category a.
- V Food products subjected to all five hazard categories.
- IV Food products subjected to any four general hazard characteristics.
- III Products subjected to any three of the hazard categories.
- II Products subjected to any two of the hazard categories.
- I Products subjected to a one of the hazard categories
- 0 Products subjected to no hazards. (Jay 1992)

2.2.5.2. Determine Critical Control Points.

A point step or a procedure where control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels
(Mortimer Wallace 1994)

2.2.5.3. Establish Critical Limits.

A critical limit is a one or more prescribed tolerances that must be met to ensure that a CCP effectively control a microbiological hazard. This could mean keeping refrigeration temperatures within a specific and narrow range or making sure that a certain minimum destructive temperature is achieved and maintained long enough to effect pathogen destruction (Jay 1992)

Critical limits are defined as criteria that separate acceptability from unacceptability. A critical limit represents the boundaries that are used to judge whether an operation is producing safe products. Critical limits may be set for factors such as temperature, time (minimum time exposure), physical product dimensions, water activity, moisture level etc. These parameters, if maintain within boundaries, will confirm the safety of the product.

The critical limit should meet requirements of government regulations and /or company standards and/or be supported by other scientific data. In some cases, food control regulatory authorities provide information on which to establish the critical limits based of known food hazards and the results of risk analysis (e.g. the time temperature requirements for thermal process such as pasteurization, cooking, retorting, maximum number and size of physical contaminants, chemical residues)

It is essential that person(s) responsible for establishing critical limits have a knowledge of the process and of the legal and commercial standards required for the product.

If monitoring shows a trend towards lack of control at a CCP, operators can take actions to prevent loss of control of the CCP before the critical limit is exceeded. The point at which operators take such action is called the "operating limit". Operating limits should not be confused with critical limits. Often, the operating limits are more restrictive and are established at a level that would be reached before the critical limit is violated, i.e. they should prevent a deviation from critical limits. (FAC 1998)

2.2.5.4. Establish procedures to monitor CCPs

The monitoring of a CCP involves the scheduled testing or observation of a CCP and its limits; monitoring results must be documented. If for example the temperature for a certain process steps should not exceed 40°C. A chart recorder may be installed.

Microbial counts generally are not satisfactory at this point since too much time is required for results. Physical and chemical parameters such as time pH temperature, and a_w can be tested can be tested and results obtained immediately.

Sampling and microbiological testing is usually not adequate by themselves to ensure food safety. Microbiological testing is seldom effective for monitoring CCPs and can not be used as means of process control because of the lengthiness of analytical procedures and the inability to provide results in real time. In addition detection of pathogenic microorganisms can be difficult if contamination of the product at the CCPs at a low level or is unevenly distributed in the food sample, necessitating large and numerous samples. (FAO 1998)

2.2.5.5. Establish Corrective actions to be taken when deviations occur in CCP monitoring

The actions taken must eliminate the hazard that was created by deviation from the plan. If a product is involved that may be unsafe as a result of the deviation, it must be disposed. While the actions taken may vary widely, in general they must be shown to bring the CCP under control. (FAO 1998) The action must ensure that the CCP is brought under control. Deviation or product disposition procedures must be documented in the HACCP record keeping.

2.2.5.6. Establish verification procedures for the HACCP plan.

Verification is embodied in HACCP principal 6: Establish Verification Procedures. The Codex guidelines define verification as "the application of methods procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan". Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly.

Careful preparation of the HACCP plan with clear definitions of all the necessary items does not guarantee the plan's effectiveness. Verification procedures are necessary to assess the effectiveness of the plan and to confirm that the HACCP system adheres to the plan. Verification allows the producer to challenge the control measures and to ensure that there is sufficient control for all possibilities; for example, verification may ensure that

adequate contingency procedure plans are in place when critical limits are exceeded at a CCP.

Verification should be undertaken by appropriate qualified individual or individuals who are capable of detecting deficiencies in the plan or its implementation. Verification should be undertaken at the completion of the HACCP study; whenever there is a change in product, ingredients, process, etc.; when a deviation occurs; in the event of newly identified hazards; and at a regular predetermined intervals.

Microbial testing does have a roll in HACCP verification, however; when critical limits are established for the elimination of pathogens or their reduction to an acceptable level, microbiological tests can be used to verify the HACCP plan effectiveness and to ensure that the identified microbiological limit have not been established. In this instance the length of time involved in the analytical procedures do not create operational difficulties (FAO, 1998).

2.2.5.7. Establish effective record keeping and document the HACCP plan.

The HACCP plan must be well documented, and at the food establishment and must be made available to official inspectors upon request. Forms for recording and documenting the system may be developed, or standard forms may be used with necessary modifications. Typically these may be forms that are completed on a regular basis and filed away. The forms should provide documentation for all ingredients, processing steps, packaging storage and distribution.

2.2.6. The logic sequence for application of HACCP.

1. Assemble the HACCP team.
2. Describe the product.
3. Identify the intended use.
4. Construct the process flow diagram.
5. On-site verification of the process flow diagram.
6. List all hazards, conduct a hazard analysis and determine control measures.
7. Determine the Critical limit and describe the control measures to control the hazard
8. Establish Critical Limits for the control measures at each CCP
9. Establish a monitoring system for each CCP
10. Establish corrective actions for deviations that may occur
11. Establish verification procedures.
12. Establish record keeping and documentation.

(Asian Canada Fisheries post harvest Technology project phase II/1996)

2.2.7. Benefits of applying HACCP in food industry

1. Control of the process can be much more proactive, allowing problems to be detected and corrected much quickly and easily, before the process go out of control.
2. Control is generally much more in the hand of the line operators, with the associated benefits of responsibility and job satisfaction. As such it lends itself well to Quality Assurance Systems.
3. Control measures can be cheaper in comparison to chemical and microbiologically based end product testing.
4. Because testing is more focused on critical control points, more measurements and better quality information on each batch can be gathered and used.
5. HACCP is a good predictive tool in determining the likely problem in areas in new product development.
6. Application of HACCP system can aid inspection by food control regulatory authorities and promote international trade by increasing buyer's confidence.

(Chesworth 1997 and SLSI 2000)

2.2.8. Supplier quality assurance as a method of assuring food safety

Supplier quality assurance can be used as a method of obtaining safe raw materials. There are a number of different elements to an effective supplier-quality assurance program, including having agreed specifications, auditing suppliers, and certificates of analysis. Supplier approval will depend on having confidence in the supplier's operations, that they are competent at managing the hazard present. It is therefore vital to develop good customer supplier relationship-partners in the management of safe raw materials and products.(Motmore & Wallace, 1995)

2.3. Ice Cream and Food safety; issues Associated with Ice Cream

2.3.1. Recently recorded food safety incidents related to ice cream.

Ice cream out of all frozen dairy products is the one made and sold in the greatest quantities worldwide. Sales vary enormously from country to country, with the USA and Australia heading the list with over 20 liters per head per annum, to about 6 liters in UK and 4.5 liters in France. (Rothwell 1990)

In commercially manufactured ice cream several outbreaks are reported Contamination with *Staphylococcus aureus* and subsequent temperature abuse of ice cream mix has permitted growth and enterotoxin production (ICMSF 1998). Pathogens if present in

ice cream may survive in ice cream for many months. *Salmonella* survived for 7 years (Geogala and Hurst 1963) several recalls of frozen dairy products including frozen novelties, ice cream, ice milk, and sherbet due to contamination by *Listeria monocytogens* have occurred in the US since 1985 (Ryser and Marth 1991). Although millions of gallons of product were recalled, no direct link to listeriosis has been documented. Because *Listeria monocytogens* does not survive pasteurization, post pasteurization contamination is the source of this contamination. The inability to grow at freezing temperatures minimizes the risk associated with this and other pathogens (Kozak *et al* 1996).

2.3.2. Ice cream Raw Materials and food safety.

Ice cream can be made with a wide variety of raw materials. Although it is a heat-treated product, it is still necessary to use raw materials of highest quality and to store them under conditions, which will not allow proliferation of any microorganisms. (J.Rothwell 1985)

2.3.2.1. Dried dairy products (Skimmed milk powder and whey powder).

The extent of microbial destruction during drying depends on the types of the microorganisms present, and on the drying temperature of the exit air in the spray drying or drum drying or the drum temperature and retention time of drum drying. Various vegetative bacteria including gram negative, enterobacteriaceae, have been shown to survive the drying process. Doyle *et al.* (1985) determined that *Listeria monocytogens* also survives at a typical spray drying process. Therefore dairy products for drying must be given a heat treatment, equal or greater than pasteurization, and the product must be protected against contamination between the pasteurizer the drier and the packaging operations. After dehydration the products will not support microbiological growth.

The principal microbiological problems associated with instant dry milk occur upon accidental contamination during rewetting or after it is reconstituted. During storage of dry milks, surviving organisms slowly die (Thompson *et al* (1978). But the spore-formers being the most resistant retain viable for long periods of time. (ICMSF 1998)

Several outbreaks of *Salmonella* associated with dried milk products is reported in ICMSF (1998). Dried milk associated with *Salmonella typhimurium* and *Salmonella agona* are also reported.

There have been no outbreaks of listeriosis linked to dry dairy products. However the persistence of *Listeria* in dairy plant environment and the association of listeriosis with other dairy products clearly indicate the potential for contamination of dairy products with *Listeria* spp. (ICMSF 1998).

An outbreak of *Staphylococcus aureus* due to contaminated milk powder has recently been reported and may have been due to preformed toxin surviving processing. In other cases illness is due to contamination and abuse of reconstituted products. (Umoh *et al* 1985)

Presence of *Bacillus cereus* at low levels in dry milk was reported in several publications. (Baker *et al* 1994) these studies shows that over 60% of milk powder supplied in the US were positive for *B cereus*. Although outbreaks of food poisoning due to *B.cerrus* have not been directly attributed to dry dairy products. Temperature abuse of the reconstituted product is the major concern. *Enterobacter Sakazakii* has been implicated in sporadic outbreaks causing neonatal meningitis after consumption of reconstituted and frequently abused products allowing thus multiplication.

Occasionally, dried milk has been found to contain Aflatoxin M1 (Galvano *et al.* 1996) Although the amount of toxin present in fluid milk is reduced somewhat by the drying process significant percentage of it appears to survive the process and will survive for extended periods in the dry products. The stability of other mycotoxins has not been investigated. (ICMSF, 1998).

2.3.2.2. Vegetable fat (margarine)

ICMSF 1998 reports that there are no genuine report cases of food borne illness associated with consumption with margarine. But it site some other reports which are associated with some product recalls and outbreaks with high salt margarine and margarine blended with butter which is out of the scope of this study.

2.3.2.3. Refined sugar.

According to ICMSF 1998, refined sugar allows only some thermophilic spores to survive. It contains more than 99% dry matter.

2.3.2.4. Cocoa Powder

The only pathogen in concern of cocoa powder is *salmonella*. Cocoa based products were not recognized as causes of *Salmonellosis* until 1970 and 1973 two outbreaks, cocoa powder contaminated with *salmonella* Durham and used in confectionery products was the origin of a n outbreak affecting 110 people in Sweden (ICMSF 1998).

