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**MICROBIOLOGICAL ASSESSMENT OF SOFT SERVE DESSERTS AS A MEANS
OF DETERMINING THE EFFECTIVENESS OF THE CURRENT FROZEN
DESSERT STANDARD**

BY

Ijeoma O.Okpala

A THESIS

**Submitted to
Michigan State University
in partial fulfillment of the requirements
for the degree of**

MASTER OF SCIENCE

Department of Food Science and Human Nutrition

2003

ABSTRACT

MICROBIOLOGICAL ASSESSMENT OF SOFT SERVE DESSERTS AS A MEANS OF DETERMINING THE EFFECTIVENESS OF THE CURRENT FROZEN DESSERT STANDARD.

By

Ijeoma O. Okpala

The Frozen Desserts Act of 1968, P.A. 298, was implemented to protect public health, and to prevent fraud and deception in the manufacture and sale of adulterated or deleterious ice cream and ice cream mix. In cooperation with Michigan State University (MSU) and local health departments, the Michigan Department of Agriculture commissioned a soft serve ice cream sampling project to assess the effectiveness of practices used in the manufacture of soft serve ice cream and to determine the level of compliance with the Act. Over a 7-month period, a total of 227 samples of frozen soft serve desserts (soft serve ice cream) were collected, 133 of those samples being vanilla and 94 being chocolate. The samples were then tested for numbers of coliform and mesophilic aerobic bacteria (SPC), and for the presence of *Listeria* spp.

Overall, 49.8% (113/227) of the samples exceeded the allowable number of aerobic mesophilic bacteria as determined by standard plate count (SPC), with 39.6% (53/134) and 65.6% (61/93) of the vanilla and chocolate samples, respectively, being non-compliant. For coliform counts, 30.6% (41/134) of the vanilla samples and 29% (27/93) of the chocolate samples were non-compliant. *Listeria* spp. were not found in any of the samples.

DEDICATION

To my family
who have supported and encouraged me throughout my study and my life.

ACKNOWLEDGEMENTS

I would like to express my heart-felt gratitude to my advisors, Dr. Thomas Wilson and Mr. Gerald Wojtala (of the Michigan Department of Agriculture) for their guidance, encouragement and enthusiasm throughout the course of my study. I would like to extend my appreciation to my guidance committee, Dr. John Kaneene, Dr. Vincent Hegarty, and Dr. Elliot Ryser for all their efforts and patience.

I would like to thank Dr. John Tilden and J. Douglas Park from the Michigan Department of Agriculture for their mentorship and friendship. I am thankful to Siobhan Kent for her friendship and enthusiasm throughout my study. I am equally thankful to all the lab technicians and inspectors who helped me with specific phases of this project. I am grateful to Roseann Miller at the Population Medicine Center for all her help in the analysis of the data. Furthermore, I would like to thank MaryAnne Verleger at the Institute for Food Laws and Regulations, for all her help, both administratively and personally.

Finally, I would like to thank my parents, Dr. Donatus Okpala and Mrs. Cecilia Okpala for all their support and for always encouraging me and making me believe that I can achieve whatever I set out to do. Last, but certainly not least, I would like to thank my brothers, Dozie and Emenem and my sisters, Ogo, Ify and Aku for all their love and support.

TABLE OF CONTENTS

List of Figures	vi
List of Tables	vii
INTRODUCTION	1
Objectives	4
1. LITERATURE REVIEW	5
1.1. Food and Dairy Division	5
1.2. Standards	6
1.3. Soft Serve Ice Cream	7
1.3.1. Cleaning and Sanitizing	11
1.3.2. Storage of Mix	13
1.3.3. Sanitizers and Cleaners	15
1.4. Soft Serve Freezers	15
1.5. Microbiological Problems	20
1.5.1. Coliform Bacteria	23
1.5.2. <i>Listeria monocytogenes</i>	25
1.6. Ice Cream Surveys	28
1.7. Ice Cream Recalls	31
1.7.1. Complaints in Michigan	32
2. Microbiological Assessment of Soft Serve Desserts	35
2.1. Introduction	35
2.2. Materials and Methods	36
2.3. Results and Discussion	40
2.4. Conclusions and Recommendations	60
2.4.1. Summary and Conclusions	60
2.4.2. Recommendations for Future Research	62
3. APPENDIX	64
3.1. Data Tables	65
3.2. Definitions	77
3.3. Regulations	81
3.4. Map of Regional Offices	86
3.5. Survey of Sanitary Practices	87
BIBLIOGRAPHY	91

Figure	List of Figures	Page
1.1. Typical composition of soft serve ice cream mix		9
1.2. Process of ice - cream production		12
1.3. Model PH71		17
1.4. Model PH84		17
1.5. Model PH85		18
2.1. Summary of Standard Plate Counts		41
2.2. Summary of Total Coliform Counts		42

List of Tables

Table	Page
1.1 Hazards and typical control in the production of ice cream	24
1.2 Coliform counts obtained from 93 milkshake samples	28
1.3 Standard plate counts obtained from 93 milkshake samples	29
2.1 Acceptable bacterial levels in vanilla soft serve ice cream	43
2.2 Analysis of "Plant A" soft serve mix	44
2.3 Analysis of "Plant B" soft serve mix	44
2.4 Bacterial levels in soft serve ice cream, by establishment	45
2.5 Bacterial levels in soft serve ice cream, by volume processed/wk	46
2.6 Acceptable bacterial levels in soft serve ice cream, by number of times the machine is completely broken down and cleaned	47
2.7 Acceptable bacterial levels in soft serve ice cream, by type of establishment	48
2.8 Acceptable bacterial levels in soft serve ice cream, by <i>observed</i> employee practices	50
2.9 Acceptable bacterial levels from "Establishment S"	51
2.10 Final multivariable logistic regression model for acceptable standard plate counts, adjusting for enterprises using "Mix S"	52
2.11 Final multivariable logistic regression model for acceptable coliform counts, adjusting for enterprises using "Mix S"	53
2.12 Summary of standard plate count test results on routine frozen dessert samples submitted to the Michigan Department of Agriculture Laboratory Division, 1998 through June 2000.	54

Table	Page
2.13 Summary of total coliform count test results on routine frozen dessert samples submitted to the Michigan Department of Agriculture Laboratory Division, 1998 through June 2000	55
2.14 Acceptable bacterial levels in soft serve ice cream by County	56
2.15 Acceptable bacterial levels in soft serve ice cream by MDA region	57
2.16 Acceptable bacterial levels in soft serve ice cream by Jurisdiction	57
2.17 Acceptable bacterial levels in soft serve ice cream, by product temperature	57
2.18 Acceptable bacterial levels in soft serve ice cream, by whether unused mix is rerun.	58
2.19 Acceptable bacterial levels in soft serve ice cream, by time mix spends in machine	58
2.20 Acceptable bacterial levels in soft serve ice cream, by number of days between last cleaning and sample collection	59

INTRODUCTION

Ice cream is a milk product which contains a variety of ingredients in addition to milk, cream and sugar. It is legally defined as “any frozen, sweetened milk product containing no less than 10% milk fat, which is stirred during the process of freezing and includes every such frozen milk product which contains milk fat or milk solids not fat and which in any manner simulates the texture or characteristics of ice cream no matter what coined or trade name it may be sold “ (21 CFR 135.110). It is a very popular product and as a result of this, its production and consumption is increasing rapidly. The International Ice Cream Association reported that in 1859, the production of ice cream was 400 gallons (Andreasen et al. 1998). In 1955, production increased to 59 million gallons with 240 million gallons produced in 1981 (Tobias et al., 1981). Today, annual production in the United States has reached more than 2 billion gallons for ice cream and related products and 34 million gallons for soft serve ice cream (USDA, 2002). Soft serve ice cream has been and continues to be a great addition to any food service operation and is also profitable as an individual operation. The soft serve freezer has allowed ice cream to be available in a wide variety of operations such as fast food restaurants and retail outlets.

In the mid 1980's, several ice cream products and other frozen dairy desserts were recalled in the United States because of contamination with *Listeria monocytogenes* and the recalls incurred expenses that exceeded several million dollars (Anon, 1986). Increased awareness and improvements in cleaning and sanitation practices have helped to minimize the presence of *L. monocytogenes*, as well as other bacteria in dairy plant environments. However, continuous recalls of ice cream products indicate that problems

still exist in current retail ice cream manufacturing practices.

Typically, soft serve frozen dessert mixes are manufactured (and pasteurized) at a processing plant and then delivered to the retail establishment in the form of a mix. The mix is then held at refrigeration temperature in the retail store until it is placed in the soft-serve freezer where it is made ready for consumption. This type of setting provides opportunities for growth of contaminating organisms. Storage space for the mixes is used for other food products as well. This means that the doors to the refrigerated storage area are opened and closed frequently, which leads to temperature abuse of the mix.

The U.S Centers for Disease Control and Prevention (CDC) estimates that there are approximately 76 million cases of food-related illnesses per year, 325,000 of which result in hospitalizations and 5,000 deaths (Mead et al. 1999). Infectious diseases are the third leading cause of death in the United States. According to the CDC, the five leading causes of foodborne illness outbreaks are inadequate cooling of foods, improper holding temperatures, poor personal hygienic practices, contaminated equipment, and obtaining food from unsafe sources.

According to the Michigan Department of Agriculture, basic food safety practices that will help reduce the risk of foodborne illness include preventing sick employees from working with foods, demonstrating food facility manager knowledge, ensuring proper time and temperature controls for food, preventing contamination of foods by employee hands, and advising consumers of the risks of eating raw or undercooked foods of animal origin.

The public's awareness of the safety of frozen desserts is heightened during the summer months with the news media often running stories on bacteria levels in ice cream

as was the case in both New York and Michigan. On August 2nd, 1998, WDIV TV-4 in Detroit aired a segment on their 11pm news entitled “Dirty Desserts II” (Dietz, K, 1998). Kevin Dietz, a correspondent for the news station collected about 48 samples of soft serve ice cream (three samples collected from each local establishment every two weeks and tested by AB labs (Detroit, MI) a state certified lab) over a period of two months. They referred to their findings as “shocking”. The results indicated that 19 of 48 (40%) samples exceeded the standard for vanilla and flavored soft serve ice cream. The counts ranged from 690 – 81,000 coliforms/g (69- 8100 times the state limit). At some establishments, all three samples exceeded the limit. They concluded that if these soft serve machines are not kept clean, bacteria could build up and cause illnesses.

The Michigan Department of Agriculture, which regulates retail soft serve ice cream facilities, has encouraged establishments that serve frozen desserts to focus on important issues such as equipment maintenance, cleaning and sanitizing, product storage, and employee practices and hygiene, in order to reduce the risk of illnesses associated with soft serve ice cream. The department also recommends that owners establish a routine sampling and inspection schedule. This will help to ensure that the cleaning and sanitizing methods are adequate to maintain a safe product. Emphasis should also be paid to routine maintenance of machines and employee knowledge of hygiene and cleaning practices. The department also recommends that establishments maintain and keep records of sampling results and cleaning schedules that can help document due diligence in managing their operations. In an effort to assess the practices used in soft serve operations, the objectives of this project were to:

- **determine the baseline levels of mesophilic aerobic bacteria, coliform bacteria and *Listeria* spp. found in soft serve desserts**
- **assess the effectiveness of handling practices currently used in soft serve production and to determine if practices have an impact on the bacterial levels, and**
- **assess the effectiveness of the current frozen dessert standard.**

CHAPTER 1

LITERATURE REVIEW

1.1. Food and Dairy Division

The mission of the Food and Dairy Division (FDD) of the Michigan Department of Agriculture (MDA) is to “protect public health by ensuring a safe and wholesome food supply, while working to maintain a viable food and dairy industry”. The FDD protects the public well - being through regulatory enforcement, problem - solving, leadership and expertise in food safety issues. It inspects more than 20,000 licensed food establishments annually. The primary goal of a food establishment inspection is to prevent foodborne disease. Inspections are the primary tool used by a regulatory agency for identifying procedures and practices that may be hazardous and taking actions to correct deficiencies. These inspections address sanitary conditions, cleanliness and safety of infrastructure, freshness and wholesomeness of foods, and truth in labeling. The department has close working relationships with local health departments, the Michigan Department of Community Health and the U.S. Food and Drug Administration. These agencies work together to identify and respond to outbreaks of foodborne illness. MDA is responsible for inspecting facilities such as grocery stores, convenience stores, warehouses and food processors, while local health departments are responsible for inspecting restaurants (including carryout food), catering trucks and commissaries, food carts and coffee houses.

In May 2000, Governor John Engler signed Michigan Food Law 2000, effectively rewriting Michigan Food regulations for the first time in nearly three decades (Michigan Food Law, 2000). The new law helped food industry managers and regulators

focus on food safety issues and prevent foodborne illnesses. Michigan Food Law 2000 or Public Act 92, establishes regulatory standards for all licensed food establishments in Michigan.

1.2. Standards

The Frozen Desserts Act of 1968, P.A. 298. (herein after referred to as the Act) was designed to protect public health, prevent fraud and deception in the manufacture and sale of adulterated, or deleterious ice cream and ice cream mix and also apply standards for ice cream.

The Act, however, does not apply to establishments that are under jurisdiction of the local health department. The Michigan Milk Manufacturing Law of 2000, Sec 2, part 1 states that “ Frozen desserts manufactured from pasteurized mix in the soft form at food service or retail food establishments licensed pursuant to the Food Law of 2000, PA 92 of 2000, MCL 289.1101 to MCL 289.1111 are exempt from the licensing requirements of this law and rules promulgated pursuant to this law (Act No. 298)”. This means that restaurants or other such establishments that offer soft serve ice cream for sale are exempt from the rules stated in the Act. The Michigan Food Law regulates retailers and the practices in retail establishments, whereas the Milk Manufacturing Law, which covers the frozen desserts standard, sets standard for manufacturing.

Under the original law, frozen desserts should not have a standard plate count (SPC) of more than 50,000 cfu/ml and should not have a coliform count of more than 10 cfu/ml for vanilla products and 20 cfu/ml for chocolate and other products. Under the newly amended law, the SPC standard was reduced to 30,000 cfu/ml. This is because

under the new law, the standard for condensed milk was 30,000 cfu/ml and hence the standard for soft serve was reduced to achieve consistency in the law. This was done, as it would not have been acceptable to increase the standard for condensed milk to match soft serve mix.

Initially, if a retail establishment wanted a soft serve freezer, they would have needed a separate “soft serve license” in order to sell the product from their store. Under the new law, establishments licensed under MDA do not need a separate license to sell soft serve ice cream in their establishment. However, the manufacturer of the mix, is required to have a license to produce, distribute and sell the mix. The department expects that all soft serve samples comply with the given standard, but will not take any action, if a single sample from an establishment violates the standard. However, if 2 of 4 and 3 of 5 consecutive samples violate the standard, then action will be taken against the establishment.

