HHS:PHS:FDA:CFSAN:OFS:DPDFS:DEB:MST

5100 Paint Branch Parkway
College Park, MD 20740-3835

November 7, 2011

IMS-a-48

To: All Regional Food and Drug Directors
Attn: Regional Milk Specialists

From: Dairy and Egg Branch (HFS-316)

Subject: Actions of the 2011 National Conference on Interstate Milk Shipments

The 33rd National Conference on Interstate Milk Shipments (NCIMS) was held in Baltimore, Maryland, April 29 through May 4, 2011. A total of 91 Proposals were submitted and deliberated at the Conference. During the Conference, the State delegates approved several changes to the *Grade "A" Pasteurized Milk Ordinance* (PMO) and related NCIMS documents. Following is a table showing the Actions taken by the voting delegates:

COUNCIL	# OF PROPOSALS	NO ACTION	PASSED AS SUBMITTED	PASSED AS AMENDED	TABLED
I	30	12	3	15	0
II	48	15	19	14	0
III	13	7	3	3	0
TOTAL	91	34	25	32	0

The following Proposals were passed and addressed changes to the PMO: 103, 106, 113, 114, 115, 116, 117, 118, 119, 120, 121, 123, 124, 126, 127, 128, 129, 205, 208, 209, 210, 212, 214, 215, 301, 308 and 309.

The following Proposals were passed and addressed changes to the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments* (Procedures): 301 and 303.

The following Proposals were passed and addressed changes to the *Methods of Making Sanitation Ratings of Milk Shippers* (MMSR): 205, 216, 217, 218, and 301.

There were not any Proposals submitted that addressed changes to the *Constitution* or the *Bylaws of the National Conference on Interstate Milk Shipments* (Constitution and Bylaws):

The following Proposals were passed and addressed changes to the *Evaluation of Milk Laboratories* (EML): 235, 236, 237, 238, 241, 242, 243, 246, and 247.

The following Proposals were identified as FDA 2400 Series Forms and were voted on as a block to be handled by FDA and the NCIMS Laboratory Committee following the procedures for issuing and updating FDA 2400 Series Forms: 219, 224, 225, 226, 227, 228, 229, 230, 231, 232, 234 and 248.

The following Proposals were passed and addressed changes to the Inspection and Rating Forms utilized in the Program:

- FORM FDA 2359-MILK PLANT INSPECTION REPORT (10/08): 301
- FORM FDA 2359a-DAIRY FARM INSPECTION REPORT (10/08): 106
- FORM FDA 2359b-MILK PLANT EQUIPMENT TEST REPORT (10/08): 301
- FORM FDA 2359j-MILK SANITATION RATING REPORT, SECTION B. REPORT OF ENFORCEMENT METHODS (10/08) (PAGE 2): 301
- FORM FDA 2359j-MILK SANITATION RATING REPORT, SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATION (10/09) (PAGE 4): 216
- FORM FDA 2359j-MILK SANITATION RATING REPORT, SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATION (10/09) (PAGE 5): 216.
- FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT (10/10): 217
- FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT (10/10): 218 and 301
- Add a new FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products (10/11): 301
- FORM FDA 2399a-BULK MILK HAULER/SAMPLER EVALUATION REPORT (10/08): 208.

A substitute solution was provided for Proposal 117 and was passed, which addressed cold filled cottage cheese. The solution included draft copies of IMS-a-45 (Supplement 2) and M-a-97. This passed substitute solution addresses cultured cottage cheese at all milk fat levels with a pH of 5.2 or below* and the addition of either potassium sorbate at a minimum concentration of 0.06% or the addition of one (1) of the specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97; filled at 13ºC (55ºF) or less*; cooled to 10ºC (50°F) or less within twenty-four (24) hours of filling**; and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling**.

*Critical factors including, but not limited to, pH, filling temperature, cooling times and temperatures, and potassium sorbate concentration or specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97, if applicable, shall be monitored and documented by the processing facility for verification by the Regulatory Agency. pH limit with a pH variance of + 0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the Regulatory Agency.

NOTE: Microbial inhibitors and/or preservatives and all of their individual components shall have GRAS status; and pathogen inhibition shall be supported by documented challenge study results that are acceptable to the Regulatory Agency and FDA.

** Cooling temperatures monitored at the slowest cooling portion, i.e., in the middle of the container, of the slowest cooling container, i.e., in the middle of the pallet.

