Extended Possibilities for the non-destructive Sterility Testing of UHT Dairy Based Products and Identification Causes for the Unsterility

By

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DECLARATION

The work describe in this thesis was carried out by me at the Department of Food Science & Technology, Faculty of Applied Sciences, Sabaragamuwa University of Sri Lanka, under the supervisor of Mr. Janitha Liyanage, Lecturer, Department of Food Science & Technology, Faculty of Applied Sciences Sabaragamuwa University of Sri Lanka & Mr Mr. Sarath P. Withanawasam, Quality Coordinator, Nestle' Lanka Ltd, Kurunegala. A report on this has not been submitted to any other university for another degree.

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Affectionately
Dedicated

To

My Parents
&
Teachers.

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ABSTRACT

In fluid milk based products such as UHT processed milk the finished products have to be checked for their quality to be certain that no unsterile product leaves the factory. In a routine quality control system, the results from incubated package controls are used as one of the parameters on which a release decision is based. Quality control of these products can be done destructively or non-destructively. Elec-Testing, is commonly used to test fully filled dairy based Tetra packs resulting from UHT processing.This study was focused basically to test the sterility of UHT dairy products in tetra packaging non-destructively by using Elec-Tester and implement the Elec-Tester on the production level.

Before starting with the testing of the units, the Tester was calibrated by using some sterile samples. The validation was carried out for every batch when packs were checked prior to releasing. When standards and tightened level are applied, 500 and 1000 number of samples were taken, from each code, respectively representing all the layers including "event" and "line" samples to test through the Tester.

All the samples which were used for the calibration and set-up the reference window, were ensured as good by opening, measuring the pH, checking the sample visually and also plating for microorganisms. The recap rejects were less than 5% of the total samples checked. No spoiled sample was found acceptable. The causes for the rejection were the variation of the net weight, changes in package integrity and sedimentation of product particles when the temperature was kept constant.

All the spoiled samples were tested for its unsterility. Sealing, product quality, packaging material damages. The most significant factor was identified as the damages during handling and it was 53% of the total effects. Secondly 34% arising from the sealing defects. Those handling defects can be minimized by paying more attention during packaging, transportation etc. and also can use shrinkable packaging materials can be used to reduce these defects. The microbial count in the air should be controlled. For that "air handling unit" can be established in the plant.

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LIST OF ABBREVIATIONS

APC	- Aerobic Plate Count
CIP	- Cleaning In Place
CCP	- Critical Control Point
°C	- Centigrade
°F	-Fahrenheit
g	-gram
H_2O_2	- Hydrogen Peroxide
Hr	-Hours
IH	- Inductive Heating
LS	- Longitudinal seal
min	-Minutes
ml	-mili Liter
NRT	-Normal Room Temperature
RTD	- Ready To Drink
s	-Second
SNF	- Solid Non Fat
SPCA	-Standard Plate Count Agar
TBA	- Tetra Brick Aseptic
TS	- Transversal Seal
UHT	- Ultra High Temperature
VRB	- Violet Red Bile Agar
VRBG	- Violet Red Bile Glucose Agar

CHAPTER 1

Introduction

Nestlé Lanka Ltd is a leading dairy company in Sri Lanka with an optimized quality management system for dairy processing. The company is engaged in the process of manufacturing a range of products including dairy products, baby foods, beverages, prepared foods, breakfast cereals and chocolate & confectionaries under different brand names, targeting all age groups in the community with the proposition of 'GOOD FOOD- GOOD LIFE'. The Nestlé has commenced as a result of the endeavor of "Henri Nestle", who introduced the first infant food.

Nestlé came to Sri Lanka in 1906 with the introduction of milk and infant foods to the local market. Today, as the largest private sector buyer of fresh milk and coconuts, Nestlé Lanka spends approximately LKR 1.5 billion each year. Almost 85% of the Nestlé products retailed in Sri Lanka are processed locally.

An Ultra Heated Treatment plant was established in the Polonnaruwa in 1998 to manufacture ready-to-drink packs marketed under the brands of MILO, NESTOMALT, NESCAFE and NESPRAY. The plant was re-established in Kurunegala factory premises from 2006.

UHT is a technique for preserving liquid food products by exposing them to brief, intensive heating. UHT treatment can be applied to a wide range of dairy and food products. Low-acid (pH above 4.5 – for milk more than pH 6.5) liquid products are usually treated at 135 – 150° C for a few seconds, by either indirect heating, direct steam injection or infusion. This treatment completely destroys the micro-organisms in the product.

The basis of UHT, or ultra-high temperature, is the sterilization of food before packaging, then filling into pre-sterilized containers in a sterile atmosphere. Milk that is processed in this way using temperatures exceeding 135° C, permits a decrease in the necessary holding time (to 2-5 s) enabling a continuous flow operation. UHT plants are fully automated and the milk is pumped through a closed system. On the

way it is preheated, highly heat treated, homogenized, cooled and packed aseptically. Compared with traditional sterilization, UHT treatment of milk saves time, labour, energy and space. UHT is a high-speed process and has much less effect on the flavor and nutritional value of milk.

In the dairy industry, finished products have to be checked for their quality to be certain that no unsterile product leaves the factory especially for fluid milk based products. Sterility test of incubated package controls is used as one of the parameters on which a release decision is based. Quality control of these products can be done destructively or non-destructively. The non-destructive sterility control method called Elec-Testing, is commonly used to test fully filled dairy based Tetra packs resulting from UHT processing.

Aseptic products can undergo contamination with micro-organisms at several places in the production process that cause spoilage. Spoilage shows up as a coagulation or a change in viscosity e.g. due to a pH drop. Other type of spoilages can cause gas formation or rarely a change of color. There are also infections. These can be traced by destructive microbiological testing but all the above causes can readily be identified through Elec-Testing accurately.

Research on the methodology of ElecTesting and the determination of the ideal settings made clear that the Tester could be used for sterility testing. The key parameters are type of spoilage, the product and the influence of the package on the sensitivity of the measurement. When considering the type of spoilage, the incubation period of a sample should be long enough for the micro-organisms to develop. The spoilage should cause a change in the visco-elastic properties of the product so that it is detectable for Elec-Tester. If the product is already too viscous, a change caused by spoilage will not change the total properties enough to be detectible. And the last parameter showed that deviations of the shape and stiffness of the pack, available head space and possible overfilling of the pack would upset this. If the sensitivity gets too low, the tester might not reject spoiled packages.

Accumulation of the results obtained from this sampling will give the average unsterility rate of a production line and will eventually shows if the line fulfils the standard sterility requirement. Final validation can be carried out timely and detailed examinations done for the rejected samples.

At present, food processing organizations which are playing in a competitive market context needs the product quality as the major factor to be considered. Development of consumer knowledge, habits etc forces the food companies to produce safe products that give minimum effect to its consumers. Therefore, to fulfill this requirement companies have to ensure the quality of their products available in the market.

This study is to test the sterility of the finished dairy based UHT products in tetra packs non-destructively. The calibration of the Elec-Tester is to be done to check for the quality and to be sure that no unsterile finished product leaves the factory. It means to develop an electronic platform which allows an optimal detection of spoiled units but avoiding too high rate of rejection of commercially sterile product.

1.1 Overall Objective:

To test the sterility of UHT dairy products in tetra packaging non-destructively by using Elec-Tester and implement the Elec-Tester on the production level.

1.2 Specific Objectives:

1.2.1 Improve the safety of the product

1.2.2 Potentially reduce the cost involved for the product release

1.2.3 Identify and evaluate the key-parameters for the application of Elec-Tester

1.2.4 Determine the sensitivity of the Elec-Tester method for packages with headspace

1.2.5 Determine the limits for viscosity of a product conforming to acceptable measurements

1.2.6 Collecting the details on operational parameters and results on the application of ElecTesting on different UHT products from the factory

1.2.7 Identification of the key causes for the unsterility in the processing plant

CHAPTER 2

Literature Review

Commercially sterile products have been on the market for a long time. Direct UHT (Ultra High Temperature) processing was introduced at the beginning of the 20th century. At that time, the technology was used only as a pre-treatment for products to be filled into cans for subsequent retorting. The 1st UHT treated and aseptically packaged products were in cans and were shown at an agricultural exhibition in London in the mid 1920s. The product (milk) was not a commercial success. During the early 1930s, aseptic canning was developed in the USA. (*Long-life products, Bernhard von Blckelmann, 1998*)

In 1961, aseptic packaging producers were introduced using flexible packaging material (a laminate of wax, paper and polyethylene): the Tetra Pack system. However, gas barrier characteristic were rather poor. In the meantime, UHT processing systems were in more general use. After initial problems, the combination of UHT processing and aseptic packaging in the TCA (*Tetra Classic Aseptic) system gained market success ("long life products"*).

In 1969, a brick shaped package was introduced. The structure of the packaging material was more complex: a PE-paper-PE-Al-PE laminate. Such a material provides protection against the entry of light and acts as an effective gas barrier. The shape of the container offered considerable advantage in storage, transportation and handling. It also provided the real breakthrough for UHT processing and aseptic packaging technology. Today, larger quantities of both high and low acid, shelf stable food products are processed by inflow (UHT) method and subsequently packaged under aseptic conditions. Milk and milk based products were the first long-life food products and still remain the largest commodity in terms of volume.

Processes that stabilize food thermally have been a major benefit to mankind by providing stability and safety in food. Although commercial canning is probably the most reliable and safest method of food preservation, it is not considered perfect. (*Long life products- Bernhard von Blckelmann, 1998*)

2.1 The UHT processes

UHT is a technique for preserving liquid food products by exposing them to brief, intensive heating. While pasteurization conditions effectively eliminate potential pathogenic microorganisms, it is not sufficient to inactivate the thermoresistant spores in milk. The term sterilization refers to the complete elimination of all microorganisms. This applies only as long as the product remains under aseptic conditions, so it is necessary to prevent reinfection by packaging the product in previously sterilized packaging materials under aseptic conditions after heat treatment. Any intermediate storage between treatment and packaging must take place under aseptic conditions. This is why UHT processing is also called aseptic processing.

Sterilizing a product means exposing it to such powerful heat treatment that all micro-organisms and heat-resistant enzymes are inactivated. The food industry uses the more realistic term "commercial sterilization"; a product is not necessarily free of all microorganisms, but those that survive the sterilization process are unlikely to grow during storage and cause product spoilage.

Milk can be made commercially sterile by subjecting it to temperatures in excess of 100° C, and packaging it in air-tight containers. Milk may be packaged either before or after sterilization. The basis of UHT is the sterilization of food before packaging, then filling into pre-sterilized containers in a sterile atmosphere. Milk that is processed in this way using temperatures exceeding 135° C, permits a decrease in the necessary holding time (to 2-5 s) enabling a continuous flow operation. The milk is unsuitable for UHT treatment if:

- It is sour
- It has the wrong salt balance
- It contains too much serum proteins – typical of colostrums

Some examples of food products processed with UHT are:

1 liquid products - milk, juices, cream, yoghurt, wine, salad dressings
2 foods with discrete particles - baby foods, tomato products, fruits and vegetables juices and soups
3 larger particles – stews

2.1.1 UHT- definition

A sterilization process is defined as a UHT (Ultra High Temperature) process, if the product is heat-treated in a continuous flow at a temperature of not less than 135°C for a very short time, aseptically packaged in sterile containers, and has undergone minimum chemical, physical and organoleptic changes in relation to the severity of the heat treatment required for sterilization.

2.1.2 Development of UHT

Experiments on sterilization of milk in bottles were already carried out by Louis Pasteur, but it was not until around 1960, when both aseptic processing and aseptic filling technologies became commercially available, that the modern development of UHT processes started. The first UHT plants operated on the principle of direct steam injection. The first indirect plants were introduced on the market some ten years later. Research and development have been intense since UHT was first introduced. Modern plants deliver a superior product with the color and nutritional values practically unchanged. (*Long life products- Bernhard von Blckelmann, 1998*)

2.1.3 UHT treatment

In a UHT plant, milk is pumped through a closed system. Low-acid (pH above 4.5 – for milk more than pH 6.5) liquid products are usually treated at 135 – 150°C for a few seconds, by indirect heating, direct steam injection or infusion. All parts of the system downstream of the actual highly heating section are of aseptic design to eliminate the risk of reinfection. Compared with traditional sterilization in hydrostatic towers, UHT treatment of milk s aves time, labor, energy and space. UHT is a high-speed process and has much less effect on the flavor of the milk. However, regular consumers of autoclave-sterilized milk are accustomed to its "cooked" or caramel flavor and may find the UHT-treated product "tasteless". (*Dairy hand book, Long-Life Dairy Products*)

2.1.4 UHT systems

UHT treatment is a process applied to a product in continuous flow. To this end, indirect or direct heating procedures can be used. In the direct systems the product comes in direct contact with the heating medium, followed by flash cooling in a vacuum vessel and eventually further indirect cooling to packaging temperature. The

direct systems are divided into:

1 Steam injection systems (steam injected into product),

2 Steam infusion systems (product introduced into a steam-filled vessel),

In the indirect systems the heat is transferred from the heating media to the product through a partition (plate or tubular wall). The indirect systems can be based on:

a) Plate heat exchangers:

Similar to that used in HTST but operating pressures are limited by gaskets. Liquid velocities are low which could lead to uneven heating and burn-on. This method is economical in floor space, easily inspected, and allows for potential regeneration.

b) Tubular heat exchangers:

All of these tubular heat exchangers have fewer seals involved than with plates. This allows for higher pressures, thus higher flow rates and higher temperatures. The heating is more uniform but difficult to inspect. A tubular system is chosen for low or medium viscosity products which may or may not contain particles or fibers.

Tubular systems are also utilized when longer processing times are required for ordinary market milk products. The processing principle, shown in figure 1, does not differ very much from plate heat exchangers. The tubular heat exchanger comprises a number of tubes assembled into modules which can be connected in series and/or in parallel to offer a complete optimized system for any heating or cooling duty. At temperature drop during production, the product is diverted into a reject tank and the plant is flushed by water. The plant must be cleaned and sterilized before restart.

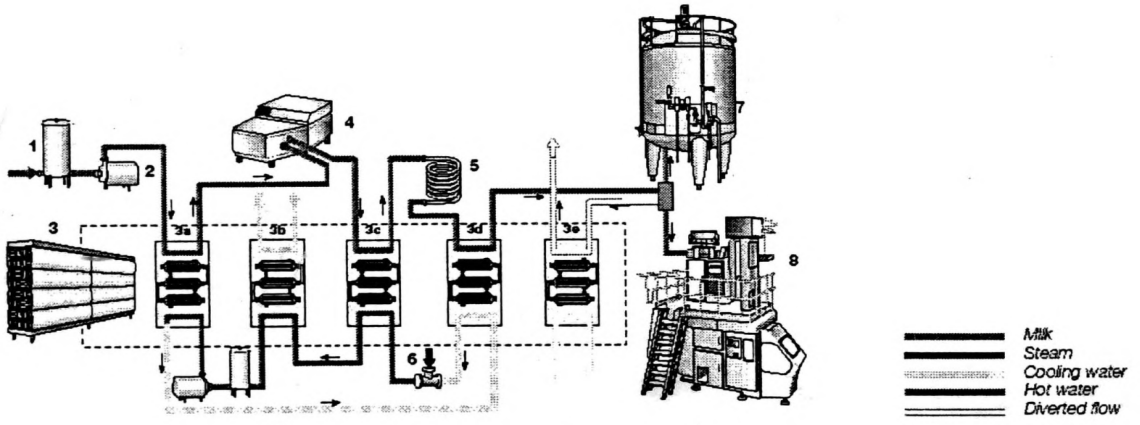


Figure 2.1. Indirect UHT system based on tubular heat exchangers

2.1.5 Aseptic tank

The aseptic tank, in figure 2, is used for intermediate storage of UHT treated dairy products. Product flow and service media connections are shown in figure 3. It can be used in different ways in UHT lines depending on plant design and the capacities.

• If one of the packaging machines incidentally stops the aseptic tank take care of the surplus product during the stoppage.

• Simultaneous packaging of two products.

The aseptic tank is first filled with one product, sufficient to last for a full shift of packaging. Then the UHT plant is switched over to another product which is packed directly in the line of packaging machines. Thus one or more aseptic tanks included in the production line offers flexibility in production planning.

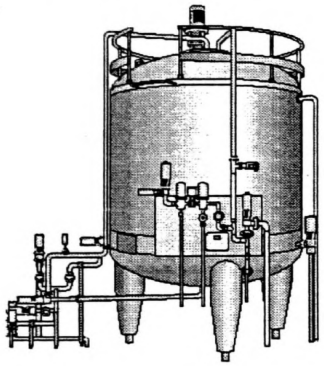


Figure 2.2 Aseptic tank

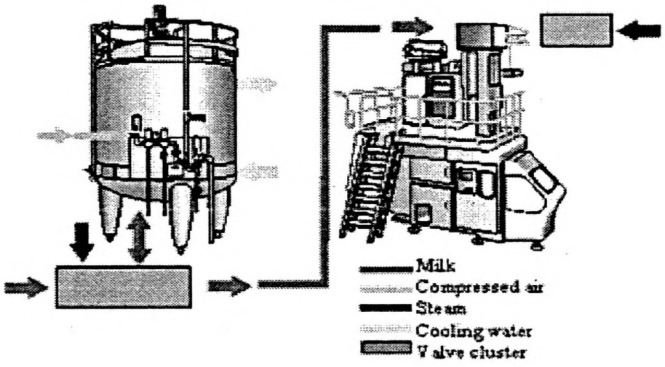


Figure 2.3 Product flow and service media connections in aseptic tank system

2.1.6 Plant sterilization

UHT plants are fully automatic and have four operating modes:

1 Plant pre-sterilization,

2 Production,

3 AIC (Aseptic Intermediate Cleaning) and

4 CIP (Cleaning In Place)

UHT treatment is a continuous process, and its application is therefore limited to products that can be pumped. UHT plants are often flexibly designed to enable processing of a wide range of products in the same plant. Both low-acid products (pH >4.5) and high-acid products (pH <4.5) can be treated in a UHT plant. However, only low-acid products require UHT treatment to make them commercially sterile.

