UHT PROCESSING AND ASEPTIC FILLING OF DAIRY FOODS

by

DAVID L. SCOTT

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Major Professor
Dr. Karen Schmidt

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Abstract

The demand for ultra high temperature processed and aseptically packaged dairy foods is growing throughout the U.S. The technology provides value-added food preservation for many foods including flavored milks, puddings, custards, creams, ice-cream mixes, whey-based drinks, sports drinks, and yogurt. Ultra high temperature nonfat milk, milk, light cream, and 18% cream are used throughout the U.S. by the restaurant and foodservice industries.

There are several advantages to aseptic processing and packaging over traditional pasteurization. Advantages include extended shelf life, lower energy costs, and the elimination of required refrigeration during storage and distribution. Challenges are present in all aspects of dairy processing. Major challenges associated with ultra high temperature processing and aseptic packaging of dairy foods include product quality loss, such as age gelation, fat separation, and flavor loss, as well as manufacturing issues such as limited production capacity, potential contamination, slow packaging speeds, and limited shelf life knowledge. This report reviews the history of aseptic processing, principles of ultra high temperature processing, principles of aseptic filling, quality control of UHT dairy foods, and regulations for dairy processors.

Table of Contents

List of Figures vi
List of Tables vii
Acknowledgments viii
Dedication ix
CHAPTER 1 - Introduction and History 1
Definition of Terms 1
Historical Development 3
UHT Dairy Foods Market 4
Growth 5
Milk and Ice Cream Composition 6
Advantages and Challenges 7
Customer Acceptance 8
CHAPTER 2 - Principles of Ultra-High-Temperature Processing 10
Types of Processing Systems 10
Indirect Heating 13
Time and Temperature Validation 14
Processing Requirements 15
Fouling 16
CHAPTER 3 - Principles of Aseptic Filling 18
Filler Types 18
Package Options 20
Filler and Container Sterilization 21
Post Process Contamination Concerns 22
CHAPTER 4 - Quality Control Aspects 24
Raw Material Quality and Microbiology 24
Product Testing - Quality 26
Chemical Changes 27
Physical Changes 28

Commercial Sterility Testing 28
Container Integrity 29
Shelf Life 30
Food Safety and HACCP 31
Record Requirements 32
CHAPTER 5 - Regulations 33
Aseptic Processing and Packaging Regulations 33
NCIMS Aseptic Pilot Program 35
Conclusions 36
References 37

List of Figures

Figure 1 Food safety pyramid for a dairy foods operation 32

List of Tables

Table 1 Aseptic processing and packaging definitions 2
Table 2 Uses of UHT and aseptic processing 3
Table 3 Typical composition of raw bovine milk 6
Table 4 Comparison of aseptic processing/packaging of dairy foods to conventional canning and the corresponding advantage or disadvantage 7
Table 5 Commercial UHT systems and heating modes 10
Table 6 Attributes of direct and indirect UHT systems 12
Table 7 Aseptic packaging systems 19

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Dedication

This paper is dedicated to my wife, Rebecca, and two children, Sheridan and Jonah. I appreciate your patience, love, and support.

CHAPTER 1 - Introduction and History

Commercial sterility is defined as a condition in which equipment and packages do not contain viable microorganisms of public health significance or microorganisms of non-health significance, which could reproduce under normal storage and distribution conditions (Anonymous 1995). In the canned food industry, commercial sterility is achieved by heat treatment of a food product inside a sealed container. Aseptic processing uses separate systems to sterilize the product and package. The sterile product is filled into sterile packages within the sterile zone of an aseptic packaging system (Anonymous 1995).

In the U.S., traditional pasteurization of milk requires a minimum heat treatment of 72º C for 15 seconds with subsequent refrigeration. The ultra high temperature (UHT) treatment is dependent upon process filings. The UHT treatment and aseptic package protects dairy foods from bacteria and external contamination. The shelf life of milk is extended from 21 days in traditional pasteurization to over four months with UHT and aseptic technology (Johnson 1984).

Definition of Terms

Table 1 lists several definitions with respect to aseptic processing and packaging. Thermal processing of milk is typically used to prolong shelf life. The U.S. classifies milk for consumption into three groups: pasteurized, ultrapasteurized (UP), and aseptic. High-temperature short-time (HTST) pasteurization is achieved by heat treatment of 72°C for 15 seconds with a negative phosphatase test but positive peroxidase test. The milk is cooled to $\leq$ 6°C and stored/distributed under refrigeration. Factors affecting shelf life include raw milk quality, processing protocols, filling sanitation, and refrigerated distribution quality (Rysstad and Kolstad 2006).

Extended shelf life (ESL) milk is not packaged aseptically and requires refrigeration post processing. Extended shelf life milk is heat treated by ultrapasteurization (UP) $\geq$ 138°C for a minimum of 2 seconds. Extended shelf life milk produced in the U.S. and Canada averages a 45 to 60 day shelf life under refrigerated conditions (Henyon 1999). Ultra high temperature processing uses continuous flow and subjects milk to 135 to 150°C for 3 to 5 seconds, then packaged, aseptically with an anticipated shelf life of 6 months stored/distributed under ambient

conditions (Vazquez-Landaverde et al. 2007). High hydrostatic pressure processing is a recent technology using pressure for a bactericidal effect. High pressure processing also influences the foaming, emulsifying, gelling, and water binding capacities of milk and milk product proteins (Balci and Wilbey 1999).

Table 1 Aseptic processing and packaging definitions

12-D concept[d] – process lethality requirement in the canning industry; the minimum heat process to reduce the survival probability of *Clostridium botulinum* spores to 10^{-12}
Acidified foods[a] – pH $\leq$ 4.6 and a water activity > 0.85
Aseptic[a] – describes a condition without microorganisms including viable spores
Aseptic packaging system[a] – any equipment that fills a sterile package or container with sterile product and hermetically seals it under aseptic conditions
Aseptic processing system[a] – the system that processes the product and delivers to a packaging system
Aseptic system[a] – the entire system (processing and packaging) necessary to produce a commercially sterile product contained in a hermetically sealed container
Aseptic technique[e] – technique to prevent contamination; sterile implements or containers used for aseptic sampling
Commercial sterility[b] – product free from microorganisms that grow and contribute to deterioration
D value[c] – decimal reduction time; heating time required at a given temperature to destroy 90% of microorganisms
F value[d] – the equivalent time in minutes at 121°C of all heat considered to destroy spores or vegetative cells of a particular organism
F_o[d] – the integrated lethal value of heat received by all points in a container during processing
Hermetically sealed container[c] – secure container against entry of microorganisms and capable of maintaining the commercial sterility of contents after processing
Low acid foods[a] – pH > 4.6 which permits growth of *Clostridium botulinum* spores and a water activity > 0.85

Shelf-stable food[c] – food stored without refrigeration at ambient environmental conditions
Sterile[b] – condition in which living cells are absent
Z value[d] – the degrees Fahrenheit required for the thermal destruction curve to traverse one log cycle

([a] Anonymous 1995)

([b] Holanowski 2008)

([c] David et al. 1996)

([d] Jay et al. 2005)

([e] U.S. Food and Drug Administration 2008)

Historical Development

Table 2 summarizes some early achievements of UHT and aseptic processes. The first system consisting of indirect heating with continuous flow (125ºC for 6 minutes) was manufactured in 1893. Patented in 1912, the continuous flow direct heating method mixed steam with milk to achieve temperatures of 130 to 140ºC. Development was hindered due to contamination potential without commercial aseptic systems. In 1953, UHT milk was filled aseptically into cans after heat treatment with an Uperiser® processor. This was followed in 1961 by packaging milk aseptically in tetrahedral paperboard cartons (Datta and Deeth 2007).

Table 2 Uses of UHT and aseptic processing

Year	Product and Process Description
1938	Chocolate milk heated at 149°C for 15 seconds using a hot-cool-fill (HCF) unit.
1942	Cream heated at 127 to 138°C using direct steam injection.
1951	Pea soup heated at 140 to 150°C for 8.8 seconds using indirect heat and a tubular heat exchanger.

