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CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

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Hazards & Controls Guide For Dairy Foods HACCP

Guidance for Processors
Version 1.1 June 16, 2006

Table of Contents

I. Introduction

A. Status

This Hazards and Controls Guide represents the National Conference on Interstate Milk Shipments (NCIMS) perspective on identifying and evaluating potential hazards in milk and milk products and their control. It is designed to assist processors in the development of Hazard Analysis Critical Control Point (HACCP) systems to satisfy the requirements of the NCIMS HACCP alternative to the traditional regulatory system for Grade A dairy products that are regulated by the states under the NCIMS milk safety system. The guide should also be useful to State Regulators who are responsible for the evaluating the completeness of a plants hazard analysis.

This Hazards and Controls Guide provides a framework for answering some of the questions to be considered when conducting a hazard analysis for the processing of milk and milk products.

This guide has been separated into two parts. The first part provides background information that can be useful in understanding the basic food safety concerns and goals to be addressed by the hazard analysis. The second part of the hazard guide is an evaluation of specific potential hazards associated with the processing of milk and milk products. It is also divided into two major sections. The first section identifies many potential food safety hazards associated with ingredients and packaging materials. In the second section, a "unit operations" approach has been used to identify food safety potential hazards which may be associated with processing.

HACCP, as it relates to the NCIMS HACCP alternative, is a food safety system whose design is based on practical experience and the scientific understanding of the potential hazards associated with various types of milk and milk products. References to the available scientific literature can be found throughout this document. A list of references can be found at the end of this guide.

B. Purpose

The purpose of this guidance is to assist you in the development of a written HACCP program, as defined by the NCIMS Voluntary HACCP System. You will find information in this guidance that will help you identify hazards that may potentially occur in your products and help you identify and use methods of controlling and preventing hazards. This guidance is also intended to serve as a tool for Federal and State regulatory officials in the evaluation of HACCP systems for dairy products.

To help understand some key aspects of the NCIMS Voluntary HACCP System and plan how you will initiate your HACCP activities, we have included information on some other important aspects of the Dairy HACCP System.

C. Comparison with the FDA Juice HACCP Regulations

The following table is provided to dairy processors as a visual comparison of the FDA Juice HACCP regulations and the NCIMS Voluntary Dairy System.

Requirements	FDA Juice HACCP	NCIMS HACCP
Regulation Implementation Dates:	1/22/02 Large Business(>500 employees)1/21/03 for Small Business(<500 employees)1/20/04 for Very Small Businesses(<100 employees)	January 1, 2004
Prerequisite Program Concept	Yes(GMP & SSOP)	Yes (PP)
Written Sanitation Standard Operating Procedure (SSOP) or Required PP	No	Yes
Sanitation Monitoring & Documentation(SSOP) or Required PP	Yes(8 elements)	Yes (8 elements)
Perform Hazard Analysis	Yes	Yes
Written Hazard Analysis	Yes	Yes
Written HACCP Plan	Yes	Yes
Written Corrective Action Plan Required:	Yes	Yes
HACCP Plan shall be signed and dated	Yes,updated annually	Yes
Plan RevalidationUpon plan development	Yes, at least once within 12 months of implementation	Yes
Upon any change that affect ingredients, process, hazard analysis or HACCP Plan	Yes	Yes
At least annually	Yes	Yes
Regulator Consumer Complaint Record Access	No	No
Maintain Customer Complaint Summary	Yes	Yes
Monitoring & Corrective Action Records Review	Within 7 days	No minimum specified, appropriate to records being kept
Required Info on Records		Yes
Name & LocationDate & Time	Yes (if more than 1 location)Yes	Yes
Monitor's Initials or Signature	Yes, where appropriate	Yes
ID of product & Code	Yes, where appropriate	Yes

Requirements	FDA Juice HACCP	NCIMS HACCP
Record Retention	1 year after the production of the product	At least 1 year after the date that such products were prepared.
Record Retention	2 years for frozen, preserved or shelf stable, or the shelf life of the product, whichever is greater.	In the case of frozen, preserved or shelf stable products 2 years or the shelf life of the product whichever is greater, after the date that the products were prepared unless longer retention time is required by other regulations.
Industry Training (HACCP plan developers, validators and record reviewers) or equivalent experience	Yes(Juice HACCP Core Curriculum)	YES(NCIMS Dairy HACCP Core Curriculum)
Confidentiality	Yes, within the limits of FOIA	Not Addressed
Copying Records	Yes	Not Addressed
Electronic Records	Yes	Yes
5-Log Pathogen Reduction Performance Standard	Yes	Mandatory CCP for pasteurization
LACF or One Step Thermally Processed Shelf-Stable Juice or Juice Concentrates	Exempt from the 5-log performance standard. Other hazards must be controlled. Shelf-stable and concentrate processors must include a copy of their thermal process in their written hazard analysis. Must be packaged in final form under single roof or 5-log needs to be done.	Hazards addressed as critical factors by process authority are not required to be addressed in the HACCP Plan Summary Table

D. Scope and Limitations

This guide addresses development of a product flow diagram, description of the product, hazard identification and hazard evaluation. It is not intended to provide examples for development of prerequisite programs, formation of the HACCP team, product distribution, risk analysis, etc.

Prior to conducting the hazard analysis, the HACCP team must complete the following preliminary steps:

1. Develop a product description;
2. Develop and verify a process flow diagram
3. Describe the intended use and distribution parameters.

II. Terms and Definitions

A. **AUDIT:** An evaluation of the entire milk plant, receiving station or transfer station facility and NCIMS HACCP System to ensure compliance with the NCIMS HACCP System and other NCIMS regulatory requirements.

B. **Centralized Deviation Log:** A centralized log or file identifying data detailing any deviation of critical limits and the corrective actions taken as required in Appendix K of the Pasteurized Milk Ordinance (PMO).

C. **Control:** To manage the conditions of an operation to maintain compliance with established criteria. The state where correct procedures are being followed and criteria are being met.

D. **Control Measure:** Any action or activity that can be used to prevent, eliminate or reduce a significant hazard that is managed at a Critical Control Point.

E. **Corrective Action:** Procedures followed when a deviation occurs.

F. **Critical Control Point (CCP):** A step at which control can be applied and is essential to prevent or eliminate a milk or milk product safety hazard or reduce it to an acceptable level.

G. **Critical Limit (CL):** A maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a milk or milk product safety hazard.

H. **CRITICAL LISTING ELEMENT (CLE):** An item on the MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT identified with a double star (**). The marking of a CLE by a State Rating Officer or FDA auditor, indicates a condition that constitutes a major dysfunction likely to result in a potential compromise to milk or milk product safety, or that violate NCIMS requirements regarding drug residue testing and trace back or raw milk sources, whereby a listing may be denied or withdrawn.

I. **DAIRY HACCP CORE CURRICULUM:** The core curriculum consists of:

   1. Basic HACCP training; plus
   2. An orientation to the requirements of the NCIMS HACCP Program

J. **DEFICIENCY:** An element inadequate or missing from the requirements of the HACCP System or Appendix K of the PMO.

K. **DEVIATION:** A failure to meet a Critical Limit.

L. **FOOD ALLERGENS:** Are proteins in foods that are capable of inducing an allergic reaction or response in some individuals. There is specific consensus that the following foods account for more than 90% of all food allergies: peanuts, soybeans, milk, eggs, fish, crustaceans, tree nuts, and wheat.

M. **HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP):** A Systematic approach to the identification, evaluation, and control of significant milk or milk product safety hazards.

N. **HACCP PLAN:** The written document, which is based upon the principles of HACCP and delineates the procedures to be followed.

O. **HACCP SYSTEM:** The implemented HACCP Plant and Prerequisite Program, including other applicable NCIMS requirements.

P. **HACCP TEAM:** The group of people who are responsible for developing, implementing, and maintaining the HACCP system.

Q. **HAZARD:** A biological, chemical, or physical agent that is reasonable likely to cause illness or injury in the absence of its control.

R. **HAZARD ANALYSIS:** The process of collecting and evaluating information on hazards associated with the milk under consideration, to decide which are reasonable likely to occur and must be addressed in the HACCP Plan.

S. **MONITOR:** To conduct a planned sequence of observations or measurements to assess that a CCP is under control or to assess the conditions and practices of all required Prerequisite Programs.

T. **NON-CONFORMITY:** A failure to meet specified requirements of the HACCP System as described in Appendix K of the PMO.

U. **POTENTIAL HAZARD:** Any hazard to be evaluated by the hazard analysis.

V. **PREREQUISITE PROGRAMS (PP's):** Procedures, including Good Manufacturing Practices (GMP's), which address operational conditions that provide the foundation for the HACCP System. The required PP's specified in Appendix K of the PMO, are something called Sanitary Standard Operating Procedures (SSOP's) in other HACCP Systems.

W. **VALIDATION:** The element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP Plan, when properly implemented, will effectively control the hazards.

X. **VERIFICATION:** Those activities, other than monitoring, that determine the validity of the HACCP Plan and that the HACCP System is operating according to the plan.

III. Overview of the NCIMS HACCP Program

The following section is a brief synopsis of Appendix K of the PMO detailing the requirements of the NCIMS alternative HACCP program. For a complete understanding of the NCIMS HACCP Alternative, please refer to the most recent version of the PMO.

A. Voluntary Nature of the Program

The NCIMS HACCP Program alternative to the traditional inspection system is a voluntary system as described in the applicable sections and Appendices of the Pasteurized Milk Ordinance (PMO). No plant, receiving station or transfer station may participate in the voluntary NCIMS HACCP Program unless the Regulatory Agency responsible for the oversight of the facility agrees to participate with the dairy plant(s), receiving station(s) and transfer station(s) in the NCIMS HACCP Program. Both parties must provide written commitment to each other that the necessary resources to support participation in the NCIMS HACCP Program will be made available. Management responsible for both the State and plant, receiving station or transfer station must be willing to provide the resources needed to develop and implement a successful HACCP System.

B. Key Requirements of the NCIMS HACCP Program

1. Specialized Training in NCIMS HACCP Principles Required

   HACCP training for industry and regulatory personnel will be based on the current "Hazard Analysis and Critical Control Point Principles and Application Guidelines" of NACMCF, the current FDA HACCP recommendations, and the regulatory requirements of Appendix K and related Sections of the PMO.

   Regulatory Agency personnel responsible for the evaluation, licensing and regulatory audits of facilities using the NCIMS HACCP Program will have equivalent training to the training required to perform traditional NCIMS functions. They shall also have specialized training in conducting HACCP System audits.

Industry, State and Federal regulatory and listing personnel should be trained together.

a. HACCP Training

- Core Curriculum. The Dairy HACCP Core curriculum consists of:
    1. Basic HACCP training; plus
    2. An orientation to the requirements of the NCIMS HACCP Program.

Basic HACCP training consists of instruction in the application of the NACMCF Principles of HACCP to Food Safety. This training includes practical exercises in conducting a hazard analysis and evaluating potential hazards; in writing a HACCP Plan, and in the validation of the plan. It should be taught by experienced instructors.

The orientation component ideally is coupled with the basic HACCP training, but can be taught separately. The content of the orientation will be conducted under the guidance of the NCIMS. It is intended to familiarize industry and regulatory personnel with specific dairy HACCP concerns and the regulatory requirements under the NCIMS HACCP Program. It is to be taught by instructors experienced in the application of HACCP under the NCIMS HACCP Program.

The industry individual(s) performing the functions listed in Part 2 of this Section shall have successfully completed appropriate training in the application of HACCP principles to milk and milk product processing at least equivalent to that received under the Dairy HACCP Core Curriculum. Alternatively, job experience may qualify an individual to perform these functions if the experience has provided knowledge at least equivalent to that provided through the standardized curriculum.

- Industry Personnel: Only industry individuals who have met the requirements of Part 1 of Appendix K Section III of the Pasteurized Milk Ordinance (PMO) - Training and Standardization, shall be responsible for the following functions.
    a. Developing the hazard analysis, including delineating control measures as required.
    b. Developing a HACCP Plan that is appropriate for the specific milk plant, receiving station or transfer station, in order to meet these requirements.
    c. Validating and modifying the HACCP Plan in accordance with the corrective action procedures and the validation activities as specified; and
    d. Performing required HACCP Plan records reviews.
- Regulatory Personnel: Regulatory personnel performing HACCP audits shall have successfully completed the appropriate training in the application of HACCP principles for milk and milk product processing at least equivalent to that received under the Dairy HACCP Core Curriculum.

2. Recordkeeping and Electronic Records

. Required Records: It is essential that plants, receiving stations and transfer stations use consistent terminology to identify each piece of equipment, record, document, or other program throughout their written HACCP System. A milk plant, receiving station or transfer station shall maintain the following records documenting the milk plant, receiving station or transfer station's HACCP System:

- A brief description of the monitoring and correction records shall be written documenting the ongoing application of the prerequisite program.
- A hazard analysis shall be written

- The written HACCP Plan
- Required HACCP documents and forms specified in a.1) through 3) of this Section shall be dated or identified with a version number. Each page shall be marked with a new date or version number whenever that page is updated.
- A Table of Contents and centralized list of the HACCP program records, by title, documenting the ongoing application of the HACCP System shall be maintained and provided for review.
- A document change log shall be kept.
- Records documenting the ongoing application of the HACCP Plan that include:
    1. Monitoring of Critical Control Points and their Critical Limits, including the recording of actual times, temperatures, or other measurements, as prescribed in the plant's receiving station's or transfer station's HACCP Plan;
        a. Corrective actions, including all actions taken in response to a deviation.
        b. A centralized deviation log is required; and
        c. Plan validation dates.
        d. Records documenting verification and validation of the HACCP System, including the HACCP Plan, hazard analysis and PP's.
    2. General Requirements: Records required include:
        a. The identity and location of the milk plant, receiving station or transfer station;
        b. The date and time of the activity that the record reflects;
        c. The signature or initials of the person(s) performing the operation or creating the record; and
        d. Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed. The records shall contain the actual values and observations obtained during monitoring.
    3. Documentation:
        a. The records in paragraphs a.1) through 3) of this Section shall be signed and dated by the most responsible individual onsite at the milk plant, receiving station or transfer station. This signature shall signify that these records have been accepted by the firm.
        b. The records in paragraphs a.1) through 3) of this Section shall be signed and dated:
            1. Upon initial acceptance;
            2. Upon any modification; and
            3. Upon verification & validation in accordance with requirements cited above
            4. Record Retention:
        c. All records, required by this section, shall be retained at the milk plant, receiving station or transfer station for perishable or refrigerated products, for at least one (1) year after the date that such products were prepared, and in the case of frozen, preserved, or shelf-stable products, for two (2) years after the date that the products were prepared or the shelf-life of the product, whichever is greater, unless longer retention time is required by other regulations.
        d. Records that relate to the adequacy of equipment or processes used, such as commissioning or process validation records, including the results of scientific studies and evaluations, shall be retained at the milk plant, receiving station or

transfer station facility for at least two (2) years after the date that the milk plant, receiving station or transfer station last used such equipment or process.

e. Off-site storage of processing records is permitted after six (6) months following the date that the monitoring occurred, if such records can be retrieved and provided on-site within twenty-four (24) hours of a requires for official review. Electronic records are considered to be on-site if they are accessible from an on-site location.

