

# **NCIMS ASEPTIC PILOT PROGRAM**

**February 13, 2008 Update**

# **NCIMS ASEPTIC PILOT PROGRAM**

## **Introduction**

The NCIMS Aseptic Committee was formed in 2003 to study aseptic processing and packaging as it relates to the Pasteurized Milk Ordinance (PMO), the Code of Federal Regulations (CFR) and the National Conference on Interstate Milk Shipments (NCIMS). With passage of proposal 319 at the 2005 NCIMS, the voting delegates instructed the Aseptic Committee to continue its work. The NCIMS Aseptic Pilot Program is the result of those efforts. The NCIMS Aseptic Pilot Program will allow a time period for implementation, training and evaluation of the regulatory and rating provisions contained in the program. The Aseptic Pilot Program is based on the record of safety for low acid canned food products, including milk and milk products, established for over 30 years through the Code of Federal Regulations (CFR), 21 CFR part 108, 110, and 113 as well as the record of milk safety established by the PMO.

## **Key Elements of the NCIMS Aseptic Pilot Program**

- Eliminates confusion stemming from differences between the PMO and CFR requirements and promotes national regulatory uniformity.
- Areas of responsibility and authority are clarified in writing for regulatory inspections, state ratings and FDA check ratings.
- The Pilot Program will not affect the process for the issuance of a State license/permit to an aseptic milk plant.
- Testing and sealing of aseptic processing and packaging equipment by the regulatory agency is no longer required.
- Clarifies that regulatory sampling and testing of aseptic finished products is not required.
- Defines aseptic processing and packaging systems in the PMO and other NCIMS documents. Aseptic processing and packaging systems are regulated under the CFRs and are rated as a part of the aseptic milk plant using the Aseptic Processing and Packaging System Critical Listing Elements (ACLEs), which are pass/fail and that constitutes grounds for denial or removal of the milk plant's aseptic milk and milk products IMS Listing. The rest of the aseptic milk plant is required to be inspected using PMO criteria at least once each six (6) months. If the receiving area is included with the aseptic milk plant IMS Listing or IMS Listed separately as an aseptic milk plant receiving station it shall be inspected at least once every six (6) months. If the receiving area is common to both the aseptic milk plant and to the pasteurization area of the aseptic milk plant, then this common receiving area may be included in the pasteurization milk plant IMS Listing. In this case, the minimum frequency for the regulatory inspection of the pasteurization milk plant and the common receiving area shall be at least every three (3) months.
- The Proposal requests the formation of an NCIMS Aseptic Pilot Program Implementation Committee (APPIC). The APPIC shall be responsible for the oversight of the NCIMS Aseptic Pilot Program including development of the forms, documents and guidance necessary to implement, evaluate and provide training for the NCIMS Aseptic Pilot Program (APP), in consultation with FDA. The APP will expire on December 31, 2009 unless extended at the 2009 NCIMS.

- The NCIMS APP substantially resolves the issues contained in the 2005 NCIMS Proposals 109 and 319.

**2007 NCIMS Aseptic Pilot Program Implementation Committee Members**

<b>First Name</b>	<b>Last Name</b>	<b>Organization</b>
Cindy	Coulter	H.P. Hood
Jason	Crafts	Gossner Foods
Becca	Durant	New York Dept. of Agriculture
Sia	Economides	Nestle USA
Susan	Esser	Michigan Dept. of Agriculture
Tom	Ford	Indiana Board of Animal Health
Dan	Geffin*	FDA
Katherine	Gehl	Gehl Guernsey Dairy
Robert	Hennes*	FDA
Roger	Hooi	Morningstar Foods
Keith	Ito **	Lab. for Research in Food Preservation. U.C. Davis
Cynthia	Leonard*	FDA
Wayne	Kasacek	Connecticut Department of Agriculture
Jeff	Merritt	Pacific Foods
Jim	Postlewait	Oregon Depart of Agriculture
Emil	Nashed	Farmland Dairies
Gena	Reich	Washington Department of Agriculture
Allen	Sayler	International Dairy Foods Assoc.
Kathy	Stodola	Wisconsin Dept. of Agriculture
Brian	Thane	Tetra Pak
Lewis	Turner	Maryland Dept. of Health
Perry	Verner	Texas Dept. of Health
	* FDA Consultant	
	** Technical Advisor	

# NCIMS ASEPTIC PILOT PROGRAM

**NOTE:** The NCIMS Aseptic Pilot Program (APP) will be conducted using the 2005 NCIMS documents with the changes indicated below as the basis for the pilot program. **During the pilot, the Aseptic Pilot Program Implementation Committee (APPIC) shall address other issues, including but not limited to, aseptic training, FDA check ratings, enforcement responsibilities, qualifications and certifications that must be included in a final Proposal.**

## GRADE "A" PASTEURIZED MILK ORDINANCE (GRADE "A" PMO)--2005 REVISION

### PAGE 1:

An *Ordinance* defining "milk" and certain "milk products", "milk producer", "pasteurization", etc.; prohibiting the sale of adulterated and misbranded milk and milk products; requiring permits for the sale of milk and milk products; regulating the inspection of dairy farms and milk plants; the examination, labeling, pasteurization, aseptic processing and packaging and distribution and sale of milk and milk products; providing for the construction of future dairy farms and milk plants; the enforcement of this *Ordinance*; and the fixing of penalties.

Be it ordained by the ... of ...<sup>1</sup> as follows:

### SECTION 1. DEFINITIONS

Terms used in this document, not specifically defined herein, are those within Title 21, *Code of Federal Regulations* (CFR) and/or the *Federal Food, Drug, and Cosmetic Act* (FFD&CA) as amended.

The following additional definitions shall apply in the interpretation and the enforcement of this *Ordinance*:

~~B. ASEPTIC PROCESSING: The term "Aseptic Processing", when used to describe a milk product, means that the product has been subjected to sufficient heat processing and packaged in a hermetically sealed container, to conform to the applicable requirements of 21 CFR 113 (Refer to the Reference in Appendix L.) and the provisions of Section 7, Item 16p of this *Ordinance*, and to maintain the commercial sterility of the product under normal non-refrigerated conditions.~~

**B. ASEPTIC PROCESSING AND PACKAGING:** Means the filling of a commercially sterilized cooled product into pre-sterilized containers, followed by aseptic hermetical sealing, with a pre-sterilized closure, in an atmosphere free of microorganisms. (*Reference* 21 CFR 113.3)

**C. ASEPTIC PROCESSING AND PACKAGING SYSTEM:** For the purposes of this *Ordinance*, the Aseptic Processing and Packaging System in a milk plant that produces aseptic Grade "A" milk or milk products shall be regulated in accordance with the FDA Low Acid

Canned Foods regulations cited in 21 CFR 108, 110, and 113 and shall be defined by the Scheduled Process filed with FDA (FORM FDA 2541c and referenced Supplemental Submission Identifier (SUP-SID) documents, or in written communication from the Process Authority or equipment manufacturer). It would begin and end with any step considered critical to the filed Scheduled Process.

**D. ASEPTIC RAW MILK RECEIVING AREA:** The raw milk receiving area of a milk plant that produces Grade "A" aseptically processed and packaged milk and milk products is that area of the milk plant where Grade "A" fluid milk and milk products are received, collected, handled, stored and/or cooled. This area may be inspected, rated and IMS Listed according to the current NCIMS requirements for a receiving station, except that it shall be inspected at least once every six (6) months. This area may be rated with the aseptic milk plant; or with a separately-listed pasteurization plant; or separately as an aseptic milk plant receiving station. All milk and milk products shall be from an IMS Listed source. NOTE: If this receiving area is IMS Listed with the pasteurization milk plant, it shall be inspected at least once every three (3) months.

**E. ASEPTIC MILK PLANT RECEIVING STATION:** A raw milk receiving area of a milk plant that produces Grade "A" aseptically processed and packaged milk and milk products that is separately inspected, rated and IMS Listed according to the NCIMS requirements for a receiving station, except that the minimum regulatory inspection frequency shall be at least once every six (6) months. All milk and milk products shall be from an IMS Listed source.

**NOTE:** Re-letter the remaining Definitions accordingly.

**PAGE 5:**

U. **MILK PLANT:** A milk plant is any place, premises; or establishment where milk or milk products are collected, handled, processed, stored, pasteurized, ultra-pasteurized, aseptically processed and packaged, condensed, dried, packaged, or prepared for distribution.

**PAGE 14:**

**SECTION 4. LABELING**

1. The identity of the milk plant where pasteurized, ultra-pasteurized, aseptically processed and packaged, condensed and/or dried.
2. The words "keep refrigerated after opening" in the case of packages containing more than one serving of aseptically processed and packaged milk and milk products.

**PAGE 15:**

**IDENTITY LABELING:** "Identity", as used in this Section, is defined as the name and address or permit number of the milk plant at which the pasteurization, ultra-pasteurization, aseptic processing and packaging, condensing and/or drying takes place. It is recommended that the voluntary national uniform coding system for the identification of milk plants, at which milk and milk products are packaged, be adopted in order to provide a uniform system of codes throughout the country.

In cases where several milk plants are operated by one firm, the common firm name may be utilized on milk bottles, containers and packages. Provided, that the location of the milk plant at which the contents were pasteurized, ultra-pasteurized, aseptically processed and packaged, condensed and/or dried is also shown, either directly or by a code. This requirement is necessary in order to enable the Regulatory Agency to identify the source of the pasteurized, ultra-pasteurized, aseptically processed and packaged, condensed and/or dried milk or milk products. The street address of the milk plant need not be shown when only one (1) milk plant of a given name is located within the municipality.

**MISLEADING LABELS:** The Regulatory Agency shall not permit the use of any misleading marks, words or endorsements upon the label. They may permit the use of registered trade designs or similar terms on the bottle cap or label, when in their opinion, they are not misleading and are not so used as to obscure the labeling required by this *Ordinance*. For dry milk products, the outer bag must be preprinted "Grade "A" before filling. The use of super grade designations shall not be permitted. However, this should not be construed as prohibiting the use of official grade designations awarded to dry milk products by the United States Department of Agriculture (USDA). Grade designations such as "Grade "AA" Pasteurized", "Selected Grade "A" Pasteurized", "Special Grade "A" Pasteurized", etc., give the consumer the impression that such a grade is significantly safer than Grade "A". Such an implication is false, because the *Ordinance* requirements for Grade "A" pasteurized, ultra-pasteurized, or aseptically processed and packaged milk and milk products when properly enforced, will ensure that this grade of milk will be as safe as milk can practically be made. Descriptive labeling terms must not be used in conjunction with the Grade "A" designation or name of the milk or milk product and must not be false or misleading.

**PAGE 16:**

## **SECTION 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS**

3. Inspect each milk plant and receiving station at least once every three (3) months, provided that, for those milk plants and receiving stations that have HACCP Systems, which are regulated under the NCIMS HACCP Program, regulatory audits shall replace the regulatory inspections described in this Section. The requirements and minimum frequencies for these regulatory audits are specified in Appendix K. Provided further, that regulatory inspections of IMS Listed milk plants producing aseptically processed and packaged product shall be conducted by the State Regulatory Agency in accordance with this *Ordinance* (Refer to the chart below for details) at least once every six (6) months, with the milk plant's aseptic processing and packaging systems inspected by FDA, or the State Regulatory Agency when designated by FDA, in accordance with 21 CFR 108, 21 CFR 110 and 21 CFR 113 at a frequency determined by FDA.

**ASEPTIC PILOT PROGRAM CFR/PMO SUMMARY REFERENCE**  
**TABLE**

<b><u>PMO, Section 7 Items</u></b>	<b><u>Changes to the PMO Under the Aseptic Pilot</u></b>	<b><u>Authority</u></b>
<u>1p. Floors - Construction</u>	<u>Floor drains are not required in storage rooms for aseptic processed and packaged milk or milk products.</u>	<u>PMO</u>
<u>2p. Walls and Ceiling - Construction</u>	<u>Ceilings requirements are exempt in aseptic processed and packaged milk or milk products storage rooms.</u>	<u>PMO</u>
<u>3p. Doors and Windows</u>	<u>None</u>	<u>PMO</u>
<u>4p. Lighting and Ventilation</u>	<u>None</u>	<u>PMO</u>
<u>5p. Separate Rooms</u>	<u>Fabrication of containers and closures for aseptic processed and packaged milk and milk products is exempt.</u>	<u>PMO</u>
<u>6p. Toilet – Sewage Disposal Facilities</u>	<u>None</u>	<u>PMO</u>
<u>7p. Water Supply*</u>	<u>The Aseptic Processing and Packaging System is exempt, but shall comply with the CFR.</u>	<u>PMO/CFR</u>
<u>8p. Hand washing Facilities</u>	<u>None</u>	<u>PMO</u>
<u>9p. Milk Plant Cleanliness</u>	<u>None</u>	<u>PMO</u>
<u>10p. Sanitary Piping*</u>	<u>The Aseptic Processing and Packaging System is exempt, but shall comply with the CFR.</u>	<u>PMO/CFR</u>
<u>11p. Construction and Repair of Containers and Equipment*</u>	<u>The Aseptic Processing and Packaging System is exempt, but shall comply with the CFR. Paper, plastics, foil, adhesives and other components of containers and closures are not required to comply with Appendix J of the PMO, originate from an IMS Listed Source, and are subject to the requirements of the CFR.</u>	<u>PMO/CFR</u>
<u>12p. Cleaning and Sanitizing of Containers and Equipment*</u>	<u>The Aseptic Processing and Packaging System is exempt, but shall comply with the CFR.</u>	<u>PMO/CFR</u>
<u>13p. Storage of Cleaned Containers and Equipment*</u>	<u>The Aseptic Processing and Packaging System is exempt, but shall comply with the CFR.</u>	<u>PMO/CFR</u>
<u>14p. Storage of Single- Service Containers, Utensils and Materials</u>	<u>None</u>	<u>PMO</u>
<u>15p.(A) Protection from Contamination*</u>	<u>The Aseptic Processing and Packaging System is exempt, but shall comply with the CFR.</u>	<u>PMO/CFR</u>
<u>15p.(B) Protection from Contamination - Cross Connections*</u>	<u>The Aseptic Processing and Packaging System is exempt, but shall comply with the CFR. Aseptic Processing and Packaging System equipment does not have to comply with the separation requirements of the PMO in relationship to instrumented steam blocks between milk and</u>	<u>PMO/CFR</u>

