

A HACCP STUDY ON YOGHURT MANUFACTURE

by

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DECLARATION

The work described in this dissertation was carried out by the author in the Department of Operations & Quality Management, Faculty of Commerce, from 11 September 2001 to 15 October 2004 under the supervision of Dr J F Mostert.

These studies represent original work by the author and have not been submitted in any form to another Tertiary Institution. Where use is made of the work of others, it has been duly acknowledge in the text.

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ABSTRACT

The increasing awareness and demand of consumers for safe and high quality food have lead many companies to undertake a comprehensive evaluation and reorganisation of their food control systems in order to improve efficiency, rationalisation of human resources and to harmonise approaches. This evaluation in food control systems has resulted towards the necessity to shift from the traditional approach that relied heavily on end-product sampling and inspection and to move towards the implementation of a preventative safety and quality approach, based on risk analysis and on the principles of the hazard analysis critical control point (HACCP) system. Yoghurt is the most popular fermented milk world-wide; the estimated annual consumption in South Africa amounts to nearly 67 million litres. The aim of this study was to implement a HACCP program in a commercial yoghurt factory and then to evaluate the program during certain critical stages of the manufacturing process.

A HACCP program was successfully implemented in a large commercial yoghurt plant within a one year period, using the SABS 0330:1999 Code of Practice, as a basis. The program was implemented within the framework of all applicable laws, by- laws, regulations and compulsory specifications. Management gave their support and provided the necessary resources for the implementation of the HACCP program. This was one of the key factors for the successful implementation of the program. The team members, selected by management, established, communicated and implemented the policies, procedures and systems. All hazards associated with each step in the process, and all measures that controlled each hazard, were documented. A proper record keeping system for the verification of all HACCP procedures, process monitoring records and corrective action records were also established. The identification of the critical control points, as well as the keeping of records, played a major role determining the validity of the HACCP plan and also to prove that the products were produced safely. In this study, the presence of antibiotics, and foreign material in raw milk, effective pasteurisation and homogenisation, as well as maintaining the correct fermentation temperature, were identified as critical control points.

Eight thousand five hundred and forty analyses were performed microbiologically, chemically and physically in total. Microbiologically and chemically there was a positive impact on the

raw milk quality after the implementation of HACCP. This was due to stricter controls in terms of GMPs, GLPs , GHPs and CCPs. From the results obtained on the final product evaluation, it is evident that the tighter controls that were implemented impacted positively on the chemical properties of the product in terms of percentage total solids as well as the viscosity and also on the microbiological quality of the product in terms of the yeast and mould counts. This has also contributed to a decrease in the number of customer complaints especially with regard to viscosity and souring of the product.

The study also emphasized that the required disciplined approach is best provided by the HACCP procedure applied as an integral element of total quality management principles, which include (GMP, GHP, GLP and document control (e.g., ISO 9000 Quality Systems). Total quality management (TQM) embracing HACCP and document control formed an important framework within which quality requirements could be communicated effectively and in a way that could be demonstrated and audited.

This study showed that there is certainly a link between implementing a formalised system such as HACCP, and the outcomes of both in-process testing and analysis, and final testing and analysis, which will significantly impact on reducing the number of customer complaints and, more importantly, the risk to the customer that could be posed by the product. This decrease in the risk to the customer will also contribute to minimising the liability of the company in terms of legal, social, financial, image and other factors that contribute to the success of any company

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LIST OF ABBREVIATIONS

approx.	approximately
AOAC	Association of Official Analytical Chemists
ATP	Adenosine-5-triphosphate
β	Beta
CCP	Critical Control Point
CCPs	Critical Control Points
°C	Degree Celsius
CP	Control Point
CPs	Control Points
DVI	direct-to-vat inoculation
EEC	European Economic Countries
e.g.	for example
etc.	etcetera
FAO	Food and Agricultural Organisation
GATT	General Agreement on Tariffs and Trade
GMP	Good Manufacturing Practice
GLP	Good Laboratory Practice
GHP	Good Hygiene Practice
HA	hazard analysis
HACCP	Hazard Analysis and Critical Control Point
IDF	International Dairy Federation
i.e.	that is
ISO	International Standards Organisation
min.	minutes
NCD	National Co-operative Dairies
no.	number
%	percentage
pH	hydronium ion concentration
QA	Quality Assurance
QC	Quality Control

SABS	South African Bureau of Standards
subsp.	subspecies
S.A.	South Africa
TQM	Total Quality Management
UHT	Ultra High Temperature
WHO	World Health Organisation

GLOSSARY

control: To take all the actions necessary to ensure and maintain compliance with the criteria established in the HACCP plan.

control measure: Any action that can be used to prevent or eliminate a food safety hazard.

corrective action: Any action taken to eliminate the cause(s) of an existing non-conformity, defect or undesirable situation in order to prevent its recurrence.

critical control point (CCP): A point, step or procedure at which control can be applied and a food safety or suitability hazard prevented, eliminated or reduced to an acceptable level.

critical limit: A value that separates that which is acceptable from that which is unacceptable.

decision tree: A sequence of questions applied to each step in the process in respect of an identified hazard to identify which steps are CCPs.

deviation: The failure to meet a critical limit.

Good Manufacturing Practice (GMP): The combination of manufacturing and quality procedures aimed at ensuring that a product is consistently manufactured to its specification.

HACCP study: The process of applying the stages used to design the HACCP system.

hazard: The potential to cause harm to, or affect, the safety of the consumer.

hazard analysis: The process of collecting and evaluating information on hazards and on conditions leading to their presence in order to determine which ones affect food safety and are therefore to be included in the HACCP system.

hazard analysis critical control point (HACCP) system: A system that identifies, evaluates and controls hazards that are significant to food safety.

monitor: To conduct a planned sequence of observations or measurements of critical limits to assess whether a CCP is under control.

record: A document that provides objective evidence of actions undertaken or results achieved.

risk: An estimate of the probability of the occurrence of a hazard or other non-conformity.

step: A point, procedure, operation or stage in the food processing/production chain, from primary production to final consumption.

validation: The obtaining of evidence that the particular requirements of the HACCP plan are effective.

verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with the HACCP plan.

CHAPTER 1

INTRODUCTION

Yoghurt is a milk product obtained by the fermentation of milk by the action of symbiotic cultures of *Streptococcus thermophilus* and *Lactobacillus delbrueckii* subsp. *bulgaricus* and resulting in reduction of pH with coagulation. These starter micro-organisms are normally viable, active and abundant in the product to the date of minimum durability. If the product is heat-treated after fermentation the requirement for viable micro-organisms does not apply (FAO/WHO, 2002).

Yoghurt is the best known of all fermented milk products and the most popular almost all over the world. Yoghurt was, reportedly, first manufactured in South Africa in the mid – 1950's (Clover S.A., 1999) in Durban (Clover Dairies (Pty) Ltd), Pietermaritzburg and Mayfair (NCD), Johannesburg (Hall, 2004). It was initially produced in half pint glass bottles and the inoculated yoghurt milk incubated in water at the desired temperature and after fermentation, cooled with chilled water (Hall, 2004). Since then, and especially during the last two decades, the production and consumption of yoghurt is steadily growing in South Africa. The annual consumption of yoghurt in 2002 / 2003 amounts to nearly 67 million litres, which represents an increase of 10%, compared to the consumption during 2001 / 2002 (Coetzee, 2004a). The demand for yoghurt is also illustrated by the fact that nearly 45 000 litres of yoghurt has been imported between January and October 2003 (Coetzee, 2004b). It is estimated that the market share for yoghurt in South Africa is R1003 million annually.

The quality of yoghurt, or any food product, can be defined against a wide range of criteria, including for example, the chemical, physical, microbiological and nutritional characteristics. Food or dairy manufacturers aim to ensure that the safety and quality of their products will satisfy the highest expectations of the consumers. On the other hand, the consumers expect to a great extent, unconditionally, that the manufacturer has ensured that the product:

- is safe for human consumption with respect to both chemical and microbial contamination;

- conforms to any regulations enshrined in law, or statutory requirements laid down by health or local authorities;
- is capable of achieving a specified shelf-life without spoilage; and
- has the highest possible organoleptic standard that can be achieved within the existing constraints of manufacture or marketing (Tamime & Robinson, 1999).

The most important raw material used in yoghurt manufacture is milk. Milk, in addition to being a nutritious medium, presents a favourable physical environment for the multiplication of micro-organisms and being an animal product is subjected to widely differing production, handling and processing methods, results in its contamination by a broad spectrum of microbial types, chemical residues and cellular material (Gilmour & Rowe, 1990). The overarching principles applying to the production, processing, manufacture and handling of milk and milk products, including yoghurt, are:

- From raw material production to the point of consumption, all dairy products should be subject to a combination of control measures. Together, these measures (good agricultural practice – GAP and good manufacturing practice GMP) should meet the appropriate level of public health protection.
- Good hygienic practices should be applied throughout the production and processing chain so that the milk product is safe and suitable for their intended use.
- Wherever appropriate, hygienic practices for milk and milk products should be implemented following the Annex to the *Codex Recommended International Code of Practice – General Principles of Food Hygiene* (IDF/FAO, 2004).

According to Tamime & Robinson (1999) the successful manufacture of yoghurt is enshrined in two compatible and, to some extent, overlapping concepts – GMP and the hazard analysis critical control point (HACCP) system. The starting point is that the product has to conform to specific legislative regulations and the manufacturer must be able to demonstrate that compliance with the regulations is being achieved in actual practice. The key word is, demonstrate, for while it is anticipated that any manufacturer can produce a faulty batch of produce, what the same

manufacturer must be able to show is that the fault arose despite due diligence being shown by all concerned. It was this blanket responsibility that gave rise to the HACCP concept, and the basic principles of the system are now widely accepted as the basis for responsible operation of a factory (Tamime & Robinson, 1999). The focus is on preventing a problem rather than solving it after it has occurred.

The HACCP system offers a structured approach to the control of hazards in food processing and, properly applied, identifies areas of concern and appropriate control measures before product failure is experienced. It represents a shift from retrospective quality control through end-product testing to a preventative quality assurance approach. End-product testing against microbiological criteria is shifted to the role of verification in a HACCP program (Jervis, 2002).

As the South African consumer is focusing more towards health and well-being, the volume of yoghurt consumption is steadily increasing. It is therefore of importance that the manufacturer can assure that this food is safe and of consistent high quality. During manufacturing there are certain stages where there is a potential for, especially microbiological and foreign object, contamination. This could have a negative impact on the quality and image of the product. To address these issues the implementation of a system based on technical and scientific principles, such as HACCP, is crucial.

The overarching objective of this study is to contribute towards improving the safety and quality of yoghurt in South Africa. The specific aims are:

- to implement a HACCP program in a commercial yoghurt factory, and
- to evaluate the HACCP program during certain stages of the yoghurt manufacturing process.

To our knowledge, no studies have been conducted in this field in South Africa. This research is therefore important and could form the basis for a reference to this subject based on local South African conditions, and it could also be a benchmark for the yoghurt industry.

CHAPTER 2

LITERATURE REVIEW

2.1 Background

Yoghurt is an acidified, coagulated product obtained from milk by fermentation with lactic acid producing bacteria. Of all cultured milk products, yoghurt is the most well known and most popular worldwide (Early, 1998). The culinary art of yoghurt making originated thousands of years ago. It is likely, however, that the origin of yoghurt was the Middle East, and the evolution of this fermented product through the ages can be attributed to the culinary skills of the nomadic people living in that part of the world. Although modern large-scale production is designed to handle thousands of litres per day, using highly sophisticated technology with mechanisation and automatisisation, the basic principles underlying the manufacturing process, have altered little with time (Tamime and Robinson, 1999). In recent years it became increasingly important, for various reasons, to manage and control all the elements of food manufacturing processes. One approach in this regard, that is well established and implemented world-wide is the HACCP system (Tamime et al., 2002).

Flavour, texture and aroma of yoghurt vary dependent upon country of origin (as well as other factors including raw material formulation and manufacture process). In some areas, yoghurt is produced in the form of a highly viscous liquid, whereas in other countries it takes the form of a softer gel. Yoghurt is also produced in a drinking form and can be frozen or blended with other ingredients to create, for example, mousse type products, sorbet, yoghurt ice-cream or other forms of dairy dessert (Early, 1998).

The initial popularity of yoghurt in Western Europe owed much to the work of the Russian bacteriologist and 1908 Nobel Prize Laureate, E. Metchnikoff, who at the turn of the century studied the bacteria used to produce yoghurt. In his book *The Prolongation of Life*, written in 1907, he attributed the good health and longevity of Balkan peasants to the effects of certain bacteria in the yoghurt they consumed. He postulated the theory that prolongation of life would follow ingestion of a lactic acid bacterium named as Bulgarian bacillus. The presence of this organism in yoghurt was supposed to inhibit the growth of putrefactive organisms in the intestine.

The Bulgarian bacillus is, in fact, *Thermobacterium bulgaricum*, later designated as *Lactobacillus bulgaricus* (currently known as *Lactobacillus delbrueckii* subsp. *bulgaricus*) (Tamime and Robinson, 1999).

Yoghurt is a very nutritious food and its continued consumption in the Western World owes much to the development of its health food image (Early, 1990). Consumption of yoghurt is highest in countries around the Mediterranean, in Asia and in Central Europe (Bylund, 1995).

The methods of production of yoghurt have, in essence, changed little over the years and although there have been some refinements, especially in relation to lactic acid bacteria, that bring about fermentation, the essential steps in the process are still the same, namely:

- raising the level of total solids in the process milk to around 14 – 16 g / 100 g;
- heating the milk, ideally by some method that allows the milk to be held at high temperature for a period of 5 – 30 min; the precise time will depend on the temperature selected;
- inoculating the milk with a bacterial culture in which *Lactobacillus delbrueckii* subsp. *bulgaricus* and *Streptococcus thermophilus* are the dominant organisms;
- incubating the inoculated milk, in bulk or retail units, under conditions that promote the formation of a smooth viscous coagulum and the desired aromatic flavour/aroma;
- cooling and, if desired, further processing, e.g. the admixture of fruit and other ingredients, pasteurisation or concentration; and
- packaging for distribution to the customer under chilled conditions.