1953	Milk heated at 150°C for 2.4 seconds using direct steam injection and then packaged in cans.
1961	Milk UHT heat treated using direct steam injection and packaged in paperboard cartons.
1964	Ice cream mix and concentrated milk formulations UHT heat treated with direct heat and packaged in four liter cans. This represented the first commercial aseptic production in Australia.
1969	Milk indirectly heat treated using a plate heat exchanger. This represented the first UHT milk in the U.S. marketplace.

(adapted from Datta and Deeth 2007)

The development of aseptic processing in the U.S. started through the efforts of C. Olin Ball. The HCF (hot-cool-fill) process was commercialized in 1938 for a chocolate milk beverage. The Avoset process followed in 1942 and eventually was used to package a cream product by utilizing a continuous hot air system and UV lamps in the filling and sealing area. The technology advanced again in 1948 with the Dole aseptic process developed by William McKinley Martin. These systems were used in 1951 for pea soup and sterilized milk. The Med-O-Milk brand also employed the Graves-Stambaugh process, which prevented milk from being exposed to air from the milking through the packaging processes. Real Fresh, Inc. became the second dairy in 1952 to use ultra high temperature and aseptic packaging (UHT-AP). In 1981, Real Fresh, Inc. was the forerunner in using hydrogen peroxide to sterilize packaging material, whereas Tetra Pak introduced the Brik Pak carton (David et al. 1996).

UHT Dairy Foods Market

A dairy drink with added vitamins and minerals was an early 1960's aseptic product. The product, vitamins in milk (VIM), was advertised as a meal replacement for weight loss and provided the consumer a ready-to-use product not requiring refrigeration. The Slim Fast Company and Nestle later introduced similar products. Product development was dependent

upon the container design and product. The "pudding cup" was a very successful concept originating in the late 1960's. The initial aluminum cups were replaced over time with transparent plastics. A shift from aseptic puddings to refrigerated puddings occurred in the 1980's. This shift resulted from mergers in the food industry, limited FDA approved aseptic fillers, and cost effective refrigerated distribution in the U.S. (David et al. 1996).

The food service industry also used aseptic dairy foods. Limited refrigeration in schools and restaurants and the ready-to-use aspect were main advantages. Pudding could be scooped from # 10 cans and served as single servings. The popularity of Mexican food led to aseptic cheese sauce packaged in # 10 cans and eventually into plastic pouches (David et al. 1996). According to Zadow (1998), UHT dairy foods include milk, modified milks, flavored milks, puddings, custards, creams, ice-cream mixes, and whey-based drinks. Datta and Deeth (2007) expanded this list to include energy and sports drinks, yogurt, and sauces.

Growth

Consumption trends show increased demand for aseptic dairy foods. Australian sales of UHT products increased approximately 18% per year with UHT products accounting for 6.1% of the total market (Zadow 1998). UHT milk sales increased 689% from 1990 to 2000 in Brazil. This equated to 69% of the 5.2 billion liter milk market (Alves 2001). UHT dairy foods represent a large share of the market in Germany, France, Italy, and Spain. Conversely, the market share is less than 10% in the U.S., U.K., and Australia (Datta and Deeth 2007).

Aseptic processing has the potential to increase dairy consumption in tropical countries. Traditionally, the tropical countries have lower milk consumption patterns due to high temperatures and limited refrigerated distribution (Goff 2008). Hedrick et al. (1981) predicted UHT milk with flavor attributes comparable to pasteurized milk would reduce energy costs since the shelf stable milk would not require refrigeration throughout distribution.

The U.S. per capita consumption of fluid milk from 1978 to 2003 decreased approximately 18% while ice cream consumption remained relatively unchanged (Goff and Griffiths 2006). However, aseptic milk is available in most U.S. grocery stores. Many fast food restaurants contract with aseptic processors to produce shelf stable ice cream mixes. The number of aseptic fillers in the U.S. increased from 417 in 1990 to 466 in 1995. The retail market utilized 237 of the aseptic fillers and produced approximately 5 billion units. The institutional

foodservice market produced an additional 3 to 5 billion units from the remaining 229 aseptic fillers (David et al. 1996). Products are manufactured with UHT and aseptic processing in over 60 countries (Burton 1988). The growth of this industry is limited by government regulations, filler speeds, and packaging costs (David et al. 1996).

Milk and Ice Cream Composition

The typical composition of raw bovine milk is listed in Table 3. Ice cream ingredients include milk, protein-based dairy ingredients, milkfat, sugars, stabilizers, and emulsifiers. Ice cream has a total solids composition of 35 to 42%: 10 to 16% milkfat, 9 to 12% milk solids-non-fat, 14 to 20% sugars, 0 to 0.4% stabilizers, and 0 to 0.25% emulsifiers. Heat treatments of ice cream mix eliminate pathogens, improve ingredient solubility, and melt milkfat. Ice cream properties are influenced by the heat treatments (Udabage and Augustin 2003).

Table 3 Typical composition of raw bovine milk

Component	Percent
Water	87.30%
Milkfat	3.90%
Protein - 76% caseins, 18% whey proteins, and 6% non-protein nitrogen	3.25%
Lactose	4.60%
Minerals - Ca, P, citrate, Mg, K, Na, Zn, Cl, Fe, Cu, sulfate, bicarbonate, etc.	0.65%
Acids - citrate, formate, acetate, lactate, oxalate	0.18%
Enzymes - peroxidase, catalase, phosphatase, lipase Gases - oxygen, nitrogen Vitamins - A, C, D, riboflavin, etc.	0.12%

(Adapted from Goff 2008)

Advantages and Challenges

Alves (2001) credited the growth of UHT in the Brazilian market to the following advantages over traditional pasteurization: refrigeration not required in storage and distribution, extended shelf life up to five months, and increased product options for consumers. Dairy operations utilizing UHT-AP have reduced energy requirements in processing (due to heat regeneration) and in ambient shipping/distribution. Food quality attributes such as flavor, nutrient loss, and color are improved with UHT versus traditional methods of rendering food commercially sterile (Dunkley and Stevenson 1987). Vitamin C and thiamin retention in aseptically processed soups (tomato, chicken) was much higher in comparison to retort processing (David el al. 1996).

Another advantage of UHT-AP is the diverse range of package sizes. Large containers such as drums, tanks, and tankers are filled through the continuous flow process. This is not practical with conventional canning due to heat transfer rates and handling issues. Laminated packages could replace semi-rigid containers since product is filled aseptically at cooler temperatures (Holdsworth 1992). Graphics can be applied to laminated packaging. Finished product storage and transportation costs are reduced due to lightweight packaging (Goff 2008). Table 4 lists a summary of advantages and disadvantages of aseptic processing and packaging of foods in comparison to conventional canning (David et al. 1996).

Table 4 Comparison of aseptic processing/packaging of dairy foods to conventional canning and the corresponding advantage or disadvantage

Criteria	Aseptic Advantage	Aseptic Disadvantage
Container speeds in production		Lower
Downtime potential		Resterilize processor and/or filler when sterility of system compromised
Energy costs	30% savings or greater	
Heat delivery during sterilization	More precise	
Nutrient loss	Minimum	
Overall product quality	Independent of size &	

	shape of container	
Product handling costs/labor	Low	
Sensory quality	Superior	
Spoilage troubleshooting		Complex
Sterilization of products containing particulates		Complex
Sterilization equipment		Complex
Survival of heat resistant enzymes		Possible
Traceability	Easier	
Value added perception	Higher	

(adapted from David et al. 1996)

Challenges are present in all aspects of food processing and UHT is not an exception. According to Zadow (1998), major problems associated with UHT-processed milks include age gelation, component separation, flavor degradation, post-process contamination, slow packaging speeds, and limited shelf life knowledge. Currently, effective UHT processing for products containing particulates has not been achieved due to solids settling and overprocessing risks (Goff 2008). UHT-AP processing requires substantial management knowledge and operator skill.