Safety aspects must be a prime consideration in the design of a UHT plant. The risk

of supplying an unsterilized product to the aseptic filling machine must be eliminated. Interlocks in the control programming must provide security against operator errors and tampering with the process. It should be impossible to start production if the plant is not properly pre-sterilized. All sequences involved in starting, running and cleaning the plant are initiated from a control panel, which contains all the necessary equipment for control, monitoring and recording of the process.

Prior to production, the equipment can be sterilized either by superheated water or by steam. Because of the expansion and infusion vessels, direct working systems must be sterilized by steam. An additional sterilization circuit is required in installation operating through an aseptic tank. The sterilization medium is always steam. Sterilization of the aseptic filling equipment is always performed separately by heat alone or by chemicals and heat. Plant sterilization is a time-temperature treatment.

2.2 Main steps in UHT processing

In production of long-life products there are 8 major steps (figure 4) from raw materials to finished products to the ultimate consumer.

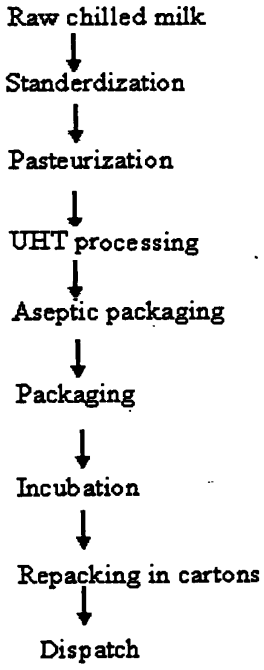


Figure 2.4 The UHT process

2.2.1 Pre processing of raw milk

Prior to actual UHT processing, the milk is usually subjected to some pre-processing procedures. This quality is not only determined by raw milk quality characteristics. The quality changes due to in plant handling and treatment contribute also. The actual raw material for a UHT process is not the milk received by the dairy but rather the product fed into the sterilizer.

Total count determinations may be helpful in evaluating the general hygienic conditions of the pre-processing treatment applied. As such they are of help and suitable quality standards could and should develop. Bacterial spore counts are of considerable interest. Bacterial spores are forms which are difficult to kill. As pasteurizing effects can be calculated and determined for pasteurizing procedures, the same accounts for sterilization operations, the difference being that spores serve as a basis.

The protein stability of milk to be processed of importance with regard to two aspects:

1 Scaling
2 Shelf-life

Scaling refers to the deposit formation on heat exchange surfaces. The amount of deposit depends on a number of factors. One of which is the protein stability. The less stable the protein, the more deposit will form. As a consequence, more frequent cleaning and plant sterilization cycles become necessary, increasing the energy consumption and the down-time of the equipment.

A suitable method for checking protein stability in milk is the alcohol test. Equal volumes of milk and ethyl alcohol of different concentrations, usually 68, 72.75 and 80% are mixed. The highest concentration of alcohol is determined which does not give a precipitate or flocculation. In a simplified way, in this test the milk protein and the alcohol compete for the water available. The higher the concentration of alcohol, the stronger will be its power to attract water. Consequently, less water will be available to keep the casein (milk protein) in suspension.

It is of importance that milk- as well as any other product- intended for UHT processing is as free as possible from particles. A determination of "dirt particles" in milk not only gives an indication of conditions prevailing during the milking and raw milk handling process, but is also useful with regard to processing characteristics. An often used procedure to determine dirt particles in milk is to filter a defined volume through a disc filter on which the dirt particles are collected. All milk intended for "in-flow-sterilization" (UHT treatment) should be classified or at least filtered prior to the processing operation.

2.2.2 UHT Process

UHT treatment of milk implies very rapid heating of the product into the temperature range of 135-150°C (275-302°F), a short holding time at this temperature, and a rapid cooling to filling temperature, usually around ambient. The goal of UHT treatment is to obtain a commercially sterile product that is a product with extended microbiological shelf-life at room temperatures. The economy of a UHT operation depends among other factors- on the length of the production run which, in turn, relates to the quality of the milk fed into the sterilizer.

2.2.2.1 Sterilizing efficiency

When micro-organisms and/or bacterial spores are subjected to heat treatment or any other kind of sterilizing/disinfectant procedure, not all microorganisms are killed at once. Instead, a certain proportion is destroyed in a given period of time while the remainder survives. If the surviving microorganisms are once more subjected to the same treatment for the same length of time, an equal proportion of them will be killed, and so on. Sterilizing efficiency depends on:

- The time/temperature combination,
- The heat resistance of the test spores, which in turn is influenced by the *Bacillus* strain used and the way the spores were produced,
- The product in which the heat treatment is taking place

Sterilizing efficiency is independent of the volume and test organisms UHT – Spores of *B. subtilis or B. stereothermophilus*. The lethal effect on bacterial spores starts at a temperature around 115°C and increases very rapidly with rising temperature. Bacteria can be divided into two groups:

1 Those existing as vegetative cells only (easy to kill by heat or other means),
2 Those existing in a vegetative state and as spores as well, i.e. spore-forming bacteria. While these bacteria are easily killed as long as they are in the vegetative state, their spores are difficult to eliminate.

Products to be sterilized usually contain a mixed flora of both vegetative cells and bacterial spores. High spore counts may be found in products with low total counts, and vice versa, so total count determination cannot serve as a reliable base for enumeration of spores in food products.

When the thermal impact on bacteria is concerned, the parameters are:

a) Logarithmic reduction of spores

The D-value, which denotes the decimal reduction time, is the time required at a specific temperature and under specified conditions to reduce a microbial population by one decimal. The decimal reduction time is dependent on the time, temperature, the type of micro-organism and the composition of the medium containing the micro-organism. The higher the temperature and the longer the holding time, the more efficient the process, i.e. the greater the sterilizing effect.
Here the effect of sterilization on micro-organisms expressed mathematically as the logarithmic function. A logarithmic function can never reach zero! To put it another way, sterility defined as the absence of living bacterial spores in an unlimited volume of product is impossible to achieve.

$$\mathbf{K \times t = \log N/Nt}$$

Where, N = number of micro-organisms (spores) originally present,
Nt = number of micro-organisms (spores) present after a given time of treatment (t), and
K = a constant
t = time of treatment

Spores of *Bacillus subtilis* or *B. stearothermophilus* are generally used as test organisms to determine the sterilizing effect of UHT equipment, since these strains–especially *B. stearothermophilus*–form fairly heat-resistant spores. *Clostridium botulinum* is used for calculation of the effect of in-container sterilization.

b) Q_{10} value

As mentioned above, the sterilizing effect of a heat sterilization process increases rapidly with increasing temperature. The Q_{10} value has been introduced as an expression of this increase in speed of a reaction. It states how many times the speed of a reaction increases if the temperature of the system is raised by 10°C. The Q_{10} value for flavor changes – and for most chemical reactions – is around 2 to 3, i.e. if the temperature of a system is raised by 10°C, the speed of chemical reactions doubles or triples. Q_{10} values can also be determined for the killing of bacterial spores. The values found range between 8 and 30. The variation is so wide because different kinds of bacterial spores react differently to temperature increases.

c) F_0 value – relationship between temperature and time of sterilization

The F-value indicates the effect of a heat treatment, which is governed by the product heating temperature and the time during which the product is held at this temperature (product holding time). The effect is directly proportional to the time; triplication of the time at the relevant temperature triplicates the effect. The effect of the heat treatment can be expressed by the following equation:

F is the effect of the heat treatment;
T is the product temperature;
To is the reference temperature;
Z is the Z-value;
It is the time during which the product is held at temperature T.

$$F = \int 10^{\frac{T - To}{z}} * dt$$

F_0 = 1 after the product is heated at 121.1°C for one minute. To obtain commercially sterile milk from good quality raw milk a F_0-value of minimum 5 – 6 is required.

d) B* and C* values

The effective working range of UHT treatments is also defined in some countries by reference to two parameters,

1 Bacteriological effect: (B*)

B* is based on the assumption that commercial sterility is achieved at 135°C for 10.1 sec. with a corresponding z value of 10.5°C. This reference process is given a B* value of 1.0, representing a reduction of thermophilic spore count of 109 per unit.

2 Chemical effect: (C*)

The C* value is based on the conditions for 3% destruction of thiamine per unit. This is equivalent to 135°C for 30.5 seconds with a z value of 31.4°C.

A UHT process operates satisfactory with regard to the keeping quality of the product when the following conditions are fulfilled: $B^* > 1$ and $C^* < 1$

2.2.2.2 Z-value

The Z-value is the increase or decrease in temperature required to reduce or increase the decimal reduction time by one decimal. It is a measure of the change in death rate with a change in temperature.

2.2.3 Aseptic transfer

After having been properly sterilized, the product has to be transferred to an aseptic filling equipment without being contaminated by microorganisms. Problems which may be encountered in this area relate to installation, maintenance, preventive maintenance, cleaning, etc.

"Aseptic transfer" covers the area between the sterilizer holding cell and the aseptic filler. Depending on the type of installation, this section may be more or less complicated. Such installation should be kept as simple and straight forward as possible: every component introduced will increase the microbiological risk of operation. Such components are sterile tanks, sterile valve batteries, manifolds etc. As far as piping is considered, a straight connection between the sterilizer and the aseptic filler is to be preferred. Unnecessary bends, up and downs, dead ends, etc. may improve the optical impression of a plant but are often difficult to clean and sterile.

2.2.4 The aseptic filling operation

The aseptic filling operation is a rather complex process. It should be fulfilled the following requirements.

a. Sterilization of the packaging material or packaging material food contact surface.
b. Creating a sterile surrounding while forming and filling the containers. This demands:

1 Sterilization of the equipment prior to the start- up of the filling operation,
2 Maintaining the sterile conditions throughout the length of the production run.

c. The production of containers which are tight enough to prevent the entry of spoilage organisms.

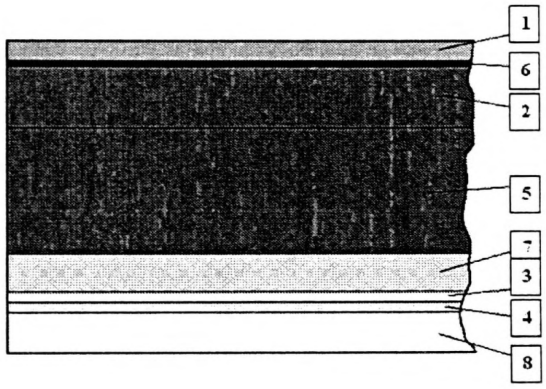
2.2.5 Aseptic packaging

Aseptic packaging has been defined as a procedure consisting of sterilization of the packaging material or container, filling of a commercially sterile product in a sterile environment, and producing containers which are tight enough to prevent recontamination. The term "Aseptic " implies the absence or exclusion of any unwanted organism from the product, package or other specific areas, while the term" hermetic" is used to indicate suitable mechanical properties to exclude the entrance of bacteria in to the package or, more stringent, to prevent the passage of micro organisms and gas or vapor into or from the container.

In general, different materials are used as aseptic packaging. I.e. metal cans, glass bottles, pure plastic materials, paper based laminates. In the present, only paper based laminates are used. From a functional point of view, the multi layered structure is shown in figure 5.

An outer PE later provides protection against moisture from the environment. The base paper layer gives stiffness and strength to the packaging material. The next layer of PE serves to bond the base paper to the Al foil, which in turn functions as a barrier against the entry of light and gas and the passage of materials and product components from the inside. The 1st inner layer of PE (Lamination) binds the last layer to the Al foil. To achieve paper adhesion, a high degree of oxidation is needed

whenever PE is used. Finally, the inner most layer, usually PE, serves as sealing and provides the contact surface with the food.(Figure 6) For it top function properly, the packaging material should be stored at the correct temperature and humidity as recommended by the manufacturer.



1. Outer coating (PE)
2. Paper board (Bleached)
3. Al-foil
4. Internal Coating 1
5. Paper board (unbleached)
6. Printing
7. Lamination (PE)
8. Internal coating 2 (PE)

Figure 2.5 packaging material structure

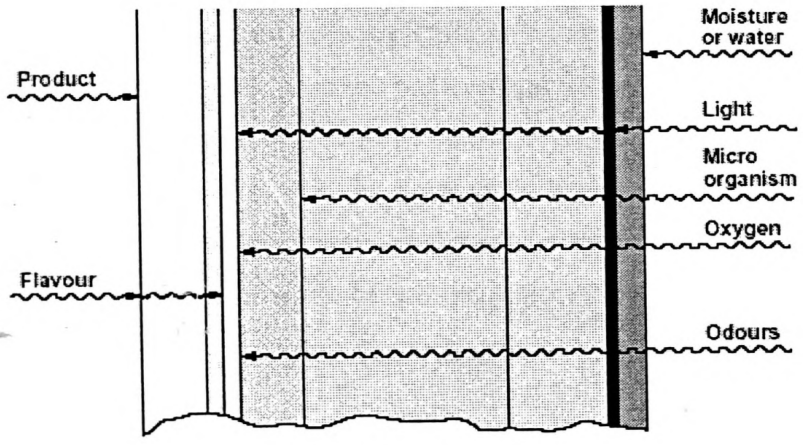


Figure 2.6 The barrier properties of the packaging material

2.2.5.1 Microbiological aspect of aseptic packaging

In the production of shelf-stable, aseptically packaged food products usually four separate process of sterilization are involved.

1. Process equipment
2. Product
3. Filling equipment
4. Packaging material

In addition, often sterile air is required in order to maintain sterility during production in the aseptic filling operation.

2.2.5.1.1Sterilization of air

The micro-biological data clearly indicate an air born infections. Nothing is known about changes in number and composition of this flora during storage, distribution and handling of packaging material. Considering the conditions prevailing, it seems unlikely that the *Pseudomonas,* other gram negative rods and yeast will survive longer periods of time.

a. Sterilization of the packaging material and its food contact surface

As far as sterilization of packaging material food contact surfaces are concerned, heat alone can usually not be used for flexible or semi-rigid materials; these materials don't tolerate the temperature-time treatment necessary. The following characteristics must be fulfilled by such sterilization procedures. The agent used must have:

Sporicidal activity
The compound must be applicable in aseptic packaging systems
Compatibility with the packaging material
Ease of removal from the packaging material food contact surface
Tolerance for residues (Low toxicity)

Sterilization of the packaging materials of food contact surface requires a minimum of 4 decimal reductions in the bacterial spore count. Different procedures can be used to this end.

1 Irradiation
2 Heat
3 Chemical treatment
4 Combinations of the above

Of these, chemical treatment in combination with some sort of heating is the most commonly apply method of sterilization if low acid foods are considered. Numerous different aseptic filling systems are offered in a market place. Most of these however are using Hydrogen Peroxide in combination with heat as a sterilizing agent.

Hydrogen peroxide as a sterilent

In the system a thin film of H_2O_2 is applied to the food contact surface by means of a roller system. The concentration of the H_2O_2 solution used is between 35 to 30 %. However cold H_2O_2 has a very slow sporicidal action on bacterial spores. In aseptic packaging rapid sterilization is needed. So the sterilization efficiency of H_2O_2 increased rapidly with an increase in temperature.

After applying the chemical on to a flat web of packaging material a tube is formed and sealed longitudally. In the center of the packaging material tube and around the filling pipe a "tube heater element" is placed. This element is heated by passing an electrical current through the spirally shaped element. Heat is transferred to the packaging material surface by irradiation and by convection thus heating the film of H_2O_2 and increasing the killing action of the sterilizing agent. At the same time H_2O_2 is evaporated leaving the packaging material food contact surface practically free from H_2O_2 residues. Having passed the tube heater element the packaging material food contact surface is sterilized as well as free from H_2O_2 residues.

b. Creating and maintain sterile surrounding while forming and filling the containers.

Prior to the start-up of the aseptic filling operation, the filling equipment has to be sterilized in order to obtain a sterile surrounding in the product filling area. The sterilization of the filler is done by hot, sterile air which is supplied by a sterile unit which is an integral part of the TCA filling machine. In this sterile air unit air from the surrounding is heated to a temperature of at least 280°C (536°F). This temperature is sufficient to achieve a satisfactory sterilization of the air. During the filler sterilization cycle, the hot air is directly admitted into the filler. All food contact surfaces are heated. After elapse of this time interval, a water cooler is activated in the sterile air system cooling down the sterile air as well as all food contact surfaces in the filling equipment.

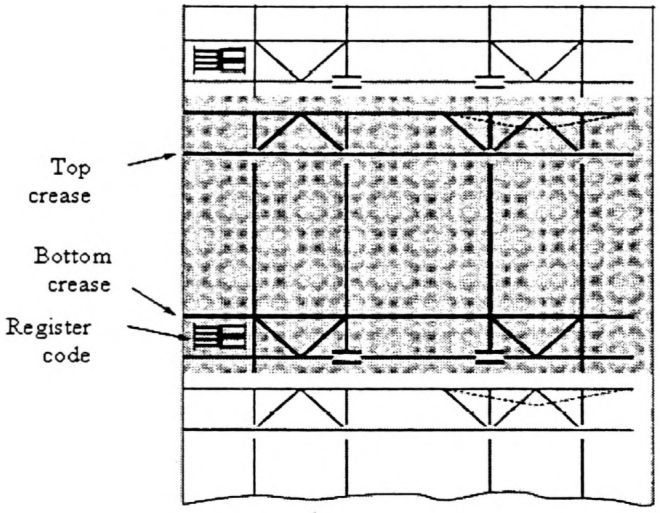


Figure 2.7 Creased packaging material

The heating application that is used for transversal sealing is called induction heating (IH). IH is clean form of heating and one of its main advantage is that the heating takes place in the work place. I.e. the Al foil, there by reducing to a minimum all the losses normally associated with heating. Figure 8 shows the principal of the IH.