IV. Prerequisite Programs

The following required Prerequisite Programs shall have a brief written description or checklist that the prerequisite programs can be audited against to ensure compliance. Prerequisite Programs shall include procedures that can be monitored, records that specify what is monitored, and how often it will be monitored.

A. Required Prerequisite Programs

1. Safety of the water that comes into contact with milk or milk products or product contact surfaces, including steam and ice
2. Condition and cleanliness of equipment product contact surface.
3. Prevention of cross-contamination from unsanitary objects and or practices to milk or milk products or product contact surfaces, packaging material and other food contact surfaces, including utensils, gloves, outer garments, etc., and from raw product to processed product;
4. Maintenance of hand washing, hand sanitizing and toilet facilities.
5. Protection of milk or milk product, packaging material, and product contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate and other chemical, physical and biological contaminants;
6. Proper labeling, storage and use of toxic compounds;
7. Control of employee health conditions, including employee exposure to high risk situations, that could result in the microbiological contamination of milk or milk products, package materials, and product contact surfaces; and
8. Exclusion of pests.
9. Required Programs (PP's) used as justification in the Hazard Analysis

In addition to the required PP's specified above, any other prerequisite programs that are being relied upon in the Hazard Analysis to reduce the likelihood of occurrence of hazards such that they are not reasonably likely to occur must also be monitored, audited, and documented as required PP's.

B. Acceptable level of protection by prerequisite programs

Prior to the implementation of a HACCP Plan, there is a requirement for dairy plants, receiving stations and transfer stations to develop, document and implement written PP's. PP's provide the basic environment and operating conditions that are necessary for the production of safe, wholesome food. Many of the conditions and practices are specified in Federal and State regulations and guidelines.

HACCP is not a stand-alone program, but is part of a larger control system. PP's are the universal procedures used to control the conditions of the plant environment that contribute to the overall safety of the product. They represent the sum of programs, practices and procedures that must be applied to produce and distribute safe products in a clean, sanitary environment. They differ from CCP's in that they are basic sanitation programs that reduce the potential occurrence of a milk or milk product safety hazard.

Frequently, both HACCP Plan CCP's and PP's control measures are necessary to control a food safety hazard.

HACCP may be implemented only in a facility that is constructed and operated to provide a sanitary environment. Milk plant, receiving station or transfer station premises, building construction, maintenance, and housekeeping shall be maintained in a manner sufficient to provide such an environment. These factors shall be controlled by effective plant, receiving station or transfer station programs or by PP's, as the plant, receiving station or transfer station chooses.

PPs are the universal procedures used to control the condition of the plant environment that contribute to the overall safety of the product. They represent the sum of programs, practices and procedures that must be applied to produce and distribute safe products in a clean, sanitary environment. They differ from CCP's in that they are basic sanitation programs that reduce the potential occurrence of a food safety hazard. Frequently, both HACCP Plan CCP's and PP's control measures are necessary to control a food safety hazard. The exact set of PP's will vary since their application is product and process specific. The existence and effectiveness of PP's should be assessed during the design and implementation of each HACCP Plan. PP's should be documented and regularly audited. An audit review consists of verifying that the company has a program implemented that indicates how the company monitors and controls each of the PP's. PP's are established and managed separately from the HACCP Plan.

V. Hazard Analysis

A. Preparing for a Hazard Analysis - Five Preliminary Steps

Although not required by the NCIMS HACCP alternative, the 5 preliminary steps of HACCP as outlined by the National Advisory Committee of Microbiological Criteria for Foods (NACMCF) will help you in conducting your hazard analysis and developing your HACCP plan, and will prove valuable for other HACCP functions. The steps you should follow are:

1. **Step 1** Assemble a HACCP Team.
2. **Step 2** Describe the food and its distribution.
3. **Step 3** Identify the intended use and consumers of the food.
4. **Step 4** Develop a flow diagram that describes the process.
5. **Step 5** Verify the accuracy of the flow diagram.

For more information, see the NACMCF publication "*Hazard Analysis and Critical Control Point Principles and Application Guidelines*," Journal of Food Protection, *Vol. 61, No. 9, pp. 1246-1259 (1998)*, (the "*HACCP Principles and Guidelines*" publication).

B. Overview of the Hazard Analysis

1. Description

   The dairy hazard analysis is a process of collecting and evaluating information on hazards associated with dairy products, to determine which hazards are reasonably likely to occur and must be addressed in a HACCP Plan. Under the dairy HACCP alternative, you are required to produce, for each type of Grade A dairy product you process, a written hazard analysis to determine whether there are food hazards that are reasonably likely to occur and to identify measures that you can apply to control those hazards. The dairy alternative requires a written hazard analysis for each type

of dairy product unless different types of dairy products have identical hazards and control measures that can be combined into one hazard analysis.

Do not conduct the hazard analysis until the prerequisite programs have been developed, implemented and documented. This Hazard and Controls Guide may be used to aid in constructing and evaluating those prerequisite programs to be considered in the hazard analysis. The hazard analysis may point out the need for additional prerequisites.

2. Relevance to HACCP Plan and Prerequisite Programs

All processors that decide to participate in the NCIMS HACCP alternative are required to prepare a written hazard analysis. If you determine that any hazard is "reasonably likely to occur" in a particular product, you must control that hazard in the product by applying control measures as part of a properly designed and implemented HACCP plan, except that some hazards can be managed under your PP's. If you determine that no hazards are "reasonably likely to occur," you are not required to develop a HACCP Plan, but you must establish and implement PP's. Your PP monitoring and correction records and your hazard analysis are still subject to the record keeping and official record review requirements. Under the NCIMS HACCP system, pasteurization must always be managed as a CCP. Useful examples of both batch and continuous flow pasteurization can be found in the PMO, Appendix H.

3. Developed by HACCP-trained Employee or Consultant

Your hazard analysis must be developed by an appropriately trained individual (or individuals) based on the Core Curriculum or comparable experience, as specified in the NCIMS HACCP Alternative. This person may be your employee or a hired outside expert.

4. Basic Steps of the Hazard Analysis
   a. Identify All Potential Hazards
      1. Biological Hazards
         a. Bacteria

The vegetative pathogens of concern associated with milk and processed milk products are *Salmonella* spp., *L. monocytogenes*, enterohemorrhagic *E. coli*, and *Campylobacter jejuni*. Spore forming bacteria of concern include C. *botulinum*, and *B. cereus*. All these organisms occur in raw milk and most have been associated with illness outbreaks in milk products. These pathogens in milk have the potential for causing severe adverse health effects with the very young, the elderly, and immune-compromised individuals being at the greatest risk. While enteric pathogens have been implicated as the cause of most food-borne illness outbreaks associated with milk products, these are not the only organisms that could occur in milk.

The potential of hazards associated with toxin-producing bacteria and spore-formers should be evaluated in processing circumstances where unusual conditions exist. In the case of toxin-producers such as *S. aureus* and *B. cereus*, these organisms must multiply to significant levels to produce sufficient toxin to be a public health risk. This is a concern when levels reach above 10^6 or greater. However, the rule of thumb for temperature control of a food is that controls should be implemented when conditions indicate that there might be a 3- log increase in *S. aureus* or *B. cereus*. [1]

Validation of processes requiring measurement of the production of enterotoxin is expensive and difficult. However, during the 2005 NCIMS, the NCIMS Scientific Committee reviewed and accepted some useful guidelines that have been actually incorporated into the PMO.

These guidelines, below, should be construed generally as "safe harbor" when conducting hazard analyses and validating control measures:

- Balance tanks or surge tanks with an average retention time of one hour or less may be safely operated for up to 24 hours regardless of product temperature in both pasteurized and unpasteurized dairy products.
- Pasteurized milk and milk products to be condensed and/or dried, can be maintained at a temperature of 10C (50F) or less until pasteurized.
- Tanks used to hold pasteurized milk and milk products to be condensed or dried that are operated above 10C (50F) must be emptied, cleaned and sanitized after each 6 hours or less.
- All whey and whey products for condensing and/or drying can be safely maintained at a temperature of 7C (45F) or less; or 57C (135F) or greater.
- Tanks used to hold whey and whey products between 7C (45F) and 57C (135F), must be emptied, cleaned and sanitized after each 4 hours or less. Except that, acid-type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below, can be safely held at any temperature.
- Crystallization of condensed whey and whey products may be accomplished without the formation of toxins if the whey or whey products being crystallized are cooled to 10C (50F) or less; within 72 hours of condensing including the filling and emptying time, unless filling occurs above 57C (135F), in which case, the 72 hour time period begins when the cooling is started.

Other properly validated times and temperatures that have been recognized by FDA and that are approved by the State Regulatory Agency may also be considered to be safe.

This guidance does not cover the hazards associated with the formation of *C. botulinum* toxin in milk products that are classified as shelf-stable acidified foods or low acid canned foods.

U.S. Food & Drug Administration
Center for Food Safety & Applied Nutrition
Foodbourne Pathogenic Microorganisms and Natural Toxins Handbook

Factors Affecting the Growth of Some Foodbourne Pathogens

Organism		Growth Temperature (°C)	Growth pH	Growth a_w
Salmonella spp.		6.5 - 47	4.5 - ?	> 0.95 [a]
Clostridium botulium	**A & B**	10 - 50	4.7 - 9	> 0.93
	Nonproteolytic B	5 - ?	(b)	NR [c]
	E	3.3 - 15 - 30	(b)	> 0.965
	F	4 - ?	(b)	NR [c]
Staphylococcus aureus		7 - 45	4.2 - 9.3	> 0.86
Campylobacter jejuni		25 - 42	5.5 - 8	NR
Yersinia enterocolitica		1 - 44	4.4 - 9	NR
Yersinia pseudotuberculosis		5 - 43	(b)	NR
Listeria monocytogenes		0 - 45	4.4 - 9.4	> 0.92 [d]
Vibrio cholerae O1		8 - 42	6 - 9.6	> 0.95
Vibrio cholerae non-O1		(b)	(b)	(b)
Vibrio parahaemolyticus		12.8 - 40	5 - 9.6	> 0.94
Clostridium perfringens		10 - 52	5.5 - 8	> 0.93
Bacillus cereus		10 - 49	4.9 - 9.3	> 0.95
Escherichia coli		2.5 - 45	4.6 - 9.5	> 0.935
Shigella spp.		> 8 - < 45	? - 9 - 11	NR
Streptococcus pyogenes		>10 - < 45	4.8 - < 9.2	NR

(a) For a genus as large as Salmonella, the a_w lower limit for species growth may vary, e.g., *S. Newport* = 0.941, *S. typhimurium* = 0.945.
(b) The value, though unreported, is probably close to other species of the genus.
(c) NR denotes that no reported value could be found, but for most vegetative cells, an a_w of > 0.95 would be expected.
(d) Updated values from the 1996 ICMSF Microorganisms in Foods 5: Characteristics of Microbiological Pathogens.
Most values taken from Microbial Survival in the Environment, E. Mitscherlich and E.H. Marth (eds.), Springer-Verlag, Berlin and Heidelberg, 1984. This is a valuable, recommended reference. [ISBN 3-540-13726-2 Springer-Verlag, Berlin, New York, Tokyo] [ISBN 0-387-13726-2 Springer-Verlag, Heidelberg, Berlin, Tokyo].

b. Viruses

Contamination of food by viruses, if it occurs, is most likely to be caused by contaminated water or an ill individual[2]. Contamination of milk by viruses is not likely to occur in a processing facility that controls employee health and hygiene conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces under its Prerequisite Programs (PP's).

2. Chemical Hazards

a. Undeclared food allergens in dairy products due to cross-contact from shared processing equipment.

Allergens, or proteins derived from allergenic foods, may be present in foods as the result of cross-contact during processing and handling. The term "cross-contact" describes the inadvertent introduction of an allergen into a product that would not intentionally contain that allergen as an ingredient.

Eight major foods or food groups--milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans-- account for 90 percent of food allergies. In addition, some food ingredients can cause food sensitivities in certain individuals. Certain ingredients which cause food sensitivities, such as sulfites, Yellow #5 (21 CFR 74.1705), and aspartame (21 CFR 172.804), require special labeling statements to alert consumers to their presence. Cross-contact is generally the result of environmental exposure during processing or handling, which may occur when multiple foods are produced in the same facility or on the same processing line, through poor re-work management or ineffective cleaning.

Cross-contact of foods with allergens has been shown to lead to allergic reactions in consumers on numerous occasions (Gern *et al.*, 1991; Jones *et al*., 1992; Yunginger *et al.*, 1983). Most cross-contact can be avoided by controlling the production environment.

Procedures to ensure that these ingredients of concern are properly identified on the label should be a part of the HACCP system. Dairy plants should implement label control as part of their allergen control program. This label control program includes verification that the label reflects the current formulation and the correct ingredient statement. Prerequisite Programs addressing product changeover(s), scheduling, and sanitation practices normally assist in managing products containing allergens or substances that cause food sensitivities.

The following references may prove useful in the area of allergen control:

1. This section of the FDA's Compliance Policy Guide Deals with Food Allergens
2. FDA Allergy Inspection Guide
3. Food Allergen Labeling and Consumer Protection Act of 2004
4. IDFA, IDFA's Dairy HACCP Plant Manual
5. Deibel, K., T. Trautman, T. DeBoom, W. H. Sveum, G. Dunaif, V. N. Scott, & D. T. Bernard. 1997. A Comprehensive Approach to Reducing the Risk of Allergens in Food. *Journal of Food Protection.* Vol. 60, No. 4: 436-441.

While not within the scope of the NCIMS Dairy product safety HACCP system, it is necessary for milk plants that manufacture juice or other food products using common equipment for both milk or milk products and these other foods to take precautions to prevent contamination of these foods with milk allergens.

b. Allergens and substances that cause food sensitivities added to dairy products as ingredients.

Allergens are not present in all products. Scheduling product changeovers and run matrices, labeling, and sanitation practices are suggested prerequisite programs used to manage products containing allergens. Some products (e.g., flavored bottled waters, cultured products of dairy-based beverages with juice) can contain ingredients such as soy protein or preservatives, such as sulfites, that can cause allergic or food intolerance reactions in sensitive individuals. The presence of any ingredient must be declared on the label in accordance with the food labeling regulations in 21 CFR Part 101. Programs to ensure that the proper labels are used should be part of the PP within the HACCP Program. Ingredient controls should be implemented for the big eight allergens and ingredients which cause food sensitivities.

c. Cleaning and Sanitizing Chemical Residues

Cleaning chemical and sanitizers are used widely in dairy plants. The proper use of cleaning and sanitizing compounds renders the risk of contamination a hazard not likely to occur when managed by a properly implemented prerequisite program. Numerous U.S. government regulatory programs address aspects of cleaning and / or sanitizer usage. Cleaning and sanitizing chemicals should be used in accordance with the manufacturer's instructions and recommendations. These chemicals must be used at proper concentrations for effective use and in the case of sanitizers for their no-rinse properties. Proper cautions must be taken to fully drain all processing equipment of cleaners and sanitizers prior to use.