At present there are many different types of yoghurt produced worldwide, and Tamime and Deeth (1980) have proposed a scheme of classification that separates all types of yoghurt into four categories based on the physical characteristic of the product. However, these products and in particular yoghurt are subdivided into different groupings based on the following aspects (Tamime and Robinson, 1999):

- legal standards (i.e. existing or proposed) to classify the product on the basis of chemical composition or fat content (full, semi-skimmed/medium or skimmed/low fat);
- physical nature of the product, i.e. set, stirred or fluid/drinking; the latter is considered

- stirred yogurt of low viscosity;
- flavours (plain/natural, fruit or flavoured; the latter two types are normally sweetened); and
- post-fermentation processing (vitamin addition or heat treatment).

Variations in milk composition, irregular behaviour of the starter organisms, faulty regulation of the incubation temperature, along with a number of other process variables, can all give rise to an end product that is deficient in respect of overall quality, and only a thorough understanding of the fermentation can provide an operative with foresight to reduce risk of product failure (Tamime and Robinson, 1999).

2.2 Process control and management tools

2.2.1 Process control

Process control can be defined as the management of all elements of a process that control the legality, safety, contractual, and commercial requirements of the product. The scope is, therefore, from farm to consumer and embraces raw materials, formulation, bacteriocidal or bacteriostatic treatments, plant and equipment hygiene, personnel practices and hygiene, packaging, distribution conditions, and consumer use (Jervis, 2002).

Historically, process requirements have evolved on a basis of need to respond to incidents of product failure and changing marketing criteria. Pasteurisation of drinking milk was, for example, introduced in the 1930's to address public health risks associated with changing patterns of milk distribution in cities. Global incidents of outbreaks of milk-borne disease in humans with "traditional" pathogens, the reality of various new emerging pathogens and the increased importance of bio-security have resulted, for example, in stricter control of plant and environmental hygiene, enhancement of process control to minimise risks and to review current process control parameters. In parallel with the emergence of public health failures has been the trend towards novel and efficient processes, changes in formulations to reduce manufacturing costs per unit of product by increased through-put on high capital plant, and the use of cheaper ingredients more likely to be obtained on a global basis. There has also been an ongoing trend towards healthier foods - for example, lower fat, less salt, and the elimination of preservatives. These factors, together with the commercial demand for longer shelf - life to accommodate

consumer shopping patterns and reduce distribution costs, can have a significant effect on the microbiological stability of products. Clearly, process control requirements need to be constantly reviewed and amended to accommodate change, and this should be done using a disciplined and documented approach that is amenable to constant review (Jervis, 2002).

Proper attention to such a broad scope requires a disciplined and documented approach. It is widely accepted in the food and dairy industry that the required disciplined approach is best provided by the HACCP procedure applied as an integral element of total quality management (TQM) principles, which include good manufacturing practice (GMP), good hygiene practice (GHP), and document control (e.g., ISO 9000 Quality Systems). HACCP is an internationally accepted hazard management tool that can be applied to all stages of food manufacture from farm to consumer. Figure 2.1 shows an integrated approach to the application of process control.

2.2.2 Total quality management

Total quality management schemes address the approach that a manufacturing organisation needs to take to ensure product quality. They aim to involve every member of the organisation in the achievement of management objectives to produce safe, wholesome food, enhance customer satisfaction and confidence, and identify means of ongoing improvement. The fundamental requirements of the TQM approach are communication at all levels, so that process and product requirements can be translated from the corporate quality statement to the operatives running the process. TQM schemes embracing HACCP and document control form an important framework within which quality requirements can be communicated effectively and in a way that can be demonstrated and audited. The overall approach is summarised in Figure 2.2 (Jervis, 2002).

2.2.3 Risk analysis

Risk analysis is a structured and formalized approach to quantifying risk and setting levels to which casual agents should be controlled to assure safety. Risk analysis has three components: risk assessment, risk management, and risk communication. Microbiological risk analysis protocols are being addressed internationally and at national levels, and they are becoming a key element in determining the level of consumer protection (Jervis, 2002). HACCP, correctly integrated into a total quality management scheme is normally the preferred risk management tool (Figure 2.3).

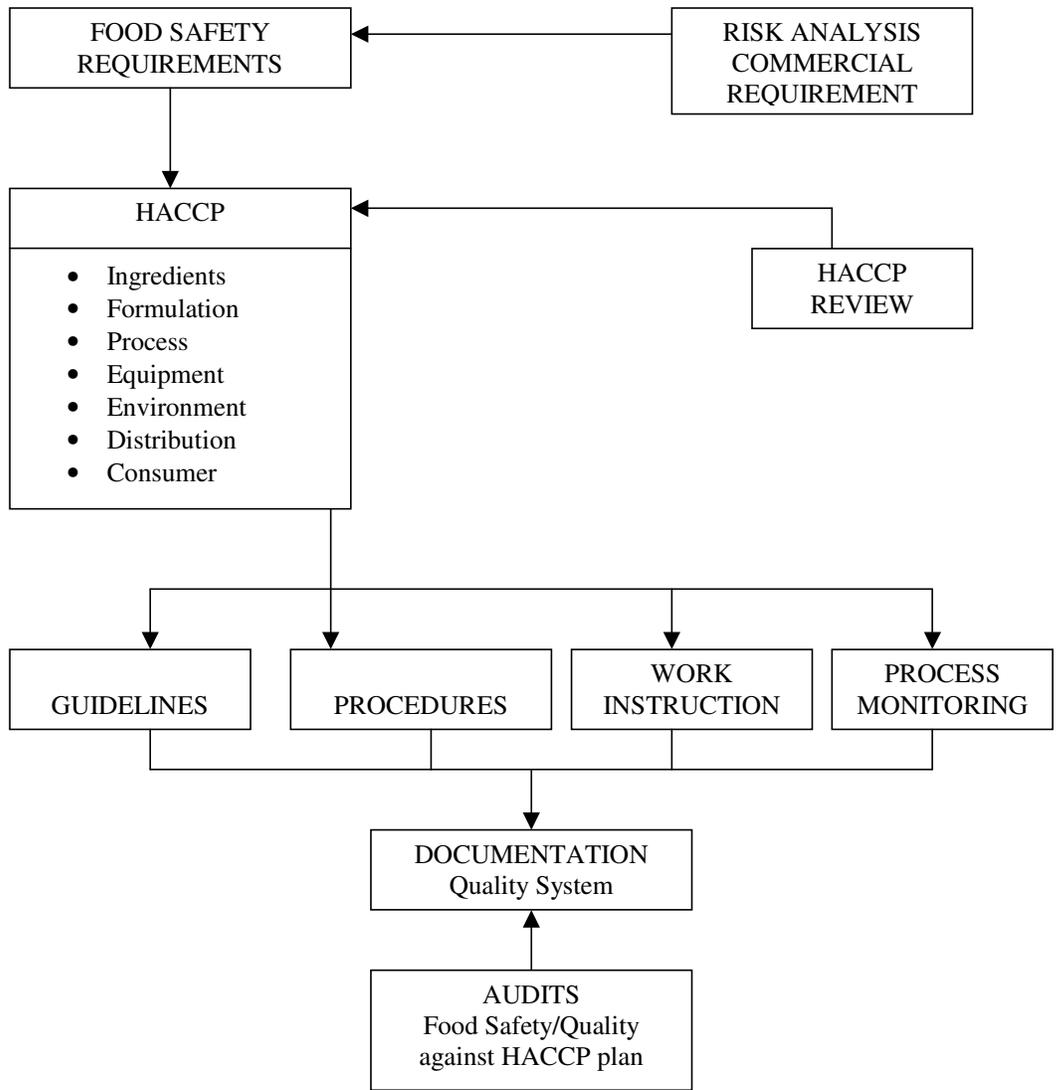


Figure 2.1 Schematic diagram of an integrated approach to the application of process control (Jervis, 2002).

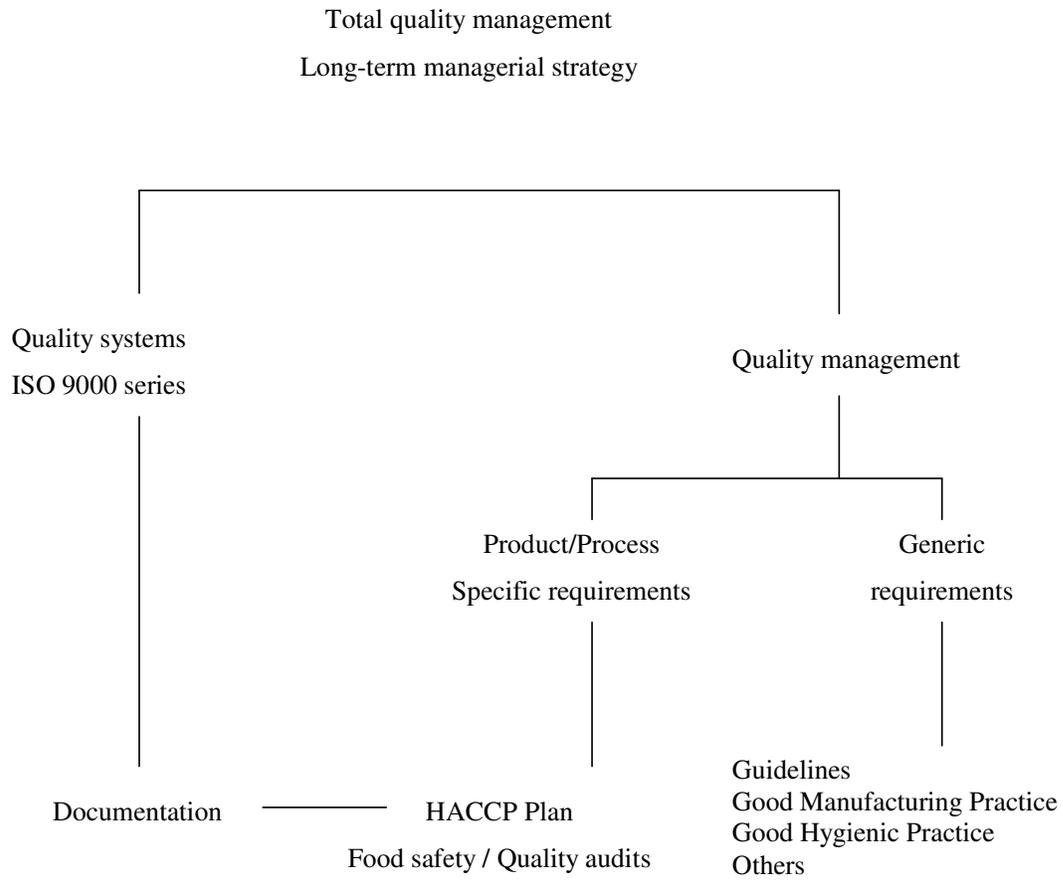


Figure 2.2 The elements of total quality management (Jervis, 2002).



Figure 2.3 Food safety objectives as the link between risk analysis and food management (Jervis, 2002).

2.2.4 HACCP

The HACCP system offers a structured approach to the control of hazards in food processing and, properly applied, identifies areas of concern and appropriate control measures before product failure is experienced. The application of HACCP is systematic because structured hazard analysis and implementation are provided. The process is also logical in that each processor understands its own operation and is able to assess controlling the specific process optimally (Jervis, 2002).

2.3 The hazard analysis critical control point system

The origins of HACCP are traced to the 1960's and the United States of America when the Pillsbury Company, the United States Army Laboratories at Natick, and the National Aeronautics and Space Administration collaborated to develop the system as a means of managing safe food production for manned space flights. The outcome was the HACCP concept, which has been adopted and developed to its current status as the food safety management tool recommended by the Codex Alimentarius Commission to advise on consumer protection under Sanitary and Phytosanitary Measures (1994) agreed at the Uruguay round of GATT negotiations. As such, HACCP is a reference point in international trade disputes, and it is increasingly enshrined in national legislation.

The HACCP procedure is generally targeted at food safety management (pathogenic micro-organisms and their toxins), but, as an approach in the context of broader quality management, it can be effectively applied to microbiological spoilage, foreign-body contaminations or pesticide contamination. It is preferable to conduct a HACCP program with a narrow scope (a single pathogen or possibly pathogens) rather than attempt to cover an extended list of hazard areas when documentation will become complex. However, an experienced team might choose to cover the whole spectrum of hazard areas, depending on (a) the resources available to produce and maintain a composite HACCP plan and (b) the way in which it is to be incorporated into the local quality plan and quality system (Jervis, 2002).

2.3.1 Principles of HACCP

In theory, the only way of ensuring that every package of yoghurt from a given production line is safe, from a chemical or microbiological standpoint, is to test every package. Clearly, such a suggestion is totally impractical, so that instead, a representative group of packages is withdrawn against a sampling plan appropriate for the product and the history of the plant. However, whilst this approach is essential to confirm that preset standards of hygiene are being met and that potential contaminants are at a low level or absent, the procedure can never prevent some spoiled packages from reaching the consumer. Consequently, the emphasis within quality assurance has turned to the avoidance of problems, a concept that forms the basis of HACCP. In particular, the system identifies seven aspects of production that merit constant attention and these aspects are enshrined in seven principles (Tamime and Robinson, 1999).

First – any potential hazards associated with yoghurt production from the collection of raw materials through to manufacture and distribution must be identified and an assessment made of:

- the likelihood that a given hazard will arise; and
- the preventative measures that are necessary to reduce any inherent risks.

Second – the precise points in the above sequence that can be controlled in order to eliminate a hazard or minimise the risk of occurrence must also be identified. If failure to control a particular hazard is a risk to public health, then the step in the process is regarded as a critical control point (CCP); if no major risk is involved, the step may be identified as a control point (CP). For example, the filling machine is a CCP, because contamination with a pathogen could present a direct risk to the consumer, whereas the failure to empty a waste bin in the same area could be treated as a CP because, however undesirable with respect to the growth of potential spoilage organisms, the failure is not likely to result in a consumer health problem. Similarly, it is important that a manufacturer has control over the chemical composition of yoghurt and the details on the label, but again such points need only be graded as CPs.