2.3.2.5. Dried fruits (Sultan Preserves)

Fruits treated with SO₂ at drying completely eliminate the micro-flora. Even during prolonged storage such product, have no microbiology. But if Unsulphurd, the dried fruits

will allow the growth of *Aspergillus niger* and some Extreme Xerophiles. But it further says that, the survival of pathogenic bacteria is usually poor and limited to a few weeks even on Unsulphured dried fruits. Relatively long storage periods before sale, normal for such products, further minimizes risk. The possibility of mycotoxin production in high moisture Unsulphured dried fruits (above 0.85 aw) exists, but has not been reported to be significant. (ICMSF 1998)

2.3.2.6. Emulsifiers and stabilizers

Various kinds of emulsifiers and stabilizers are used in ice cream manufacture. Materials of animal origin (Eg. Gelatin) can carry pathogenic microorganisms. But commonly used stabilizers of plant origin usually do not contain pathogenic flora in significant amounts (Rothwell, 1985).

2.3.2.7. Cashew nuts

ICMSF 1998 says that fungal spoilage and Mycotoxin production do not cause serious problems in cashew.

2.3.2.8. Ice cream containers, lids, sticks, spoons

Containers, lids, sticks and spoons used for ice cream packaging, may cause a considerable contamination. Nataraja *et al.* had reported a yeast and mould count of 16000 and a total Colony count of 30,000 from surface of a single container, which was intended for packaging ice cream.

2.3.3. Process operations

Several factors are important in processing of high quality ice cream. A summary of the main hazards associated with the stages of ice cream processing is given in the table 2.4 together with a list of typical actions required controlling those hazards. (: ICMSF 1998).

Bacteriological testing for aerobic plate counts and coliforms at various stages of preparation and handling are useful to monitor plant sanitation and are required in many countries (ICMS, 1998).

2.3.3.1. Mix preparation

The bacterial quality of the mix depends on the quality of ingredients used for the mix preparation. Prolonged temperature abuse of the reconstituted mix will cause a potential health hazard to consumers.

2.3.3.2. Pasteurization

The time and temperature requirements for ice cream mix pasteurization vary from country to country. But such regulation for pasteurization of ice cream mix is not still established in Sri Lanka. In USA the parameters for pasteurization are based on but higher than time temperature combinations held for milk. Heat treatments must be 3°C higher than those used for milk for each minimum holding time. Table 3 gives the pasteurization requirements for different countries and illustrates the large range of legislative requirements for the pasteurization of the ice cream mix.

In Sri Lanka following Time temperature combinations are Recommended for Sri Lankan standard for Ice Cream, although it is not mandatory to follow these time temperature combinations.

Table 2.2. Pasteurization Requirements for Ice cream in Sri Lanka

60°C	for at least 30 minutes
70°C	for at least 10 minutes
79°	C for at least 15 seconds
149°	C for at least 2 seconds

Source: SLS223:1989 First Revision

Table 2.3. Pasteurization Requirements of several countries as enforced by the Governments

Country	Pasteurization Requirement
Australia	70°C or equivalent within one hour of preparation
China	78°C for 20 minutes, then cool to 60°C for homogenize
Denmark	At least 65 °C for 30 minutes within one hour of mixing of ingredients
Finland	72°C for 15 seconds
France	60 to 65°C for at least 30 minutes
Hong Kong	66 °C for not less than 30 minutes
	71°C for not less than 10 minutes
	79 °C not less than 10 minutes
India	68.3°C for at least for at least 30 minutes
	79.5°C for at least 25 Seconds
Italy	63°C for 30 minutes or equivalent
Japan	68 °C for 30 minutes or by a method having equal or better effect
Pakistan	72 °C for 15 seconds
Portugal	65 °C for at least 30 minutes
Singapore	66 °C for 30 minutes
	72 °C for 10 minutes
Thailand	80 °C for 25 seconds
UK	65.5°C (150 °F) for at least for at least 30 minutes
	71°C (160 °F) for at least for at least 10 minutes
	79.5 (175°C) for at least 15 seconds
	148.2°C for two seconds
USA	68°C (155 °C , for at least 30 minutes
	79 °C for (175 °F) for 25 seconds

Source ICMSF 1998

2.3.3.3. Cooling and Aging

Pasteurized mix is cooled and aged to allow some physical and chemical changes. The mix should be immediately cooled to the aging temperature as soon as possible. Pasteurized mix should be cooled to 7°C within 90 minutes (SLS 223:1989 first revision). Both temperature abuse and recontamination of the mix may easily occur. Improper refrigeration may permit bacterial growth to levels exceeding the microbial limits specified by the regulations. Maximum storage time recommended for ice cream mixes is 3 days (ICMSF 1998).

2.3.3.4. Freezing

Freezing is the step, which converts the liquid ice cream mix into a semi solid. In continuous ice cream freezers the temperature is reduced from around 5°C to around -5°C within few seconds. Meanwhile air is incorporated and the volume is doubled. Air incorporated into Ice Cream if not filtered will lead to a considerable increase of the microbiological count of the ice cream (Rothwell, 1990).

2.3.3.5. Ice cream Storage

The lowest recorded temperature of growth of microorganisms of concern in foods is -34°C, in this case Pink Yeast. Growth of temperatures below 0°C more likely to be that of yeasts and moulds than bacteria. This is consistent with the growth of fungi under lower a_w conditions. Bacteria have been reported to grow at -20°C and around -12°C. Foods that are likely to support microbial growth at sub zero temperatures include fruit juice concentrates, bacon, ice cream, and certain fruits. These products contain Cryoprotectants that depress the freezing point of water. (Jay 1992)

The Sri Lanka standard on ice cream specifies a storage temperature of -18°C or below for Ice Cream storage.

Table 2. 4 A Summary of the main Hazards Associated with Ice Cream Processing.

Process	Hazard	Quality Assurance Action
Raw materials	Presence of pathogens and toxin	Purchase from approved suppliers. Link testing according to risk.
Pasteunzation	Survival of pathogens	Correct time:temperature. Maintenance of equipment flow diversion valve. Calibration of sensors.
Ageing	Recontamination Growth of microorganisms Spoilage.	Hygienic design cleaning and disinfection. Temperature at or below 5°C & Freez within 3 days.
Filling/Extrusion	Recontamination	Hygienic design of equipment/ environment. cleaning and disinfection. Personnel training.
Post pasteunzation additions	Recontamination	Purchase materials from approved suppliers. Hygiene of addition. Cleaning and disinfection.
Hardening	Recontamination	Hygienic design Cleaning and disinfection.

Sauce ICMSF(1998)

2.4. Pathogens, which can be associated, ice cream raw materials and the processing environment.

2.4.1. *Staphylococcus aureus*

Staphylococcus aureus is ubiquitous in man's environment. The primary habitat is the skin, and in the nose and the throat of man and animals. A larger portion of healthy people carries *Staphylococcus aureus*. Nasal carriers from 40 to 44% of the population, hand carriers vary from 14 to 40%. (Shapton and Shapton 293)

In humans the main source of *S. aureus* is the nasal cavity. From this source the organism finds its way to the skin and in to wounds either directly or indirectly. The most common skin sources are the arms hand and the face. In addition to the skin and the nasal cavities, *S. aureus* may be found in the eye throat and the intestinal tract. From the sources the organism finds its way in to air and dust, in to clothing and in other places from which it may contaminate food.

Although *S. aureus* is a mesophile some strains of *S. aureus* can grow at a temperature as low as 6.7°C. In general growth occurs over the range of 7 to 47.8°C and enterotoxins are produced between 10°C and 47°C. These minimum and maximum temperatures of growth and toxin production assume optimal conditions relative to the other parameters (Jay 1992)

Regarding pH *S. aureus* can grow over the range of 4 to 9.8, but its optimum is in the range of 6 to 7. As in the case with the other growth parameters, the precise minimum growth pH is dependent on the degree to which all other parameters are not optimal levels.

With respect to a_w the *Staphylococci* are unique to being able to grow at values over than for any other nonhalophilic bacteria. Growth has been demonstrated as low as 0.83 under otherwise ideal conditions, although 0.860 is the generally recognized minimum a_w .

Heat Resistance of shows great variation as reported by various workers. Little work had been done at 71°C the legal pasteurization temperature

Table 2.5 Heat resistance of in *Staphylococcus aureus* milk

Temperature (°C)	D Values in Milk
61.7°C	20 minutes
62	20 to 65 Seconds (a mixture of strains were Heated)
71.7	4.1 Seconds

Source. Shapton & Shapton, 1991

Table 2.6. Parameters for toxin production of *Staphylococcus aureus*

	Minimum	Optimum	Maximum
Temperature (°C)	10	40-45	48
pH	4	7-8	9.6
Water Activity (a _w)	0.85	0.98	0.99

Source. Shapton & Shapton, 1991

2.4.2. *Listeria Monocytogenes*.

Listeria monocytogenes is a Gram-positive coccoid rod. It is motile at 20-25°C. *L. monocytogenes* is an Aerobe, or microaerophilic Psychrotroph. It is 0.4 to 0.5 by 2µm in size.

The organism is ubiquitous in nature. In general *listerae* may be expected to exist where lactic acid bacteria, *Brochothrix* and some coryneform bacteria occur. Their association with certain dairy products and silage is well known. (Jay 1992)

Significance.

Immunocompromised people are the most susceptible, contracting mainly meningitis and septicaemia. Abortions can occur when pregnant women become ill due to *Listeria Monocytogenes*. Approximately 30% of confirmed cases of Listeriosis in out breaks have died. Pasteurized milk in an out break in Massachusetts in 1983 (Shapton & Shapton, 1991).

Although *Listeria monocytogenes* occurs commonly in the environment, listeriosis is comparatively rare, but the case fatality rate is high that is approximately a third of cases have been fatal or resulted in still births.

(Hobbs and Roberts 1993)

The infective dose of *Listeria monocytogenes* is unknown. Out breaks have extended over a period of time, and the implicated food has been examined for presence or absence of *L. monocytogenes* in 25 g or ml of food rather than direct count of the bacteria.

As far as immunocompromised people are concerned, relatively low numbers of *Listeria monocytogenes* in food would cause illness, whereas non-immunocompromised people would be unaffected by high numbers of *L. monocytogenes*.

Table 2.7 Heat Resistance of *Listeria monocytogenes*

Temperature °C	D value (seconds) in milk.	
	Freely suspended	Intra cellular
57.8	331	429
62.8	38	55.2
61.1-Sealed tubes	16.9	16.7
-Slug-flow plant	19.1	18.4
68.9 Sealed tubes	8.6	3.9
-Slug flow plant	5.1	9.1
71.7 Sealed tube	0.6-2.0	0.6-2.0
74.4	1.1	1.5

Source Shepton & Shepton

In ice cream mix *Listeria monocytogenes* (Strain Scott A in free suspension) gave a D value of 2.6 sec by heating at 79.4°C and a Z value of 7°C. (Jay 1992 page 525)

Table 2.8. Generation times and lag periods at temperatures between 0 and 13 °C.

Temperature (°C)	Generation time (Hours)	Lag period. (days)
0	62-131	3-33
2.5	24-45	3-0
5	13-25	1-3
8	12-13	<1-2
9.3	5-9	
10	4-10	
13	3-4	

Source: Shapton & Shapton (1991)

The range of values is a result of either differing growth media or because of strain variation in different experiments. For example at 10°C the generation time is 4 hours in whole milk 5 hours in skim milk and 10 hours in 11% cream.