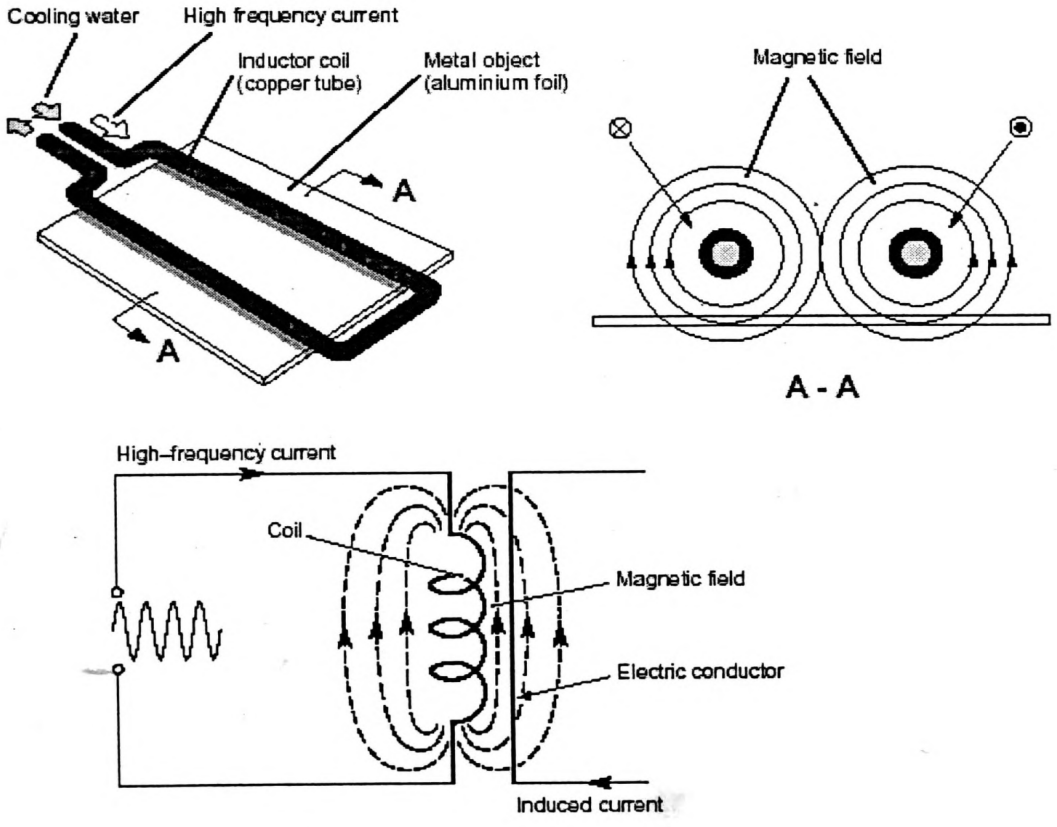


Figure 2.8 The principle of inductive heating

The IH generator generates a current of high frequency, the inductor function as a coil and creates a magnetic field. This magnetic field oscillates at time (at the same frequency) with the current, inducing a current in an electric conductor placed in the magnetic field. In this turn, the induce current oscillate in time with the magnetic field and produce the energy that heats the material. Heat is induced in the Al foil, this leads to the melting of the PE layer, so that they can be sealed (Fig. 9).

Maintenance and preventive maintenance is needed to ensure satisfactory seam quality as well as to prevent damage of the packaging material in general which may interfere with the tightness of the container. Thus, units are produced which are sufficiently tight to prevent reinfection of the product.

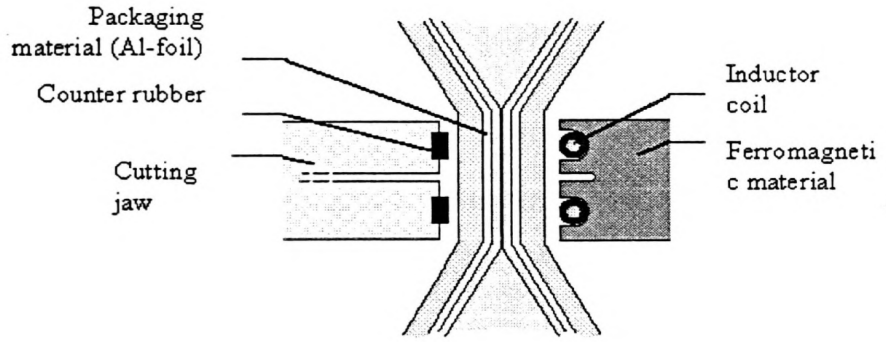


Figure 2.9 Transversal sealing

Furthermore, the package as a total must provide the barrier characteristics necessary for the intended shelf- life of the product. Gas and light barrier characteristics are placed on both, the packaging material as such and the seams of the package as wall. As far as flexible and semi-rigid materials are concerned, paper based laminates are with an Al foil incorporated provide excellent barrier characteristics against the entry of gas (oxygen) and light as well. Also, evaporation of water and/or aromatic compounds from and in to the packaged product is partially eliminated.

2.2.5.2 The basic principles of the aseptic filling operation

1 Cleaning

It is recommended that the filling equipment is cleaned by a separate cleaning unit, not together with the sterilizer/ product line cleaning circuit.

2 Sterilization

Depending on the aseptic packaging system, sterilization of the equipment is either done by hot sterile air alone or by a combination of a hydrogen peroxide spray followed by drying with hot sterile air. Temperatures should be checked. Where applicable, hydrogen peroxide concentration, spray volume and time should be controlled. Through these steps are subject to automation, they should be checked with a certain frequency. Special attention should be paid to the proper disinfection of some specified parts.

3 Maintenance

Tetra Pak recommends maintenance and preventative maintenance procedures. It is essential that these recommendations are followed to ensure a satisfactory functioning of the filling equipments. Records should be kept of all repairs and spray parts used.

4 Inspection

Cleanliness must be observed. Unnecessary splashing of water must be avoided. The filling area should be kept free from people who do not work there. Proper record keeping is important: all events during a production run and connected with the filling operation must be listed.

5 Surrounding, environment

Sterilization process operate with a certain built-in sterilizing efficiency: the result achieved thus depends upon the microbial load fed into the system. This microbial load is strongly affected by the hygienic conditions: prevailing in the filling area. Microbiological checks should be done regularly on the air in the filling area.

6 Packaging material storage, handling and stock holding

The packaging material should be handled and stored correctly. Unnecessary dust, moisture and water must be prevented. Dust and dirt which has collected on the outer wrapping of the packaging material reels should be removes before the reels are bought into the filling area. During handling of the packaging material, mechanical damages must be avoided and damaged reels must be removed from the stock.

7 Package integrity

Tight packages are a precondition for a safe production of long life products. Consequently, control of the package integrity becomes an important activity. Tightness control must be done by the machine operator. Should check on container integrity at regular intervals.

8 Sampling of containers for incubation

Packages should be removed from the production line for incubation and sterility testing. To this end, a sampling plan must be developed by the quality control department.

2.2.6 Internal transport and handling

The area of internal transport and handling consist of three different activities:

a. Product line equipment (PLE), such as straw applicators, tray packers, shrink film units, conveyor belts, etc.
b. Transportation of the product into the storage area
c. The actual storage of the product prior to its release into the market place.

During these handling and storage procedures, the container may be damaged, an event which should be kept to an acceptable minimum. PLE will only function properly and will not damage packages if it is maintained. Schedules for maintenance and preventive maintenance should be established and executed. Inspection of machine operator performance is a further important activity. Preferably, a certain number of samples should be taken from the first packages having passed the PLE line and checked for mechanical damage.

After being cleared by "quality control", the product is released into the market place. As this stage, the product leaves the immediate sphere of influence of production but has not reached the consumer yet.

2.2.7 Distribution

This covers the transportation of the finished product from the production plan to the sales outlets or to the consumer. It is important to consider about the transport damages and recontamination.

2.2.8 In-shop handling

Acceptance of a product by the consumer relates not only to price, quality, etc. but also to the way in which the product is presented. Exposition must be right. Suitable information to the consumer may be needed.

2.2.9 The consumer

The importance of the consumer for the success of an industrial operation cannot be overestimated. The success of a long-life product operation is actually determined by the consumer acceptance. To this end, a certain quality level is required which can only be guaranteed- within reasonable limits- if the long-life product production is controlled by a functional quality control system. In this aspect, it is not only of importance that the product leaving the production plant meets certain well defined standards and specifications but also-and even more so- that the product is of a consistence and acceptable quality level when it is actually consumed.

As far as the consumer is concerned, the most important quality aspect of long-life products is the flavor. Unfortunately, during the shelf-life of most long-life products, the flavor changes continuously. These changes are not only dependent upon storage time but also on storage temperature. Not specific, generally valid statement can be made with respect to the shelf-life of long-life products as measured by its organoleptic characteristics. Differences in flavor acceptance exist between different products, different markets, etc.

2.3 Changes during UHT processing

The product should have been subjected to a heat treatment having a sufficiently high lethal effect - so that, after incubation at 30°C ± 1°C for 5 days - no spoilage occurs and the changes in flavor, odor, color, and nutritional value are minimized. In addition to ensuring the destruction of micro-organisms, the heat treatment of milk also results in a number of other reactions and changes.

Choosing the type of process and temperature-time combination best suited to the handling of a range of products of widely varying initial quality and composition, should be based on the bacteriological and physio-chemical changes referred to above. The question then arises how the effect of the heat treatment, in particular, can

be measured and assessed. Understanding the various parameters will afford an insight into the manner in which a sterilization process should best be affected.

2.3.1 Chemical changes at high heat treatment

When milk is kept at a high temperature for a long time, certain chemical reaction products are formed, which results in discoloration (browning). It also acquires a cooked and caramel flavor, and there is occasionally a great deal of sediment. These defects are largely avoided by heat treatment at a higher temperature for a shorter time. It is important that the time/ temperature combination is chosen so that the spore destruction is satisfactory and at the same time the heat damage to the milk is kept at the lowest possible level.

At refrigeration temperature, some 5 – 7 °C, the UHT flavor will be suppressed. Therefore, when, for instance comparison of the influence of various methods of UHT treatment are made, the organoleptic evaluation should be made at 20 °C after the samples have been stored at 20 °C for various periods, say 2; 4 and 6 weeks. Tests made in this way show that significant differences exist between direct and indirect methods, the latter exposing the milk to a higher temperature load.

2.3.2 Nutritional effects

Table 2.1 : Effect of nutrient value

Constituents	Heat effects
Fat	No change
Lactose	Marginal changes
Protein	Partial denaturation of whey proteins
Mineral salts	Partial precipitation
Vitamins	Marginal loss

2.3.3 Vitamin loss

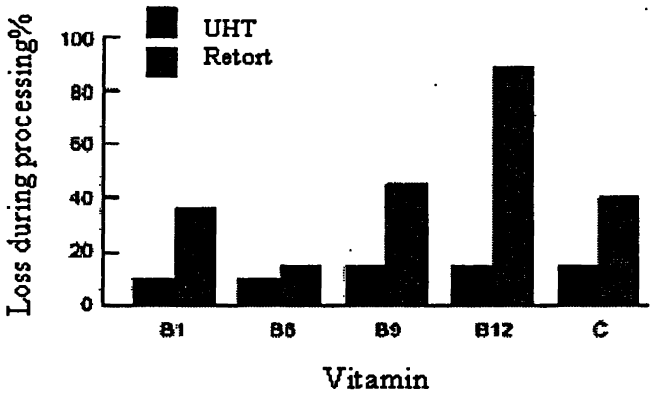


Figure 2.10 Vitamin losses during processing

2.3.4 Age gelation

Age gelation is an aggregation phenomenon that affects sterilized dairy products. After weeks to months storage of these products, there is a sudden sharp increase in viscosity accompanied by visible gelation and irreversible aggregation of the micelles into long chains forming a three-dimensional network. The actual cause and mechanism is not yet clear, however, some theories exist:

1 Proteolytic breakdown of the casein: bacterial or native plasmin enzymes that are resistant to heat treatment may lead to the formation of a gel
2 Chemical reactions: polymerization of casein and whey proteins due to Maillard type or other chemical reactions
3 Formation of kappa-casein-ß -lacto globulin complexes

2.3.5 Shelf life

Another term used in UHT treatment to characterize the quality is the shelf life of the product. This is defined as the time for which the product can be stored without the quality falling below a certain acceptable, minimum level. The physical and chemical limiting factors of shelf life are incipient gelling, increase of viscosity, sedimentation and cream lining. The organoleptic limiting factors are deterioration of taste, smell and color.

2.4 Quality control of long-life products:

2.4.1 Incubated pack control

Quality control of long-life products implies complex activities in different areas. Sampling, incubating and evaluating a certain number of containers in only one of many other activities. In "incubated pack control" the commercial sterility of the packaged product is checked for microorganisms capable of multiplication under normal conditions of storage and distribution. The microbiology of long-life products permits three solutions:

I. The product is free from living microorganisms
II. The product contains microorganisms which do not grow under normal conditions of storage and distribution
III. The product contains microorganisms capable of multiplication under the conditions of storage and distribution

The bacteriology of long-life milk is actually a bacteriology of failure. The task of an incubated pack control is to detect such failure and, within specified limits, to "guarantee" the microbiological quality of the product released into the market. It is an undesirable desire of the management of a long-life product production plant to have certainly about the bacteriological quality of the production. This, however, would demand 100% destructive inspection an action which is hardly acceptable. As a consequence, only a limited number of packages can be tested. Incubated pack control consist of:

a) A sampling scheme
b) Incubation of the sample units
c) Evaluation of the incubation units

(a) A sampling scheme

When looking at sampling schemes, three different situations must be distinguished:

a. Commissioning of a plant:

The purpose of commissioning is to determine whether or not a certain installation performs to specifications. In a long-life product production plant, the raw materials, the sterilizer, the aseptic transfer and the aseptic packaging operation are to be tested. Evaluation has to be destructive or non destructive; pH or better oxygen tension

measurements are recommended for the larger portion of the incubated packs. Some should be tested by microbiological test procedures. Incubation should be done for a minimum of 5 days; the temperature of incubation depends on the product, the area and legal regulations. The areas of Sri Lanka with moderate temperatures (up to 25-30°C) an incubation temperature of 30-35°C is recommended for low-acid products.

b. Start of commercial production

Acceptable defective rates should be clearly defined before starting commercial production. Also, re-sampling schemes should be prepared well in advance of any problems and applied if the situation requires. After a proper period of time and after an acceptable result has been obtained, sampling should be switched to "normal production sampling".

c. Normal production sampling

The plant is now in normal operation and some routines have been established. Successful marketing of a product subjected to 100% inspection is possible only if non-destructive methods of evaluation are available. If all the methods which can be used for checking commercial sterility are destructive, 100% inspection becomes an impossibility. The new computerized Elec-Tester MK IV quality control unit is designed for 100% inspection without opening the milk package.

Many sampling procedures, only high levels of defective rate can be detected with any degree of safety. At this point it should be pointed out that two different sampling procedures can be applied.

1) Random sampling

Random sampling implies collecting of units (packages) evenly distributed over the entire production run. Each individual package must have the same chance of being sampled. Normal procedures for Random sampling are drawing samples at regular time interval, i.e. every 15, 30 and so on minutes. Regarding the construction of the filling equipment, consecutive packages should be drawn for incubation.

2) Aimed sampling

Aimed sampling is trying to cover those areas and steps in a production run, where an increased risk for defective exists. "Higher risk moments" depend on the installation, but the following points can be mention generally.

1. Start of production.
2. Change of packaging material reel.
3. Change of longitudinal strip.
4. End of production run.

Obviously aimed sampling will always give a high level of defective than random sampling, while the average defective level of a long life product production line can be determine by the accumulation of the results from random sampling, aimed sampling will indicate operative faults etc. Both the sampling schemes are important and runs regularly at the UHT plant. The results were recorded separately, since both indicate different aspects.

Quality control means spending money. The total cost of incubator pack control may be express by the following equation.

$$a = nb + nc$$

In this equation, "a" represents the total cost of incubator pack controller. The number of units making up the sample to be tested is designated "n". "b" is stands for the cost connected with loss of products .e.g. Milk, loss of packaging material, while the expenses of evaluation are expressed by "c".

Obviously "n" is directly related to the probability of including a defective unit in the sample. In other words, the more units are tested, the more likely it becomes that a defective unit will be included in the sample. On the other hand,"c" is co-related to the exactness with which a defective unit present in the sample will be detected. The more expensive the method of evaluation, the more accurate will be the result.

(b) Incubation of the sampled units

1. Incubation period

An incubation period of the sample unit is necessary in order to allow the very limited number of micro organisms presents in a defective unit to grow, thus making detection possible. Incubation of containers is a time/temperature combination. Two different incubation procedures can be discussed and considered.

1. Storage control incubation proper:

The incubation temperature is determined by the temperature in the storage area, which of course, varies from day to day and from season to season. The pallets thus collected are then put under control temperature conditions, for instance at 30-35°C, in an incubation area. After the lapse of the required incubation time each unit is checked individually for possible signs of unsterility.

2. Selection of storage containers:

Which are placed under control temperature condition and checked by non distractive methods of evaluation. For this purpose normally used 55 ° C temperatures for 5-7 days. At higher temperatures the metabolic rate of microorganisms is high. This gives rapid results if the product was contaminated than in normal room temperature storage.

2. Time of incubation

Longer the time period of a sample is kept at incubation temperature is better. But an increase in incubation time usually also implies an increase in cost. In order to protect the consumer from receiving substandard product and at the same time protect the reputation of the commercial processor, incubation is carried out.

(c) Evaluation of the incubated units

An incubated sample is a sample which has been exposed for certain period of time at a certain defined temperature. Evaluation means the application of methods and procedures to decide whether or not incubated units are commercially sterile. As previously mentioned, practically all such methods available today are destructive, the "Elec-tester" being the exception.

Recently a number of testing methods are being offered on the market claming reduction of time of incubation, reduced time for evaluation etc. and at the same time

maintaining the high level of accuracy as obtained with bacteriological checking method. In choosing methods of evaluation, the following aspects should be considered.

1. Cost of the procedure used.
2. Accuracy of the method applied
3. Time of evaluation.
4. Legal requirements

The lack of quality control in general and incubator pack control in particular is to determine whether the product is within specification or not. To this end it becomes necessary to defined and specify the process: acceptance limits have to be established. Regarding the very limited number of packages tested and the high defective rate necessary to give a positive result, the acceptance level should obviously be 0. If one or more unstarile units are detected, a resampling plan must be activated. Such resampling plans should be prepared well in advanced.

Also, bacteriological testing should be done on all defective units found. Valuable information can be gathered from such testing. A rough identification of the spoilage flora should be attempted.