Third – there must be an established set of targets which must be achieved in order for a Section to claim control over a CCP/CP, e.g. total colony counts on product contact surfaces (CCP) or the viscosity of stirred yoghurt with agreed tolerances (CP).

Fourth – a monitoring system must be established to record the particular facets of production that are under control.

Fifth – if the monitoring procedure indicates that a CCP/CP is not under control, then an agreed program of corrective action must be capable of immediate implementation.

Sixth – there must be procedures for verification that the HACCP system is working throughout the factory, e.g. the introduction of supplementary checks to ensure that the principal components of the system are operating to the required standard.

Seventh – a system of documentation must be in place that records accurately the details of all operations, e.g. times/temperatures and microbiological parameters, but also the responsibilities of the individual operators associated with that specific section of the process.

In any HACCP system it is vital that the different stages, within each principle, be considered in order and that the required information and conclusion be completed for each stage before moving on to the next. HACCP is designed as a structured approach, and the proper sequencing of activities is crucial to obtain an effective output. The seven HACCP principles and fourteen sequential stages are outlined in detail by Jervis (2002) and will be referred to in 2.3.3.

2.3.2 Benefits of HACCP

The key benefits of HACCP in the food and dairy industry are many, and can be summarised as follows:

- HACCP has the potential to identify all hazards in the manufacturing process so that controls can be established to assure food safety/quality.
- HACCP is a systematic approach relevant to all stages of food processing covering agriculture and horticultural practices, harvesting, processing, product distribution, and customer practices.

- HACCP is the preferred risk management tool in total quality management.
- HACCP focuses technical resources on critical parts of the process and provides a cost-effective control of food-borne hazards.
- HACCP facilitates the move from retrospective end-product testing to a preventative quality assurance approach enabling the manufacturer to get it right the first time and reduce reject waste.
- HACCP recognized and promoted by international bodies (such as the Codex Alimentarius Commission) as the system of choice for ensuring food safety and is becoming enshrined in national legislation. Proactive application in the food industry will facilitate compliance with developing legislation and demonstrates a diligent approach to food safety (Jervis, 2002).

2.3.3 Application of HACCP

This section addresses in detail what needs to be done at each of the HACCP stages, and it refers to generic flow diagrams and HACCP plan records that have been produced in order to illustrate the points made. It is essential that each HACCP study be based on the specific process and product details, and generic plans should never be adopted as a shortcut to save time and resources. The different sequential stages are as follows (SABS, 1999; Jervis,2002).

Stage 1: Define terms of reference

Terms of reference should clearly define the scope of the intended HACCP study and address the following points:

- the product to be considered;
- the process site and, if relevant, the process line within that site. It is not advisable to group together apparently similar products and processes where what might be minor variations in formulation and/or process conditions could significantly change the preservation characteristics of the product;
- what the study will cover - biological, chemical, or physical hazards (or combinations of these) - and whether the study will be limited to food safety considerations or cover broader quality issues (i.e., spoilage). The study will proceed more quickly if the terms of

reference are limited to biological food safety issues, or even the consideration of one pathogen relevant to the food; and

- the point in the process at which safety or other quality attributes are to meet: at point of manufacture or at point of consumption?

Stage 2: Select a HACCP team

It is important that senior management in the company be made aware of the resources necessary to carry out an effective HACCP study (personal time, appropriate meeting room, secretarial support, and the need to consult outside resources for information) and are committed to providing these resources. The time required to complete the study will depend on the complexity of the process and the terms of reference agreed as Stage 1. If resources cannot be assured to meet the study defined in Stage 1, then the study should not be progressed. HACCP requires a multidisciplinary approach, and the HACCP team should include the following skills:

- a quality assurance/quality control specialist who understands the hazards and risks for the product and process under study. Depending on the study terms of reference, this might involve a microbiologist or chemist; and, if this resource is not available in-company, consultation with an external resource might be necessary to obtain information relating to microbiological risk and hazards;
- a production specialist to contribute details of what actually happens on the production line throughout all shift patterns;
- an engineer to provide information on (a) the operating characteristics of the process equipment under study and (b) the hygienic design of equipment and buildings; and
- others co-opted onto the team as necessary. These might include specialist equipment operators, hygiene manager, ingredient and packaging buyers, and distribution managers. It might also be appropriate to consider co-opting specialist technicians from companies to which various scheduled maintenance and calibration functions are contracted (e.g., temperature measurement equipment, pasteurizer plate and jacketed silo integrity, clean-in-place systems).

An individual experienced in HACCP should be nominated as chairman to be responsible for managing the study. The chairman should have received training in the principles of HACCP and

be experienced in HACCP team work. While HACCP team members will be selected for their specialist knowledge, it is important that they will also have a working knowledge of the HACCP procedure so that they can contribute effectively to the study. Team members may need some training before commencement of the study, and this can be provided either internally by the HACCP team or externally.

It is important that a HACCP team member or co-opted person is identified to keep notes as the work progresses and from which both the HACCP plan and the HACCP study notes can be derived. HACCP study notes should record background information and the basis for conclusions reached in sufficient detail to be helpful when the HACCP plan is reviewed. The HACCP study notes might also be used as background information in trouble-shooting in the event of product failure or inadequate outcome from the verification program.

Stage 3 : Describe the product

The product under study should be fully described. This stage often tends to be inadequately covered, but diligent attention to detail here is crucial to the identification of hazards. The product description should be considered against the following headings and recorded as HACCP study notes:

Composition. All factors that might influence the preservative characteristics of the food should be recorded. Basic compositional data should be noted including that on solids/moisture levels, fat levels, type of preservative, if used, etc. Compositional data should also be recorded for any additives used, particularly where these are supplied as fresh, hydrated materials.

Processing. All relevant processing parameters should be recorded. They should be validated as giving the required effect with respect to micro-organisms of concern and the appropriate operating conditions recorded at this stage in a HACCP study.

Packaging system. The type of packaging should be noted. This note will include differentiation between shrink wrapping, vacuum packing, and sealed plastic tub packing. Aseptic or ultra clean packaging regimes should also be noted where appropriate. In the context of dairy products, it is useful to record the conditions of storage of intermediate stages of production. The degree of

exposure to the process plant environment during filling should also be recorded.

Storage and distribution conditions. The storage temperature regimes (ambient, chilled, and frozen) throughout the product shelf life should be recorded where possible, and this should include anticipated variations (e.g., retail display, customer's shopping bag, and home storage conditions).

Required shelf life. The total shelf-life requirement together with "life after opening," where appropriate, should be recorded.

Instruction of use. Dairy products are usually consumed without further processing (heating), so that this section should record instructions given with regard to refrigerated storage (where appropriate) and 'use within' times, after opening, together with overall "use by or best before" dates.

Stage 4: Identify intended use

The consumer target group for the product should be noted. This will range from suitable for all consumer groups.

Stage 5: Construct a flow diagram

The purpose of a flow diagram in a HACCP study is to elicit a thorough examination of the process, which is recorded in a way that assists and directs subsequent stages. There is no specified format to be used in HACCP flow diagrams, but they should sequentially set out all steps in the process together with relevant technical data. Consideration should be given to the following:

- the sequence of all process steps within the scope or the study including rework/recycle loops;
- interaction of services (e.g., cooling water, air, compressed air, clean-in-place systems);
- temperature/time history for all raw materials, intermediate products, and final products within the scope of the study, together with microbiological and analytical data with appropriate floor plans and equipment;

- equipment design with particular attention to ease of cleaning and presence of void spaces that might accumulate contamination; and
- personnel and hygiene disciplines.

Stage 6: On-site confirmation of flow diagram

The flow diagram produced at Stage 5 should be confirmed, on site, by the HACCP team. Points to be confirmed are that any effect of shift patterns and weekend working are included on the flow diagram, together with circumstances of any reclaim or rework activity that might be introduced from time to time. If the HACCP study is being applied to a proposed new process line/product, flow diagram confirmation will not be possible. In this case the HACCP plan can be completed, but it must be subject to review as the line/product is finalised.

Stage 7: List all potential hazards associated with each process step, conduct a hazard analysis, and consider and measures to control the identified hazards

This is the final stage in HACCP Principle 1 (Conduct a hazard analysis), and it should be emphasised that no attempt should be made to pre-empt HACCP Principle 2 without considering the critical control points. Stage 7 consists of three parts: listing hazards, conducting a hazard analysis and identifying control measures.

List all potential hazards. The flow diagram (Stage 5) and the product description (Stages 3 and 4), should be used to list all potential hazards relevant to the terms of reference of the study (Stage 1). This activity should involve all disciplines in the HACCP team (QA/QC, production, engineering) in a “brainstorming” session that identifies all actual and potential hazards. It is important that the following areas are considered:

- hazards in raw materials;
- hazards introduced during the process (cross-contamination, factory environment, equipment design, equipment cleaning, and introduction by process air or personnel);
- hazards that survive the process steps; and
- the microbiological stability of the product during distribution and in the home.

In these considerations, the intrinsic factors of the product (e.g., pH, structure, preservatives, temperature) will be important from the point of view of both (a) the lethal effect of a heating or other process and (b) the way in which the potential for pathogen multiplication might occur before consumption. It is emphasised here that all potential hazards should be listed. This requirement should not be undermined by the concept of Prerequisite Programs that is being developed by Codex Alimentarius and actively applied in some cases.

Hazard analysis. The process of collecting and evaluating information on hazards and conditions leading to their presence and to decide which are significant within the scope of exercise should be addressed in the HACCP plan. The objective of Stage 7 is to consider all of the potential hazards identified and identify those that need to be eliminated or reduced to an acceptable level if food, meeting the established Food Safety Requirements (or any other objective set out in terms of reference), is to be produced. To a large extent expert judgement and opinion will be involved and, if the necessary expertise is not available in house, external experts may need to be consulted or co-opted to the HACCP team hazard analysis should consider the following points:

- The consequence of the target micro-organism(s) or toxins being present at harmful levels in the final product at the point of consumption.
- The likelihood of the target micro-organism(s) or toxins being present at harmful levels in the final product at the point of consumption. Conclusions for this and the previous point might be based on previous company or industry experience, on epidemiological data, or on a microbiological risk assessment output.
- The survival and/or multiplication of target micro-organism(s) in the product or the potential for production of the toxin that will persist to the point of consumption at significant (toxic) levels.
- The hurdle effect (the synergistic preservative effect of two or more inhibitory factors) is relevant to these assessments. It should be noted, however, that unless the conclusions with respect to the ability of a formulation to inhibit the growth of, or eliminate, the target micro-organism is definitive, it might be necessary to carry out “spiking trials” to validate the formulation.
- The numbers of consumers potentially exposed and their vulnerability.
- Any relevant food safety objectives or manufacturer’s food safety requirements.

The data from microbiological risk assessments, in the context of risk analysis, will be useful in the hazard analysis stage of HACCP. In the absence of a formal risk analysis output, hazard analysis in HACCP will be made on quantitative data with appropriate expert input and/or reference to external data sources.

Identification of control measures. For each of the hazards concluded to be significant in the hazard analysis, the HACCP team should identify control measures that will eliminate the hazard or reduce it to an acceptable level. There may be more than one control measure required to control a hazard. In other cases, one control measure at a single point can control more than one hazard (e.g., pasteurisation eliminates all vegetative pathogens and spoilage micro-organisms). One control measure can be relevant to several process steps where a hazard is repeated (e.g., application of CIP cleaning or environmental cleaning to control recontamination). Where no control measure can be identified to control a hazard, redesign or modification of the process or product formulation may need to be considered. A final point to note is that in identifying control measures in a HACCP study on an established product and process, the team should not restrict consideration to measures already in place but should be prepared to propose other control measures that might be appropriate.

Stage 8: Determine CCPs (Principle 2)

The objective of Stage 8 (Principle 2) is to systematically assess the hazards and related control measures identified in step 7 by considering each process step (as recorded in the flow diagram) in turn and reaching a conclusion on its “CCP” status before moving on to the next process step- that is, to identify process steps at which control can be applied and which are essential to prevent or eliminate a hazard or reduce it to an acceptable level. It is useful to be guided by a CCP decision tree as shown in Figure 2.4.

Stage 9: Establish critical limits for each CCP (Principle 3)

A critical limit is a criterion that separates acceptability from unacceptability at each CCP. It should be measurable in real time (while the process is running) and might include measurements of temperature/time/pH or acidity, moisture, the phosphatase test for pasteurised milk, ATP methodology to assess cleaning efficiency, or other observations. A critical limit might be

mandatory (e.g., pasteurisation temperature and time) or based on data collected under good manufacturing practice where a specific target level and tolerances are set.

Stage 10: Establish a monitoring system for a CCP (Principle 4)

Monitoring involves a planned sequence of observations or measurements against critical limits to assess whether a CCP is under control. Ideally, monitoring should identify a trend toward a critical limit maximum or minimum so that corrective action can be taken before the process is out of control and, in any event, should aim to identify violation of critical limits as soon as possible to minimize the amount of embargoed/rejected product. Monitoring can be on-line with automated corrective action (e.g., flow diversion systems on pasteurisers), or they can be off-line when corrective action might involve the rejection of any product implicated. Physical and chemical measurements are preferred to microbiological testing because they can be completed rapidly and often be indicative of conditions that control the microbiology of the product (e.g., phosphatase test on pasteurised milk).

Stage 11: Establish a corrective action plan (Principle 5)

This specifies the action(s) necessary when monitoring shows a potential or actual loss of control at a CCP. The action(s) will aim to bring the process back into control before critical limits are reached (e.g., a temperature drift from a target of 5°C to near the tolerance value of 7°C will call for an engineer to adjust the refrigerator plant), or it will specify the disposal of product that has breached a critical limit. Monitoring requirements and corrective action plans should be considered together by the HACCP team, and a clear decision should be reached and recorded on responsibilities for corrective actions.