Table 2.9 Conditions for Development of *Listeria momocytogenes*

		Minimum	Optimum	Maximum
Temperature		0°C	25°C	45°C
pH	30°C+	4.4	6.5-8	9.5
	25°C	4.5		
	20°C	4.5		
	7°C	4.8		
	4°C	5.2		

Source: Shapton & Shapton (1991)

2.4.3. Salmonella.

Salmonellae are small gram-negative non spore forming rods that are widely distributed in nature, with human and animal being their primary reservoir

Salmonella food poisoning results from the ingestion of food containing appropriate strains of this genus in significant numbers. *Salmonellae* attack the intestine walls causing the symptoms of nausea, vomiting, abdominal pain, diarrhea and headache, which were the most usually found. Generally 5% of the people need the hospital treatment.

The parameters such as pH, a_w , nutrient content, and temperature are inter related and same as for most bacteria. The pH for optimal growth is nearly 6.6- 8.2 with values above 9 and below 4 are being bactericidal. The lowest temperature at which the growth has been reported are 5.3-6.2°C and temperature around 45 °C have been reported by several authors to be upper limit of growth.

The following values have been found with *Salmonella typhinurium* recovered from the US 1985 outbreak.

Table 2.8. D values of *salmonella typhinurium*

Temperature °C	D value (Minutes)
62.8	0.11
71.7	0.003

Source: Shapton & Shapton

From these values HTST pasteurization should give 68 log cycles in most *Salmonella species*.

D values of *Salmonella* can be increased by Heat shock of a suspension, or by lowered water activity of the suspension.

2.4.4. *Bacillus cerus*

Bacillus cerus is an organism commonly found in dried dairy products. But direct link to food bone illness with dried dairy product is not identified.

Bacillus cerus is a gram-negative rod with central spores. They can be aerobic or facultative anaerobic. It is found in majority of most bulk milks. They may contaminate milk from farm and dairy equipment. The primary source of this contaminant is not clear. In UK only one milk related incident has been reported and it was due to pasteurized cream.

Bacillus cerus produces 2 distinct types of gastroenteritis.

- i. Diarrhoeal type caused by strains of *Bacillus cerus* that produce a heat sensitive enterotoxin. The toxin is formed during growth in the food and also in the intestine, after ingestion of vegetative cells.
- ii. Emetic type caused by strains of *Bacillus cerus* that produce a heat stable enterotoxin formed in the food during the stationery phase of the growth.

The infective dose for *B. cerus* of diarrhoeal type is around 5×10^5 cfu/g-1 and emetic type 1.0×10^3 - 5.0×10^{10} cfu g-1. The organism does not compete well with normal spoilage flora and it is not a hazard at the low numbers usually present in foods. It grows rapidly when background flora is removed by heating.

The vegetative cells of *Bacillus cerus* are no more heat resistant than vegetative cells from non-spore formers. But the spores are more heat resistant. The D values are 220, 71, and 13 in temperatures 85, 90, and 95 °C respectively. The organism is capable of growing

at temperatures between 10°C and 50°C. But some strains have been found to multiply at 4°C. (Shapton and Shapton, 1991)

CHAPTER - 3 METHOD

3.1. Identification of the scope of the HACCP study

The area of the process, which is to be covered under the HACCP study, was identified.

3.2. Assembly of the HACCP Team

3.3. Product Description.

The product was described with respects to its features regarding its safety. The intended use was also identified. It was identified as form 1.

3.4. The process flow diagram

The flow diagram was drawn in a way that it contains all details start to end of the production process. All process parameters related to food safety were included. The product rework loops and other inputs such as packaging also were included (Form 2).

3.5. Review of Incoming materials

For this activity the product description and the list of product ingredients and the incoming materials were used.

Information of the product description was reviewed to determine that how it would influence Food safety.

For each incoming material biological chemical and physical hazards were identified and marked B, C, or P in the list of incoming materials all potential to a biological physical or a chemical hazards were studied.

The hazards were (specifically) described in an appropriate form (Review of incoming materials) for biological chemical and physical hazards respectively.

3.6. Evaluation of the processing steps.

This step was followed to identify all realistic potential hazards related to each processing operation. This was accomplished by reviewing the process flow diagram and the plant schematic.

Each step of the process flow diagram was examined to find whether hazards exist for that operation.

The hazards identified from incoming materials and the process operations were fully described in the hazard analysis forms.

Some measurements of the in-process and finished products were made to check whether they comply with the scheduled operations and to evaluate them to determine the safety achieved at each step.

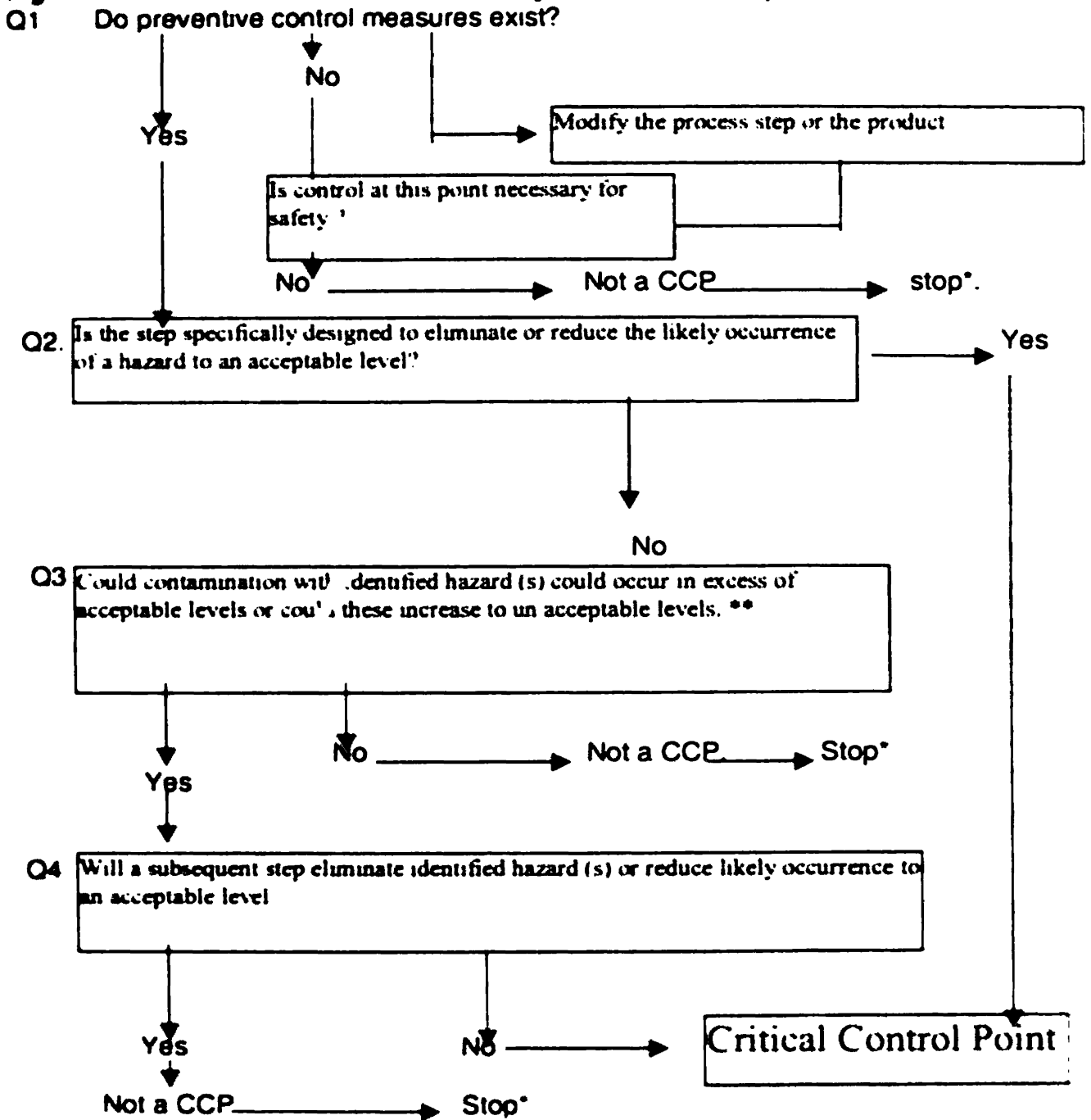
The measurements (the process parameters) and intrinsic factors of the product at various processing steps were compared with the growth kinetics of potential microorganisms and regulatory requirements.

3.7. Determination of the critical control points.

Prior to the determination of the critical Control points the biological chemical and physical hazards listed in the form (3) were reviewed to verify if any of the identified hazards are fully controlled by the application of the codex general principals of food hygiene. And it was verified on site.

The critical control points were determined by application of the decision tree which is included in the *Codex Hazard analysis and critical control point (HACCP) system and guide line* for its application. In some steps decisions were made out of the decision tree.

Figure 3.1 The decision tree to identify Critical Control points.



*Proceed to the next identified Hazard of the described process

** Acceptable and unacceptable levels need to be defined within the overall objectives in defining the CCPs of the HACCP plan.

Adopted from CAC/RCP1-1969, Rev 3(1997)

The last column of the form determination sheet was where CCPs were identified. They were numbered for their identification with characters B,C or P respectively for biological physical and chemical hazards. This identification protocol was used to identify CCPs sequentially independent of process operation numbering.

3.8. Establishment of the HACCP plan

3.8.1 Establishment of critical limits

Critical limits were established for each CCP. Information from various sources were associated in establishing of critical limits.

They included

1. Scientific publications/ Research data.
2. Regulatory requirements and guidelines.
3. Experts.

Operating limits were established. Operating limits were set in a way that they will become more restrictive than the Critical Limits facilitating the operators to make process adjustments before the parameter reach the critical limit.

3.8.2. Establishment of monitoring procedures

Monitoring procedures were established in a continuous basis, which is preferred than a batch basis. The procedures were established in a way that only measurements of time and temperature are to be monitored during the process operations. What is to be monitored, who is to monitor, frequency of monitoring and how to monitor all were decided for each critical limit. Each monitoring activity will be record in a daily record.

3.8.3. Establishment of corrective action procedures

Procedures were established for corrective actions to be taken when the monitoring results show a deviation from the critical limits at a CCP.

3.8.4. Establishment of verification procedures

Verification activities for each Critical Control Point were established. The responsibility of verification was assigned to a responsible person, and the schedule for verification activities was established.

3.8.5. Establishment of Record Keeping Procedures

Record keeping system was established to record the activities carried out within the HACCP system.

CHAPTER- 4 RESULTS AND DISCUSSION.

4.1 The Scope of the HACCP Study

The scope was identified to be from the resaving of raw materials to the dispatching of products from the finished product storage.

4.2 The HACCP Team

No regular HACCP team was established. Bur the following persons were consulted by the researcher during the project period.

1. The general manage
2. Quality Assurance manager
3. Assistant Quality Assurance Manager
4. Ice Cream Factory manager
5. Assistant Ice Cream factory manager
6. Quality Assurance and production Executives
7. The External supervisor of the project
8. The internal supervisor of the project.

4.3. The product description

Form1.

Product Description

(1.) Name of the Product

Product Name	Common Name
Elephant House ice Cream	Ice Cream
Wonder bar	Ice Chocks

(2).Ingredients: -

Main Ingredients:

1. Skimmed milk powder
2. Sugar
3. Whey powder
4. Emulsifier and stabilizer systems (Dncoid& Cremodan)
5. Cocoa Powder
6. Gelatine
7. Vegetable fat
8. Water

Additional Ingredients:

1. Cashew nuts
2. Pumpkin Preserves
3. Sultan Plums
4. Chocolate Coating (Callebout)
5. Mango sauce
6. Chocolate Sauce
7. Strawberry Sauce
8. Citric Acid.