Customer Acceptance

The market share of UHT milk consumed varies considerably by country: Australia 9%, France 88%, Spain 83%, Germany 63%, Italy 55%, and the United Kingdom 5 to13%. Tetra Pak Australia discovered in a 1986 survey that consumers perceived UHT milk as a milk substitute, nutritionally poor, impure, and containing preservatives. Customer acceptance of unflavored UHT-AP milk is limited by a less desirable flavor in comparison to pasteurized milk, generally greater UHT-AP milk costs in various markets, and consumption habits of milk drinkers (Perkins and Deeth 2001).

Mottram (1998) defined taint or off-flavor as any flavor considered unacceptable for a particular food. Tainted and off-flavors result from external contamination or chemical or microbial reactions, respectively (Mottram 1998). Burton (1988) differentiated between a

‘heated’ flavor and ‘sterilized’ flavor associated with UHT milk. The heated flavor is unstable and develops when milk is heated above 70°C. The serum proteins (ß-lactoglobulin) then denature and the –SH groups oxidize to hydrogen sulphide. The sterilized flavor is stable and develops above 90°C. This flavor is thought to develop as a result of the Maillard reaction and becomes more pronounced throughout storage. Diacetyl, lactones, alcohol ketones, maltol, vanillin, benzaldehyde, and acetophenone are compounds possibly contributing to the sterilized flavor. Goff (2008) used the following descriptors for cooked flavor: slightly cooked, nutty-like, scorched, and caramelized. Sensory quality in UHT milks is related to the lactulose content (Nursten 1997).

A flavor difference exists between pasteurized and UHT milk. Flavor differences between UHT milks are attributed to the method of heat treatment (direct versus indirect) and the age of the milk (Perkins and Deeth 2001). Based on sensory work, Oupadissakoon (2007) reported butyric acid, sour aromatics, and lack of freshness as negative attributes with UHT milk. UHT milk quality depends more on the manufacturing process than country of origin or fat content. Customer acceptability of UHT milk is positively correlated to consumption habits which include UHT milk (Oupadissakoon 2007).

Chapman and Boor (2001) concluded that children ages 6 to 11 preferred HTST milk, UHT milk, and UP milk in that respective order. The preference of HTST milk over UHT milk is applicable as well to the U.S. adult population. In terms of ice cream, Bower and Baxter (2003) noticed that terminology such as ‘home-made’ was positively viewed by consumers. Chapman et al. (2001) stated quantitative descriptive analysis (QDA) and principal component analysis (PCA) could assist in marketing new dairy foods. The objective of perceptual mapping is to identify product attributes that influence purchase patterns and ascertain the positioning of a target brand versus the competition.

CHAPTER 2 - Principles of Ultra-High-Temperature Processing

UHT processing uses continuous flow, which renders less chemical change to the product in comparison to retort processing. Minimum processing times and temperatures are determined by the inactivation of thermophilic bacterial spores (Datta and Deeth 2007). Product characteristics such as pH, water activity, viscosity, composition, and dissolved oxygen dictate the processing conditions necessary to achieve commercial sterility (Overman 1998). The selection criteria of UHT and aseptic packaging systems reflect customer preferences. The production process must be designed to ensure commercial sterility and acceptable sensory attributes throughout shelf life (Anonymous 1996/1997).

Types of Processing Systems

Steam, hot water, and electricity are heating methods for UHT equipment. The sterilizers utilizing steam or hot water can be subcategorized as direct or indirect heating systems. In the indirect system, the product and heating medium do not have contact, as a barrier (stainless steel) is present. Direct heating systems mix pressurized culinary steam directly into the product. Regeneration allows heat transfer between sterile product and the raw product (Burton 1988). Regeneration heat transfer reduces energy consumption and is used for direct and indirect heating systems.

Direct heating modes include steam injection, steam infusion, and scraped surface. Indirect heating modes include indirect spiral tubes, indirect tubes, indirect plate, scraped surface, and electricity. Indirect heating with electricity includes electric elements, conductive heating, and friction (Burton 1988). Table 5 lists commercial UHT systems and their respective heating modes.

Table 5 Commercial UHT systems and heating modes

Commercial UHT Sterilizer	Heating Mode
Actijoule	Indirect electrically heated
Gerbig, Sterideal System	Indirect heat with tubes
High Heat Infusion, Tetra Therm Aseptic Plus	Combined heating modes

Two	
Languilharre System, Thermovac, Palarisator, Steritwin UHT Sterilizer, Ultra Therm, Da-Si Sterilizer	Direct heat with steam infusion
Rotatherm	Direct heat with scraped surface
Spiratherm	Indirect heat with spiral tubes
Ultramatic, Ahlborn Process, Sordi Sterilizer, UHT Steriplak-R, Dual Purpose Sterilizer	Indirect heat with plates
Votator Scraped Surface heater, Thermutator Heater	Indirect heat with scraped surface
VTIS, ARO-VAC Process, Uperiser, Grindrod	Direct heat with steam injection

(adapted from Datta and Deeth 2007).

Direct heating systems include steam injection (steam into milk) and steam infusion (milk into steam). The culinary steam must be high quality and impart no off-flavors to the product. The product temperature increases almost instantly due to the latent heat of vaporization. The condensed steam dilutes the milk and is removed later as the heated milk is cooled in a vacuum chamber.

Plate or tubular heat exchangers are two heating modes for indirect heating. Heat conducts from the heating medium through a metal surface to the product. Heating in the indirect system occurs at a slower rate; therefore, the milk is subjected to the overall heat treatment for a longer time. Additional considerations are taken into account with tubular and plate heat exchangers. Medium to high viscosity products are processed most frequently using tubular heat exchangers. The heat transfer coefficient is greater with plate heat exchangers due to turbulence. Production run time is limited more with plate heat exchangers than tubular heat exchangers due to fouling or burn-on (Datta et al. 2002). The potential for contamination due to pinholes in the stainless steel barrier is minimized by maintaining a greater product pressure on the sterile side compared to the raw side. Table 6 summarizes the attributes of direct and indirect UHT heating systems.

Table 6 Attributes of direct and indirect UHT systems

Criteria	Comments
Culinary steam	Culinary steam is required for direct systems but not for indirect systems.
Down time	Direct systems have longer processing times than indirect systems.
Fat separation	Fat separation is more common for indirect systems than for direct systems.
Flavor attributes	Indirect systems impart more cooked flavor than direct systems.
Fouling	Fouling is an issue with indirect systems but not direct systems.
Heat regeneration	Heat regeneration is approximately 50% in direct systems and 90% in indirect systems.
Heat resistant sporeformers	Indirect systems have a lower ability than do direct systems to destroy sporeformers without chemical damage to the product.
Heating medium failure	Contamination is more likely due to pinholes in indirect systems than direct systems. Pressure differential is monitored to control this issue.
Homogenizer location	The homogenizer is located post processor for direct systems and pre or post processor for indirect systems.
Oxygen levels	Oxygen levels of product at packaging are greater for indirect systems (7 to 9 ppm) than for direct systems (< 1 ppm).
Plasmin and plasminogen levels	Plasminogen is the precursor for plasmin, which is a protease in milk contributing to gelation and flavor problems (David et al. 1996). Plasmin is typically inactivated in indirect systems but not in direct systems.
Power	Direct systems have greater power requirements than indirect systems.
Preheating	Preheating is common for indirect systems but not for direct systems.
Process control	Water removal is important for direct systems in controlling total

	solids. Temperature and pressure differentials for indirect systems can be affected by fouling.
Product gelation	Gelation issues are lower for indirect systems than for direct systems.
Product viscosity	High viscosity is more limiting in indirect systems than in direct systems.
Sterilizing temperatures	Temperatures are 3 to 4°C greater for direct systems to accomplish sterilization comparable to indirect systems.
Sediment formation	Sediment formation is less for indirect systems than for direct systems.
System costs	Costs associated with direct systems are greater than indirect systems.
Temperature capacity	Direct systems can reach greater temperatures than indirect systems.
Water	Indirect systems require less water than direct systems.
Vitamin retention	Folic acid and vitamin C retention are less for indirect systems than for direct systems due to higher oxygen levels.