1.3. Soft Serve Ice Cream

There are two main categories of ice cream, according to the methods by which it is made and stored (Hyde, 1973). Ice cream is a frozen dairy dessert which can be manufactured in the soft or hard form. The term soft serve is used when the product is sold in a soft form and usually sold on the same day that it is made or as soon after as possible. Soft serve is distinctly different from hard ice cream for many reasons. Different procedures and equipment are used in their preparation, they are served at a different temperatures (18-20°F for soft serve) and they are usually frozen on the premises of the retailer (Arbuckle, 1986). With soft serve freezers, the freezer maintains

the ice cream within the freezer barrel at the correct serving temperature, and therefore with intermittent re-freezing and whipping, there is little problem of lactose crystallizing out and giving a “rough” texture (Crowhurst, 1974). There are three main benefits of soft serve. Firstly, it is a nutritious product, as it is low in butterfat and contains an average of 135 calories/4oz. serving (Cummings, 1985). Secondly, it is manufactured and dispensed directly to the patron with no need for further handling or preparation. Lastly, it is highly profitable, with a 400-500% mark-up (Casper, 1987).

Soft serve mix is commercially produced at a plant. The mix is then sold to a retailer who then places it in a special freezer and also serves it at that location. Soft serve mix goes through the steps of homogenization, pasteurization, and aging. After freezing, the semisolid ice cream can be sold at retail as “soft serve” ice cream. Soft serve ice cream mix can be processed with an ultra high temperature (UHT) processing system, which aseptically processes the mix to avoid the cooked taste and gold color sometimes associated with UHT milk and its products (Catalana et al. 1986).

Ice cream, whether it be in the soft or hard form, is a dairy product produced by freezing a pasteurized mix of milk, cream, nonfat milk solids, sugars, emulsifiers and stabilizers. The main ingredients of ice cream include whole milk, skimmed milk, cream, condensed milk products and/or milk solid. Other ingredients such as fruits, nuts, candies and syrups are added for flavor enrichment and for variation. Figure 1.1 illustrates the composition of ice cream mix. Water is the major component with milk and cream being the source of the water. The composition of soft serve ice cream mix varies between manufacturers. A consumer panel composed of 259 males and 250 females found that soft serve ice cream products were widely accepted by consumers even when drastic

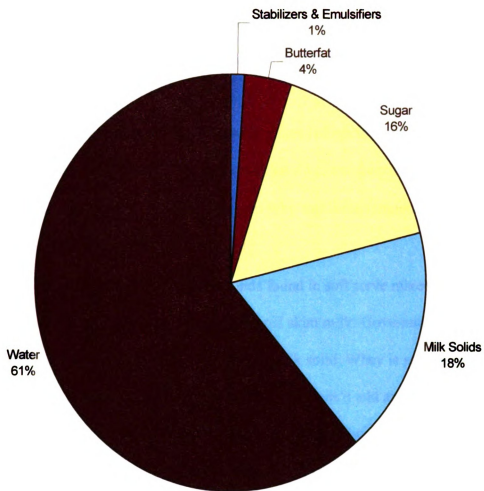


Fig 1.1. Typical composition of soft serve ice cream mix (MDA, soft serve facts, 2001).

variations (substituting vegetable fat for milk fat) were made (Lowenstein et al, 1972).

A disadvantage of soft serve is that one cannot blend in any extra ingredients during manufacture and therefore toppings must be added later to provide variety (Cummings, 1984).

One of the sugars most widely used in mixes is high fructose corn syrup. Mixes that utilize a high percentage of this sugar will have a lower freezing point than mixes prepared with cane sugar. This partly explains why soft serve temperatures of 14°F and 16°F are more common now than previously.

Milk solids form the bulk of the solids found in soft serve mixes. These are obtained from condensed skim milk or powdered skim milk. Government ruling has allowed the use of some whey in place of skim milk solid. Whey is primarily lactose sugar and does not add any sweetness to the mix nor does it add any body to the soft serve product. Milk solids are primarily proteins that contribute greatly to the body and smoothness of the soft serve product. Some lowering of the freezing point is noticeable with high percentages of whey usage. Stabilizers are added to increase the firmness of the frozen product. The ability of the mix to hold air is also increased by the addition of stabilizers. Stabilizers are primarily carbohydrates derived from plants and include carrageenan (Irish moss), sodium carboxymethylcellulose, locust bean gum, guar gum and pectin. Each has different advantages and most often combinations of the above are used. Excessive use of stabilizers will mask off-taste of the product.

By definition, soft serve has a butterfat content of less than 10 percent (Cummings, 1982). Anything more than that is classified as “ice cream”.

Emulsifiers are added to increase the dryness and firmness of the soft serve

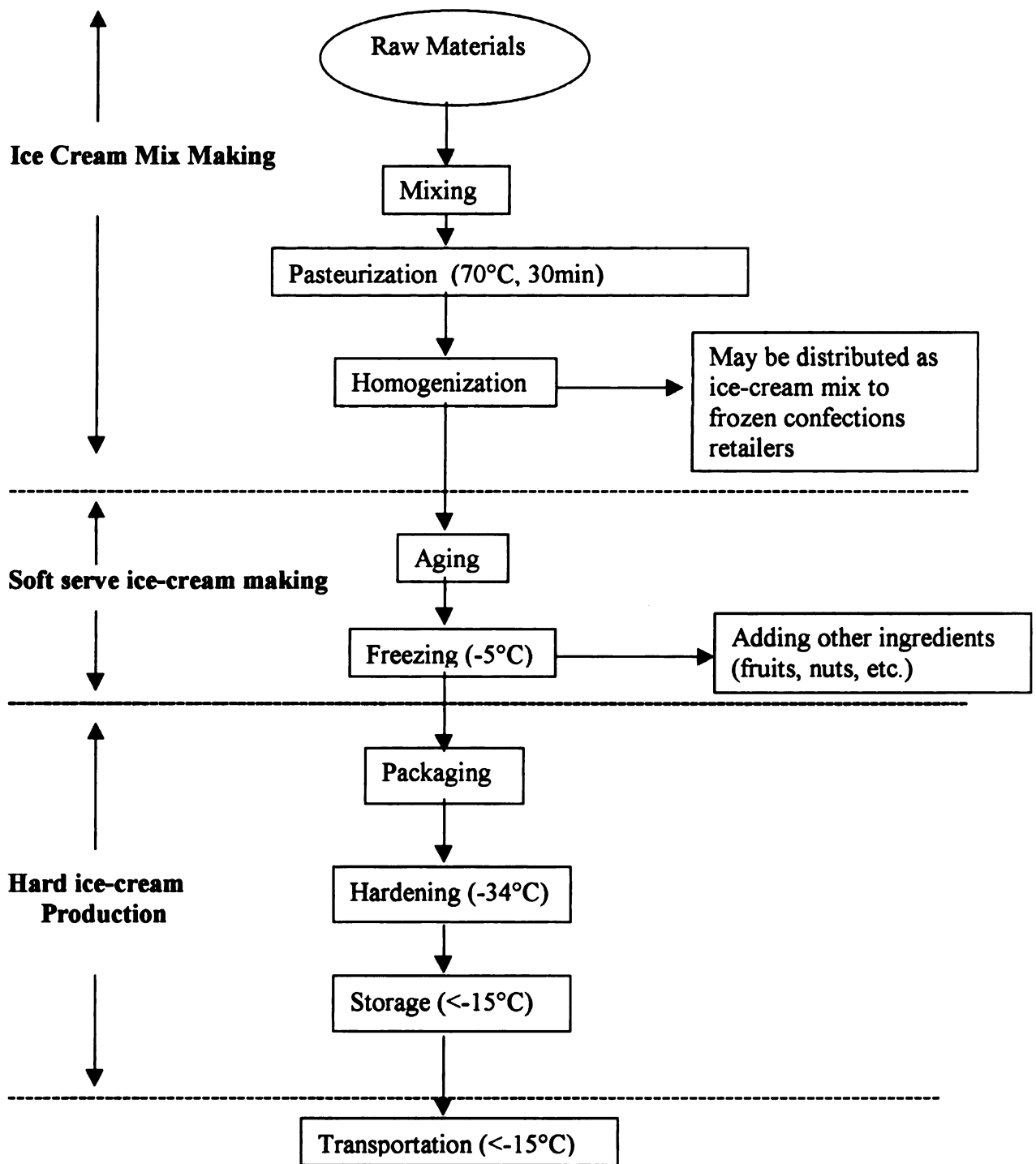
product. Emulsifiers act to combine fats with water. Commonly used emulsifiers include mono-and diglycerides and polysorbates with polysorbate 80 being the most popular. However recent shortages have almost eliminated its use. Polysorbate 80 was extremely effective and replacement with other emulsifiers does not give the product equivalent qualities. Formulations are constantly changing and freezers must be adapted for the mix available. Temperatures of 20°F with some mixes will give the same consistency as 14°F with other mixes. Overrun (% of volume increase to a product by the addition of air) may also vary as well as the rapidity of product breakdown.

Ice cream production is an 8-step process which consists of pasteurization, homogenization, aging, freezing, packaging, hardening, storage and transportation (Fig 1.2).

1.3.1. Cleaning and Sanitizing

Sanitation is the most significant concern for any operation involving frozen desserts, especially those with dairy ingredients. Most health departments require systems to be cleaned and sanitized daily (except for heat treatment freezers). This is necessary for the health and safety of consumers since dairy products are susceptible to bacterial contaminations (Bendall, 1997). Cleaning and sanitizing a machine is very time consuming and sometimes tends to be overlooked by employees. Equipment cleaning and set up takes an hour or more of an employee's time each day. Consequently, automated heat treatment systems were introduced into soft serve operations. The machine still requires daily cleaning and sanitizing, but rather than manually disassembling the equipment and discarding leftover mix, the heat treatment systems automatically heats

Fig 1.2. Process of ice cream Production (Andreasen et al., 1998)



the mix to kill the bacteria and then re-chills it (Bendall, 1997). All soft serve freezers should be disassembled, cleaned, and sanitized periodically. Ice cream freezer manufacturers like Taylor™ (Rockton, IL) have manuals that outline procedures that should satisfy local laws. Deviations from the manuals should occur only when manual procedures contradict local laws or when an insert accompanies the manual. To keep bacterial growth to a minimum, levels of coliforms and other bacteria must be below legal limits and sanitary conditions must be used when handling mix. Also, all components of the freezer must be lubricated with acceptable food grade lubricants and the parts must be sanitized with an approved sanitizing solution. Sanitary conditions must be used when removing product from the freezer to be used as rerun.

Lapses in good practices when handling the mix could lead to problems. For example, inadequate brush scrubbing will allow the build up of milkstone. Milkstone harbors bacteria and contributes to counts above 50,000 cfu/ml. Improper mix handling greatly accelerates bacterial growth.

1.3.2. Storage of Mix

The mix is received in a refrigerated truck about twice a week (varies by establishment). The temperature at which the mix is received may or may not be checked. The mix is then placed in a holding refrigerator or a walk-in cooler for 1-5 days at 32-42°F. The mixes are rotated based on dates of delivery (which is also based on dates of production). The mix is then moved to a second holding refrigerator (34°F). Mix is poured into a hopper in the lower refrigerated unit of the machine with the hopper refilled as needed. During summer, the hopper is filled more frequently than in spring and the

fall. The hopper is at about 36°F. At some locations, mix is poured into metal or plastic storage buckets (usually covered) and conveyed through tubing, to the soft serve machine. The buckets are emptied and sanitized about twice a week, while the tubing is cleaned and sanitized daily.

At some locations, the product is drained nightly from the machine and the machine is washed, rinsed and sanitized each morning before use. For others with heat treatment freezers, the external and removable parts are cleaned and sanitized each night, while the mix remains in the hopper. Mix is kept and used as re-run at every other complete breakdown. Complete breakdown varies depending on what type of machine the establishment is using.

Most frozen dessert mixes are not sterile, but generally have a low bacteria count when fresh (Cornell University, Dairy Science Facts). Storing soft serve mixes under proper refrigeration until used is very important in maintaining quality. Body and texture are particularly important attributes to control in frozen dairy desserts (Chandan, 1977) and proper temperature maintenance will do so. Soft serve freezer operators can avoid problems with high bacteria counts and flavor defects developing in their mix from these high counts if the mix is handled properly.

Other types of bacteria also may be present in the mix if the mix bags and other processing equipment in the dairy plant that the mix contacts are not properly cleaned and sanitized. Milk cans are hard to clean properly and as a result many mix manufacturers are marketing mix in single service plastic lined corrugated boxes. Use of these boxes greatly reduces the chance of contaminating the pasteurized mix with spoilage bacteria.

Storage of the mix at a low temperature (below 40°F) is the only practical way of

controlling the multiplication of spoilage bacteria. Many of these bacteria can grow in cold mix but they grow much slower than at their usual 70° - 80°F optimum temperature.

1.3.3. Sanitizers and Cleaners

Commercial sanitizers and cleaners are used to clean and sanitize the internal and external surfaces of various food preparation utensils and equipment. Heat is a reliable sanitizing agent, but chemical sanitizing agents such as hypochlorites, chloramines, iodophors, and quaternary ammonium compounds (QUATS) can be used and are very effective under the right set of conditions (Arbuckle, 1986). Cleaners and detergents are chemicals that are used to remove debris from food surfaces, while sanitizers are intended to sanitize surfaces by deposition of chemical onto surfaces. A detergent is typically combined with a chlorine compound, to produce a dual-purpose, dry chemical. When mixed with water, in the proper ratio, a suitable 100 ppm (free chlorine) solution can be produced. This will eliminate the need for separate cleaning and sanitizing. A proper balance of all ingredients must be maintained to ensure easy removal of butterfat and other fats deposited on surfaces. A good sanitizer will also prevent damage to materials in contact, injury to the user, and dissolve easily and completely in water.

1.4. Soft Serve Freezers

A soft serve machine is a horizontal cylinder into which ice cream mix is poured or pumped (Cummings, 1982). The first soft-serve freezers were in operation in the U.S in 1930 (Hyde, 1973). Many individual brands of these freezers exist, all of which vary by design. However, they all contain a small mix reservoir, a freezing cylinder and a

refrigeration unit. The detailed designs differ, but generally soft serve freezers are small-scale horizontal continuous freezers (Rothwell, 1982). These machines are relatively simple to operate with temperature control being an integral part of maintenance. The product must be dispensed at 18 - 20°F (Cummings, 1984). If the temperature is too high, the product will appear soft and wet. If it is too low, the product will add pressure to the moving parts which could result in equipment failure.