During processing, pipelines and equipment used to contain or conduct milk products shall be effectively separated from tanks or circuits containing cleaning and / or sanitizing solutions. Proper guidelines for proper chemical and product separation can be found in the PMO section 15p (B).

d. Agricultural Chemical Residues (Chemicals used in animal health and crop production).

Pesticides are used widely to treat (e.g., for insect control) fruits, vegetables, grains and other foods, and may be present in small amounts as residues on these foods. Numerous U.S. government regulatory programs address aspects of pesticide usage. Experience in

the U.S. has demonstrated that domestically grown fruits and vegetables have a high level of compliance with U.S. pesticide tolerance regulations and that the occurrence of unlawful pesticide residues in food is likely to be infrequent and unlikely to have a severe public health impact. Based on current regulatory programs and FDA market basket surveys, pesticide residues do not present food hazard likely to occur in dairy products and do not need to be addressed in the hazard analysis.

Animal drug residues are present at low levels in a very low percentage of raw milk received at milk plants in the U.S. These residues are regulated under PMO Appendix N for both the traditional and the HACCP alternative systems.

Information in recent National Milk Drug Residue Database Reports showed that less than one-tenth of 1 percent of milk samples from bulk milk pick-up tankers (the form in which raw milk is received at milk plants) tested positive for drug residues last year. The report contains data on samples and tests conducted during fiscal year 2003 (October 1, 2002 - September 30, 2003). During this period, 4,382,974 total samples were analyzed for drug resides. Samples included bulk milk pickup tankers (78 percent, or 3,571,834 samples), producer milk (18 percent), pasteurized products (2 percent), and other (2 percent). Fifty-three methods were used to analyze these samples for residues. The most recent National Drug Residue data base should be consulted to obtain the latest information on drug residues in milk.

e. Over Fortification of Pasteurized Fluid Milk with Vitamin A and D.

Jacobus et al[3] reported that "Vitamin D has been added to milk in the United States since the 1930's." In an article published in the New England Journal of Medicine, Holick[3] discusses vitamin D intoxication caused by drinking milk fortified with excess vitamin D over an extended period of time that led to questions about the level of vitamin D in milk. Jacobus[3] also reported an analysis of the amount of vitamin D, in milk from a dairy implicated in an intoxication that revealed concentrations that ranged from undetectable to as high as 232,565 IU per quart. Vitamin A can also be toxic if consumed at extremely high levels (see PMO Appendix O).

f. Mycotoxins

In many parts of the country mycotoxins are not normally a potential hazard. However in those milk plants that receive milk from an area that has a history of aflatoxin contaminated feed or if weather conditions are appropriate for mycotoxin growth, it should be considered.

3. Physical Hazards

Foreign material includes such things as metal, glass, or plastic fragments or any other material that might cause injury or present a choking hazard. Consideration of potential hazards associated with metal fragments should be a part of the hazard analysis when metal fatigue, wear of metal parts, or metal to metal contact can occur in processing equipment. See FDA compliance policy guide chapter 5 sub 555 section 555.425 (Adulteration involving hard or sharp objects March 1999).

VI. The HACCP Hazard Decision Process

a. Evaluate All Potential Hazards

Evaluate each of the potential hazards (from Step 1) by assessing the likelihood of occurrence and the severity of health consequences associated with the potential hazard. For instance:

Although potential hazards that may be introduced into food through pests in your facility may be of low to moderate severity, they are unlikely to occur if your facility carries out an effective pest control program as part of its required PP's.

b. Determine If Potential Hazards Will Require Controls in Your HACCP Plan.

c. Potential Hazards "Reasonably Likely to Occur"

If a potential hazard has a severe, acute public health impact, that hazard is reasonably likely to occur, even at an extremely low frequency of occurrence, and thus should be identified as a hazard that is reasonably likely to occur (e.g., pathogenic microorganisms or injury caused by ingestion of metal fragments). Milk containing enteric microbial pathogens such as *E. coli* O157:H7 and various Salmonella species have caused serious food borne illness outbreaks.

Those hazards which are determined to be "reasonably likely to occur" in the hazard analysis must be controlled by a CCP.

d. Potential Hazards "Not Reasonably Likely to Occur"

The determination that a potential hazard is "not reasonably likely to occur" is made in the hazard analysis and takes into account existing PP's, GMP's, etc. This determination is based on the unique conditions at the plant making the hazard analysis.

If conditions in the plant change, the hazard needs to be reevaluated. If the hazard analysis is performed correctly, based on the individual conditions at the milk plant and if the HACCP system is validated at least once each year as required, these types of determinations will be more likely to be sustained during regulatory and listing audits of the plants HACCP system.

e. Hazards Related to Facility Sanitation

When the hazard analysis identifies hazards classified as hazards "not reasonably likely to occur," they should be managed by the PP's or GMP's.

HACCP may be implemented only in a facility that is constructed and operated to provide a sanitary environment. Milk plant premises, building construction, maintenance and housekeeping shall be maintained in a manner sufficient to provide such an environment. These factors shall be controlled by effective plant, receiving station or transfer station programs or by PP's, as plant, receiving station or transfer station chooses.

f. Controls for Potential Hazards Arising from Food Contact Surfaces

Hazards can occur in milk due to unsanitary food contact surfaces that can contaminate milk with pathogens or with residual allergens from product processed on the equipment in prior runs that can cause allergic reactions in sensitive individuals. Hazards that arise from unsanitary food contact surfaces have the potential to affect the safety of a milk product because they arise from points within the process and not from general conditions within the facility. Control of these hazards may be accomplished by the use of Prerequisite Programs. For example, an appropriate PP could be to establish a procedure for cleaning equipment with a cleaning solution, e.g., a pre-rinse followed by a caustic wash followed by a rinse. The procedure could include maintaining a log of which foods, e.g., juice, eggnog, soy drinks, were processed on the equipment, the sequence in which the foods were processed, and how/when the equipment was cleaned. The operator could check that log prior to starting any production run for milk. The procedure could provide that the equipment would not be used for milk until the prescribed cleaning procedure was carried out, recorded in the log, and the equipment was visually checked for cleanliness.

g. Identify Control Measures and CCPs.

h. HACCP Control Measures

Under the voluntary HACCP alternative, you are required to implement HACCP control measures if you determine in your hazard analysis that a food hazard is reasonably likely to occur in your dairy product. Examples of HACCP control measures used in the processing of dairy products include measures carried out at CCPs specified in a HACCP plan such as pasteurization of dairy products for the elimination or reduce to an acceptable level of micobiological pathogens

1. Control Measures for Biological Hazards

   The pasteurization of milk is the most effective single control measure for protecting consumers from pathogenic microorganisms. Therefore, the pasteurization process is a required control measure for pathogens.

2. Control Measures for Chemical Hazards

   When a chemical hazard is identified that is reasonably likely to occur in milk, a control measure needs to be established in the HACCP plan for that hazard. Chemical hazards that are most commonly identified in the hazard analysis include equipment cleaning and sanitizing chemicals, animal drug residues and over addition of food grade vitamins. The likelihood of occurrence of each of these hazards will vary according to the plant and its procedures. If control measures are warranted for any of these hazards they are addressed below.

   a. Equipment Cleaning and sanitizing chemicals - Control of his hazard, if deemed "reasonably likely to occur" must address establishing CCPs at all product storage tanks, all processing equipment that is not self-draining, and at each CIP system. In the case of product storage tanks and non-draining processing equipment, the critical limit will be presence of no cleaning or sanitizing chemicals prior to use. The monitoring record for this CCP can be manual check logs, electronic sensor logs, etc. For each CIP system, the critical limits will be the measurements used for controlling cleaning and sanitizing chemical concentration. The monitoring record will usually be a graph or computer-generated CIP monitoring document.
   b. Animal drug residues - This chemical hazard, if deemed "reasonably likely to occur", will be controlled through a CCP at raw milk receiving with the critical limit being the no detectable

animal drug residue present in the raw milk. The monitoring record for this CCP will be the animal drug residue testing record maintained by the on-site industry laboratory.

c. Food-grade vitamins - This chemical hazard, if deemed "reasonably likely to occur" will be controlled by a CCP at the point of injection or addition into the milk stream. The critical limit will be the FDA-established levels of vitamin A and D for fluid drinking milk and possible the actual measurement of the vitamin addition via pump speed or volume per batch. Monitoring will be based on manual logs capturing the actual measurements of vitamin addition (pump speed recorded at least daily, volume of addition per batch, etc.), as well as the theoretical versus actual vitamin reconciliation records required by the PMO.

3. Control Measures for Physical Hazards

   The necessity for control measures for any potential physical hazard is dependent upon a conclusion from the hazard analysis that the specific hazard is reasonably likely to occur in the milk product. FDA has issued a Compliance Policy Guide (CPG Section 555.425) describing when hard or sharp foreign objects in food, such as glass or metal fragments, could pose a health hazard. If it is reasonably likely that the milk product may become contaminated with hard or sharp foreign objects that meet the criteria in this CPG, you should regard the object as a potential hazard in the milk.

i. Other Interventions

The hazard analysis may identify hazards that can be eliminated or reduced to hazards not likely to occur if adequate changes are made in the plant facility or its environment, by equipment replacement or modifications, or adjustments to operating procedures. Engineering the hazard out of the process is usually the best alternative to eliminate or reduce the likelihood of occurrence.

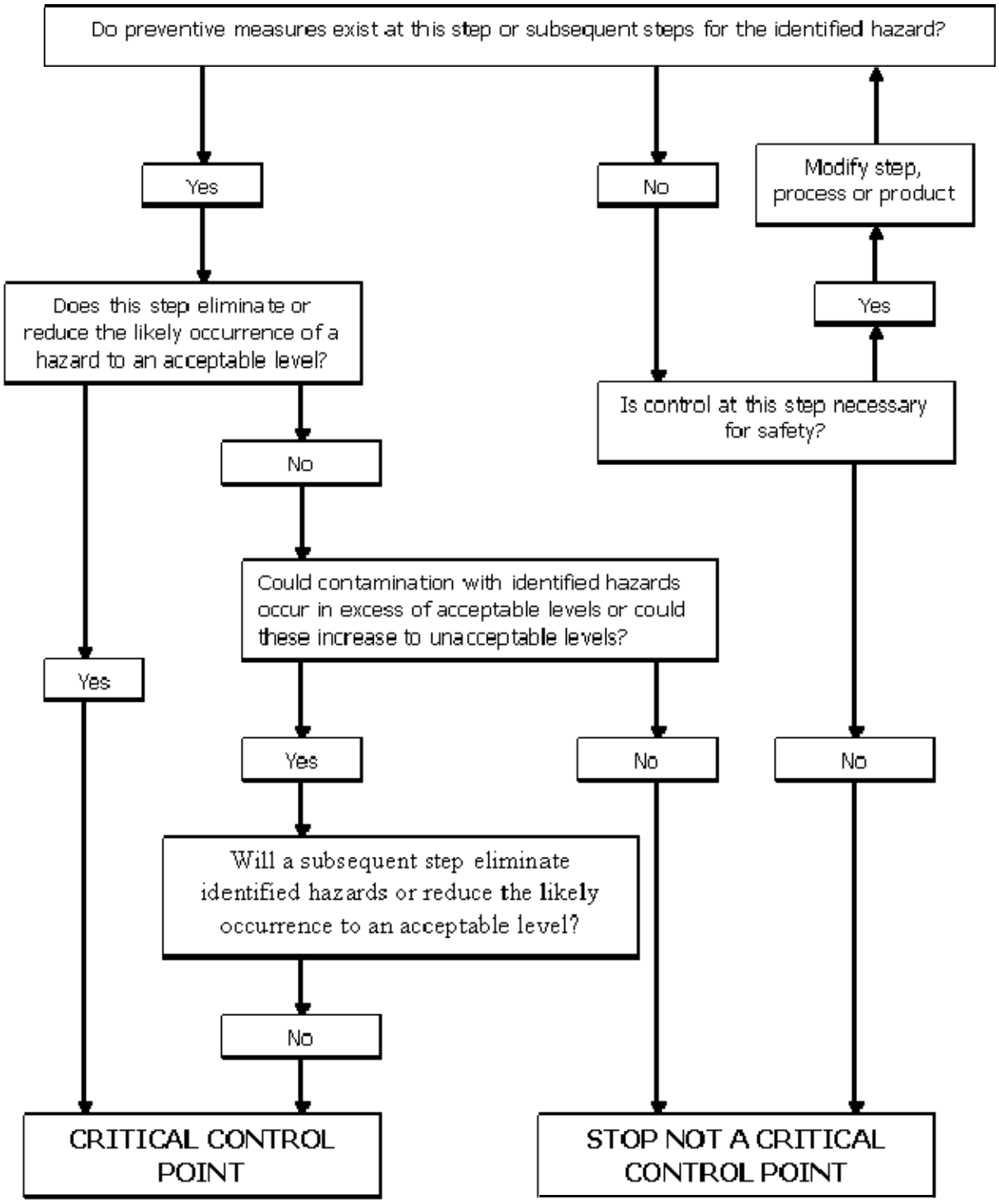
VII. HACCP Decision Trees

CCP decision trees have been developed to assist HACCP developers in determining CCP's in the facilities process. Three example CCP decision trees are in the following pages of this hazard guide. Two decision trees are prepared by the NACMCF and the third has been developed by IDFA. The HACCP team may use decision trees to evaluate each hazard to determine if each hazard can be prevented, eliminated or reduced to an acceptable level.