(adapted from Datta and Deeth 2007)

Indirect Heating

Burton (1988) stated plate heat exchangers used in UHT processing must withstand greater temperatures and internal pressures than equipment used for HTST pasteurization. The gasket material must be durable and replaced at scheduled intervals. Plate heat exchangers provide greater turbulence and heat transfer area when compared to tubular heat exchangers (Burton 1988). David et al. (1996) state plate heat exchangers are used primarily for preheating functions due to the difficulty in maintaining plate sterility. Concentric tubes and shell-and-tube heat exchangers are two types of tubular heat exchangers. Concentric tubes consist of two or three stainless steel tubes separated by spacers and wound into coils. The two-tube design simultaneously heats and cools (regeneration) product flowing in opposite directions. The triple tube system doubles the heat transfer area in the final heating stage and can be used in the final

cooling sections. Tubular systems typically have thicker metal transfer barriers in comparison to plate heat exchangers. Therefore, tubular systems can withstand higher internal pressures with less susceptibility to contamination. Scraped surface heat exchangers use mechanical forced convection to increase heat transfer. Scraper blades minimize fouling and provide turbulence as heated product passes through a heat transfer cylinder. Scraped surface heat exchangers are used only for highly viscous products due to lower energy efficiency and higher equipment cost in comparison to the other indirect heating systems (Burton 1988).

Time and Temperature Validation

The scheduled process is considered adequate when manufacturing conditions for a specific product achieve commercial sterility (Anonymous 1995). The thermal process is dependent upon the following factors:

1. Product (pH, water activity, viscosity, specific gravity)
2. Microbial profile (number, type, heat resistance)
3. Equipment design
4. Package

A process filing is a joint effort between the UHT-AP dairy operation and the process authority. The F_o value and thermophysical properties of the dairy food are determined through experimentation and research (David et al. 1996). The F_o value represents a 12 decimal reduction in *Clostridium botulinum* spores and is considered the absolute minimum process in conventional canning to guarantee food safety (Burton 1988). Calculations for microbial destruction consider the time and temperature of the heat treatment. FDA accepts F_o values for thermal processes calculated only from the time and temperature of the product in the holding tube (David et al. 1996). The D-value is defined as the required time to decrease microorganism numbers tenfold at a given temperature (Singh 2007). The process filing and supporting documentation (trial run data, critical factors, equipment sterilization, quality control procedures, and operational procedures) are submitted to FDA for approval of a scheduled process (David et al. 1996).

Ideal time-temperature profiles inactivate bacterial endospores and limit chemical changes with minimal decrease in nutritional and sensory quality (Datta et al. 2002). The major

challenge in UHT milk production is sufficient heat treatment with minimal flavor change. Direct heating imparts less flavor change but requires more energy in comparison to indirect heating. Total microbial lethality at constant time and temperature varies between direct and indirect heating systems (Westhoff 1981).

The residence time distribution (RTD) is the time range for a fluid product such as milk to enter and exit the holding system (Singh 2007). Flow through the heating system is controlled by timing or metering pumps. The residence time is determined by hold tube volume, flow rate, and flow rate attributes (viscosity) of specific products (Anonymous 1995). Positive reactions in the hold tube include destruction of bacteria, inactivation of enzymes, and hydration of thickeners. Negative reactions include development of off-flavor, initiation of off-color, and destruction of vitamins (David et al. 1996).

Processing Requirements

Common attributes for all aseptic processing systems include:

1. Product must be pumpable.
2. Flow rate of product must be controlled and verified.
3. Process time and temperature must sterilize the product.
4. Product must be held at temperatures to achieve sterilization.
5. Product must be cooled before the aseptic fill.
6. System must be pre-sterilized and must maintain sterility throughout production.
7. System must be engineered to keep non-sterile product from entering the filler.

(Anonymous 1995)

The processing steps for UHT milk include preheating, homogenizing, holding at preheat temperature, heating to sterilization temperatures, and cooling (Datta et al. 2002). The UHT-AP system must be cleaned prior to equipment sterilization. CIP (clean-in-place) circuits are utilized to clean UHT systems. Alkaline detergents (caustic) remove protein deposits and saponify fat whereas acid detergents remove mineral deposits (Burton 1988). The cleaning cycles consist of 3 basic steps:

1. Water pre-rinse to remove loose deposits.

2. Chemical treatment to solubilize deposits.

3. Final rinse to remove the chemicals.

The flow velocity and circulation temperature are critical in the CIP process (Holdsworth 1992). Intermediate cleaning is completed at predetermined intervals throughout production without losing sterility. An in-line aseptic surge tank allows filling to continue during the intermediate cleaning of the processor. The water/caustic/water is circulated at production temperatures and flow rates until pressures decrease (Burton 1988).

Cleaning should be completed at established frequencies to prevent residue and biofilm buildup. Biofilms may contain bacteria and spores within the matrix, adhere to equipment surfaces, and resist removal during cleaning and sanitizing. The biofilms can detach and contaminate the product being manufactured (Faille et al. 2001). Monitoring programs such as ATP swabbing should be implemented to verify cleaning effectiveness (Grow 2000).

For sterilizing the process, heated water can be circulated for a prescribed time and temperature. Recording devices and thermocouples are used to verify equipment sterilization (Anonymous 1995). The homogenizer is typically sterilized in-line with the processor and associated pipes. Sterilization cycles can be automated to ensure proper sequencing, to ensure minimum temperature requirements are met, and to ensure the timing starts/stops only when the system is above the minimum temperature setpoint (Burton 1988).

Fouling

Varzakas and Labropoulos (2007) stated that fouling is a term used to describe burn-on, which occurs within indirect heating systems. Processing times are limited by the quantity and location of fouling deposits. Fouling is the primary reason for decreased heat transfer in a UHT processor. The lower product temperature after the hold tube is compensated by the system increasing the steam temperature (Varzakas and Labropoulos 2007). Fouling results in greater down time, chemical costs, and capital costs. There are two types of fouling deposits: Type A and Type B. Type A fouling is mainly protein (50 to 70%) and results from process temperatures below 110°C. Type A deposits are described as soft and curd-like, and can occupy a significant volume of space. Type B fouling contains mostly minerals (70 to 80%) and occurs when process temperatures exceed 110°C. Type B deposits are described as gritty and brittle. Type A deposits

typically form in the preheating section, whereas type B deposits form in the high temperature section of the UHT processor (Datta and Deeth 2007).

Holdsworth (1992) identified several factors that affect fouling: product characteristics (e.g., pH, seasonal variation of milk, age, ammonia concentration, composition), process variables (e.g., velocity, exposure time, wall temperature, processing temperature, bulk fluid temperature), combined variables (e.g., heat barrier-product temperature difference, heating media-product temperature difference), and pre-treatment heating.

Datta and Deeth (2007) list methods for reducing fouling. Preheating the product increases whey protein denaturation, which inversely affects the quantity of type A deposits. Additives in the product formulation that increase milk pH reduce fouling. For example, sodium pyrophosphate decahydrate stabilizes the casein micelles, which in turn reduces calcium phosphate fouling during high temperature heating. Calcium phosphate contributes to type B fouling due to reverse solubility at high temperatures (Datta and Deeth 2007). Bansal and Chen (2006) stated fouling can be accentuated by prolonged raw milk storage, which allows for proteolytic action to occur and air bubbles to form.

CHAPTER 3 - Principles of Aseptic Filling

Aseptic packaging systems fill sterile product into sterile packages within the confines of the sterile zone of the filler. The aseptic zone/sterile zone extends from the point where sterilized packaging enters the sterile zone to where the sealed package is evacuated. Common attributes to all aseptic packaging systems include:

1. The sterile product, sterile package, and sterile zone prevent post-processing contamination.
2. The food contact surfaces of the package are sterile.
3. Product is filled aseptically into the package.
4. Packages are sealed hermetically.
5. Automation exists in monitoring and controlling the critical points.