Although these freezers are very convenient and serve as the point of sale for the soft serve product, this machine can serve as a significant source of contamination if the machine is not adequately cleaned and maintained. As with the State of Michigan, the Pennsylvania Department of Agriculture (PDA), and other regulatory agencies also have been concerned about the number of licensed food service operations that make soft serve products that do not meet quality standards.

Taylor™ Company (Rockton, IL) manufactures and distributes an extensive line of soft serve and yogurt dispensing freezers to meet the space and volume needs of food service operations. These freezer units come in a variety of models. They range from Single Flavor Units to Twin Twist Units and Heat Treatment Units (Fig 1.3-1.5).

The single flavor units yield single cones, while the twin twist units allow consumers a choice of two individual flavors or an equal combination of both with a twist effect. The heat treatment process reduces labor and daily maintenance costs because the freezer is able to run for two weeks without dismantling and cleaning. The machine re-pasteurizes the mix on a daily basis. The contents of the mix hopper and the freezing cylinder are raised to 150°F within 90 minutes during heating (Durocher, 1992).

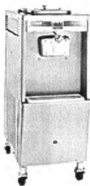


Fig 1.3. Model PH71. Single flavor freezer. Used for low or non-fat soft serve ice cream, yogurt, and sorbet. Has one 3.4quart freezing cylinder and one 20-quart hopper. Features an Air/Mix Pump. Heat Treatment System. Similar to Model 8751. (Courtesy of Taylor™ Freezer, Rockton, IL)

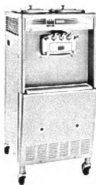


Fig 1.4. Model PH84. Twin Twist Freezer. Used for two flavors and twist: low or non-fat soft serve ice cream, yogurt, sorbet, and sundaes. Has two 3.4 quart freezing cylinders, two 20-quart mix hoppers and features an Air/Mix Pump. Heat Treatment System. Similar to Model 8754 (Courtesy of Taylor™ Freezer, Rockton, IL).



Fig 1.5. Model PH85. Twin Twist Freezer. Used for two flavors and twist, low or non-fat soft serve ice cream, yogurt, sorbet, and sundaes. Has two 3.4-quart freezing cylinders, two 20-quart mix hoppers and features an Air/Mix Pump with a syrup rail. Heat Treatment System (Courtesy of Taylor™ Freezer, Rockton, IL).

The survival of naturally occurring microorganisms in soft-serve ice cream mix stored in a dispensing freezer equipped with a heat treatment system was examined by Ayoung and Doores, 1995. *L. monocytogenes* was inoculated into the mix at 10^5 - 10^6 cfu/ml and samples were collected from the hopper and the spigot before and after the daily heat treatment. The heat treatment system effectively inactivated up to 10^6 cfu/ml of *L. monocytogenes* because the organism was not recovered in any of the hopper or spigot samples. Results also showed that there were no apparent changes in the microbial quality of the un-inoculated commercial mix and hence there was no increased hazard associated with keeping the mix for two weeks in the freezer unit equipped with a heat treatment cycle. Although ice crystal diameter was affected after 9 days due to continuous heating and agitation, texture, firmness and meltdown were not affected.

A “Heat treatment cycle” is a cycle in which the heat treatment dispensing freezer elevates the product temperature during the heating phase to at least 150°F (65.5°C) within no more than 90 minutes, maintains the product at that temperature during the holding phase for at least 30 minutes, then cools it to of 41°F (5°C) or below within no more than 2 h. The heat treatment freezer completes a heat treatment cycle at least once every 24 h. The heat treatment dispensing freezer is equipped with a monitoring device which indicates the length of time since the last heat treatment cycle, the length of time that the most recent heat treatment cycle was at 150°F (65.5°C) or above, and the length of the heating, holding and cooling phases. The freezers have a temperature probe, accurate to plus or minus 2°F (-1°C), showing the product temperature in the hopper. The freezer is equipped with an internal lockout device that cannot be reset without complete disassembly of the machine. The internal lockout device mechanically shuts down the

heat treatment dispensing freezer so that the unit is unable to dispense frozen product if the heat treatment cycle is not properly completed, the cycle has not been completed at least once in the preceding 24 h, or the freezer has not been disassembled for cleaning and sanitizing within the preceding 14 days.

The freezer needs to be disassembled, cleaned and sanitized at least every 14 days, except for those parts specified by the manufacturer such as hopper covers, design caps, door spouts, and bottoms of draw valves that need to be cleaned and sanitized daily. The product in the hopper must be maintained at 41°F (5°C) or below during a heat treatment cycle. A daily log should be maintained to record the cycles. All remaining products in the freezer should be discarded whenever the heat treatment dispensing freezer is disassembled for cleaning.

The effect of the sanitation schedule on microbiological quality of soft-serve ice cream was studied at the Louisiana Agricultural Experiment Station (White et al., 1985). The study compared bacterial quality of soft serve mixes taken from two different types of dispensers that recommended either daily or weekly cleaning and sanitizing. Bacterial counts (coliform and standard plate count) from the machine that required bi-weekly cleaning and sanitation were equal to or below those of the machine that required daily cleaning and sanitizing.

1.5. Microbiological Problems

Soft serve mix must arrive at a temperature of 40°F (4.4°C) or below. The product should also have an SPC count of less than 250 CFU per ml and less than 10 coliforms/ml. An increase in the standard plate count and coliforms can be due to a

number of factors, including time (shelf life), temperature, mix handling and the condition of the storage containers.

Local codes require that machines be cleaned and sanitized at the end of each day (except for heat treatment machines) and that the parts that come in contact with the mix be washed, left out overnight and then rinsed with a sanitizing solution before being reassembled (Cummings, 1984). Soft serve ice cream is rich in nutrients making it a good medium for microbial growth. It has a pH value of approximately 6.6. Pasteurization will eliminate these microbiological hazards. Pasteurization, which is the most commonly applied heat treatment in the dairy industry, can destroy all pathogenic bacteria in milk. Freezing can also inhibit the growth of any flora that was not killed during pasteurization.

There have been recent attempts to implicate frozen dairy products as vehicles of infection in listeriosis cases. In 1986, a 21-year old mother gave birth to a premature infant who died 5 days later. The mother had consumed ice cream sandwiches a few days before her delivery, and although it was determined that ice cream was not the source of infection (*L. monocytogenes* was isolated from amniotic fluid following the premature birth of the baby), all suspect product was withdrawn from store shelves (Ryser et al., 1999). Although well over 4 million gallons of frozen dairy products thought to be contaminated with *Listeria* have thus far been recalled from the market at a cost in excess of \$88 million, not one case of listeriosis has been directly linked to the consumption of frozen dairy products in the United States. The only proven case comes from Belgium involving a 62-year old immune-compromised man (Ryser et al. 1999).

Studies have shown that the components of ice cream (fat, casein and lactose) are protective against freeze damage to *L. monocytogenes*. (El-kest and Marth, 1991).

Palumbo and Williams (1991) also noted that the presence of food components might partially explain increased resistance to freezing. Peptides, carbohydrates, milk and viscous products have been reported to protect bacterial cells against freezing damage (Speck et al., 1977).

Typically, soft serve mixes are stored in refrigeration units until they are placed in the freezer for consumption. In the meantime, the refrigerator door is constantly opened to obtain other stored products. Martin et al. (1971) studied the effect of pasteurization conditions, type of bacteria and storage temperature on the keeping quality of UHT-processed soft –serve-frozen dessert mixes. Some processing plants have changed to UHT pasteurization in an attempt to improve the shelf - life of these products (Martin et al., 1971). Reports from industry reveal that UHT - treated products may actually have a shorter shelf - life because it was not established that the spoilage organisms did not survive UHT treatment (Martin et al., 1971). The results of the study showed that when approximately one million spores/ml were present, only 12.4% were destroyed by heating for 3 sec at 104.5°C, and 99.5% at 137.7°C. During storage at 4.4°C, even with more than 1 million spores/ml surviving 104.5°C, the products had a shelf life of more than 8 weeks and the number of viable *B. cereus* organisms actually decreased by more than one-third during this time. At a storage temp of 10°C, the product pasteurized at 104.5°C was spoiled after 4 weeks, and that pasteurized at 137.7°C was spoiled after 5 weeks with *B. cereus* numbering in the millions. When stored at 15°C, the numbers of *B. cereus* were in the millions and the product was spoiled after 2 weeks regardless of the UHT treatment.

There are some steps in the production of ice cream that can promote microbial contamination of the product. However, the potential microbiological hazards found in

the final product can still be introduced by adding contaminated ingredients to the product and improper handling procedures (Bell et al., 1998). This is especially important in the preparation of soft-serve ice cream as its final stage of production is carried out at the point of sale, i.e. freezing. Flavorings are not added into the pasteurized mix, but rather after freezing. Addition of these ingredients has the potential to contaminate the product if they are themselves contaminated. Some pathogens that can survive in food even at low temperature include *Salmonella* spp., *Listeria monocytogenes*, and *Yersinia* spp. (Marshall, 1998). Table 1.1 summarizes the possible hazards associated with different stages of ice-cream production (ICMSF, 1998).

1.5.1 Coliform Bacteria

Coliform and fecal coliform are commonly used as a measure of sanitation. These microorganisms thrive in the human intestinal tract and include some strains that are pathogenic for infants and adults. They are facultatively anaerobic, gram-negative, non-spore forming, rod - shaped bacteria that produce acid and gas from lactose within 48 hours at 35°C. Coliform bacteria include *E.coli*, *Citrobacter* spp., *Enterobacter aerogenes*, and *Klebsiella pneumoniae*. Not all of these organisms are of intestinal origin, with some species living free in the environment. They have "sanitary significance," in that their presence at detectable levels in finished products or at higher than minimal levels in pasteurized milk indicates unsanitary manufacturing practices. Most are not capable of causing disease in humans.

Table 1.1. Hazards and typical control in the production of ice cream

Process	Potential Hazard	✓ Control Measure
Raw Materials	Presence of pathogens	✓ Test materials before intake
Pasteurization	Survival of pathogens	✓ Ensure correct time/temp control ✓ Equipment maintenance
Aging	Recontamination Growth of microorganisms	✓ Hygienic design, cleaning and disinfection of equipment and utensils ✓ The temp should be <5°C
Freezing	Survival of microorganisms	✓ The product should be at correct temp
Addition of ready-to-eat ingredients	Recontamination	✓ Purchase materials from a reputable source ✓ Environmental hygiene of storage area, equipment and utensils ✓ Hygiene during addition step
Filling in packing step	Recontamination	✓ Hygienic design and environmental hygiene of equipment and utensils
Storage & Transportation	Survival of microorganisms	✓ Keep temp at <-18°C ✓ Discard the defrosted products.

Source: ICMSF. Microorganisms in Foods 6-Microbial Ecology of Food Commodities. p 563

Fecal coliform bacteria are a group of bacteria that are passed through the fecal excrement of humans, livestock and wildlife. Fecal coliforms ferment lactose to acid and gas within 48 h at 44.5 to 45.5°C. *E. coli* is one specie of fecal coliform bacteria. The presence of fecal coliform bacteria in food indicates that it has been contaminated with the fecal material from man or other animals. They will grow at 44.5°C (above body temperature). *E. coli* and *K. pneumoniae* belong to this group, although the latter is not necessarily of fecal origin.

The presence of *E. coli* in soft serve ice cream or any food product is an indication that the food has been contaminated due to manufacturing practices conducted under unsanitary conditions. Fecal coliforms are destroyed by pasteurization and the presence of these microorganisms in a pasteurized product indicates that there has been post-process contamination. Contamination with coliforms is a reliable indicator of post-process contamination of the product, even if the source of contamination is not fecal.

1.5.2. *Listeria monocytogenes*

Listeria monocytogenes is a ubiquitous bacterium commonly found in the environment and is a foodborne pathogen for humans. This pathogen is able to survive and even grow in the food-processing environment (Eklund et al., 1995). In one study in which 2545 samples were collected over a 7-year period from various locations (environment, equipment, raw materials, unfinished product, and ice cream), 71 of 2545 (2.8%) samples contained *L. monocytogenes* (Miettinen et al., 1999). In 1994, when most of the samples were taken, and when sampling focused on previously known *L.*

monocytogenes positive sites, the prevalence of *L. monocytogenes* was 3.2%. In the equipment and environmental samples, the prevalence of *L. monocytogenes* was 5.1%, and was 0.6% in raw material and ice cream samples. The 71 *L. monocytogenes* positive samples obtained during 1990-1996 yielded 41 isolates for serotyping and strain-specific typing by pulse-field gel electrophoresis (PFGE) (Miettinen et al., 1999). The isolates characterized were obtained from the ice cream processing environment and equipment with six strains isolated from the finished product. The findings indicated that isolates of *L. monocytogenes* PFGE type II had survived in an ice cream plant for at least 7 years.

Most strains of *L. monocytogenes* are pathogenic and have the ability to grow at temperatures as low as -2°C, permitting multiplication in refrigerated foods. This organism is also very resistant to freezing, drying and heat. Although, *L. monocytogenes* is killed by pasteurization, post-process contamination can occur within the plant. Foodstuffs associated with listeriosis epidemics have included among other foods, both milk and dairy products with soft cheese most commonly associated with listeriosis outbreaks.

L. monocytogenes is widespread in the environment and has been isolated from water, soil, dust, vegetation, animal feed, feces and sewage and has been associated with mammals and birds. Many animals, including dairy cows, can carry the bacterium in their intestinal tract without becoming sick. Foods from which *L. monocytogenes* has been isolated include unpasteurized milk, ice cream, cheeses, red meat, poultry, seafood, vegetables and fruits. It is also a common contaminant in the dairy industry, both on the farm and in the processing plant. On the farm, sources include improperly fermented silage and manure.

Dairy processors can take steps to prevent *Listeria* contamination in the processing environment by separating raw and finished product areas. Access to processing areas should be restricted, especially to individuals such as truck drivers and raw milk handlers. Employees should practice good sanitary practices and adequate training and guidance should be provided for all workers. Cleaning and sanitizing procedures are important activities that should not be delegated to any employee without proper training.

Since 1985, enhanced surveillance of the dairy industry by the FDA has prompted over 50 recalls of *Listeria* –contaminated frozen dairy products, including ice cream and ice cream novelties (Ryser et al., 1999). Data from several environmental surveys of dairy plants show that *Listeria* can be found throughout the processing facility (Nelson, 1990). In one study, nisin effectively reduced the numbers of viable *Listeria* in ice cream with *L. monocytogenes* populations in ice cream prepared without nisin remaining constant during 3 months (Dean et al., 1996). However, other studies contradict the findings of Dean et. al, 1996. El-Kest and Marth, 1991, found that although fat, casein and lactose were protective against freeze damage, a substantial reduction in the viable *L. monocytogenes* population was seen throughout frozen storage.