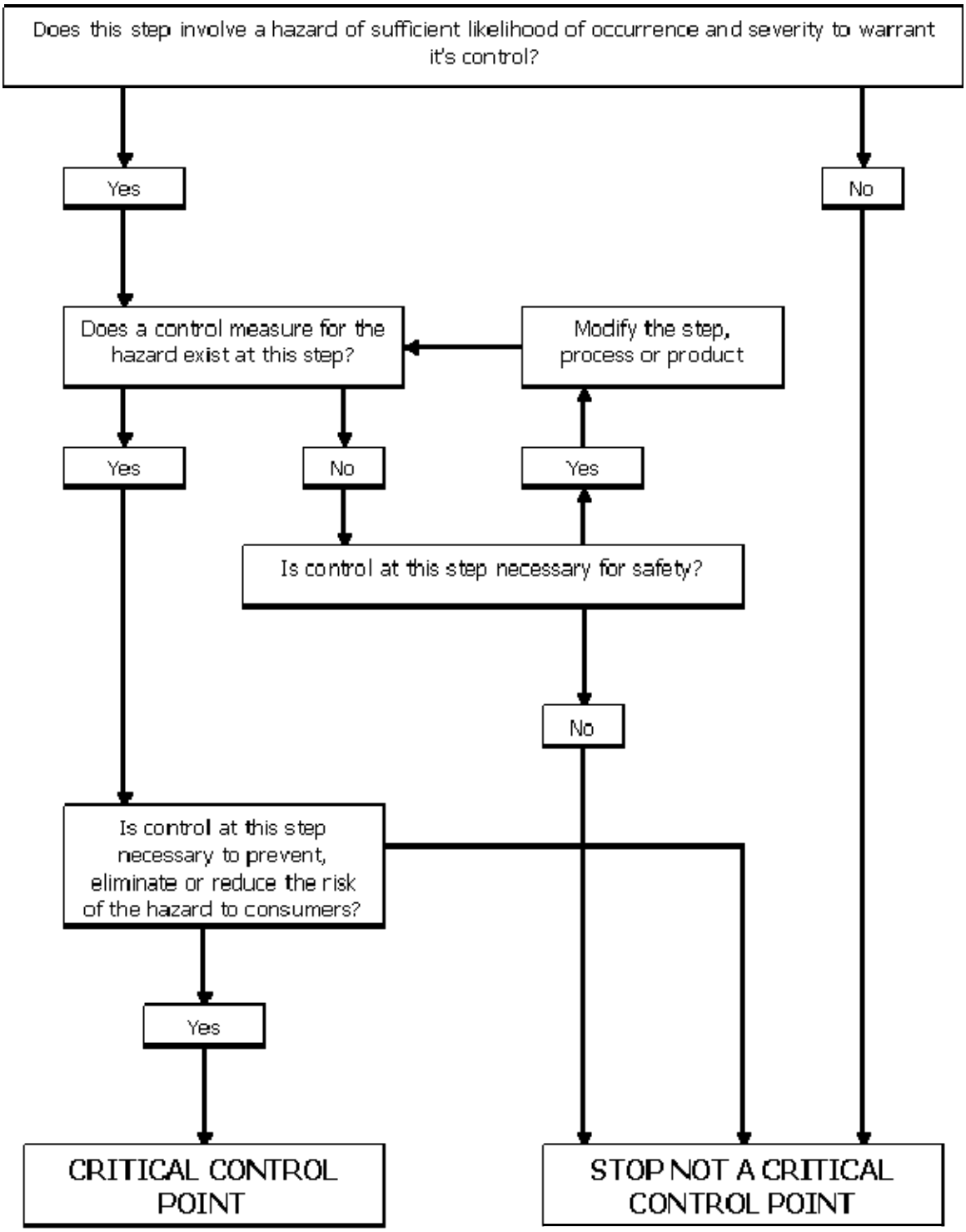
A common problem with using existing HACCP decision trees is trying to apply the questions prior to completion of the hazard analysis. Decision trees sometimes also show results which common sense says is incorrect. Thus, decision trees should be used with caution.

Decision trees are only tools that can be used to assist in determining CCP's. Milk plants are not required to use them to determine CCP's. Many HACCP teams determine CCP's based on the knowledge and experience of their process and existing plant control measures.

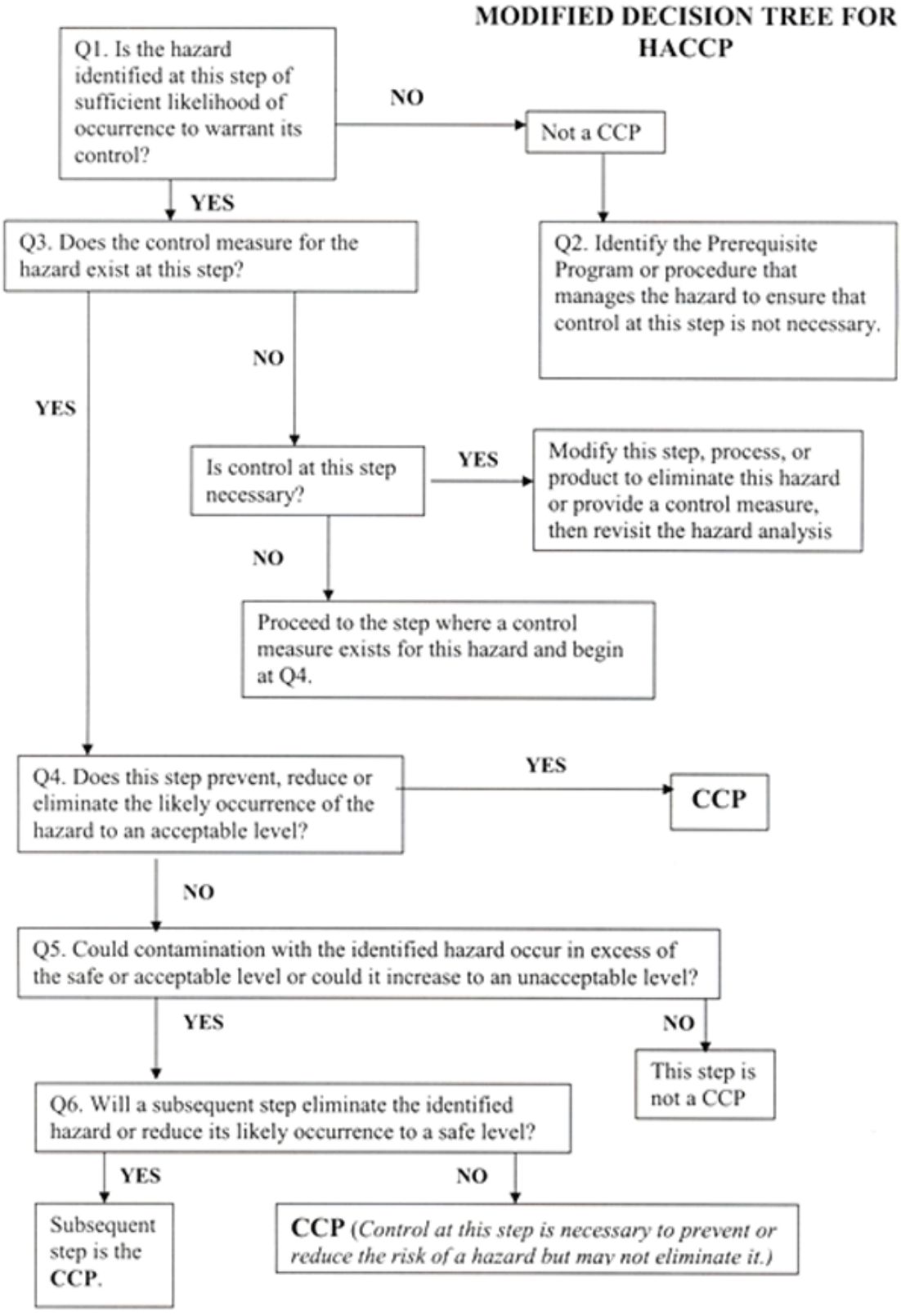
NACMCF CCP Decision Tree #1



NACMCF CCP Decision Tree #2



NACMCF CCP Decision Tree - IDFA Modification



VIII. Control Measures

A. HACCP Control Measures

Under the voluntary HACCP alternative, you are not required to implement control measures if you determine in your hazard analysis that a food hazard is not reasonably likely to occur in your dairy product.

Examples of HACCP control measures used in the processing of dairy products include measures carried out at CCP's specified in a HACCP plan such as pasteurization of dairy products for the elimination or reduction to an acceptable level of microbiological pathogens.

B. Activities Not Considered to be HACCP Control Measures

1. Other Regulatory Requirements that are not a part of the NCIMS HACCP System
    a. Raw Milk Supply Source;
    b. Labeling Compliance;
    c. Adulteration;
    d. Licensing Requirements;
    e. Drug Residue and Trace Back Requirements;
    f. Regulatory Samples in Compliance;
    g. Approved Laboratory Utilized for the Regulatory Tests; and
    h. Pasteurization Equipment Design and Installation

2. GMPs (note building and facilities)

    Some activities that firms may undertake in processing milk and milk products and in related functions are not HACCP control measures. These include Good Agricultural Practices (GAPs) and Current Good Manufacturing Practices (cGMP).

3. GAPs

    GAPs are measures voluntarily undertaken by these parties which are not HACCP controls. However, if a hazard originating from the agricultural environment is determined to be reasonably likely to occur in your incoming dairy products, it must be identified in your hazard analysis and controlled through your HACCP plan. If control of such a hazard involves actions that will be carried out by your supplier, your control measure could be based upon a supplier guarantee to this effect implemented as part of your HACCP plan.

    However, we encourage you to work with your suppliers to evaluate and modify agricultural practices in accordance with FDA's GAPs guidance document.

4. CGMPs

    As noted above, dairy processors are still required to comply with the CGMPs requirements of 21 CFR Part 110. One common misconception about HACCP is that some hazards that are reasonably likely to occur can be controlled under a firm's CGMP programs under 21 CFR Part 110. Because programs to comply with 21 CFR Part 110 are general in nature and are not designed to control specific hazards, they are not HACCP control measures. Therefore, you cannot use CGMP programs to control a specific hazard that you have concluded is reasonably likely to occur in your hazard analysis. You must use HACCP controls for any such hazard.

IX. Preparing for HACCP

A. Getting People Ready

Successful implementation of HACCP requires trained people who cooperate from the preliminary stages to the implementation and ongoing operation of the HACCP system. We strongly recommend that you begin with Step 1 of NACMCF's 5 preliminary steps of HACCP, by assembling a HACCP team that includes plant level and corporate level personnel.

B. HACCP Training and HACCP Resource Materials

1. Dairy Foods HACCP Core Curriculum Training
2. USDA / FDA HACCP Training Programs and Resources Database

X. Hazards and Control Guide

These tables may be used by the milk plant HACCP team as a guide to the identification of potential hazards that may be associated with the incoming raw materials (Table 1) and the processing steps (Table 2) used by a typical dairy processing plant.

This guide may, or may not, be relevant to the conditions found at a specific milk plant.

Each milk plant HACCP team must determine, for itself, the relevance of the potential hazards identified in the tables or other potential hazards, identified independently by the milk plant HACCP Team or by experts the HACCP Team may employ when developing its HACCP system.

The "*Ingredient or Process*" column presents typical steps used in milk processing. It is not intended to be complete or accurate for any specific milk plant or to serve as a template for describing process steps in specific milk plants.

The "*Potential Hazard*" column identifies some hazards that might be expected at various processing steps. Additional hazards may exist in individual circumstances and MUST be identified and considered in the hazard analysis.

The "*Hazard Rationale*" column provides the reasons why each hazard was listed in the Hazard Identity column for a particular processing step.

The "*Hazard Management Controls*" column provides examples used to illustrate the accepted level of public health protection that is likely to be found acceptable for regulatory licensing and IMS listing. Any measure that can be demonstrated to provide a similar level of public health protection, but is not listed in this Guide, is also acceptable, as long as it meets the requirements of the NCIMS Dairy HACCP Program and is consistent with relevant state and federal laws or regulations.

The "*Additional Resources*" column provides references to the following sources of information: Key to Abbreviations and References Used in Tables 1 and 2

1. Pasteurized Milk Ordinance (PMO)
2. U. S. Code of Federal Regulations (CFR)
3. Interpretive Memoranda published by the FDA IMS List, M-a, M-b, and M-I memoranda
4. IMS List Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers

5. FDA Compliance Policy Guides (CPG)
6. 3-A Sanitary Standards (3-A SS) and 3-A Accepted Practices (3-A AP)
7. Dairy Practices Council (DPC) Guidelines. References are to specific guideline identification numbers, "DPC 8".
8. Good Agricultural Practices (GAPs)
9. Current Good Manufacturing Practices (cGMPs)
10. National Drug Residue Database (NMDRD) Report

TABLE 1 - MILK PLANT RAW MATERIALS

INGREDIENT OR PROCESS	TYPE OF HAZARD	POTENTIAL HAZARD	HAZARD RATIONALE	HAZARD MANAGEMENT OR CONTROLS	ADDITIONAL RESOURCES
Raw Milk	**Biological**	**B-1:** Presence of vegetative Pathogens	**B-1:** Scientific studies have shown that a wide range of pathogens (organisms which can cause illness in humans) can be present in unpasteurized milk. [4, 5]	**B-1:** Minimize the incoming bacterial load by purchasing Grade "A" IMS listed raw milk and testing incoming product. Verify that tank trucks were cleaned and sanitized prior to picking up the milk being unloaded (wash tags or in the case of trucks that only deliver to one plant, plant cleaning records) and that milk has been maintained at the proper temperature.	PMO Sec 4 PMO Item 12p IMS List PMO Item 17p DPC 25 DPC 50
	Chemical	**C-1:** Presence of Therapeutic Drugs	**C-1:** This hazard must be addressed based on "Other NCIMS Requirements".	**C-1:** At a minimum, screen all tankers for animal drug residues as required by Appendix N or other regulatory mandates. In addition, plants are encouraged to screen for other residues as indicated by available information.	M-a-75 M-a-86 PMO Appendix N DPC 22
	Chemical	**C-2:** Presence of Mycotoxins	**C-2:** Mold growth in animal feed can contaminate milk with aflatoxin M_1.	**C-2:** Aflatoxin has been shown to be present in raw milk dependent on geographic locations, growing season conditions and past history. Other management controls may include supplier guarantees and COA's.	
	Physical	**P-1:** Extraneous Material	**P-1:** If dairy cattle are not kept clean or if milk is drawn in an unclean environment and is not properly protected, physical objects from	**P-1:** Not to be included in the hazard analysis if purchasing milk from Grade "A" IMS listed sources to minimize the contamination.	