(Anonymous 1995)

Filler Types

The two primary aseptic packaging systems fill UHT product into preformed sterile packages or use a form-fill-seal system (Datta and Deeth 2007). Table 7 lists several manufacturers of aseptic equipment. Commercial manufacturers include Tetra-Pak, Scholle, and the Dole Aseptic Canning System®. Aseptic packaging systems available for dairy foods include drum and bin systems, heat during blow molding, carton packaging machines, bag-in-box packaging systems, bulk tanks and containers, plastic cups/pots/cartons, and pouches/sachets (Holdsworth 1992).

Table 7 Aseptic packaging systems

System	Package	Sterilant
Asepak	Bags	Heat
ASTEC	Bins and tanks	Pressurized steam
CKD	Cups	Hydrogen peroxide
Combibloc	Cartons	Hydrogen peroxide + heat
Dole Aseptic Canning System	Steel/aluminum cans and lids	Superheated steam
DuPont Canada	Bags, pouches	Hydrogen peroxide
ERCA	Cups	Hydrogen peroxide + heat
Evergreen	Cartons	Hydrogen peroxide + heat
Gasti	Cups	High pressure steam
Gaulin	Bags	Ethylene oxide
Hamba Manufacturing	Cups	Ultraviolet rays
Hassia	Cups	Hydrogen peroxide + heat or pressurized steam
Ingko	Bags	Chlorine solution + heat
Inpaco	Pouches	Hydrogen peroxide + heat
International Paper Co.	Rectangular packages	Hydrogen peroxide + heat
Lieffeld & Lemke	Cups	Hydrogen peroxide + heat
Liqui-Box Corp.	Bags	Gamma radiation
Manccini	Bags	Gamma radiation
Mead Packaging Co.	Cups	Citric acid + heat

Metal-Box Freshfill (Autoprod)	Cups	Hydrogen peroxide + heat
Pure-Pak, Inc.	Cartons	Hydrogen peroxide + heat, oxonia
Purity Packaging Co.	Cups	Hydrogen peroxide
Remy	Cups	Hydrogen peroxide + heat
Remy	Bottles	Hydrogen peroxide or oxonia
Scholle Corporation	Bags	Gamma radiation or ethylene oxide
Serac	Bottles	Hydrogen peroxide
Tetra Pak, Inc.	Cartons	Hydrogen peroxide
Wright Sel	Bags	Gamma radiation or ethylene oxide

(adapted from David et al. 1996)

Package Options

Package options include metal and rigid containers, webfed paperboard containers, preformed paperboard containers, preformed rigid/plastic containers, thermoform-fill seal containers, flexible bags/pouches, and blowmolded plastic containers (Dunkley and Stevenson 1987). The metal and rigid container category includes metal cans, composite cans, plastic cups, glass containers, and drums (Anonymous 1995). Plastics used in aseptic packages can consist of acetal, nylon, polypropylene, polyester, polycarbonate, acrylic, ABS (acrylonitrile-butadiene-styrene), PVC (polyvinyl chloride), polystyrene, high-density polyethelene, low-density polyethelene, EVAL (ethyl vinyl acetate), EVOH (ethyl vinyl alcohol), and PVDC (polyvinylidene chloride) (David et al. 1996).

The primary objective of packaging is to preserve the product quality (Henyon 1999). Flavor scalping is a reduction in quality due to volatile flavors being transmitted between the product and package material (Sajilata et al. 2007). Selection of aseptic packaging is based upon the following:

1. Product compatibility
2. Dispensing requirements
3. Storage conditions
4. Transportation costs
5. Waste minimization

(Anonymous 1996/1997).

Richmond and Stine (1982) extended the selection of packages for fluid products to include convenience, appearance, safety, consumer preference, filling and handling, durability, and protection. Considerations for package material properties include geometry, mechanical properties, and barrier properties. The sealing strength must be adequate to maintain package integrity (Holdsworth 1992). Packaging must provide a microbial barrier and prevent light, oxygen, and moisture transmission (Eyer et al. 1996). Packaging must withstand environmental changes and sterilization temperatures/chemicals. The package must comply with legal requirements and meet environmental concerns. Environmental concerns include all steps from the package manufacturing through its disposal (Holdsworth 1992). Richmond and Stine (1982) stated that the polyethylene pouch used for aseptic packaging received the top ranking by the Environmental Protection Agency (EPA). The polyethylene pouch consumed less energy to produce and resulted in less waste.

Filler and Container Sterilization

Aseptic fillers have sections containing sterile contact pipes and valves along with non-contact sections (sterile chambers). Both sections must be sterilized prior to production and must maintain sterility throughout production (Burton 1988). Rippen (1969) stated aseptic fillers and associated pipes are sterilized typically with heat in the form of steam. In-line gaskets must tolerate sterilization temperatures. Sterilization temperatures are monitored with thermocouples to verify sterilizing procedures (Rippen 1969). Wet heat sterilization using saturated steam is the

most dependable sterilant, as microorganisms are more resistant to dry heat, which necessitates higher temperatures (Burton 1988).

Sterilants are applied uniformly to the aseptic zone by misting equipment, whereas packaging typically is sterilized by misting or passing through a sterilant bath. Examples of sterilants include chlorine, iodine, oxonia, food acids, ozone, hydrogen peroxide, and ultraviolet light. Hydrogen peroxide is most effective at higher temperatures with an FDA minimum concentration of 30% (David et al. 1996). The residual level of hydrogen peroxide is regulated with a maximum level of 0.5 PPM. Infrared radiation and vaporized hydrogen peroxide have been studied as sterilants for packaging materials (Kulozik and Guilmineau 2003).

Post Process Contamination Concerns

Rippen (1969) cited typical spoilage in UHT-AP production at a defect rate of 1/1000. Manufacturers of aseptic fillers target a defect rate of $\leq$ 1/1000 or $\leq$ 1/3000 whereas $\leq$ 1/10,000 is an industry standard for aseptically packaged low acid foods in rigid, semi-rigid, and flexible containers (David et al. 1996). The following seven potential failure modes exist for aseptic processing and packaging of foods.

- Type 1 failure results from raw ingredient, handling, storage, or batching issues.
- Type 2 failure results from processor and filler CIP, sanitation, preventive maintenance, and pre-sterilization issues.
- Type 3 failure results from the thermal process heating cycle including regeneration.
- Type 4 failure results from the cooling cycle including surge tanks.
- Type 5 failure results from sterilization issues with the package.
- Type 6 failure results from sterility loss in the aseptic zone or from environmental load.
- Type 7 failure results from loss of package integrity.

(David et al. 1996)

Contamination issues must be identified with subsequent corrective action. Post process contamination of the aseptic zone can be attributed to several variables: environmental bioburden, positive air pressure, processing equipment or line turbulence, system gasping, indexing operations, condensate accumulation, unsterile product entry, or bacteriological seeding (David et al. 1996). Post process contamination occurs in individual cartons if package integrity

is compromised. Contamination from isolated package integrity issues occurs more frequently than processing contamination.

Hydrolytic enzymes (proteases, lipases) from Pseudomonas species can survive UHT treatment and result in rancidity and proteolysis (Rajmohan et al. 2002). Bacterial cells communicate when adequate levels of AHL (acyl homoserine lactones) are produced at threshold concentrations. This quorum sensing is related to the production of protease and biofilm (Goff and Griffiths 2006). Examples of thermophilic sporeformers most commonly found in UHT dairy foods include *Bacillus stearothermophilus* and *Bacillus licheniformis*. These organisms produce acid without gas resulting in a "flat sour" defect in the low-acid, thermal processed shelf stable foods. The thermophiles do not grow under ambient storage/shipping temperatures as they have optimum growth at approximately 55°C. The fungus *Fusarium oxysporum* produces gas and is evident by swollen or bloated containers. This organism enters the filling system through contaminated air or when positive air pressure is lost in the aseptic zone (Datta and Deeth 2007). Contamination by *Bacillus cereus* indicates improper cleaning and sterilization of the UHT-AP system. Contamination through gaskets or condensate in the lower temperature sections of the processor are indicated by a single organism, whereas package integrity or packaging sterilization issues typically result in a flora of microorganisms (Burton 1988).