In the United States, an estimated 2500 persons become seriously ill with listeriosis each year, with a fatality rate of approximately 20-30% (CDC). This high mortality rate makes listeriosis an important concern for the food industry. Since the early 1980's, *L. monocytogenes* has been implicated in several major foodborne outbreaks in North America. In 1981, coleslaw was implicated in a Canadian outbreak involving 41 cases and 11 deaths. In 1983, pasteurized milk was the probable vehicle for

an outbreak in Massachusetts, with 49 confirmed cases and 14 deaths. A third major outbreak associated with a Mexican-style cheese occurred in 1985 in California, with 142 cases and 48 deaths (Weinstein et al., 2001). In response to the later outbreak, the USDA and FDA established a “zero” tolerance policy for *L. monocytogenes* in ready-to-eat products. However, in 1999, an outbreak was linked to hot dogs and deli meats (100 cases with 21 deaths). The recall cost the Sara Lee Corporation \$76 million) and meat sales dropped about \$200 million in the six month period after the recall (USDA).

1.6. Ice cream surveys

A) *Milkshakes purchased at fast food outlets* (Pennsylvania Department of Agriculture)

In order to determine whether the fast food outlets were complying with set standards, milkshakes were purchased from fast food outlets and tested for mesophilic aerobic bacteria and coliforms (Barnard et al., 1991). Ninety-three samples were purchased from January through June 1998, just as consumers would have purchased them (in a container with a cover). Standard plate and coliform counts were obtained from samples within 24 hours of purchase. Between 33% and 41% of the sample did not meet the maximum bacterial standards (<50,000 cfu/ml for SPC and <10 cfu/ml for CC) of the Pennsylvania Department of Agriculture, as shown in Table 1.2 and 1.3.

Table 1.2. Coliform counts obtained from 93 milkshake samples.

Range	Percentage
Less than 1 per ml	38.7
1 to 10 per ml	20.4
More than 10 per ml	40.9

Table 1.3. Standard Plate counts tests done on 93 milkshake samples.

Range	Percentage
Less than 1000 per ml	41.3
1000 to 10000 per ml	13.8
10000 to 50000 per ml	12.1
More than 50000 per ml	32.8

For coliform counts, 59.1% of the samples complied with the standards while 40.9% were in violation of the standard (Table 1.2). For the standard plate count, 32.8% of the samples were in violation of the standard while 67.2% of the samples complied with the standard (Table 1.3).

B) Soft Serve Ice cream

Another study was conducted by the New York State Department of Agriculture to evaluate retail soft serve ice cream and frozen yogurt for microbial quality (Brown et al. 1991). New York State has no regulatory requirement for routine testing of retail soft serve ice cream and frozen yogurt. During the summer of 1990, samples were collected from the point of sale, i.e. dispensed from the freezer, from retail operations located in rural and major metropolitan markets of New York. The samples were evaluated for total numbers of mesophilic aerobic bacteria and coliforms. The results indicated that there was concern over the microbial quality of soft frozen desserts as offered for sale. Overall, 40% of the 58 ice cream samples had an SPC that exceeded the 100,000 CFU/g standard and 52% were above the 20 CFU/g coliform standard. In addition, 24% of the 76 samples of frozen yogurt also exceeded the coliform standard.

C) Soft Serve Ice-cream

A study on the bacteriological quality of soft-serve mixes and products in Louisiana was conducted by the Louisiana Agricultural Experiment Station (Ryan et al, 1982) over a 21-month period. The study focused on standard plate counts and coliform counts of soft-serve mixes and products from retail outlets. A total of 252 mix and 817 frozen dessert samples were collected. Of the mixes, 89.3% contained less than 50,000 cfu/g (10.7% contained >50,000 cfu/g), 7.1% contained between 50,000 and 300,000 cfu/g, and 3.6% contained over 300,000 cfu/g. In addition, 7.5% of the mix samples had coliform counts that exceeded 10 cfu/g. Overall, 61.4% of the soft serve product samples contained less than 50,000 cfu/g (38.51% contained >50,000 cfu/g), 22.3% contained between 50,000 and 300,000 cfu/g, and 16.3% contained over 300,000 cfu/g. In addition, 51.2% of the samples had a coliform count greater than 10 cfu/g (Ryan et. al, 1982). These results indicate that the mixes had relatively low bacterial counts, whereas the actual product, as dispensed from the machine was far more heavily contaminated. Hence, contamination of the mix likely occurred before or during freezing (i.e. contaminated by the freezer).

In other studies, Van der Zant and Moore (1954) examined 50 soft ice milk samples obtained from vendors in 19 Texas cities. The results showed that 50% of the samples contained >50,000 SPC/ml and 36% contained >10 coliforms/ml. In a similar study, 44% of the soft –serve ice milk samples contained >50,000 SPC/ml.

In other work, Foltz and Mickelsen (1964) examined 100 vanilla milkshakes purchased in Manhattan, Kansas and found that 61% of the samples contained >10 coliforms/ml.

Finally, Martin et al (1968) examined soft serve mixes and products from several Georgia soft-serve retail outlets which were collected over three one-year periods. An average of 21.5% of the mix samples had an SPC >50,000cfu/ml, while 47.7% of the soft-serve product had an SPC >50,000 cfu/ml. Overall, 27.3% and 50% of the mixes and products contained >10cfu/ml respectively.

1.7. Ice cream recalls

The 1980's saw a large number of recalls that were associated with ice cream. In July of 1986, ice cream bars were recalled because of possible contamination with *Listeria* spp. In August of the same year, a nationwide recall of ice cream was conducted because of suspected contamination with *L. monocytogenes*. By the end of 1987, over 500 million *Listeria*-contaminated products were recalled, with a cost of \$70 million to the industry (MMWR 1990)

In the summer of 1994, consumption of Schwans ice cream (MMWR 1994.) contaminated with *Salmonella enteritidis* sickened 224,000 people in the United States. This was the largest outbreak of salmonellosis ever reported and was caused by transporting the ice cream in tainted tanker trailers. This was an unusual outbreak as most other ice cream - related food poisoning cases had been caused by homemade or unpasteurized commercial ice cream. However Schwan's ingredients had undergone pasteurization to kill any disease-causing microbes. It was later determined that the delivery truck had also carried unpasteurized eggs from Minnesota to the Midwest with this company also contracted for transporting ice cream mix to Schwan's factory. Health regulations require that tanks be cleaned and washed after hauling liquid eggs. However,

the trucks were not clean and the trailers were not inspected regularly. After inspection, the trailer was found to have cracks in its lining that could harbor bacteria.

1.7.1. Complaints in Michigan

Although none of the following cases were confirmed, during the course of sampling, several local Michigan health departments received complaints from consumers that were potentially related to the consumption of soft serve ice cream.

Complaint #1 (District Health Department #2): Five members of a family ate soft serve ice cream at a restaurant in Hubbard Lake City, Caledonia Township in Alcona County and experienced nausea, bloating, lightheadedness, weakness, difficulty breathing and indigestion approximately 15 minutes after ingesting the ice cream. Some members of the group had strawberry sundaes, while others had Oreo blizzards with vanilla soft serve as the base in both. On another occasion a consumer ate ice cream at the same establishment which reportedly had a “sour” taste with symptoms disappearing within 24 h. Ice cream samples were collected from the restaurant, however they were not of the same batch that the family members consumed. No testing was done on these samples because the incident was not considered to be a foodborne illness. The extremely short onset time of 15 minutes suggests that the problem may have been due to chemical poisoning, perhaps from a sanitizer. However none of the clients reported a burning sensation within their mouths or throats. For the chemical used to sanitize the machine, the MSDS listed burning of the mouth, throat and stomach. Also, family members spent time together that day and might have shared other common meals. No other complaints were noted at the hospitals or at the facility.

Complaint #2 (Genesee County): A consumer, her daughter and her sister ate soft serve ice cream and approximately five hours later, began to experience symptoms of abdominal pain and diarrhea. No follow up was done on this case, because it was not believed to be a foodborne disease.

Complaint #3 (Livingston County Health Department): A woman and her family had eaten soft serve ice cream at a local establishment and had later experienced some symptoms of foodborne illness. The Livingston County Environmental Health Food Service Sanitarians conducted an onsite investigation and found the establishment to be clean and orderly. However, the chocolate soft serve supply line from the cooler to the soft serve machine contained product at 55°F. The chocolate product was not used as frequently as the vanilla product, thereby remaining in the line longer than vanilla. The department recommended drawing product from this line every hour to keep the product below 41°F. No food or stool samples were made available and all of the complainants refused to see a physician as requested, therefore no determination could be made as to the cause of illness pertaining to this complaint.

Complaint #4 (Macomb County Health Department): A family of five (3 children and 2 adults) ate chocolate and twist cones at a local establishment and complained of illness approximately 2.5 hours later. The family had consumed previous meals together and upon inspection of the establishment, no critical violations were found. There were no power outages, no sewage back ups, and no ill employees. No leftover samples were available from either the consumer or the establishment, therefore the product was sampled on a different day. On the day of inspection, both vanilla and chocolate ice cream were at a temperature of 20°F and the walk- in cooler was at a 40°F. The person in

charge also indicated that the machines were sanitized twice a day and all disassembled parts were washed, rinsed and sanitized in a three-compartment sink. No other complaints were received that implicated this particular establishment.

CHAPTER 2

Microbiological assessment of soft serve desserts as a means of determining the effectiveness of the current frozen dessert standard.

2.1. Introduction

The microbiological safety of soft serve desserts has received increased awareness during summer and with the Michigan Department of Agriculture being concerned about the number of licensed food service establishments that produce soft serve ice cream from freezers that may not meet quality standards. Therefore, a study was undertaken to determine the microbial quality of soft serve ice cream. In cooperation with Michigan State University (MSU), the Michigan Department of Agriculture (MDA) and local health departments, soft serve ice cream commercially available in the State of Michigan was examined for baseline levels of mesophilic aerobic bacteria and coliform count as well as presence of *Listeria* spp. In an effort to supplement information on soft serve ice cream as well as to regulate the sale of soft serve, a study was undertaken in which the objectives were to (1) determine the baseline levels of mesophilic aerobic bacteria, coliform bacteria and *Listeria* spp. found in soft serve desserts, (2) assess the effectiveness of current handling practice in minimizing microbial contamination and (3) assess the effectiveness of the current frozen dessert.

2.2. Materials and Methods

Images in this thesis are presented in color.

A total of 250 samples of Soft serve ice cream samples were collected once a week over a 7 - month period, from May 13 to November 26, 2001. With the help of food service inspectors from local MDA office, samples were dispensed directly from the soft serve freezer into 300ml vile.

Factors such as leaking samples, improper storage temperatures and incomplete surveys reduced the useable sample size from 250 to 227. Samples covered the range of available soft serve freezers from retail stores and food service establishments. All of the samples were assessed for Standard Plate Count (SPC) and Coliform Count (CC) and for the presence of *Listeria* spp. Bacteriological testing procedures were done in accordance to FDA/BAM methods.

Establishments were selected in alphabetical order from a pre-established list of food service and retail establishments. The list was then divided into Regions (see appendix) and sampled weekly, with Regions 1& 2 being sampled on the same day. If the chosen establishment had a soft serve freezer, a sample was obtained from that establishment. If the establishment did not have a soft serve machine, then the next establishment on the list that did have a machine was sampled. The number of samples collected from each region varied with the size of the region and the availability of establishments with that particular region.

Control tests done on mixes from dairy plants were used as a comparison to ensure that the samples complied with the standard for mixes when delivered to the establishment. "Plant A" (Detroit, MI) and "Plant B" (Port Huron, MI) supplied mixes to

most of the establishments.

Using gloves, approximately, 240 ml of product was aseptically dispensed from the freezer into sterile 300-ml vials with twist caps. The vials were then sealed, labeled and placed in a plastic zip lock bag. This zip-lock bag was placed in a cooler that was filled with ice, and transported to the lab for testing. At each sampling time, a survey questionnaire (see appendix) was completed, either with the manager or the person in charge.

According to “Standard Methods for the Examination of Dairy Products”, soft serve products should be maintained at 0–4.4°C and must arrive at the laboratory so that microbiological analysis can begin within 36 hours. Samples were transported to Geagley Laboratory (East Lansing, MI), within 24 hrs of collection and logged in by a licensed lab technician. The time, date and temperature at which the samples were received were recorded. To determine the temperature, a pre-cooled thermometer was inserted into the temperature control (an extra vial of sample was collected during the day to be used as a temperature control). The temperature control was at least half the size of the largest test container. Samples were rejected if there was no temperature control. However, one test sample could be used as a temperature control when necessary. Samples were also rejected if the containers were leaking or if the temperature was deemed inadequate, as two sets were.

Testing included standard plate counts, coliform counts and an assessment for the presence of *Listeria* spp. Testing was done in accordance with FDA/BAM methods. The test kit for *Listeria* spp. was supplied by BioControl Systems, Inc., Bellevue, WA).

a) Standard Plate Count

Soft serve mix (11g) was pipetted into 99ml of buffer solution. Thereafter, 1 ml and 0.1 ml of the mix was pour-plated using standard methods agar. These plates were counted after 48 hrs ± 3 hours of incubation at $32 \pm 2-3^{\circ}\text{C}$.

b) Coliform Count

Soft serve mix (11g) was pipetted into 99ml of buffer solution. Thereafter, 3.3 ml was pour –plated in triplicate and later overlaid using Violet Red Bile Agar (VRBA). All plates were counted after 24 h ± 2 h of incubation at $32 \pm 2-3^{\circ}\text{C}$.

c) Listeria spp.

Soft serve ice cream (25g) was pipetted into 225 ml of modified Fraser Broth with lithium chloride. The broth was then incubated at 28 ± 2 hours at 30°C . Thereafter, 1ml of modified broth was transferred into 9 ml of Buffered *Listeria* Enrichment Broth (BLEB). The tube was then incubated at 24 ± 2 h at 30°C . Following incubation, 1ml of this enrichment was transferred into a test tube immersed in boiling water for 15 minutes to inactivate the organism. After cooling, samples were tested along with 2 positive controls and one blank. In each case, 100 microliter (μL) of sample and positive control were pipetted into their respective wells (microwells were fitted into a holder). The wells were incubated for 30 min at $35-37^{\circ}\text{C}$. Following incubation, the wells were washed, after which the antibody, conjugate and substrate were added. The microwells were read at 410nm.

d) Data Analysis

Results from the standard plate and coliform counts were analyzed using multivariable logistic regression with the final result deemed either acceptable or unacceptable. Because the outcome of interest had a binomial distribution (yes or no), logistic regression was used. In order to evaluate the effect of different risk factors simultaneously, a multivariable logistic model was used. This program essentially determined how each variable contributed to the results that were obtained. A chi-square (χ^2) analysis yielded results based on each individual factor, whereas this method took all factors into consideration.