M-a-97 provides a list of the specified microbial inhibitors and specified concentrations and provides for a process to update this list in a similar manner to how FDA currently updates M-a-85.

Proposal 219 was passed and addressed changes to be made to M-a-85 (Issue a New Revision #14)-Beta lactam Test Methods for Use Under Appendix N and Section 6 of the Grade "A" Pasteurized Milk Ordinance (PMO) and consequently to M-I-96-10 (Issue a New Revision #8)-Drug Residue Test Methods for Confirmation of Presumptive Positive Results and Initial Producer Trace Back for the approved Charm Beta lactam and Flunixin Test. Also, Proposal 224 addressed changing the existing citation for Neogen's Beta Star US to the newly approved BetaStar Plus (Beta lactam) Test in both of these coded memoranda cited above.

The following Proposals were passed and addressed the formation of Study Committees: 101 (Science Advisory Committee), 120 (Other Species Committee), 222 (Laboratory Committee), 233 (Laboratory Committee), 308 (Aseptic Pilot Program) and 313 (Liaison Committee).

The following Proposals were passed and did not reference any document or Forms: 101, 222, 233, 312 and 313.

FDA responded in writing to the NCIMS Conference Chair on August 29, 2011 and met with the NCIMS Executive Board on October 4-5, 2011 concerning the Proposals passed during the 2011 Conference. Within FDA's letter dated August 29, 2011, FDA concurred with all of the passed Proposals with the exception of Proposal 209. During the October 4-5, 2011 NCIMS Executive Board meeting, FDA and the Executive Board mutually concurred with all of the Proposals concurred with by FDA, accepted FDA's non-concurrence of Proposal 209, and the changes cited within this IMS-a.

All Proposals that were passed, with the exception of Proposal 208, which was non-concurred with by FDA, and the ones noted below, will become effective within one (1) year of the electronic publication of the affected document(s); or by the official notification to the States through the transmittal of this IMS-a, as applicable, following the Conference at which the changes were passed. For States that can legally enforce the new regulations based on the issuance of this IMS-a, the effective date will be November 7, 2012.

- Proposal 117 became effective June 15, 2011.

- Proposal 301 establishes the Aseptic Program as a permanent part of the NCIMS Interstate Milk Shipments Program and extends the NCIMS Aseptic Pilot Program (APP) until December 31, 2013, unless extended by future Conference action.

This provision shall take immediate effect upon the issuance of the IMS-a, Actions from the 2011 National Conference on Interstate Milk Shipments, following FDA concurrence with the NCIMS Executive Board.

- Proposal 308 requests that a NCIMS Retort Pilot Program shall be assigned as a part of the NCIMS Aseptic Pilot Program Implementation Committee's (APPIC) current charge that addresses aseptically processed and packaged Grade "A" low acid milk and milk products. The APPIC shall also be responsible for the oversight of the NCIMS Retort Pilot Program addressing retort processed after packaging Grade "A" milk and milk products in consultation with FDA; and shall include the development of required forms, documents and guidance necessary to implement, evaluate and provide training, as well as study current and new retort technology and its application. The APPIC shall provide a report to the 2013 NCIMS.

  All milk plants producing retort processed after packaging Grade "A" milk and/or milk products, as defined by the PMO and regulated under the NCIMS program shall participate in the NCIMS Retort Pilot Program for those milk and/or milk products.

  This provision shall take immediate effect upon the issuance of the IMS-a, Actions from the 2011 National Conference on Interstate Milk Shipments, following FDA's concurrence with the NCIMS Executive Board.

- Proposal 309 extends the voluntary NCIMS International Certification Pilot Program (ICPP) until December 31, 2013, unless extended by future Conference action.

  This provision shall take immediate effect upon the issuance of the IMS-a, Actions from the 2011 National Conference on Interstate Milk Shipments, following FDA concurrence with the NCIMS Executive Board.

- Proposal 312 allows once a Third Party Certifier (TPC) under the voluntary International Certification Pilot Program has their existing four (4) plants IMS Listed and the completion and issuance of the equivalent of a State Program Evaluation, with a determination that the TPC is in **Compliance** with the PMO, the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments* (Procedures) and other NCIMS related documents, including the ICPP's Policies and Procedures, Letter of Intent (LOI) and Code of Ethics, the TPC may request from the ICCP Committee permission to add two (2) additional plants for a maximum of six (6) listed plants.

  This provision shall take immediate effect upon the issuance of the IMS-a, Actions from the 2011 National Conference on Interstate Milk Shipments, following FDA concurrence with the NCIMS Executive Board.