INGREDIENT OR PROCESS	TYPE OF HAZARD	POTENTIAL HAZARD	HAZARD RATIONALE	HAZARD MANAGEMENT OR CONTROLS	ADDITIONAL RESOURCES
			the farm environment may become incorporated into the milk.		
Pasteurized milk, heat treated milk or cream, and condensed skim milk	**Biological**	**B-1:** Presence of vegetative Pathogens	**B-1:** Heat-treated milk products may not have been heated sufficiently to deactivate these organisms.	**B-1:** Heat-treated milk or cream should be treated as raw milk and come from approved sources.	IMS List PMO Sec 7
	Biological	**B-2:** Contamination by vegetative pathogens	**B-2:** Bulk shipped pasteurized milk products may have been subject to recontamination during transit.	**B-1:** Verify that tank trucks were cleaned and sanitized prior to picking up the milk being unloaded (wash tags or in the case of trucks that only deliver to one plant, plant cleaning records) and that milk has been maintained at the proper temperature.	PMO Items 12p, 17p, & 21p 3-A SS 605
	Chemical	None			
	Physical	None			
Other Ingredients / Packaging Materials	**Biological**	**B-1:** Presence of vegetative Pathogens	**B-1:** Pathogens may be present in ingredients. [6, 7, 8]	**B-1:** Supplier certificates of analysis.	21 CFR 110.80(a)
	Chemical	**C-1:** Presence of toxic or carcinogenic substances	**C-1:** Adulteration with toxic or carcinogenic chemicals has been documented. [9, 10, 11]	**C-1:** IMS Listed packaging suppliers. Supplier letter of guarantee.	21 CFR 110.80(a) 21CFR 176.260 21CFR 178.010
	Physical	**P-1:** Extraneous Material	**P-1:** Free of foreign materials which constitute food safety hazards. [7, 12]	**P-1:** Supplier letter of guarantee.	21 CFR 110.80(a) CPG 555.425

TABLE 2 - MILK PLANT PROCESSING OPERATIONS

INGREDIENT OR PROCESS	HAZARD	TYPE OF HAZARD	HAZARD RATIONALE	HAZARD MANAGEMENT OR CONTROLS	ADDITIONAL RESOURCES
Receiving - Materials shipped by bulk tanker, e.g. fluid milk and milk products	**Biological**	**B-1:** Contamination with vegetative pathogens.	**B-1:** The truck unloading area has the potential to contaminate liquid milk products. These products are normally transmitted through equipment that if unclean, (or uncleanable) can result in bacterial contamination.	**B-1:** Truck unloading are should be constructed to protect the milk (at a minimum overhead protection and concrete, or equivalent surface under the truck that is properly drained). Maintain the truck unloading area and equipment clean. Protect the milk that is being unloaded by closing in the unloading area or using filters over the vent /personnel access port area. Using equipment meeting sanitary design guidelines.	DPC 8 PMO Item 5p(4) & 15p(A)(3) 3-A SS 02-, 11-, 28-,29-,53-, 58-, 59-, 62-, 63-, 74-
	Chemical	**C-1:** Cleaning & Sanitizing Residues	**C-1:** Without proper separation between cleaning & sanitizing solutions and product there could be contamination of the product. [9]	**C-1:** Maintain proper separation or a physical break between circuits containing cleaning solutions and vessels and lines used to contain or conduct product	PMO Item 15p(B)(1) 3-A AP 605 21CFR178.1010(a)
	Physical	**P-1:** Extraneous Materials	**P-1:** Free of foreign material which constitute food safety hazards. [7, 12]	**P-1:** Use a filter, screen or other appropriate device at some point in the system.	3-A SS 10- & 42- PMO Item 11p(8)
	Physical	**P-2:** Metal shavings, gasket material & other foreign material from receiving equipment	**P-2:** Equipment in poor repair or improperly assembled may contaminate product with foreign material.	**P-2:** An effective preventive maintenance program and routine (daily) inspection of equipment for wear or missing parts. Use of a filter, screen or other appropriate device at some point in the system.	PMO Item 11p 3-A SS 10- & 42-
Receiving - Materials shipped by common carrier, e.g. dry ingredients, flavors and packaging materials.	**Biological**	**B-1:** Contamination with vegetative pathogens	**B-1:** Product may become contaminated if product containers are damaged during shipment.	**B-1:** Inspect product during unloading operations for damage.	DPC 8 21CFR 110.80(a)(2)

INGREDIENT OR PROCESS	HAZARD	TYPE OF HAZARD	HAZARD RATIONALE	HAZARD MANAGEMENT OR CONTROLS	ADDITIONAL RESOURCES
	Chemical	**C-1:** Toxic Chemicals	**C-1:** Delivery trucks may have been used to transport toxic chemicals prior to food products or packaging materials. [9]	**C-1:** Inspect vehicles prior to unloading for evidence of unsanitary conditions, spilled chemicals, off odors, of evidence that might indicate the delivered product may have been contaminated.	DPC 8
	Physical	**P-1:** Extraneous Materials	**P-1:** Vehicles may have not been maintained in good repair or have been used to carry metal or wood articles. [12]	**P-1:** Inspect vehicles prior to unloading for evidence of foreign materials that may have contaminated the product.	DPC 8
Raw Milk Storage	**Biological**	**B-1:** Contamination with vegetative pathogens	**B-1:** These products are normally stored in vessels that, if unclean (or uncleanable), can result in bacterial contamination. [9, 11]	**B-1:** Verify that storage vessels and associated lines and valves similar appurtenances are constructed in such a way that they can be cleaned. Maintain records storage vessels are cleaned after each use. Maintain records that the associated lines, valves and similar appurtenances are cleaned as needed but at least each day used. Pipeline openings (e.g., flow control panels) and outlet valves are capped when not in use, other openings are closed with tight fitting covers. Associated pipelines and similar appurtenances are similarly protected.	PMO Item 12p 3-A SS 22- & 63- 3-A AP 605- 21CFR 110.35(d) PMO Item 15p(A)(3)
	Biological	**B-2:** Growth of vegetative pathogens	**B-2:** Without proper temperature and time controls, vegetative pathogens can multiply to levels that may be capable of overwhelming the pasteurization process with out proper temperature and time controls. [9, 11]	**B-2:** Maintain the temperature sufficiently low to minimize the growth of pathogens. Clean the storage vessels and associated lines and valves similar appurtenances at frequencies that do not allow for bacterial growth of pathogens in the product at the product temperature used. Note: If times or temperatures less stringent than specified in the PMO are used, they must be reviewed and found acceptable to the State and FDA.	PMO Item 17p PMO Item 12p 21CFR 110.35(d) PMO Item 12p
	Chemical	**C-1:** Cleaning & Sanitizing Solution Residues	**C-1:** Without proper separation between cleaning & sanitizing solutions and product there could be product contamination. [9]	**C-1:** Maintain proper separation or physical break between circuits containing cleaning solution and vessels and lines used to contain product.	PMO Item 15p(B) 3-A AP 605 21CFR 178.1010(a)
	Physical	None			

INGREDIENT OR PROCESS	HAZARD	TYPE OF HAZARD	HAZARD RATIONALE	HAZARD MANAGEMENT OR CONTROLS	ADDITIONAL RESOURCES
Storage, Blending & Addition of Ingredients	**Biological**	**B-1:** Contamination with vegetative pathogens	**B-1:** Pathogens can be present in the environment in the dry blending area. Product is usually exposed during blending. Ingredients may become contaminated by equipment that is unclean or uncleanable. [9]	**B-1:** Verify that blending equipment and associated lines and valves similar appurtenances are constructed in such a way that they can be cleaned. Maintain records that they are cleaned as needed but at least each day used. Maintain the addition / blending environment clean and relatively free of dust or soil that could contaminate product during addition / blending. Equipment used for addition / blending is constructed to minimize product or ingredient exposure.	DPC 8 3-A SS 32-, 63-, & 73- 21CFR 110.35(d) 3-A AP 605- PMO Item 9p(3) & 9p(4)
	Chemical	**C-1:** Cleaning & Sanitizing Solution Residues	**C-1:** Without proper separation between cleaning & sanitizing solutions and product there could be product contamination. [9]	**C-1:** Maintain proper separation or physical break between circuits containing cleaning solution and vessels and lines used to contain product.	PMO Item 15p(B) 3-A AP 605 21CFR 178.1010(a)
	Chemical	**C-2:** Allergens being mixed with products that are not labeled as containing allergens	**C-2:** Foods which contain undeclared allergens may cause life threatening reactions in sensitive individuals.	**C-2:** Documented PP's or other effective practices and programs must be in place and monitored in such a way that will assure allergen containing ingredients (other than milk and milk products) are used only in Grade A milk and milk products that are properly labeled as containing those allergens in the ingredients. These documented and monitored programs need, at a minimum to include requirements and procedures to assure: • Separation and identification of such allergens during storage. • Addition only of those products that are properly labeled must be monitored and documented. • Equipment that is used for storage, blending or addition of both ingredients that do not, must be thoroughly cleaned after the equipment has been used for allergen containing ingredients for foods which do not declare that allergen. • If plant programs other than PP's or CCP's are used, those records needed to ensure allergens are adequately addressed at this step must be part of the overall HACCP system in such a way that those records are available for regulatory review.	FDA CPG 555.250

INGREDIENT OR PROCESS	HAZARD	TYPE OF HAZARD	HAZARD RATIONALE	HAZARD MANAGEMENT OR CONTROLS	ADDITIONAL RESOURCES
	Physical	**P-1:** Extraneous Materials	**P-1:** Inadvertent addition of packaging material and other objects which are present in the blending area.	**P-1:** Opening of ingredients is conducted in a manner that will minimize the opportunity for bits of packaging, cutting tools, etc. from entering the product. Verification that, at some point in the process ingredient or the milk product to which the ingredient is added, will pass through a filter, screen, small orifice (such as occurs during homogenization or other appropriate device.	DPC 8 3-A SS 10- & 42- PMO Item 9p(3) & 9p(4)
Separation	**Biological**	**B-1:** Contamination with vegetative pathogens	**B-1:** If this equipment is unclean or uncleanable, it can contaminate products that pass through it. [12]	**B-1:** Verify that the separation equipment and associated lines and valves and similar appurtenances are constructed in such a way that they can be cleaned. Maintain records that the equipment is cleaned after each day used.	DPC 8 3-A AP 605- 21CFR 178.1010(a)
	Chemical	None			
	Physical	None			
Skim and / or Cream Cooling and Storage	**Biological**	**B-1:** Cold separated or heat treated skim or cream can have vegetative pathogens	**B-1:** Vegetative pathogens can multiply to levels that may be capable of overwhelming a pasteurization process. [11]	**B-1:** Maintain the temperature sufficiently low to minimize the growth of pathogens. Clean the storage vessels and associated lines and valves and similar appurtenances at frequencies that do not allow for bacterial growth of pathogens in the product at the product temperature used. Note: If times or temperatures less stringent than specified in the PMO are to be used, they must be reviewed and found acceptable to the State and FDA.	3-A AP 605- 3-A SS 22- & 63-
	Chemical	**C-1:** Cleaning & Sanitizing Solution Residues	**C-1:** Without proper separation between cleaning & sanitizing solutions and product there could be product contamination. [9]	**C-1:** Maintain proper separation or physical break between circuits containing cleaning solution and vessels and lines used to contain product.	PMO Item 15p(B) 3-A AP 605 21CFR 178.1010(a)
	Physical	None			
Pasteurization	**Biological**	**B-1:** Survival of vegetative pathogens	**B-1:** Minimum pasteurization times and temperatures have been well documented and are required for the elimination of pathogens normally present in unpasteurized milk. [9, 11, 13, 14]	**B-1:** Under NCIMS Dairy HACCP program, pasteurization and the design, construction and operation and testing of pasteurization equipment must conform to all of the requirements of the Grade A Pasteurized Milk Ordinance. Note: If cleaning frequencies are to be performed at frequencies less than those specified in PMO Item 12p, the cleaning frequencies are to be reviewed and found acceptable to the State and FDA.	PMO Items 12p, 15p(B), 16p and Appendices H & I 3-A AP 603- 3-A AP 605-

INGREDIENT OR PROCESS	HAZARD	TYPE OF HAZARD	HAZARD RATIONALE	HAZARD MANAGEMENT OR CONTROLS	ADDITIONAL RESOURCES
	Biological	**B-2:** Contamination with vegetative pathogens	**B-2:** Pasteurizer regenerator sections have been documented to occasionally leak. Raw and pasteurized milk are on opposite sides of a metal barrier (plate or tubular) in these regenerator sections. [11]	**B-2:** Under NCIMS Dairy HACCP program, pasteurization and the design, construction and operation and testing of pasteurization equipment must conform to all of the requirements of the Grade A Pasteurized Milk Ordinance.	PMO Item 16p 3-A AP 603- 3-A AP 605-
	Chemical	**C-1:** Cleaning & Sanitizing Solution Residues	**C-1:** Without proper separation between cleaning & sanitizing solutions and product there could be product contamination. [9]	**C-1:** Maintain proper separation or physical break between circuits containing cleaning solution and vessels and lines used to contain product. Particular attention is needed to assure that the required separation remains in place during partial washes, sometimes called "short washes" or " inter-washes" that may be done during an operating day.	PMO Item 15p(B) 3-A AP 605 21CFR 178.1010(a)
	Chemical	**C-2:** Allergens being mixed with products that are not labeled as containing allergens.	**C-2:** Foods which contain undeclared allergens may cause life threatening reactions in sensitive individuals.	**C-2:** Pasteurization equipment and associated piping and valves that are used for both Grade "A" milk and milk products foods that do not, must be thoroughly cleaned after use for allergen containing foods before it is used for foods that do not declare that allergen.	3-A 603- 3-A 605- FDA CPG 555.250
	Chemical	**C-3:** Boiler Additives	**C-3:** Some boiler water compounds used in the production of steam to be used in contact with food or food contact surfaces may contain toxic substances.	**C-3:** If indicated by the hazard analysis, boiler water additives may be managed by PP #1 - Safety of Water. Compliance to 21CFR 173.310 may be verified by a letter of guarantee from the chemical supplier.	21CFR 173.310
	Chemical	**C-4:** Cooling water / Media Additives.	**C-4:** Some cooling water / media additives that may come in contact with food or food contact surfaces may contain toxic substances.	**C-4:** Cooling water additives that are non-toxic under the condition of use should be used and their safety verified by a letter of guarantee form the chemical supplier.	
	Physical	None			

INGREDIENT OR PROCESS	HAZARD	TYPE OF HAZARD	HAZARD RATIONALE	HAZARD MANAGEMENT OR CONTROLS	ADDITIONAL RESOURCES
Pasteurized Milk & Milk Product Storage (Except dry products)	**Biological**	**B-1:** Contamination with vegetative pathogens	**B-1:** Human illness outbreaks have been linked to post-pasteurization contamination of milk and milk products. [11, 15, 16, 17]	**B-1:** Openings and outlet valves are capped when not in use, other openings are closed with tight fitting covers. Associated pipelines and similar appurtenances are similarly protected. Verify that storage vessels and associated lines and valves and similar appurtenances are constructed in such a way they can be cleaned. Maintain records storage vessels are cleaned after each use. Maintain records that associated lines and valves and similar appurtenances are cleaned as needed but at least each day used.	3-A AP 605 3-A SS 22- & 63-
	Biological	**B-2:** Growth of Vegetative Pathogens	**B-2:** Human illness outbreaks have been linked to post-pasteurization contamination of milk and milk products. [11, 15, 16, 17]	**B-2:** Maintain the temperature sufficiently low to minimize the growth of pathogens. Clean the storage vessels and associated lines and valves and similar appurtenances at frequencies that do not allow for bacterial growth of pathogens in the product at the product temperature used. Note: If times or temperatures less stringent than specified in the PMO are to be used, they must be reviewed and found acceptable to the State and FDA.	3-A AP 605
	Chemical	**C-1:** Cleaning & Sanitizing Solution Residues	**C-1:** Without proper separation between cleaning & sanitizing solutions and product there could be product contamination. [9]	**C-1:** Maintain proper separation or physical break between circuits containing cleaning solution and vessels and lines used to contain product.	PMO Item 15p(B) 21CFR 178.1010(a)
	Physical	None			
Pasteurized Milk and Milk Product - Packaging (Except Dry Products)	**Biological**	**B-1:** Contamination with vegetative pathogens	**B-1:** Human illness outbreaks have been linked to post-pasteurization contamination of milk and milk products. [9]	**B-1:** Packaging may come from an IMS listed source with associated letters of guarantee, or the milk plant may perform tests to verify the ongoing safety of the packaging. After receipt, single service containers and other single service items must be protected from recontamination. Filling equipment and appurtenances must be cleanable and inspectable and must be constructed and operated to protect the product being packaged from contamination. Acceptable criteria for such construction can be found from such sources as the PMO and 3A Sanitary Standards and Practices.	IMS List 3-A SS 17- & 23- 21CFR 178.1010