Multivariable Models: Variables were included for analysis in the multivariable logistic regression model if: (1) they demonstrated some level of association with bacterial counts ($p \leq 0.1$), and 2) had low levels of missing data (excluding variables for time from machine cleaning to sample collection and observed employee practices). The remaining variables were combined into a full model. Interaction terms were generated where interaction between two model variables were expected.

A modified backwards model building approach was used. A variable was removed from the model based on its Wald χ^2 probability value (checking for $p > 0.05$), with the odds ratios of the remaining variables also checked. When removal of the variable resulted in significant changes in odds ratios of the remaining variables (a $\geq 10\%$ change in the odds ratio), the presence of a confounding variable was suspected with the original variable then remaining. This process of removal and checking was repeated until the “final” model was obtained.

2.3. Results and Discussion

According to the Frozen Desserts Act, frozen desserts should have an SPC of $\leq 30,000$ cfu/ml and a coliform count of ≤ 10 cfu/ml for vanilla and 20 cfu/ml for chocolate. Overall, 50.2% (114/227) of the samples had an SPC no more than 30,000 cfu/ml and therefore were in compliance with the current standard requirement. Of the 134 vanilla samples, 81 (60.4%) complied with the standard for SPC with 32 of 93 (34.4%) chocolate samples also in compliance (Figure 2.1).

Up to 70% of the soft serve samples met the current standard for Coliform Counts, whereas 67 of 277 (29.5%) samples did not comply with the standard. (Appendix Table 3.4). While 69.4% (93/134) of the vanilla samples and 71% (66/93) of the chocolate samples complied with the standard, 30.6% and 29% of the vanilla and chocolate samples, respectively were out of compliance (Figure 2.2). This means that for vanilla, 93 of the 134 samples had a coliform count ≤ 10 cfu/ml, while 66 of the 93 chocolate samples had coliform counts ≤ 20 cfu/ml. *Listeria monocytogenes* was not isolated from any of the samples.

Overall, more vanilla samples had acceptable standard plate counts, while there was no difference in the percentage of acceptable coliform counts between vanilla samples and chocolate samples. (Table 2.1).

Fig 2.1. Summary of Standard Plate Count (SPC) results on 227 soft serve ice cream samples

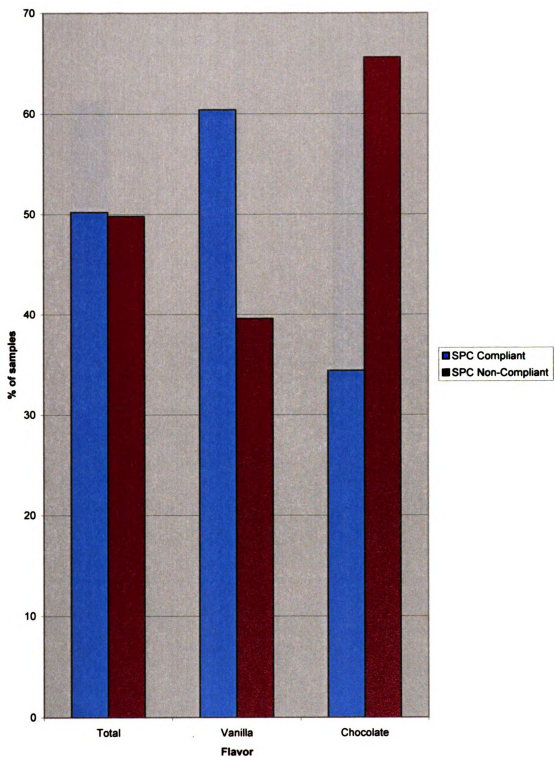


Figure 2.2 Summary of Coliform Count (CC) results on 227 soft serve ice cream samples

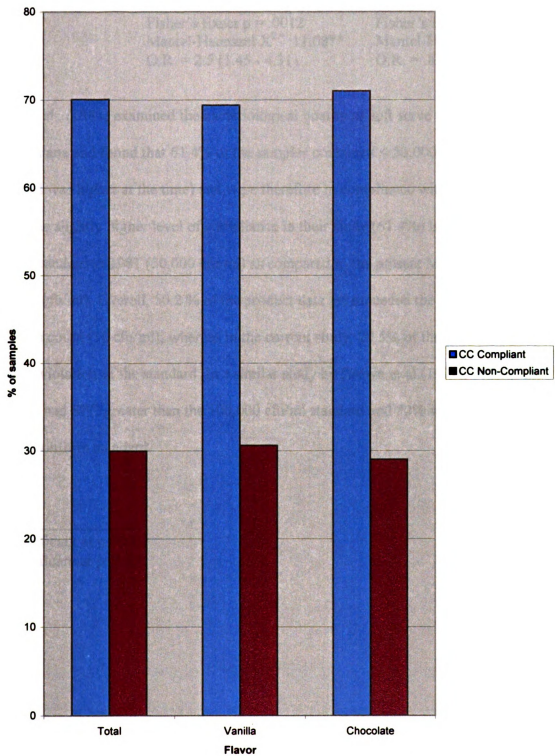


Table 2.1. Acceptable bacterial levels in soft serve ice cream

<i>Type</i>	<i>Overall</i>	<i>Acceptable SPC (%)</i>	<i>Acceptable CC (%)</i>
Vanilla	134	81 (60.44)	93 (69.40)
Chocolate	93	32 (34.41)	66 (70.96)
Fisher's Exact p = .0012		Fisher's Exact p = .5588	
Mantel-Haenszel X ² = 11.08**		Mantel-Haenszel X ² = 40	
O.R. = 2.5 (1.45 - 4.31)		O.R. = .82 (.46 - 1.48)	

Ryan et al., (1981) examined the bacteriological quality of soft serve mixes and products in Louisiana and found that 61.4% of the samples contained < 50,000 cfu/ml (the standard was higher at the time) and were therefore in compliance with the standard for SPC. The slightly higher level of compliance in their study (61.4%) is likely due to the higher standard in 1981 (50,000 cfu/ml) as compared to the present Michigan standard (30,000 cfu/ml). Overall, 50.2 % of the product data set exceeded the standard for coliform count (10 cfu/ml), whereas in the current study, 29.5% of the product data set were in violation of the standard. In a similar study by Brown et al.(1991), 40% of the samples had SPC greater than the 100,000 cfu/ml standard and 52% were above the 20 cfu/ml coliform standard.

*= significant at $p \leq 0.1$

** significant at $p \leq 0.05$

Soft serve mix from two different distribution plants was tested for SPC and CC.

Soft serve mixes had low bacterial counts when they left the plant but had higher microbial counts by the time the mix was been served as a soft serve ice cream to the consumer (Table 2.2 and 2.3).

Table 2.2. Analysis of “Plant A” Soft Serve Mix

Date	Sample	SPC(cfu/ml)	CC (cfu/ml)
10/24/01	Premium Vanilla Soft Serve Mix	<250	<1
9/25/01	Premium Vanilla Soft Serve Mix	<250	<1
8/28/01	Premium Vanilla Soft Serve Mix	<250	<1
	Premium Chocolate Soft Serve Mix	290	<1
7/30/01	Premium Vanilla Soft Serve Mix	<250	<1
	Premium Chocolate Soft Serve Mix	<250	<1
6/27/01	Premium Vanilla Soft Serve Mix	<250	<1
	Premium Chocolate Soft Serve Mix	<250	<1
5/29/01	Premium Vanilla Soft Serve Mix	<250	<1
	Premium Chocolate Soft Serve Mix	620	<1

Table 2.3. Analysis of “Plant B” Soft Serve Mix

Date	Sample	SPC (cfu/ml)	CC (cfu/ml)
9/4/01	Vanilla Soft Serve Mix	<250	<1
	Chocolate Soft Serve Mix	950	3
8/7/01	Vanilla Soft Serve Mix	<250	11
7/17/01	Vanilla Soft Serve Mix	<250	<1
	Chocolate Soft Serve Mix	<250	<1
5/15/01	Vanilla Soft Serve Mix	<250	<1
	Chocolate Soft Serve Mix	<250	<1

The data further proves that the “brand of mix” was not a determining factor in the microbial quality of the soft serve product (Table 2.4) since the mixes were delivered to a wide range of establishments. Contamination likely occurred after the product was

opened and handled in the food service establishments.

Table 2.4. Bacterial levels in soft serve ice cream, by establishment

Establishment	# of samples	% Exceeding SPC standard	% Exceeding CC standard
A	14	71 (10/14)	43 (6/14)
B	6	83 (5/6)	50 (3/6)
C	10	50 (5/10)	40 (4/10)
D	3	33 (1/3)	0
E	4	100 (4/4)	0
F	4	100 (4/4)	50 (2/4)
G	2	100	50 (1/2)
H	34	74 (25/34)	44 (15/34)
I	10	90 (9/10)	20 (2/10)
J	7	29 (2/7)	14 (1/7)
K	1	100	100
L	1	0	0
M	20	60 (12/20)	35 (7/20)
N	3	67 (2/3)	0
O	2	100	50 (1/2)
P	2	0	50 (1/2)
Q	2	0	0
R	14	29 (4/14)	43 (6/14)
S	50	6 (3/50)	8 (4/50)
T	5	60 (3/5)	0
U	1	100	0
V	12	92 (11/12)	50 (6/12)
W	3	33 (1/3)	0
X	2	0	0
Y	2	100	50
Z	2	100	50
A1	4	25 (1/4)	50 (2/4)
A2	1	0	0
A3	4	75 (3/4)	100
A4	1	100	100
A5	1	0	0

There were significant differences in SPC based on volume processed per week, with higher volumes associated with acceptable standard plate counts. Table 2.5 indicates that contamination increased as the product was held in the machine longer. Residence time in

the machine can be determined by the volume used per week. The lower the amount used per week, the longer the product must have been in the soft serve machine.

Table 2.5. Bacterial levels in soft serve ice cream, by volume processed/wk.

Vol/Week (gal)	# of samples	% Exceeding SPC standard	% Exceeding CC standard
0-10	27	81 (22/27)	44 (12/27)
11-20	34	65 (22/34)	15 (5/34)
21-30	26	46 (12/26)	38 (10/26)
31-40	23	48 (11/23)	26 (6/23)
41-50	21	43 (9/21)	33 (7/21)
51-60	13	38 (5/13)	23 (3/13)
61-70	15	33 (5/15)	20 (3/15)
71-80	17	59 (10/17)	35 (6/17)
81-90	3	67 (2/3)	0
91-100	9	11 (1/9)	0
101-110	1	0	0
111-120	2	50 (1/2)	50 (1/2)
121-130	2	0	0
131-140	2	0	0
141-150	8	63 (5/8)	63 (5/8)
191-200	6	50 (3/6)	33 (2/6)
201-210	2	50 (1/2)	100 (2/2)
221-230	1	0	0
241-250	1	0	0
271-280	1	0	0
291-300	8	50 (4/8)	13 (1/8)
321-330	1	0	0
391-400	1	0	0
591-600	3	67 (2/3)	100 (3/3)

This study also examined the association between the cleaning schedule and the levels of bacteria found in the mix. Acceptable standard plate and coliform counts were associated with *decreasing* numbers of times the machine was cleaned during one month (Table 2.6).

Table 2.6. Acceptable bacterial levels in soft serve ice cream, by number of times the machine is completely broken down and cleaned

<i>Times per month</i>	<i>Overall</i>	<i>Acceptable SPC (%)</i>	<i>Acceptable CC (%)</i>
Less than weekly	58	53 (91.38)	54 (93.10)
Weekly	43	13 (30.23)	23 (53.49)
8 - 14 times/month	70	18 (25.71)	47 (67.14)
Daily	44	21 (47.73)	28 (63.64)
Total	215	105 (48.83)	152 (70.70)
		Fisher's Exact $p \leq 0.0005$ Mantel-Haenszel $X^2 = 27.08^{**}$	Fisher's Exact $p \leq 0.0005$ Mantel-Haenszel $X^2 = 8.78^{**}$

These findings are in support of White et al, (1985) who examined the effect of sanitation schedule on microbiological quality of soft-serve ice cream. Dispensers cleaned and sanitized only on day zero (i.e. those cleaned less frequently) maintained bacterial counts equal to, or below those of the dispenser cleaned and sanitized daily, for an average of seven days. The more a machine is broken down and “cleaned”, the more it’s interior components are coming in contact with hands that may not necessarily be clean. Soft serve freezers with heat treatment capabilities require bi-weekly cleaning because during heat treatment, the machine pasteurizes the mix on a daily basis. In this situation, the interior of the machines has less contact with the environment. One would expect that the more a machine is dismantled and cleaned, the cleaner it will remain. However, in reality, one cannot ensure that cleaning is done thoroughly. The heat treatment machine, however, reduces the amount of human contact with the inner parts of the machine.

The levels of bacteria found in the soft serve samples were also analyzed, by type of establishment. Results indicated that soft serve ice cream taken from certain establishments had higher microbial counts than those taken from other establishments. There were significant differences in standard plate counts by type of establishment, but not in coliform counts. Fast food establishments had higher levels of acceptable standard plate counts, while gas station/convenience stores had no acceptable standard plate counts (Table 2.7).

Table 2.7. Acceptable bacterial levels in soft serve ice cream, by type of establishment

<i>Establishment</i>	<i>Overall</i>	<i>Acceptable SPC (%)</i>	<i>Acceptable CC (%)</i>
Convenience Store	18	3 (16.67)	10 (55.56)
Fast Food	58	50 (86.21)	51 (87.93)
Gas/Convenience	7	0	4 (57.14)
Ice Cream Shop	39	18 (46.15)	21 (53.85)
Restaurant	72	30 (41.67)	53 (73.61)
Retail Store	33	13 (39.39)	20 (60.61)
Total	227	114 (50.2)	159 (70.04)
		Fisher's Exact $p \leq 0.0005$	Fisher's Exact $p \leq 0.0005$
		Mantel-Haenszel $X^2 = 7.36^{**}$	Mantel-Haenszel $X^2 = 2.84^*$

All 7 samples obtained from "Gas /Convenience" were in violation of the SPC standard, while 57.14% of the samples violated the standard for coliforms. Overall, 83% of the samples obtained from "Convenience Stores" (convenience stores with no gas stations) violated the SPC standard, while 50% of the samples were in violation of the coliform standard. Overall, fast food restaurants had the lowest standard plate and coliform counts. This is an expected result, as it was noted that most fast food restaurants sampled had soft serve ice cream machines with "heat treatment". As stated earlier, these

machines must be completely broken down and cleaned every 14 days, whereas older model machines that were found in, for example, gas stations, needed to be dismantled and cleaned daily. Heat treatment machines pasteurize the mix in the hopper every night, while employees of establishments with older machines had to break the machines apart and either dispense the mix, or use it as re-run on the next business day. Results from the study showed that the more the machine was broken down and cleaned, the higher the microbial counts (Table 2.6).