2.4.2 Testing the packages for the sterility

In case of faulty packaging of UHT milk products, bacterial action in the milk may occur after a short period of storing. This action can cause possible changes in the hydrodynamic features of the product. The Elec-Tester MK IV quality control unit showed in Figure 11, is designed for detecting such changes without opening the milk package. During testing the sample package is subject to mechanical motion only; it is not damaged in any way and can be sold normally.

The destructive method also have the random and aimed samples. These samples were incubated as in non-destructive method. In here all the event samples and 55° C incubated samples were cut opened.

The Elec-Tester is designed for precise and reliable results in practical process. The connection to a monitor and a printer makes it easier to visualize the measurement. This type makes it possible to save the values and to process the results digitally. Elec-Tester MK IV is operate manually, by changing the packages on the Brik holder.

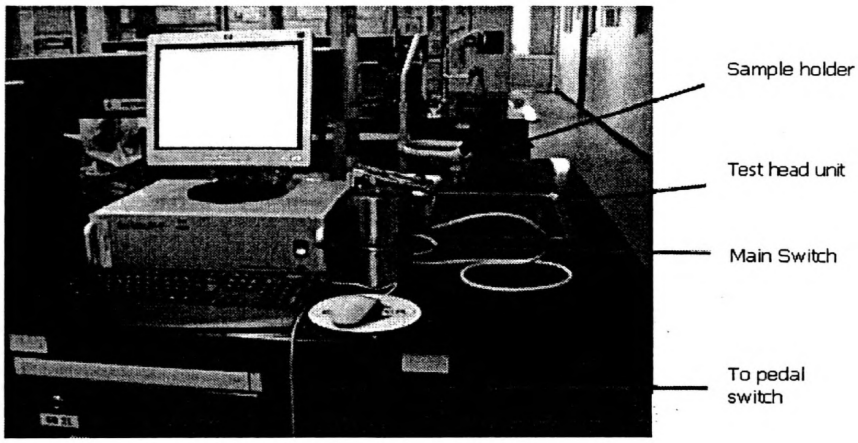


Figure 2.11 The Elec-Tester MK IV

Samples should always be tested after the incubation period, so that microbes have time enough to cause measurable changes in the hydrodynamic behavior of the UHT milk product. The speed of coagulation depends on the bacteria and on the product itself. The normal practice for thermophilic microorganisms is incubation 5±1 days at 55°C. For mesophilic ones it is advised to incubate for 10 ± 3 days at 30°C.

2.4.2.1 Basic theory of operation

The Brik holder on top on each test head is connected to a steel spring. In the beginning of each measurement cycle, the sample package is made to oscillate after movement of an electronic magnet, which is connected to the other end of the spring. This motion is dependent on the physical property of the product in the package. The unit sensors the smallest difference in these properties. The following two values are measures during an oscillation.

1. Damping factor; which represent damping speed.
2. Period time; which represents the length of the vibration cycle.

These values are independently measured at the same time but this information is not enough to decide whether to accept or reject package. The unit must also have reference values from sterile package and knowledge how much the measured value can differ from the reference due to influencing parameters like room temperature changes. The results of the measurement is presented in the main display of Elec-tester Figure 12 where damping factor is x coordinate and period time is y coordinate. Limits of acceptable value are shown as a window.

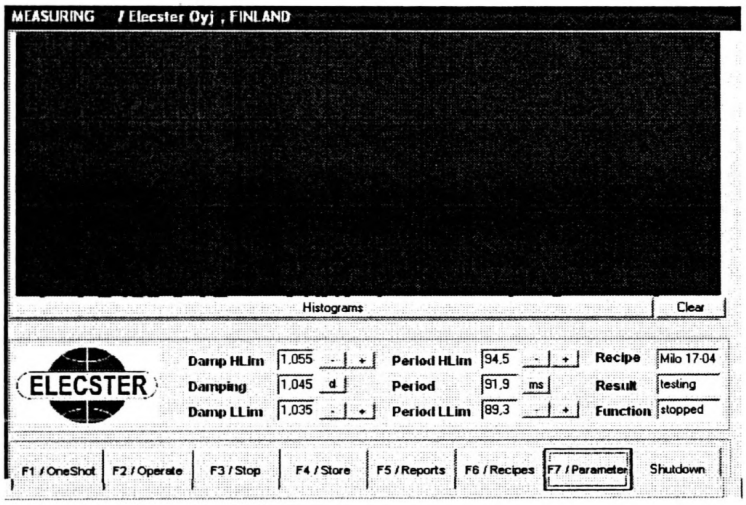


Figure 2.12 Main display of Elec-tester

There are two ways to define the reference value.

1. The operator define the value for new product
2. The stored receipt value is used during everyday measurement.

The unit is comparing the damping factor and period time independently to the reference value. Depending on the "window" adjustment, the unit more or less critical to accept the sample packages. The measured results is displayed as a red dot on the display. In case a dot is outside the acceptability window, the device considered the pack as being spoiled. There is an optional odibal rejection signal, or a red "bad" window shown on the display for a short time.

The display is divided into two sections, the upper, green colored; side shows a graphic display of result from the last 50 measured packages. The vertical lines are the window limit for damping measurement. The horizontal line is the limits on period measurements.

Accepted values are not absolute values. It is possible to compare them to a present preference window, but it is not possible to co-relate a certain damping factor to a viscosity. Other parameters like storage temperature, package stiffness, and the tightness of sample holder influence value. Each Elec-Tester and each sample holder also has its influence on the figures caused by factors like different in weight and tightness. So to compare results the same conditions should be maintained. Even the screwing on and off of the sample holder can cause variations.

2.4.2.2 Product and package properties

The normal viscosity of the product influences the values produced by Elec-Tester. The deviation in this characteristic determines the size of the reference window. The difference between a sterile and a spoiled sample should be as big as possible. Therefore all other sample properties should be as constant as possible. Package geometry, serum building and possible sedimentation should not influence the reference window so not sterile samples are accepted. This is important when packages with headspace are used.

2.4.2.3 Constant temperature of the measured samples

The temperature in the room where the measurement takes place should be as constant as possible to assure consequent values. The samples should taken out of the incubation room and leave them at ambient temperature for at least 8 hours to reach that particular temperature. In this way all measured samples will have the same temperature. The package material also influences this. The temperature can make certain package types more flexible, which will influence the final value.

2.4.2.4 Decreasing the false-positive rate

The Elec-tester settings should be set in a way that all spoiled samples are rejected. It is possible that this will include the rejection of some so called false positive. The rate of false positive says something about the effectiveness of the Elec-tester. The lower this rate the more samples can be saved from destruction.

1. Increase the reference window size without accepting any spoiled samples
2. Increase the incubation time to enlarge the difference between a spoiled and a sterile sample.

These are the things that can be done to decrease the false positive rate. In quality assurance point of view the defective units are gathered from the storage area. The defective units show a detectable changes selected from the storage area. In any event, enough storage time has to pass in order to allow sufficient microbial multiplication leading to recognizable changes. Only defective units showing such changes can be sorted out. Gas formation results in blown packages and can be easily detected in a storage control procedure.

1.5 Advantages of UHT processing

1 High quality: The D and Z valves are higher for quality factors than microorganisms. The reduction in process time due to higher temperature (UHTST) and the minimal come-up and cool-down time leads to a higher quality product.

2 Long shelf life: Greater than 6 months, without refrigeration, can be expected.

3 Packaging size: Processing conditions are independent of container size, thus allowing for the filling of large containers for food-service or sale to food manufacturers (aseptic fruit purees in stainless steel totes).

4 Cheaper packaging: Both cost of package and storage and transportation costs; laminated packaging allows for use of extensive graphics

1.6 Difficulties with UHT

5 Sterility: Complexity of equipment and plant are needed to maintain sterile atmosphere between processing and packaging (packaging materials, pipe work, tanks, and pumps); higher skilled operators; sterility must be maintained through aseptic packaging

6 Particle Size: With larger particulates there is a danger of overcooking of surfaces and need to transport material - both limits particle size

7 Equipment: There is a lack of equipment for particulate sterilization, due especially to settling of solids and thus over processing

8 Keeping Quality: Heat stable lipases or proteases can lead to flavor deterioration, age gelation of the milk over time - nothing lasts forever! There is also a more pronounced cooked flavor to UHT milk.

CHAPTER 3

Materials and Methodology

3.1 Quality Testing of Milk

3.1.1 Fresh Milk analysis

3.1.1.1 Organoleptic Quality

Materials

Fresh cow milk

Methodology

Fresh cow milk was examined for its organoleptic properties, such as taste, smell and color.

3.1.1.2 Analysis with Milco Scanner

Materials

Milco Scanner

Distilled water

Methodology

The standard sample was warmed for 5 minutes at < 40 °C, turned upside down 10 times. Placed enough sample in a beaker under milk intake tube and pressed completely the milk in once and collected immediately the mixture of dilutent in the notch of the mix intake tube and operate the pump handle 3 times smoothly. The results were recorded and compared with standard values of milk fat, protein, SNF (Solid Non Fat) and FPD (Freezing Point Depression).

3.1.1.3 Enumeration of Mesophilic Aerobic Plate Count

Material

Raw milk sample

0.1 % Tryptone water

SPCA

Test tubes

Petri Plates

1ml micro pipette

Methodology

1ml of raw milk was pipetted and added into 9 ml of 0.1% Tryptone water under aseptic conditions. A dilution series from 10^{-1} to 10^{-5} was prepared. Each tube was mixed well. From each dilution, 1.0 ml each was transferred into two sterile Petri dishes under aseptic conditions to form two sets of plates of all dilutions. To the plates 15 ml of SPCA tempered to 45 ± 1^0 C was poured. The contents of each plate were mixed well and the plates were left for some time to solidify. After solidification, the plates were placed in an incubator with a temperature of 30^0 C $\pm$ 1^0 C and were incubated aerobically for 3 days.

3.1.1.4 Alcohol test

Materials

78% Ethyl Alcohol

Fresh milk sample

Test tubes

Pipettes

Methodology

Milk sample was mixed well and 2 ml of milk is pipetted to a test tube. 2 ml of 78% alcohol was poured into milk using pipette and sample was mixed well without shaking.

3.1.1.5 Delvo test

Materials

Delvo incubator

Fresh milk sample

Delvo test kit

Methodology

0.1ml of well mixed milk sample to be tested was added to an ampoule in Delvo test kit. It was incubated for 3 hours at 64 ^{0}C $\pm$ 0.5 ^{0}C in Delvo incubator. Ampoule was withdrawn and result were taken. A yellow colour indicates the absence of antibacterial substances whilst purple colour indicates the presence antibacterial substances.

3.1.1.6 Test for adulteration of fresh milk

3.1.1.6.1 Determination of Acidity

Material

Fresh milk

Homogenizer

Test tubes

Pipettes

Burette

magnetic stirrer

0.25 N NaOH solution

2% phenolphthalein solution

Methodology

A 10ml of homogenized fresh milk portion was pippeted into a test tube. 1 ml of 2% phenolphthalein was added and stirred on a magnetic stirrer. It was titrated with 0.25 N NaOH until a slight pink colour persists for 30 seconds. Acidity was calculated in Soxhlet Hankle degree using NaOH volume.

3.1.1.6.2 Detection of Urea

Material

Fresh milk

Homogenizer

Test tubes

Pipettes

Urease solution

Water bath

Phenol red solutionMethodology

A 5 ml test portion from homogenized fresh milk sample is pippeted into a test tube. 5 ml of Urease solution is added .mixed well and is place in a water bath at 40 ^{0}C for 15 minutes. Test tube is taken out and two drops of phenol red is added and mixed. If sample is urea positive it gives a pink-violet colour, if not colour is light brown.

3.1.1.6.3 Detection of sucrose - Cayaux method

Materials

Fresh milk

α napthol

Test tubes

Pipettes

37% HCl solution

Boiling water bath

Stop clock

Methodology

Two drops of fresh milk and one drop of α napthol was added into a test tube and mixed well. 3 ml of 37% HCl was also added and test tube was placed in boiling water bath for 10 seconds. Then it was placed in normal water for 5 seconds. If solution turns to blue- violet colour, sucrose positive, if it remains colorless then no added sucrose.

3.1.1.6.4 Detection of $NaHCO_3$

Materials

Fresh milk

Bromothymol blue solution

Test tubes

Pipettes

Methodology

Two drops of bromothymol blue was added to a 5 ml of fresh milk sample in a test tube and was mixed well. If solution turns to blue, $NaHCO_3$ was added and if $NaHCO_3$ negative a yellow colour solution was resulted.

3.1.1.6.5 Detection of NaCl

Materials

Fresh milk

Potassium chromate

Silver nitrate

Test tubes

Pipettes

Methodology

One drop of potassium chromate and 1 ml of silver nitrate was added to 1 ml fresh milk sample in a test tube. NaCl positive samples were turned to yellow colour while negative samples gave a brick red colour.

3.1.1.6.6 Detection of H_2O_2

Materials

H_2O_2 detection strip

Fresh milk

Methodology

If there was added H_2O_2 detection point of the strip was turned to blue colour. An idea of the quantity of added H_2O_2 was given by intensity of the strip, compared to the colour chart of the strip container.

3.1.1.7 Determination of Chemical properties

3.1.1.7.1 Fat by Mojonnier method

Material

Fresh milk

Mojonnier extraction flask

Weighing balance

Ammonia

Ethyl alcohol

Diethyl ether

Petroleum ether

Centrifuger

Congo red solution

Dishes

Methodology

The test portion of the products was weighed and poured into a Mojonnier extraction flask and dissolved by adding distilled water at 60 ^{0}C. If the product contain starch, starch was digested with α amylase for 2 hours by placing in a water bath at 60 ^{0}C. It was treated with ammonia, ethyl alcohol, diethyl ether and petroleum ether by mixing after each addition and centrifuged. A colour indicator, Congo red was added after ethanol addition to separately identify chemical layer from residue. The ether layer

was poured into pre treated, weighed dish. The second extraction, centrifugation, decantation and evaporation were done to the residue and the ether layer is poured into the same dish. For the products containing more than 30% fat a third extraction was performed. The solvent was completely removed by evaporation and vacuum. After cooling the dish to room temperature weight was measured and the fat % is calculated.

3.1.1.7.2 Moisture by Oven method

Material

Fresh milk

Water bath

Moisture dishes

Desiccators

Oven

Tweezers or clean gloves

Weighing balance

Moisture evaporator

Methodology

A cleaned dish with lid was oven dried for overnight at 102 ^{0}C. The dish was transferred to the desiccators with a tweezers or clean gloves. It was allowed to cool for 45 minutes. The dish was weighed with the lid and homogenized 2 g test portion was weighed to the dish. Sample was spreaded over the whole surface of the dish to enhance the moisture evaporation. The dish with lid to one side was placed into the oven. It was dried at the temperature and for the length of time depending on the product to be analyzed. Lid was replaced on dish and immediately transferred into the desiccators. After 45 minutes cooling time it was weighed to the nearest 0.1 mg and calculated the moisture content %.

3.2 Quality testing of the final product

3.2.1 Enumeration of Mesophilic Aerobic Spore Count

Materials

Product sample

0.1% Tryptone water

SPCA

Test tubes

Petri Plates

1ml micro pipette

Methodology

Product was incubated in a 80 ± 1^0 C water bath for 30 minutes. 1ml of the heated raw milk was pipetted and added into 9 ml of 0.1% Tryptone water under aseptic conditions. A dilution series from 10^{-1} to 10^{-7} were prepared. Each tube was mixed well. From each dilution, 1.0 ml each was transferred into two sterile Petri dishes under aseptic conditions to form two sets of plates of all dilutions. To the plates 15 ml of SPCA (Appendix – A.1) tempered to 45 ± 1^0 C was poured. The contents of each plate were mixed well and the plates were left for some time to solidify. After solidification, the plates were placed inverted in an incubator with a temperature of 30^{0}C ± 1^0 C and were incubated aerobically for 3 days.

3.2.2 Enumeration of Thermophilic Aerobic Spore Count

Materials

0.1% Tryptone water

SPCA

Test tubes

Petri Plates

1ml micro pipette

Methodology

Product was incubated in a 100 ± 1^0 C water bath for 30 minutes. 1ml of the boiled raw milk was pipetted and added into 9 ml of 0.1% Tryptone water under aseptic conditions. A dilution series from 10^{-1} to 10^{-7} were prepared. Each tube was mixed well. From each dilution, 1.0 ml each was transferred into two sterile Petri dishes under aseptic conditions to form two sets of plates of all dilutions. To the plates 15 ml of SPCA tempered to 45 ± 1^0 C was poured. The contents of each plate were mixed well and the plates were left for some time to solidify. After solidification, the plates were placed in an incubator with a temperature of 55^0 C ± 1^0 C and were incubated aerobically for 3 days.

3.2.3 Swabbing For Hygiene Evaluation

Material

Sterile swabs

0.1 % Peptone water

SPCA

VRBA

Test tubes

Petri Plates

1ml micro pipette

Methodology

A sterile swab was withdrawn from its tube and the swab was rubbed firmly across the surface to be tested, the swab was rotated during this procedure. Swab was rubbed back and forth over 5 cm x 5 cm of the surface where possible. The same swab was repeat using at an angle of 90^0 to the initial rubbing. The swab was placed to into a 9 ml of 0.1% peptone water containing test tube. Tube was mixed well. 1.0 ml was transferred into two sterile Petri dishes under aseptic conditions to form two sets of plates of all dilutions. To one ml of SPCA tempered to 45 ± 1^0 C was poured. The contents of each plate were mixed well and the plates were left for some time to solidify. After solidification, the plates were placed in an incubator with a temperature of 30^0 C $\pm$ 1^0 C and were incubated aerobically for 3 days. To the other plate 15 ml of VRBA tempered to 45 ± 1^0 C was poured. The contents of each plate were mixed well and the plates were left for some time to solidify. After solidification, the plates were placed in an incubator with a temperature of 37^0 C $\pm$ 1^0 C and were incubated aerobically for 2 days.

3.2.4 Detection of Yeast and Moulds

Material

Finished sample

DG 18 medium

Sterile Petri dishes

Sterile spreader

Incubator

Pipettes

Methodology

DG 18 medium was prepared and poured aseptically into sterile Petri dishes and were left to solidify. 0.1ml of Sample was poured into the plate under aseptic conditions. And the inoculant was spreaded using a sterile spreader. The plates were inverted and incubated aerobically at room temperature for 5 days.