<u>PMO, Section 7 Items</u>	<u>Changes to the PMO Under the Aseptic Pilot</u>	<u>Authority</u>
	<u>milk products and cleaning and/or chemical sanitizing solutions.</u>	
<u>16p. Pasteurization and Aseptic Processing ((A) through (E))*</u>	<u>The Aseptic Processing and Packaging system is exempt, but shall comply with the CFR. The State Regulatory Agency is not required to conduct the quarterly equipment testing and sealing of aseptic processing equipment. Records and recording charts are not required to be reviewed during routine inspections, state ratings or check ratings.</u>	<u>CFR</u>
<u>17p. Cooling of Milk and Milk Products*</u>	<u>The Aseptic Processing and Packaging System is exempt, but shall comply with the CFR.</u>	<u>PMO/CFR</u>
<u>18p. Bottling, Packaging and Container Filling*</u>	<u>The Aseptic Processing and Packaging System is exempt, but shall comply with the CFR.</u>	<u>CFR</u>
<u>19p. Capping, Container Closure and Sealing and Dry Milk Product Storage*</u>	<u>The Aseptic Processing and Packaging System is exempt, but shall comply with the CFR.</u>	
<u>20p. Personnel -Cleanliness</u>	<u>None</u>	<u>PMO</u>
<u>21p. Vehicles</u>	<u>None</u>	<u>PMO</u>
<u>22p. Surroundings</u>	<u>None</u>	<u>PMO</u>

\* NOTE: In areas of the milk plant where these Items fall under the Aseptic Processing and Packaging System, as defined by the PMO, they shall be inspected according to the FDA LACF program (21 CFR 108, 110 and 113).

**PAGES 16-17:**

.... Provided, that when the Regulatory Agency finds that a critical processing element violation involving:

1. Proper pasteurization, whereby every particle of milk or milk product may not have been heated to the proper temperature and held for the required time in properly designed and operated equipment;
2. A cross-connection exists whereby direct contamination of pasteurized milk or milk product is occurring; or
3. Conditions exist whereby direct contamination of pasteurized milk or milk product is occurring.

The Regulatory Agency shall take immediate action to prevent further movement of such milk or milk product until such violations of critical processing element(s) have been corrected. Should correction of such critical processing element(s) not be accomplished immediately, the Regulatory Agency shall take prompt action to suspend the permit as provided for in Section 3 of this *Ordinance*. ~~Provided, that in the case of milk plants producing aseptically processed milk and milk products, when an inspection of the milk plant and its records reveal that the process used has been less than the required scheduled process, it shall be considered an imminent hazard~~



~~to public health and the Regulatory Agency shall take immediate action to suspend the permit of the milk plant for the sale of aseptically processed milk and milk products in conformance with Section 3 of this Ordinance.~~

**PAGE 17:**

### **ADMINISTRATIVE PROCEDURES**

**INSPECTION FREQUENCY:** For the purposes of determining the inspection frequency for dairy farms transfer stations, and IMS Listed milk plants producing aseptically processed and packaged milk and milk products and an associated IMS Listed aseptic milk plant receiving area or station, the interval shall include the designated six (6) month period plus the remaining days of the month in which the inspection is due.

For the purposes of determining the inspection frequency for all other milk plants and receiving stations the interval shall include the designated three (3) month period plus the remaining days of the month in which the inspection is due.

One (1) milk tank truck inspection every twelve (12) months; or bulk milk hauler/sampler's or industry plant sampler's pickup and sampling procedures inspection each twenty-four (24) months; or one (1) producer, transfer station, IMS Listed milk plant producing aseptically processed and packaged milk and milk products and an associated IMS Listed aseptic milk plant receiving area or station, or milk tank truck cleaning facility inspection every six (6) months, or one (1) milk plant producing pasteurized, condensed or dried milk and milk products or receiving station inspection every three (3) months is not a desirable frequency, it is instead a legal minimum. Bulk milk hauler/samplers, industry plant samplers, milk tank trucks, milk tank truck cleaning facilities, dairy farms, milk plants, receiving stations and transfer stations experiencing difficulty meeting requirements should be visited more frequently. Milk plants that condense and/or dry milk or milk products and which operate for a short duration of time or intermittent periods of time should also be inspected more frequently. Inspections of dairy farms shall be made at milking time as often as possible and of milk plants at different times of the day in order to ascertain if the processes of equipment assembly, sanitizing, pasteurization, cleaning and other procedures comply with the requirements of this *Ordinance*.

For the purpose of determining the minimum audit frequency for milk plants, receiving stations and transfer stations regulated under the NCIMS HACCP Program the interval shall include the remaining days of the month in which the audit is due.

**PAGE 18:**

**ENFORCEMENT PROCEDURES:** This Section provides that a dairy farm, bulk milk hauler/sampler, milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor, ~~except those processing aseptically processed milk and milk products,~~ shall be subject to suspension of permit and/or court action if two (2) successive inspections disclose a violation of the same requirement.

**PAGE 19: -**

~~**ENFORCEMENT PROCEDURES – ASEPTIC PROCESSING MILK PLANTS:** Because aseptically processed milk and milk products are stored at room temperature and are not refrigerated after processing they must be considered an imminent hazard to public health whenever it is revealed by an inspection or a review of the processing records that the process is less than the required scheduled process and the products produced have not maintained their commercial sterility. Prompt action by the Regulatory Agency to suspend the permit must be initiated in order to protect the public health. The Regulatory Agency shall stop the sale of all under-processed milk or milk product and follow at least the minimum requirements of 21 CFR 113.89 before releasing any product. (Refer to Appendix L.)~~

**PAGE 21:**

## **SECTION 6 THE EXAMINATION OF MILK AND MILK PRODUCTS**

1. During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization or aseptic processing and packaging shall be collected from each producer, in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained under the direction of the Regulatory Agency or shall be taken from each producer under the direction of the Regulatory Agency and delivered in accordance with this Section.

2. During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization, ultra-pasteurization or aseptic processing and packaging, shall be collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained by the Regulatory Agency, from each milk plant after receipt of the milk by the milk plant and prior to pasteurization, ultra-pasteurization or aseptic processing and packaging.

**PAGE 22:**

4. During any consecutive six (6) months, at least four (4) samples of pasteurized milk, flavored milk, flavored reduced fat or low fat milk, flavored nonfat (skim) milk, each fat level of reduced fat or low fat milk and each milk product defined in this *Ordinance*, shall be collected by the Regulatory Agency in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days from every milk plant. All pasteurized, ~~(including Aseptically Processed and Ultra-Pasteurized)~~, milk and milk products required sampling and testing is to be done only when there are test methods available that are validated by FDA and accepted by the NCIMS. Products with no validated and accepted methods are not required to be tested.

All pasteurized, ~~(including Aseptically Processed and Ultra-Pasteurized)~~, milk and milk products required sampling and testing to be done only when there are test methods available that are validated by FDA and accepted by the NCIMS, otherwise there would be no requirement for sampling. Required bacterial counts, coliform counts, drug tests, phosphatase and cooling

temperature determinations shall be performed on Grade "A" pasteurized milk and milk products defined in this *Ordinance* only when there are validated and accepted test methodology.

**NOTE:** When multiple samples of the same milk or milk products, except for aseptically processed and packaged milk and milk products, are collected from the same producer or processor from multiple tanks or silos on the same day, the laboratory results are averaged arithmetically by the Regulatory Agency and recorded as the official results for that day. This is applicable for bacterial (standard plate count and coliform), somatic cell count and temperature determinations only.

Whenever two (2) of the last four (4) consecutive bacterial counts (except those for aseptically processed and packaged milk and milk products), somatic cell count, coliform determinations, or cooling temperatures, taken on separate days, exceed the standard for the milk and/or milk products as defined in this *Ordinance*, the Regulatory Agency shall send a written notice thereof to the person concerned. This notice shall be in effect as long as two (2) of the last four (4) consecutive samples exceed the standard. An additional sample shall be taken within twenty-one (21) days of the sending of such notice, but not before the lapse of three (3) days. Immediate suspension of permit, in accordance with Section 3, and/or court action shall be instituted whenever the standard is violated by three (3) of the last five (5) bacterial counts (except those for aseptically processed and packaged milk and milk products), somatic cell counts, coliform determinations or cooling temperatures.

**PAGE 23:**

~~Whenever a container or containers of aseptically processed milk or milk product is found to be non-sterile, due to under processing, the Regulatory Agency shall consider this to be an imminent hazard to public health and shall suspend the permit of the milk plant for the sale of aseptically processed milk and milk products. No aseptically processed milk and milk product shall be sold until it can be shown that the processes, equipment and procedures used are suitable for consistent production of a sterile product. All products from the lot that were found to contain one (1) or more non-sterile units shall be recalled and disposed of as directed by the Regulatory Agency.~~

Samples shall be analyzed at an appropriate official or officially designated laboratory. All sampling procedures, including the use of approved in-line samplers, and required laboratory examinations shall be in substantial compliance with the most current edition of *Standard Methods for the Examination of Dairy Products* (SMEDP) of the American Public Health Association, and the most current edition of *Official Methods of Analysis of AOAC INTERNATIONAL* (OMA). Such procedures, including the certification of sample collectors and examinations shall be evaluated in accordance with the *EML*. ~~Aseptically processed milk and milk products packaged in hermetically sealed containers shall be tested in accordance with FDA's *Bacteriological Analytical Manual* (BAM).~~

**PAGE 24:**

### **ADMINISTRATIVE PROCEDURES**

**ENFORCEMENT PROCEDURES:** All violations of bacteria, coliform, confirmed somatic cell counts and cooling temperature standards should be followed promptly by inspection to determine and correct the cause. (Refer to Appendix E. Examples of Three (3)-out-of-Five (5) Compliance Enforcement Procedures)

~~Aseptically processed milk and milk products packaged in hermetically sealed containers are exempt from the refrigerated storage requirements of this Ordinance. Therefore, whenever a breakdown in the processing or packaging of these products occurs an imminent hazard to public health exists. Prompt action is needed by the Regulatory Agency. Milk plants aseptically processing milk and milk products in hermetically sealed containers should be encouraged to perform bacterial and other quality tests on each lot of aseptically processed milk and milk product produced in order to ascertain that these products have been properly processed and have not been rendered non-sterile after aseptic processing and packaging. The Regulatory Agency may utilize industry records, of each lot of aseptically processed milk and milk products, to determine when lots can be released for sale after a violation of the bacterial standards has existed.~~

**PAGE 26:**

### **SECTION 7. STANDARDS FOR GRADE "A" MILK AND MILK PRODUCTS**

All Grade "A" raw milk or milk products for pasteurization, ultra-pasteurization, or aseptic processing and packaging and all Grade "A" pasteurized, or ultra-pasteurized ~~or aseptically processed~~ milk and milk products, shall be produced, processed, manufactured and pasteurized, or ultra-pasteurized, ~~or aseptically processed~~ to conform to the following chemical, physical, bacteriological and temperature standards and the sanitation requirements of this Section.

**PAGES 28-29:**

<b>Table 1. Chemical, Physical, Bacteriological, and Temperature Standards</b>		
GRADE "A" RAW MILK AND MILK PRODUCTS FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING	Temperature.....	Cooled to 10°C (50°F) or less within four (4) hours or less, of the commencement of the first milking, and to 7°C (45°F) or less within two (2) hours after the completion of milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10°C (50°F). <b>NOTE:</b> Milk sample submitted for testing cooled and maintained at 0°C (32°F) to 4.4°C (40°F), where sample temperature is >4.4°C (40°F), but ≤7.0°C (45°F) and less than three (3) hours after collection has not increased in temperature.
	Bacterial Limits.....	Individual producer milk not to exceed 100,000 per mL prior to commingling with other producer milk. Not to exceed 300,000 per mL as commingled milk prior to pasteurization. <b>NOTE:</b> Tested in conjunction with the drug residue/inhibitory substance test.
	Drugs.....	No positive results on drug residue detection methods as referenced in Section 6 - Laboratory Techniques.
	Somatic Cell Count*...	Individual producer milk not to exceed 750,000 per mL.
GRADE "A" PASTEURIZED MILK AND MILK PRODUCTS AND BULK SHIPPED HEAT-TREATED MILK PRODUCTS	Temperature.....	Cooled to 7°C (45°F) or less and maintained thereat. <b>NOTE:</b> Milk sample submitted for testing cooled and maintained at 0°C (32°F) to 4.4°C (40°F), where sample temperature is >4.4°C (40°F), but ≤7.0°C (45°F) and less than three (3) hours after collection has not increased in temperature.
	Bacterial Limits**.....	20,000 per mL, or gm.*** <b>NOTE:</b> Tested in conjunction with the drug residue/inhibitory substance test.
	Coliform**** .....	Not to exceed 10 per mL. Provided, that in the case of bulk milk transport tank shipments, shall not exceed 100 per mL. <b>NOTE:</b> Tested in conjunction with the drug residue/inhibitory substance test.
	Phosphatase*****.....	Less than 350 milliunits/L for fluid products and other milk products by approved electronic phosphatase procedures.
	Drugs** .....	No positive results on drug residue detection methods as referenced in Section 6 - Laboratory Techniques which have been found to be acceptable for use with pasteurized and heat-treated milk and milk products.