NOTE: Some of the language as adopted by the delegates was editorialized in order to maintain continuity with the present language and to ensure compatibility with existing sections of the affected NCIMS document(s). The edits have not changed the intent of the voted actions.

Deletions to the current document's language are identified by ~~strikeout~~ and additions are identified by underlined text, unless otherwise noted.

Proposal: 301
Document: 2009 PMO (Table of Contents; Tables; Sections 1, 4, 5, 6, 7-Items 1p, 2p, 5p, 11p, 12p, 15p, 16p, 17p and 18p, 8, 9, 11, 13 and 14; Appendixes H, I, K, L, M, O, R and add a new S; Index; and FORMS 2359, 2359b 2359j-Section B, 2359n and a new 2359p)
Pages: viii, ix, xiii, xv, 1-11, 15-20, 23-26, 28-31, 55-58, 66, 70, 78, 79, 81, 82, 84, 88, 92, 95-106, 109, 113, 117, 118, 120-125, 216, 217, 219, 220, 222, 251-253, 273-276, 281-292, 295-297, 299, 305-311, 328, 335, 337, 356, 359 and 362-379

*Make the following changes to the **TABLE OF CONTENTS** on Pages viii, ix, and xiii:*

STANDARDS FOR GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING AND PACKAGING ……

Page ix:

STANDARDS FOR GRADE "A" PASTEURIZED, ULTRA-PASTEURIZED AND ASEPTICALLY PROCESSED AND PACKAGED MILK AND MILK PRODUCTS …

ITEM 16p. PASTEURIZATION AND ASEPTIC PROCESSING AND PACKAGING .....
~~ITEM 16p.(C). ASEPTIC PROCESSING SYSTEMS ……~~
ITEM 16p.(~~D~~C). PASTEURIZERS ~~AND ASEPTIC PROCESSING SYTEMS~~
EMPLOYING REGENERATIVE HEATING …….
MILK OR MILK PRODUCT-TO-MILK OR MILK PRODUCT REGENERATIVE HEATING …….....
MILK OR MILK PRODUCT-TO-WATER-TO-MILK OR MILK PRODUCT REGENERATIVE HEATING …….
ITEM 16p.(~~E~~D). PASTEURIZATION ~~AND ASEPTIC PROCESSING~~ RECORDS,
EQUIPMENT TESTS AND EXAMINATIONS …….

Page xiii:

APPENDIX Q. OPERATION OF AUTOMATIC MILKING INSTALLATIONS FOR THE PRODUCTION OF GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING AND PACKAGING ……..

APPENDIX S. ASEPTIC PROCESSING AND PACKAGING PROGRAM …….....

*Make the following changes to **TABLES** on Page xv:*

Table 4. Equipment Tests – Batch Pasteurizers, and HTST~~,~~ and HHST ~~and Aseptic Processing~~ Pasteurization Systems ……

*Make the following changes to **SECTION 1. DEFINITIONS** on Pages 1-11:*

B. **ASEPTIC PROCESSING AND PACKAGING:** The term "Aseptic Processing and Packaging", when used to describe a milk or milk product, means that the milk or milk product has been subjected to sufficient heat processing and packaged in a hermetically sealed container, to conform to the applicable requirements of 21 CFR Parts 108, 110 and 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.

C. **ASEPTIC PROCESSING AND PACKAGING SYSTEM (APPS):** For the purposes of this *Ordinance*, the Aseptic Processing and Packaging System in a milk plant is comprised of the processes and equipment used to process and package aseptic Grade "A" milk or milk products. The APPS shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. The APPS shall begin at the constant level tank and end at the discharge of the packaging machine, provided that the Process Authority may provide written documentation which will clearly define additional processes or equipment that are considered critical to the commercial sterility of the product.

~~C~~D. **AUTOMATIC MILKING INSTALLATION (AMI):** …

Re-letter remaining definitions accordingly.

Page 5:

V. **LOW-ACID ASEPTIC MILK AND MILK PRODUCTS:** Milk or milk products having a water activity (a_w) greater than 0.85 and a finished equilibrium pH greater than 4.6 and are regulated under 21 CFR Parts 108, 110 and 113. Aseptically processed and packaged low-acid milk and milk products are stored under normal non-refrigerated conditions. Excluded from this definition are low-acid milk and milk products that are labeled for storage under refrigerated conditions.

Re-letter remaining definitions accordingly.

~~V~~X. **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.