3.2.5 Detection of microbes in the finished product

Material

Nutritive medium

Streaking loop

Sterile Petri dishes

Bunsen burner

Scissor

Incubator

Methodology

The media was poured on to the sterile petridishes aseptically. Dishes were kept to solidify. A loop-full of sample was taken and directly streaking in the agar plates. These plates were kept 3 days in an incubator at 30^0 C.

3.3 Measuring the strength of Hydrogen Peroxide

Material

Used Hydrogen Peroxide solution

Thermometer

Hydrometer

Hydrogen Peroxide concentration chart

Ruler

Methodology

Take some volume of Hydrogen Peroxide into a measuring cylinder. Put a thermometer and take the temperature. Then put a hydrometer and take the reading. According to the Hydrogen Peroxide concentration chart the concentration was taken.

3.4 Production process of UHT RTD products

Material

Fresh milk

Electronic balance

Water

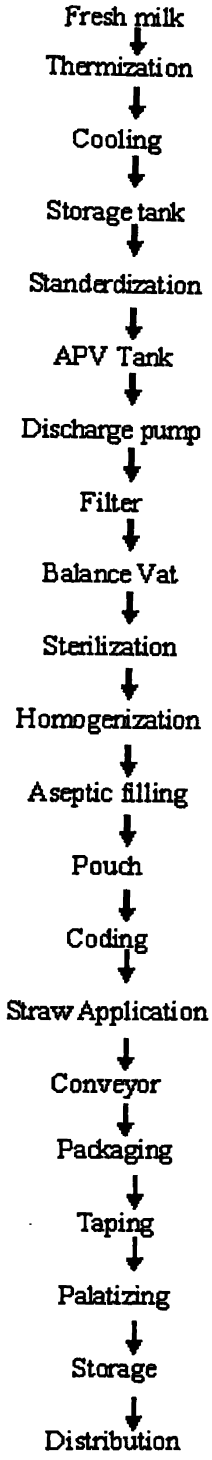
Additives

Packaging material

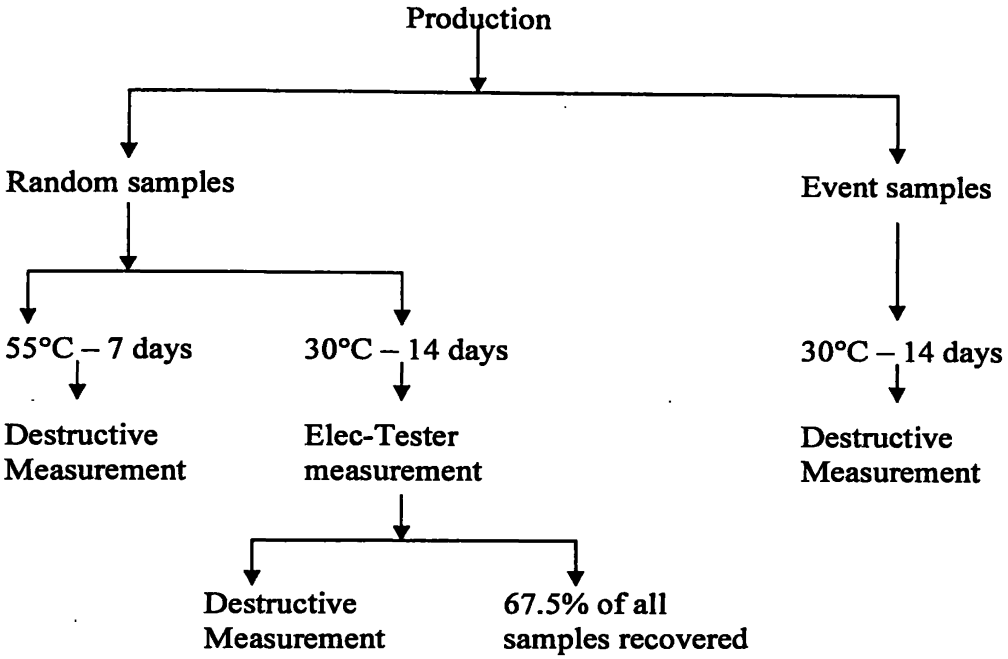
Outer cartons

Tape

Methodology



3.5 Incubation and sampling procedure



3.6 Calibration of the Elec-Tester

3.6.1 Set-up a reference window

For NRT incubated samples

Material

Elec-Tester

30 UHT packs from the same batch incubated at NRT

Methodology

30 sample packages (these are supposed to be not-spoiled) were taken. The main menu was appeared on the screen. F7 (parameters) button was clicked to enter the Parameters menu. F1 (Autoparametring) was clicked to enter the Auto-calibration menu. The Auto-calibration menu was divided in to two parts: Measurement parameters and Reference window parameters. The Reference window parameter menu was opened and the Reset button was clicked to empty the results of a previous measurement from the screen.

The "Start amplitude" was set to 10. The "Precycles" was set on 1 or 2, and "cycles" to 10. The first package was placed on the Brik holder and clicked the Start Testing button. The Elec-Tester startd to measure and the start amplitude value would change

automatically. A text "parameters ok" was appeared on the display after the unit was found suitable start amplitude for this product. All rest of the packages were measured once using F1 (measure once) button after returned to the main menu. After finding out correct reference values, that the test samples were good was ensured by opening, measuring the pH and checking the sample visually. At the same tine the net weight was calculated too.

Return to the Autocalibration menu after measuring all the test samples by clicking F7 Parameters followed by the Autoparametring option. The Elec-Tester was automatically calculated the reference and deviation values as well as a window percentage by pushing the Calculate button. The "Accept references" button was clicked if these values were acceptable.

For 55°C incubated samples

Material

Elec-Tester

30 UHT packs from the same batch incubated at 55°C

Methodology

See the method used in the 3.3.1 for NRT samples

3.6.2 Measuring of the samples

Material

Elec-Tester

Incubated UHT packs

Incubation room and an incubator

pH meter

Scissor

Tissue papers

Distilled water

Methodology

The sample was put on the sample holder. The particular recap was selected. Measuring was started by clicking F2 Continuous measurement. The foot switch was pushed to start measuring cycle. All the NRT and 55°C incubated samples were tested like this. All the rejected samples were tested for sterility and quality.

3.6.3 Validation of the Tester

Material

Elec-Tester

UHT packs from the same batch

Incubation room

pH meter

Scissor

Tissue papers

Distilled water

Methodology

Another set of samples were taken from the production line prior to the incubated samples including one sample per pallet. These should be representative samples. Then the samples were incubated at NRT and tested after the incubation period. Then these were cut opened and checked for quality and stetrility.

3.7 Air survey

Material

MSA – 100 Microbiological Air Sampler- 100l/min

90mm standard Petri dishes

Incubator

Plate count agar

Methodology

The plate count agar medium was poured in to the Petri dish and allows solidifying. Then the Air sampler was placed on a solid support. The perforated lid was opened and closed agar Petri dish was placed on the top of the dish support and pushed it between the jaws. The Petri dish lid was taken off and perforated lid was closed. The Air Sampler was programmed according to the instructions. Dust cover was removed and starts collection cycle. The dust cover was replaced and the sampling head was opened and finally Petri dish was closed with the Petri dish cover after the operation was completed. Then the Petri dish was incubated at 30°C for 3 days.

3.8 Test for sealing

3.8.1 Test ink

Material

Ink solution (Rodamine)

Paper tissues

Syringe

Scissor

Water

Methodology

Check the TS sealing

The packaging material was cut through the middle. Then ink was poured into both halves and kept for few hours after drained off the ink. Then the TS from one end was pulled with a rolling movement. One third of the sealing length was pulled and pulled apart the seal from the other end and checked for leakages.

Check the LS sealing:

The packaging material was cut through the middle of the LS strip, along the edge without disturbing the long seal. Ink was taken in to a syringe and insert from one end of the long seal until it runs alone the seal. Then it was kept for sometime to dry and checked. And,

The packaging material was cut through the middle of the LS strip, along the edge without disturbing the long seal. Overlapping packaging material layer was pulled off along the outside of the package. The strip sealing was checked by slowly pulling approximately 20 mm of the strip outwards at an angle of 90 °C. This was continued along the whole edge.

Package checks:

For both destructive and non distractive checks the first two consecutive packages were selected. For head space checks, another 10 consecutive packs were selected. Also check the packages at intervals according to internal quality procedure. During production the start check was repeated at intervals of maximum 30minutes.

I. **Non distractive tests:**

a. Shape and bottom crease

b. Printing and

c. weight were checked.

II. **Distructive checks:**

Material

Samples

Scissor

Salt solution

Conductivity meter

Methodology

a. Flaps: Flaps were unfolded
b. Crease lines: The crease lines were checked
c. Overlaps: The width of the overlap was checked
d. Surfaces: Outside and inside surfaces were checked
e. Hole: checked for holes anywhere in the pack through conductivity test
f. TS: The TS was bent. The crosses (where TS and LS meet) and corners were checked. About 1 mm from each side of the package was cut off at a right angle to the TS.

3.8.3 Conductivity test

Material

Salt solution

Plastic container

Conductivity meter

Scissor

Tissue paper

Methodology

The package was cut into two halves as it results top and bottom seal. Then the salt solution was poured in to one half and it was dipped in the same salt solution. Then it was checked through the conductivity meter.

CHAPTER 04

Results and Discussion

4.1 The significance of good quality Raw milk

Industry demand for extended refrigerated storage of milk, both prior to and following pasteurization, has resulted in new quality concerns for processed dairy products. Microorganisms and spores are widespread in the natural environment, with soil, water, plants and animals serving as reservoirs. Some degree of contamination of raw milk during production is inevitable, milking and milk storage being the major source of contamination.

If milk is produced under sanitary conditions, the typical bacteria of the udder surface, *Micrococcaceae*, predominate and less than 10% of the total flora are psychrotrophs. Under unsanitary conditions of production, milk can contain more than 75% psychrotrophs. Reduced quality in raw and processed milk is generally a consequence of the growth and metabolic activities of psychrotrophic bacteria that reproduce at refrigeration temperatures. Although most psychrotrophic bacteria are destroyed by pasteurization, some have the potential to produce proteolytic and lipolytic enzymes that can survive pasteurization and sometimes even Ultra High Treated (UHT) processing. These enzymes can degrade protein and fat in the processed products and can, thus, reduce the product shelf-life even in the absence of viable bacteria.

The number and types of microorganisms that develop subsequently during refrigerated storage are determined by the temperature and duration of the storage. It is unlikely that all bacteria can be eliminated from the raw milk supply. Most important is to minimize contamination at the farm and keep the levels as low as possible by good hygienic practices. These include proper cleaning and sanitizing of milking equipment and rapid cooling to temperature of 4^0C or less.

The raw milk must be transported to the dairy under such conditions that the microbiological quality of the raw milk is not reduced. Milk collection tankers should be designed and constructed according to the IDF code of practice and during transport, the temperature of the milk should not exceed 7^0C. The milk tankers should

be cleaned and disinfected at least daily, and whenever there is a gap of four hours or greater between collections. The sufficiency of cleaning and disinfection should be checked regularly.

Microbial contamination can generally occur from three main sources; from within the udder, from the exterior of the udder and from the surface of milk handling and storage equipment. The health and hygiene of the cow, the environment in which the cow is housed and milked, and the procedures used in cleaning and sanitizing the milking and storage equipment are all key factors in influencing the level of microbial contamination of raw milk. Equally important are the temperature and length of time of storage which allow microbial contaminants to multiply and increase in numbers. All these factors will influence the total bacteria count and the types of bacteria present in bulk raw milk. Some other groups of thermoduric spoilage bacteria survive pasteurization temperatures and reproduce in processed products, thus, reducing product quality. As the dairy industry moves toward increased production of products with extended shelf-life, the bacterial quality of raw milk is increasingly important to the final product quality.

4.2 Quality testing of milk

4.2.1 Organoleptic test

Taste	= Slightly sweet and salty taste
Smell	= Pleasant smell
Colour	= Yellowish white

To improve organoleptic quality of final product, receiving milk should have good organoleptic qualities, such as pleasant sweet taste, flavour, smell and colour. Slightly sweet and salty taste results from the balance between lactose and milk minerals. Flavour and aroma of milk are derived from the fat and the milk fat globule membrane. Compounds involved in determining flavour include carbonyls, alkanals, lactose, ester, sulphur- compounds, nitrogen- compounds and both aliphatic and aromatic hydrocarbons. Carotene pigment, which present in milk fat is responsible for yellowish white colour. (Harding, 1995)

4.2.2 Analysis with Milco Scanner

The accuracy control of the Milco scanner will be made with the standard milk samples. The addition of water decreases the percentage of all components. Fat shows the greater variation in milk and consequently the determination of the solid-non-fat is frequently used as an index of watering. The range for SNF is given as 7.5-10.6 %, but if the value is closed to the bottom of this range, it would be surely suspicious.

Pure milk freezes between -0.530 and -0.566°C with the average of -0.545°C. Milk which has been watered will have a freezing point closer to zero. The presence of dissolving substances, salt, lactose, etc. depresses the freezing point.

The basic structure of milk fat (buffer fat) involves esterification of fatty acids onto glycerol molecules. It is essential to know the fat content to determine the Fat/SNF ratio to maintain the quality of the UHT products.

The protein in milk amounts to about 3.2% and of this casein is by far the most important accounting for 80% of the total protein. Mastitis infection does not change the total protein greatly but the amount of casein falling. All the measurements of the Milco Scanner is essential to maintain and control the product quality.

4.2.3 Enumeration of Mesophilic Aerobic Plate Count

The Aerobic Plate Count (APC) provides an indication of the level of mesophilic Micro-organisms in a product. The method is suitable for estimating the microbial populations of raw milk as well as finished dairy products. When used to test samples taken from various stages of raw milk delivering, the method is also suitable for detecting sources of contamination. It is useful for determining the adequacy of temperature control during storage and also bacterial quality of raw milk is directly affects the final product quality. The method selects only for those microorganisms that are aerobic and which produce visible colonies in the medium, at the incubation temperature and within the incubation time. (See App.1)

4.2.4 Alcohol test

Milk exposed to high heat treatment must be of very good quality. It is particularly important that the proteins in the raw milk do not cause thermal instability. The heat stability of the proteins can be quickly determined by an alcohol test. Production and shelf life problems can usually be avoided if the milk remains stable at an alcohol concentration of 75%. The alcohol test is typically used to reject all milk which is unsuitable for UHT treatment because:

- It is sour, due to high bacterial count of acid producing micro-organisms
- It has the wrong salt balance,
- It contains too much serum proteins – typical of colostrum.

The absence of precipitate or flocculation after addition of 78% alcohol shows milk to have an acceptably low developed acidity. The alcohol acts by dehydrating and denaturing milk proteins. In this test the milk protein and the alcohol compete for the water available. The higher the concentration of alcohol solution is without flocculation, the better the heat stability of the milk and the stronger will be its power to attract water. Consequently, less water will be available to keep the casein (milk protein) in suspension. If the protein is damaged, either by enzymatic action, or by acid formation, or any other means, the power of the protein to bind water is reduced and flocculation is observed at lower concentration of alcohol.

The highest concentration of alcohol, which doesn't result in flocculation of precipitation, is called the "alcohol number". It is recommended that milk intended for "in-flow-sterilization" (UHT treatment) should have an alcohol number or alcohol stability of at least 72. The results of the milk samples tested in the laboratory shows negative for 78% alcohol.

The alcohol test has its limitations. Some instabilities of the milk protein are not detected, as for example some disturbances in the salt balance affecting protein stability. Positive results are obtained with colostrums or near-sour milks. The test can give false positives where mineral imbalance of the milk rather than developed acidity can be caused of flocculation. (Varnam and Sutherland, 1991)

4.2.5 Delvo test

This is a standard diffusion test for the detection of antibacterial substances in raw milk. This test is extremely sensitive to antibacterial substances (antibiotics, sulphur compounds, disinfectants, detergents etc.). The detection level for penicillin-G lies between 2 & 3ng/ml, and for sulphadiazine between 100 & 150ng/ml. The microbiological quality of the raw milk can be identified through this test. (See App.2)

4.2.6 Adulteration tests

4.2.6.1 Determination of Acidity

Normally the pH of the cow's milk commonly stated as falling between 6.5 and 6.7, with 6.6 the most usual value. The pH of milk exhibits a greater dependence on temperature than that of such buffers and as phosphate. The acid-base equilibria of milk have come to be much used in process control. In dairy processing operations the pH is influenced by heat treatment that may be applied. Also concentration of milk lowers the pH. Where milk is stored at ambient temperature, mesophilic bacteria tend to predominate. These produce acid (lactic from lactose). The production of lactic acid and other acids can give rise to problems where milk is heated, so determination of acid is essential prior to the production.

Bulk must have a constant initial acidity of 0.14%. Any acids increases above this indicates developed acidity. From 50 up to 98% of developed acidity in milk may be lactic acid. Therefore normally lactic acid determine for acidity. The ph test has the great advantage of speed too.

4.2.6.2 Detection of Urea

Normally urea was added to the fresh milk to increase the SNF. This directly affects to the product's quality by varying the Fat/SNF ratio.

If colour changes to Pink - Urea Positive

If colour remains Yellow - Urea Negative

The above test detects minimum of 0.1 Urea W/V. A control should carried out along with the above test using unadulterated milk.

4.2.6.3 Detection of sucrose

Sucrose is added to fresh milk to increase SNF. It is a critical factor for fresh milk payments. This is critical as it promotes protein coagulation during heating of milk. These suspended particles appear to adsorb protein and tends to lowers the protein stability, which quickly destabilizes the entire system.

4.2.6.4 Detection of $NaHCO_3$

$NaHCO_3$ is added to fresh milk to increase the shelf life. This neutralizes any developed acidity of the milk.

4.2.6.5 Detection of NaCl

The non-protein components play a critical role in the physical stability of milk. The inorganic components are a complex mixture, dispersed in both the micelles and the serum phase. These salts increase the solid content and at the same time variations in the milk like altering the heat stability, etc. A reddish colour indicates the absence of added salt in the milk sample. A yellowish colour is suggestive of the presence of added salt.