<b>Table 1. Chemical, Physical, Bacteriological, and Temperature Standards</b>		
GRADE "A" PASTEURIZED CONCENTRATED (CONDENSED) MILK AND MILK PRODUCTS	Temperature.....	Cooled to 7°C (45°F) or less and maintained thereat unless drying is commenced immediately after condensing.
	Coliform.....	Not to exceed 10 per gram. <i>Provided</i> , that in the case of bulk milk transport tank shipments shall not exceed 100 per gram.
GRADE "A" ULTRA-PASTEURIZED MILK AND MILK PRODUCTS	Temperature.....	Cooled to 7°C (45°F) or less and maintained thereat.
	Bacterial Limits**.....	20,000 per mL, or gm.***
	Coliform****.....	Not to exceed 10 per mL. <i>Provided</i> , that in the case of bulk milk transport tank shipments, shall not exceed 100 per mL.
	Phosphatase*****.....	Phosphatase testing of Ultra-Pasteurized milks is not required.
	Drugs**.....	There are no validated and accepted drug residue tests for Ultra-Pasteurized Milk and Milk Products
GRADE "A" ASEPTICALLY PROCESSED AND PACKAGED MILK AND MILK PRODUCTS <u>(NOTE: Regulatory sampling and testing is not required.)</u>	Temperature.....	None.
	Bacterial Limits.....	Refer to 21 CFR 113. 3(e)(1)*****
	Drugs**.....	<del>There are no validated and accepted drug residue tests for Aseptically Processed Milk and Milk Products.</del>
GRADE "A" NONFAT DRY MILK	Butterfat..... Moisture..... Titratable Acidity..... Solubility Index..... Bacterial Estimate..... Coliform..... Scorched Particles Disc B.....	No More Than: 1.25% 4.00% 0.15% 1.25mL. 30,000 per gram 10 per gram 15.0 per gram
GRADE "A" WHEY FOR CONDENSING AND/OR DRYING	Temperature.....	Maintained at a temperature of 45°F (7°C) or less, or 57°C (135°F) or greater, except for acid-type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below.
GRADE "A" PASTEURIZED CONDENSED WHEY AND WHEY PRODUCTS	Temperature.....	Cooled to 10°C (50°F) or less during crystallization, within 72 hours of condensing.
	Coliform Limit.....	Not to exceed 10 per gram.
GRADE "A" DRY WHEY, GRADE "A" DRY WHEY PRODUCTS, GRADE "A" DRY BUTTERMILK, AND GRADE "A" DRY BUTTERMILK PRODUCTS	Coliform Limit.....	Not to exceed 10 per gram.

- \* Goat Milk 1,000,000 per mL
- \*\* Not applicable to acidified or cultured products, eggnog and flavored (non-chocolate) milk and milk products.
- \*\*\* Results of the analysis of dairy products which are weighed in order to be analyzed will be reported in # per gm. (Refer to the current edition of the *SMEDP*)
- \*\*\*\* Not applicable to bulk shipped heat-treated milk products.
- \*\*\*\*\* Not applicable to bulk shipped heat-treated milk products; UP products that have been thermally processed at or above 138<sup>0</sup>C (280<sup>0</sup>F) for at least two (2) seconds to produce a product which has an extended shelf life (ESL) under refrigerated conditions; and condensed products.
- \*\*\*\*\* 21 CFR 113.3(e)(1) contains the definition of “COMMERCIAL STERILITY”.

**PAGE 30:**

**STANDARDS FOR GRADE “A” RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING AND PACKAGING**

**PAGE 54:**

**STANDARDS FOR GRADE “A” PASTEURIZED, ULTRA-PASTEURIZED AND ASEPTICALLY PROCESSED AND PACKAGED MILK AND MILK PRODUCTS**

In the case of IMS Listed milk plants that produce aseptically processed and packaged milk or milk products and are inspected in accordance with Section 5, #3 on Page 16 of this Ordinance, the aseptic processing and packaging systems, as defined by this Ordinance, shall be exempt from Items 7p, 10p, 11p, 12p, 13p, 15p, 16p, 17p, 18p, and 19p of this Ordinance and shall comply with the applicable portions of 21 CFR 108, 21 CFR 110, and 21 CFR 113. These Items, contained within the aseptic processing and packaging system, shall be inspected by FDA, or a State Regulatory Agency designated by FDA, under the FDA LACF program.

In the case of milk plants, receiving stations and transfer stations, which have HACCP Systems regulated under Appendix K. of this *Ordinance*, the HACCP System shall address the public health concerns described in this Section in a manner that provides protection equivalent to the requirements in this Section.

Milk plants that have HACCP Systems, which are regulated under the NCIMS HACCP Program, shall comply with all of the requirements of Item 16p. Pasteurization ~~and Aseptic Processing~~ of this *Ordinance*, and pasteurization shall be managed as a CCP as described in Appendix H. MILK AND MILK PRODUCT CONTINUOUS-FLOW (HTST AND HHST) PASTEURIZATION---CCP MODEL HACCP PLAN SUMMARY; and MILK AND MILK PRODUCT VAT (BATCH) PASTEURIZATION---CCP MODEL HACCP PLAN SUMMARY.

**PAGE 55:**

**ITEM 1p. FLOORS - CONSTRUCTION**

**ADMINISTRATIVE PROCEDURES**

This Item is deemed to be satisfied when:

3. The floors are provided with trapped drains. Cold-storage rooms used for storing milk and milk products need not be provided with floor drains when the floors are sloped to drain to one or more exits. Storage rooms for dry ingredients, dry packaged milk or milk products, aseptically processed or packaged milk or milk products, and/or packaging materials need not be provided with drains.

**PAGE 55:**

**ITEM 2p. WALLS AND CEILINGS - CONSTRUCTION**

**ADMINISTRATIVE PROCEDURES**

This Item is deemed to be satisfied when:

1. Walls and ceilings are finished with smooth, washable, light-colored impervious materials.
2. Walls, partitions, windows and ceilings are kept in good repair.

**NOTE:** Refer to Item 11p for requirements for walls for drying chambers. Dry sStorage rooms used for the storage of packaged dry milk or milk products and aseptically processed and packaged milk or milk products are exempt from the ceiling requirements of this Item.

**PAGE 57:**

**ITEM 5p. SEPARATE ROOMS**

4. The fabrication of containers and closures for milk and milk products, except for aseptically processed and packaged milk and milk products that are fabricated within the aseptic processing and packaging system.

**PAGE 65:**

**ITEM 11p. CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT**

**ADMINISTRATIVE PROCEDURES**

This Item is deemed to be satisfied when:



12. Provided that all paper, plastics, foil, adhesives, and other components of containers and closures used in the packaging of milk or milk products that have been aseptically processed and packaged are governed under 21 CFR 113 and shall not be subject to this Section.

**PAGE 65:**

### **12p. CLEANING AND SANITIZING OF CONTAINERS AND EQUIPMENT**

The product-contact surfaces of all multi-use containers, utensils and equipment used in the transportation, processing, condensing, drying, packaging, handling, and storage of milk or milk products shall be effectively cleaned and shall be sanitized before each use. Provided, that cloth-collector systems used on dryers shall be cleaned and sanitized or purged at intervals and by methods recommended by the manufacturer and approved by the Regulatory Agency. ~~Provided further, that piping, equipment and containers used to process, conduct or package aseptically processed milk and milk products, beyond the final heat treatment process, shall be sterilized before any aseptically processed milk or milk product is packaged and shall be re-sterilized whenever any nonsterile product has contaminated it.~~

**PAGE 69:**

### **ADMINISTRATIVE PROCEDURES**

5. All multi-use containers, utensils and equipment are sanitized before use, .....

Assembled equipment must be sanitized prior to each day's run, unless FDA and the Regulatory Agency have reviewed and accepted information supporting the sanitizing of multi-use containers, utensils and equipment at frequencies extending beyond one (1) day. Tests to determine the efficiency of sanitization should be made by the Regulatory Agency at intervals sufficient to satisfy the Regulatory Agency that the sanitization process is effective. ~~Provided, that all piping, equipment and containers used to conduct, process or package aseptically processed milk and milk products, beyond the final heat treatment process, shall be sterilized by heat, chemical sterilant(s) or other appropriate treatment before use and re-sterilized whenever it has been contaminated by nonsterile product.~~

**PAGES 76-77:**

### **ITEM 15p. PROTECTION FROM CONTAMINATION**

#### **ITEM 15p (B)**

1. During processing, pipelines and equipment used to contain or conduct milk and .....

c. In the case of ~~aseptically processed~~ and higher-heat-shorter-time (HHST) pasteurized milk and milk products that are processed and the equipment cleaned and/or chemically sanitized above the atmospheric boiling point of the milk or milk product or cleaning and/or sanitizing solutions, the required separation between pipelines and equipment, used to

contain or conduct milk and milk products, and tanks or circuits containing cleaning and/or chemical sanitizing solutions, may be accomplished using an alarmed steam block(s), located between the milk and milk product and cleaning and/or chemical sanitizing solutions if:

(4) The temperature sensor is integrated with automatic controls, such that when there is milk or milk products on one (1) side of the steam block and cleaning and/or chemical sanitizing solutions on the other side of the steam block, and the temperature sensor in the steam trace detects a temperature that indicates that liquid, rather than steam, is present in the steam trace, the cleaning pump will be de-energized, and when needed to prevent solution pressure on the steam block, the cleaning and/or chemical sanitizing solution are automatically drained away from the steam block. Except that ~~i) In~~ systems where the cleaning and/or sanitizing solution is circulated by the timing pump, that pump may continue to operate during an alarmed condition, provided a legal flow-diversion device (FDD) is used to divert the cleaning and/or chemical sanitizing solution flow away from the steam block.

~~ii) In aseptic processing systems that are not equipped with a legal FDD and where the cleaning and/or sanitizing solution is circulated by the timing pump of the aseptic processing system, that pump may continue to operate during an alarmed condition, provided there are at least two (2) instrumented steam blocks between the milk and milk product and the cleaning and/or chemical sanitizing solutions and at least one (1) of the blocks remains uncompromised.~~

**NOTE:** The valve arrangement(s) described in this Section shall not be used to separate raw products, dairy, non-dairy or water, from pasteurized milk or milk products. Provided that, nothing in this Section shall be construed as barring any other means to separate milk and milk product from cleaning/sanitizing solution in systems, which have been recognized by FDA ~~and in the case of aseptic processing equipment, by the Processing Authority,~~ to be equally effective and which are approved by the Regulatory Agency.

**PAGE 78:**

### **ITEM 16p. PASTEURIZATION AND ASEPTIC PROCESSING**

Pasteurization shall be performed as defined in Section 1, Definition EE of this *Ordinance*. Aseptic processing and packaging shall be performed in accordance with 21 CFR 110 and 21 CFR 108 113 ~~the Administrative Procedures of Item 16p, sub-items (C), (D) and (E) of this Section.~~ (Refer to Appendix L.)

**PAGES 92-96:**

### **ITEM 16p.(C) ASEPTIC PROCESSING SYSTEMS**

#### **PUBLIC HEALTH REASON**

~~Aseptically processed milk and milk products are being packaged in hermetically sealed containers and stored for long periods of time under non-refrigerated conditions. These~~

conditions are favorable to the growth of many types of bacteria, including pathogenic, toxin producing and spoilage organisms. Because of this, every precaution must be taken to ensure that the chosen heat process, for the particular milk or milk product, destroys all viable organisms and their spores. The subsequent handling, packaging and storage processes do not provide an opportunity for recontamination of the milk or milk product. The selected process must conform to the acceptable requirements for low acid canned foods.

## ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

The design and operation of aseptic processing systems comply with the applicable specifications and operational procedures of Item 16p, sub-items (C), (D) and (E). Provided, that nothing shall be construed as barring any other aseptic processing system which have been recognized by FDA to be equally effective and which is approved by the Regulatory Agency.

### **1. INDICATING THERMOMETERS AND RECORDER/CONTROLLER INSTRUMENTS:**

All indicating thermometers, recorder/controller instruments and devices, used in connection with aseptic processing systems, used for the aseptic processing of milk or milk products shall comply with the applicable specifications set forth in Appendix H.

### **2. ASEPTIC PROCESSING EQUIPMENT:**

a. **Temperature Indicating Device:** Each aseptic processing system shall be equipped with at least one (1) mercury in glass thermometer or an equivalent temperature indicating device.

b. **Temperature Recorder/Controller:** An accurate temperature recorder/controller shall be installed in the milk or milk product at the holding tube outlet and before the inlet to the cooler or regenerator. The following requirements shall be met with respect to the instrumentation of the temperature recorder/controller:

(1) The temperature recorder/controller shall be set and sealed so that during milk or milk product processing the forward flow of milk or milk product cannot start unless the temperature at the controller sensor is above the required temperature for the milk or milk product and the process used, nor continue during descending temperatures when the temperature is below the required temperature.