Flavours and Colours

1. Vanilla Flavour
2. Strawberry flavour
3. Citric acid
4. Mocca Coffee Flavour
5. Rum Flavour.
6. Butter Scotch Flavour.
7. Mango flavour

(3.) Potential for Microbiological Growth

The product, ice cream, is a highly nourishes low acid food made without preservatives. The growth of micro organisms is controlled totally by pasteurisation and low temperature storage.

Under abused temperatures there is a potential for the growth of micro organisms.

(4.) Type of packaging

Rigid plastic containers and lids (1/2 l, 1l, 2l, 4l,)	Ice cream
Printed cups and lids (80 ml)	Ice cream
Polymer coated food grade wrapping material	Ice chocks
Wooden sticks	Ice chocks
Ploythene bags	Wrapping filled cups
Corrugated cartons	Packing wrapped chocks
Plastic crates	Handling packaged products

(5.) Shelf life of the product

One year at -18°C

(6.) How the Product is to be used

The product is consumed directly by general public including high-risk groups.

(7.) Where the product is to be sold:

Retail Shops.

(8.) Labelling instructions

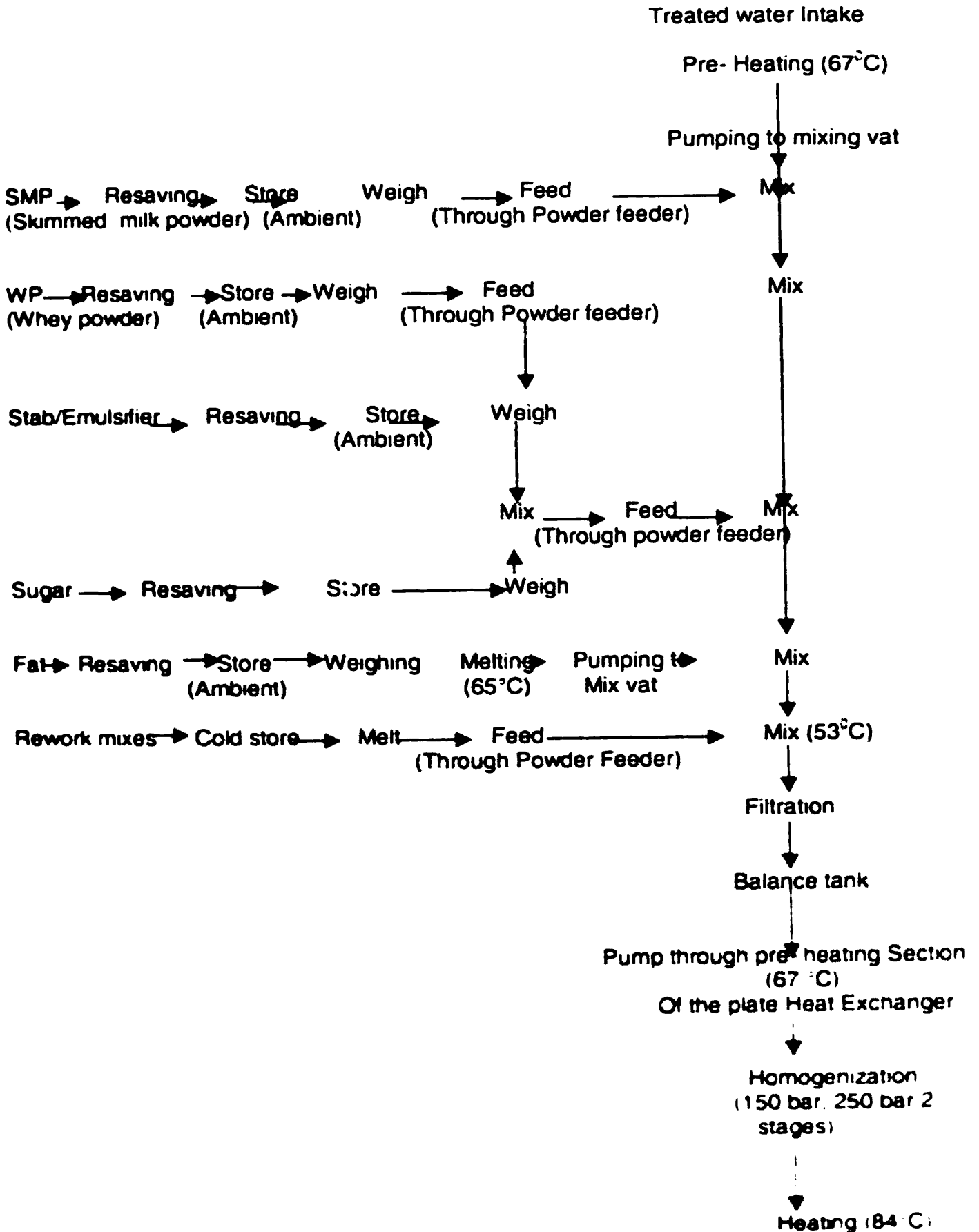
Following Instructions Are given in the labels

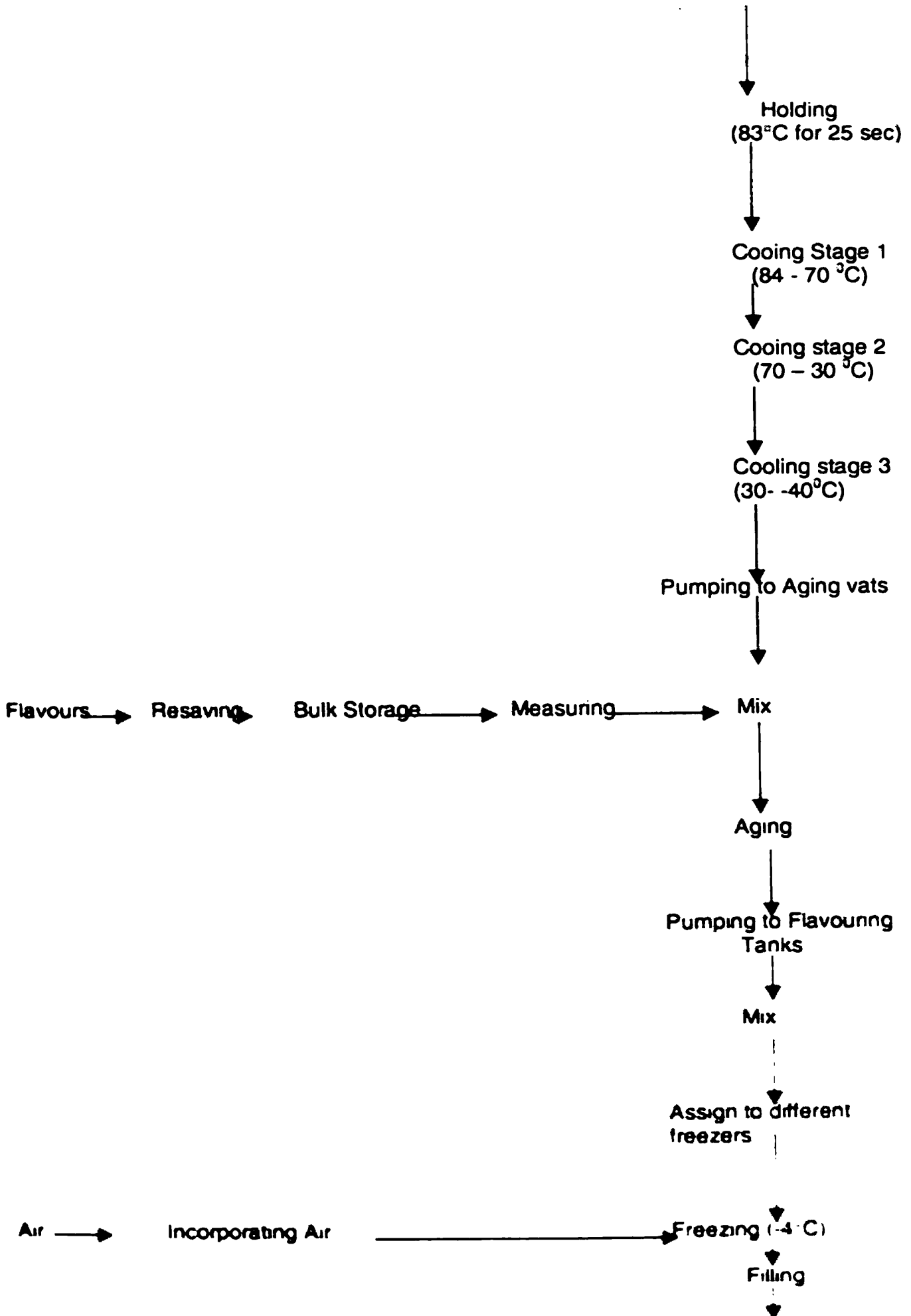
1. The date before which the product should be consumed, as it is stored under proper conditions of storage (the date of expiry).
2. The temperature below which the product should be stored
3. The batch code and the date of manufacture marked by a stamp.

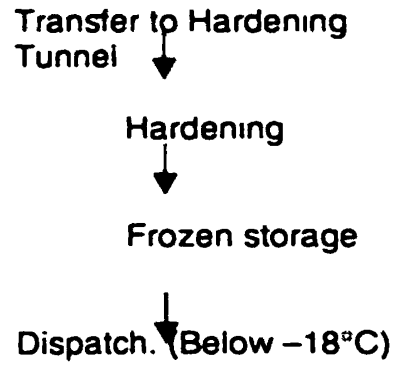
4.4. Process Flow Diagram.