Stage 12: Verification (Principle 6)

Verification applies methods, procedures, product tests, and evaluations other than monitoring, to determine compliance with the HACCP plan; that is, it demonstrates that the HACCP plan and its application is consistently controlling the process so that product meets the food safety or quality requirements. The HACCP team should specify methods and frequency of verification procedures which might include the following:

- microbiological examination of intermediate and final product samples;
- review of complaints from consumers or regulatory bodies and outcomes of investigations into these complaints, if they were substantiated, indicating that the HACCP plan did not completely control the process;
- auditing all monitoring and corrective actions records to establish whether the HACCP plan is fully implemented and demonstrates control; and
- a review of validation records and, if appropriate, the application of more searching tests at selected CCPs to confirm the efficacy of the control measure.

Stage 13: Establish documentation and record keeping (Principle 7)

The complexity and quality of documentation necessary will depend on the size and type of operation. The key point is that the manufacturer must be able to demonstrate that the seven principles of HACCP have been correctly applied. To be effective, HACCP must be fully integrated into the unit quality systems as an element of total quality management.

The following documentation should be issued as controlled documents:

- The finalised HACCP plan. Process steps assessed as not being CCP's should also have critical limits, monitoring procedures, and corrective actions identified on the HACCP plan, and they can be designated as control points that contribute to good manufacturing practice.
- Guidelines, procedures and work instructions/records sheets.

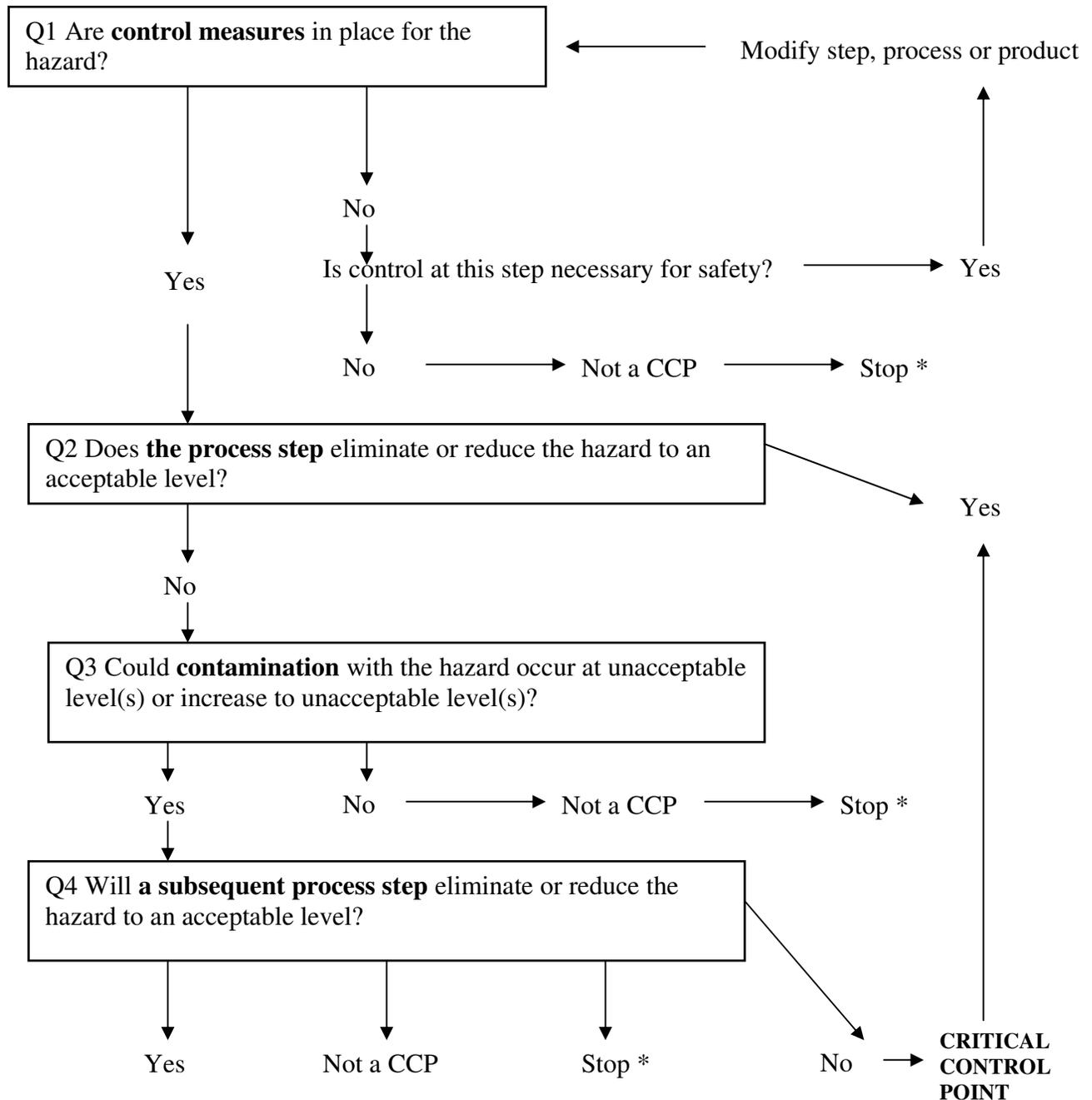
Guidelines on good hygienic practice (GHP) are an essential element of the documentation required. Any issues specific to the HACCP study that are missing can be covered either by amendment of the guidelines or by inclusion in the HACCP plan.

Procedures cover the following:

- training for hygiene and operation;
- personnel hygiene and sickness reporting;

on-site food services;

Answer each question in sequence at each process step for each identified hazard.



* Proceed to the next step in the described process

Figure 2.4 A CCP decision tree for the determination of critical points in HACCP plans (Jervis, 2002).

- use of protective clothing;
- inspection and maintenance of equipment, manufacturing services (water, compressed air, drainage), and the building/site;
- raw materials/ingredients - specification/audit/sourcing;
- waste disposal; and
- cleaning - equipment/environment; CIP /manual.

In all cases the procedures should state clearly what should be done, how equipment or materials should be used, and by whom and how defects should be recorded, remedial action initiated, and action signed-off when completed. As with guidelines, current procedures should be reviewed in an HACCP study and modified, if necessary, on the basis of the hazard analysis.

Work instructions give detailed instruction to employees as to what has to be done at each process step. This will include, as appropriate, equipment manufacture's instructions, product recipe (ingredient quantities, process times and temperatures, routing of intermediate product and final product through the factory), and action to be taken in abnormal circumstances. Monitoring record sheets should be prepared to support, as necessary, work instructions, preferably with critical limits shown, and instructions on how to complete them and action to be taken if critical limits are challenged (process adjustment and/or notify management). The work instructions should be generated directly from the HACCP plan, and the monitoring record sheet gives the detail that would otherwise complicate HACCP documents. Furthermore, there should be a clearly defined mechanism by which abnormal results are notified on an exception reporting system that calls for a traceable record of corrective or remedial action taken and the outcome of these actions, signed-off at a designated management level.

HACCP study notes. While the HACCP plan should be issued as a controlled document as part of site quality systems, it is important that the background notes made during the HACCP study be kept as a file for reference in HACCP review or trouble-shooting exercises. As a minimum, these notes should include the following:

- product description notes (Stage 3);
- basis for decisions taken in Stage 7 (Hazard analysis);

- a note of any “judgment” decision taken at Stage 8 (Determination of CCPs), together with data referred to and/or external expert advice source;
- recommended verification schedule (Stage 12);
- notes on any verification exercise undertaken (Stage 12);
- a schedule of other quality system documents that are derived from/support the HACCP plan; and
- data derived from HACCP reviews.

Stage 14: Review of HACCP plans

The review of a HACCP plan evaluates any changes in process, product, or manufacturing site against the current HACCP plan to determine whether new hazards have been introduced that are not covered by existing control measures at critical control points or control points. HACCP study notes will afford a valuable background to the review process. If new hazards that are not adequately controlled are identified, the HACCP plan should be amended accordingly and notes of the review should be added to HACCP study notes. HACCP plan reviews should be triggered under the following circumstances:

- by routine schedule at a frequency determined by the HACCP team based on risk;
- change in product formulation;
- change in process;
- change in raw materials;
- change in consumer use/longer shelf life assigned;
- evidence of health or spoilage risk in the market place;
- emergence of “new” food- borne pathogens;
- change to factory layout and environment;
- modification to process equipment;
- changes in packaging, storage, and distribution;
- change in cleaning and sanitation program;
- change in staff levels and responsibilities; and
- verification findings.

2.4 Background to yoghurt manufacturing process

2.4.1 Monitoring the process plant

The acidity of yoghurt means that spoilage is often associated with yeasts and moulds and the latter in particular often have their origin in the microbial population of the air. The control of the atmosphere within the factory environment will depend on the level of air cleanliness that is essential for completion of a particular operation. It is important, however, that plants designed to induce air flow through a filling room or production area can also act as a source of contamination (Tamime and Robinson, 1985).

Packaging materials stored adjacent to the filling line can also cause problems, as can the unnecessary movement of personnel and these aspects of plant operation deserve constant attention. Although yeasts and moulds of atmospheric origin can be important, especially at certain times of the year, it is the product contact surfaces of the plant that usually pose the greatest threat to product security (Tamime and Robinson, 1999).

Different methods and/or techniques have been devised to monitor the hygiene of dairy equipment surfaces, thus contributing to maintaining production of high quality products, and at the same time ensuring compliance with legal requirements. Whatever tests are employed, it is essential that they are applied routinely, for individual readings are in themselves meaningless, only when values for a typical, high standard of hygiene have been established for a given plant, along with acceptable tolerances, do the results of any microbiological/hygiene test become valuable (Mostert & Jooste, 2002).

Enumeration of total counts of bacteria, coliforms, yeasts and moulds are the most common microbiological examinations carried out to assess the bacteriological contamination of surfaces. The types of micro-organisms present, reflect to some extent, the standard of plant hygiene (Tamime and Robinson, 1999). Selective and differential culture media may also be used to test specifically for given groups of organisms. Although a given method may not remove all the organisms, its consistent use in specific areas can still provide valuable information as long as it is realised that not all organisms are being removed. The most commonly methods for surface assessment are outlined by Mostert & Jooste (2002) and include the swab / swab – rinse - , surface

rinse -, agar flooding – and agar contact plate methods. Some suggested standards for prior to pasteurisation/heat treatment, according to Mostert & Jooste (2002), are shown in Table 2.1

Table 2.1 Suggested standards for dairy equipment surfaces prior to pasteurisation/heat treatment

Colony forming units / 100 cm²	Conclusion
500 (coliforms < 10)	Satisfactory
500 - 2500	Dubious
> 2500 (coliforms > 100)	Unsatisfactory

Different plants will achieve different levels of cleanliness, even under ideal conditions, and the manufacturer of yoghurt is perhaps fortunate that the product is fairly “resistant” to spoilage, at least of bacterial origin. Contamination with yeasts and moulds is, however, quite different. If yeasts become the dominant contaminant, then numerous problems can be expected during retailing. The results can again be related to a known area of plant surface, and as with data obtained in other ways, can provide an indication of the efficacy of the cleaning procedures. It is clear, therefore, that examinations of this type are valuable as a means both of monitoring cleaning performance and of eliminating potential hazards. The testing of raw materials has much the same function.

2.4.2 Processing

The pre-incubation stages are common to both the stirred and set type yoghurts.

2.4.3 Preparation of ingredients

The first stage of yoghurt manufacture is to combine all the ingredients which are included in the fermentation base material. Solids-non-fat and total solid levels will vary dependent upon the type of yoghurt to be manufactured, as well as the inclusion of other ingredients such as sugar, skimmed milk powder, water and cream.

Dry ingredients require sufficient time for hydration and de-aeration and these ingredients (milk

powders, stabiliser, and sugar) are likely to be added via a recirculation loop containing a venture or tri-blender to facilitate their addition in “batch method” manufacture or could be pre-dispersed in part of milk or water and dosed into the main milk stream in continuous method. Sugar may be added as liquid sugar but care must be taken not to add too much sugar to the pre-fermented white base, since this can result in dehydration of the starter organisms via osmosis (Early, 1998). Fortification of milk solids may be achieved in a number of ways, including the addition of skimmed milk powder, dilution of evaporated milk and use of membrane technology to increase milk solids levels.

2.4.4 Emulsification

It is necessary to prevent the separation of fat during fermentation and at later stages of storage and transportation. This is particularly important where fat levels are relatively high and also for set yoghurt manufacture where there is no further agitation of the coagulum. Yoghurt milk is an oil-in-water emulsion and the function of the homogenizer in this respect is to reduce the size of the discontinuous phase i.e. fat, in order to assist the creating of a stable emulsion.

The diameter of the fat globules in milk ranges between 1 and 20 microns dependent upon those factors which influence chemical composition i.e. breed of animal, type and method of feeding, age of animal, lactation stage, etc. The function of homogenising is to reduce the average diameter of fat globules to less than 2 microns. Homogenisation will also assist in mixing dry milk ingredients as a result of high velocity level being achieved in the space between the outer ring and core and also by virtue of pumped passage through the homogeniser head which develops powerful shearing forces (Early, 1998).

Two-stage homogenisation is generally used with first and second stage pressures of 15 MPa (150 bar) and 4 MPa (40 bar) respectively. Since the fat is required to be in a liquid state, homogenization needs to take place above 50°C and will probably be closer to 65°C depending on the pre-homogenisation heating process used to treat the milk. In some instances, sterilisation, or UHT temperatures are used for post-homogenisation heat treatment. Homogenisation should be carried out prior to heat treatment of the yoghurt milk. Increasing number of fat globules affects light reflectance and scattering, resulting in a whiter colour. Pumping yoghurt milk via homogenising can increase foaming potential and the increase in fat globule surface may lead to lipolysis (Early, 1998).

2.4.4 Heat treatment

The objectives of heat treatment in the processing are to:

- eliminate vegetative food poisoning micro-organisms;
- eliminate or reduce food spoilage micro-organisms to acceptable levels;
- reduce the total microbiological population to a level which will not compromise the growth of the starter micro-organisms;
- denature the whey proteins in order to improve the texture of this final product and to assist in the prevention of whey separation at any subsequent time during shelf life (this is particularly important in the manufacture of set type yoghurt); and
- hydrate certain stabilizers.