The seal shall be applied by the Regulatory Agency after testing and shall not be removed without immediately notifying the Regulatory Agency. The system shall be so designed that no milk or milk product can be bypassed around the controller sensor, which shall not be removed from its proper position during the processing of aseptic milk and milk products.

(2) Additional temperature controllers and timers shall be interwired with the thermal limit controller, and the control system shall be set and sealed so that forward flow of milk or milk product cannot start until all product contact surfaces between the holding tube and FDD have been held at or above the required sterilization temperature, continuously and simultaneously for at least the required sterilization time. The control system shall also be set and sealed so that forward flow cannot continue when the temperature of the milk or milk product in the holding tube is below the required temperature. The seal shall be applied by the Regulatory Agency after being tested and shall not be removed without immediately notifying the Regulatory Agency. The system shall be so designed that no milk or milk

product can be bypassed around the control sensors, which shall not be removed from their proper position during the processing of aseptic milk and milk products.

(3) Manual switches for the control of pumps, homogenizers or other devices that produce flow through the holding tube, shall be wired so that the circuit is completed only when the milk or milk product is above the required temperature for the milk or milk product and the process used, or when the FDD is in the fully diverted position.

**c. ~~Timing Pump:~~**

(1) A timing pump shall be located upstream from the holding tube and shall be operated to maintain the required rate of milk or milk product flow. The motor shall be connected to the timing pump by means of a common drive shaft, or by means of gears, pulleys or a variable-speed drive, with the gear box, the pulley box or the setting of the variable speed protected in such a manner that the hold time cannot be shortened without detection by the Regulatory Agency. This shall be accomplished by the application of a suitable seal(s) after being tested by the Regulatory Agency and such seal(s) shall not be broken without immediately notifying the Regulatory Agency. This provision shall apply to all homogenizers used as timing pumps. Variable speed drives, used in connection with the timing pump, shall be so constructed that wearing or stretching of the belt results in a slowdown, rather than a speed-up, of the pump. The metering or timing pump shall be of the positive displacement type or shall comply with the specifications for magnetic flow meter based timing systems.

(2) The holding time shall be taken to mean the flow time of the fastest particle of milk or milk product throughout the holding tube section, i.e., that portion of the system that is outside of the influence of the heating medium; and slopes continuously upward in the downstream direction; and is located upstream from the FDD.

**d. ~~Milk or Milk Product Holding Tube:~~**

(1) The milk or milk product holding tube shall be designed to give continuous holding of every particle of milk or milk product for at least the minimum holding time specified in the scheduled process. The holding tube shall be designed, so that no portion of the holding tube between the milk or milk product inlet and the milk or milk product outlet can be heated. In addition, it must be sloped upward at least 2.1 centimeters per meter (0.25 inches per foot). Supports for holding tubes shall be provided to maintain all parts of the holding tubes in a fixed position, free from any lateral or vertical movement.

(2) No device shall be permitted for short-circuiting a portion of the holding tube to compensate for changes in rate of milk or milk product flow. Holding tubes shall be installed so that sections of pipe cannot be left out, resulting in a shortened holding time. The holding time for the processes must be determined from the pumping rate, rather than by the salt conductivity test.

(3) The holding tube length must be such that the fastest flowing particle of any milk or milk product will not traverse the holding tube in less than the required holding time.

**NOTE:** With the direct addition of steam, the holding time is reduced because the milk or milk product volume increases as the steam condenses to water during heating. This surplus water is evaporated as the aseptically processed milk or milk product is cooled in the vacuum chamber. For example, with a 66°C (120°F) increase by steam injection, which is probably the maximum temperature rise that will be used, a volume increase of twelve percent (12%) will occur in the holding tube. The measurement of the average flow rate at the discharge of the aseptic processor

does not reflect this volume increase in the holding tube. However, this volume increase, i.e., holding time decrease, must be considered in the calculations.

~~(4) An aseptic processing system which can operate with milk or milk product in forward-flow mode, with less than 518 kPa (75 psig) pressure in the holding tube shall be equipped with a pressure limit indicator/pressure switch in the holding tube to assure that the heated milk or milk product remains in the liquid phase. In systems that do not have a vacuum chamber between the holding tube and the aseptic milk or milk product side of the regenerator, this can be established by verifying that the aseptic processing equipment cannot operate in forward flow with less than 518 kPa (75 psig) pressure on the aseptically processed side of the regenerator. (Refer to Appendix I., Test 9). The pressure limit indicator/pressure switch must be interwired so that the FDD, milk or milk product divert system, milk or milk product divert valve or other acceptable control system will move to the divert position, if the milk or milk product pressure falls below a prescribed value. The instrument must be set at a pressure 69 kPa (10 psi) above the boiling pressure of the milk or milk product at its maximum temperature in the holding tube. If this pressure is too low, the resultant vaporization in the holding tube will substantially reduce residence times.~~

~~(5) With the steam injection process, a differential pressure limit indicator, across the injector, is needed to ensure adequate isolation of the injection chamber. The instrument must have a differential pressure switch so that the FDD will move to the divert position if the pressure drop across the injector falls below 69 kPa (10 psi).~~

~~e. **Heating by Direct Addition of Steam:** Steam injection is an inherently unstable process; accordingly, when steam is injected into a fluid, condensation of the steam may not be completed inside the injector unless the proper design criteria are used. Lack of complete condensation inside the injector would cause temperature variations in the holding tube, which could lead to some milk or milk product particles being processed below filed process temperature. When culinary steam is injected directly into milk or milk products, as the means of terminal heating to achieve aseptic processing temperature, the steam injector shall be designed, installed and operated to comply with the following or equally satisfactory specifications:~~

~~(1) The milk or milk product and steam flows must be isolated from pressure fluctuations inside the injection chamber. One (1) method of isolation is to insert supplementary orifices on the milk or milk product inlet and the heated milk or milk product outlet of each injector. The two (2) supplementary orifices must be sized for at least a 69 kPa (10 psi) milk or milk product pressure drop across the injector during a simulation of normal operations. Excessive vibrations, pressure fluctuations or erratic noise levels indicate an unstable steam injection system and a need to check the isolation of the injection chamber.~~

~~(2) The process should be as free as possible of non-condensable gases that may evolve from the milk or milk product or be carried in the steam supply. Any two (2) phase flow, caused by the non-condensable gases, would displace the milk or milk product in the holding tube, resulting in reduced residence times. In addition, these gases in the steam supply may also markedly alter the condensation mechanism at the point of injection. Accordingly, the steam boiler shall be supplied with a de-aerator. The de-aerator will aid in keeping the milk or milk product in the holding tube as free as possible of non-condensable gases.~~

~~f. **Prevention of Milk or Milk Product Adulteration with Added Water:**~~

~~(1) When culinary steam is introduced directly into the milk or milk product, automatic means, i.e., stand alone and/or PLC-based ratio control system, shall be provided to maintain a proper temperature differential between incoming and outgoing milk or milk products to preclude dilution with water.~~

~~(2) Where a water feed line is connected to a vacuum condenser and the vacuum condenser is not separated from the vacuum chamber by a physical barrier, means shall be provided to preclude the back-up and overflow of water from the vacuum condenser into the vacuum chamber. This provision may be satisfied by the use of a safety shutoff valve, located on the water feed line to the vacuum condenser that is automatically actuated by a control that shuts off the in-flowing water. This valve may be actuated by water, air or electricity and shall be so designed that failure of the primary motivating power will automatically stop the flow of water into the vacuum condenser.~~

~~g. FDD: All FDDs used in continuous aseptic process systems shall comply with Item 16p(B)2.b. or equally satisfactory specifications.~~

**PAGES 96-99:**

**ITEM 16p.(D) PASTEURIZERS AND ASEPTIC PROCESSING SYSTEMS  
EMPLOYING REGENERATIVE HEATING**

**ADMINISTRATIVE PROCEDURES**

This Item is deemed satisfied when:

**MILK OR MILK PRODUCT-TO-MILK OR MILK PRODUCT REGENERATIVE  
HEATING**

~~Pasteurizers and aseptic processing systems~~ employing milk or milk product-to-milk or milk product regenerative heating with both sides closed to the atmosphere shall comply with the following or equally satisfactory specifications:

- ~~1. Regenerators shall be constructed, installed and operated so that pasteurized or aseptic milk or milk product in the regenerator will automatically be under greater pressure than raw milk or milk product in the regenerator at all times.~~
- ~~2. The pasteurized or aseptic milk or milk product, between its outlet from the regenerator and the nearest point downstream open to the atmosphere, shall rise to a vertical elevation of 30.5 centimeters (12 inches) above the highest raw milk or milk product level, downstream from the constant-level tank, and shall be open to the atmosphere at this or a higher elevation.~~
- ~~3. No pump or flow-promoting device which can affect the proper pressure relationships within the regenerator shall be located between the pasteurized or aseptic milk or milk product outlet from the regenerator and the nearest downstream point open to the atmosphere.~~
- ~~4. No pump shall be located between the raw milk or milk product inlet to the regenerator and the constant-level tank, unless it is designed and installed to operate only when milk or milk product is flowing through the pasteurized or aseptic milk or milk product side of the regenerator and when the pressure of the pasteurized or aseptic milk or milk product is higher than the~~

maximum pressure produced by the pump. This may be accomplished by wiring the booster pump so that it cannot operate unless:

- a. The timing pump is in operation;
- b. The FDD is in forward-flow position; and
- c. The pasteurized ~~or aseptic~~ milk or milk product pressure exceeds, by at least 6.9 kPa (1 psi), the maximum pressure developed by the booster pump. Pressure gauges shall be installed at the raw milk or milk product inlet to the regenerator and the pasteurized ~~or aseptic~~ milk or milk product outlet of the regenerator or the outlet of the cooler. The accuracy of these required pressure gauges shall be checked, by the Regulatory Agency, on installation; quarterly thereafter; and following repair or adjustment.

9. When vacuum equipment is located downstream from the FDD, means shall be provided to prevent the lowering of the pasteurized ~~or aseptic~~ milk or milk product level in the regenerator during periods of diverted-flow or shutdown. An effective vacuum breaker, plus an automatic means of preventing a negative pressure, shall be installed in the line between the vacuum chamber and the pasteurized ~~or aseptic~~ milk or milk product inlet to the regenerator.

10. In the case of pasteurization systems, with the FDD located downstream from the regenerator and/or cooler section, the requirements of paragraphs (2), (3), (5), (7) and (8) of this Section may be eliminated. Provided, that a differential pressure controller is used to monitor the highest pressure in the raw milk or milk product side of the regenerator and the lowest pressure in the pasteurized side of the regenerator, and the controller is interlocked with the FDD and is set and sealed so that whenever improper pressures occur in the regenerator, forward-flow of milk or milk product is automatically prevented and will not start again until all milk or milk product-contact surfaces between the holding tube and FDD have been held at or above the required pasteurization temperature, continuously and simultaneously for at least the required pasteurization time as defined in Definition EE of this *Ordinance*.

~~In the case of aseptic processing systems used for producing aseptic milk and milk products, there shall be an accurate differential pressure recorder-controller installed on the regenerator. The scale divisions shall not exceed 13.8 kPa (2 psi) on the working scale of not more than 138 kPa (20 psi) per 2.54 centimeters (1 inch). The controller shall be tested for accuracy against a known accurate standard pressure indicator upon installation; at least once every three (3) months of operation thereafter; or more frequently if necessary, to ensure its accuracy. One (1) pressure sensor shall be installed at the aseptic milk or milk product regenerator outlet and the other pressure sensor shall be installed at the raw milk or milk product regenerator inlet.~~

11. When culinary steam is introduced directly into milk or milk product to achieve pasteurization ~~or aseptic~~ processing temperature, and vacuum equipment is located downstream from the holding tube, the requirement that a vacuum breaker be installed at the inlet to the pasteurized ~~or aseptic~~ side of the regenerator may be eliminated. Provided, that the differential pressure controller is installed and wired to control the FDD as described in paragraph 10 of this Section.

## **MILK OR MILK PRODUCT-TO-WATER-TO-MILK OR MILK PRODUCT REGENERATIVE HEATING**

**Option 2.** Milk or milk product-to-water-to-milk or milk product regenerators may also be constructed, installed and operated such that the pasteurized ~~or aseptic~~ milk or milk product in

the regenerator will be under greater pressure than the heat-transfer-medium in the pasteurized or aseptic milk or milk product side of the regenerator:

- a. A differential pressure controller shall be used to monitor pressures of the pasteurized milk or milk product and the heat-transfer-medium.
- ~~b. In the case of aseptic processing systems, a differential pressure recorder shall be used to monitor pressures of the aseptic milk or milk product and the heat transfer medium.~~
- e. ~~In either case,~~ One (1) pressure sensor shall be installed at the pasteurized or aseptic milk or milk product outlet of the regenerator and the other pressure sensor shall be installed at the heat-transfer-medium inlet of the pasteurized or aseptic milk or milk product side of the regenerator. This controller or recorder-controller shall divert the FDD whenever the lowest pressure of pasteurized or aseptic milk or milk product in the regenerator fails to exceed the highest pressure of the heat-transfer-medium in the pasteurized or aseptic milk or milk product side of the regenerator by at least 6.9 kPa (1 psi). Forward-flow of milk or milk product shall be automatically prevented until all milk or milk product-contact surfaces between the holding tube and the FDD have been held at or above the required pasteurization or sterilization temperature continuously and simultaneously for at least the pasteurization or sterilization time.
- ~~d.~~ b. The heat-transfer-medium pump shall be wired so that it cannot operate unless the timing pump is in operation.