Figure 4.1. Process Flow Diagram Form 2

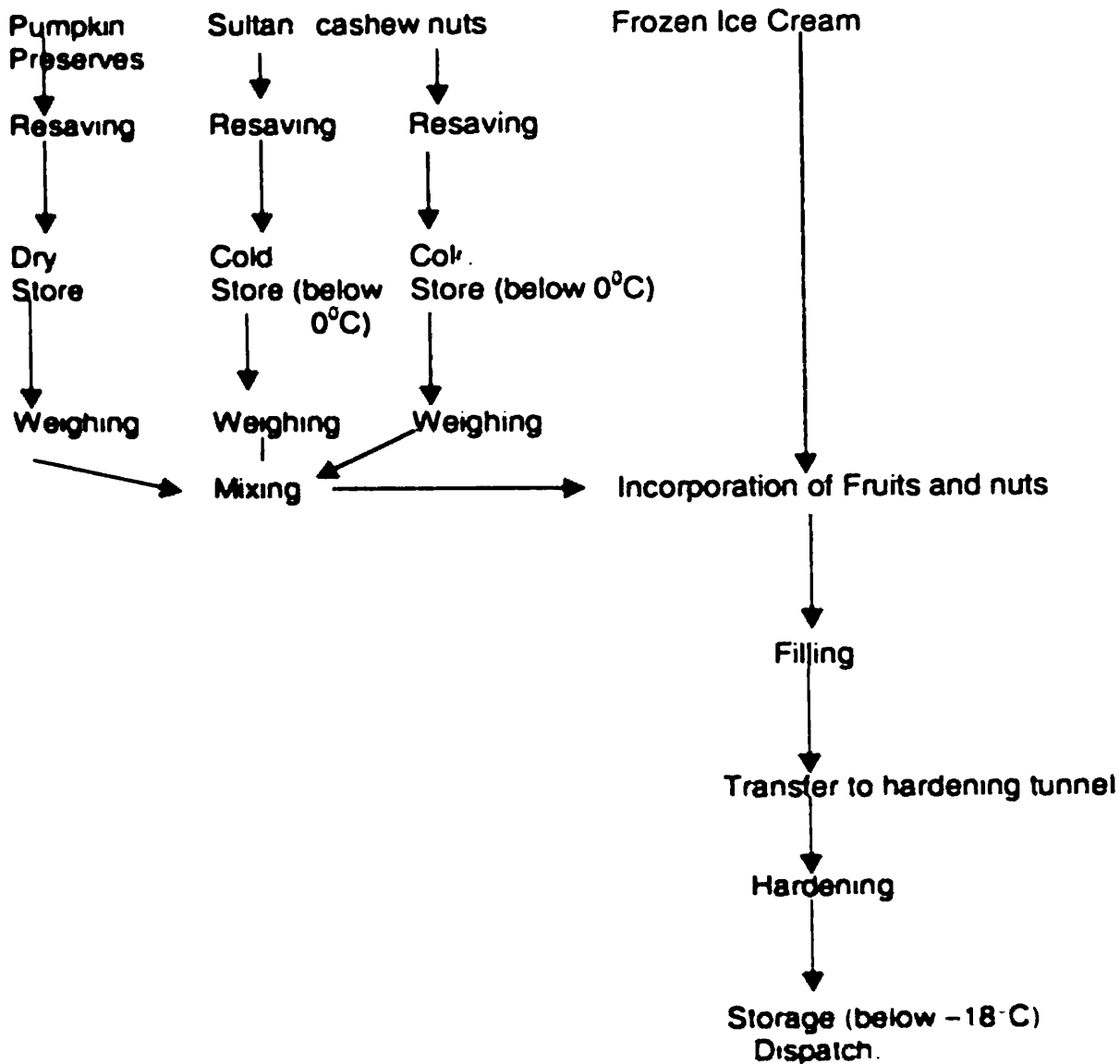
Process flow diagram





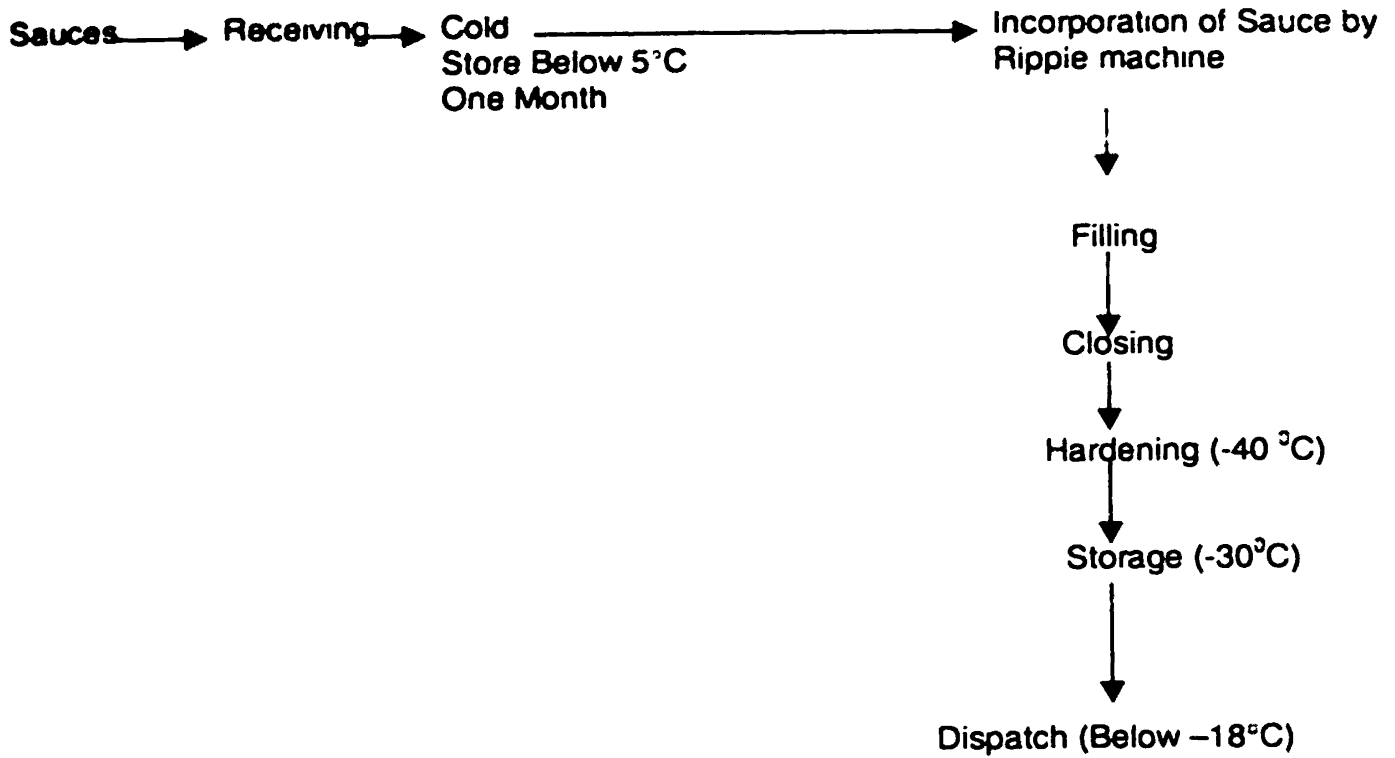


4.4.1. Alternate flow diagram for Fruit and nut Ice Cream

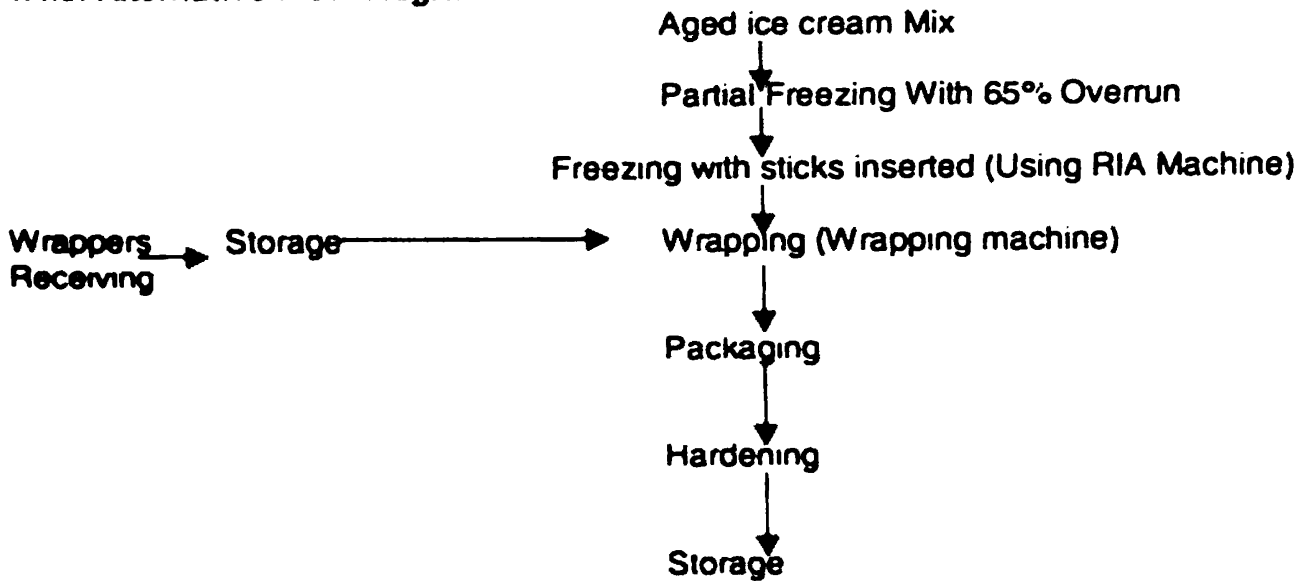


4.4.2. Alternate flow diagram for Ripple Ice Cream

Frozen ice cream



4.4.3. Alternative Flow diagram For Ice Chocks.



4.5. Review of incoming materials

Table 4.1. Review of incoming materials

Raw Material and Hazard	Controlled at
<p>Skimmed milk powder Biological <i>Salmonella</i> <i>Eccherisia coli</i> <i>Staph.aureus</i> <i>Clostridium perferingense</i> <i>Listeria monocytogense</i> <i>Bacillus serus</i></p> <p>Chemical Mycotoxin M1</p>	<p>Controlled at</p> <p>Suppliers Assurance (CCP 1 B)</p> <p>Mix Pasteurisation (CCP 15&CCP 16)</p> <p>Not addressed by the system</p>
<p>Whey powder Biological <i>Salmonella</i> <i>Eccherisia coli</i> <i>Staph.aureus</i> <i>Clostridium perferingense</i> <i>Vibreao parahemolyticus</i> <i>Bacillus serus</i></p> <p>Chemical Mycotoxin M1</p>	<p>Mix pasteurisation (CCP 15& CCP 16)</p> <p>Not Addressed by the System</p>
<p>Sugar Physical Contamination with objectionable foreign matter (Packaging materials etc.)</p>	<p>Mix filtration (CCP 13)</p>
<p>Vegetable fat Physical. Contamination with objectionable foreign mater (Packaging materials etc.)</p>	<p>Mix filtration.(CCP 13)</p>
<p>Cocoa powder Biological <i>Salmonella</i></p> <p>Chemical Contamination with Mycotoxins</p> <p>Physical Contamination with objectionable physical matter</p>	<p>Mix Pasteurisation (CCP 14 & CCP 15)</p> <p>Suppliers assurance (Not addressed in the system)</p> <p>Visual Inspection Mix filtration (CCP .14.)</p>
<p>Gelatine Biological <i>Salmonella</i></p> <p>Objectionable foreign Matter</p>	<p>Product Pasteurisation (CCP 15 &CCP 16)</p> <p>Mix Filtration (CCP 14)</p>

Raw Material and Hazard	Controlled at
Cremodan (Stabiliser/Emulsifier) Biological Pathogenic Micro organisms from Cross Contamination	Supplier's Assurance Mix Pasteurisation (CCP 15 & CCP 16)
Dncoid Biological Pathogenic Micro organisms from Cross Contamination	Supplier's Assurance Mix Pasteurisation (CCP 15 & CCP 16)
Cashew nuts <i>Physical</i> Objectionable Foreign matter	Raw material specification (CCP 2)
Pumpkin preserves <i>Physical</i> Objectionable physical matter	Raw material Specification (CCP 3).
Sultan plums Physical Objectionable physical matter	Specification. (CCP 4).
Chocolate sauce Biological Salmonella	Supplier Quality Assurance (CCP 5)
Strawberry sauce Biological Pathogenic Bactena	Suppliers quality assurance (CCP 6)
Mango sauce Biological Pathogenic bactena	Suppliers quality assurance (CCP 7)
Chocolate Coating Biological Pathogenic Vegetative and spore forming Bactena	Specification (CCP 8).
Plastic tubs for packaging Chemical Packaging migration in to the food Biological Contamination with pathogens	Suppliers assurance (CCP 10) Suppliers assurance (CCP 11)
Wooden sticks for ice chocks Biological Contamination with pathogens	Suppliers assurance (CCP 12)
Ice Chock wrapping material Ccntamination due to packaging migration.	Suppliers assurance (CCP 13)