CHAPTER 4 - Quality Control Aspects

Quality assurance is a program to ensure the product meets company specifications and federal guidelines, whereas a quality control program focuses on the production of non-defective product. The quality control department in UHT-AP dairy operations is responsible for monitoring raw materials, batches, in-process control points, sampling, labeling, commercial sterility testing, regulatory inspections, and customer audits. The Safe Quality Food (SQF) program is an emerging certification audit program in the food industry and is a recognized Global Food Safety Initiative (GFSI) standard. The SQF Codes (SQF 1000 Code, SQF 2000 Code) use HACCP guidelines to manage food safety and quality. The SQF 2000 Code applies to processing plants and consists of prerequisite programs, food safety plans, and food quality plans (Safe Quality Food Institute 2008).

Quality control programs maintain food safety and product quality. The quality monitoring scheme (QMS) should include GMP's, processing protocols, and HACCP. GMP's coverage is vast and addresses plant sanitation, employee hygiene, water quality, pest control, maintenance protocols, proper labeling, transportation procedures, rework, and product tracking. Quality protocols include environmental sampling, production retains, commercial sterility testing, finished product testing, weight checks, package integrity checks, and equipment calibration (Grow 2000). Supplemental programs within quality control include vendor approval programs, customer complaint analysis, laboratory cross-check verification, product specifications, GMP monthly audits, and employee training of laboratory procedures.

Raw Material Quality and Microbiology

UHT requires raw milk that is heat stabile with low microbial counts and an acceptable flavor. The alcohol test (74% ethanol) screens raw milk for heat stability (Farahnik 1982). Other raw milk tests with desired targeted ranges include:

1. milkfat (3.2 to 4.0%)
2. pH (6.40 to 6.80)
3. protein content (3.0 to 3.5%)

4. standard plate counts (< 100,000 cfu/g for single producers and <300,000 cfu/g for commingled loads)
5. titratable acidity (0.13 to 0.15%)
6. total solids (11.5 to 12.0%)

The Pasteurized Milk Ordinance mandates temperatures of < 7° C for raw milk delivery, storage and transportation (Grade "A" Pasteurized Milk Ordinance 2005).

Unwanted attributes of UHT-AP milk would be gelation, sedimentation, or separation, and often these defects can be traced to the raw milk supply (Dunkley and Stevenson 1987). Spoilage of raw milk prior to processing can occur from poor sanitation and inadequate storage temperatures. The *Staphylococcus aureus* toxin is heat resistant and not inactivated by the majority of UHT processes (David et al. 1996). Thus, UHT milk is susceptible to enzymatic spoilage without vegetative growth. Pseudomonads degrade over 100 organic compounds and produce proteinases and lipases contributing to enzymatic spoilage of milk and dairy foods (Stepaniak 2004). Pseudomonas is the most common gram negative psychrotrophic microbe in both raw and pasteurized milks (Tondo et al. 2004). Psychrotrophic organisms are more prolific in summer months, while spore populations are higher in the winter months for raw milk (Russell 1999). Microbial contamination is minimized by maintaining healthy cow herds, milking process GMP's, and plant sanitation (Prejit and Latha 2007). Burton (1988) reported that *Bacillus licheniformis* is the most common spore isolated in raw milk and *Bacillus subtilis* is the most common spore isolated in sterilized milk. Poor quality raw milk contains gram negative organisms, which can produce heat resistant enzymes. The load of bacterial lipopolysaccharides can be quantified by the limulus test (Burton 1988). The aerobic spore-forming Bacillus genre is common in raw milk and linked to spoilage in UHT products (McGuiggan et al. 2002). *Bacillus sporothermodurans* produces endospores that are heat resistant and can survive UHT processing (Scheldeman et al. 2002). Scheldeman et al. (2006) hypothesized that heat resistant spores adapted to sublethal stress conditions in commercial dairy operations and this adaptation is dependent on many factors.

The microbial load in raw milk is a critical quality factor for UHT dairy foods due to the extended shelf life. Psychrotrophic bacteria can produce enzymes, which result in off-flavor development from milk protein hydrolysis (Gillis et al. 1985). Proteinases and lipases can withstand the UHT process if initial bacterial counts exceed 10^6 CFU/ml. The proteinases can

produce a bitter taste and gelation, whereas the lipases can produce rancid flavors during storage. Heat stable amylases can cause thinning in UHT desserts such as puddings and custards. Thermoduric spoilage is uncommon in UHT dairy foods due to the process times and temperatures. *Bacillus sporothermodurans* possesses high heat resistance and exhibits optimal growth at 25°C. This organism results in milk discoloration and is a challenge to eliminate from contaminated processing equipment. *Bacillus stearothermophilus* and *Bacillus flavothermus* spores can be so great in milk powder that UHT processing is ineffective as a commercial sterilization method (Datta and Deeth 2007).

Product Testing - Quality

Raw materials such as milk, cream, nonfat dry milk, whey powder, oils, and liquid sugar are tested before receipt. Incoming ingredients are tested randomly at a frequency determined by purchasing GMP's, HACCP risk analysis, and supplier history. Batches of formulated product are tested prior to processing for composition (e.g., butterfat, protein and total solids content) and product characteristics (e.g., brix, pH, and viscosity). Batch adjustments are made until product is within specifications (Grow 2000).

Finished product testing and sensory analysis are completed at predetermined frequencies following UHT-AP. The frequency should ensure consistency from the beginning through end of production. Line quality control personnel are responsible for package closure inspections, weight checks, sampling protocols, and label verifications. Process checks include raw temperatures, process temperatures, process alarm temperature verification, process speeds, and homogenization pressures (Grow 2000).

A study conducted by Korel and Balaban (2002) suggested that odor changes in milk samples inoculated with *Pseudomonas fluorescens* or *Bacillus coagulans* could be detected by an electronic nose. The odor changes correlated with microbial and sensory data. Maillard browning, as a function of heat treatment given to milk, was detected by front face fluorescence spectroscopy and HMF analyses (Schamberger and Labuza 2006). Elliott et al. (2003) concluded lactulose is the most reliable index of heat treatment since it is not affected by milk storage before or after UHT processing. Heat treatment involves two reactions. Type 1 reactions involve the denaturation, degradation, and inactivation of whey proteins, enzymes, and vitamins. Type 2 reactions involve the formation of lactulose, hydroxymethylfurfural, furosine, etc. which are not

detected in the raw milk (Morales et al. 2000). Singh (2004) stated the ability of milk to undergo high heat treatment without coagulating or gelling is defined as heat stability. Solutions to improve heat stability include preheating product in the UHT processor, adjusting pH to the ideal heat stability maximum, and adding phosphate, buttermilk, or phospholipids to the formulations (Singh 2004).

Chemical Changes

Chemical and physical changes in milk depend on raw ingredient quality, the processor, and the scheduled process. Direct heat processing imparts less adverse chemical changes compared to indirect heat processing (Elliott et al. 2003). The process holding time accounted for > 80%, the process heating time < 10%, and the cooling phase < 2% of the accumulated chemical changes for an indirect continuous flow coiled tube system (Labropoulos and Varzakas 2008).

Hsu (1970) reported that dairy foods undergo the following chemical changes to varying degrees: flavor, acidity (decreases following direct UHT process), enzyme inactivation, and vitamin decomposition. The heated flavor after UHT processing is due to sulphydryl groups, which oxidize 5 to 10 days after processing. The oxidation reduces the cooked flavor (Hsu 1970). Milk oxidative rancidity is the reaction of oxygen on milkfat components resulting in short-chain aldehyde and ketone volatiles (Solano-Lopez et al. 2005). Light and storage temperatures exceeding 35°C accelerate this oxidation reaction (Hsu 1970). Enzyme inactivation is a positive chemical change of UHT processing. Raw milk enzymes are present via bacterial growth. Natural enzymes present in raw milk include alkaline and acid phosphatases, catalase, peroxidase, xanthine oxidase, lipases, and proteases. The holding of milk at 55°C for one hour inactivates these enzymes, reduces gelation, and minimizes off flavors (Burton 1988).