These objectives are usually achieved in the heating section of a plate heat exchanger or tubular heat exchanger where the temperature can be raised to 90°C. Functional properties of whey proteins become more apparent after heating milk and they begin to become denatured above 60°C. The nature and reactions of proteins are extremely complex but there is evidence to suggest that starter cultures may be inhibited or stimulated when added to milk which has received different temperature/time combinations and there are reactions between different protein factors at different temperature/time combinations. Optimum hydrophilic properties of the proteins and, hence, coagulation of the yoghurt milk are obtained when the milk is heated to 85°C for 30 minutes (Early, 1998) or when maximum hydration of the protein occurs.

The effect of heat on protein is a two-staged process (Early, 1998). Firstly, the structure is altered, causing denaturation and secondly, aggregation takes place followed by coagulation. This is dependent upon degree and duration of heating. Pasteurisation temperatures (80 – 95°C), sterilisation temperatures (115 – 120°C) or UHT temperatures (135 – 140°C) have also been used to heat treat yoghurt milk.

2.4.6 Cooling of milk

After heat treatment the milk is required to be cooled to a suitable temperature prior to inoculation. In most cases this will be carried out in the regenerative section of the plate heat exchanger. Yoghurt, manufactured in a batch tank or churn, can simply be allowed to cool via cold water

jackets or tank (effectively in a water bath) (Early, 1998). The inoculation temperature for short set method will approximate to 42°C. This temperature can be lowered if an extended incubation period is required (approximately 30 – 32°C).

Allowances need to be made for incubation tank wall temperature, cold starter addition and latent heat effects and, therefore, the actual cooling temperature as measured on exiting cooling (regeneration) section, is likely to be 1 – 2°C higher than required, dependent upon volume, agitation system, distance travelled, etc. For short set incubation it is critical to achieve an accurate inoculation temperature since too high a temperature can inhibit and ultimately kill starter culture micro-organisms and too low temperature will result in unnecessary extension of fermentation time (Early, 1998).

2.4.7 Fermentation

In modern automated plants, stirred type and set type yoghurts are often produced concurrently. As has already been indicated, the short set method of incubation of yoghurt milk, using traditional starter organisms such as *Streptococcus salivarius* subsp. *thermophilus* and *Lactobacillus delbrueckii* subsp. *bulgaricus*, will require the incubation temperature environment for the micro-organisms to metabolise synergistically. There should be no agitation during incubation. The yoghurt curd or “coagulum” begins to form as more lactic acid is produced as the iso-electric point of casein (pH 4.6 – 4.7) is approached. A “solidity” of the gel will begin to be seen at approximately pH 5.6. Since the protein is most insoluble at its iso-electric point and has lowest water binding properties, the yoghurt gel is very sensitive at this pH. In the case of stirred manufacture, the point at which incubation is stopped is dependent upon a number of factors, such as volume of fermentation vessel and therefore time taken to empty the tank, final pH required and time taken to completely arrest further acidity development. This last point is particularly important in batch (churn) manufacture and with reference to the partial cooling technique employed in continuous manufacture where coagulum may be filtered through a fine mesh screen prior to fruiting, filling and secondary cooling in retail container. Fermentation will be arrested at approximately pH 4.2 – 4.4, sometimes even lower (pH 3.8 – 4.0) (Early, 1998).

2.4.8 Striking

This stage applies only to stirred and liquid/drinking type yoghurt and is essentially the operation

of breaking the warm gel/curd and re-incorporation of the whey. Slow speed paddle agitation (e.g. 2 - 4 rpm) for approximately 5 - 10 minutes is usually sufficient to obtain a homogeneous mix. Agitation also tends to inhibit the culture activity and slows the rate of acidity development (Early, 1998).

2.4.9 Cooling of the coagulum

Cooling the coagulum commences directly after the fermented yoghurt reaches the desired acidity. The desired acidity will be dependent upon type of yoghurt being produced, method of cooling, time taken to empty fermentation vessel and desired final acidity. This will take place at approximately pH 4.5 - 4.6. Cooling is achieved in stirred/liquid yoghurt by pumping the yoghurt via a gentle action positive displacement pump, through a plate or tubular cooler in order to achieve a temperature which is low enough to retard starter culture activity. The capacities of pump and cooler are dimensioned in order that a large fermentation tank will take approximately 20 minutes to be emptied in order to maintain uniform product quality (Early, 1998).

Localized protein precipitation often referred to as 'nodulation' can be a major characteristic fault in stirred or liquid yoghurt. There has been significant research into the cause of nodulation in an attempt to prevent its development or reduce the degree of nodulation. Increased ratio of lactobacilli to streptococci in the culture addition, too high a temperature of incubation, excessive pH development and high inoculation levels have all been cited as examples as to the reason for nodulation.

One physical method of eliminating this problem is to pass fermented yoghurt through a fine screen in order to break up the 'nodules' and produce a smooth consistent product. This operation can be done when the yoghurt base is cooled. However, this can result in whey release and loss of viscosity in the final product. This is why some manufacturers conduct two-stage cooling. By passing partially cooled-yoghurt at approximately 20-25°C through the screen, any physical damage, including wheying off and reduction in viscosity can be healed to a large extent by reforming of the coagulum on final cooling in the retail container. Care needs to be taken, however, in allowing for some acidity increase if the yoghurt is only partially cooled for as long as it stays at this temperature before it is finally chilled (Early, 1998).

Yoghurt coagulum is broken by the treatment it receives in the pump and cooler. The mechanical treatment will decrease the viscosity but in a well-designed plant, the yoghurt viscosity will increase again after some hours in the chill store. It is vitally important that tanks, pipes and heat exchangers are designed with consideration to the total permitted mechanical treatment of yoghurt.

Cooling temperatures vary and are dependent upon the:

- composition of yoghurt and its inherent ability to withstand cold mechanical handling;
- filling capability of the process;
- duration of intermediate storage;
- efficiency of refrigeration plant; and
- cooling capability after post-filling, i.e. chill room temperature, air circulation, etc.

Traditional continuous manufacture involves single stage cooling to 8 - 10°C, holding in intermediate tanks and then blending with fruit preparation. The stabilisation requirements for these manufacture extremes are very different and attention must be paid to stabiliser activity in order for the stabiliser to be effective and avoid any quality problems. In the case of set yoghurt, cooling takes place inside the retail container and is generally started before the final pH is reached. Care must be taken when transferring the retail containers from the incubation room to the chill store because of the fragility of the coagulum at this point. The main problem to be avoided is 'wheying off' or syneresis and any unnecessary physical movement which will encourage this problem. On cooling, the curd becomes much firmer and if the yoghurt is formulated correctly, surface whey will be re-absorbed after 24 hours chilled storage (Early, 1998).

2.4.10 Intermediate storage of stirred yoghurt

Intermediate storage is often necessary due to yoghurt production rate and filling rate incompatibility. It is also a necessary requirement to have cooled yoghurt available to fruit, so production should have the capacity to hold cooled yoghurt as a stock. However, it is important that these stocks are not too great and that storage times are shorter than 24 hours and, ideally much less than this, nominally, a few hours. Ideally a temperature of 8 - 10°C is optimal, depending upon storage time. Intermediate storage should be as short as possible since physical

changes take place that can affect final yoghurt quality. The product may release whey that is difficult to re-incorporate, resulting in loss of yield. Viscosity and body will develop that will largely be lost when the yoghurt is disturbed again. The ability of the yoghurt to bind whey will be reduced by cold disturbance (Early, 1998).

2.4.11 Packaging

Primary packaging will include glass, polyethylene, polypropylene, polystyrene, polyvinyl chloride, polyvinylidene chloride, plastic sachets and paper cartons. The majority of containers used in South Africa are manufactured from polystyrene and polypropylene.

Aluminum foil is widely used to seal yoghurt containers. Due to the acidity of yoghurt and the requirement for the foil to be heat sealed to the plastic container, the aluminum foil is normally coated with a layer of plastic.

Individual packages may be further collated into packs of four, six, twelve etc. and the most popular secondary packaging is either cardboard in the form of an outer sleeve or tray or semi-rigid plastic crates. Cardboard trays can be over wrapped with heat seal material. Current EEC labelling regulations (1984 Food Labelling Regulations) require that all pre-packed foods exhibit nature of food, ingredients list, name of manufacturer, packer or seller and expiry (Early, 1998).

2.4.12 Contamination during packaging

Despite all the possible sites in the processing chain at which bacteria can be introduced, the step that has the greatest influence on the keeping quality of heat-treated dairy products is the filling operation. The new generation of packaging machines incorporates features such as exclusion of air from the filler (by using bellows instead of pistons) and carton sterilisation by UV light and hydrogen peroxide. Real contamination may also occur at the filling stage from condensation formed on the machines as well as from smearing of products by moving parts of filling valves (Nriagu and Simmons, 1990). Packaging material, such as properly prepared plastic and laminated plastic materials, are not considered an important source of bacteria (Lück, 1981).

2.4.13 Chill storage

Yoghurt which has not been subjected to any form of heat treatment in its final product form be it via pasteurisation, sterilisation or UHT processes, needs to be kept cold until it reaches the customer. This includes the majority of yogurts which will have a shelf life of approximately 15 - 21 days. Temperature variation will affect texture, viscosity, syneresis as well as improving the environment for potential food spoilage and food poisoning micro-organisms. Exposure to higher temperatures than recommended below, can increase biochemical reactions such as fat oxidation, hydration of protein constituents in yoghurt, slight dehydration of exposed yoghurt surface and changes in colour of fruit (Early, 1998). Chill storage should be between 2 and 5°C, with no rise above 10°C at intermediary stages in distribution, i.e. palletized transport, non-refrigerated stockholding, retail cabinet exposure. Although classified as a 'low-risk food', attention requires to be paid to good manufacturing practice and temperature control legislation has to be adhered to (Early, 1998).

2.4.14 Distribution

Quality assurance principles should extend to monitoring food products throughout the distribution chain. Although the final yoghurt is likely to be stored for only a short period of time prior to distribution to customers' premises, any identified hazards such as rodent/insect infestation, exposure to temperature increase, potential for physical damage etc., need to be monitored and preventative action taken where appropriate.

Yoghurt can be subjected to textural stress during transportation. Set yogurt is particularly sensitive to transportation and poor formulation or processing can result in broken curd structure and excessive wheying off. Fluctuating temperatures during distribution can adversely affect the coagulum stability reducing viscosity and encouraging syneresis. Any significant fluctuation in temperature may also result in the continuation of fermentation by starter culture micro-organisms, which will affect quality in an adverse manner (i.e. over acidification, increase in syneresis). During the first 24 to 48 hours of cold storage, improvements in the physical characteristics take place, mainly as a result of hydration and/or stabilization of the casein micelles. If practically possible, it would therefore be an advantage to retain yoghurt in chill storage for at least 24 hours before commencing distribution (Early, 1998).

2.4.15 Quality appraisal and retail products

However advisable it may be to monitor standards of plant hygiene or to insist that raw materials meet agreed specifications, it is the end product that must pass the final test – does it meet the legal requirements and is the quality acceptable to the consumer? In some countries the imposition of compositional standards aims to encourage the maintenance of quality but, for the most part, the nature of the product in terms of the consistency and related features ensures that the proposed standards are met with as little difficulty. Nevertheless, analysis of the end product is an essential feature of quality control, because problems in manufacture are almost certain to manifest themselves as faults in the product. Consequently, examinations at this stage:

- protect the consumer from the purchase of poor quality product or, in extreme cases, product that might constitute a health hazard;
- protect the manufacturer from the inconvenience and expense of a barrage of returned goods; and
- assist in the smooth operation of a plant by identifying variations in product quality at an early stage, so that the necessary corrective action can be taken before the onset of serious problems.

The appraisals of product quality have therefore become a vital function of factory operations.

A comprehensive overview of actual manufacturing processes of various types of yoghurt is discussed by Tamime and Robinson (1999).

CHAPTER 3

METHODOLOGY

3.1 Implementation of the HACCP program

The SABS 0330:1999 Code of Practice (SABS, 1999) was used as a basis which contains the requirements for a HACCP system for the development, implementation and effective management of a functional process hazard control program in the food and allied industries to enhance food safety. The following steps were followed in the HACCP implementation program:

3.1.1 Terms of reference

The terms of reference defined the scope of the intended HACCP program and addressed the following applicable laws, by-laws, regulations and compulsory specifications:

- Act 54 of 1977 (Health Act and Regulations)
- Regulation 908 of 27 June 2003 (Regulations relating to the application of the HACCP system).
- Regulation 918 of 30 July 1999 (Regulations governing general hygiene requirements for food.
- Act 77 of 1973 – Trade Metrology Act.

3.1.2 Resources

The management's representative was appointed and top management provided documented proof of their commitment to provide the necessary resources.

3.1.3 Management review

Management reviewed the HACCP plan in accordance with the schedule to ensure its effectiveness and improvement. Data obtained from the HACCP reviews were documented which formed part of the HACCP record keeping system. Any changes that arose from the review were incorporated into the HACCP plan, especially where additional CCPs or control measures had to

be put into place or control measures or tolerances had to be changed.

3.1.4 Organisational structure

The responsibilities, authorities and hierarchy of employees responsible for the control of, and the safety of, the product were defined according to an organogram. Every team member accepted, in writing, his assignment and commitment to the HACCP team.

3.1.5 Select the HACCP team (Stage 1)

3.1.5.1 Assembling of the HACCP organisational team (steering group)

Members were drawn from each part of the yoghurt plant, for example, production, finance, engineering and quality, purchasing and technical. The objectives of this team were to ensure that:

- management's commitment was visible;
- a clear route for multi- directional communication was established; and
- a forum for resolving conflict was established.