4.6 Evaluation of process steps

Table 4.2. Evaluation of process steps

Process steps and hazards	Preventive/Control measures.
Melting of vegetable fat Contamination with un-cleaned vat	GMP
Feeding dry ingredients Contamination with packaging materials Contamination From Raw material handlers and operators	Filtration of the mix (CCP 14) GMP
Feeding melted fat Contamination with uncleaned pipes and fittings	GMP
Contamination of dry ingredients at storage	GMP
Contamination of Packaging materials at storage	GMP
Contamination of Sauces at storage	GMP
Temperature abuse of sauces	GMP
Mixing Contamination from un-cleaned pipes and fittings	GMP
Balance tank Microbiological contamination due to improper cleaning Contamination From operators	GMP GMP
Pumping and pre heating Contamination through un-cleaned plate heat exchanger and connected pipes	GMP
Homogenisation Contamination by inadequately cleaned homogeniser components	GMP
Heating stage of Plate heat exchanger Survival of pathogens due to Insufficient heating Contamination due to inadequate cleaning	CCP 15 GMP
Cooling stage Growth of microbes and spores due to slow cooling Contamination due to inadequate cleaning of the cooling section of the plate heat exchanger	CCP 16 GMP
Pumping the mix to aging vats through pipes Contamination due to inadequate cleaning of pipes and fittings	GMP
Aging Unacceptable growth of micro organisms due to increased temperature at aging Unacceptable microbiological growth due to prolonged	CCP 17

Process steps and hazards	Preventive/Control measures.
aging Contamination due to inadequate cleaning of aging vats	CCP 18 GMP
Pumping to flavouring vats Contamination by inadequate cleaning of pipes . Contamination by operators	GMP
Freezing Contamination through unclean freezer Contamination with air which is incorporated with ice cream	GMP Process should be modified
Incorporation of fruits and nuts Contamination with handlers Contamination with inadequately cleaned fruit and nut feeder Contamination with pipes and fittings Contamination with buckets etc	GMP GMP GMP GMP
Incorporation of Sauce Contamination with inefficiently cleaned ripple machine and connected pipes Contamination with workers	GMP GMP
Filling Contamination from employees	GMP
Closing Contamination from employees	GMP
Storage Growth micro organisms due to increased temperature.	CC 20P

4.7. Determination of CCP s

Table 4.3. CCP Determination form -1

Process Step/Incoming Materials	Category and Identified hazards	Question 1	Question 2	Question 3	Question 4	CCP No
SMP Receiving	Salmonella and other microbiological hazards					CCP 1
Whey powder Receiving	Salmonella and other microbiological hazards	Yes	No	No		Not a CCP
Cocoa powder	Salmonella	Yes	No	Yes		Not a CCP
	Contamination With Mycotoxins					Not addressed in the System
Discoid (Stabiliser/emulsifier)	Pathogens from cross contamination	Yes	No	No		Not a CCP
Gelatine Receiving	Salmonella	Yes	No	No		Not a CCP
Cashew nuts/ Receiving (Specification)	Objectionable foreign Matter	Yes	Yes			CCP 2
Pumpkin Preserves Receiving.	Physical Objectionable foreign matter	Yes	Yes			CCP 3
Sultana Plums: Receiving	Objectionable foreign Matter	Yes	Yes			CCP 4
Chocolate Sauce Receiving (Specification)	Pathogenic Bacteria	Yes	Yes			CCP 5
Strawberry Sauce: Receiving (Specification)	Pathogenic Bacteria	Yes	Yes			CCP 6
Mango Sauce Receiving (Specification)	Pathogenic Bacteria	Yes	Yes			CCP 7

Process Step/Incoming Materials	Category and Identified hazards	Question 1	Question 2	Question 3	Question 4	CCP No
Chocolate Coating Receiving/ Specification	<i>Salmonella</i>	Yes	Yes			CCP 8
Chocolate chips	<i>Salmonella</i>	Yes	Yes			CCP 9
All plastic Packing materials	Packaging migration to the food	Yes	Yeses			CCP 10
	Contamination with pathogens	Yes	Yes			CCP 11
Wooden sticks for ice chocks	Contaminated with pathogens	Yes	Yes			CCP 12
Wrapping material for ice chocks	Packaging Migration	Yes	Yeses			CCP 13

Table 4.4. CCP Determination form-2

Process Step	Category And Identified Hazard	Question 1	Question 2	Question 3	Question 4	CCP No
Filtration	Physical Objects Un-dissolved in the mix	Yes	Yes			CCP 14
Heating and Holding Stages of the Pasteunsation	Survival of Pathogens due to insufficient heating of the mix	Yes	Yes			CCP 15
Cooling Stage of Pasteunsation	Growth of Pathogenic Spores due to slow cooling	Yes	Yes			CCP 16
Aging	Unacceptable growth of Micro Organisms Due to increase in temperature at Aging	Yes	No	Yes	No	CCP 17
	Unacceptable growth of Micro Organisms Due to prolonged Aging	Yes	No	Yes	No	Yes 18

Process Step	Category And Identified Hazard	Question 1	Question 2	Question 3	Question 4	CCP No
Freezing	Contamination With air Incorporated in to ice Cream	No	Yes			CCP 19 Modify the process Step. Introduce air filtration Equipment
Storage	Growth of Pathogenic / Spoilage, organisms due to Increased store temperature.	Yes	Yes			CCP 20

4.8. HACCP Plan

4.5. HACCP Control Chart 1 for Identified Critical Control Points

Step	Hazard	Control Measure	CCP No	Critical Limits	Monitoring Procedure	Monitoring Frequency	Responsibility	Corrective Action	Records
Receiving Skummed Milk powder	Microbiological	Specification	1	SLS : All microbiological limits Total colony count Coliforms Salmonella	Report From an Accredited Laboratory of the exporting Country	Each Consignment	QAM	Reject Consignment	Raw material file- SMP
Receiving roasted Cashew nuts	Objectionable Foreign matter	Supplier quality Assurance (Specific attention)	2	Free of objectionable foreign matter	Laboratory Examination of the Samples	Each Consignment	QA Executive	Reject Consignment	-Raw material file Roasted Cashew
Receiving Pumpkin Preserves	Objectionable Foreign Matter	Supplier quality Assurance (Specific attention)	3	-do-	Laboratory Examination of the Samples	Each Consignment	-Do-	Reject Consignment	Raw material file P'Preserves

Step	Hazard	Control Measure	CCP No	Critical Limits	Monitoring Procedure	Monitoring Frequency	Responsibility	Corrective Action	Records
Sultan Plums	Objectionable Foreign Matter	Specification	4	-do-	Laboratory examination of samples	Each consignment	-Do-	Reject consignment	
Receiving Chocolate Sauce	Pathogenic Bacteria (<i>Salmonella</i>)	Suppliers Assurance	5	pH below 4.5 and	Laboratory examination of samples as a part of SQA	Each consignment	-QA Executive	Reject consignment Contact supplier	Raw material file - Sauces
Receiving Strawberry Sauce	Pathogenic Bacteria	Suppliers assurance	6	pH below 4.5 and	Laboratory examination of samples as a part of SQA	Each consignment	-QA Executive	Reject consignment	-do-
Receiving Mango Sauce	Pathogenic Bacteria	Suppliers assurance	7	pH below 4.3 and	Laboratory examination of samples as a part of SQA	Each consignment	-QA Executive	Reject consignment	-do-
Receiving Chocolate coating	Salmonella	Suppliers assurance	8	Free from Salmonella	A certificate from the supplier as a part of SQA	Once a year	QAM	Reject consignment	Raw material file Chocolate coating

Step	Hazard	Control Measure	CCP No	Critical Limits	Monitoring Procedure	Monitoring Frequency	Responsibility	Corrective Action	Records
Chocolate chips receiving	Salmonella	Supplier quality assurance	9	Absence of Salmonella	A Certificate from the supplier as a part of SQAsupplier.	Once a year	QAM	Contact Supplier Change supplier	Raw material file chocolate chips
Receiving Plastic packing material	Packaging migration	Supplier quality assurance	10	Made with approved raw materials	A Certificate from the supplier (with other SQA actions)	Once a year	QAM	Contact Supplier/Change supplier	Raw material file Packaging
	Contamination with pathogenic bacteria	Supplier quality assurance	11	No pathogens free of Coliforms	-do-	Once a Year	QAM	Contact Supplier/Change supplier	-do-
Receiving Wootton sticks	Contamination with pathogens	Supplier quality assurance	12	Free of Coliforms	A Certificate from the supplier	Once a year	QAM	Contact supplier Change the supplier	-do-

Step	Hazard	Control Measure	CCP No	Critical Limits	Monitoring Procedure	Monitoring Frequency	Responsibility	Corrective Action	Record
Receiving ice chock wrappers	Packaging migration	Supplier quality assurance	13	Made with approved materials	A Certificate from the supplier	Once a year	QAM	Contact supplier Change the supplier	-Do-

QAM: Quality Assurance Manager
SQA - Supplier Quality Assurance
QA Executive - Quality Assurance Executive.

4.6. HACCP control chart 2 for identified hazards

Step	Hazard	Control Measure	CCP no	Critical Limits	Operational limits	Monitoring Procedure	Monitoring Frequency	Responsibility	Corrective Action	Records
Filtration	Passing Undissolved solid matter through the filters	Routine checking of filters	14	Filters in good order	Filters in good order	Visual inspection	Before start the operation	Production assistant	Clean any debris and wash. Inform Prod EX if Damaged.	Monitoring record Mixing
Heating Stage of pasteurisation	Insufficient Heating / Survival Of pathogens	(Automatic) Flow diversion to the balance tank by 3 way valve when temperature is below 84 °C	15	79 °C	84 °C	Reading the temperature from the control panel	Each batch	Production assistant	Inform the production assistant for process adjustments unless temperature recovers within few minutes.	Monitoring record - Mixing

Step	Hazard	Control Measure	CCP no	Critical Limits	Operational Limits	Monitoring Procedure	Monitoring Frequency	Responsibility	Corrective Action	Records
Cooling Stage of Pasteurisation	Growth of pathogenic Spores due to slow cooling	Rapid cooling	16	7°C within 1.5 hours from pasteurisation	°C at the outlet from the plate heat exchanger	Reading the value of the outlet thermometer	Each batch	Production assistant	Decrease the chill water temperature. Increase the chill water circulation of the aging vat.	Monitoring record - Mixing
Aging	Growth of Micro organisms due to increased Temperature	Effective temperature control	17	0 °C to 7°C	2 - 4 °C	Reading the value of the Aging vat thermometer	Once every 6 hrs.	Production assistant	Adjusting the chill water supply to the vat.	Aging time/temperature record
Limiting the time allowed for aging	Growth of Pathogenic Micro organisms due to Prolonged aging									

Step	Hazard	Control Measure	CCP no	Critical Limits	Operational limits	Monitoring Procedure	Monitoring Frequency	Responsibility	Corrective Action	Records
Freezing	Contamination with air incorporated in to the ice cream	Filtration of air with microbial filters	19							
Storage	Growth of pathogenic micro organisms due to increased store temperature	Maintaining the store temperatures	20	Below 0 °C	Below -18°C	Reading the value of the store thermometer	Once every 6 hrs	Production assistant	Inform the factory manager for immediate action.	Store temperature record

Process Modification Required
(Introduce air filtration equipment to the freezers)

4.9. Monitoring and Corrective Action procedures

4.9.1. Monitoring and Corrective Action procedures for raw materials

CCP1 Skimmed milk powder (receiving)

Frequency: Each consignment

Procedure: An analysis report of samples of the respective consignment is obtained from an accredited laboratory of the exporting country. In which the tests are carried out according to Sn Lanka standard methods. The report will be compared with Sri Lanka standard values, to check whether it agrees with Sn Lankan standard.