Employee practices were also observed during sampling. Hand washing, use of gloves, use of hairnets and use and changing of gloves were observed. Significant associations were seen between acceptable standard plate counts and hand washing and changing gloves, and coliform counts and changing gloves (Table 2.8).

“Establishment S” which was sampled more frequently than the others had significantly higher levels of acceptable standard plate counts and coliform counts (Table 2.9). In addition, “Establishment S” used soft serve machines that had heat treatment cycles, further supporting the fact that these types of machines are better at producing product with acceptable standard plate and coliform counts.

Table 2.8. Acceptable bacterial levels in soft serve ice cream, by observed employee practices

<i>Practice</i>	<i>N</i>	<i>Acceptable SPC (%)</i>	<i>Acceptable CC (%)</i>
Washed hands	107	63 (58.88)	72 (67.29)
Did not wash	65	22 (33.85)	47 (72.31)
		<i>Fisher's Exact p = .0017</i> <i>Mantel-Haensel X² = 10.08**</i> <i>O. R. = 2.80 (1.47 - 5.32)</i>	<i>Fisher's Exact p = .6097</i> <i>Mantel-Haensel X² = .47</i> <i>O. R. = .78 (.40 - 1.55)</i>
Used gloves	80	39 (48.75)	60 (75.0)
Did not use gloves	39	20 (51.28)	28 (71.79)
		<i>Fisher's Exact p = .8466</i> <i>Mantel-Haensel X² = .07</i> <i>O.R. = .90 (.42 - 1.94)</i>	<i>Fisher's Exact p = .8243</i> <i>Mantel-Haensel X² = .14</i> <i>O. R. = 1.18 (.50 - 2.79)</i>
Used hair covers	83	45 (54.22)	59 (71.08)
Did not cover hair	22	7 (31.82)	17 (77.27)
		<i>Fisher's Exact p = .0922</i> <i>Mantel-Haensel X² = 3.46*</i> <i>O.R. = 2.54 (.94 - 6.87)</i>	<i>Fisher's Exact p = .7890</i> <i>Mantel-Haensel X² = .33</i> <i>O. R. = .72 (.24 - 2.18)</i>
Changed gloves	77	45 (58.44)	60 (77.92)
Did not change	65	21 (32.31)	38 (58.46)
		<i>Fisher's Exact p = .0024</i> <i>Mantel-Haensel X² = 9.61**</i> <i>O.R. = 2.95 (1.48 - 5.87)</i>	<i>Fisher's Exact p = .0176</i> <i>Mantel-Haensel X² = 6.20**</i> <i>O. R. = 2.51 (1.21 - 5.21)</i>

Table 2.9. Acceptable bacterial levels in mix from “Establishment S” .

<i>Mix S</i>	<i>Overall</i>	<i>Acceptable SPC (%)</i>	<i>Acceptable CC (%)</i>
Yes	38	36 (94.74)	35 (92.11)
No	189	76 (40.21)	124 (65.61)
		<i>Fisher's Exact $p \leq .0001$</i> <i>Mantel-Haenszel $\chi^2 = 37.47^{**}$</i> <i>O.R. = 26.76 (6.26-114.47)</i>	<i>Fisher's Exact $p \leq .001$</i> <i>Mantel Haenszel $\chi^2 = 10.54^{**}$</i> <i>O.R. = 6.12 (1.81 - 20.65)</i>

Significant associations were seen between increasing levels of acceptable standard plate counts and “Establishment S” and cleaning soft serve machines less than once a week (Table 2.10). This means being supplied by “Establishment S” and having your machines cleaned less than once a week would result in acceptable standard plate counts. However, convenience stores were associated with decreasing levels of acceptable standard plate counts.

Table 2.10. Final multivariable logistic regression model for acceptable standard plate counts, adjusting for enterprises using “Mix S” (n = 214, 105 acceptable samples, 109 unacceptable samples)

<i>Risk Factor</i>		<i>Wald X^2 p</i>	<i>Odds Ratio</i>	
			<i>Point Est.</i>	<i>95% C.I.</i>
“Mix S” used		.0274	6.96	1.24 - 39.02
Ice cream shop		.7230	1.22	.40 - 3.72
Restaurant		.6751	1.22	.48 - 3.12
Convenience store		.0467	.22	.05 - .98
Gas station/convenience store [†]		-	-	-
Vanilla sample		.1065	1.75	.89 - 3.47
Machine completely cleaned	Less than weekly	< .0001	10.08	2.68 - 37.88
	Weekly	.2080	1.03	.37 - 2.88
	8 - 14 times/month	.0003	.57	.23 - 1.41
	Daily	-	-	-
Volume served (in units of 10)		.2147	1.02	.99 - 1.06

[†] - baseline of comparison for type of establishment

Model log likelihood = 207.62; AIC score = 227.62

Estimated model R^2 = 34.30 %; Likelihood Ratio X^2 = 90.32, 9 d.f., $p < .0001$

Significant associations were seen between increasing levels of acceptable aerobic plate counts and using Mix “S” and cleaning soft serve machines less than once a week (Table 2.11). Convenience stores were significantly associated with decreasing levels of acceptable standard plate counts.

Table 2.11. Final multivariable logistic regression model for acceptable coliform counts, adjusting for enterprises using “Mix S” (n = 215, 152 acceptable samples, 63 unacceptable samples)

<i>Risk Factor</i>		<i>Wald X^2 p</i>	<i>Odds Ratio</i>	
			<i>Point Est.</i>	<i>95% C.I.</i>
Mix “S”		.2362	2.44	.56 - 10.68
Convenience Store		.5440	1.40	.47 - 4.15
Restaurant		.0215	2.43	1.14 - 5.19
Gas station/convenience store [†]		-	-	-
Vanilla sample		.0957	.57	.29 - 1.11
Mix rerun		.6638	1.18	.55 - 2.54
Machine completely cleaned	Less than weekly	.0005	8.08	2.10 - 31.15
	Weekly	.0048	.58	.21 - 1.64
	8 - 14 times/month	.3000	1.12	.46 - 2.73
	Daily	-	-	-
Volume served (in units of 10)		.1740	.98	.94 - 1.01

[†] - baseline of comparison for type of establishment

Model log likelihood = 222.22; AIC score = 242.22

Estimated model R^2 = 16.15 %; Likelihood Ratio X^2 = 37.86, 9 d.f., $p < .0001$

When data collected from previous years were compared to those collected in this study, average SPC and CC decreased markedly from 1998 –2000 (Table 2.12 and 2.13).

Table 2.12. Summary of Standard Plate Count (SPC) test results on routine frozen dessert samples submitted to the Michigan Department of Agriculture Laboratory Division, 1998 through June 2000.

Year	n	# exceeding SPC standard (%)
1998	343	39 (11.37)
1999	345	26 (7.54)
2000	129	1 (0.78)
1998-2000	817	66 (8.08)

However, the number of samples collected in 2000 was significantly less than that collected in 1998, which could reduce the chance of finding a violative sample. An accurate comparison cannot be made with the 2001 data, as one would be comparing data against two different standards. In 2001, 49.8% of the samples exceeded the standard. However, the data collected in 2001 was analyzed against a lower standard than that of 2000. The data collected in 2001 were to be analyzed against the old standard of 50,000/ml, the percentage of samples exceeding the standard in 2001 would be 46.26%. This still represents a drastic increase from the numbers seen during 1998-2000.

Table 2.13. Summary of Total Coliform Count (TCC) test results on routine frozen dessert samples submitted to the Michigan Department of Agriculture Laboratory Division, 1998 through June 2000.

YEAR	n	# exceeding TCC standard (%)
1998	415	87 (20.96)
1999	375	45 (12.00)
2000	138	13 (9.42)
1998-2000	928	145 (15.63)

Coliform counts decreased markedly from 1998-2000. However, the number of samples collected in 2000 was significantly less than that collected in 1998, which could reduce the chance of finding a violative sample. The standard for coliform counts has not changed, therefore, an accurate comparison can be made with the data collected in 2001. The percentage of samples exceeding the standard in 2001 was 29.5%, which still represents an increase from the numbers seen during 1998-2000.

County – wide sampling was unequal and often insufficient to ascertain microbial differences between counties. The counties did not have the same types of establishments and the same types of soft serve freezers, therefore, an accurate conclusion cannot be made based on county. For example, only one sample was obtained from Alcona County (Table 2.14). If the establishment happened to be taken from a fast food establishment, based on prior information from this study, one can expect that it will meet SPC and coliform standard. The types of establishments influenced the results seen by county. The same reasoning would apply to counties like Cheboygan which had 100% compliance. This does not necessarily mean that the entire county is in compliance, but rather the single sample taken happened to be one from an establishment that complied with the standard.

Table 2.14. Acceptable bacterial levels in soft serve ice cream, by County

County	# of samples	% exceeding SPC standard	% exceeding CC standard
Alcona	1	100	100
Allegan	2	100	0
Alpena	1	100	0
Antrim	1	100	100
Barry	2	100	50
Calhoun	2	100	50
Cheboygan	1	0	0
Clinton	8	38	13
Delta	4	75	75
Dickinson	2	50	0
Eaton	1	0	100
Genesee	15	40	27
Grand Traverse	6	67	33
Holland	1	0	0
Ingham	28	46	21
Iron	1	0	0
Kalamazoo	17	65	35
Kalkaska	2	100	0
Kent	1	100	100
Mackinac	1	0	0
Macomb	5	40	60
Menominee	1	0	100
Oakland	41	49	32
Otsego	9	67	0
Ottawa	17	65	47
Saginaw	10	50	20
St. Clair	5	40	20
Van Buren	1	100	100
Wayne	41	34	27

The same would apply to any comparison made by Region and Jurisdiction (Table 2.15 and 2.16). The different regions and jurisdictions did not have the same types of establishments with the same types of soft serve machines, therefore, an accurate conclusion cannot be made on the effect the region had on levels of bacteria in soft serve ice cream (Table 2.15).

Table 2.15. Acceptable bacterial levels in soft serve ice cream, by MDA Region

Region	# of samples	% exceeding SPC standard	% exceeding CC standard
1	9	44	44
2	18	78	28
3	24	67	50
4	30	47	23
5	19	74	32
6	32	38	22
7	95	42	28

Table 2.16 Acceptable bacterial levels in soft serve ice cream, by Jurisdiction

Jurisdiction	# of samples	% exceeding SPC standard	% exceeding CC standard
LHD: Local Health Department	173	45	28
MDA: Michigan Department of Agriculture	54	69	35

There were no visible trends associated with temperature and the levels of bacteria found in soft serve desserts (Table 2.17).

Table 2.17. Acceptable bacterial levels in soft serve ice cream, by product temperature

Product Temp (°F)	n	% exceeding SPC standard	% exceeding CC standard
14-16	9	44	44
17	14	57	21
18	31	42	16
19	40	53	33
20	55	38	35
21	30	77	40
22	28	64	29
23	3	33	0
24	8	75	13
25	3	0	67
26-40	6	33	17

The use of rerun was also examined to see for potential impact on microbial levels in soft serve ice cream. Samples having the highest SPC and coliform counts were associated with those establishments that used re-run (Table 2.18). This may be due to improper storage and handling of the re-run product.

Table 2.18. Acceptable bacterial levels in soft serve ice cream, by whether unused mix is rerun.

Re-run used	n	% exceeding SPC standard	% exceeding CC standard
No	177	49	29
Yes	50	62	32

Based on the data, samples remaining in the machine for 24-48 h yielded higher percentages of violative coliform standard plate counts (Table 2.19).

Table 2.19. Acceptable bacterial levels in soft serve ice cream, by time mix spends in machine.

Time in machine	n	% exceeding SPC standard	% exceeding CC standard
<24HRS	161	47	29
24-48HRS	33	64	36
>48HRS	33	55	30

Significant associations were seen between bacterial counts and the number of days between the machine's last cleaning and when samples were collected (Table 2.20). Acceptable levels of standard plate counts and coliform counts were associated with *increasing* numbers of days between cleaning and sample collection.

Table 2.20. Acceptable bacterial levels in soft serve ice cream, by number of days between last cleaning and sample collection

<i>Days</i>	<i>n</i>	<i>Acceptable SPC (%)</i>	<i>Acceptable CC (%)</i>
0	41	25 (60.98)	28 (68.29)
1	56	25 (44.64)	39 (69.64)
2 - 3	40	10 (25.0)	23 (57.50)
4	24	11 (45.83)	19 (79.17)
5+	31	25 (80.65)	26 (83.87)
Total	192	96 (50.0)	135 (70.31)
		<i>Fisher's Exact $p \leq 0.0005$</i>	<i>Fisher's Exact $p = .1491$</i>
		<i>Mantel-Haenszel $X^2 = 1.62$</i>	<i>Mantel-Haenszel $X^2 = 2.13$</i>

2.4. Conclusions and Recommendations

2.4.1. Summary and Conclusions

The microbial quality of 227 samples of soft serve ice cream was assessed over a 7-month period (133 of those samples being vanilla, and 94 being chocolate). Overall, 50.2% of the samples complied with the standard for standard plate count. Of these, 60.4% of the vanilla samples and 34.4% of the chocolate samples complied with the standard. Furthermore, 69.4% of the vanilla samples and 71% of the chocolate samples complied with the standard for coliform count. *Listeria* spp. were not detected in any of the samples.

Significant increases in standard plate and coliform counts of soft serve ice cream mixes were noted after mixes originally containing low bacterial counts were dispensed from retail outlets. A greater number of acceptable standard plate and coliform counts were seen with heat treatment machines. Samples taken from establishments with heat treatment freezers had lower standard plate and coliform counts than their counterparts. Increased dismantling and cleaning of the machine increased microbial contamination. This also explains why samples that had the highest number of unacceptable counts were associated with those establishments that use re-run.

Although the findings indicate that the type of soft serve freezer used is a determining factor in acceptability of the product, it is necessary and recommended that regulators, manufacturers and industry focus on preventative factors as well as conduct regular sampling to ensure that these preventative measures are effective. These preventative factors could include, but are not limited to the training of employees in cleaning and sanitizing equipment, as well as providing manuals for re-training and for

reference. It is logical to assume that if done properly, cleaning and sanitizing will decrease microbial levels in product. Preventative factors are especially important, as it is not feasible for all establishments to be equipped with a soft serve machine that has a heat treatment cycle. While the standard is set to serve as a guideline for manufacturers and retail outlets, without regular sampling, there is no way of determining and ensuring that the products are meeting these standards. Therefore, continuous sampling is essential in assuring that the manufacturers and workers at retail outlets are not only self-regulating, but are supplying products that are low in bacterial counts.

2.5.2 Recommendations for Future Research

1) Due to a lack of current information on soft serve products and in order to supplement and update already existing data, State Departments of Agriculture across the country should implement programs or add to their already existing programs, an inspection schedule that includes soft serve products. Local governments should make food safety a priority and take funding of such projects into consideration when making budget increases or cutbacks.