INGREDIENT OR PROCESS	HAZARD	TYPE OF HAZARD	HAZARD RATIONALE	HAZARD MANAGEMENT OR CONTROLS	ADDITIONAL RESOURCES
	Chemical	**C-1:** Cleaning & Sanitizing Solution Residues	**C-1:** Without proper separation between cleaning & sanitizing solutions and product there could be product contamination. [9]	**C-1:** Maintain proper separation or physical break between circuits containing cleaning solution and vessels and lines used to contain product.	PMO Item 15p(B) 3-A AP 605 21CFR 178.1010(a)
	Chemical	**C-2:** Toxic or Carcinogenic substances in the packaging	**C-2:** Packaging material that does not meet CFR requirements may contain non-food grade substances. [18]	**C-2:** Packaging material or components comes from a sourced from suppliers to be free of certain toxic or carcinogenic substances. One way to do this is to use packaging from IMS listed sources	CFR IMS List
	Chemical	**C-3:** Allergens being mixed with products that are not labeled as containing allergens.	**C-3:** Foods that contain undeclared allergens may cause life threatening reactions in sensitive individuals.	**C-3:** Packaging machinery and associated piping and valves that are used for both Grade A milk and milk products foods that contain allergens (other than milk) and Grade A milk and milk products that do not, must be thoroughly cleaned after use for allergen containing foods before it is used for foods that do not declare that allergen.	FDA CPG 555.250
	Physical	**P-1:** Glass	**P-1:** Glass fragments may be present in processors packaging in glass.	**P-1:** Maintain a glass free zone.	
Packaged Milk Product Storage (Except Dry Products)	**Biological**	**B-1:** Contamination with vegetative pathogens	**B-1:** Condensate which drips on the pouring lip of the container may contaminate the pouring lip of the container with pathogens.	**B-1:** Product needs to be stored away from areas where condensate could drip on the container.	
	Biological	**B-2:** Growth of Pathogens	**B-2:** Lack of temperature control in coolers may result in growth of pathogens if present in the product. [19]	**B-2:** Thermometers need to be located in the warmest sections of product coolers and monitored to be sure that the coolers will hold product below the bacterial growth range. Temperature meets the NCIMS requirements.	
	Chemical	None			
	Physical	None			

INGREDIENT OR PROCESS	HAZARD	TYPE OF HAZARD	HAZARD RATIONALE	HAZARD MANAGEMENT OR CONTROLS	ADDITIONAL RESOURCES
Bulk Pasteurized Product - Load Out (Except Dry Products)	**Biological**	**B-1:** Contamination with vegetative pathogens	**B-1:** Pathogens have been found in bulk pasteurized product either from the load out process or from loading into tankers which have not been cleaned and sanitized. [9, 11]	**B-1:** Load out product "fitting to fitting" with the truck openings closed or otherwise adequately protected. Use and properly maintain a system of lies and valves for load out that is separate from that used to receive products for pasteurization or repasteurization. Tank trucks must not be used to haul contaminating substances such as unpasteurized liquid eggs without a through cleaning and a detailed inspection. Verify that the trucks were clean and sanitized prior to loading (wash tags or in the case of trucks that only deliver to one plant, plant cleaning records).	3-A AP 605- PMO Section 4 3-A SS 02- & 62-
	Chemical	**C-1:** Cleaning & Sanitizing Solution Residues	**C-1:** Without proper separation between cleaning & sanitizing solutions and product there could be product contamination. [9]	**C-1:** Maintain proper separation or physical break between circuits containing cleaning solution and vessels and lines used to contain product.	PMO Item 15p(B) 3-A AP 605 21CFR 178.1010(a)
	Physical	None			
Starter Media Preparation, Starter Media Culturing and Product Culturing	**Biological**	**B-1:** Contamination with vegetative pathogens.	**B-1:** Starter media and culture is added to product post-pasteurization.	**B-1, B-2:** Starter media is pasteurized as required in the PMO prior to culturing and is protected during culturing of the media and during addition to the product to be cultured. Dairy products being cultured will be protected from contamination during set either by enclosing or covering the vats during set or by controlling environmental conditions around the vats during set. Some environmental controls would include, positive air pressure in the set room (the incoming air must be filtered or otherwise treated to prevent it from being a source of bacterial contamination). Pallets of packaging or other potential sources of contamination must not be present during set. Packaging or other operations that could be a source of contamination must be isolated from the vats being set. A separate room for setting open vats is preferred.	PMO Item 16p 3-A AP 603- 3-A SS 25- 3-A SS 02-, 25-, & 38- 3-A AP 605- 3-A AP 604-
	Biological	**B-2:** Growth of Pathogens	**B-2:** Dairy products are cultured under conditions conductive to the growth of pathogens.		

INGREDIENT OR PROCESS	HAZARD	TYPE OF HAZARD	HAZARD RATIONALE	HAZARD MANAGEMENT OR CONTROLS	ADDITIONAL RESOURCES
	Biological	**B-3:** Development of Toxins	**B-3:** Dairy products are cultured under conditions that may allow toxin-producing bacteria to grow and produce toxins in the case of starter culture failure or partial failure.	**B-3:** The plant needs a procedure to handle "Slow" vats that will eliminate the possibility that cultured products containing toxins sold or distributed as food.	
	Chemical	**C-1:** Cleaning & Sanitizing Solution Residues	**C-1:** Without proper separation between cleaning & sanitizing solutions and product there could be product contamination. [9]	**C-1:** Maintain proper separation or physical break between circuits containing cleaning solution and vessels and lines used to contain product. If curd wash water is treated with a disinfectant, the levels shall be controlled to prevent adulteration.	PMO Item 15p(B) 3-A AP 605 21CFR 178.1010(a)
	Physical	**P-1:** Extraneous Material	**P-1:** Market withdrawals and recalls have occurred for foreign materials in dairy products. [12]	**P-1:** Openings on the starter media and cultured products vessels and associated equipment are kept closed. All product-handling equipment is properly designed and maintained in good repair.	3-A SS 24- & 25-
Milk or Milk Product - Direct Set	**Biological**	None			
	Chemical	**C-1:** Cleaning & Sanitizing Solution Residues	**C-1:** Without proper separation between cleaning & sanitizing solutions and product there could be product contamination. [9]	**C-1:** Maintain proper separation or physical break between circuits containing cleaning solution and vessels and lines used to contain product.	PMO Item 15p(B) 3-A AP 605 21CFR 178.1010(a)
	Physical	**P-1:** Extraneous Material	**P-1:** Market withdrawals and recalls have occurred for foreign materials in dairy products. [12]	**P-1:** Openings on the starter media and cultured products vessels and associated equipment are kept closed. All product-handling equipment is properly designed and maintained in good repair.	3-A SS 24- & 25-
Ingredient / Flavoring other than dry - Added Post Pasteurization	**Biological**	**B-1:** Contamination with vegetative pathogens	**B-1:** Ingredient / flavorings are added post pasteurization.	**B-1:** Ingredients to be added after pasteurization are verified / certified to be sterilized and hermetically sealed, incapable of supporting bacterial growth (salt and some alcohol based flavors, etc.) or otherwise rendered incapable of carrying pathogens into the product. Use of fresh fruit having a pH of 4.7 or less, or ingredients having a water activity of 0.85 or less, or	

INGREDIENT OR PROCESS	HAZARD	TYPE OF HAZARD	HAZARD RATIONALE	HAZARD MANAGEMENT OR CONTROLS	ADDITIONAL RESOURCES
				a high acid content product or roasted nuts, or flavoring extracts having high alcohol content as part of a plant quality assurance programs to assure that these ingredients do not contaminate the dairy product.	
	Chemical	**C-1:** Contaminates in the Ingredient	**C-1:** Ingredients may contain unintended contaminates.	**C-1:** Supplier guarantees obtained for all post pasteurization added ingredients.	
	Chemical	**C-2:** Allergens being mixed with products that are not labeled as containing allergens.	**C-2:** Foods that contain undeclared allergens may cause life threatening reactions in sensitive individuals.	**C-2:** Ingredient addition equipment such as hoppers and feeders and associated piping and valves that are used for milk and milk products that contain allergens (other than milk) and milk and milk products that do not , must be thoroughly cleaned after use for allergens before it is used for foods that do not declare that allergen.	3-A SS 02-, 32-, 35-, 51-, 52-, 63-, 68-, 73-, 81- FDA CPG 555.250
	Physical	**P-1:** Extraneous Material	**P-1:** Market withdrawals and recalls have occurred for foreign materials in dairy products. [12]	**P-1:** Openings on the starter media and cultured products vessels and associated equipment are kept closed. All product-handling equipment is properly designed and maintained in good repair.	3-A SS 24- & 25-
Whey - Handling and Storage	**Biological**	**B-1:** Contamination with vegetative pathogens	**B-1:** Pathogens may be introduced during whey handling and storage.	**B-1:** Verify that storage vessels and associated lines and valves and similar appurtenances are constructed in such a way they can be cleaned. Maintain records storage vessels are cleaned after each use. Maintain records that associated lines and valves and similar appurtenances are cleaned as needed but at least each day used.	3-A SS 01-, 02-, 22-, 25-, 32-, 57- 3-A AP 605-
	Biological	**B-2:** Growth of Pathogens	**B-2:** Pathogens, if present, may grow during storage.	**B-2:** Condensed products (including foam and splash) are not held in bacteria growth range. Maintain the temperature sufficiently low to minimize the growth of pathogens. Clean the storage vessels and associated lines and valves and similar appurtenances at frequencies that do not allow for bacterial growth of pathogens in the product at the product temperature used. Note: If times or temperatures less stringent than specified in the PMO are to be used, they must be reviewed and found acceptable to the State and FDA.	

INGREDIENT OR PROCESS	HAZARD	TYPE OF HAZARD	HAZARD RATIONALE	HAZARD MANAGEMENT OR CONTROLS	ADDITIONAL RESOURCES
	Chemical	**C-1:** Cleaning & Sanitizing Solution Residues	**C-1:** Without proper separation between cleaning & sanitizing solutions and product there could be product contamination. [9]	**C-1:** Maintain proper separation or physical break between circuits containing cleaning solution and vessels and lines used to contain product.	PMO Item 15p(B) 3-A AP 605 21CFR 178.1010(a)
	Physical	None			
Milk and Whey Product - Membrane Filtration	**Biological**	**B-1:** Contamination with vegetative pathogens	**B-1:** Pathogens may be introduced during membrane filtration.	**B-1:** Product balance bowl and other openings into the system must be kept tightly closed during processing.	3-A AP 610 3-A SS 26- PMO Item 16p 3-A A 603
	Chemical	**C-1:** Cleaning & Sanitizing Solution Residues	**C-1:** Without proper separation between cleaning & sanitizing solutions and product there could be product contamination. [9]	**C-1:** Maintain proper separation or physical break between circuits containing cleaning solution and vessels and lines used to contain product.	PMO Item 15p(B) 3-A AP 605 21CFR 178.1010(a)
	Physical	None			
Milk and Whey Product - Condensing	**Biological**	**B-1:** Growth of Pathogens	**B-1:** Pathogens, if present, may grow during storage. [10]	**B-1:** Product to be condensed must be pasteurized prior to entering the condenser.	3-A AP 607
	Chemical	**C-1:** Cleaning & Sanitizing Solution Residues	**C-1:** Without proper separation between cleaning & sanitizing solutions and product there could be product contamination. [9]	**C-1:** Maintain proper separation or physical break between circuits containing cleaning solution and vessels and lines used to contain product.	PMO Item 15p(B) 3-A AP 605 21CFR 178.1010(a)
	Physical	None			
Whey Product Crystallization	**Biological**	**B-1:** Contamination with vegetative pathogens	**B-1:** Pathogens may be introduced during crystallization.	**B-1:** Openings into crystallization vessel are closed with tight fitting covers.	
	Biological	**B-2:** Growth of Vegetative Pathogens	**B-2:** Pathogens, if present, may grow during the crystallization process.	**B-2:** The control limit is the maximum limit on the crystallization time.	

INGREDIENT OR PROCESS	HAZARD	TYPE OF HAZARD	HAZARD RATIONALE	HAZARD MANAGEMENT OR CONTROLS	ADDITIONAL RESOURCES
	Chemical	**C-1:** Cleaning & Sanitizing Solution Residues	**C-1:** Without proper separation between cleaning & sanitizing solutions and product there could be product contamination. [9]	**C-1:** Maintain proper separation or physical break between circuits containing cleaning solution and vessels and lines used to contain product.	PMO Item 15p(B) 3-A AP 605 21CFR 178.1010(a)
	Physical	None			
Condensed Milk and Whey Product Storage	**Biological**	**B-1:** Contamination by Pathogens	**B-1:** Pathogens may be introduced during storage.	**B-1:** Outlet valves and other openings into tanks are protected with tight fitting covers.	
	Biological	**B-2:** Growth of Pathogens	**B-2:** Pathogens, if present, may grow during storage.	**B-2:** Condensed product (including foam and splash) are not held in bacterial growth range.	
	Chemical	**C-1:** Cleaning & Sanitizing Solution Residues	**C-1:** Without proper separation between cleaning & sanitizing solutions and product there could be product contamination. [9]	**C-1:** Maintain proper separation or physical break between circuits containing cleaning solution and vessels and lines used to contain product.	PMO Item 15p(B) 3-A AP 605 21CFR 178.1010(a)
	Physical	None			
Milk and Whey Product - Drying	**Biological**	**B-1:** Contamination by Pathogens	**B-1:** Cracks and crevices in dryers have been found to contain Salmonella capable of surviving in dry environment. [12]	**B-1:** Dryers need to be carefully inspected and any cracks, crevices or similar dead end areas repaired or the dryer removed from service.	3-A AP 607 & 608
	Chemical	None			
	Physical	**P-1:** Extraneous Material	**P-1:** Market withdrawals and recalls have occurred for foreign materials in dairy products. [12]	**P-1:** Openings on the dryer and associated equipment are kept closed. All product-handling equipment is properly designed and maintained in good repair. Product should pass through screens to remove extraneous materials.	3-A SS 24- & 25-
Packaged and Bulk Dry Milk and Whey Products - Storage and Shipment	**Biological**	**B-1:** Contamination with Pathog. e.g.*Salmonella* that may survive in dry environments and products .	**B-1:** Salmonella has been found in environmental testing in dry product storage areas. [9, 12]	**B-1:** Keep dry product storage areas, including overhead ledges and beams as well as electrical boxes and similar areas clean. Do not salvage damaged bags for human food. Bags, bulk containers & totes in storage areas are dust tight. Bulk powder storage must be of sanitary construction and cleanable.	T14 3-A SS 34-