4.2.6.6 Detection of H_2O_2

H_2O_2 is added to fresh milk to delay the spoilage. A rapid destruction of the most resistant *Bacillus* spores and also mould spores, vegetative bacteria and yeast cells are easily killed by H_2O_2. To obtain high quality fresh milk, H_2O_2 test should be carried out. (See App.3)

4.2.7 Determination of Chemical properties

4.2.7.1 Fat by Mojonnier method

There is a direct relationship between fat and moisture content. Higher the moisture content lowers the fat content. To obtain the Nestle quality in the finished UHT RTD products the Fat/SNF ratio should kept constant. Change of this ratio also leads to increase the rejection percentage when testing with Elac-Tester. If any deviation, standardization should be done. For that determination of fat content is a must. (See App.4)

4.2.7.2 Moisture by Oven method

The moisture content of the analyzed fresh milk samples were varied with the collecting area, season, breed etc. For an instant milk from the up-country area have high moisture content while low in Anuradhapura like dry zones. The moisture in milk is evaporated in an oven and the reside is reported as total solids. Normally total solid content ranges between 11.4 – 14.5%.

As the moisture percentage was increased, there was a decrease in the solid content of the milk. If the fat percentage was increased, the moisture and protein content also decreased. The decrease in the overall amount of moisture is much more less than that of the protein amount. The moisture determination is very important because this leads to judge the added amount of water in producing of UHT RTD products. (See App.4)

4.3 Quality testing of the final product

4.3.1 Enumeration of Mesophilic Aerobic Spore Count

Most of the bacteria present in raw milk are contaminants of the outside and gain entrance into the milk from various sources including soil, bedding, manure, feed, and milking equipment. Therefore raw milk contains levels of a few to several thousands of bacteria and spores.

Bacterial spore formers regarded as potential spoilage organisms. The main reason for the spoilage was the capability of growth of large number of different spoilage organisms even in the absence of oxygen. When milk is stored at ambient temperature mesophilic bacteria spores tend to grow. Enumeration of mesophilic aerobic spore count is important with regard to the shelf-life of the product. (See App.5)

4.3.2 Enumeration of Thermophilic Aerobic Spore Count

In the UHT processing the most possible survivors are thermophilic spores due to its high heat stability. Most of the spore formers were pathogens, so it is essential to make sure that the final product is free of these kinds of organism. This also regarded as a quality factor too. (See App.5)

4.3.3 Swabbing For Hygiene Evaluation

In a UHT plant good hygiene practices is a must to minimize contamination. Swab samples were taken from several (normally 8) places to determine the cleanliness of the machines and the plant. Comparing the results with norm values, can take certain precautions to maintain good hygiene condition.

4.3.4 Enumeration of Yeast and Moulds

The results were obtained from the Yeast and Molds test shows positive, only if the final product gets contaminated. Positive incidents could be found only in the spoiled samples according to the test results. All the other samples checked were negative for the test. This implies that there's no pre processing contamination and the problem arises during post-processing stages that is during handling, packing, transporting, etc. (See App.6)

4.3.5 Detection of microbes in the finished product

The streak plate is used primarily to isolate pure cultures but it is essential in UHT products to determine microorganisms, where qualitative results are involved. The agar surface should be smooth and moist, but without excessive moisture which should cause confluent growth (merging of colonies). These organisms were found only in spoiled samples and negative in all other samples. (See App.6)

4.4 Measuring the strength of Hydrogen Peroxide

In aseptic packaging system, H_2O_2 is often used for the chemical sterilization of the packaging material (food contact surface). For this 30-35% concentration of H_2O_2 can be used. This concentration is determined through the H_2O_2 nomogram. (See App.7) Below 30%, the strength of the H_2O_2 solution is not enough for the sterilization process. The measuring the strength of H_2O_2 is very important so this is considered as a CCP. The peroxide was changed when the concentration reaches 30%. (See App.8)

4.5 Calibration of the Elec-Tester

4.5.1 Set-up a reference window

Because of the variation of the products, it is thoroughly mentioned to set-up reference values for each and every UHT product and also for the same product held at different temperatures. There are five UHT RTD products namely: MILO, NESCAFE, NESTOMALT, VANILLA and STRAWBERRY MILK SHAKE. The lab samples of these products kept in NRT as well as at 55°C. Altogether 10 recipes, 2 recipes per each, have to build. (See App.9)

Among those recipes most appropriate recipe was selected. This recap rejects all the unsterile packs while reducing the faults positive rate. (See App.10) All the samples were taken for the recipe were tested for quality and sterility. All units were within the acceptable range. The importance of having norms for pH and net weight was highlighted during calibration and testing of the packages. By using Elec-Tester accepted samples, production norms for the UHT products were created. (See App.11)

The accuracy of the values produced by the Elec-Tester depends certain influencing factors like different in weight and tightness. So have to use the same materials. Even the screwing on and off of the sample holder can cause variations.

When considering the product and package properties, the normal viscosity of the product influences the values produced by Elec-Tester. The deviation in this characteristic determines the size of the reference window. The difference between a sterile and a spoiled sample should be as big as possible. Therefore all other sample properties should be as constant as possible. Package geometry, serum building and possible sedimentation should not influence the reference window so not sterile samples are accepted. This is important when packages with headspace are used.

Table 4.1 The reasons for the package rejection

Reason	Number
Sedimentation	112
Package defect	12
No defects	9

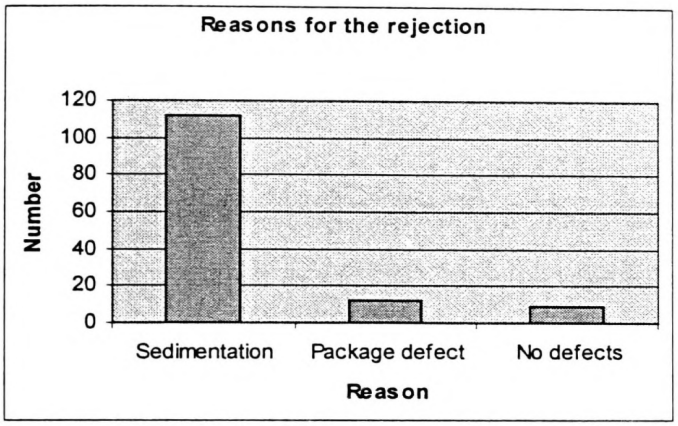


Figure 4.1 Reasons for the package rejection

Sedimentation is an aggregation phenomenon that affects shelf-stable, sterilized dairy products, such as concentrated milk and UHT milk products is known as age gelation. This occurs after storage of the products for few weeks to months. There is a increase in viscosity accompanied by visible gelation and irreversible aggregation of the micelles into long chains forming a three-dimensional network.

Before set-up the reference values, the samples kept around 8 hours in the room temperature where the measurement took place. So the product inside the pack also came to that particular temperature. The calibration and checking for sterility cannot be assure if this condition is not reached. The Tester gives different results as its high sensitivity to temperature.

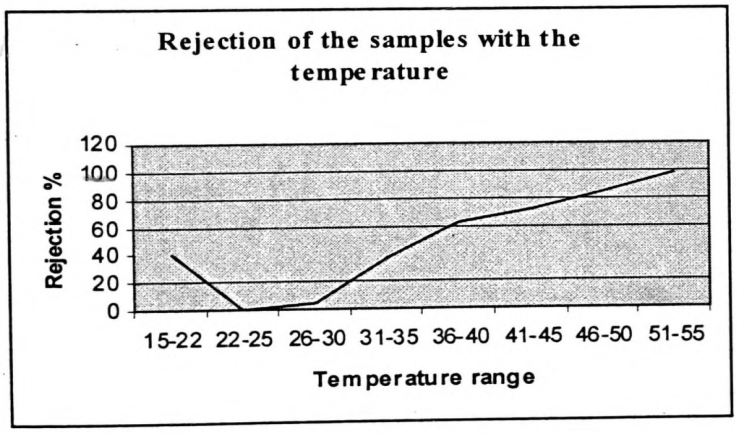


Figure 4.2 Rejection of the sample with the temperature

The difference in viscosity of the product in the pack is translated into values and display. For that two values have being measured. Damping and period values. Damping factor; which represent damping speed. Period time; which represents the length of the vibration cycle. Setting of the reference figures for damping and period values must be carried out daily and/or after a change in product to confirm that the machine is constantly operating within the established range.

In case of faulty packaging of sterile milk products, bacterial action in the milk may occur after a short period of storing. This action can cause possible changes in the hydrodynamic features of the product. These were rejected by the tester.

During testing with the MK IV unit, the sample package is subject to mechanical motion only; it is not damaged in any way and can be sold normally.

Samples should always be tested after an incubation period of 7-14 days at temperatures of 30-38 °C, so that microbes have time enough to cause measurable changes in the hydrodynamic behavior of the milk product. The speed of coagulation depends on the bacteria and on the product itself. Therefore a suitable time/temperature combination must be found by experience.

The normal practices for incubation for thermophilic microorganisms are 5±1 days at 55°C. For mesophilic ones it is advised to incubate for 10 ± 3 days at 30°C. In the beginning of each measurement cycle, the sample package is made to oscillate after movement of an electronic magnet, which is connected to the other end of the spring. This motion quite or damps down in a manner, which is dependent on the physical property of the product in the package. The unit sensors the smallest difference in these properties.

The results of the measurement is presented in the main display of Elec-tester. Limits of acceptable value are shown as a window. The characteristics of the product shows by the x coordinate and y coordinate indicates the package qualities like package integrity, etc. by looking at the display, can get rough idea about the rejection of a product.

The unit is comparing the damping factor and period time independently to the reference value. Depending on the "window" adjustment, the unit more or less critical to accept the sample packages. Accepted values are not absolute values. It is possible to compare them to a present preference window, but it is not possible to co-relate a certain damping factor to a viscosity. Other parameters like storage temperature, package stiffness, and the tightness of sample holder influence value.

4.5.2 Measuring of the samples

The temperature in the room where the measurement takes place should be as constant as possible to assure consequent values. Therefore it is advised to prepare the testing the day before by taking the samples out of the incubation room and leave them at ambient temperature for at least 8 hours. In this way all measured samples will have the same temperature. The package material also influences this. The temperature can make certain package types more flexible, which will influence the final value.

When using products with sedimentation, a set of additional pre-shaken samples should be considered. This will cause a slight difference in results from that of the non-shaken samples and can be considered for the determination of the reference window.It is best that the same team of operators handles the equipment so that they becomes familiar with the behavior of the individual Elec-Tester as each Tester has a different sensitivity, even more with a low level filled product.

The Elec-tester settings were set in a way that all spoiled samples are rejected. It is possible that this will include the rejection of some so called false positive. The rate of false positive says something about the effectiveness of the Elec-tester. The threshold limits for the fault positive samples are 5% of the total samples.

Two things can be done to decrease the false positive rate:

1. Increase the reference window size without accepting any spoiled samples
2. Increase the incubation time to enlarge the difference between a spoiled and a sterile sample.

Elec-Tester tends to reject products with a high level of sediment. If less than 5% of the samples are rejected these rejected samples are cut open to confirm the product quality. If more than 5% of the samples are rejected (due to high sedimentation), randomly 1% of these samples have to be cut open to confirm. If the product quality appears to be acceptable the Elec-Tester reference figure will require resetting to accept briks with high sediment content.

4.5.3 Validation of the Tester

Validation can be carried out in several ways other than as mentioned in the materials and methodology section. When the samples were taken for the incubation process, another set of samples, one form each pallet, were taken and incubate at NRT. Those samples should be representatives of all the other line samples. After the incubation period these are also checked and were cut open to check the sterility and quality. At the same time its parallel line samples, event samples and samples incubated at55°C samples also checked in the same way. Through the results can assure the accuracy of the calibration as well as the product's sterility.

4.6 Microbial count in the air

The air survey results shows there was an increment of the microbes in the plant when compared with previous results. This exceeds the threshold level of 500 m^3. So this should be minimized. (See App.12)

4.7 Test for sealing

Air born infections- either through untight gaskets in the processing and packaging equipment or through untight (leaking) packages- seems to be the most frequent cause of unsterility. Airborne infections will almost always give rise to a mixed type of infection flora and thus usually leads to gas formation.

a) Package checks:

When selecting packages for quality checks, always selected in pairs. First two consecutive packages were select to check whether there's any problem a package made in one of the jaws when the system is running. During production it is suggested that the start check be repeated at intervals of maximum 30minutes.

I. **Non destructive tests**

a. Shape and bottom crease: to check whether it is correctly positioned

b. Printing was checked to clarify whether it is within the stamping area

c. Measures weight to assure that it is within the specified range.

II. **Destructive checks:**

a. Flaps were unfolded to check that they are properly sealed

b. Crease lines: The position of the performed crease lines were checked

c. Overlaps: The width of the overlap was checked

d. Surfaces: Outside and inside surface for scratches or other defects were checked

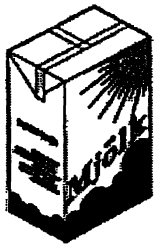
e. Hole: critical factor for the spoilage.

f. TS: The sealing is defective if there are lumps or ridges in the sealing area. This may be caused by a too high sealing temperature

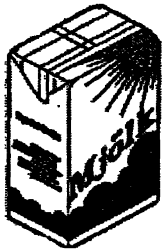
On a finished package, the creases coincide with the edges of the package. This means that the package must be made from a particular section of the packaging material web. In order to achieve this, the machine must

1. Synchronize the material web with the jaw system, so that the jaw seal and cut the package in the right place.
2. Feed the material one package at a time in order to maintain synchronization with the jaws.

Design correction system synchronizes material and jaws and causes one package at a time to be fed forward. When this is done, the crease of the package is correctly placed as the jaws move against the tube, so that the machine produces packages of the right shape.



This package is shaped correctly and folded alone the creases; it has been made from the correct section of the material web.



On this package, the creases in the web and the edges of the package do not coincide; it has been made from the wrong section of the web.

Figure 4.3 The integrity of the package

b) Check the TS sealing

The sealing is acceptable if

- The seal remains intact but a breakage takes place in the paper board layer. This may due to sealing temperature is very close to the highest limit
- The seal remain intact when the joint is pulled apart, but the Al-foil comes off on one of the sides presenting a shiny metal surface
- The seal remains intact but a delamination between the two inner coating takes place.

The sealing is defective if the seal is so weak that the two plastic layers separate without breaking. This may be caused by a too low sealing temperature.

The sealing has been found as the second major problem for the spoilage. Temperature is the most critical from all. For the sealing point of view there are two methods of heating.

Inducting heating - Used for Transversal Sealing TBA

IH is a clean form of heating and one of its main advantages is that the heating takes place in the work place. I.e. The Al foil, there by reducing to a minimum all the losses normally associated with heating. The high frequency current inducers heat in the Al foil layer of the packaging material. The heat causes the plastic (PE layer) to melt, and these the packages can be sealed.

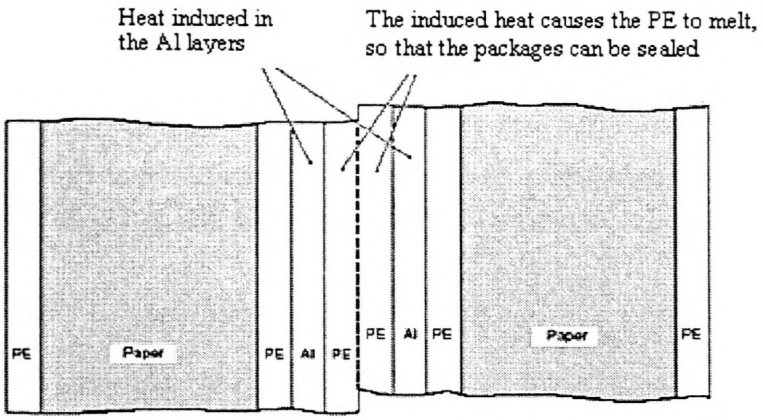


Figure 4.4 Sealing of the packaging material by IH

The heat exchanges the structure of the PE layer, making the plastic more brittle. For this reason, the package becomes easier to open. IH is used to heat materials only which are electrically conductive. This is the method employed in the TBA machine. For transversal sealing, zone heating at the opening arrangement of the package, longitudinal sealing, strip application and splicing of the packaging material.

c) Check the LS sealing:

The LS strip is symmetrically positioned on one package. There shouldn't be any blisters in the Al-foil. The LS seal is acceptable if the seal remain intact when the joint is pulled apart when pulling the strip outwards at an angle of 90 °C, but the Al-foil comes off on one of the sides presenting a shiny metal surface

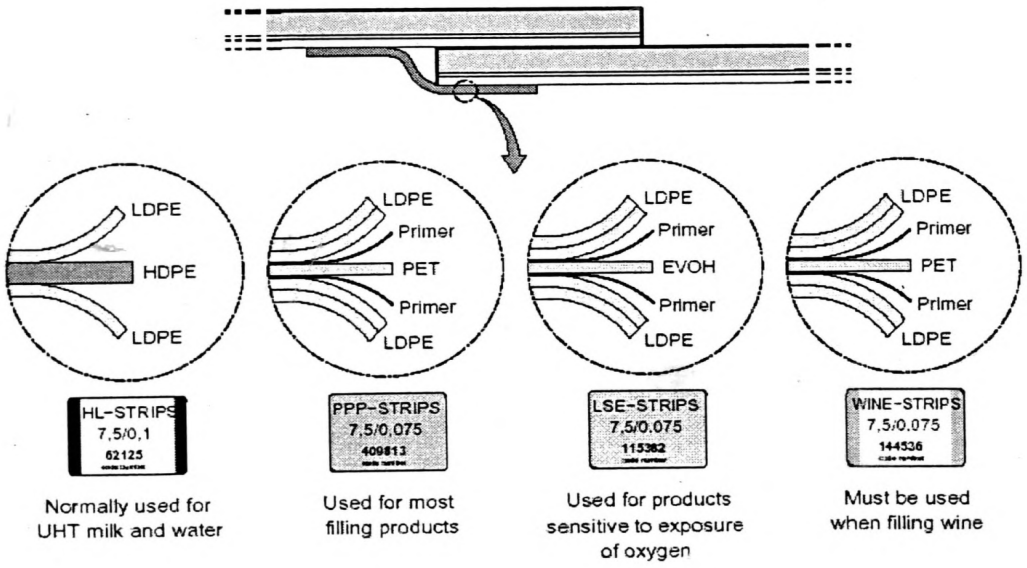


Figure 4.5 Longitudinal seal strips

The sealing is critical if:

- All the inner layers including the Al-foil come off with the strip, although possibly leaving paper board fibers. Wrinkles may appear along the sealing. Here the sealing temperature might be very close to the highest.