*Re-letter remaining Definitions accordingly and make specific Definition re-lettering citations throughout the **PMO** on Pages 6 (QQ to SS), 79, 81, 89-93, 100 (all FF to HH), 127 (II to KK), 176 and 359 (FF to HH and MM to OO).*

*Make the following changes to **SECTION 4. LABELING** on Pages 15-17:*

All bottles, containers and packages containing milk or milk products, except milk tank trucks, storage tanks and cans of raw milk from individual dairy farms, shall be conspicuously marked with:

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 aseptically processed and packaged milk and milk products…

Pages 16 and 17:

ADMINISTRATIVE PROCEDURES

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 and milk products will be as safe as ~~milk~~ they 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.

Make the following changes to ***SECTION 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS*** *on Pages 17-20:*

3. Inspect each milk plant and receiving station at least once every three (3) months, ~~except~~ 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 a milk plant or portion of a milk plant that is IMS listed to produce aseptically processed and packaged milk or milk products shall be conducted by the State Regulatory Agency in accordance with this *Ordinance* at least once every six (6) months. (Refer to Appendix S.) The milk plant's APPS shall be inspected by FDA, or the State Regulatory Agency when designated by FDA, in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113 at a frequency determined by FDA. …

Page 18:

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 19:

ADMINISTRATIVE PROCEDURES

INSPECTION FREQUENCY: For the purposes of determining the inspection frequency for dairy farms, ~~and~~ transfer stations and milk plants or the portion of a milk plant that is IMS listed to produce aseptically processed and packaged milk or milk products, 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, milk plant or portion of a milk plant that is IMS listed to produce aseptically processed and packaged milk or milk products or milk tank truck cleaning facility inspection every six (6) months~~,~~; or one (1) milk plant producing pasteurized, ultra-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. …

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 20:

ENFORCEMENT PROCEDURES - ASEPTIC PROCESSING AND PACKAGING 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.)~~ The State Regulatory Agency shall take appropriate regulatory action, in coordination with FDA when applicable, to assure that the Grade "A" aseptic milk plant and the Grade "A" aseptic milk and milk products meet the applicable requirements of this *Ordinance*.

Make the following changes to ***SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS*** *on Pages 23-26:*

1. 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 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. …

4. During any consecutive six (6) months, at least four (4) samples of pasteurized milk, ultra-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 and ~~(including Aseptically Processed and Ultra-Pasteurized)~~ 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. Aseptically processed and packaged milk and milk products shall be exempt from the sampling and testing requirements of this Item …

Required bacterial counts, somatic cell counts and cooling temperature checks shall be performed on raw milk for pasteurization, ultra-pasteurization or aseptic processing and packaging. In addition, drug tests on each producer's milk shall be conducted at least four (4) times during any consecutive six (6) months.

Page 24:

All pasteurized ~~(including Aseptically Processed~~ and ~~Ultra-Pasteurized)~~ 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 and ultra-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 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 milk and milk products)~~, somatic cell counts, coliform determinations or cooling temperatures. …

~~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 aseptic samplers for milk tank trucks, 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 *Procedures*. ~~Aseptically processed milk and milk products packaged in hermetically sealed containers shall be tested in accordance with FDA's *Bacteriological Analytical Manual* (BAM).~~ …

Page 25:

Assays of milk and milk products as defined in this *Ordinance*, including aseptically processed and packaged milk and milk products, to which vitamin(s) A and/or D have been added for fortification purposes, shall be made at least annually in a laboratory, which has been accredited by FDA and which is acceptable to the Regulatory Agency, using test methods acceptable to FDA or other official methodologies, which gives statistically equivalent results to the FDA methods. Vitamin testing laboratories are accredited if they have one (1) or more certified analysts and meet the quality control requirements of the program established by FDA. Laboratory accreditation and analyst certification parameters are specified in the Evaluation of Milk Laboratories (EML) manual. …

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.~~

Make the following changes to ***SECTION 7. STANDARDS FOR GRADE "A" MILK AND MILK PRODUCTS*** *on Pages 28-31:*