**PAGE 99:**

**ITEM 16p. (E) PASTEURIZATION AND ASEPTIC PROCESSING RECORDS,  
EQUIPMENT TESTS AND EXAMINATIONS**

**1. PASTEURIZATION AND ASEPTIC PROCESSING RECORDS:**

All temperature and flow rate pasteurization recording charts or alternative records, acceptable to FDA, in place of charts shall be preserved for a period of three (3) months. ~~Provided, that all records and recording charts for aseptic milk and milk product systems shall be retained for a period of three (3) years.~~ The use of such charts shall not exceed the time limit for which they are designed. Overlapping of recorded data shall be a violation of this Item. The following information shall be entered on the charts or other records acceptable to FDA in place of charts as applicable:

**PAGES 100-101:**

- c. **Continuous-Flow Pasteurizers or Aseptic Processing Equipment with Magnetic Flow Meter Based Timing Systems:** Flow rate recording charts shall be capable of continuously recording flow at the flow alarm set point and at least 19 liters (5 gallons) per minute higher than the high flow alarm setting. Flow rate recording charts shall contain all the information specified in Subitem a. above, except (3), (4), (5), and (6), and in addition, shall include the following:
  - (1) A continuous record of the status of the high and low-flow/loss of signal alarms; and
  - (2) A continuous record of the flow rate.



~~d. **Aseptic Processing Systems:** Recording thermometer charts shall contain all the information specified in Subitem a. above, except (4) and (5). In addition these records shall include Subitem c. above, if applicable, and the following:~~

~~(1) A continuous record of the time during which the FDD, valve or system is in the forward-flow position;~~

~~(2) A continuous record of applicable regenerator pressures;~~

~~(3) Not later than one (1) working day after the actual process, and before shipment or release for distribution, a representative of the milk plant management, who is qualified by suitable training or experience, shall review all processing and production records for completeness and to ensure that the milk or milk product received the schedule process. The records, including the recording thermometer chart(s), shall be signed or initialed and dated by the reviewer; and~~

~~(4) Number (6) from above shall also be recorded immediately after a chart has been changed.~~

**PAGE 101:**

## **2. EQUIPMENT TESTS AND EXAMINATIONS:**

In the case of milk plants with HACCP Plans regulated under the NCIMS HACCP Program, pasteurization ~~and aseptic processing~~ equipment may be tested and sealed by industry personnel acceptable to the Regulatory Agency, if the following conditions are met:

a. Test results for Pasteurization ~~and Aseptic Processing~~ Equipment Testing shall be recorded on a similar document for all milk plants. (Refer to the reference in Appendix M. for an example.)

b. Industry personnel conducting the Pasteurization ~~and Aseptic Processing~~ Equipment Testing must be adequately trained and must be able to demonstrate an acceptable understanding and ability to conduct these tests to the Regulatory Agency.

c. Pasteurization ~~and Aseptic Processing~~ Equipment Tests shall be conducted at a frequency not less than the requirements of this *Ordinance*. Industry shall have responsibility for the performance of all required tests. At least each six (6) months the Regulatory Agency shall physically supervise these tests. Regulatory supervised tests shall include the semi-annual HTST and HHST tests. These six (6) month tests should be performed at a time that is mutually convenient to all parties. Because these tests are required to support a CCP, the industry is responsible for conducting these tests even in the absence of the regulatory official.

d. Upon initial installation or extensive modification of any pasteurization ~~and aseptic processing~~ equipment, tests shall be physically supervised or conducted by the Regulatory Agency.

f. During an audit, the auditor may conduct any or all of the Pasteurization ~~or Aseptic Processing~~ Equipment Tests. The auditor should, through a combination of physical examination of the equipment and a records review, satisfy themselves that the equipment is properly installed and operated.

**PAGE 103:**

**Table 4. Equipment Tests - Batch, HTST, and HHST and Aseptic Processing Systems-Pasteurizers**

(Refer to Appendix I.)

1.	Vat, HTST, HHST, Aseptic indicating and airspace thermometers	Temperature accuracy
2.	Vat, HTST, HHST, Aseptic recording thermometer	Temperature accuracy
3.	Vat, HTST, HHST, Aseptic recording thermometer	Time accuracy
4.	Vat, HTST, HHST, Aseptic indicating and recording thermometer	Recording vs. Indicating thermometer
5.1	HTST, HHST FDD	Leakage pass FDD
5.2	HTST, HHST FDD	FDD freedom of movement
5.3	HTST, HHST FDD	Device assembly (single stem)
5.4	HTST, HHST FDD	Device assembly (dual stem)
5.5	HTST FDD	Manual diversion
5.6	HTST, HHST FDD	Response time
5.7	HTST, HHST FDD	Time delay (inspect)
5.8	HTST, HHST FDD	Time delay (CIP)
5.9	HTST FDD	Time delay (leak-detect flush)
6.	Vat leak-protector valve(s)	Leakage
7.	HTST indicating thermometers	Response time
8.	HTST recording thermometers	Response time
9.1	HTST pressure switches	Regenerator pressures
9.2.1	HTST, HHST, Aseptic differential pressure controllers	Calibration
9.2.2	HTST differential pressure controllers	Regenerator pressure
9.2.3	HTST*, HHST and Aseptic differential pressure controllers	Regenerator pressure
9.3.1	HTST booster pump/FDD	Inter-wiring check
9.3.2	HTST booster pump/metering pump	Inter-wiring check
10.1	HTST FDD	Temperature cut-in/cut-out
10.2	HTST*, HHST FDD, Aseptic divert system (indirect heat)	Temperature cut-in/cut-out
10.3	HTST*, HHST FDD, Aseptic divert system (direct heat)	Temperature cut-in/cut-out
11.1	HTST holding tubes/timing pumps (except magnetic flow meter based timing systems-MFMBTS)	Holding time
11.2.a	HTST holding tubes/ MFMBTS	Holding time
11.2.b	HTST, HHST, Aseptic MFMBTS	Flow alarm
11.2.c	HTST, HHST, Aseptic MFMBTS	Loss of signal/low flow
11.2.d	HTST magnetic flow meter based timing systems	Flow rate cut-in/cut-out
11.2.e	HTST magnetic flow meter based timing systems	Time delay
11.2.f	All magnetic flow meter based timing systems	High flow alarm response time
11.3	HHST holding tubes indirect heat	Holding time
11.4	HHST holding tubes direct injection heat	Holding time
11.5	HHST holding tubes direct infusion heat	Holding time
12.1	HTST*, HHST, Aseptic systems indirect heating	Sequence logic
12.2	HTST*, HHST, Aseptic systems direct heating	Sequence logic
13.	HHST, Aseptic systems	Pressure in the holding tube
14.	HTST*, HHST, Aseptic systems using direct injection heating	Pressure differential across injector
15.	HTST, HHST, Aseptic (all electronic controls)	Electro-Magnetic Interference

\* For HTST systems with the FDD located downstream of the regenerator and/or cooler section.

**PAGE 106:**

**ITEM 17p. COOLING OF MILK AND MILK PRODUCTS**

**ADMINISTRATIVE PROCEDURES**

6. Each refrigerated room in which milk and milk products are stored, ~~except aseptically processed milk and milk products,~~ is equipped with an indicating thermometer that complies with the applicable specifications of Appendix H. Such thermometer shall be located in the warmest zone of the refrigerated room.

**PAGE 109:**

**ITEM 18p. BOTTLING, PACKAGING AND CONTAINER FILLING**

**ADMINISTRATIVE PROCEDURES**

~~12. In the case of aseptic processing systems, the milk and milk product shall be aseptically filled into sterilized containers and hermetically sealed in conformance with the applicable requirements of and 21 CFR 113.~~

**PAGE 113:**

**SECTION 8. ANIMAL HEALTH**

3. Goat, sheep, water buffalo, or any other hooved mammal milk for pasteurization, ultra-pasteurization or aseptic processing and packaging, defined under this *Ordinance*, shall be from a herd or flock that:

**PAGE 115:**

**SECTION 9. MILK AND MILK PRODUCTS WHICH MAY BE SOLD**

From and after twelve (12) months from the date on which this *Ordinance* is adopted, only Grade "A" pasteurized, ultra-pasteurized, or aseptically processed and packaged milk and milk products shall be sold to the final consumer, to restaurants, soda fountains, grocery stores or similar establishments. Provided, only Grade "A" milk and milk products shall be sold to milk plants for use in the commercial preparation of Grade "A" milk and milk products. Provided further, that in an emergency, the sale of pasteurized milk and milk products, which have not been graded, or the grade of which is unknown, may be authorized by the Regulatory Agency, in which case, such milk and milk products shall be labeled "ungraded".

**PAGE 116:**

**SECTION 11. MILK AND MILK PRODUCTS FROM POINTS BEYOND THE LIMITS OF ROUTINE INSPECTION**

Milk and milk products, from points beyond the limits of routine inspection of the ... of... or its jurisdiction, shall be sold in..., <sup>1</sup> or its jurisdiction provided they are produced and pasteurized, ultra-pasteurized, aseptically processed and packaged, concentrated (condensed) or dried under regulations which are substantially equivalent to this *Ordinance* and have been awarded acceptable Milk Sanitation Compliance and Enforcement Ratings or have been awarded a satisfactory HACCP listing, under the NCIMS HACCP Program as specified in Appendix K. of this *Ordinance*, or are from a country that PHS/FDA has determined, after conferring with NCIMS, to have in place a public health regulatory program and government oversight of that program that have an equivalent effect on the safety of regulated milk and/or milk products. Except that during the aseptic pilot program, a NCIMS ASEPTIC MILK PLANT REGULATORY AGENCY REVIEW REPORT will be substituted for the Enforcement Rating for an IMS Listed aseptic milk plant.

**PAGE 117:**

**ADMINISTRATIVE PROCEDURES**

The Regulatory Agency should accept, without their actual physical inspection, supplies of milk and milk products from an area or an individual shipper not under their routine inspection. Provided, that:

2. After receipt, pasteurized, ultra-pasteurized, aseptically processed and packaged, concentrated (condensed) or dried milk and milk products shall comply with Sections 2, 4 and 10.

10. Aseptically processed and packaged milk and milk products in Definition W of this Ordinance shall be considered to be Grade "A" milk or milk products. The source of the milk and milk products shall be IMS listed and the aseptic raw milk receiving area/aseptic raw milk receiving station of the milk plant where the aseptic milk and milk products are processed and packaged shall be IMS listed. The milk plant shall be awarded a Milk Sanitation Compliance Rating of a least ninety percent (90%) and a satisfactory ASEPTIC MILK PLANT REGULATORY AGENCY REVIEW REPORT or a satisfactory HACCP listing by a SRO trained under the NCIMS Aseptic Pilot Program. The NCIMS Aseptic Pilot Program will expire on December 31, 2009 unless extended by future conference action.

**PAGE 208:**

**APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES**

**PRESSURE RELIEF VALVES, LOCATED WITHIN HTST, HHST ~~AND ASEPTIC~~ PROCESSING SYSTEMS**

**PAGE 250:**

**APPENDIX I. PASTEURIZATION EQUIPMENT AND CONTROLS – TESTS, II TEST PROCEDURES**

**TEST 1.**

**INDICATING THERMOMETERS - TEMPERATURE ACCURACY**

**Application:** To all indicating thermometers used for the measurement of milk or milk product temperature during pasteurization ~~or aseptic processing~~, including airspace thermometers.

**Criteria:** Within  $\pm 0.25^{\circ}\text{C}$  ( $\pm 0.5^{\circ}\text{F}$ ) for pasteurization ~~and aseptic processing~~ thermometers and  $\pm 0.5^{\circ}\text{C}$  ( $\pm 1^{\circ}\text{F}$ ) for airspace thermometers, in a specified scale range. Provided, that on batch pasteurizers used solely for thirty (30) minute pasteurization of milk or milk products at temperatures above  $71^{\circ}\text{C}$  ( $160^{\circ}\text{F}$ ), indicating thermometers shall be accurate to within  $\pm 0.5^{\circ}\text{C}$  ( $\pm 1^{\circ}\text{F}$ ).

**Procedure:**

1. Prepare a quantity of water, oil or other suitable media in a bath, by raising the temperature of the media to within  $2^{\circ}\text{C}$  ( $3^{\circ}\text{F}$ ) of the appropriate pasteurization, or airspace temperature, ~~or aseptic processing~~ temperature.

**PAGE 252:**

**TEST 2.**

**RECORDING THERMOMETERS - TEMPERATURE ACCURACY**

**Application:** To all recording and recorder-controller thermometers controllers used to record milk or milk product temperatures during pasteurization ~~or aseptic processing~~.

**NOTE:** When this Test is performed on recorder-controllers used with HHST pasteurization ~~or aseptic processing~~ systems that operate at or above the boiling point of water, an oil or other suitable media bath shall be substituted for the processing (operating) temperature water mentioned in **Procedures** 1, 4, 5, 6, and 7 as well as the boiling water mentioned in **Procedures** 2, 3 and 5. The temperature of the oil bath that is used in place of the boiling water shall be above the normal operating range but below the highest temperature division on the chart.