The sealing is acceptable if: Both inner coatings come off with the strip, leaving the Al-foil bare.

These faults were identified

1. Scratch through the inner PE layer. (2)
2. Scratch through both inner PE layer. (1+2)
3. Crack / hole in the Al foil.
4. Crack / hole through both inner PE layers and the Al foil.
5. Crack / hole through both inner PE layers, Al foil and the lamination PE without moisture penetration.
6. Crack / hole through both inner PE layers, Al foil and the lamination PE with moisture penetration.
7. Scratch through the outer PE layer.

Through the cause and effect diagram, the key causes were identified. (See App.13)

Table 4.2 Data for various sealing defects (from May-July)

Sealing defects	# of defects
During Handling	127
Through Machine	41
During Storage	38

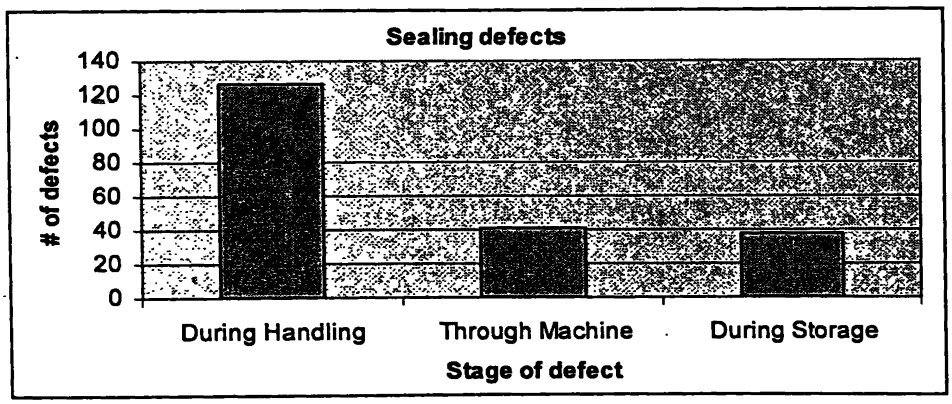


Figure 4.6 Sealing defects

The data set shows that the handling causes for the sealing defects mainly. This is a post sealing effect from the packing to the ultimate consumer. But here data from distribution to the consumer is not included. During packing, sealing gets weaken due to the inappropriate packing. This mainly weakens the sealing of the corners of the pack. Other reasons are identified as lack or poor in technique, speed, rhythm, lack of manpower, experience, mental condition, physical condition and also carelessness, negligence and shift especially in night shifts those defects were increased.

Table 4.3 Causes for the defects (from May-August)

Source	Stages where causes occur
Operator/Crew	Shift
	Group
	Age
	Experience
	Skill
	Individual
Machine	Machines/ Instruments
	Equipment / Tools
	Sterilizing efficiency
	Sterility
Raw material	Source
	Lot
	Kind
	Quality
Operation method	Conditions
	Arrangements

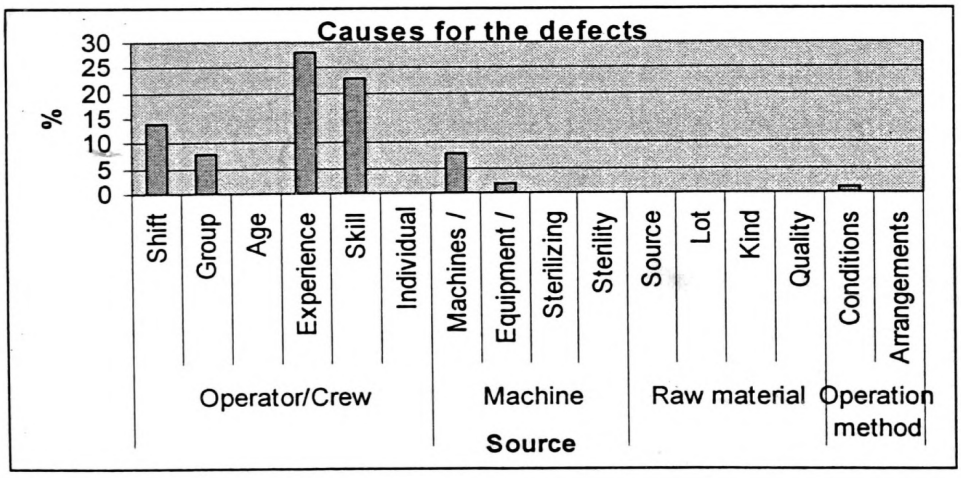


Figure 4.7 Causes for the defects

According to the collected results the major source for the defective samples was highlighted as crew/operator errors. Others are in a low levels. Among the causes, lack or poor in experience being the most critical factor for the defects. Lack of skill becomes next.

Table 4.4 Causes for the unsterility (from May-August)

Type of defect	# of defects
Handling	53
Top seal	34
Bottom seal	26
Machine	8
Top & Bottom	6
Straw hole	2
Others	13
Total	142

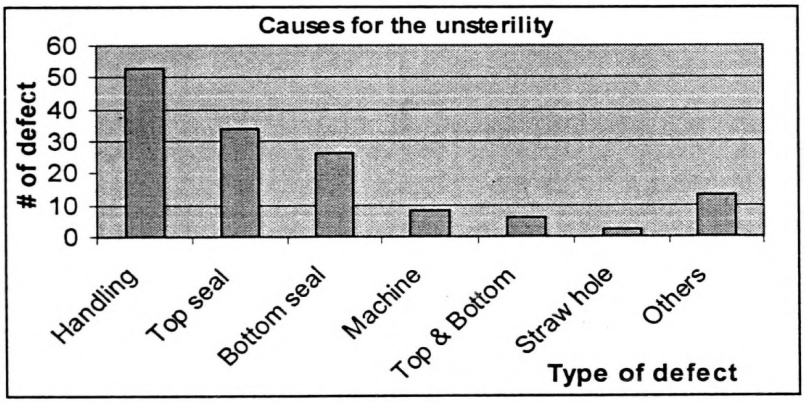


Figure 4.8 Causes for the unsterility

Table shows that the unsterility is mainly due to the handling defects. These results were obtained after checking spoiled packages returned from distribution centre.

4.7.1 Ink test

Ink test was used to check any cracks or holes in the package.

Long seal: identified properly sealed if the ink line runs alone the LS without any breaks. If there's any sealing defect leakages can be observed.

Transversal seal: sealing can be checked as mentioned above as LS.

4.7.2 Conductivity test

If the conductivity meter indicates any current passes while testing, there is a problem in the seal. During the test should avoid spreading the salt solution in the rest of the package, especially the newly cut surface. Because this also leads to pass a current.

4.8 Quality testing

4.8.1 Determination of pH values

The pH of the Elec-Tester accepted samples were taken to determine a norm for UHT products. This varies from product to product. This is calculated by using statistical software "Q-STAT". If the pH of a unit is vary from above determined range, considered as spoiled. (See App. 4)

Table 4.5 Norms for the pH of the UHT products

	Higher limit		Lower limit		Average	
	NRT	55°C incubated	NRT	55°C incubated	NRT	55°C incubated
A	6.95	6.89	6.84	6.58	6.89687	6.750597
B	6.67	6.61	6.57	6.52	6.60215	6.53189
C	6.66	6.61	6.58	6.53	6.61312	6.524631
D	6.61	6.5	6.56	6.44	6.55615	6.4506
E	6.62	6.59	6.56	6.48	6.56555	6.498532

4.8.2 Net weight determination

The net weight of the Elec-Tester accepted samples were taken to determine a norm for UHT products. This is calculated by using statistical software "Q-STAT". This also use as a quality parameter as well as to limit the Elec-Tester rejection percentage. Varying from above range, Tester detects as a spoiled sample. (See App.11)

Table 4.6 Norms for the net weight of the UHT products

	Higher limit		Lower limit		Average	
	NRT	55°C incubated	NRT	55°C incubated	NRT	55°C incubated
A	197.07	196	191.83	190.6	194.7154	193.0356
B	193.32	191.8	190.54	189.15	191.864	190.1246
C	194.02	193.98	192.89	192.06	191.874	192.6412
D	193.87	192.23	192.54	190.82	192.945	191.62
E	195.26	194.85	193.94	192.86	194.679	193.5203

Aseptic packaging procedures should maintain the high level of micro biological quality of the sterilize product. Unsterial, defective packages in an aseptic operation, however, do not only originate from the packaging operation but also from the products sterilization process as well as from any recontamination of the properly sterilized product on its way from sterilizer to the packaging machine. The shelf-life of the UHT products can be increased by maintaining and monitoring the following factors.

- The sterilization efficiency of the product sterilizer
- The microbial load of the product fed in to the sterilizer
- Cleaning and plant sterilization procedures applied
- Efficiency of the packaging material on sterilization process
- Microbial load on the packaging material food contact surface
- Cleaning and filler-sterilization procedures
- Service and maintenance of the plant
- Operational care

4.8.3 Influence of Equipment Cleaning and Sanitizing Procedures

The occurrence of various bacterial species adhering to rubber and stainless steel in a milk installation has been reported. Gram-negative organisms predominated (96-100%) the majority being *Acinetobacter spp.*, followed by *Psuedomonas spp.*, and *Flavobacterium.*

Cleaning is done in two ways. CIP and External cleaning.

External cleaning: provision has been made on the TBA filling machine to externally wash certain parts directly concerned with the sealing of packages. This should regularly applied

-. To remove deposits released from the packaging material

- To loosen and wash away any product deposits

- To remove surplus oil deposits

- To drastically reduce any microbial concentrations

This is applied to the jaw systems and final folder.

The degree of cleanliness of the milking system probably influences the total bulk milk bacteria count as much, if not more than any other factor. Milk residue left on equipment contact surfaces supports the growth of a variety of microorganisms. This generally holds true for organisms associated with contagious mastitis (i.e. *S. agalactiae*) though it is possible that certain strains associated with environmental mastitis (i.e. coliforms) may be able to grow to significant numbers.

CIP – cleaning steps

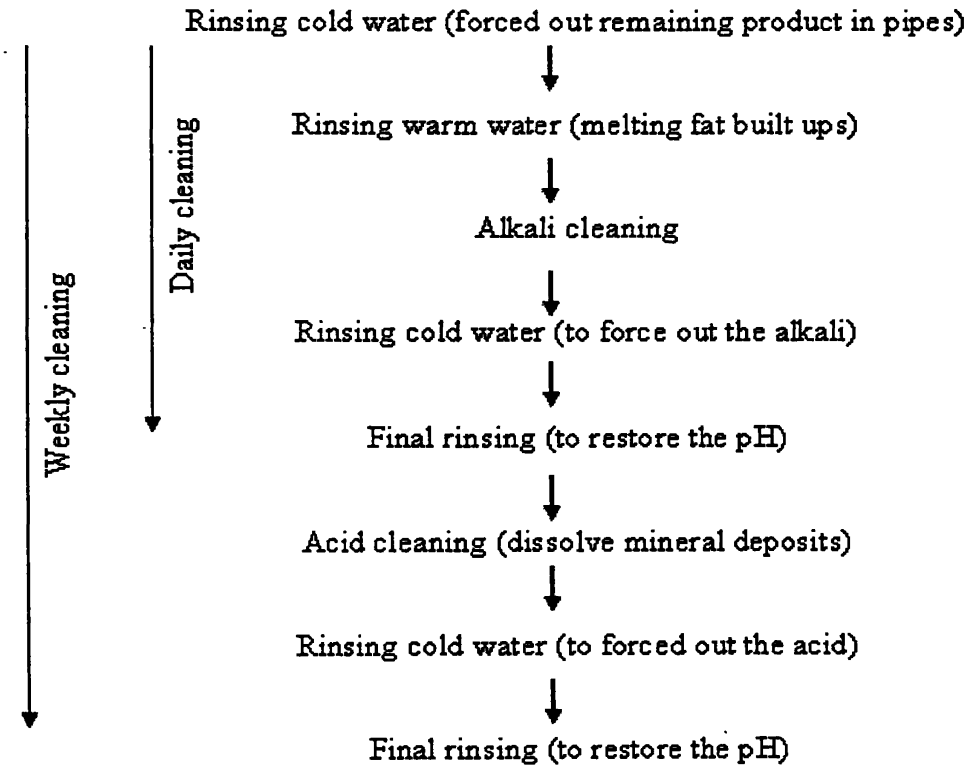


Figure 4.9 Steps in the CIP cleaning process

Cleaning and sanitizing procedures can influence the degree and type of microbial growth on milk contact surfaces by leaving behind milk residues that support growth, as well as by setting up conditions that might select for specific microbial groups. More resistant and/or thermoduric bacteria may endure in low numbers on equipment surfaces that are considered to be efficiently cleaned with hot water. If milk residue is left behind (i.e. milk stone) growth of these types of organisms, though slow, may persist. Old cracked rubber parts are also associated with higher levels of bacteria.

Less efficient cleaning, using lower temperatures and/or the absence of sanitizers tends to select for the faster growing, less resistant organisms, principally Gram-negative rods (coliforms and *Pseudomonads*) and *lactic, streptococci*. Effective use of chlorine or iodine sanitizers has been associated with reduced levels of psychrotrophic bacteria. Psychrotrophic bacteria tend to be present in higher count milk and are often associated with occasional neglect of proper cleaning or sanitizing procedures and/or poorly cleaned refrigerated bulk tanks.

4.8.4 The effects of raw milk hygienic quality on product quality

Maintaining high standards of raw milk quality is important not only because it gives greater flexibility to the processor in terms of holding milk prior to processing but most importantly because of the impact it ultimately has on product quality.

Milk produced under careless conditions can contain a wide range of bacteria, pathogens (*Salmonella, Listeria,* etc) from faecal contamination, pathogens from udder infection (*Streptococcal* organisms) and milk spoilage organisms which maybe mesophilic, psychrotrophic or thermoduric. The type of organisms and predominate will depend on the storage time - temperature – history of the milk.

Where milk is stored at ambient temperature, mesophilic bacteria tend to predominate. These produce lactic acid from lactose. The production of lactic acid can give rise to problems where milk is heated. Raw milk of bad quality has an adverse effect on both processing conditions and on the final product quality. Sour milk has poor thermal stability and causes both processing problem and sedimentation, e.g. burning-on on the heating surfaces resulting in short running times and difficulties with cleaning as well as sedimentation of proteins on the bottom of the packages during storage.

Milk stored for long time at low temperature may contain high numbers of Psychrotrophic bacteria which can produce heat-resistant enzymes which are not completely inactivated by sterilization. During storage they can cause taste changes such as rancidity, bitterness or even gelation problems (age-thickening or sweet curdling). The bacteriological quality of the milk must be high. This applies not only

to the total bacteria count but also, and even more important, to the spore count of spore-forming bacteria which influence the rate of unsterility.

Because of this all the milk samples were checked prior to the production. The TPC count should not exceed 2.5 million CFU's when receiving the raw milk for the production in order to maintain good hygiene condition. Also should maintain the TPC count less than 2 million in the collection centers. Maintaining this condition assure the high quality of the product.

4.8.5 Storage control system, a tool for quality assurance

Analysis of statistical situation involved leads to the conclusion that a laboratory quality control as the only means to assure commercial sterility of the production can not be regarded as an adequate means. Consequently, a laboratory control should be combined with an additional control system, in order to increase safety levels of production control. A storage control systems is such a procedure, permitting, furthermore, a feed back to production in order to improve production conditions and results in respects of failure rate. There are two storage control systems

a. Laboratory control.

Laboratory control is based on random sample subjected to control incubation and evaluation procedures. At the present time no possibility exists to select defective units for incubation using laboratory sampling scheme. Since the ratio of defectives in productions of long life products usually is rather low, very large numbers of units have to be tested before a defective will be detected.

b. Storage control system.

In storage control system, defective units are gathered from the storage area; a condition of such a control system is of course that the defective units show a detectable change allowing units to be selected from the storage area. Unsterillity in long life products may show one of the following four different pictures.

1. No recognizable change at all.
2. Development of microbial growth may result in gas formation.
3. The consistency of content of the package may be altered by microbial activity.
4. The growth of micro organism may lead to flavor changes of the product

The above-mentioned four alternatives necessitate an incubation of the production. In any event, enough storage time has to pass in order to allow sufficient microbial multiplication leading to recognizable changes. Only defective units showing such changes can be sorted out. Gas formation results in blown packages and can be easily detected in a storage control procedure but it is much more difficult to identify other spoilages. Because of this laboratory control methods is used for the finished product analysis. The Elec-Tester, which allows detection of units with changes in the consistence of the content. This handles each and every individual carton so the results are very accurate.

4.9 Causes for the unsterility

Three forms of unsterility.

- Gas formation
- Acid formation
- Flavor change

The situation is more complex in the case of low-acid long-life products. The main reason is to be found in the number of different spoilage organism capable of growth in such products even in the absence of oxygen. Bacterial spore formers, Gram-positive and Gram-negative bacteria, yeasts and moulds may all be regarded as potential organisms. The consequence of such microbial activity may also be many. Gas-formation, changes in consistency, flavor etc may all be a result of multiplication of spoilage organisms in this group of products.

Air born infections- either through untight gaskets in the processing and packaging equipment or through untight (leaking) packages- seems to be the most frequent cause of unsterility. Airborne infections will almost always give rise to a mixed type of infection flora and thus usually leads to gas formation.

With regard to milk and milk products, an estimate has been made of the proportion of the different "types" of unsterility mentioned above by the heads of the laboratories from all German Dairies producing long-life milk products. This estimate,

Gas formation	85% of unsterility
Coagulation	10% of unsterility
Flavor changes	5% of unsterility

This is a clear indication that the major part of unsterility in milk and milk-based products is combined with the formation of gas. Detection of the defective units can be determined by five factors.