Fat-soluble vitamins are affected minimally by heat whereas water-soluble vitamins can be destroyed partially in UHT processing. UHT processing reduces B vitamins by 10%, folic acid by 15%, and vitamin C by 25%. The nutritional value of proteins, minerals, and fats are affected minimally by UHT processing (Holdsworth 1992). Nutrient loss is correlated to the storage temperatures of commercially sterile products, initial oxygen content, and packaging choice. Nutritional value is preserved by including a deaerating process step, packing into

opaque hermetically sealed containers, and storing under refrigerated conditions (Dunkley and Stevenson 1987).

Physical Changes

Brown color, sediment, protein destabilization and separation are unwanted physical attributes potentially found in UHT milk (Hsu 1970). Milk proteins change more than any other milk constituent due to UHT processing. Milk protein changes contribute to loss of color, flavor, and nutrition, as well as gelation and sedimentation. Denatured whey proteins (β-lactoglobulin and α-lactalbumin) form complexes with other whey proteins, caseins, and fat globules (Dunkley and Stevenson 1987). Thermal inactivation of a transglutaminase (TG) inhibitor provides improved cross-linking of casein micelles, resulting in an improved product texture (Bonisch et al. 2004).

The color of UHT milk products is affected by milk composition, homogenization pressure, heat treatment, and storage conditions. Dairy foods with greater quantities of reducing sugars have more issues with browning (Dunkley and Stevenson 1987). Product browning is more pronounced with increases in process severity and storage temperature (Burton 1988).

Sediment is more prevalent in products that are more severely processed, that have a targeted pH of < 6.6, and that have undergone direct versus indirect UHT processing (Holdsworth 1992). Other factors affecting sedimentation include homogenization pressure which is used to control fat separation, time and temperature profile which is used to ensure product sterility, and formulations which can increase product variability (Hsu 1970). For example, sodium citrate inhibits sedimentation whereas calcium salts increase sedimentation. Gelation, a result of protein-protein interactions, is affected by the raw milk supply, process conditions, storage conditions, and producer location (Dunkley and Stevenson 1987).

Commercial Sterility Testing

Scheduled processes in retort operations and UHT processes inactivate vegetative cells and spores of pathogenic bacteria. The genera Bacillus and Clostridium are the primary sporeforming spoilage microbes (Ravishankar and Maks 2007). Spoiled packages are identified as “flat sours” or swells. Spoilage organism identification is useful in troubleshooting the cause of spoilage and the origin of contamination (Burton 1988). Underprocessing is indicated by spoilage due to spore-forming rods whereas post process contamination is indicated by mixed

flora containing heat sensitive organisms (Dunkley and Stevenson 1987). Lewis (1999) stated UHT milk microbial counts should be $\leq$100 cfu/g following 15 days at 30°C. Hsu (1970) stated that souring and/or coagulation would be identified after incubating UHT-AP products 7 to 10 days at 37°C.

An incubation and inspection program is recommended by FDA to verify sterility of aseptically packaged products (Anonymous 1995). The incubation and inspection program can use a variety of standard and/or rapid methods to test the commercial sterility of the final product. The incubation and inspection program should be representative for given lot codes, traceable through record keeping, and not a replacement for GMP's (Anonymous 1995).

Sampling plans are more extensive when commissioning an aseptic filler than during routine production (Burton 1988). Sampling between 0.1 to 1.0 % for routine production is recommended with samples taken at the beginning of production, filler restarts, and production end. An ideal sampling plan provides sterility assurance within a reasonable cost structure (Farahnik 1982). Microbial testing should be viewed as an additional verification quality program and is completed through traditional and rapid methods (Dunkley and Stevenson 1987). Visual inspections, sensory analysis, and pH measurements are done in conjunction with rapid methods to verify product quality (Grow 2000). Quantitative methods include direct enumeration and viable enumeration. Viable cells are counted using standard plate counts, most probable number, membrane filtration, plate loop methods, or spiral plating. Qualitative methods include measuring metabolic activity or cellular constituents (Goff 2008). The Cellscan Innovate System by Celsis uses bioluminescence to measure adenosine tryphosphate (ATP) found in living microorganisms (Grow 2000).

Container Integrity

Package closure inspections are completed as verification that the hermetic seal can withstand handling, distribution, and storage. Food packaging for shelf stable products must provide barrier properties and physical strength. Package closure inspections are completed for metal, glass, semi-rigid, and flexible containers (Anonymous 1995). Package integrity inspections for flexible containers include visual observation, dye test, squeeze test, seal teardown, and conductivity (Grow 2000). Additional tests identified by Holdsworth (1992) include the inflation test, compression test, decompression test, biotesting, ultrasound imaging,

mechanical tests, and headspace indicators. The mechanical tests on filled packages include stress testing, stack testing, load vibration, and impact resistance.

Shelf Life

The extended shelf life and shelf stability are definite advantages of UHT-AP dairy foods. Shelf life is the storage time before quality drops to an unacceptable level. Holanowski (2008) stated that subjective attributes can include taste, color, odor, gelation, sedimentation, separation, and viscosity. These attributes can be affected by raw product quality, pretreatment process, process type, homogenization pressure, deaeration, post process contamination, aseptic packaging, and package barriers. UHT milk flavor is affected by milk quality, scheduled process, process type, package material, storage temperature, and storage duration (Holanowski 2008). For example, in terms of package material, ultrapasteurized milk (UP) packaged in standard packaging boards deteriorated more rapidly than UP milk packaged in barrier and foil boards (Simon and Hansen 2001).

Refrigeration can extend product quality throughout shelf life. Temperature abuse throughout storage and distribution can result in discoloration, separation, and gelation (Rippen 1969). Sensory attributes of UHT and microwave sterilized white milk change throughout storage, as Clare et al. (2005) reported that sweet aromatic flavors and taste decreased as color intensity, astringency, and stale flavor increased. The white milk samples were stored at ambient temperature with testing conducted at 3 month intervals over a 12 month period. Sensory analysis can be correlated to emulsion stability, flocculation, coalescence, creaming, and sedimentation (Goff and Griffiths 2006). Methyl ketones and saturated aldehydes form through lipid oxidation and Maillard reactions, respectively. These compounds form a stale flavor defect within 30 days of storage and this undesired flavor defect then increases in intensity over time. Heat resistant lipases when present liberate free fatty acids resulting in a rancid flavor during storage (Perkins et al. 2005). The shelf life of direct-heated UHT milk is limited by gelation and bitter taste development (Nursten 1997).

Milk deterioration is due to microbial, structural, and chemical degradation (Wilbey 1997). UHT-AP products should be protected from light to prevent vitamin loss in storage, as ascorbic acid and folic acid have the greatest potential for degradation (Burton 1988). Milk that has been UHT-AP processed can spoil. Both intrinsic and extrinsic factors should be considered

if UHT-AP milk spoils before the end of shelf life. Intrinsic factors to be considered include pH, buffering capacity, water activity, redox potential, nutrients, biological structures, and antimicrobials. Extrinsic factors to be considered include storage conditions, process systems, and package materials. Food spoilage is considered a quality issue not a food safety issue (Ravishankar and Maks 2007).

Food Safety and HACCP

Hazard Analysis of Critical Control Points is a systematic food safety program of prevention. The emphasis is placed on monitoring the product while in process to reduce finished product testing. HACCP addresses biological (e.g., pathogens, bacteria,), chemical (e.g., antibiotics, lubricants, detergents, allergens), and physical hazards (e.g., metal, wood, glass). Hazards are controlled through standard operating procedures, prerequisite programs, and processing steps designed to eliminate/reduce an identified hazard to an acceptable level (Smith 1997). The following are examples for controlling the respective hazards:

1. Biological – heat treatment
2. Chemical – antibiotic testing, allergen policy
3. Physical – screens and in-line filters

The twelve HACCP steps are listed below. Steps one through five are preliminary steps in a HACCP plan development. Figure 1 lists several prerequisite programs which must be implemented in a dairy operation and form the building blocks of HACCP. The prerequisite programs consist of GMP's and standard operating procedures (Smith 1997).