Responsibility: Quality Assurance Manager.

Records: Raw material File SMP

Corrective action: Reject the consignment.

CCP 2 Roasted Cashew nuts (Receiving)

Frequency: Each consignment

Procedure. 2 samples of 500 g should be collected from each 10 bags. The samples should be checked thoroughly one by one for any objectionable physical matter. The bags should be thoroughly shaken

And inspected.

Critical limit: No objectionable physical matter in any of the samples.

Records: Raw material file Roasted Cashew nuts.

Responsibility: Quality assurance Executive.

CCP 3 Pumpkin preserves (Receiving)

Frequency - Each consignment

Procedure. 2 samples of 1 kg should be collected from each 10 bags. The samples should be checked thoroughly one by one for any objectionable foreign matter.

Critical limit: No objectionable physical matter in any of the samples.

Corrective action: Reject consignment

Records Raw material file pumpkin preserves

Responsibility: Quality assurance executive

CCP 4 Receiving Sultan Plums

Frequency: Each consignment

Procedure. Samples of 250 g should be collected from each 10 bags. The samples should be checked thoroughly one by one for any objectionable physical matter. All the polythene bags should be shaken and visually observed.

Critical limit: No objectionable physical matter in any of the samples.

Records: Raw material file sultan plums

Responsibility: Quality assurance executive..

CCP 5 chocolate sauce (Receiving)

Responsibility: Quality Assurance executive

Frequency: Each consignment

Procedure. Samples for each 10 cans should be collected. The samples should be analyzed for the pH value.

Critical limit: pH should be below 4.5

Records: Raw material file Sauces

CCP 6 Straw berry sauce (Receiving)

Responsibility: Quality Assurance manager

Frequency Each consignment

Procedure Samples for each 10 cans should be collected . The samples should be analyzed for the pH.

Critical limit: pH should be below 4.5

Records: Raw material file Sauces

CCP 7 Mango sauce (Receiving)

Responsibility: Quality Assurance manager

Frequency: Each consignment

Procedure 2 Samples for each 10 cans should be collected. The samples should be analyzed for the pH

Critical limit: pH should be below 4.3 and the sugar content 40°.

Records: Raw material file Sauces

CCP8 Chocolate coating(Receiving)

Responsibility: Quality assurance manager

Frequency Each consignment

Procedure. An analysis report is obtained from the manufacturer.

Critical limit : No Salmonella.

Corrective action: Reject consignment

Records: Raw material file chocolate coating

CCP 9 Chocolate Chips (Receiving)

Responsibility: Quality Assurance manager

Frequency: Each consignment

Procedure: The analysis certificate from the supplier

Critical Limit: Absence of salmonella:

Corrective action: Reject consignment

Records: Raw material file Chocolate coating

CCP 10 –plastic packaging materials (Receiving)

Responsibility: Quality Assurance manager

Frequency: Once a year

Procedure: A certificate provided by the supplier, conforming the packaging material is of food grade.

Critical Limit: Absence of migrating/ toxic compounds

Corrective action: Change the supplier/ contact supplier.

Records: Packaging material file - Plastic tubs.

CCP 11 – Receiving plastic packaging materials

Responsibility: Quality Assurance manager

Frequency: Each year

Procedure: Obtain a certificate of the Hygienic manufacture and handling of packaging material

Critical Limit: Certificate accepted

Corrective action: Contact suppliers/ Change supplier

Records Packaging material file- Plastic tubs.

CCP 12- Receiving sticks for chocks

Responsibility: Quality Assurance manager

Frequency: Annually

Procedure: Obtain a certificate from the exporter that The materials are manufactured and handled hygienically.

Critical Limit: Free of coliform organisms.

Corrective action: Contact supplier/change supplier

Records: Packaging material file Ice chock Sticks.

CCP 13 Ice chock Wrapping materials Receiving.

Responsibility: Quality Assurance manager

Frequency: Annually

Procedure: Obtain a certificate from the manufacturer that The wrapping material is made from approved raw material or use for food packaging.

Critical Limit: Use only approved material, QAM Satisfied with the evidence.

Corrective action: Contact supplier/ change the supplier

Records: Packaging material file Ice Chock wrapping material.

CCP 14 - Filtration

Responsibility: The production assistant

Frequency: - At the start of the day's production.

Procedure: Disassemble the filters and check them whether any damage has occurred. And filters are intact

Corrective action: Replace the filters.

Record: Daily CCP monitoring record/ Mix Plant.

CCP 15 Heating and Holding

Responsibility: The production Assistant

Frequency: Each batch

Critical limit: 79°C

Operational limit: 83°C

Procedure: Read the pasteurization temperature from the control panel. The production assistant involved should sign on the chart recorder.

Record: Daily CCP monitoring record Mix Plant.

Corrective action: When the temperature deviates below 83°C the process flow diversion will occur automatically if the flow diversion continues for more than 3 minutes, process

adjustments should be made to increase the extent of heating. Flow diversion can be turned to manual mode to pass the re-circulating mix to aging vats. This is possible only if the pasteurization temperature is higher than the Critical limit (79 °C). In continued situations inform the production executive.

CCP 16 Cooling

Responsibility: The production Assistant

Critical limit: 7°C within 1.5 hours of the heat treatment.

Operational Limit: 4°C when the mix leaves the HTST plant

Monitoring procedure: The mix out temperature should be read from the control panel and the responsible person should sign in the chart recorder for cooling.

Record: Daily CCP monitoring record Mix Plant.

Corrective action: If the chill Water temperature is increased than 2°C, decrease it up to 2°C. Increase the chill water supply to the respective aging vat and cool it as fast as possible.

CCP 17: Aging (Temperature control)

Responsibility: The production Assistant

Critical limit: 7°C

Operational Limit: 2-4°C

Monitoring procedure: The temperature of mix in the vats should be read from the thermometers of respective vat

Record CCP monitoring record Aging.

Corrective action: If the chill Water temperature is increased than 2°C, decrease it up to 2°C Increase the chill water supply to the respective aging vat and cool it as fast as possible

If temperature abused for more than 12 hours consult the Factory manager.

CCP 18 Aging (Time control)

Responsibility: The production Assistant

Critical limit: 72 hours (3 Days)

Operational Limit: 6-8 Hours (2 Days)

Monitoring procedure: Each time the CCP 17 is monitored, the time is also entered in the same record.

Record: CCP monitoring record Aging.

Corrective action: If the critical limit is exceeded, Inform the Production executive./ Factory manager

Discard the vat with his permission.

Do not send the mix for freezing.

CCP 20 Store temperature control

Critical limit: below -18°C

Operational limit : $-25-30^{\circ}\text{C}$

Monitoring procedure: Read the temperature from respective digital thermometers of each cold store.

Record: Finished product store thermometer record.

Responsibility: Production assistant.

4.10. Verification Procedures

4.10.1. Verification procedures for Critical control points of Raw materials

CCP1 Skimmed milk powder

Responsibility: Quality Assurance manager

Procedures: Laboratory analysis of the milk powder samples by Sri Lanka Standards Institution. The test report is obtained.

Frequency: Each consignment

Records: Raw material verification file.

CCP 2 Roasted Cashew Nuts:

Responsibility: Quality assurance Manager

Procedure: Auditing the manufacturing process of the suppliers

Records: Raw material verification file

Records: Raw material verification file.

CCP 3 Pumpkin preserves (Receiving)

Responsibility: Quality assurance manager

Procedure: Auditing the suppliers manufacturing process (As a part of supplier quality assurance)

Records: Raw material verification file.

CCP 4 Sultan Plums

Responsibility: Quality Assurance Manager

Procedure : Auditing the suppliers packing operations.

Records: Raw material verification file.

CCP6,7,8 Sauces for ripple ice cream.

Responsibility: Quality Assurance manager

Procedure: Analyze samples for the presence of Coliform organisms (should be negative), Evaluate the suppliers manufacturing process as a part of supplier quality assurance program.

Records: Raw material verification file.

CCP 9 – Chocolate coating (Receiving)

Responsibility: Quality Assurance manager

Procedure: Analyze samples of chocolate coating by an accredited Sri Lankan laboratory for *Salmonella*.

Records: Raw material verification file.

CCP 10 Chocolate chips (Receiving)

Responsibility: Quality Assurance manager

Procedure: Analyze samples of chocolate chips by a Sri Lankan accredited laboratory for *Salmonella*.

Records: Raw material verification file.

CCP 12 – Plastic Packaging Materials/ Hygienic Quality

Responsibility: Quality Assurance manager

1. Procedure: 1. Audit the suppliers manufacturing process
2. Analyse rinse samples of the packaging materials for the presence of *E.coli* and *Coliform organisms*. Periodically

Records: Raw material verification file

CCP 13. Receiving Wooden Sticks

Responsibility: Quality Assurance Manager

Procedure: Analyse rinse sample: of ice chocks for presence of *coliform*.

Records:

CCP 14 Wrappers for Ice chocks

Responsibility: Quality Assurance manager

Procedure:

Records: Raw material verification file

4.10.2. Verification procedures for the Critical Control Points Of the Process

CCP 15 Heating and holding of the pasteurisation

Responsibility: Quality assurance executive

Procedures

1. Calibration of the digital thermometers Heating and pasteurisation and cooling in the mix plant control panel.
2. Measuring the flow of the plant, and compare it with the capacity, which it is designed for (2000 liters per hour).

Frequency: Once every 6 months.

Records: Process steps verification file.

CCP – 17 No Aging

Responsibility: Quality assurance executive

Procedure

1. Calibrate the aging vat thermometers.
2. Random checking of records.

Frequency -once every 6 months

Records Process steps verification file.

CCP-19 Freezing:

Responsibility:

Procedure:

(The monitoring procedure to be established according to the method of air filtration to be introduced))

CCP 20 - Ice cream store

Responsibility Quality Assurance Executive

Procedure

1. Calibration of the ice cream store thermometers
2. Random checking of the records.

Records Process steps verification file.

4.103. HACCP Plan Validation

Following activities should be carried out to validate the HACCP Plan time to time.

- a. Reviewing of hazard analysis
- b. Reviewing of CCP determination
- c. Reviewing of critical limits based on current scientific information.
- d. Reviewing of audit reports.
- e. Reviewing of changes made to HACCP plan and reasons for that changes.
- f. Reviewing of monitoring and corrective action records.
- g. Reviewing of consumer complains
- h. Reviewing of hygiene and sanitation practices.

4.10.4. HACCP System audits

4.10 HACCP system audits can be carried out as decided by the Management, or as required by the Regulatory bodies in the case of system certification.