INGREDIENT OR PROCESS	HAZARD	TYPE OF HAZARD	HAZARD RATIONALE	HAZARD MANAGEMENT OR CONTROLS	ADDITIONAL RESOURCES
	Chemical	None			
	Physical	None			
Aseptic Product - Processing	**Biological**	**B-1:** Contamination by pathogens, such as *C. botulinium*	**B-1:** Botulism toxin is one of the most toxic substances that can be found in food. [15, 20, 21]	**B-1:** Under the NCIMS Dairy HACCP program, aseptic processing and the design, construction and operation and testing of aseptic processing equipment must conform to all of the requirements of the Grade "A" Pasteurized Milk Ordinance, 21CFR 108 and 113, and the filed process for the products being produced. Note: If cleaning frequencies are to be performed at frequencies less than those specified in the PMO Item 12p, they are to be reviewed and found acceptable to the State and FDA.	PMO Section 5 21 CFR 108 & 113 PMO Items 12p, 15p(B), 16p & Appendices H & I PMO Item 16p(D)
	Biological	**B-2:** Survival of pathogens such as *C. botulinium*	**B-2:** Botulism toxin is one of the most toxic substances that can be found in food. [15, 20, 21]	**B-2:** Under the NCIMS Dairy HACCP program, aseptic processing and the design, construction and operation and testing of aseptic processing equipment must conform to all of the requirements of the Grade "A" Pasteurized Milk Ordinance, 21CFR 108 and 113, and the filed process for the products being produced.	21 CFR 108 & 113 PMO Item 16p(C)
	Chemical	**C-1:** Cleaning & Sanitizing Solution Residues	**C-1:** Without proper separation between cleaning & sanitizing solutions and product there could be product contamination. [9]	**C-1:** Maintain proper separation or physical break between circuits containing cleaning solution and vessels and lines used to contain product. Particular attention is needed to assure that the required separation remains in place during partial washes, sometimes called "short washes" or " inter-washes" that may be done during an operating day.	PMO Item 15p(B) 3-A AP 605 21CFR 178.1010(a)
	Physical	None			
Aseptically Processed Product (bulk) - Storage	**Biological**	**B-1:** Survival of pathogens such as *C. botulinium*	**B-1:** Pathogens, if present, can grow during storage. [15, 20, 21]	**B-1:** Aseptic processing and the design, construction and operation and testing of aseptic processing equipment must conform to all of the requirements of the Grade "A" Pasteurized Milk Ordinance, 21CFR 108 and 113, and the filed process for the products being produced. Note: If cleaning frequencies are to be performed at frequencies less than those specified in the PMO Item 12p, they are to be reviewed and found acceptable to the State and FDA.	
	Chemical	**C-1:** Cleaning & Sanitizing Solution Residues	**C-1:** Without proper separation between cleaning & sanitizing solutions and product there could be product contamination. [9]	**C-1:** Maintain proper separation or physical break between circuits containing cleaning solution and vessels and lines used to contain product.	PMO Item 15p(B) 3-A AP 605 21CFR 178.1010(a)

INGREDIENT OR PROCESS	HAZARD	TYPE OF HAZARD	HAZARD RATIONALE	HAZARD MANAGEMENT OR CONTROLS	ADDITIONAL RESOURCES
	Chemical	**C-2:** Toxic or carcinogenic substances in the packaging	**C-2:** Packaging material, which does not meet CFR requirements, may contain toxic or carcinogenic substances. [18]	**C-2:** Packaging material comes from a source that has been verified to be free of toxic or carcinogenic substances. One way to do this is to use packaging from IMS listed sources.	IMS List 21CFR 110.80
	Physical	None			
Product lines and Equipment (General Concerns)	**Biological**	**B-1:** Contamination by Vegetative Pathogens	**B-1:** May introduce pathogens if unclean or uncleanable.	**B-1:** Verify that product lines and equipment are constructed in such a way that they can be cleaned. Maintain records that storage vessels are cleaned after each use. Maintain records that the product lines and equipment cleaned as needed nut at least each day unless a longer interval has been reviewed and found acceptable to the State and FDA.	3-A AP 605- PMO Item 10p, 11p, &12p
	Chemical	**C-1:** Allergens being mixed with products that are not labeled as containing allergens	**C-1:** Foods may contain undeclared allergens may cause life threatening reactions in sensitive individuals.	**C-1:** Ingredient addition equipment such as hoppers and feeders and associated piping and valves that are used for milk and milk products that contain allergens (other than milk) and milk and milk products that do not , must be thoroughly cleaned after use for allergens before it is used for foods that do not declare that allergen.	3-A SS 02-, 32-, 35-, 51-, 52-, 63- , 68-, 73-, 81- FDA CPG 555.250
	Physical	**P-1:** Extraneous Materials	**P-1:** Maintain equipment in good repair. [12]	**P-1:** Foreign materials that may have contaminated the product.	3-A SS 10- & 42-
Use of water reclaimed from condensing or membrane processing of milk or whey Products	**Biological**	**B-1:** Contamination by & growth of pathogen	**B-1:** Water used in contact with product and product contact surfaces must be free of pathogens.	**B-1:** Properly implemented mandatory PP #1 - Safety of Water may reduce the likelihood of the occurrence of pathogens.	PMO Appendix D - IV PMO Appendix K
	Chemical	None			
	Physical	None			
Direct Addition of Steam	**Biological**	None			
	Chemical	**C-1:** Toxic Substances	**C-1:** Some boiler water compounds used in the production of steam may contain toxic substances.	**C-1:** Supplier guarantees that boiler water additives comply with 21CFR 173.310 and PMO requirements for culinary steam.	3-A AP 609 PMO Appendix H(III) 21CFR 173.310

INGREDIENT OR PROCESS	HAZARD	TYPE OF HAZARD	HAZARD RATIONALE	HAZARD MANAGEMENT OR CONTROLS	ADDITIONAL RESOURCES
	Physical	None			
Air Under Pressure (Incorporated into product or directed at a food contact surface.)	**Biological**	**B-1:** Contamination by Pathogens	**B-1:** Pathogens may be introduced in the air supply.	**B-1:** Air is drawn from a clean area, is filtered at the intake as needed, and is provided to the point of use oil free and with free of excess moisture. A final filter is provided as near as possible to the point of use to verify these aspects.	PMO Appendix H (II) PMO Item 15p(A)(4) DPC 8
	Chemical	**C-1:** Toxic Substances	**C-1:** Air compressor lubricants may be carried over into air and may be toxic.	**C-1:** Air is drawn from a clean area, is filtered at the intake as needed, and is provided to the point of use oil free and with free of excess moisture. A final filter is provided as near as possible to the point of use to verify these aspects.	3-A AP 604 21CFR 110.40(g)
	Physical	None			
Addition of reworked or reclaimed product	**Biological**	**B-1:** Contamination by Pathogens	**B-1:** Reclaimed or reworked product may have been handled in such a way to subject it to contamination with pathogens.	**B-1:** Product, which has not been continuously in control of the plant, to be reclaimed or reworked is assumed to contain pathogens. When product is no longer under the control of the plant, it can not be assumed to have been held to preclude temperature abuse or adulteration. Only product that has not left the control of the plant should be used, kept segregated, handled, protected and cooled as appropriate for the product with the exception of product approved by the regulatory agency. Reworking is done in a clean area and in a manner that will not contaminate the product being salvaged.	PMO 15p(A)(2), 15p(B)(4), 5p(3) & 18p(3) 21CFR 110.80(a) DPC 8 DPC 63
	Chemical	**C-1:** Allergens being mixed with products that are not labeled as containing allergens	**C-1:** Foods may contain undeclared allergens may cause life threatening reactions in sensitive individuals.	**C-1:** Rework foods containing allergens "like into like".	21CFR 110.80(a)(5) 21CFR 101.100(a)(3) FDA CPG 555.250
	Physical	**P-1:** Extraneous Materials	**P-1:** These can result in choking or other physical harm to consumers. [9, 12]	**P-1:** Opening of products is conducted in a manner that will minimize the opportunity for bits of packaging, cutting tools, etc. from entering the product. Verification that, at some point in the process ingredient or the milk product to which the ingredient is added, will pass through a filter, screen, small orifice (such as occurs during homogenization or other appropriate device.	3-A 10 & 42

XI. References

A. Published Text

- Alzamora, S. M., M. S. Tapia, and A. López-Malo; *Minimally Processed Fruits and Vegetables*; Aspen Publishers, Inc. (2000)
- *Bergey's Manual of Systematic Bacteriology, Volume 2*; Williams & Wilkins Publishers (1986)
- Cliver, D. O. (editor); *Foodborne Diseases*; Academic Press (1990)
- Defigueiredo, M. P. and D. F. Splittstoesser (editors); *Food Microbiology- Public Health & Spoilage Aspects*; AVI Publishing Company (1976)
- Doyle, M. P., L. R. Beuchat, and J. M. Thomas (editors); *Food Microbiology: Fundamentals and Frontiers*; ASM Press
- Downing, D. L.; *A Complete Course in Canning, 13th edition (in 3 volumes)*; CTI Publications, Inc. (1996)
- Hanlon, J. F.; *Handbook of Package Engineering, 2nd edition*; Technomic Publishing Co., Inc. (1992)
- Heldman, D. R. and R. W. Hartel; *Principles of Food Processing*; Chapman & Hall (1997)
- Hobbs, B. C. and R. J. Gilbert; *Food Poisoning & Food Hygiene, 4th edition*; Food & Nutrition Press (1978)
- IDF Bulletin No. 275; *Bacillus cereus in Milk and Milk Products*; 1992
- Imholte, T. J.; *Engineering for Food Safety and Sanitation*; Technical Institute of Food Safety (1984)
- Jay, J. M.; *Modern Food Microbiology, 4th edition*; Chapman & Hall publishers (1992)
- Lund, B. M., T. C. Baird-Parker, and G. W. Gould (editors); *The Microbiological Safety and Quality of Food, Volumes I and II*; Aspen Publishers (2000)
- Marshall, R. T. (editor); *Standard Methods For The Examination Of Dairy Products, 16th edition*; American Public Health Association (1992)
- Oliveira, F. A. R. and J. C. Oliveira (editors); *Processing Foods- Quality Optimization and Process Assessment*; CRC Press (1999)
- Ray, B.; *Fundamental Food Microbiology*; CRC Press (1996)
- Roberts, T. A., A. C. Baird-Parker, and R. B. Thompkin (editors); *Microorganisms in Foods 5- Characteristics of Microbial Pathogens*; International Commission on Microbiological Specifications for Foods, Blackie Academic & Professional publishers (1996)
- Roberts, T. A., J. I. Pitt, J. Farkas, and F. H. Grau (editors); *Microorganisms in Foods 6- Microbial Ecology of Food Commodities*; International Commission on Microbiological Specifications for Foods, Blackie Academic & Professional publishers (1998)
- Robinson, R. K. and R. A. Wilbey; *Cheesemaking Practice, 3rd edition*; Aspen Publishing (1998)
- Shapton, D. A. and N. F. Shapton (editors); *Principles and Practices for the Safe Processing of Food*; Woodhead Publishing Limited (1998)
- Shibamoto T and L. F. Bjeldanes; *Introduction to Food Toxicology*; Academic Press (1993)
- Silliker, J. H., R. P. Elliott, A. C. Baird-Parker, F. L. Bryan, J. H. B. Christian, D. S. Clark, J. C. Olson, and T. A. Roberts (editors); *Microbial Ecology of Foods 2- Food Commodities*; International Commission on Microbiological Specifications for Foods, Academic Press (1980)
- Silliker, J. H., R. P. Elliott, A. C. Baird-Parker, F. L. Bryan, J. H. B. Christian, D. S. Clark, J. C. Olson, and T. A. Roberts (editors); *Microbial Ecology of Foods 1- Factors Affecting Life and Death of Microorganisms*; International Commission on Microbiological Specifications for Foods, Academic Press (1980)
- Spreer, E.; *Milk and Milk Product Technology*; Marcel Dekker, Inc. (1998)

- Vanderzant, C. & D. F. Splittstoesser (editors); *Compendium of Methods for the Microb. Examin. of Foods, 3rd edition*; Amer. Public Health Assoc. (1992)
- Vanderzant, C., D. F. Splittstoesser, et al (ed.); *Evaluation of the Role of Microbiological Criteria for Foods & Food Ingred.*; National Academy Press (1985)

B. Articles Published in Peer Reviewed Scientific Journals

- Ahmed, Moustafa, and Marth; *Incidence of Bacillus cereus in Milk and Some Milk Products*; J Food Prot 1983 Feb;46(2):126-8
- Andrade, Bridgeman, and Zottola; *Bacteriocidal activity o. sanitizers against Enterococcus faecium attached to stainless steel as determined by plat count and impedance methods*; J Food Prot 1998 Jul;61(7):833-8
- Arizcun, Vasseur, and Labadie; *Effect of several decontamination procedures on L. monocytogenes growing in biofilms*; J Food Prot 1998 Jun;61(6):731-4
- Assanta, Roy, & Montpetit; *Adhesion of Aeromonas hydrophila to water distribution system pipes*; J Food Prot 1998 Oct;61(10):1321-9
- Austin and Bergeron; *Development of Bacterial Biofilms in Dairy Processing Lines*; J Dairy Research 1995; 62:509-19
- Baker and Griffiths; *A Research Note: Evidence for Increased Thermostability of Bacillus cereus Enterotoxin in Milk*; J Food Prot 1995 Apr;58(4):443-5
- Berry and Foegeding; *Cold Temperature Adaptation and Growth of Microorganisms*; J Food Prot 1997 Dec;60(12):1583-94
- Bouman, Lund, Driessen, and Schmidt; *Growth of Thermoresistant Streptococci and Disposition of Milk Constituents on Plates of Heat Exchangers During Long Operating Times*; J Food Prot 1982 Sep;45(9):806-12
- Bradshaw, Peeler, Corwin, Hunt and Twedt; *Thermal Resistance of Listeria monocytogenes in Dairy Products*; J Food Prot 1987 Jul;50(7):543-4
- Buchanan, Damert, Whiting, and Schothorst; *Use of Epidemiologic and Food Survey Data to Estimate a Purposefully Conservative Dose-Response Relationship for Listeria monocytogenes Levels and Incidence of Listeriosis*; J Food Prot 1997 Aug;60(8):918-22
- Budu-Amoako, Toora, Ablett and Smith; *Competitive Growth of L. monocytogenes & Y. enterocolitica in Milk*; J Fd Prot 1993 Jun;56(6):528-32
- Bunning, Crawford, Tierney and Peeler; *Thermotolerance of heat-shocked Listeria monocytogenes in milk exposed to high temperature, short-time pasteurization*; Appl Environ Microbial 1992 Jun;58(6):2096-8
- Bunning, Crawford, Tierney, & Peeler; *Thermotolerance of L. monocytogenes & S. typhimurium after sublethal heat*; Appl Env. Microb. 1990 Oct;56(10);3216-9
- Buncic and Avery; *Relationship between variations in pathogenicity and lag phase at 37 degrees C of Listeria monocytogenes previously stored at 4 degrees C*; Lett Appl Microbial 1996 Jul;23(1):18-22
- Butzler and Oosterom; *Campylobacter: pathogenicity and significance in foods*; Int J Food Microbiol 1991 Jan;12(1):1-8
- Collins; *Mycobacterium paratuberculosis: a potential food-borne pathogen?*; J Dairy Sci 1997 Dec;80(12):3445-8
- Cotton and White; *Listeria monocytogenes, Yersinia enterocolitica, and Salmonella in dairy plant environments*; J Dairy Sci 1992 Jan;75(1):51-7
- Crawford, Beliveau, Peeler, Donnelly, and Bunning; *Comparative recovery of uninjured and heat-injured Listeria monocytogenes cells from bovine milk*; Appl Environ Microbiol 1989 Jun;55(6):1490-
- D'Aoust, Park, Szabo, Todd, Emmons, and McKellar; *Thermal inactivation of Campylobacter species, Yersinia enterocolitica, and hemorrhagic Escherichia coli O157:H7 in fluid milk*; J Dairy Sci 1988 Dec;71(12):3230-6
- Doyle and Roman; *Prevalence and survival of Campylobacter jejuni in unpasteurized milk*; Appl Environ Microbiol 1982 Nov;44(5):1154-8
- Evenson, Hinds, Bernstein, and Bergdoll; *Estimation of human dose of staphylococcal enterotoxin A from a large outbreak of staphylococcal food poisoning involving chocolate milk*; Int J Food Mictobiol 1988 Dec 31;7(4):311-6
- Fernandez et al; *Listeria monocytogenes in pasteurized milk*; Can J Microbiol 1986 Feb;32(2):149-50