**Procedure:**

2. Prepare a second media bath by heating to the boiling point, or in the case of HHST ~~or aseptic~~ systems, to a temperature above the normal operating range but below the highest temperature division on the chart, and maintain temperature. Prepare a third container with melting ice. Place all media baths within working distance of the temperature-sensing element(s).

3. Immerse the recording thermometer sensing element into the boiling water, or in the case of HHST ~~or aseptic processing systems~~ into the media bath described above, for not less than five (5) minutes, two (2) minutes for electronic recording thermometers.

**PAGE 253:**

### **TEST 3.**

#### **RECORDING THERMOMETERS - TIME ACCURACY**

**Application:** To all recording and recorder-controller thermometers used to record the time of pasteurization ~~or aseptic processing~~, including those used to record flow rates in magnetic flow meter based timing systems.

**Criteria:** The recorded time of pasteurization ~~or aseptic processing~~ shall not exceed the true elapsed time.

**PAGE 253:**

### **TEST 4.**

#### **RECORDING THERMOMETERS - CHECK AGAINST INDICATING THERMOMETERS**

**Application:** To all recording and recorder-controller thermometers used to record milk or milk product temperatures during pasteurization ~~or aseptic processing~~.

**Method:** This test requires only that the reading of the recording thermometer or the recorder-controller thermometer be compared with the indicating thermometer at a time when both are exposed to milk or milk product at a stabilized pasteurization ~~or aseptic processing~~ temperature.

**Procedure:**

1. While the indicating and recording temperatures are stabilized at or above the minimum legal pasteurization ~~or aseptic processing~~ temperature, read the indicating thermometer.

**PAGE 254:**

### **TEST 5.**

#### **FDD - PROPER ASSEMBLY AND FUNCTION**

**Application:** Test 5 (parts 1 through 9) ~~does not apply to aseptic processing divert systems, valves or other acceptable controls which may be used in place of a FDD.~~ Parts 1 to 4 and 6 to 8 apply to all FDDs used with continuous-flow pasteurizers. Parts 5 and 9 apply only to FDDs used with HTST pasteurizers.

PAGE 263:

## TEST 9.

### REGENERATOR PRESSURE CONTROLS

#### 9.2 DIFFERENTIAL PRESSURE CONTROLLER

**Application:** Test 9.2.1 applies to all differential pressure controllers used to control the operation of booster pumps on HTST systems or used to control the operation of FDDs on HHST and HTST Pasteurization systems with the FDD located downstream of the pasteurized regenerator and/or final cooler ~~and aseptic processing systems.~~

Test 9.2.2 applies only to HTST systems with the FDD located immediately following the holding tube.

Test 9.2.3 applies to the testing of continuous flow pasteurization systems in which the differential pressure controller is used to control the operation of the FDD. ~~Test 9.2.3 also applies to aseptic processing systems in which the differential pressure controller is used to control the FDD, milk or milk product divert system, milk or milk product divert valve or other acceptable control system.~~

**Criteria:** The booster pump shall not operate, or the pasteurizer shall not operate in forward flow, unless the milk or milk product pressure in the pasteurized side of the regenerator is at least 6.9 kPa (1 psi) greater than the milk or milk product pressure in the raw side of the regenerator. When the differential pressure controller is used to control the FDD on HHST ~~or aseptic processing~~ systems, and improper pressure occurs in the regenerator, the FDD shall move to the diverted-flow position and remain in diverted-flow until the proper pressures are re-established in the regenerator and all milk or milk product-contact surfaces between the holding tube and FDD have been held at or above the required pasteurization ~~or aseptic processing~~ temperature, continuously and simultaneously for at least the required time.

**Method:** The differential pressure switch is checked and adjusted to prevent the operation of the booster pump, or prevent forward-flow, unless the milk or milk product pressure in the pasteurized, ~~or aseptic,~~ side of the regenerator is at least 6.9 kPa (1 psi) greater than the pressure in the raw side of the regenerator.

PAGE 265:

#### 9.2.3 INTERWIRING OF THE PRESSURE DIFFERENTIAL CONTROLLER WITH THE FDD IN AN HHST CONTINUOUS FLOW PASTEURIZATION SYSTEM; ~~OR AN ACCEPTABLE ALTERNATIVE DEVICE, OR SYSTEM IN ASEPTIC PROCESSING EQUIPMENT~~

**Application:**

1. To all differential pressure controllers used to control the operation of FDDs on continuous flow pasteurization systems with the FDD located downstream of the regenerator and/or final cooler, and

2. To all differential pressure controllers used to control the operation of FDDs, milk or milk product divert systems, milk or milk product divert valve(s) ~~or other acceptable control systems used in aseptic processing equipment.~~

**Method:** The differential pressure switch is checked and adjusted to prevent forward-flow, unless the milk or milk product pressure in the pasteurized side of the regenerator is at least 6.9 kPa (1 psi) greater than the pressure in the raw milk or milk product side of the regenerator. In the case of milk or milk product-to-water-to-milk or milk product regenerators, protected on the pasteurized ~~or aseptic~~ side, the "water side" of the regenerator shall be considered to be the "raw product side" for purposes of this Test.

**Procedure:**

1. Wire the test lamp in series with the signal from the pressure differential switch to the FDD.
2. Calibrate the pressure switch and probes. (Use Test 9.2.1.)
3. Adjust the pressure on the pressure switch sensors to their normal operating pressures, with the pasteurized ~~or aseptic~~ pressure at least 14 kPa (2 psi) higher than the raw product pressure.
  - a. The test lamp should be lit. If not, increase the pasteurized ~~or aseptic~~ pressure, or lower the raw product pressure, until the test light is lit.
  - b. Gradually lower the pasteurized ~~or aseptic~~ side, or raise the raw product pressure, until the test light turns off.
  - c. The test light should turn off when the pasteurized ~~or aseptic~~ pressure is at least 14 kPa (2 psi) higher than the raw product pressure.
  - d. Note the differential pressure at the point the light turns off.
  - e. Gradually raise the pasteurized ~~or aseptic~~ pressure, or lower the raw product pressure, until the test light turns on.
  - f. The test light should not turn on until the pasteurized ~~or aseptic~~ pressure is at least 14 kPa (2 psi) higher than the raw product pressure. Note the differential pressure at the point the light turns off.

**PAGE 268:**

**TEST 10**

**MILK OR MILK PRODUCT-FLOW CONTROLS AND MILK OR MILK PRODUCT TEMPERATURE AT CUT-IN AND CUT-OUT**

**10.2 PASTEURIZERS AND ~~ASEPTIC PROCESSING SYSTEMS~~ USING INDIRECT HEATING**

**Application:** All HHST and HTST pasteurizers with the FDD located downstream of the regenerator and/or final cooler ~~and aseptic processing systems~~ using indirect heating. ~~When testing aseptic processing systems, the "milk or milk product divert system", or "milk or milk product divert valve" or "acceptable control system" may be substituted for the "FDD" when it is referenced in this Test.~~

**Criteria:** The pasteurizer ~~or aseptic processor~~ shall not operate in forward-flow unless the pasteurization ~~or aseptic processing~~ temperature has been achieved. The milk or milk product



flow shall be diverted at a temperature lower than the chosen pasteurization ~~or aseptic processing~~ standard.

**Procedure:**

2. After the cut-in temperature has been determined and while the bath is above the cut-in temperature, allow the bath to cool slowly at a rate not exceeding 0.5°C (1°F) per thirty (30) seconds. Observe the temperature reading on the thermal-limit-controller when the test lamp goes out, cut-out temperature. Determine that the cut-out temperature, on the thermal-limit-controller is equivalent to or greater than the chosen pasteurization ~~or aseptic processing~~ standard. Where adjustment is necessary, refer to the manufacturer's instructions. After adjustment, repeat the procedure above, and when the results are satisfactory, record the results for the office records.

**PAGE 268:**

**10.3 PASTEURIZERS AND ~~ASEPTIC PROCESSING SYSTEMS~~ USING DIRECT HEATING**

**Application:** All HHST and HTST pasteurizers with the FDD located downstream of the regenerator and/or final cooler ~~and aseptic processing systems~~ using direct heating. ~~When testing aseptic processing systems, the "milk or milk product divert system" or "milk or milk product divert valve" or "acceptable control system" may be substituted for the "FDD" when it is referenced in this Test.~~

**Criteria:** The pasteurizer ~~or aseptic processor~~ shall not operate in forward-flow unless the pasteurization ~~or aseptic processing~~ temperature has been achieved. The milk or milk product flow shall be diverted at a temperature lower than the chosen pasteurization ~~or aseptic processing~~ standard.

**Procedure:**

2. After the cut-in temperature has been determined and while the bath is above the cut-in temperature, allow the bath to cool slowly at a rate not exceeding 0.5°C (1°F) per thirty (30) seconds. Observe the temperature reading on the thermal-limit-controller when the test lamp goes out, cut-out temperature. Determine that the cut-out temperature, on the thermal-limit-controller, is equivalent to or greater than the chose pasteurization ~~or aseptic processing~~ standard. Where adjustment is necessary, refer to the manufacturer's instructions. After adjustment, repeat the procedure above and when the results are satisfactory, record the results for the office record.

**PAGE 273:**

**11.2B CONTINUOUS-FLOW HOLDING TUBES - FLOW ALARM**

**Application:** To all continuous-flow pasteurization ~~and aseptic processing~~ systems using a magnetic flow meter based timing system to replace a timing pump. ~~When testing aseptic~~

~~processing systems, the "milk or milk product divert system" or "milk or milk product divert valve" or "acceptable control system" may be substituted for the "FDD" when it is referenced in this Test.~~

**Criteria:** When flow rate equals or exceeds the value at which the holding time was measured, the flow alarm shall cause the FDD to assume the diverted position, even though the temperature of the milk or milk product in the holding tube is above the pasteurization ~~or aseptic processing~~ temperature.

**Procedure:**

1. Operate the pasteurizer ~~or aseptic processing equipment~~ in forward-flow, at the flow rate at which holding time was measured, using water above the pasteurization ~~or aseptic processing~~ temperature.

**NOTE:** The appropriate temperature elements may be placed in a water or oil bath to simulate the normal pasteurization ~~or aseptic processing~~ temperature of the holding tube as an alternative to heating the water in the system above the pasteurization ~~or aseptic processing~~ temperature. Observation and recording of this temperature should be done as described in **Procedures 3** and 4 below.

2. Adjust the set point on the flow alarm slowly downward until the frequency pen on the flow recorder/controller indicates that flow has been diverted.

**NOTE:** When performing this Test on systems that operate above the boiling point of water, be sure that the system is cooling to avoid the possibility of serious burns.

3. Observe that the FDD moved to the diverted position, while water passing through the holding tube remained above the pasteurization ~~or aseptic processing~~ temperature.

**PAGE 274:**

### 11.2C CONTINUOUS-FLOW HOLDING TUBES - LOW FLOW/LOSS-OF-SIGNAL ALARM

**Application:** To all continuous-flow pasteurization ~~and aseptic processing~~ systems using a magnetic flow meter based timing system to replace a timing pump. ~~When testing aseptic processing systems, the "milk or milk product divert system" or "milk or milk product divert valve" or "acceptable control system" may be substituted for the "FDD" when it is referenced in this Test.~~

**Procedure:**

1. Operate the pasteurizer ~~or aseptic processing equipment~~ in forward-flow, at a flow rate below the flow alarm set point and above the low flow/loss-of-signal alarm set point, using water.

**PAGE 276:**

### **11.2F HIGH FLOW ALARM RESPONSE TIME**

**Application:** To all continuous-flow pasteurization ~~and aseptic processing~~ systems using a magnetic flow meter based timing system to replace a timing pump. ~~When testing aseptic processing systems, the "milk or milk product divert system" or "milk or milk product divert valve" or "acceptable control system" may be substituted for the "FDD" when it is referenced in this Test.~~

**Procedure:**

1. Operate the pasteurizer ~~or aseptic processing equipment~~ in forward-flow, at a flow rate 25% below the high flow alarm as determined in Test 11.2B (Procedure 2).

**NOTE:** The appropriate temperature elements may be placed in a water or oil bath to simulate the normal pasteurization ~~or aseptic processing~~ temperature of the holding tube as an alternative to heating the water in the system above the pasteurization ~~or aseptic processing~~ temperature. Observation and recording of this temperature should be done as described in Procedures 3 and 4 below.