4.11 Discussion

Skimmed milk powder (SMP) receiving was considered as a special Critical Control Point although as a raw material : receives the pasteurization treatment. Milk powder is the major food ingredient of ice cream manufacturing process. Therefore if it contains *Salmonella* or any other food borne pathogen there is a potential, that the internal environment of the plant to be contaminated with these pathogens. Therefore it was considered as a special Critical Control Point out of the systematic method of determining CCPs using the decision tree. Monitoring is accomplished by obtaining a certificate of analysis from an accredited laboratory of the

Roasted cashew nuts, sultan preserves and pumpkin preserves are added to the fruit and nut ice cream as additional ingredients. Cashew nuts as a roasted product has very low probability to contain pathogenic micro organisms, unless they are miss handled after the step of roasting. If there was an objectionable foreign matter with cashew nuts it will come already after the step of roasting which, is carried out by the supplier. Therefore objectionable foreign matter was considered as a Critical Control Point while absence from objectionable foreign matter is set as the limit. According to ICMSF 1998, Cashew nuts contain no significant biological hazard.

Supplier's assurance can not be expected with its all elements from small-scale processors. Sample collection and checking should be carried out from each consignment. But efforts should be made to apply the concepts of Supplier Quality Assurance (SQA) also with these suppliers because sample inspection is not a control measure allowed in HACCP. Specifications, supplier audits, and testing can be used with these suppliers although it is impossible to gain a certificate of assurance from them. Same set of monitoring and verification activities is applied to the foreign matter control of the pumpkin preserves.

Sultan plums is a dried sulfured fruit. According to ICMSF (1998) sulphured dried fruits do not contain any significant food borne biological hazard. But they can contain objectionable foreign matter. So objectionable foreign matter in sultan plums was identified as a hazard, which no process step is applied to reduce that hazard to an acceptable level. Therefore at receiving of the raw material the hazard should be controlled. Inspection should be carried out at receiving for any foreign matter. The frequency of inspection should be rather high for sultan plums, as supplier quality assurance is not possible with the supply. But it is recommended to establish a constant and stable supply for this material.

Chocolate coating and chocolate chip resaving is critical as these ingredients are not subjected to a treatment against salmonella within the manufacturing process of the ice cream factory. A certificate of analyses should be obtained from the supplier. Supplier quality assurance is more effective as these ingredients are received from internationally recognized suppliers. Verification should be carried out by periodic analysis carried out by accredited laboratories.

Plastic packaging materials used to pack bulk ice creams should be made of approved plasticizers for food packaging. A report should be obtained from the supplier certifying that the materials are of food grade. A certificate should be obtained annually as a step of verification. Same steps of monitoring and verification should be carried out with the packaging foil used for packing the ice chocks. The sticks for ice chocks should be of good hygienic quality. Vegetable fat, and the stabilizer (dricoid), are not biologically unsafe materials, although they can contain any pathogen by cross contamination, after the step of pasteurization, those hazards will be eliminated.

Cocoa powder as a raw material which can contain salmonella and mycotoxins as hazards. *Salmonella* is eliminated at the step of pasteurization. Effective SQA should be established for cocoa powder with the supplier regarding the control of both salmonella and mycotoxins. Flavors do not contain any hazard as they are in an alcohol base. The safety of colouring materials should be established through a SQA program. Verification is achieved by testing these materials in an accredited laboratory annually.

The sticks used for ice chocks are also not subjected to any treatment before insertion to the ice chock. Supplier quality assurance can be used as the main control measure. A certificate should be obtained from the supplier with each consignment. Verification should be carried out by analyzing the rinse samples of the sticks for Coliforms. Necessarily, they should be free of any *Coliform* organisms.

Filtration (CCP 14) is the Critical Control Point, which remove all un-dissolved solid matter from the ice cream mix. If control is lost at this point it will allow un-dissolved solids with the mix causing them to clog between the plates and creating problems with the homogenizer. However if passed to the ice cream they will be a physical hazard to the consumer. Filters in good order is the critical limit.

Heating and holding stages of pasteurization is the Critical Control Point.

which control all pathogenic and spoilage organisms, which may be included in the raw materials. The critical limit is set at 79°C for 25 seconds. This is the limit specified in India and United States at the temperature for a holding time of 25 Seconds (ICMSF 1998). Sri Lankan Standard for ice cream (SLS 233:1989) specifies a minimum of 79.5°C in a holding time of 15 seconds. As the system is designed for a holding time of 25 seconds, Sri Lankan standard heat treatment could not be adopted. The operating limit was set at 83°C for 25 seconds, the treatment, which the plant is designed for. All above mentioned for standard heat treatments for ice creams are set for ice creams mixes, which can also contain sensitive ingredients like raw milk and raw cream. But as this factory uses medium heat spray dried milk powder and vegetable fat instead of raw milk and raw cream, the potential of microbiological hazards is less compared to above products. There for the established critical limit is safe.

Cooling (CCP) controls the growth of microorganisms that are not killed at the step of heating and holding. The Sri Lankan Standard for Ice Cream) specifies a maximum cooling time of 90 minutes to reach the mix temperature to 7°C. It was adopted as the critical limit. The operating limit was set at 4°C, which the system is designed for its optimum operation. Temperature control and limiting the time of aging is important. Prolonged storage at low temperature can result in spoilage and acidification by Psychrophilic bacteria. Also there is a potential for the growth of *Listeria* if the mix was contaminate after pasteurisation. But the set critical limit prevents the growth of it. Because at 7°C. At 8°C *Listeria* have a Lag period of more than 2-3 Days and a generation time of 12 to 13 hours. At an operating limit of 6 hours it is still safe to use the product although it is accidentally contaminated with *Listeria*. But there is no potential for accidental contamination, as the system is a closed one. At the operating limits of 2-4°C *Listeria* has a lag period of 3 to 8 days with a generation time of more than 24 hours. (Shapton and Shapton 1991) The time limit was set as 3 day maximum assuming the temperature control of the mixes at aging at 2-4 °C. The operating limit. The critical limit (temperature) for aging was set at 7°C (SLS 223).

At freezing air is incorporated in to the mix. In ice cream freezers no air filters are in operation. This feature should be included in to ice cream freezers. Incorporation of unfiltered air does not create and obvious' Hazard but no one can say that it is almost safe.

The critical limit for ice cream storage was set at -18° and the operating limit at -25 to -30°C. Above -18 also there is not a hazard associated with ice cream at the frozen storage. But this limit was chosen due to impractical nature of selecting a limit below -18°C. SLS 223:1889 Specifies a storage temperature of -18°C for ice cream.

HACCP alone can't assure the safety of the products. HACCP requires implementation of accurate practicing of Good Manufacturing Practices (GMPs) or Good

Hygienic Practices (GHPs) that are already implemented by the currently implemented ISO 9002 quality management system is essential. The quality of water used, personal hygiene, pest control, cleaning and disinfection, should be covered under the good manufacturing practices. The management should pay enough attention to these areas.

5. CONCLUSION

All biological hazards were identified in hazard analysis (in form review of incoming materials and evaluation of process steps).

The control measures hazards applied to hazards associated with the ingredients, which are added after pasteurisation, were found as critical control points. The process steps, Mix filtration, pasteurisation, aging, freezing and finished product storage was found to be the critical control points.

Supplier Quality Assurance (SQA) was the main element of controlling hazards, which are associated with raw materials, which are not subjected to treatments against these hazards during the manufacturing process of the factory.

Filters in order for filtration, 79°C for 25 seconds, for pasteurisation, 7°C within 90 min for cooling, 7°C for temperature of Aging, and 72 hrs maximum as the time for Aging was established as critical limits of the manufacturing process. Introduction of air filtration to ice cream freezers was suggested as a process modification to be made. All process step monitoring were designed in a way that it requires only time and temperature measurements to be made, except in the case of the filter inspection.

Activities like Thermometer calibration, obtaining analysis report from accredited laboratories, microbiological analysis were proposed as verification activities.

By properly implementing the HACCP system the factory will be able to assure the safety of its products. Also it requires constant attention of management and all who are involved in the processing operations. HACCP system can be easily coupled with the currently implemented ISO 9002 quality management system. It is of prime importance to continue the Good Manufacturing Practices, which are implemented under the clause Hygiene Practices and House keeping of the ISO 9002 system.

6. References

- 1. Asean Canada fisheries post harvest technology phase-II An introduction to HACCP for fish processors. 2nd ed., Asian Canada Fisheries Post Harvest Technology Phase II. Changi Fisheries Complex, 300 Nicell Drive, Singapore. 498929.**
- 2. Backer H.E, Bassiony, T.A. and Terplan, G.(1989). Incidence of Bacillus Cereus in infant foods and dried milk powders. International J. of Food Microbiology,23,1-15**
- 3. CAC /RCP-1 1969, Rev 3 (1997) Recommended Code of Practices – General Principles of Food Hygiene, The Codex Alimentarius Commission Rome.**
- 4. Chesworth N, (1997) Food Hygiene Auditing,1st ed, Balckie Academic and Professional, London.**
- 5. Doyle, M.P., Meske L.M., Marth E.H.,(1985) survival of *Listeria monocytogens* during the manufacture and storage of Non fat dry milk. J of Food Protection, 48,740-2**
- 6. FAO Of The United Nations (1998) A Training Manual on Food Hygiene and Hazard Analysis Critical Control Point System. F.A.O.of the United Nations, Rome.**
- 7. Georgala,D.L. Hurst,A. (1963) Survival Of Food Poisoning Bacteria on Frozen food.**
- 8. Hobbs B.C. Roberts,D. Food Hygiene and Food Poisoning 6th Ed. (1998), Arnold International, 338, Eston Rd. London.**
- 9. ICMSF(1998), Micro organisms in Foods-6, Microbial Ecology of Food Commodities, International Commission for Microbiological Specifications of Food.**
- 10. Jay,J.M.(1992) Modern Food Microbiology 4th Ed.(1st Indian Ed) CBS Publishers and Distributors, New Delhi, India.**

11. Kozak, J., Balmer T, Byrne, R and Fisher K. (1988). Prevention of *Listeria Monocytogenes* in Foods-Incidence In Dairy Industry, Food Control 7, 215-21
12. Mortimore S. and Wallece C. (1992) HACCP A PRACTICAL approach. 1st Ed, Chapman and Hall, 2-6, London.
13. Natarajan A.M., Nambudripad p. (1980) Microbial contamination from Ice Cream containers, Indian J. of Dairy Science., 33,4, 500-503.
14. Rothwell J. (1985) Microbiology of Frozen Dairy Products in Microbiology of Frozen Foods (Ed, R.K.Robinson) Elsevier applied Science Publishers, New York.
15. Ruysr E.T., Maryth E.H.(1991) *Listeria Listeriosis* and Food Safety, Marcel Decker Inc, New York
16. S.L.S.I.(2000) HACCP System, (Hazard Analysis Critical Control Points) Sri Lanka Standards Institution , Colombo.
17. Shapton D., Shapton N. (1991) Safe Processing of Food, Butterworth – Heinemann Ltd., Oxford.
18. SLS:223 (1989). Specifications For Ice Cream, Sri Lanka Standards Institution, Colombo.
19. Thompson S.S., Harmon.L.G, Stine C.M. Survival of Selected organisms during Spray Drying of skimmed milk and storage of Non fat Dry milk. J. fo Food Protection., 41,16-19
20. Umoh, V.J., Obawade, K.S. and Umoh, J.U.(1985). Contamination of Infant Powdered Milk within use with enterotoxigenic *Staphulococcus* . Food Microbiology, 2,255-61.