3.1.5.2 Assembling the HACCP core team

The HACCP core (study) team consisted of personnel with specific knowledge of, and expertise with regard to, the product and process. The HACCP core team was multi-disciplinary. As many skills as practicable were made available for the implementation of the HACCP plan. The core team conducted the necessary studies, supervised the implementation of the HACCP plan and maintained its performance. The following personnel were included in the core team:

- A team leader, who had leadership abilities, defined responsibilities, authority and adequate HACCP training. The team leader's responsibilities were to establish, implement and maintain the HACCP system in accordance with the standard. The team leader also reported on the performance of the HACCP system to management for review and on a basis for improving the system. The function of the team leader and facilitator were fulfilled by the same person. The facilitator's functions were as follows:

- assist in the organisation of meetings, organise training and act as a secretary; and
 - ensure that specialist advice is available when required, communicate progress to --- everyone, remove any obstacles to the proper implementation and maintenance of the system, and ensure that follow-ups are completed in time.
- The other members consisted of a food technologist, a microbiologist, an engineer and a production expert. The selection of the following team members were based on their academic qualifications, expertise and experience in the dairy industry:
 - A microbiologist who understood the microbiological hazards and risks associated with the product.
 - A mechanical engineer to provide the information on the operating characteristics of the process equipment under study, the hygienic design of the equipment and the buildings.
 - A production expert who contributed details of what actually happens on the production line throughout all shift patterns.
 - A food technologist – who kept records of the work as it progressed and from which the HACCP plan and HACCP study notes were derived.

Where the necessary skills were not available, the services of a consultant were acquired. The consultant was not a member of the HACCP team and the consultant’s assistance was utilized in the following areas:

- training of team members in HACCP techniques;
- the assessment of HACCP studies and HACCP implementation; and
- assistance in the documentation process.

3.1.6 Describe the product (Stage 2)

Factors that would have an influence on the preservative characteristics of yoghurt were recorded including basic compositional data, important product characteristics such as pH. The instructions on the use of the product as well as the type of packaging were noted. Included in the description were also the labeling instructions, legal requirements, storage and distribution control and total

shelf life requirement. The above was drawn up by the Food Technologist and the Team Leader at the initial stage of HACCP implementation.

3.1.7 Identify the intended use of the product (Stage 3)

Customer groups were identified. Attention was focused on the likely uses or abuses of the product after it left the controls at the yoghurt plant. Factors such as the vulnerability of the consumer group, relevant legislation and instructions for use were taken into account.

3.1.8 Construct a product flow diagram (Stage 4)

After Stage 2 of HACCP implementation, a comprehensive process flow was constructed with the aid of each team member. The process under study was fully automated, thus making it impossible to override the system or make manual changes at crucial steps in the process. The following aspects were addressed:

- customer handling of the product;
- floor plans, flow conditions of liquids and solids;
- the product rework loops and recycle;
- the routes of potential cross-contamination;
- the segregation of light risk areas;
- the microbiological, chemical and physical data and requirements pertaining to all raw material(s), ingredients, the water used, packaging materials, cleaning chemicals, detergents and use for plant sanitation;
- the time / temperature history of all raw materials, intermediate and final product;
- the storage and distribution conditions; and
- packaging used.

3.1.9 Arrange on-site confirmation of the flow diagram (Stage 5)

The team on-site confirmed the flow diagram and technical data compiled by the HACCP team during all stages of operation, so as to ensure that the flow diagram and the data gave an accurate representation of the operation.

3.1.10 List all hazards associated with each step in the process and list all measures that will control the hazards (Stage 6)

The HACCP team used the amended flow diagram(s), including the technical data, as a guide to identify all the biological, chemical and physical hazards and the mandatory requirements that might readily be expected to occur at each step and to describe the preventative measures that can be introduced to control such hazards. Preventative measures related to hygiene and GMP, where practicable, were included in procedures for GMP and operation and sanitation, to simplify the HACCP plan.

3.1.11 Determine the critical control points (CCPs) (Stage 7)

Using the flow diagram and the product description the HACCP team listed all hazards relevant to the terms of reference in Stage 1. All potential hazards were identified. For each of the hazards concluded to be significant, control measures were identified to eliminate the hazard or reduce it to an acceptable level. In some instances there was more than one control measure required to control the hazard.

3.1.12 Establish target levels and tolerances for each CCP (Stage 8)

At this stage the HACCP team identified process steps at which control could be applied and which were essential to prevent or eliminate the hazard or reduce it to an acceptable level. In order to achieve this the HACCP team used the CCP decision tree of SABS (1999).

3.1.13 Establish a monitoring system for each CCP (Stage 9)

A documented monitoring system had been established and maintained that described control measures and procedures used in their implementation.

3.1.14 Establish corrective action plans (Stage 10)

Documented procedures were established and maintained for implementing corrective action when monitoring the critical limits of a particular CCP, which indicated any deviation(s) from the specified tolerance. Formal records for all corrective actions have been kept. Specific corrective action procedures for each CCP included:

- the effective handling of consumer complaints and HACCP-related reports of product non-

conformities.;

- the investigation of the cause of unsafe or unsuitable product, or process, or HACCP system failure and recording of the results of such investigations;
- the determination of the corrective action needed to eliminate the cause of product failure, including preventative action;
- the application of controls, or system reviews (or both), to ensure that corrective action is taken and that it is effective; and
- ensuring that relevant information on actions taken is submitted for management review of the HACCP plan.

3.1.15 Establish verification and review procedures verification (Stage 11)

A proper system for the verification of all HACCP procedures, process monitoring, records and corrective action records had been established. Periodic in-house verifications (for example, internal audits and inspections) had been conducted to ensure that the monitoring system and corrective action plans were being properly applied. Records of such checks have been kept. The specific methods, the frequency and specific dates in respect of the verification procedures, were specified. The following types of verifications were conducted regularly:

- inspection of the HACCP study and records;
- evaluation of any deviations, product dispositions, corrective action and consumer complaints that might indicate a failure of the HACCP system;
- microbiological, chemical and physical results obtained by examining intermediate and final product samples;
- validations of established target levels and tolerances; and
- surveys of the market place for unexpected health or spoilage problems.

The HACCP plan was also reviewed in accordance with a schedule by management to ensure its effectiveness and its improvement. Provision for procedures were made that would have automatically triggered a complete review of the HACCP plan as soon as verification of the system indicated major failure and before changes in operations might have compromised food safety. Data obtained from the HACCP reviews were documented and formed part of the HACCP record keeping system. Any changes that arose from the review were incorporated into the HACCP plan, especially where additional Controls or control measures had to be put into place, or control measures, or specified tolerances, had to be changed.

Establish record keeping and documentation (Stage 12)

A document control procedure was established and is being maintained to ensure that:

- all personnel who should receive copies of documents are provided with copies and new revised copies are also issued to the respective personnel;
- no change is made without proper authorization;
- authorized changes are incorporated into all the copies of the documents in use;
- obsolete documents are removed;
- the unofficial copying of documents was discouraged; and
- the latest versions of all documents were entered on a master list. Each document issued was identified by an issue number and date of issue, and was approved (signed) by authorized managers.

3.1.16 Records (Stage 13)

Documented procedures for the identification, collection, indexing, accessing, filing, storage, maintenance and disposition of all records generated during HACCP studies, HACCP implementation, HACCP maintenance, tests and verification data, reviews and assessments or audits had been established and maintained.

Records generated during the normal monitoring of CCPs had to be retained for a defined and documented period. Records of the hazard analysis procedures described were kept for reference, for verification by the authorities or outside audits, or for review of the system.

The following HACCP records have also been kept:

- cleaning and disinfection records (operation and sanitation records);
- yoghurt plant construction and maintenance records;
- records on the nature, source and basis for acceptance of raw material(s), water, additives and ingredients, cleaning chemicals and packaging materials;
- complete processing records, including storage, distribution and recall procedures;
- deviations, corrective action and product disposition;
- in-house verification data;
- review data; and
- HACCP plan modification(s).

3.1.18 Training (Stage 14)

The organisation established and maintains documented procedures for identifying training needs and made provision for the training of all personnel involved with HACCP studies, HACCP implementation, verification, auditing and reviews. Personnel involved in critical measurements and checks had to be trained appropriately. Training was directed at personnel who were to implement HACCP at the practical level. HACCP training of personnel extended down to as low a level as practicable to create an overall awareness of the HACCP system.

3.2 Microbiological, chemical and physical analyses

3.2.1 Sampling

Samples were taken at different stages during the yoghurt manufacturing process and analysed, before and after implementation of the HACCP program, for the parameters as shown in Table 3.1 (Mostert & Jooste, 2002). Samples for microbiological analysis were taken aseptically and kept between 1 – 5°C and analysed within three hours. Samples for chemical analysis were analysed immediately.

3.2.2 Microbiological analyses

3.2.2.1 Preparation of dilutions

1 ml of each milk sample and 1 g of yoghurt sample was diluted in 9 ml sterile quarter-strength Ringer's buffer solution. Appropriate serial decimal dilutions were made using sterile Ringer's solution.

3.2.2.2 Total plate counts

Standard Plate Count Agar (Merck 1.05463) was used to determine the total bacterial count. The media was prepared according to the manufacturer's instructions and the pour plates incubated for 72 hours at 32°C (IDF, 1991a).

3.2.2.3 Coliforms

Violet Red Bile Agar (Merck 1.01406.05) was used for the enumeration and detection of coliform bacteria. The media was prepared according to the manufacturer's instructions and the pour plates incubated for 24 ± 2 hours at $30 \pm 1^\circ\text{C}$ (IDF, 1985a).

3.2.2.4 Yeast and mould counts

Rose Bengal Chloroamphenicol Agar (Merck C107) was used for the enumeration and detection of yeasts and moulds. The media was prepared according to the manufacturer's instructions and the pour plates incubated for 5 days at $25 \pm 1^\circ\text{C}$.

3.2.2.5 Swab rinse method

This method was used for the assessment of effective cleaning of milk contact surfaces e.g. milk silos (Mostert & Jooste, 2002).

3.2.2.6 Psychrotrophic counts

Standard Plate Count Agar (Merck 1.05463) was used to determine the psychrotrophic counts. The media was prepared according to the manufacturer's instructions and the pour plates incubated at 21°C for 25 hours (IDF, 1985b).

3.2.2.7 Spore counts

The method is based on thermal treatment at 100°C for 5 min and serves to render the vegetative forms inactive and stimulate the process of spore formation (Mostert & Jooste, 2002).

Table 3.1 Samples taken at different stages during the yoghurt manufacturing process for microbiological, chemical or physical analyses.

Sample	Manufacturing stage	Microbiological tests	Chemical/physical tests
Raw milk	Individual compartments of milk tankers	Total plate count Coliform count Psychrotrophs Spore count	pH % Butterfat Temperature Freezing point
Pasteurised milk*	Every silo of pasteurised milk	Total plate count Coliform count	pH % Butterfat Temperature % Total solids
Standardised milk*	Standardised milk	Total plate count Coliform count Yeast and mould count	pH % Total solids
Ingredient mixing*	Mixing tank	Total plate count Coliform count Yeast and mould count	pH % Total solids
Pasteurised yoghurt* base	Pasteurised tank	Total plate count Coliform count Yeast and mould count	pH % Total solids
Fermented yoghurt 1*	Fermented tank	Total plate count Coliform count Yeast and mould count	pH % Total solids
Fermented yoghurt 2*	Intermediate tank	Total plate count Coliform count Yeast and mould count	pH % Total solids
Final product	Filling – yoghurt base and fruit	Coliform count Yeast and mould count	pH % Butterfat % Total solids Viscosity

* Samples taken during in-process manufacture

3.2.3 Chemical and physical analyses

3.2.3.1 *Total solids*

Total solids were determined using a Mettler Toledo Halogen Moisture Analyzer HR73.

3.2.3.2 *pH*

The pH was measured using a Schott CG 842 laboratory bench top pH meter.

3.2.3.3 *Temperature*

The temperature was measured by a Testo 926 Digital Thermometer, calibrated by the SABS.

3.2.3.4 *Viscosity*

Viscosity was determined by the use of the Bostwick apparatus (Tamime & Robinson, 1999).

3.2.3.5 *Butterfat*

The percentage butterfat was determined by means of the Gerber method (IDF, 1981; 1997).

3.2.3.6 *Antibiotic inhibition*

The paper disc test was used with Kundrat Agar (Kundrat, 1972) as the culture medium. The medium was prepared according to the manufacturer's instructions. This is also referred to as the agar diffusion method.

3.2.3.7 *Freezing point*

A cryoscope was used to measure the freezing point of milk according to IDF (1991b).

3.3 Statistical analysis

Data were analysed using the statistical program GenStat (2000). The experiment was designed as a completely random design (CRD) with two treatments, the before and after measurements taken. Student's two-sample unpaired t-test was used to test for differences between the before and after means. Significance was obtained at the 5 % level of significance ($P < 0.05$) (Snedecor &

Cochran, 1980). Bacterial counts were usually skew in distribution with heterogeneous variances. The logarithmic transformation (base10) was used to stabilise treatment variances in such cases.

CHAPTER 4

RESULTS AND DISCUSSION

4.1 Implementation of the HACCP program

The HACCP program was implemented within the framework of all the applicable laws, by-laws, regulations and compulsory specifications. Act 54 of 1977 (Health Act and Regulations), Regulation 908 of 27 June 2003 (Regulations relating to the application of the HACCP System), Regulation 918 of 30 July 1999 (Regulations governing general hygiene requirements for food) and Act 77 of 1973 (Trade Metrology Act) were used in this regard.

4.1.1 Conducting a hazard analysis

The HACCP system should, firstly, provide safe, high quality milk as raw material, and yoghurt up to the point where it is manufactured and consumed, and secondly, the system should be set up to avoid microbiological, chemical or physical hazards (or any combination of these) for yoghurt.

The study was done on fat free yoghurt, low fat fruit yoghurt and the low fat smooth yoghurts. This discussion will generally be based on low fat fruit yoghurt as the process is the same for all the variants although the final specifications differ.

Top management provided documented proof of their commitment to provide the necessary resources and the management representative was also appointed. Management then selected the HACCP team members based on their technical background and experience. The team's expertise covered all the various disciplines applicable to the factory processes. The team leader had the responsibility and authority to implement HACCP and report back to the Plant Manager and Quality Assurance at Head Office. The facilitators established, communicated and implemented the HACCP policies, procedures and systems and conducted hands-on training with the shop floor personnel. The control of all documentation was handled by the administrator. Identification of the critical points, investigation of deviations and non-conformances and recommendations on the best practical applications were done by the experts in each field. The organisational structure of the HACCP team is shown in Figure 4.1.