**PAGE 283:**

## **TEST 12.**

### **THERMAL-LIMIT-CONTROLLER FOR CONTROL - SEQUENCE LOGIC**

**References:** Items 16p (B) and (E)

Thermal-limit-controllers used with HHST and HTST pasteurizers that have the FDD located downstream from the regenerator and/or cooler ~~and aseptic processing systems~~ shall be tested by one (1) of the following applicable Tests at the frequency prescribed:

#### **12.1 PASTEURIZATION ~~AND ASEPTIC PROCESSING~~ - INDIRECT HEATING**

**Application:** To all HHST and HTST pasteurizers that have the FDD located downstream from the regenerator and/or cooler ~~and aseptic processing systems~~ using indirect heating. ~~When testing aseptic processing systems, the "milk or milk product divert system" or "milk or milk product divert valve" or "acceptable control system" may be substituted for the "FDD" when it is referenced in this Test.~~

**Criteria:** The pasteurizer, ~~or aseptic processing equipment,~~ shall not operate in forward-flow until the milk or milk product surfaces downstream from the holding tube have been sanitized, ~~or in the case of aseptic processing equipment, sterilized.~~ Upon start-up, surfaces shall be exposed to fluid at pasteurization temperature, ~~or in the case of aseptic processing equipment, sterilizing temperature,~~ for at least the required pasteurization ~~or sterilization~~ time. If any public health control causes the FDD to assume the diverted flow position due to incorrect temperature, pressure or flow, forward-flow shall not be re-achieved until the milk or milk product-contact

surfaces downstream from the holding tube have been re-sanitized, ~~or in the case of aseptic processing equipment, re-sterilized.~~

**Procedure:**

3. Immerse the sensing element from the holding tube in the bath. The test lamp should light up, i.e., forward-flow after a minimum time delay of one (1) second for continuous-flow pasteurization systems. ~~For aseptic processing systems no delay is required if the filed process includes a documented sterilization period.~~

**PAGE 284:**

**12.2 PASTEURIZATION AND ASEPTIC PROCESSING - DIRECT HEATING**

**Application:** To all HHST and HTST pasteurizers that have the FDD located downstream from the regenerator and/or cooler ~~and aseptic processing systems~~ using direct contact heating. ~~When testing aseptic processing systems, the "milk or milk product divert system" or "milk or milk product divert valve" or "acceptable control system" may be substituted for the "FDD" when it is referenced in this Test.~~

**Criteria:** The pasteurizer, ~~or aseptic processing equipment,~~ shall not operate in forward-flow until the milk or milk product surfaces downstream from the holding tube have been sanitized, ~~or in the case of aseptic processing equipment, sterilized.~~ Upon start-up, surfaces shall be exposed to fluid at pasteurization temperature, ~~or in the case of aseptic processing equipment, sterilizing temperature for at least the required pasteurization or sterilization time.~~ If the milk or milk product temperature falls below the pasteurization or sterilization standard in the holding tube, forward-flow shall not be re-achieved until the milk or milk product-contact surfaces downstream from the holding tube have been re-sanitized, ~~or in the case of aseptic processing equipment, re-sterilized.~~

**Procedure:**

5. Immerse the third sensing element located at the holding tube, into the bath. The test lamp should light up, i.e., forward-flow, after a minimum time delay of one (1) second for continuous-flow pasteurization systems. ~~For aseptic processing systems no delay is required if the filed process includes a documented sterilization period.~~

**PAGE 285:**

**TEST 13.**

**SETTING OF CONTROL SWITCHES FOR MILK OR MILK PRODUCT PRESSURE IN THE HOLDING TUBE**

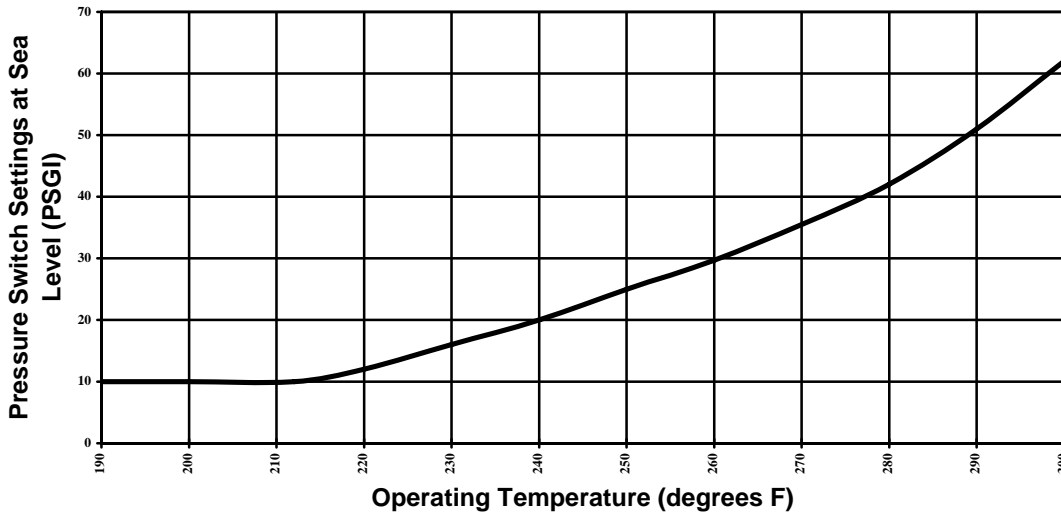
**Application:** To all HHST pasteurizers ~~and aseptic processing systems,~~ which are capable of operating with product in forward-flow mode, with less than 518 kPa (75 psig) pressure in the holding tube. ~~When testing aseptic processing systems, the "milk or milk product divert system"~~

or "milk or milk product divert valve" or "acceptable control system" may be substituted for the "FDD" when it is referenced in this Test.

**Criteria:** The pasteurizer ~~or aseptic processor~~ shall not operate in forward-flow unless the product pressure in the holding tube is at least 69 kPa (10 psi) above the boiling pressure of the product.

**Procedure:**

For each HHST pasteurizer ~~or aseptic processing system~~ temperature, the milk or milk product pressure switch setting is as follows:



**Figure 45. Pressure Switch Setting**

**PAGE 286:**

**TEST 14.**

**SETTING OF CONTROL SWITCHES FOR DIFFERENTIAL PRESSURE ACROSS THE INJECTOR**

**Application:** To all continuous flow pasteurizers ~~and aseptic processing systems~~ using direct contact heating. ~~When testing aseptic processing systems, the "milk or milk product divert system" or "milk or milk product divert valve" or "acceptable control system" may be substituted for the "FDD" when it is referenced in this Test.~~

**Criteria:** The pasteurizer ~~or aseptic processor~~ shall not operate in forward-flow unless the milk or milk product pressure drop across the injector is at least 69 kPa (10 psi).

**Procedure:**

1. Remove both pressure sensing elements from their original locations on the pasteurizer, ~~or aseptic processor~~. Install a sanitary pressure gauge of known accuracy and the pressure-sensing element, which is installed prior to the steam injection, on the pneumatic testing device.

**PAGE 287:**

**TEST 15.**

**ELECTRO-MAGNETIC INTERFERENCE FROM HAND-HELD COMMUNICATION DEVICES**

**Application:** To all electronic controls used to assure compliance with public health safeguards on continuous flow pasteurization ~~and aseptic processing~~ equipment that are installed in milk plants where hand-held communication devices are used.

**Procedure:**

5. Repeat the Test for each electronic control used to regulate a pasteurization ~~or aseptic processing~~ public health safeguard.

**For Example:** For temperature set point, operate the pasteurizer ~~or aseptic processor~~ on water in diverted-flow in the “Product” mode, at a steady temperature within 3°C (5°F) of the lowest cut-in temperature. In this example, an adverse effect is defined as forward-flow movement of the FDD or any artificial increase in temperature.

**PAGE 305**

**APPENDIX K. HACCP PROGRAM**

**VERIFICATION AND VALIDATION:**

1. **Verification:** Every milk plant, receiving station or transfer station shall verify that the HACCP System is being implemented according to design, except that the aseptic processing and packaging system, as defined in this *Ordinance*, ~~critical factors for aseptically processed Grade “A” milk and milk products, as determined by the process authority and listed on the scheduled process under 21 CFR 113~~ shall be managed separately from the NCIMS HACCP System, even if identified as a CCP in the hazard analysis. ~~Critical factors shall be monitored under the operating supervision of an individual who has successfully completed an approved course of instruction in low-acid canned foods as required under 21 CFR 108.35. Compliance with the provisions of 21 CFR 113 shall satisfy the requirements of this Section, regardless of whether a critical factor has also been designated as a CCP.~~

# METHODS OF MAKING SANITATION RATINGS OF MILK SHIPPERS 2005 Revision

## PAGE 1:

### A. DEFINITIONS

Terms used in this document not specifically defined herein are those within *Title 21, Code of Federal Regulations* (CFR) and/or the *Federal Food, Drug and Cosmetic Act* (FFD&CA) as amended.

1. **AREA RATING:** An area rating, if used, shall apply to raw milk for pasteurization only. An area rating consists of more than one (1) producer group operating under the supervision of a single Regulatory Agency and which is rated as a single entity.

2. **ASEPTIC PROCESSING AND PACKAGING CRITICAL LISTING ELEMENTS (ACLEs):** Are those Critical Listing Elements for Aseptic Processing and Packaging Systems described in Section C., 2., a. 4.) of this document.

3. **ASEPTIC PROCESSING AND PACKAGING SYSTEM:** For the purposes of this Ordinance, the Aseptic Processing and Packaging System in a milk plant that produces aseptic Grade "A" milk or milk products shall be regulated in accordance with the FDA Low Acid Canned Foods regulations cited in 21 CFR 108, 110, and 113 and shall be defined by the Scheduled Process filed with FDA (FORM FDA 2541c and referenced Supplemental Submission Identifier (SUP-SID) documents, or in written communication from the Process Authority or equipment manufacturer). It would begin and end with any step considered critical to the filed Scheduled Process.

4. **ASEPTIC MILK PLANT RATING:** A rating of a milk plant that produces Grade "A" aseptically processed and packaged milk and milk products that is separate from the rating of other Grade "A" milk and milk products produced within the milk plant (the raw milk receiving area may be rated with the aseptic milk plant, or with a separately-listed pasteurization plant, or separately as an aseptic milk plant receiving station. This rating shall be made for all milk plants producing Grade "A" aseptically processed and packaged milk and milk products.

5. **ASEPTIC RAW MILK RECEIVING AREA:** The raw milk receiving area of a milk plant that produces Grade "A" aseptically processed and packaged milk and milk products is that area of the milk plant where Grade "A" fluid milk and milk products are received, collected, handled, stored and/or cooled. This area may be inspected, rated and IMS Listed according to the current NCIMS requirements for a receiving station, except that it shall be inspected at least once every six (6) months. This area may be rated with the aseptic milk plant; or with a separately-listed pasteurization plant; or separately as an aseptic milk plant receiving station. All milk and milk products shall be from an IMS Listed source. NOTE: If this receiving area is IMS Listed with a the pasteurization milk plant, it shall be inspected at least once every three (3) months.

**6. ASEPTIC MILK PLANT RECEIVING STATION:** A raw milk receiving area of a milk plant that produces Grade “A” aseptically processed and packaged milk and milk products that is separately inspected, rated and IMS Listed according to the NCIMS requirements for a receiving station, except that the minimum regulatory inspection frequency shall be at least once every six (6) months. All milk and milk products shall be from an IMS Listed source.

*(Re-number remaining Definitions)*

**PAGE 8:**

## **C. RATING METHODS FOR MILK PLANTS, RECEIVING STATIONS AND TRANSFER STATIONS**

### **2. COLLECTION OF DATA**

#### **a. Recording of Inspection Data**

3.) The average number of pounds of milk and milk products processed daily is needed for computing the rating and is entered in the appropriate place at the top of FORM FDA 2359-MILK PLANT INSPECTION REPORT. When a deficiency in a milk plant affects only one (1) type of packaging, i.e., paper, glass, single-service plastics, multi-use plastics, dispenser, cottage cheese, sour cream or yogurt containers; or the capping of these containers; or an individual pasteurization unit used, i.e., vat, HTST, HHST, ~~or aseptic processing~~; or product(s) that have not been pasteurized at minimum pasteurization times and temperatures; only the quantity of all products affected by the deficiency, rather than the entire plant's production, is recorded for use in the computation of the plant's Sanitation Compliance Rating. Only violations of Items 16p, 18p and 19p of the *Grade “A” PMO* are to receive partial debits. Provided, that bacterial count, coliform count and cooling temperature may be partially debited for the particular product involved. All other violations should be considered as affecting the entire production of the milk plant.

**NOTE:** The sampling and testing of Grade “A” aseptically processed and packaged milk and milk products is not required.

4.) Grade “A” aseptically processed and packaged milk and milk products shall be rated and IMS Listed separately from other Grade “A” milk and milk products that are produced within the Grade “A” IMS Listed milk plant. A significant deficiency involving one (1) or more of the ACLEs with the potential to impact human health constitutes grounds for the denial or removal of the milk plant's IMS Listing. The rest of the aseptic milk plant, including the raw milk receiving area/station, shall be inspected, rated and listed, according to the current NCIMS requirements. Provided that Items 7p, 10p, 11p, 12p, 13p, 15p, 16p, 17p, 18p and 19p of Section 7 of the *Grade “A” PMO* shall not be evaluated within the aseptic processing and packaging system. All milk and milk products shall be from an IMS Listed source.



**NCIMS ASEPTIC PILOT PROGRAM CRITICAL LISTING ELEMENTS**  
**(ACLES)**

(To be included with all NCIMS Aseptic Pilot Program State Ratings/Listings and FDA  
Check Ratings/Audits.)

1. Is the milk plant registered with FDA LACF and are all of the milk plant's aseptic Grade "A" milk and milk products covered by a filing with the FDA LACF using FORM FDA 2541c or equivalent electronic filing?
2. Are the milk plant's filed scheduled processes for all of its aseptic Grade "A" milk and milk products developed by a recognized process authority qualified as having expert knowledge of thermal processing requirements?
3. Are the operators of the milk plant's aseptic processing and packaging systems under the supervision of a person who has attended a school approved by the FDA (such as Better Process Control School or recognized equivalent)?
4. Is the milk plant currently under the enforcement of an emergency permit or is an emergency permit pending according to the FDA LACF office?

**PAGE 12:**

B.) Significant deficiencies involving one (1) or more CLE's constitute grounds for denial or withdrawal of a plant's, receiving station's or transfer station's NCIMS HACCP Listing.