2) Further, more in depth sampling projects should be done that will include

- a. Taking swabs from different areas of the machine, such as in the hopper and in the spigot in order to identify the location where contamination would most likely occur.
- b. The role that economics plays in the results obtained from different counties and regions. This is important, as business owners living in affluent counties have access to better resources and may be able to equip their establishments with modern soft serve freezers, such as those with heat treatment capabilities. In addition, local governments in more affluent counties may be able to provide better training and better inspection services to establishments in their counties.
- c. An assessment of county populations and the relationship between the number of samples collected i.e. the risk of population exposure to violative samples.
- d. Proper sampling methods that would allow adequate sampling of all counties.

- 3) Investigate the age and type of freezers and its effects on the microbial levels found in soft serve products.
 - a. Set up an experimental design simply based on heat treatment freezers vs. non heat treatment freezers.
- 4) A study that focuses on training and preventative measures for establishments that are not equipped with heat treatment machines, e.g. cleaning and sanitizing strategies.

APPENDIX

Appendix 3.1. Data Tables

Table 3.1. Summary of Standard Plate Counts (Total)

Standard Plate Count (/ml)	Number of Samples	%
<250	53	23.3
250-30,000	61	26.9
30,001-49,999	8	3.5
50,000-99,999	22	9.69
100,000-199,999	14	6.18
200,000-299,999	5	2.20
300,000-399,999	1	0.44
400,000-499,999	0	0.00
500,000-600,000	4	1.76
>600,000	59	26.00
TOTAL	227	100.00

Summary: 50.2% (114/227) of the samples complied with the standards, while 49.8% (113/227) did not comply with the standard.

Table 3.2. Summary of Standard Plate Counts (Vanilla Samples)

Standard Plate Count (/ml)	Number of Vanilla Samples	%
<250	45	33.58
250-30,000	36	26.87
30,001-49,999	5	3.73
50,000-99,999	12	8.96
100,000-199,999	5	3.73
200,000-299,999	2	1.49
300,000-399,999	1	0.75
400,000-499,999	0	0.00
500,000-600,000	3	2.24
>600,000	25	18.66
TOTAL	134	100.00

Summary: 60.4% (81/134) of the vanilla sample complied with the standard, while 39.6% (53/134) were in violation of the standard.

Table 3.3. Summary of Standard Plate Counts (Chocolate Samples)

Standard Plate Count (/ml)	Number of Chocolate Samples	%
<250	8	8.6
250-30,000	24	25.8
30,001-49,999	3	3.23
50,000-99,999	11	11.83
100,000-199,999	9	9.68
200,000-299,999	3	3.23
300,000-399,999	0	0.00
400,000-499,999	0	0.00
500,000-600,000	0	0.00
>600,000	35	37.63
TOTAL	93	100.00

Summary: 34.4% (32/93) of the chocolate samples complied with the standard, while 65.6% (61/93) of the chocolate samples were in violation of the standard.

Table 3.4. Summary of Coliform Counts

Coliform Counts (/ml)	Number of Samples	%
<1	130	57.27
1--10	19	8.37
11--20	11	4.85
21--49	13	5.73
50--99	9	3.96
100--150	10	4.41
>150	35	15.42
TOTAL	227	100.00

Summary: 29.5% (67/227) of the samples were in violation of the standard, whereas 66-70% complied with the standard (depending on whether it was chocolate or vanilla).

Table 3.5. Summary of Coliform Counts (Vanilla Samples)

Coliform Counts (/ml)	Number of Vanilla Samples	%
<1	83	61.94
1--10	10	7.46
11--20	4	2.99
21--49	8	5.97
50--99	3	2.24
100--150	6	4.48
>150	20	14.93
TOTAL	134	100.00

Summary: 69.4% (93/134) of the vanilla samples complied with the standard while 30.6% (41/134) of the vanilla samples were in violation of the standard.

Table 3.6. Summary of Coliform Counts (Chocolate Samples)

Coliform Counts (/ml)	Number of Chocolate Samples	%
<1	50	53.76
1--10	9	9.68
11--20	7	7.53
21--49	7	7.53
50--99	4	4.30
100--150	4	4.30
>150	12	12.90
TOTAL	93	100.00

Summary: 71% (66/93) of the chocolate samples complied with the standard while 29% (27/93) of the chocolate samples were in violation of the standard.

Table 3.7. Acceptable bacterial levels in soft serve ice cream, by MDA regions

Region	Overall	Acceptable SPC (%)	Acceptable CC (%)
1	9	5 (55.56)	5 (55.56)
2	18	4 (22.22)	13 (72.22)
3	24	8 (33.33)	12 (50.0)
4	30	15 (50.0)	23 (76.67)
5	19	5 (26.32)	13 (68.42)
6	32	20 (62.50)	25 (78.13)
7	95	55 (57.89)	68 (71.58)
Total	227	112 (49.34)	159 (70.04)
Fisher's Exact $p \leq 0.0005$		Fisher's Exact $p < 0.0005$	
Mantel-Haenszel $X^2 = 1.68$		Mantel-Haenszel $X^2 = 7.81^{**}$	

There were no significant differences in standard plate counts by MDA region, but there were differences in coliform counts: lower levels of acceptable coliform counts were seen in regions 3 and 1.

*significant at $p \leq 0.1$

** significant at $p \leq 0.05$

Table 3.8. Acceptable bacterial levels in soft serve ice cream, by product temperature

	<i>n</i>	<i>Mean</i>	<i>Std. Dev.</i>	<i>Quartiles</i>	<i>F</i>	<i>Kruskall-Wallis X²</i>
Overall	227	20.08	2.58	14, 19, 20, 21, 38		
Aerobic Plate Counts						
Acceptable	112	20.01	2.89	14, 18, 20, 20.5, 38	.13	1.74
Unacceptable	115	20.14	2.25	15, 19, 20, 21, 29		
Coliforms						
Acceptable	159	20.09	2.73	14, 18, 20, 21, 38	.02	.21
Unacceptable	68	20.04	2.19	15, 19, 20, 21, 29		

Table 3.9. Acceptable bacterial levels in soft serve ice cream, by brand of mix

Brand	Overall	Acceptable SPC (%)	Acceptable CC (%)
A	14	4 (28.57)	8 (57.14)
B	10	5 (50.0)	6 (60.0)
C	33	8 (24.24)	18 (54.55)
D	20	8 (40.0)	13 965.0)
E	38	36 (94.74)	35 (92.11)
F	12	1 (8.33)	7 (58.33)
G	100	50 (50.0)	72 (72.0)
Total	227	112 (49.34)	159 (70.04)
		Fisher's Exact $p \leq 0.0005$ Mantel-Haenszel $X^2 = 3.15^*$	Fisher's Exact $p \leq 0.0005$ Mantel-Haenszel $X^2 = 3.15^*$

*significant at $p \leq 0.1$

** significant at $p \leq 0.05$

While not significant at $p \leq 0.05$, there were differences in levels of acceptable bacterial counts and brand of soft serve mix used. In particular, levels of acceptable bacterial counts were very high for establishments using "Mix S"(did not include subsets of Mix S).

Table 3.10. Acceptable bacterial levels in soft serve ice cream, by volume processed per week

	n	Mean	Std. Dev	Quartiles	F	Kruskal-Wallis X ²
Overall	227	74.98	95.12	2, 20, 45, 80, 600		
Aerobic Plate Counts						
Acceptable	112	85.53	92.65	6, 30, 58, 100, 600	2.74*	13.43**
Unacceptable	115	64.7	96.76	2, 15, 35, 75, 600		
Coliforms						
Acceptable	159	67.72	72.30	2, 20, 50, 80, 325	3.11*	.01
Unacceptable	68	91.94	133.31	2, 22.5, 43.5, 80, 600		

There were significant differences in volume processed per week by standard plate count, with higher volumes associated with acceptable standard plate count.

Table 3.11. Acceptable bacterial levels in soft serve ice cream, by time mix spends in machine

Time in machine	Overall	Acceptable SPC (%)	Acceptable CC (%)
< 24 hours	161	85 (52.8)	115 (71.43)
24 - 48 hours	33	12 (36.36)	21 (63.64)
> 48 hours	33	15 (45.45)	23 (69.70)
Total	227	112 (49.34)	159 (70.04)

Fisher's Exact p = .2133
Mantel-Haenszel X² = 1.53

Fisher's Exact p = .6329
Mantel-Haenszel X² = .21

Table 3.12. Acceptable bacterial levels in soft serve ice cream, by whether unused mix is rerun

Mix rerun	Overall	Acceptable SPC (%)	Acceptable CC (%)
Yes	50	19 (38.0)	34 (68.0)
No	177	93 (52.54)	125 (70.62)

Fisher's Exact p = .0791	Fisher's Exact p = .7290
Mantel-Haenszel $X^2 = 3.28$	Mantel-Haenszel $X^2 = .13$
O.R. = .55 (.29 - 1.05)	O.R. = .82 (.46 - 1.48)

Table 3.13. Acceptable bacterial levels in soft serve ice cream, by number of times the machine is completely broken down and cleaned

Times per month	Overall	Acceptable SPC (%)	Acceptable CC (%)
Less than weekly	58	53 (91.38)	54 (93.10)
Weekly	43	13 (30.23)	23 (53.49)
8 - 14 times/month	70	18 (25.71)	47 (67.14)
Daily	44	21 (47.73)	28 (63.64)
Total	215	112 (49.34)	152 (70.70)

Fisher's Exact p ≤ 0.0005	Fisher's Exact p ≤ 0.0005
Mantel-Haenszel $X^2 = 27.08^{**}$	Mantel-Haenszel $X^2 = 8.78^{**}$

There were significant associations between bacterial counts and the number of times the soft serve machine was completely broken down and cleaned in a one-month period. Acceptable levels of standard plate counts and coliform counts were associated with *decreasing* numbers of times the machine was cleaned during one month.

Table 3.14. Acceptable bacterial levels in soft serve ice cream, by type of sanitizer/disinfectant used

Type of disinfectant	Overall	Acceptable SPC (%)	Acceptable CC (%)
SDSTD	157	84 (53.50)	112 (71.34)
Other	70	28 (40.0)	47 (67.14)

Fisher's Exact p = .0636
Mantel-Haenszel $X^2 = 3.52^*$
O.R. = 1.73 (.97 - 3.06)

Fisher's Exact p = .5337
Mantel-Haenszel $X^2 = .40$
O.R. = 1.22 (.66 - 2.23)

Table 3.15. Acceptable bacterial levels in soft serve ice cream, by number of days between last cleaning and sample collection

Days	Overall	Acceptable SPC (%)	Acceptable CC (%)
0	41	25 (60.98)	28 (68.29)
1	56	25 (44.64)	39 (69.64)
2 - 3	40	10 (25.0)	23 (57.50)
4	24	11 (45.83)	19 (79.17)
5+	31	25 (80.65)	26 (83.87)
Total	192	96 (50)	135 (70.31)

Fisher's Exact p ≤ 0.0005
Mantel-Haenszel $X^2 = 1.62$

Fisher's Exact p = .1491
Mantel-Haenszel $X^2 = 2.13$

There were significant associations between bacterial counts and the number of days between the machine's last cleaning and when samples were collected. Acceptable levels of standard plate counts and coliform counts were associated with *increasing* numbers of days between cleaning and sample collection.

Table 3.16. Acceptable bacterial levels in soft serve ice cream, by cleaning water temperature (Fahrenheit)

	n	Mean	Std. Dev.	Quartiles	F	Kruskall-Wallis X ²
Overall	201	122.34	33.27	40, 100, 120, 150, 190		
Aerobic Plate Counts						
Acceptable	95	122.13	35.14	40, 100, 120, 165, 190	.01	.07
Unacceptable	106	122.54	31.66	75, 100, 120, 150, 190		
Coliforms						
Acceptable	138	122.77	34.97	40, 100, 120, 155, 190	.07	.02
Unacceptable	63	121.41	29.44	75, 100, 120, 150, 170		

For both bacterial counts, two different multivariable logistic regression models were developed: one with and one without adjustment for whether an establishment was an “Establishment S” restaurant.

Table 3.17. Final Multivariable Logistic Regression Model for Acceptable Aerobic Plate Counts (n = 214, 105 acceptable samples, 109 unacceptable samples)

Risk Factor		Wald X^2 ^p	Odds Ratio Point Est.	95% C.I.
Fast food establishment		.2408	2.11	.61 - 7.36
Restaurant		.3201	1.58	.64 - 3.89
Ice cream shop		.4527	1.54	.40 - 4.72
Gas station/convenience store [†]		-	-	-
Vanilla sample		.0587	1.90	.98 - 3.71
	Less than weekly	< .0001	9.70	2.57 - 36.67
Machine completely cleaned	Weekly	.0584	.71	.25 - 2.00
	8 - 14 times/month	.0003	.49	.20 - 1.20
	Daily	-	-	-
Volume served (in units of 10)		.2421	1.02	.99 - 1.06
Use of sanitizer with STSTD		.5921	1.22	.59 - 2.54

Model log likelihood = 218.93; AIC score = 238.93

Estimated model R^2 = 30.43 %; Likelihood Ratio X^2 = 77.66, 9 d.f., $p < .0001$

[†] - baseline of comparison for type of establishment

Based on the model developed without adjusting for “Establishment S”, significant associations were seen between acceptable levels of aerobic plate counts and establishments cleaning soft serve machines less than once a week.

Table 3.18. Final Multivariable Logistic Regression Model for Acceptable Coliform Counts (n = 215, 152 acceptable samples, 63 unacceptable samples)

Risk Factor		Wald X ² p	Odds Ratio	
			Point Est.	95% C.I.
Restaurant		.0303	2.19	1.08 - 4.43
	Less than weekly	< .0001	8.37	2.41 - 29.13
Machine completely cleaned	Weekly	.0005	.51	.20 - 1.31
	8 - 14 times/month	.1730	1.01	.43 - 2.35
	Daily	-	-	-
Volume served (in units of 10)		.0771	.97	.94 - 1.00

Model log likelihood = 226.40; AIC score = 238.40

Estimated model R² = 14.5 %; Likelihood Ratio X² = 33.68, 5 d.f., p < .0001

Based on the model developed without adjusting for “Establishment S”, significant associations were seen between increasing acceptable levels of aerobic plate counts with restaurants and establishments cleaning soft serve machines less than once a week.

Appendix 3.2. Definitions

Ice cream: “any frozen, sweetened milk product which is stirred during the process of freezing and includes every such frozen milk product which contains milk fat or milk solids not fat and which in any manner simulates the texture or characteristics of ice cream no matter under what coined or trade name it may be sold.”