1. The form of spoilage

Gas formation, acid formation, flavor change are the main forms of the spoilage.

Blown packages & Burst packages: Blown packages will still remain there are contains, while burst packages are spilt open, releasing there are content. The blown package can only be detected if it is directly seen, while a burst package may be detected by products dripping from the pallet.

2. The outer wrapping used for multi pack units

Selection of defective units from a storage area has to be done visually. The blown packages will only be discovered if the packages are exposed. I.e. the side and top layer of the container (provided the container is not fully enclosed). With the restrictions mentioned in section, the outer wrapping used for multipack units, burst packages may even be detected if these are buried inside the container.

3. The size of pallets.

A further factor influencing the possibility of detecting defective units in a storage control system is the size, shape and construction of the "storage container" pallets. Each individual package or multipack units may easily be checked for defectives by restacking prior to distribution. Also in the case of the size, shape, or construction of the storage container has a very limited effect upon the detectability of defectives in a storage controller system. The percentage of packages may become subject to detection depends on the size of the load carried container: the larger the carrier the smaller the detectable portion of packages.

4. The method of checking.

Different methods and procedures may be applied when checking the defective units in storage controller systems. An evaluation method consists of an incubation period. I.e. time/temperature combination to- allow microbial multiplication, and procedures to detect consequence of such a multiplication.

5. The lay-out of the storage area

There should be an easy access to the storage area.

4.10 Classification of Defectives

1. Faulting package
2. Mechanical damage (See App. 14)
3. No visible defect

Classification of Defectives is probably the most difficult part of the entire storage control system. The purpose of classification is to establish the most likely cause of the fault leading to the blown (or defective) package. This information is an essential part of the control system, since measures to be taken to improve production condition in respect of failure rate have to be based on these results. The tools available for this purpose are the packages, the term (and their experience) inspecting the package and the laboratory which can help with certain microbiological tests etc.

Basically defective packages can be classified in one of the following three major groups, which then should be sub divided further,

1. Fault detectable in the package
2. Transport, handling and storage damage.
3. No detectable fault

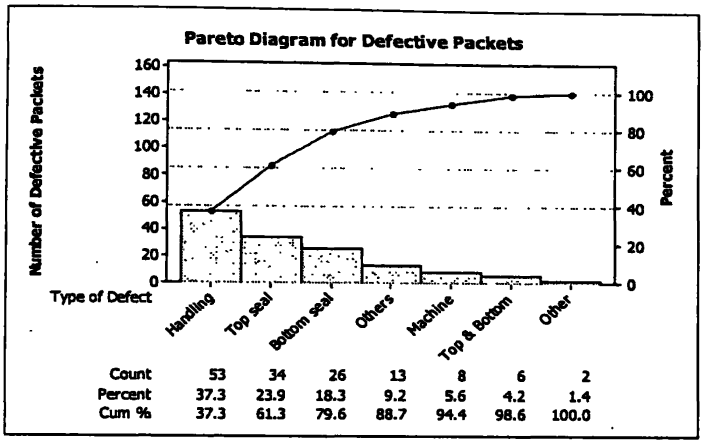


Figure 4.10 Pareto diagram for defective packets

Different possibilities exists further sub divided these three major groups. One such system, which has been successfully used for a number of years by a major producer of UHT milk and milk products, contains the following sub group.

1.1Operation of the packaging machine

Fault in date making

Longitudinal strip splice

Packaging material splice

Longitudinal strip sealing too hot

Longitudinal strip sealing too cold

Longitudinal strip displaced

Longitudinal seal without strip

Channel (pores) in longitudinal seal

Packaging material damage while changing packaging material reels

Defective transversal seal

Other causes

1.2 Maintenance of the packaging machine

"Climbing" of packaging material edge damage

K-creases

Mechanical damage in longitudinal sealing zone

Defects in transversal seal

Defects in corner of the packages

Damaged internal plastic coating
Other causes

1.3 Packaging material
Factory splice of packaging material
Factory splice of longitudinal strip
Packaging material fault
Fault in longitudinal strip
Other causes

2.1 Storage
Damage by truck in storage area
Date expired
Other causes

2.2 Internal transportation
Damage by truck
Damage by conveyors
External damages
Other causes

2.3 Outer wrapping equipment
3.1 Product packaged
Impurities in product
Sedimentation, flocculation
Other causes

At least some of the above groups have to be split up into further sub-subgroups to provide the necessary feed back to production. The more refined system becomes, the more attention has to be paid to the specific condition prevailing at the site of the production, i.e. at the particular production plant intending to implement such a system. Classification of Defectives the most important aspect, permits a very rapid feedback of the results to the production. Those defectives as well as failure of other activities can be determine and overcome by the "Troubleshooting activities".

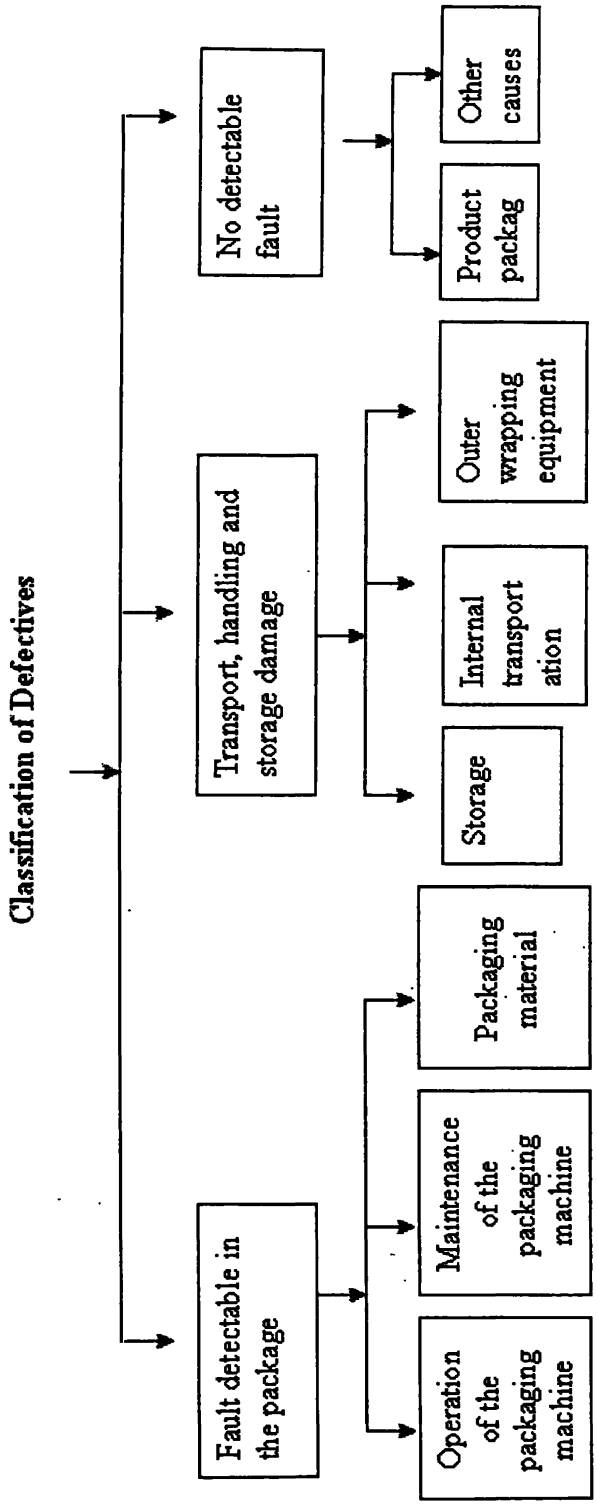


Figure 4.11 The classification of the defectives

4.11 Preconditions and tools for fault identification

The preconditions and tools are needed for fault identification and actions to rectify the fault identified as;

a) Specifications of the process and /or product

In quality control, establishing specifications of the process and/or product has great importance. As far as troubleshooting is concerned such specification serves as basics for trigger the mechanism. The parameters that a long-life product production plant needed specification was found as:

1. Microbiological results of row material analysis
2. Results of the incubated pack control
3. Storage waste records
4. Clams from the market

1. Microbiological results of raw material analysis

Bacterial spore count limits should be established for raw materials used in a low acid long life product production plant

2. Results of the incubated pack control

Only a very limited number of packages can be subjected to normal routing incubated pack control. The incubation results are a very rough tool only. Further more because of the statistic involve there is a definite risk for wrong interpretation. Only in extreme cases justifiable to "destroy" (rework, reprocess) etc. an entire production run (lot) if the decision is based upon the results from incubated pack alone. The number of units drawn does not justify such an action, a resampling procedure is needed.

3. Storage waste records

Storage waste is the difference in numbers of packages entering and leaving the storage area. A certain storage waste must be regarded as normal. Some packages are going to be damage by handling and so on. But there should be a minimum acceptable limit. This limit depends upon the specific conditions prevailing and should be establish for each enterprise.

4. Claims from the market

The unsterility in long life product production plant is of limited interest only. The reaction of the market is more important than" Incubated unsterility". A maximal acceptable clam rate should be established. Clam figures should be reported regularly and followed up in a proper way.

b) Trigger mechanisms by which quality control is change into Troubleshooting

Trigger mechanisms are needed in order to be able to change quickly and effectively from quality control to troubleshooting control charts should be prepared separating at least two, preferably three or four different areas

Normal situation
Action area
Limit of the process
Too good
Legal limits

The "normal situation" is the one desired the process can processed without any anticipated problem. In the "action area" the quality of the materials etc. involved is approaching the quality limits of the operation. Consequently, action should be initiated to rectify the situation. Once the limit of the process is reached, quality parameters of the operation or materials have disintegrated to such and extend that the desired quality level of the end product can no longer be achieved. Action and activities must be started aiming at getting the process back to normal: troubleshooting becomes necessity. Some parameters may show a result which is" too good". Even in such a situation action should be taken in order to elucidate the reason for the result obtained. "Legal limits" must, of course be observed.

c) Competent experienced and trained staff

Troubleshooting can only be done successfully if the staff members involved have a proper knowledge of the technology involved

Intuitive troubleshooting

In intuitive trouble shooting a number of usually uncoordinated activities are done simultaneously depending on skill.

Systematic trouble shooting

Systematic trouble shooting can be taught a logical approach to a problem is persuade and a solution is found by step by step. The staff involved in Systematic trouble shooting must have a thorough knowledge of the technology involve and they must have the capability to work in an "objective "way.

d) An action plan

An action plan has to be adapted to the condition existing at the respective plants.

CHAPTER 5

Conclusion and Recommendation

Conclusion

The Elec-Tester unit was implemented successfully in the plant. The rejection percentage always less than the specified value. The rejection of the spoiled sample was 100% through the tester.

According to the results the main cause for the unsterility was identified as handling defects. Spoilage after the incubation period occurs mostly because of these handling defects.

Recommendation

From the study the following recommendations can be sudjested.

The main cause for the sterility was identified as handling defects. Those handling defects can be minimized by paying more attention during packaging, transportation etc. and also shrinkable packaging materials can be used to reduce these defects. In the case of blown packages these shrinkable packaging material can hold the leakage and protects other units of that perticular pallet.

If a plant is operating with unsatisfactory sterility result, resampling must be applied, a sample big enough to contain at least five defective units should be drawn from the production in question. Incubation and evaluation of these samples should be done alone the same lines as above. Bacteriological test are however gaining in importance.

As far as sampling is concerned random and aimed sampling schemes should be implemented simultaneously. So the actual probability level of detecting a defective unit is very much higher than following a one sampling method. The number of units included in a sample should be as large as possible too.

Mostly, spoilage will be caused by microorganisms which occur at the highest frequency. These are Mesophilic ones, an incubation temperature between 30 to 37°C

should be chosen. In order to increase the probability of including a possible defective unit within the sample, the sample should incubate in total at the temperature chosen.

In areas with a moderate climate the temperature of storage and distribution does not exceed an average of 30 to 35°C, thermophilic microorganisms will not grow. They cannot be regarded as potential spoilage organisms. The thermophilic microorganisms (*Bacillus stearothermophilus*) usually enter a plant with the raw material. *B. stearothermophilus,* however, may establish itself in the plant due to inadequate cleaning and plant sterilization procedures. Aimed sampling may help to clarify this situation: unsterility of this kind usually shows predominantly at start of the production run. A certain number of packages (10 to 25) could be drawn at production start and incubated at 55°C, checking for the presence of *B. stearothermophilus.*

As an average, and depending to a certain extent upon the method of evaluation, about 50% of the total number of defectives present in a test sample can be detected after 3 days of incubation. This percentage increases to about 75 and 85% after five or seven days of incubation respectively. This never reaches the 100% level because of the selective effect introduced by the choice of a certain temperature of incubation.

The cost of storage will increase by the same amount for every day of storage. Comparing detection level and storage cost a reasonable compromise can be established: an incubation time of between 5 and 7 days will give the best results at comparatively low cost. An incubation period of less than three days cannot be generally recommended and incubating the sample for more than 9 days is not going to add significantly to the detection level but will increase the cost.

A number of different methods of evaluation can be used but all have some problems in common. Bacteriological method (plating) are very accurate but at the same time they are also a rather expensive requiring both material, labor and time. Titration is a labor consuming procedure with a fair degree of accuracy. pH measurements are both inexpensive and rapid but also rather inaccurate. In certain situation, oxygen tension measurements can be used. They are easy to perform, inexpensive and surprisingly accurate, but require an initial oxygen tension of at least 2ppm of oxygen.

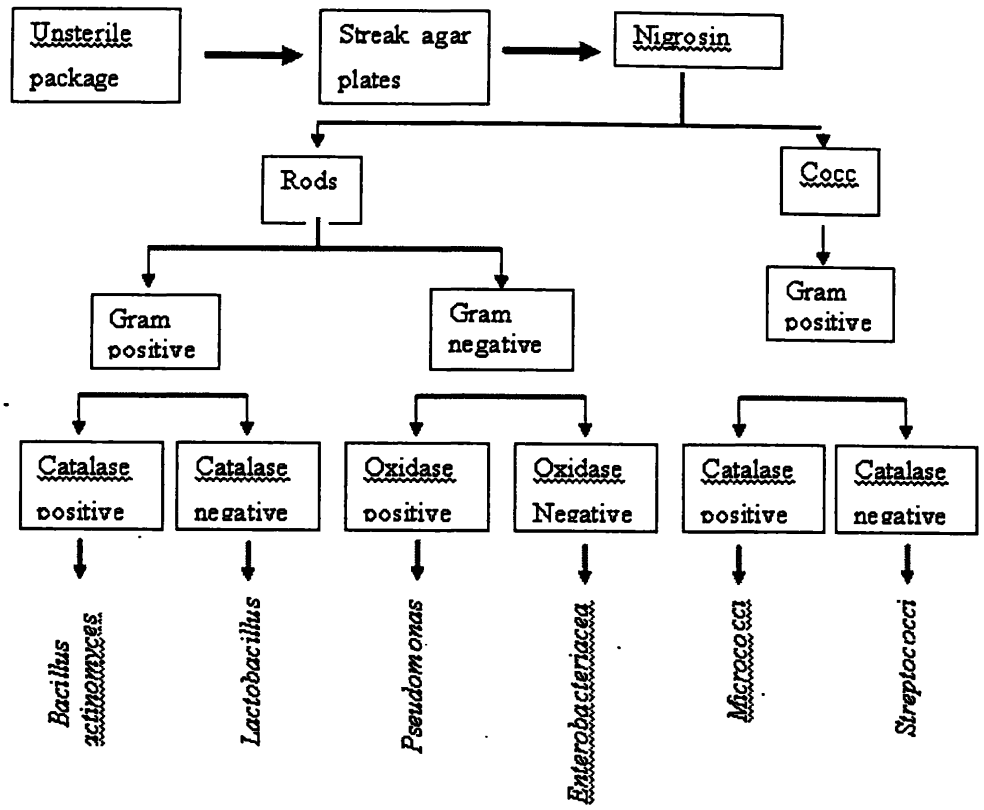
Alcohol stability, especially if combined with a pH indicator may you satisfactory results. Using sensoric evaluation, the situation becomes somewhat more complicated. Sensoric evaluation implies a subjective judgment and there fore depends to a large extend upon the experience and suitability of the individual performing the test. Sensoric evaluation may be quite sensitive provided a trained and capable person judged the sample. Also, sensoric evaluation is fast and inexpensive. Since the results obtained are not express in figures but rather as an opining. Non-destructive method maintaining a high level of accuracy by testing large a number of units.

It is essential to control the microbial count within the plant. The importance of a Air Handling Unit (AHU) becomes a must. In order to keep the microbial count as low as possible, should implement an AHU at least to the UHT filling room.

In the production plant proper cleaning is one of the most important operation. The normal CIP and weekely CIP's should be carried out and also the good house keeping practices should be carried out. In here all visible dirt should be removed whether they are in contact with the product or not. Satisfactory results can only be expected from an operation if both the surrounding and the inside of the plant are in acceptable condition.

In the section on quality control, the importance of establishing specifications of the process and/or product has been stressed. As far as troubleshooting is concerned such specification serves as basics for trigger the mechanism, giving an indication to change from quality control to troubleshooting. A number of such areas can be mentioned like microbiological results of row material analysis, results of the incubated pack control etc.

The identification of the type of spoilage flora is very helpfull for decision making. For this reason a "rough identification scheme" has been developed which is easy to execute, inexpensive and quick.



It is important to conduct training programmes to the workers. This programmes should cover hygiene practices as well as safety practices of both human and the product.

Training requirement for production personnel will be an additional advantage. This group includes junior management, manufacturing Managers and production crew. The training program can be divided in to the following categories.

Quality

-Quality Responsibilities

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-Parameters Influencing Quality

-Line Controls (Line Labs)

-New Employees Hygiene Training

-Zoning Wet/ Dry

-Net Weight Control

-Packaging materials

-Correct Operation of Forklifts

- Basics in warehouse Operation (GMP)

Communication / Leadership

- English
- Promoting Teamwork

Technical Knowledge

-Machine Performance/ Influence on Production

- Parameters/ Quality

-Net weight Control

Productivity

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-Job Responsibility Training & Assessment

-Waste/ Loss Control and Environment Protection Productivity / Employees in-Valmont

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