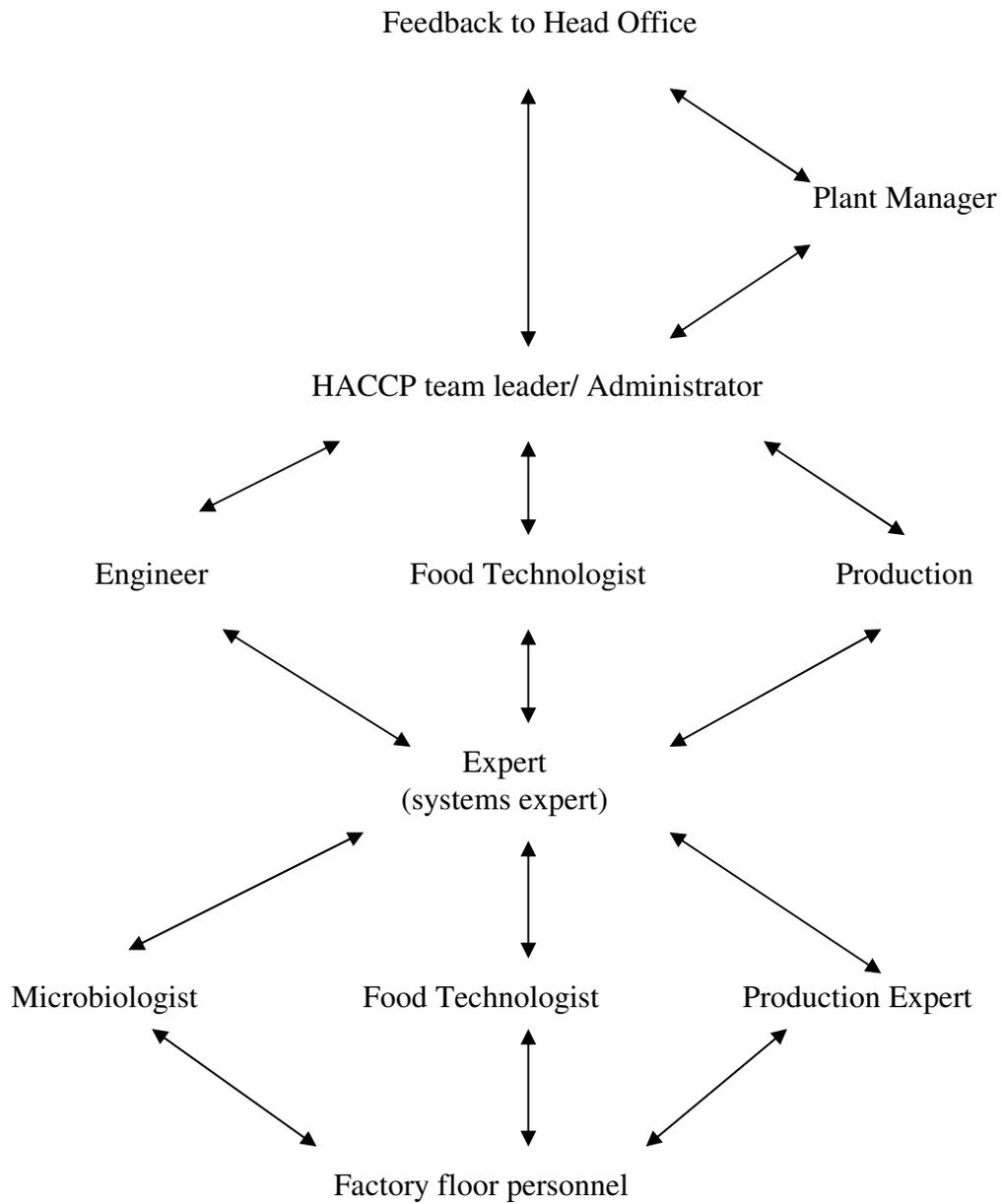


Figure 4.1 Organisational structure of the HACCP team.

A complete description of the product and its intended use is shown in Table 4.1, in terms of type and composition which includes microbiological, chemical, processing, presentation, packaging, storage and distribution conditions as well as the required shelf-life under the prescribed conditions.

A detailed flow diagram of the specified areas of the operation, and technical data was confirmed by the HACCP team on site during all stages of the operation, so as to ensure that the flow diagram and the data gave an accurate representation of the operation. Figure 4.2 is a representation of the flow diagram for the manufacture of low fat fruit yoghurt.

4.1.2 Management of the yoghurt manufacturing process

Table 4.2 lists all hazards associated with each step in the process and all measures that will control the hazards. The presence of antibiotics and foreign material were identified as critical control points. This is of importance as antibiotics have a direct impact on the lactic fermentation of milk. The major effect of antibiotic residues in yoghurt milk is to cause a breakdown in the associative growth between *S. thermophilus* and *L. delbrueckii* subsp. *bulgaricus* as well as other yoghurt starter cultures, or it may decrease the rate of acid development (i.e. longer processing time) and this can also lead to syneresis or wheying-off. Foreign material will negatively influence the appearance of the final product. The pasteurisation process is important as it plays a role in the destruction and/or elimination of pathogens and other undesirable micro-organisms; production of stimulatory/inhibitory factors to the yoghurt starter organisms, and changes in the physico-chemical properties of the milk constituents which are important in yoghurt manufacturing. Homogenisation and fermentation temperature will impact on the characteristic physical and sensory properties of the end product. A monitoring system that describes control measures and procedures was also documented when monitoring the critical limits of a particular CCP which indicates any deviation from a specified tolerance. A proper record keeping system for the verification of all HACCP procedures, process monitoring records and corrective action records had also been established and the details regarding the ingredients, product safety, processing, packaging, storage and distribution are shown in Table 4.3.

The HACCP program was successfully implemented within 12 months in a large commercial yoghurt factory.

Table 4.1 Product description of low fat yoghurt, flavoured with fruit and the intended use of the product.

Process/product type name: yoghurt	
1. Product name(s):	Low fat yoghurt, flavoured with fruit
2. Composition:	Skim milk, skim milk powder, fruit, preservatives, bacterial cultures
3. Important product characteristics (a _w , pH, preservatives, processing):	pH
4. How it is to be used:	Direct consumption
5. Packaging:	Plastic cup and foil – sealed
6. Shelf life:	No of days
7. Where it will be sold:	Retailers
8. Labelling instructions:	Within legal limits
9. Legal requirements (e.g. compulsory specifications, etc.):	Butterfat, total solids
10. Special storage and distribution control:	Refrigerated at < 5°C

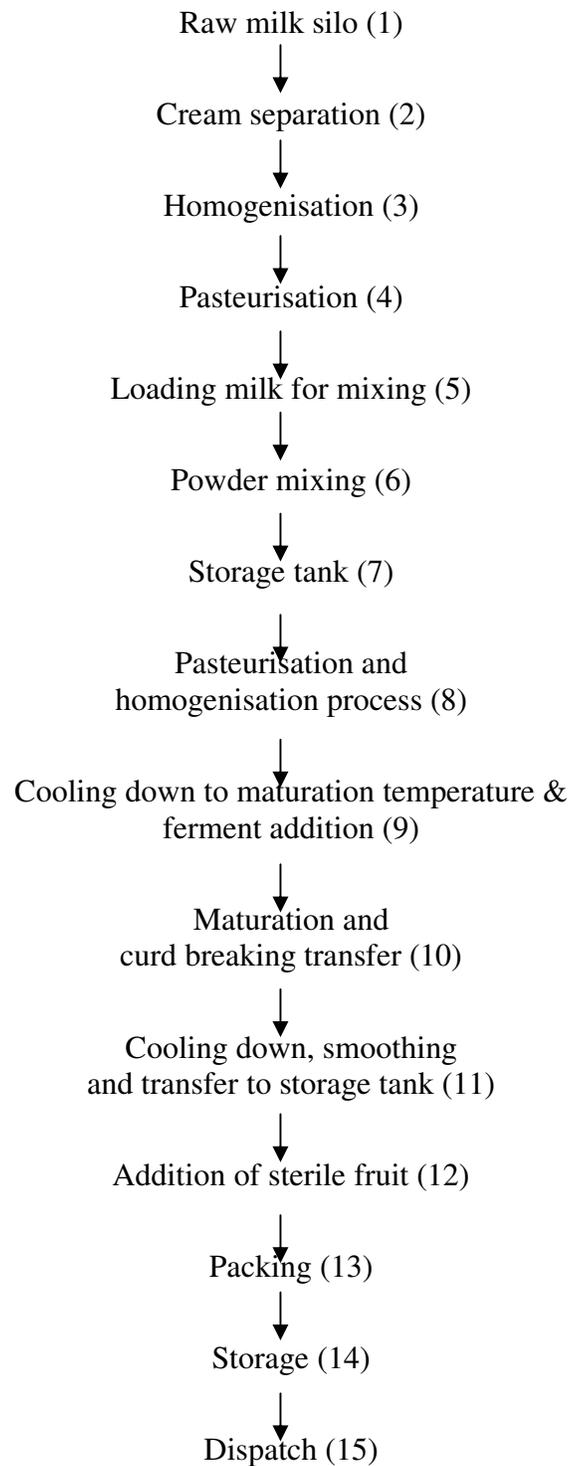


Figure 4.2 Flow diagram for the manufacture of low fat yoghurt, flavoured with fruit. (The numbers in brackets indicate each stage in the manufacturing process).

Table 4.2 HACCP plan for the management of the manufacture of low fat yoghurt, flavoured with fruit.

Stage	Process step	Hazards	Control measures	Control point	Critical limits	Monitoring procedures	Corrective action
1	Raw milk (Receive milk)	Presence of micro-organisms	Microbiological analysis. Keep records for each tanker route	CP	Bactoscan results pH	Raw milk procedure	Reject milk if not compliant to microbiological limits
1	Raw milk (Release: tests)	Antibiotics	Rosa test Kundrat test ATK test	CCP	Negative	Raw milk procedure	Reject milk Follow up
		Foreign material	In-line filter. Inspect tanker before offloading. Quality of gaskets	CCP	No damaged gaskets	Raw milk procedure	Daily tanker inspections
1	Raw milk (Cooling)	Microbial	Temperature	CP	Milk cooled to < 3°C	Cold chain procedure	Maintenance of ice banks
1	Raw milk (Silo release)	Microbial	Temperature and time	CP	Milk to be kept at minimum of 3°C	Cold chain procedure	Maintenance of silos
		Chemical risk	Cleaning	GMP	Within parameters	GMP /WI	Quarterly check by supplier of chemicals
2	Cream separation	Chemical risk	Cleaning	GMP	Within parameters	GMP SOCP	Quarterly check by supplier of chemicals.
3	Homogenisation	Chemical risk	Cleaning	GMP	Within parameters	GMP SOCP	Quarterly check by supplier of chemicals.
4	Pasteurisation	Microbial	Temperature and time	CCP	Temperature and time	GMP WI GLP	Re- pasteurise

Table 4.2 HACCP plan for the management of the manufacture of low fat yoghurt, flavoured with fruit (Continued).

Stage	Process step	Hazards	Control measures	Control point	Critical limits	Monitoring procedures	Corrective action
4	Pasteurisation (Transfer of milk to holding tank)	Microbial	Cleaning	GMP	Wash not more than 24 h before	Visual on PC display	Wash
5	Loading milk for mixing	Microbial	Cleaning	GMP	Wash not more than 24 h before	Visual on PC display	Wash
6	Powder mixing	Physical foreign material	Production and process control	GMP	Wash not more than 24 h before	Visual on PC display	Wash
7	T105 to storage tank	Microbial	Cleaning	GMP	Wash not more than 24 h before	Visual on PC display	Wash
8	Pasteurisation and homogenisation process	Microbial	Time and temperature	CCP	Pasteurisation temperature and time	Temperature and recorder and visual on PC display	Empty pasteuriser and repeat washing and sanitisation
9	Cooling down to maturation temperature and ferment addition	Microbial	Temperature	CCP	Temperature	Temperature recorder and visual on PC display	Too high : can be cooled with ice water; too low: stop the process
10	Maturation and breaking of curd	Microbial	Cleaning	GMP	Wash not more than 24 h before	Visual on PC display	Wash
11	Cooling down, smoothing with filter and transfer to storage tank	Microbial	Cleaning	GMP	Wash 1 h before	Visual on PC display	Wash
12	Addition of sterile fruit	Microbial	Cleaning	GMP	Wash 24 h before	Visual on PC display	Visual on PC display
13	Packing	Microbial	Cleaning	GMP	Wash 24 h before	Visual on PC display	Visual on PC display
14	Storage	Microbial	Lab test	CP	< 4°C 24 h	Viscosity Coliform count	Visual on PC display
15	Dispatch	Microbial	Temperature	CP	< 4°C	Pre-cool temperature checklist	Visual on PC display

Table 4.3 Record keeping of the HACCP program.

Ingredients	Product safety	Processing	Packaging	Storage and distribution	Deviations and corrective actions
Supplier certification - documenting compliance with processor's specifications, along with Certificates of Analysis	Data and records to establish the efficacy of barriers in maintaining product safety	Records from all monitored CCP's	Records indicating compliance with specifications of packaging materials	Temperature records	Indicating approved revisions and changes in ingredients, formulations, processing, packaging and distribution control
Processor audit records verifying supplier compliance	Data and records establishing the safe shelf life of the product, as age of product can affect safety	Records verifying the continued adequacy of the process	Records indicating compliance with sealing specifications	Records showing that no product is shipped after shelf life date	
Storage temperature records for all ingredients	Documentation of the adequacy of the processing procedures from a knowledgeable process authority				
Storage temperature records for temperature sensitive ingredients					

4.2 Evaluation of the HACCP program on the yoghurt manufacturing process

4.2.1 Raw milk quality

The basic ingredient of yoghurt is whole milk or skimmed milk and hence the quality of the incoming milk is an important consideration.