- Fleming et al; *Pasteurized milk as a vehicle of infection in an outbreak of listeriosis*; N Engl J Med 1985 Feb;312(7):404-7
- Fonden, Fitger, and Pettersson; *Salmonella bacteria in double cream*; Nord Vet Med 1976 Jul-Aug;28(7-8):385-9
- Francis, Spaulding, and Lovett; *Enterotoxin production and thermal resistance of Yersinia enterocolitica in milk*; Appl Environ Microbiol 1980 Jul;40(1):174-6
- Gomez-Lucia et al; *Production of enterotoxin A by supposedly non-enterotoxigenic S. aureus strains*; Appl Environ Microbiol 1989 Jun;55(6):1447-51
- Gruetzmacher and Bradley; *Identification and control of processing variables that affect the quality and safety of fluid milk*; J Food Prot 1999 Jun;62(6):625-31
- Grant, Ball, and Rowe; *Effect of high-temperature, short-time (HTST) pasteurization on milk containing low numbers of Mycobacterium paratuberculosis*; Lett Appl Microbiol 1998 Feb;26(2):166-70
- Grant, Ball, and Rowe; *Effect of higher pasteurization temperatures, and longer holding times at 72 degrees C, on the inactivation of Mycobacterium paratuberculosis in milk*; Lett Appl Microbiol 1999 Jun;28(6):461-5
- Grant, Ball, Neill, & Rowe; *Inactivation of M. paratuberculosis in cows' milk at pasteurization temperatures*; Appl Environ Microbiol 1996 Feb;62(2):631-6
- Greenwood, Hooper, and Rodhouse; *The source of Yersinia spp. in pasteurized milk: an investigation at a dairy*; Epidemiol Infect 1990 Jun;104(3):351-60
- Gruetzmacher and Bradley; *Identification & Control of Processing Variables That Affect the Quality and Safety of Fluid Milk*; J Food Prot 1999 Jun;62(6):625-31
- Harp, Fayer, Pesch, & Jackson; *Effect of pasteurization on infectivity of C. parvum oocysts in water and milk*; Appl Environ Microbiol 1996 Aug;62(8):2866-8
- Helke & Wong; *Survival & Growth Characteristics of L. monocytogenes &S. typhimurium on Stainless Steel & Buna-N Rubber*; J Fd Prot 1994 Nov;57(11):963-8
- Helke, Sommers and Wong; *Attachment of Listeria monocytogenes and Salmonella typhimurium to Stainless Steel and Buna-N in the Presence of Milk and Individual Milk Components*; J Food Prot 1993 Jun;56(6):479-84
- Holick, M. F., Q. Shao, W. W. Liu, and T. C. Chen; *The Vitamin D Content of Fortified Milk and Infant Formula*; New England Journal of Medicine 1992 Apr;326(18): 1178-1181
- Hood and Zottola; *Growth Media and Surface Conditioning Influence the Adherence of Pseudomonas fragi, Salmonella typhimurium, and Listeria monocytogenes Cells to Stainless Steel*; J Food Prot 1997 Sep;60(9):1034-7
- Jacobus, C. H., M. F. Holick, Q. Shao, T. C. Chen, I. A. Holm, J. M. Kolodny, G. E. Fuleihan, and E. W. Seely; *Hypervitaminosis D Associated With Drinking Milk*; New England Luornal of Medicine 1992 Apr;326(18):1173-1177
- Jacquet, Rocourt, & Reynaud; *Study of L. monocytogenes contamination in a dairy plant & characterization of the strain*; Int J Food Microb 1993 Oct;20(1):13-22
- Junttila, Niemela and Hirn; *Minimum growth temperatures of Listeria monocytogenes and non-haemolytic Listeria*; J Appl Bacteriol, 1988 Oct;65(4):321-7
- Keswani and Frank; *Thermal Inactivation of Mycobacterium paratuberculosis in Milk*; J Food Prot 1998 Aug;61(8):974-8
- Kim and Frank; *Effect of Nutrients on Biofilm Formation by Listeria monocytogenes on Stainless Steel*; J Food Prot 1995 Jan;58(1):24-8
- Knabel, Walker, Hartman and Mendonca; *Effects of growth temperature and strictly anaerobic recovery on the survival of Listeria monocytogenes during pasteurization*; Appl Environ Microbiol, 1990 Feb;56(2):370-6
- Krysinski, Brown & Marchisello; *Effect of Cleaners & Sanitizers on L. monocytogenes Attached to Product Contact Surfaces*; J Food Prot 1992 Apr;55(4):246-51
- Lin, Schraft, Odumeru, and Griffiths; *Identification of contamination sources of Bacillus cereus in pasteurized milk*; Int J Food Microbiol 1998 Sep 8;43(3):159-71
- Lou and Yousef; *Resistance of Listeria monocytogenes to Heat after Adaptation to Environmental Stresses*; J Food Prot, 465-71, Vol. 59(5), 1996
- Lovett, Wesley, Vandermaaten, Bradshaw, Francis, Crawford, Donnelly, and Messer; *High-Temperature, Short-Time Pasteurization Inactivates Listeria monocytogenes*; J Food Prot, 734-8, Vol. 53(9), 1990
- Lovett, Bradshaw, and Peeler; *Thermal inactivation of Yersinia enterocolitica in milk*; Appl Environ Microbiol 1982 Aug;44(2):517-9

- Mackey, Boogard, Hayes and Baranyi; *Recovery of heat-injured Listeria monocytogenes*; Int J Food Microbiol, 1994 Jun;22(4):227-37
- Olsvik and Kapperud; *Enterotoxin production in milk at 22 and 4° C by E. coli and Y. enterocolitica*; Appl Environ Microbiol 1982 May;43(5):997-1000
- Pagan, Condon, & Sala; *Effects of several factors on the heat-shock-induced thermotolerance of L. monocytogenes*; Appl Env Microb. 1997 Aug;63(8):3225-32
- Palumbo, Call, Schultz, and Williams; *Minimum and Maximum Temperatures for Growth and Verotoxin Production by Hemorrhagic Strains of Escherichia coli*; J Food Prot, 352-6, Vol. 58(4), 1995
- Patchett, Watson, Fernandez, and Kroll; *The effect of temperature and growth rate on the susceptibility of Listeria monocytogenes to environmental stress conditions*; Lett Appl Microbiol 1996 Feb;22(2):121-4
- Pearson and Marth; *Listeria monocytogenes threat to a safe food supply: a review*; J Dairy Sci 1990 Apr;73(4):912-28
- Pritchard, Beliveau, Flanders, & Donnelly; *Environmental Surveillance of Dairy Plants for the Presence of Yersinia Species*; J Fd Prot, 395-7, Vol. 58(4), 1995
- Pritchard, Flanders, and Donnelly; *Comparison of the incidence of Listeria on equipment versus environmental sites within dairy processing plants*; Int J Food Microbiol 1995 Aug;26(3):375-84
- Radmore, Holzapfel, and Luck; *Proposed guidelines for maximum acceptable air-borne microorganism levels in dairy processing and packaging plants*; Int J Food Microbiol 1988 Feb;6(1):91-5
- Rajkowski, Calderone, and Jones; *Effect of polyphosphate and sodium chloride on the growth of Listeria monocytogenes and Staphylococcus aureus in ultra-high temperature milk*; J Dairy Sci 1994 Jun;77(6):1503-8
- Rushing, J. E. and D. P. Wesen; *Preventing Antibiotic Residues in Milk*; Department of Food Science, North Carolina State University (FSE 99-21)
- Schiemann; *Yersinia enterocolitica in milk and dairy products*; J Dairy Sci 1987 Feb;70(2):383-91
- Skirrow; *Epidemiology of Campylobacter eneritis*; Int J Food Microbiol 1991 Jan;12(1):9-16
- Smoot and Pierson; *Effect of environmental stress on ability of L. monocytogenes Scott A to attach to food contact surfaces*; J Food Prot 1998 Oct;61(10):1293-8
- Smoot and Pierson; *Influence of Environmental Stress on the Kenetics and Strength of Attachment of Listeria monocytogenes Scott A to Buna-N Rubber and Stainless Steel*; J Food Prot, 1286-1292, Vol. 61, No. 10 (1998)
- Soudah and Boor; *Persistence of Escherichia coli O157:H7 in Dairy Fermentation Systems*; J Food Prot, 1602-8, Vol. 61(12), 1998
- Sung and Collins; *Thermal tolerance of Mycobacterium paratuberculosis*; Appl Environ Microbiol 1998 Mar;64(3):999-1005
- Wang, Zhao, and Doyle; *Survival and Growth of Escherichia coli O157:H7 in Unpasteurized and Pasteurized Milk*; J Food Prot, 610-3, Vol. 60(6), 1997
- Williams and Ingham; *Changes in Heat Resistance of Escherichia coli O157:H7 Following Heat Shock*; J Food Protection, 1128-1131, Vol. 60, No. 9 (1997)
- Wong; *Biofilms in Food Processing Environments*; J Dairy Science, 2765-2770, Vol. 81, No. 10 (1998)
- Wong, Chang, and Fan; *Incidence and characterization of Bacillus cereus isolates contaminating dairy products*; Appl Environ Microb. 1988 Mar;54(3):699-702
- Wong and Cerf; *Biofilms: Implications for Hygiene Monitoring of Dairy Plant Surfaces*; IDF Bulletin 302 (1995)
- Zottola; *Scientific Status Summary: Microbial Attachment and Biofilm Formation- A New Problem for the Food Industry?*; Food Tech, 107-14, Vol. 48(7), 1994

Endnotes

1. [1] IFT, 2001. Evaluation and Definition of Potentially Hazardous Foods. Report for IFT/FDA Contract No. 223-98-2333, Task Order No. 4. Chapter 6, Microbiological Challenge Testing.
2. [2] Cliver, D. O.; Virus Transmission via Food; Institute of Food Technologists' (1997)
3. [3] Jacobus, C. H. , M. F. Holick, Q. Shao, T. C. Chen, I. A. Holm, J. M. Kolodny, G. E. Fuleihan, and E. W. Seely; *Hypervitaminosis D Associated With Drinking Milk;* New England Journal of Medicine 1992 Apr; (18):1173-1177
4. [4] Robinson, R. K. and R. A. Wilbey; *Cheesemaking Practice, 3 rd edition;* Aspen Publishing (1998)
5. [5] Shibamoto T. and L. F. Bjeldanes; *Introduction to Food Toxicology;* Academic Press (1993)
6. [6] Alzamora, S. M., M. S. Tapia, and A. Lopaz-Malo; *Minimumally Processed Fruits and Vegetables;* Aspen Publishers, Inc. (2000)
7. [7] Roberts, T. A., J. I. Pitt, J. Farkes, and F. H. Grau (editors); *Microorganisms in Foods 6 - Microbial Ecology of Food Commodies;* International Commission on Microbiological Specifications for Foods, Blackie Academic & Professional Publishers (1998)
8. [8] Silliker, J. H., R. P. Elliott, A. C. Baird-Parker, F. L. Bryan, J. H. B. Christian, D. S. Clark, J. C. Olson, and T. A. Roberts (editors); *Microbial Ecology of Foods 2 - Food Commodities;* International Commission on Microbiological Specifications for Foods, Academic Press (1980)
9. [9] Lund , B. M., T. C. Baird-Parker, and G. W. Gould (editors); *The Microbiological Safety and Quality of Food, Volumes I and II;* Aspen Publishers (2000)
10. [10] Spreer, E.; *Milk and Milk Product Technology;* Marcel Dekker, Inc. (1998)
11. [11] Vanderzant, C. and D. F. Splittstoesser (editors); *Compendium of Methods for the Microbiological Examination of Foods, 3 rd edition;* American Public Health Association (1992)
12. [12] Shaton, D. A., and N. F. Shapton (editors); *Principles and Practices for the Safe Processing of Food;* Woodhead Publishing Limited (1998)
13. [13] Heldman, D. R., and R. W. Hartel; *Principles of Foods Processing;* Chapman & Hall (1997)
14. [14] Oliveria, F. A. R. and J. C. Oliveira (editors); *PROCESSING Foods - Qualtiy Optimization and Process Assessment;* CRC Press (1999)
15. [15] Cliver, D. O. (editor); *Foodbourne Diseases;* Academic Press (1990)
16. [16] Defigueiredo, M. P. and D. F. Splittstoesser (editors); *Food Microbiology - Public Health and Spoilage Aspects;* AVI Publishing Company (1976)
17. [17] Jay, J. M.; *Modern Food Microbiology, 4 th edition;* Chapman & Hall Publishers (1997)
18. [18] Hanlon, J. F.; *Handbook of Package Engineering, 2 nd edition;* Technomic Publishing Co., Inc. (1992)
19. [19] Ray, B.: *Fundamental Food Microbiology;* CRC Press (1996)
20. [20] *Bergey's Manual of Systematic Bacteriology, Volume 2;* Williams & Wilkins Publishers (1986)
21. [21] Roberts, T. A., A. C. Baird-Parker, and R. B. Thompkin (editors); *Microorganisms in Foods 5 - Characteristics of Microbiological Pathogens;* International Commission on Microbiological Specifications for Foods, Blackie Academic & Professional Publishers (1996)