Ice cream mix: an “unfrozen food product, made from wholesome ingredients as provided for use in the manufacturing or processing of ice cream....respectively, and shall meet the same requirements as the foods made from those mixes.”

Frozen desserts: means ice cream...and other new related products which are defined in the future by rule.

Ice cream plant: any place, premises, or establishment where ice cream....is manufactured, prepared, processed, or frozen for distribution or sale.

Soft Serve: a generic term used to describe a complete category of ice cream and frozen dessert products. Soft Serve products are frozen in and dispensed directly from the freezer to the customer. The mix used determines the type of product served. Reduced Fat, Low Fat, Non-Fat, Fat Free Ice Creams, Ice Milk, Frozen Custard, Sherbet, and Sorbet are some of the products consumers know and order. Soft Serve is a profitable menu item because the food cost associated with Soft Serve is low, resulting in a 70-80% profit margin.

Bacteria Count: The amount of bacteria in the soft-serve mix or the finished product. If the bacteria count in test samples taken by the health inspector exceeds the allowable limit, penalties can result, including suspension or total shutdown of business.

Coliform: Gram negative, non-spore forming, facultatively anaerobic rods that ferment lactose to produce acid and gas at 35°C within 48hrs. Coliform bacteria include *E.coli*, *Citrobacter* spp., *Enterobacter aerogenes*, and *Klebsiella pneumoniae*.

Re-Run: Mix that has been frozen and allowed to melt down for reuse. Re-run is most commonly acquired while cleaning the freezer. Re-run should never be used during the initial start-up. Where health codes allow, re-run should be added to the freezer during high volume periods during the business day. There is danger that, if improperly handled, re-run can contaminate fresh mix and lead to poor product quality and a high coliform count.

Overrun: As mix is frozen, air is introduced into it to increase its volume. Overrun is the percentage of volume that a gallon is increased when air is added. Ice cream mix has a composition of : 63% moisture, 37% dry material (10% fat, 11.5% MSNF, 15% Sugar, 0.5% Emulsifiers and Stabilizers).

Pressurized Freezer: a freezer equipped with mix pumps that transfer mix from a container or hopper to the freezing cylinder. As mix is pumped into these freezers, a controlled amount of air is added to the product. These freezers use the pressure from the

pump to force product from the cylinder when dispensing.

Twist Freezer: any soft serve freezer that has two freezing cylinders and one dispensing head designed to dispense two flavors individually or combine the two flavors into a single serving.

Butterfat/Milkfat Content: The percentage of dairy fat contained in the mix. A 6% butterfat mix, for example, contains 6 pounds of milkfat per 100 pounds. Product richness will normally increase as the butterfat content increases.

Hopper Models: Freezers that have mix reservoirs on the top of the machine.

Mix: A general term that refers to any unfrozen liquid mixture designed for use in the manufacture of frozen dairy products such as soft serve. Mixes can be both dairy and non-dairy products in either liquid or powdered form. Mixes come packaged in cartons, bags, cans, etc.

Mix Level Indicator: A flashing light on the machine automatically tells the operator that mix needs to be added to the mix container or hopper.

C.I.P: Clean in Place, the procedure by which sanitary pipelines or pieces of dairy equipment are mechanically cleaned in place by circulation

Frozen Dairy Dessert: any frozen or partially frozen combination of two or more products such as milk, milk products, eggs, etc.

Dairy Plant: a place, premise, or establishment where milk or dairy products are received or handled for the processing or manufacturing of mix and frozen dairy desserts.

Heat Treatment Dispensing Freezers: This is a freezer that has a product reservoir that processes previously pasteurized products, freezes the product, dispenses frozen dairy products, and maintains microbiological quality by elevating the temperature of the product using heating methods that are an integral part of the dispensing freezer.

Appendix 3.3. Regulations

Regulation No. 405: Frozen Desserts

Reg. 285.405.1. Definitions A to F

Rule 1. (1) The definitions of terms in the act are applicable to these rules.

(2) “Act” means Act No. 298 of the Public Acts of 1968, being sections 288.321 to 288.334 of the Compiled Laws of 1948.

(3) “Department” means the State Department of Agriculture

(4) “Freezer” means mechanical equipment used to lower the temperature of a mix, while at the same time incorporating air into the mix.

Reg. 285.405.2. Definitions M to T

Rule 2. (2) “Mix” means ice cream mix, ice milk mix, sherbet mix, and any other unfrozen pasteurized liquid mixture which is to be manufactured into a frozen dessert, including a liquid mixture intended for processing into frozen confections.

(3) “Rerun” means a frozen dessert that is not placed in its final container immediately after passing through the freezing process and is intended to be melted and reprocessed or refrozen.

(4) “Sanitation” means the application of an effective method or substance to a clean surface for the destruction of organisms as fast as is practicable, which treatment does not adversely affect the equipment, the frozen dessert or the health of consumers, and is acceptable to the department.

285.405.14. Cleaning of equipment.

- (1) Immediately before use, equipment in an ice cream plant coming in contact with milk, dairy products, mix or frozen desserts shall have an effective sanitizing treatment. (2) After each use, equipment not designed for cleaning in place, shall be disassembled and thoroughly cleaned. Dairy cleaners, wetting agents, detergents, sanitizing agents, or other similar material may be used that will not contaminate or adversely affect dairy products. Steel wool or metal sponges shall not be used in cleaning dairy equipment or utensils. (3) Circulating-in-place cleaning shall be used only on equipment and pipeline systems designed and engineered for that purpose, installation and cleaning procedures shall be in accordance with 3-A accepted practices for permanently installed sanitary product pipelines and cleaning systems, and be approved by the department. An outline of the cleaning procedures to be followed should be posted near the CIP equipment.

Reg.285.405.15. Storage of equipment and supplies.

After cleaning, multi-use utensils, containers and equipment in an ice cream plant shall be stored to drain dry, and in such a manner as not to be contaminated before usage. Equipment stored in sanitizing solution is permissible. Caps, parchment paper, wrappers, liners, gaskets, and single service sticks, spoons, covers and containers for frozen desserts, mix or their ingredients, shall be purchased and stored only in sanitary tubes, wrappings or cartons; shall be kept therein in a clean, dry place until used; and shall be handled in a sanitary manner.

Reg. 285.405.16. Handling of ingredients, mix and frozen desserts.

(1) Milk, cream and milk products in fluid form received at an ice cream plant for use in mixes, shall immediately be cooled at a temperature of 50°F or less and maintained at that temperature until pasteurized. Mixes shall be assembled and pasteurized in an ice cream plant. Mix which is not frozen at the plant in which it was pasteurized shall be transported to the place of freezing in properly covered and protected containers. (2) Spilled frozen desserts and ingredients shall be discarded. Rerun shall be handled in sanitary containers properly covered and stored, or shall be piped directly back to vats. Rerun, which has been strained to remove nuts, fruits or other ingredients, should be re-pasteurized. Partially full containers, if not damaged, broken or contaminated, may be returned to the manufacturer for re-pasteurization and processing. After opening, it is recommended that all syrups used for flavoring or topping be refrigerated at all times. Flavoring ingredients may be added to mix after pasteurization. (3) Frozen desserts and mix shall be packaged in commercially acceptable containers and packaging material that will protect the quality of the contents in regular channels of trade. The packaging, cutting, molding, dispensing, and other handling or preparation of mix or frozen desserts and their ingredients shall be done in a sanitary manner. Plastic or rubber gloves should be worn when handling frozen desserts for molding, cutting, or similar hand contact work. (4) When an ice cream plant is identified by code number on containers of frozen desserts, the distributor's name and address or the retailer's name and address shall be shown on the container label.

Reg. 285.405.17. Standards for mix, ingredients and frozen desserts.

(1) Pasteurized mix, pasteurized dairy ingredients and frozen desserts shall comply with the following standards:

Table 2.1. Bacterial standards for frozen desserts and frozen desserts mix

	Standard Plate Count	Coliform Count	Storage Temperature
Mix	≤30,000/ml	≤10/ml	≤ 45°F
Frozen desserts	≤30,000/ml	≤10/ml*	≤ 32°F

* ≤20/ml for chocolate, fruit, nuts or other bulky flavored frozen desserts.

(2) When 2 of the last 4 consecutive Standard Plate Counts, Coliform Counts, or temperatures taken on separate days exceed the limit of the standard established in the paragraph (1), the department shall send a written notice thereof to the person concerned. This notice shall be in effect so long as 2 of the last 4 consecutive samples exceed the limit of the standard and shall inform the person that an additional sample will be taken within 14 days of the receipt of such notice, but not before the lapse of three days. It shall further state that when the standard is in violated by 3 of the last 5 bacteria counts, coliform determinations, or cooling temperatures, the plant shall discontinue manufacturing the specific product involved until the cause of the violation is corrected. Court action may also be instituted. An inspector may send the establishment a “notice of intent to suspend permit”, a “notice of seizure” or a “frozen desserts warning notice”.

Reg. 285.405.21. Personal Health.

The plant management shall take all reasonable measures and precautions to assure the following:

(a) No person affected with a communicable disease or while a carrier of such disease shall work at an ice cream plant in a capacity which brings them in contact with the processing, handling or storage of frozen desserts, or the containers, equipment and utensils.

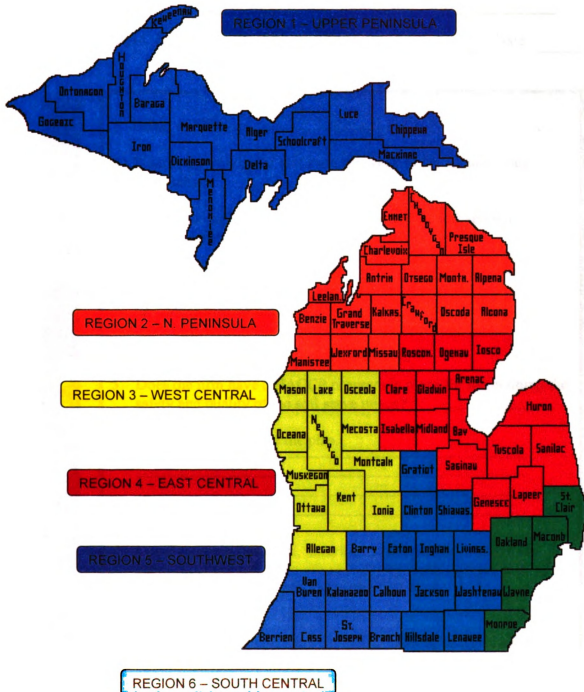
(b) No person shall be employed in an ice cream plant that is suspected of having any diseases in a communicable form or of being a carrier of such disease.

Reg. 285.405.23. Vehicles.

A vehicleused for the transportation of mix, frozen desserts and their ingredients, shall be constructed and operated so as to protect its contents from heat, sun and contamination. The vehicle shall be kept clean, and no substance capable of contaminating mix, frozen desserts and their ingredients, shall be transported therein.

Where applicable, an ice cream plant shall provide an area for unloading vehicles that can be maintained in a sanitary condition. This area should be surfaced with concrete or blacktop.

Appendix 3.4. Map of Regional Offices



Appendix 3.5. Soft Serve Machines

Survey of Sanitary Practices

Type of Establishment: _____ Est. ID#: _____

Jurisdiction: MDA ☐ LHD ☐ County: _____ Date: _____

Soft Serve Mix

1. Brand of Mix: _____
2. What is the volume of mix used per week in the summer (peak season) Gallons: _____
3. On the average, how long does one "batch" of soft serve mix remain in the machine?
 - ☐ Less than 24 hours
 - ☐ Between 24-48 hours
 - ☐ More than 48 hours
4. Is the re-run used? _____
5. Does the firm have a HACCP program in place for maintaining the safety and quality of the soft serve mixes? _____
6. If yes, briefly describe the plan.

7. Using a simple flowchart, describe the protocol for storage and handling of the soft serve mixes including holding times and temperatures. *Please place flowchart on back.*
8. Briefly describe the protocol for storage and handling of cones, cups, spoons, etc.

1. Describe the protocol for the cleaning/sanitizing of the soft serve machines.

Check all boxes that apply:

How Often?

	Daily	Once/wk	Twice /wk	Other
☐ Clean in Place	☐	☐	☐	_____
☐ Complete Breakdown	☐	☐	☐	_____
☐ Partial Breakdown	☐	☐	☐	_____

2. Are the above methods in compliance with the manufacturer's recommendations?

3. Name and type of cleaning product used _____

4. Type of Sanitizer _____
 Active Ingredient _____
 Concentration of Sanitizer _____

5. Temperature of water used during cleaning _____

6. Are cleaning procedures readily accessible? Yes ____ No ____

7. Type of Utensil Sink: Two-compartment ☐ Three-compartment ☐

8. How/where are the cleaning materials (brushes, buckets) stored?
 Do you see a problem with where the cleaning materials are stored? Are they adequately maintained?

9. Last day the machine was cleaned prior to sampling? _____

10. Last day the machine was sanitized prior to sampling? _____

11. Water Source: Well: _____

Municipal: _____

12. Is the water source certified? _____

Employee Hygiene

1. What measures are taken to ensure adequate employee hygiene? Check if observed.

	Yes	No	Not Observed
Handwashing	☐	☐	☐
Nearest Hand sink is _____ feet away			
Gloves	☐	☐	☐
Hairnets or Covers	☐	☐	☐
Clean Garments	☐	☐	☐

Are gloves properly changed? _____

2. How often are employees encouraged to wash their hands? Describe employee-hand-washing procedure and indicate frequency.

After every operation _____ Once a day _____ Twice a day _____ Other _____

Operation of Equipment

1. Make & Model of Soft Serve Machine: _____ Record temp. Indicated on machine: _____

2. How many days a week does the machine run? _____

3. In what area of the establishment is the machine located?

- ☐ Employee service area
- ☐ Customer self serve

4. Number of employees operating the machine during a work shift? _____

5. Do the employees have dedicated job duties for the soft serve service? _____

6. Is there any other food/non-food operation near the soft serve machine that could be a possible source of cross-contamination? Explain. _____

Recordkeeping

1. Are there accurate record keeping procedures in place? _____

2. What types of activities are logged? (temperature, cleaning, etc.)

Inspector's Evaluation

1. How do you rate the following about this establishment's soft serve practices?

	P	M	A	G	N*
a. Cleaning & Sanitation	☐	☐	☐	☐	☐
b. Employee Hygiene	☐	☐	☐	☐	☐
c. Equipment use & maint.	☐	☐	☐	☐	☐
d. Compliance w/GMP's	☐	☐	☐	☐	☐
e. Soft Serve Mix Handling	☐	☐	☐	☐	☐
f. Record-keeping	☐	☐	☐	☐	☐
g. Knowledge of PIC	☐	☐	☐	☐	☐

* P = Poor
M = Marginal
A = Adequate
G = Good
N = No observation

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