(viii)**HACCP SYSTEM AUDIT FOLLOW-UP ACTION:** A series of observations that lead to a finding of a potential HACCP System failure that is likely to result in a compromise to milk or milk product safety.

In the case of an Aseptic Processing and Packaging Systems in a HACCP listed Grade "A" milk plant, a significant deficiency involving one (1) or more of the ACLEs, as cited on page 8, with the potential to impact human health also constitutes a Critical Listing Element deficiency under the NCIMS HACCP System and constitutes grounds for the denial or removal of the milk plant's aseptic milk and milk products IMS Listing.

**PAGE 13:**

**3. COMPUTATION OF SANITATION COMPLIANCE RATINGS**

b. The name of the plant and the total pounds of milk and milk products processed daily, expressed to the nearest 100 pound unit (cwt.), are entered in the first, "Name of Plant", and second, "Pounds Processed Daily (100# Units)", columns, respectively, of FORM FDA 2359L-STATUS OF MILK PLANTS.

If the plant's daily output varies, the recorded quantity is the daily average, based on actual operating days, for the week preceding the rating. Violations of Items or sub-items are

indicated by an "X" or by inserting the point value of the violation in the appropriate column(s). When a deficiency in a milk plant affects one (1) type of packaging, capping, or individual pasteurization unit used, the number of pounds of all products so packaged, capped or pasteurized are debited. In such cases, entries are made on separate lines below the name of the plant. The name or names of the product(s) affected by the violation(s) of Items 16p, 18p, 19p, or bacterial, coliform or cooling temperature standards of the *Grade "A" PMO* is entered in the "Name of Plant" column, together with a parenthetic entry of the total volume in 100 pound units (cwt.) of the product(s) involved. Care must be taken not to enter this quantity in the "Pounds Processed Daily (100# Units)" column where it would again be included in the total pounds processed daily. (Refer to Section H, #'s 9 and 10 for examples.) Except that in the case of an Aseptic Milk Plant Rating, a significant deficiency involving one (1) or more of the ACLEs, as cited on page 8, with the potential to impact human health constitutes grounds for the denial or removal of the milk plant's aseptic milk and milk products IMS Listing.

If all of the ACLEs are determined to be in compliance ("pass") by the SRO then the full credit for Items 16p, 18p and 19p (41 points) of Section 7 of the *Grade "A" PMO* shall be granted for the aseptic milk plant's Sanitation Compliance Rating. Also, in areas of the aseptic milk plant where Items 7p, 10p, 11p, 12p, 13p, 15p, and 17p of Section 7 of the *Grade "A" PMO* are directly related to the Aseptic Processing and Packaging System, as defined by the *Grade "A" PMO*, they shall be inspected and regulated in accordance with the FDA LACF program (21 CFR 108,110 and 113).

Care must be taken not to enter any quantity in the "Pounds Processed Daily (100# Units)" column for the pro-rating of aseptically processed and packaged *Grade "A"* milk or milk products for Items 16p, 18p and 19p of Section 7 of the *Grade "A" PMO* as these Items shall be inspected and regulated in accordance with the FDA LACF program (21 CFR 108, 110 and 113).

The rest of the milk plant, including the raw milk receiving area and/or receiving station shall be inspected, rated and IMS Listed according to the current NCIMS requirements. All milk and milk products shall be from an IMS Listed source.

**PAGE 15:**

#### **D. COMPUTATION OF ENFORCMENT RATINGS**

For all NCIMS HACCP HTST, HHST and Ultra-Pasteurized milk and milk product listings, complete the NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT. Enforcement ratings shall be made for dairy farms that are listed with milk plants, receiving stations, or transfer stations that are listed under the NCIMS HACCP listing procedure. These enforcement ratings shall be made using the procedures for raw milk for pasteurization addressed in 2. of this Section.

For all NCIMS aseptic milk plant listings under the NCIMS Aseptic Pilot Program, complete the NCIMS ASEPTIC PILOT PROGRAM REGULATORY AGENCY REVIEW REPORT.

**PAGE 24:**

4. PREPARATION OF THE “INTERSTATE MILK SHIPPER’S REPORT” FOR ASEPTIC MILK PLANT LISTINGS UNDER THE NCIMS ASEPTIC PILOT PROGRAM

The provisions of this Section apply to aseptic milk plants listed under the NCIMS aseptic milk plant listing procedure, except that:

a. A statement regarding the acceptability or unacceptability of the degree to which the enforcement provisions of the *Grade “A” PMO* are being applied by the Regulatory Agency will be substituted on FORM FDA 2359i-INTERSTATE MILK SHIPPER’S REPORT for the Enforcement Rating; and

b. FORM FDA 2359-MILK PLANT INSPECTION REPORT, FORM FDA 2359j-MILK SANITATION RATING REPORT (Pages 1-SECTION A: REPORT OF THE MILK SANITATION RATING and 3-SECTION C-EVALUATION OF SAMPLING PROCEDURES), FORM FDA 2359L-STATUS OF MILK PLANTS, FORM FDA 2359o-PERMISSION FOR PUBLICATION and the NCIMS ASEPTIC PILOT PROGRAM REGULATORY AGENCY REVIEW REPORT shall be submitted with all FORM FDA 2359i’s.

*Note: NCIMS Aseptic Pilot Program Forms and Examples will be added at a later date.*

**PROCEDURES GOVERNING THE COOPERATIVE STATE-PUBLIC  
HEALTH SERVICE/FOOD AND DRUG ADMINISTRATION PROGRAM  
OF THE NATIONAL CONFERENCE ON INTERSTATE MILK  
SHIPMENTS**

**2005 Revision**

**PAGE 2:**

**SECTION III. DEFINITIONS**

- H. **IMS LISTED SHIPPER:** An interstate milk shipper (BTU, receiving station, transfer station, or milk plant), which has been certified by the State Rating Agency as having attained the milk Sanitation Compliance and Enforcement Ratings necessary for inclusion in the *IMS List*. Provided that for IMS Listed milk plants producing Grade "A" aseptically processed and packaged milk and milk products, the NCIMS ASEPTIC MILK PLANT REGULATORY AGENCY REVIEW REPORT shall be used in lieu of traditional Enforcement Ratings as a part of State Ratings. The ratings are based on compliance with the requirements of the *Grade "A"PMO* and were made in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers* (MMSR).

**SECTION IV. OVERSIGHT AND RESPONSIBILITIES**

**A. PHS/FDA RESPONSIBILITIES**

8. Check Ratings of the Sanitation Compliance Status of Listed Interstate Milk Shippers

**PAGE 9:**

- a. PHS/FDA shall conduct, each year, check ratings of the sanitation compliance status of listed interstate milk shippers. Check ratings shall be conduct of IMS Listed milk plant and aseptic raw milk receiving area and/or aseptic milk plant receiving station of Grade "A" aseptic milk plants to determine the Aseptic Pilot Program compliance status of IMS Listed interstate milk shipper. These check ratings shall be conducted using the requirements identified in the NCIMS Aseptic Pilot Program. Within a State, check ratings will be made of a representative number of IMS Listed shippers. The selection of shippers for check rating in a given State will be made randomly.

**PAGE 10:**

- g. Enforcement ratings will be made as part of check ratings. For IMS Listed milk plants producing Grade "A" aseptically processed and packaged milk and milk product, the NCIMS ASEPTIC MILK PLANT REGULATORY AGENCY REVIEW REPORT shall be used in lieu of traditional Enforcement Ratings as a part of check ratings.

h. FDA shall review the Regulatory Agency records for the aseptic milk plant and aseptic raw milk receiving area and/or aseptic milk plant receiving station. Based on this review, if FDA determines there is reason to doubt the safety of any Grade “A” aseptically processed and packaged milk or milk products related to a substantial operational weakness in the State Regulatory Agency’s enforcement program, FDA shall send a written notice requiring corrections to the State Regulatory Agency, with copies to the State Rating Agency and the specific aseptic milk plant producing such Grade “A” aseptically processed and packaged milk or milk product(s).

If, after sixty (60) days following the issuance of such written notice, FDA determines that the Grade “A” aseptically processed and packaged milk or milk product’s safety related to a substantial operational weakness in the State Regulatory Agency enforcement program still exists, FDA shall immediately remove the aseptic milk plant’s IMS Listing. Additionally, FDA shall inform the NCIMS Executive Board and complete a State Program Evaluation within ninety (90) days following the removal of the aseptic milk plant’s IMS Listing.

## **SECTION VIII. PROCEDURES GOVERNING THE CERTIFICATION OF MILK PLANT, RECEIVING STATION AND TRANSFER STATION NCIMS HACCP SYSTEMS FOR IMS LISTED SHIPPERS**

### **C. PHS/FDA RESPONSIBILITIES**

#### **8. FDA Audits of HACCP Listing**

#### **PAGE 27:**

h. FDA shall conduct on-site plant, receiving station and transfer station audits of the HACCP compliance status of listed interstate milk shippers. These FDA HACCP audits shall be conducted using the procedures for State HACCP listing audits as described in the MMSR. These audits will be used in the overall State Program Evaluation. Provided, that for NCIMS HACCP IMS Listed milk plants producing Grade “A” aseptically processed and packaged milk and milk products, FDA HACCP audits shall be conducted using the procedures identified in the NCIMS Aseptic Pilot Program. The NCIMS ASEPTIC MILK PLANT REGULATORY AGENCY REVIEW REPORT shall be used in lieu of FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT as part of FDA audits.

j. FDA shall review the Regulatory Agency records for NCIMS HACCP IMS Listed milk plants producing Grade “A” aseptically processed and packaged milk and milk products, being audited. Based on these audits, if FDA determines there is reason to doubt the safety of any Grade “A” aseptically processed and packaged milk or milk products related to a substantial operational weakness in the State Regulatory Agency’s enforcement program, FDA shall send a written notice requiring corrections to the State Regulatory Agency, with copies to the State Rating Agency and the specific aseptic milk plant producing such Grade “A” aseptically processed and packaged milk or milk product(s).

If, after sixty (60) days following the issuance of such written notice, FDA determines that the Grade “A” aseptically processed and packaged milk or milk product’s safety related to a substantial operational weakness in the State Regulatory Agency enforcement program still exists, FDA shall immediately remove the aseptic milk plant’s IMS Listing. Additionally, FDA shall inform the NCIMS Executive Board and complete a State Program Evaluation within ninety (90) days following the removal of the aseptic milk plant’s IMS Listing.

**PAGE 28:**

**D. STATE HACCP RESPONSIBILITIES**

1. State HACCP Listings for Milk Plants, Receiving stations and Transfer Stations

c. When the sanitation compliance status of a listed shipper's supply changes as a result of a new listing made within the twenty-four (24) month eligibility period, the most recent listing and the MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT and the NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT, shall apply and shall be submitted to PHS/FDA. Provided that for IMS Listed HACCP milk plants producing Grade “A” aseptically processed and packaged milk and milk product, the NCIMS ASEPTIC MILK PLANT REGULATORY AGENCY REVIEW REPORT shall be used in lieu of FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT as part of a State Ratings.

2. NCIMS HACCP Enforcement Responsibilities

a. A NCIMS HACCP System Regulatory Agency review shall be conducted and the NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT shall be completed and provided to FDA as a part of all NCIMS HACCP listings.....

After the 180 days, if the State is still unable to fulfill its obligations under the NCIMS HACCP Program and milk or milk product safety remains in doubt FDA will not accept new HACCP listings from the State and FDA may audit the existing listings as necessary to protect the public health.

b. For NCIMS HACCP IMS Listed milk plants producing Grade “A” aseptically processed and packaged milk and milk products, the NCIMS ASEPTIC MILK PLANT REGULATORY AGENCY REVIEW REPORT shall be used in lieu of FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT as part of State Ratings. The NCIMS ASEPTIC MILK PLANT REGULATORY AGENCY REVIEW REPORT shall be completed and provided to FDA as a part of all NCIMS HACCP aseptic milk plant listings.

Based on this report, if FDA determines there is reason to doubt the safety of any Grade “A” aseptically processed and packaged milk or milk products related to a substantial operational weakness in the State Regulatory Agency’s enforcement program, FDA shall send a a written

notice requiring corrections to the State Regulatory Agency, with copies to the State Rating Agency and the specific aseptic milk plant producing such Grade “A” aseptically processed and packaged milk or milk product(s).

If, after sixty (60) days following the issuance of such written notice, FDA determines that the Grade “A” aseptically processed and packaged milk or milk product’s safety related to a substantial operational weakness in the State Regulatory Agency enforcement program still exists, FDA shall immediately remove the aseptic milk plant’s IMS Listing. Additionally, FDA shall inform the NCIMS Executive Board and complete a State Program Evaluation within ninety (90) days following the removal of the aseptic milk plant’s IMS Listing.

**PAGE 34:**

**E. QUALIFICATIONS AND CERTIFICATIONS**

3. HACCP Listing

a. An acceptable HACCP listing shall be substituted for an acceptable sanitation and enforcement rating for a milk plant, receiving station or transfer station participating in the NCIMS HACCP Program. A MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT and a NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT shall be completed as a part of all milk plant, receiving station or transfer station HACCP listing audits. Provided that for NCIMS HACCP IMS Listed milk plants producing Grade “A” aseptically processed and packaged milk and milk products and HTST, HHST and/or UP milk and milk products that are listed separately, the NCIMS ASEPTIC MILK PLANT REGULATORY AGENCY REVIEW REPORT shall be used in lieu of FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT as part of State HACCP Listings.