Preliminary Steps

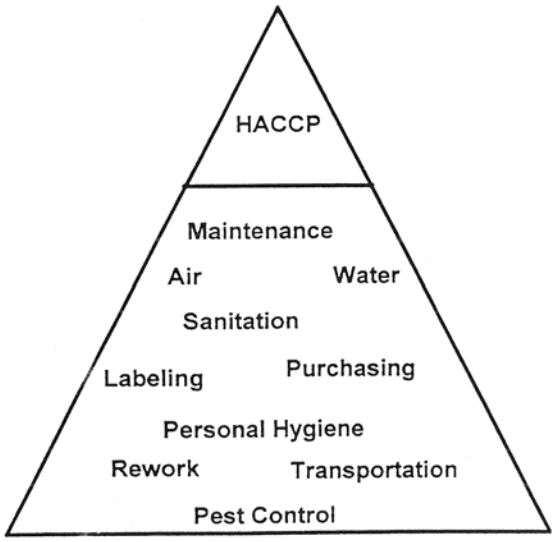
1. Designate HACCP team
2. Describe the food and its distribution
3. Identify intended use and customers
4. Develop flow diagram for the process
5. Verify the flow diagram

HACCP Principles

6. Assess ingredient and processing hazards
7. Identify critical control points and prerequisite programs to control these hazards
8. Determine controls and critical limits for each CCP
9. Establish methods to monitor each CCP
10. Establish methods of corrective action

11. Identify a record keeping system to document the HACCP plan
12. Establish methods to verify and validate the HACCP system

Figure 1 Food safety pyramid for a dairy foods operation



(Smith 1997)

Record Requirements

The success of aseptic operations is dependent on accurate and complete record keeping. Production records include processor logs, processor charts, filler logs, filler charts, and silo charts. Processing records for an aseptic filler contain information such as peroxide concentration, peroxide temperature, sterile air pressure, and sterile air temperature. Processor records include temperatures before and after the hold tube, steam seal inspections, and pressure differentials (Anonymous 1995). Quality control records should include package closure inspections and commercial sterility results (Grow 2000).

CHAPTER 5 - Regulations

Aseptic processing and packaging is subject to three types of regulatory requirements enforced by FDA or USDA.

1. Grade "A" milk and milk products are regulated by the Grade "A" Pasteurized Milk Ordinance and FDA regulations.
2. Aseptic processing and packaging are detailed in FDA regulations under 21 CFR 113.40.
3. In 1986 the USDA Canning Regulations did not specifically reference aseptic processing in parts 318.300-311 or 381.300-311. However, USDA-FSIS requirements are available in "Guidelines for Aseptic Processing and Packaging Systems in Meat and Poultry Plants" (Anonymous 1995). These guidelines are listed below and outline the USDA-FSIS steps for approving aseptic processing and packaging operations (Holdsworth 1992).
    1. Review USDA-FSIS guidelines and requirements
    2. Plant submits proposed process and control to FSIS
    3. FSIS provides initial authorization to proceed with plans
    4. Plant construction and installation of equipment
    5. Details of quality program (container tests, pre-production operations, sterilization of equipment and container) submitted to FSIS
    6. FSIS authorization to produce for 90 day period
    7. FSIS inspection following 90 days
    8. FSIS issues letter of approval for aseptic processing and packaging equipment

Aseptic Processing and Packaging Regulations

According to David et al. (1996), European regulations use spoilage data in evaluating aseptic systems, whereas FDA requires microbiological challenge tests and chemical tests to approve aseptic systems. These differences delayed the approval for aseptic packing systems in the U.S. until the 1981 approval of hydrogen peroxide as an equipment and packaging sterilant.

Ultra high temperature and aseptically packaged products are regulated by the Code of Federal Regulations and industry approved process authorities. Regulations pertaining to milk and milk products are contained in Title 21 CFR Parts 108, 113, and 114. These products are also governed under the PMO (David et al. 1996). The respective Title 21 CFR parts are outlined below.

Part 108 – Emergency Permit Control

Part 110 – Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food

Part 113 – Thermally Processed Low-acid Foods Packaged in Hermetically Sealed Containers

Part 114 – Acidified Foods

Supervisors of low acid food processors must attend FDA approved short courses such as Better Process Control School (Anonymous 1995). Each plant must be FDA registered and file scheduled processes. Scheduled processes are specific to the operation and product. FDA control points include differential pressures in indirect heating systems (pressure of sterilized product at least one pound per square inch greater than pressure of unsterilized product), flow rates (notice from management to prevent unauthorized changes), alarm temperatures, hold tube slope (upward slope of 0.25"/foot), peroxide concentration, peroxide temperature, positive air pressure in the filler, and visual monitoring of steam seals (Anonymous 1995).

The Milk Safety Branch of FDA reviews the sanitary design of equipment for conformance to the PMO. The Milk Safety Branch and the Interstate Milk Shippers Association (IMS) are involved with labeling of milk products. UHT milk must be labeled as UHT with the statement "Refrigerate After Opening". The 3A Sanitary Standards Committee has established sanitation standards for milk and egg processing equipment (David et al. 1996).

Aseptic regulations are dynamic in nature with differences between countries. The European Union in January 2006 revoked Dairy Hygiene Directive 92/46/EEC and replaced it with regulations 852/2004 and 853/2004. The regulations state that processors are responsible for food safety and must apply HACCP principles to dairy operations (Komorowski 2006). The minimum time and temperature for UHT milk products varies between the U.S. (138°C for $\geq$ 2 seconds) and the European Union (135°C for $\geq$ 1 second). The Codex Alimentarius Draft Code of Hygienic Practice for Milk and Milk Products lists a UHT range of 135 to 150°C in

combination with adequate hold times to ensure commercial sterility (Datta and Deeth 2007). United Kingdom regulations for milk and milk products provide specific information regarding time and temperature conditions, thermometers, automatic diversion equipment, and microbiological testing. Germany requires equipment testing at designated locations (Holdsworth 1992). Other countries adhere to a Code of Practice with guidance provided by trade associations, research organizations, and government influence without legislation (Burton 1988).

NCIMS Aseptic Pilot Program

In January 2008, the International Dairy Foods Association (IDFA) notified aseptic dairy industry members regarding the National Conference on Interstate Milk Shipments (NCIMS) Aseptic Pilot Program. The NCIMS is conducting a two-year Aseptic Pilot Program (APP). The Aseptic Pilot Program Implementation Committee (APPIC) began October 1, 2007 and is comprised of representatives from FDA, state dairy agencies, and the dairy foods industry. Twenty-two aseptic dairies were included in the Aseptic Pilot Program. The objective of the program is to monitor operations with future consideration for revising Grade "A" plant regulations. Plant inspection responsibilities are outlined in the CFR and PMO. The NCIMS APPIC will make recommendations for revising the current inspection procedures at the 2009 NCIMS. The key elements of the NCIMS Aseptic Pilot Program under Proposal 303 include the following:

- Traditional Grade "A" labeling required
- Aseptic processing and packaging systems (termed "the bubble") inspected and regulated only under FDA low acid canned food (LACF) program per 21 CFR 108, 21 CFR 110, and 21 CFR 113; the APPS starts/stops with any step considered critical to the filed Scheduled Process
- The APPS evaluated using Aseptic Critical Listing Elements (ACLE)
- Plant areas outside the APPS (milk receiving, milk storage) inspected a minimum of every six months and regulated under the PMO

(Anonymous 2008)

Conclusions

Ultra high temperature and aseptic packaging of dairy foods is a well established technology in many countries and continues to be in demand in the U.S. Direct and indirect heating systems are used for UHT. Preformed sterile packages and form-fill-seal systems are used primarily for AP. Advantages of UHT-AP dairy foods include reduced energy consumption, extended shelf life, and ambient storage and distribution conditions. Challenges of UHT-AP dairy foods include post process contamination, customer acceptance of UHT-AP milk, and chemical/physical changes resulting from heat treatment and extended storage. Regulations pertaining to aseptic dairy foods are contained in the Code of Federal Regulations and Pasteurized Milk Ordinance. The current NCIMS Aseptic Pilot Program could result in future changes regarding the inspection of UHT-AP operations.

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