In total 4 004 samples were analysed; the mean and standard deviations of the results for the various tests before and after the implementation of HACCP are shown in Table 4.4. Before implementation of HACCP the mean percentage butterfat of 434 milk samples was 3.982 and after HACCP implementation it was 3.761 for the same number of samples. Butterfat is an important component in raw milk, since it has direct financial implications on the company, as butterfat content is used in the milk payment scheme for milk producers.

Microbiologically, there was a positive impact on the raw milk quality after the implementation of HACCP. The maximum total plate count before HACCP implementation was, for example, 200 000 cfu/ml which was still within the legal specification and after HACCP implementation it was 85 000 cfu/ml. The standard deviation for the psychrotrophic bacterial counts was much smaller after the implementation of HACCP. Stricter controls in terms of the GMPs, GLPs and CCPs have resulted in this marked improvement.

These results suggested a positive impact on the shelf-life of the product as well as the overall quality of the product as the chances of customers identifying significant off – flavours in the product, will also be greatly reduced. Although there was a statistically significant difference between the before and after HACCP values for pH and temperature of the raw milk, all the test results complied with the standards/specifications for pH (6.60 - 6.75) and temperature (< 6°C). Although the mean value for the freezing point was statistically not significant, it was also within the specification.

4.2.2 In – process manufacture

One thousand six hundred and thirty eight samples were analysed. The mean and standard deviations of the various tests before and after the implementation of HACCP are shown in Table 4.5.

Table 4.4 Mean and standard deviation of the percentage butterfat, freezing point, pH, temperature, total plate count, psychrotrophic count and spore count in raw milk before and after the implementation of HACCP.

Sample	Test	Treatment	Probability level (under null hypothesis)
		Mean and standard deviation before (B) and after (A) HACCP	
Raw milk	% Butterfat	B: 3.982 ± 0.481 (n = 434) A: 3.761 ± 0.292 (n = 434)	P < 0.001
	Freezing point	B: - 0.5223 ± 0.0037 (n = 419) A: - 0.5207 ± 0.0032 (n = 419)	NS ¹
	pH	B: 6.757 ± 0.048 (n = 420) A: 6.731 ± 0.037 (n = 420)	P < 0.001 ^a
	Temperature	B: 3.717 ± 0.697 (n = 241) A: 3.318 ± 1.791 (n = 241)	P < 0.001 ^a
	Total plate count (log ₁₀)	B: 3.560 ± 1.804 (n = 123) A: 3.220 ± 0.921 (n = 123)	P = 0.139 NS
	Psychrotrophic count (log ₁₀)	B: 0.1403 ± 0.5707 (n = 198) A: 0.0318 ± 0.3162 (n = 198)	P = 0.020
	Spore count (log ₁₀)	B: 0.7491 ± 0.8038 (n = 167) A: 0.4033 ± 0.6746 (n = 167)	P < 0.001

¹ NS = Not significant

^a Although a statistically significant difference was found, it is practically unimportant

Table 4.5 Mean and standard deviation of the pH, percentage total solids, coliform count and yeast and mould count of various samples, during in- process manufacture, before and after the implementation of HACCP.

Sample	Test	Treatment	Probability level (under null hypothesis)
		Mean and standard deviation before (B) and after (A) HACCP	
Standardised milk	pH	B: 6.661± 0.232 (n = 82) A: 6.601 ± 0.254 (n = 66)	P = 0.139 NS ¹
	% Total solids	B: 16.80 ± 1.44 (n = 53) A: 16.17 ± 1.67 (n = 52)	P = 0.039
Pasteurised yoghurt base	pH	B: 6.509 ± 0.410 (n = 55) A: 6.508 ± 0.060 (n = 56)	P = 0.985 NS
	Coliform count (log ₁₀)	B: 0.00 ± 0.00 (n = 55) A: 0.00 ± 0.00 (n = 55)	NS
	Yeast and mould count (log ₁₀)	B: 0.00 ± 0.00 (n = 55) A: 0.00 ± 0.00 (n = 55)	NS
	% Total solids	B: 16.62 ± 1.56 (n = 56) A: 16.42 ± 1.54 (n = 55)	P = 0.487 NS
Yoghurt (Fermented tank)	pH	B: 4.539 ± 0.082 (n = 56) A: 4.539 ± 0.912 (n = 55)	P = 0.964 NS
	% Total solids	B: 16.50 ± 1.45 (n = 54) A: 16.14 ± 1.76 (n = 54)	P = 0.254 NS
	Coliform count (log ₁₀)	B: 0.00 ± 0.00 (n = 55) A: 0.00 ± 0.00 (n = 55)	NS
	Yeast and mould count (log ₁₀)	B: 0.00 ± 0.00 (n = 55) A: 0.00 ± 0.00 (n = 55)	NS
Yoghurt (Intermediate tank)	pH	B: 4.434 ± 0.087 (n = 71) A: 4.884 ± 0.924 (n = 71)	P < 0.001
	% Total solids	B: 16.48 ± 1.37 (n = 71) A: 15.42 ± 2.70 (n = 71)	P = 0.004
	Coliform count (log ₁₀)	B: 0.00 ± 0.00 (n = 55) A: 0.00 ± 0.00 (n = 55)	NS
	Yeast and mould count (log ₁₀)	B: 0.00 ± 0.00 (n = 55) A: 0.00 ± 0.00 (n = 55)	NS

¹ NS = Not significant

The mean pH values of standardised milk, pasteurised yoghurt base and yoghurt in the fermentation tank were statistically not significant. Before the implementation of HACCP the mean pH of the yoghurt in the intermediate tank was 4.4 and after the implementation of HACCP it was 4.8. The pH of yoghurt will impact on the organoleptic characteristics of the product. If the pH of the yoghurt in the intermediate tank is too low this may result in a very sour product. On the other hand, if the pH is too high (e.g. ≥ 4.8) the product may show signs of syneresis

4.2.3 Final product quality

Altogether 2 898 samples were analysed microbiologically, chemically and physically. The mean and standard deviations of the various tests before and after the implementation of HACCP are shown in Table 4.6.

Although there was a statistically significant difference between the mean pH values before and after HACCP implementation, it is practically unimportant.

The mean percentage total solids in the final product before HACCP implementation were 21.46 % for 152 samples and after HACCP implementation it was 21.03 % for the same number of samples. There was a significant difference in the results before and after the implementation of HACCP. After HACCP the tighter control measures that were implemented resulted in more accurate dosing of the fruit pulp to the yoghurt base which has impacted on the total solids content of the final product. Results on viscosity and % butterfat before and after HACCP implementation were statistically not significant and are within specifications.

No coliforms or yeast and moulds were detected after HACCP implementation in 306 and 305 samples, respectively. It is important to note that the mean yeast and mould count decreased from log 4.66/ml before HACCP to < 1 /ml after HACCP implementation. The coliform count before HACCP implementation was already within specification (< 20 cfu/ml) in practice. The hygienic quality of yoghurt is dependent on the effective heat treatment of the milk base, the microbiological quality of added ingredients and packaging materials, the cleanliness of surfaces coming into contact with the yoghurt and the efficiency of the plant sterilisation. The absence of coliforms and yeast and moulds is an indication of efficient plant hygiene and sanitation. This contributed to a decrease in the number of customer complaints after the implementation of

HACCP, especially regarding the presence of foreign objects, souring of yoghurt and the viscosity of the product.

Table 4.6 Mean and standard deviation of the pH, percentage total solids, percentage butterfat, viscosity, coliform count and yeast and mould count of the final product before and after the implementation of HACCP.

Sample	Test	Treatment	Probability level (under null hypothesis)
		Mean and standard deviation before (B) and after (A) HACCP	
Final product	pH	B: 4.241 ± 0.082 (n = 326) A: 4.212 ± 0.071 (n = 326)	P < 0.001 ^a
	% Total solids	B: 21.46 ± 1.22 (n = 152) A: 21.03 ± 1.01 (n = 152)	P < 0.001
	% Butterfat	B: 1.817 ± 0.125 (n = 154) A: 1.800 ± 0.079 (n = 154)	P = 0.151 NS ¹
	Viscosity	B: 87.17 ± 7.17 (n = 206) A: 86.43 ± 6.24 (n = 206)	P = 0.266 NS
	Coliform count (log ₁₀)	B: 0.620 ± 1.086 (n = 306) A: 0.000 ± 0.000 (n = 306)	N/A ⁺
	Yeast and mould count (log ₁₀)	B: 4.666 ± 40.748 (n = 305) A: 0.000 ± 0.000 (n = 305)	N/A

¹ NS = Not significant

^a Although a statistically significant difference was found, it is practically unimportant

⁺ N/A = Could not be analysed statistically

CHAPTER 5

CONCLUSIONS AND RECOMMENDATIONS

The hazard analysis and critical control points system is a logical scientific process control system for eliminating hazards at critical areas in the food production chain. The application of HACCP is based on technical and scientific principles that assure food safety.

The most important aspect of HACCP is that it is a preventative system rather than an inspection system of controlling food safety hazards. Prevention of hazards cannot efficiently and effectively be accomplished by end product inspection. The application of HACCP is systematic because structured hazard analysis and implementation are provided. The process is logical in that each processor understands its own operation and is able to assess controlling the specific process optimally. HACCP is also science based as the controls in the process are based on scientific information.

The HACCP system has two major components. Firstly, hazard analysis (HA) which identifies the where and how of hazards, and secondly, the critical control points (CCPs) that provide the control of the process and the proof of control. The primary objective of HACCP is to make the product as safe as possible and to prove that the end product was manufactured as safe as possible. Obviously, this does not mean that HACCP provides hundred percent assurance of food safety to consumers, but it does mean that a company is doing its utmost to ensure safe food production. The assurance of safety is based on the process of identifying the hazards, establishing controls for the identified hazards, monitoring the controls and periodically verifying that the system works.

5.1 Conclusions

A HACCP program was successfully implemented in a large commercial yoghurt plant within a one year period. The following conclusions can be based on this study:

- It is crucial to develop a culture that allows members of staff the freedom to act to ensure product safety at all stages of manufacture and storage in the context of their specific roles within the organisation. This enables people to take ownership of their ideas and be more flexible in executing them, thus allowing them to add value to the organisation.

- In this study, the presence of antibiotics and foreign material in raw milk, effective pasteurisation and homogenisation, as well as maintaining the correct fermentation temperature, were identified as critical control points.
- The implementation procedures and actions to ensure that the CCPs and activities are in line with the requirements of the HACCP system are crucial.
- The properly implemented and working corrective action system, the effective reviews of the CCPs, and the effectiveness of the HACCP system can be viewed as the backbone of the HACCP system.
- Indicators of efficient and effective implementation of the HACCP system include the trend(s) in the customer complaints, the nature of the customer complaints, credits passed, legal liabilities due to alleged claims of unsafe products, in- process deviations, finished goods compliance with specifications (defect levels and defect rates).
- Records generated during the normal monitoring of CCPs, hazard analysis procedures, and all other identified records of the HACCP system are very important to prove due diligence to the system.
- This study also showed that there is certainly a link between implementing a formalised system such as HACCP, and the outcomes of both in-process testing and analysis, and final testing and analysis, which will significantly impact on reducing the number of customer complaints and, more importantly, the risk to the customer that could be posed by the product. This decrease in the risk to the customer will also contribute to minimising the liability of the company in terms of legal, social, financial, image and other factors that contribute to the success of any company.
- The implementation of the HACCP system also contributed towards the ability to measure product characteristics and ensured that these were closer to the specifications. In so doing, the consistency of the quality of the product was enhanced, thereby meeting the customers' expectations. Furthermore, in minimising the deviation from the specification, the level of wastage was reduced. This reduction in wastage should contribute towards the profitability

of the product and, thereby, the company. It can therefore be concluded, as was identified in this study, that the implementation of a HACCP system not only minimises the risk of the product to the consumer, but also contributed positively towards the overall quality of the product in terms of characteristics other than product safety. The return in terms of product quality consistency, wastage reduction, and the reduction of significant customer complaints could be viewed as an investment payback, or return on the expenses, incurred in the implementation of the HACCP system.

5.2 Recommendations

- Commitment and direct involvement from the most senior levels in the company as well as from the plant's management is crucial to ensure the success of any initiative, such as HACCP. Successful implementation of the HACCP based approach requires the synergistic interaction between all role players in the HACCP team.
- The criteria used for the selection of the HACCP team leader are very important. Adequate HACCP training, knowledge of the product (s) and the manufacturing process are also some of the key requirements of the team leader. The person should also have leadership abilities, defined responsibilities, and authority.
- In line with senior management's commitment to the implementation of a HACCP system, the necessary resources, for example, finance, time, personnel, and facilities must be provided.
- The level of representation on the HACCP team should not be limited to managerial level personnel only. Shop floor level personnel should also be involved to buy into the program.
- Ongoing education, training and motivation of all personnel on HACCP principles are essential, especially when employee turnover is high.
- The HACCP system must be seen as an integral component of the company's formalized systems and must be viewed in the same level of importance as systems such as financial, occupational health and safety, legal and corporate governance.

- The implementation process should be undertaken as any other project in the company such as the installation of a new production line, the launch of a new product, and others.
- The project plan should clarify details such as objectives, timeframes/timelines, responsibilities, costs, reviews, and milestones.
- A formalized structure ensures compliance with the targets and objectives, and clarifies responsibilities.
- The process of identifying critical control points is important and should be a comprehensive exercise and approached on a scientific basis.
- The HACCP team members who identify the CCPs, should comprise of the necessary skills in the relevant fields. Non-managerial personnel (e.g., shop floor personnel) could contribute significantly to the project as these personnel may have a better understanding of the process, limitations, problems and practical concerns.
- Depending upon the level of the maturity and the scope of the HACCP system in a dairy company, and the nature of the products, backward and / or forward integration of the HACCP system can be done. In the case of a yoghurt manufacturer, the quality of raw milk can be improved by the implementation of HACCP at farm level (milk suppliers to the company) – this is an example of backward integration of the HACCP system. An example of forward integration of the HACCP system is where the customer or chain stores, are incorporated into the HACCP system.
- A suggestion for future research is to establish, in detail, what the financial implications of implementing a system such as HACCP, and what the payback on this investment, will be.

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