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

No process or manipulation other than pasteurization, ultra-pasteurization or aseptic processing and packaging; processing methods integral therewith; and appropriate refrigeration shall be applied to milk and milk products for the purpose of removing or deactivating microorganisms, provided that filtration and/or bactofugation processes are performed in the milk plant in which the milk or milk product is pasteurized, ultra-pasteurized or aseptically processed and packaged. Provided, that in the bulk shipment of cream, nonfat (skim) milk or reduced fat or lowfat milk, the heating of the raw milk, one time, to temperatures greater than 52ºC (125ºF) but less than 72ºC (161ºF), for separation purposes, is permitted when the resulting bulk shipment(s) of cream, nonfat (skim) milk or reduced fat or lowfat milk are labeled heat-treated. In the case of heat-treated cream, the cream may be further heated to less than 75ºC (166ºF) in a continuing heating process and immediately cooled to 7ºC (45ºF) or less when necessary for enzyme deactivation (such as lipase reduction) for a functional reason. …

Pages 29-30:

GRADE "A" RAW MILK AND MILK PRODUCTS FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING AND PACKGING	Temperature.....	Cooled to 10ºC (50ºF) or less within four (4) hours or less, of the commencement of the first milking, and to 7°C (45ºF) 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 10ºC (50ºF). NOTE: Milk sample submitted for testing cooled and maintained at 0ºC (32ºF) to 4.4ºC (40ºF), where sample temperature is >4.4ºC (40ºF), but ≤7.0ºC (45oF) 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. NOTE: 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" ASEPTICALLY PROCESSED MILK AND MILK PRODUCTS**~~	~~Temperature.....~~	~~None.~~
	~~Bacterial Limits.....~~	~~Refer to 21 CFR 113. 3(e)(1).******~~
	~~Drugs**.....~~	~~There are no validated and accepted drug residue tests for Aseptically Processed Milk and Milk Products.~~

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~~****** 21 CFR 113.3(e)(1) contains the definition of "COMMERCIAL STERILITY".~~

STANDARDS FOR GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING AND PACKAGING

Make the following changes to ***SECTION 7. STANDARDS FOR GRADE "A" PASTEURIZED, ULTRA-PASTEURIZED AND ASEPTICALLY PROCESSED MILK AND MILK PRODUCTS*** *on Page 55:*

STANDARDS FOR GRADE "A" PASTEURIZED, ULTRA-PASTEURIZED AND ASEPTICALLY PROCESSED AND PACKAGED MILK AND MILK PRODUCTS

Milk plants shall comply with all Items of this Section. Provided, in the case of milk plants or portions of milk plants that are IMS Listed to produce aseptically processed and packaged milk or milk products, the APPS, 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 Parts 108, 110 and 113. Those Items, contained within the APPS, shall be inspected by FDA or a State Regulatory Agency, when designated by FDA. …
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 and Packaging of this *Ordinance*, and pasteurization shall be managed as a CCP as described in Appendix H. VIII- 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.

Make the following changes to ***ITEM 1p. FLOORS - CONSTRUCTION*** *on Page 56:*

ADMINISTRATIVE PROCEDURES

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 and packaged milk or milk products and/or packaging materials need not be provided with drains. …

Make the following changes to ***ITEM 2p. WALLS AND CEILINGS - CONSTRUCTION*** *on Page 57:*

NOTE: Refer to Item 11p for requirements for walls for drying chambers. Storage 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.

Make the following changes to ***ITEM 5p. SEPARATE ROOMS*** *on Page 58:*

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 APPS.

Make the following changes to ***ITEM 11p. CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT*** *on Page 66:*

ADMINISTRATIVE PROCEDURES

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 are governed under the applicable provisions of 21 CFR Parts 110 and 113 and shall not be subject to this Section.

Make the following changes to ***ITEM 12p. CLEANING AND SANITIZATION OF CONTAINERS AND EQUIPMENT*** *on Pages 66 and 70:*

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 non-sterile product has contaminated it.~~

Page 70:

ADMINISTRATIVE PROCEDURES

5. All multi-use containers, utensils and equipment are sanitized before use, employing one or a combination of the methods prescribed under Item 11r. Additionally, for milk plants that condense or dry milk or milk products the following methods are acceptable, or any other method, which has been demonstrated to be equally efficient:
   a. Exposure to an enclosed jet of steam for not less than 1 minute.
   b. Exposure to hot air at a temperature of at least 83°C (180°F) for at least twenty (20) minutes as measured by an acceptable indicating thermometer located in the coldest zone.

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 resterilized whenever it has been contaminated by nonsterile product.~~ …

Make the following changes to ***ITEM 15p. PROTECTION FROM CONTAMINATION*** *on Pages 78 and 79:*

15p.(B)

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 pipe lines 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~~:~~

Page 79:

~~i) In~~ <u>in</u> 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.

Make the following changes to ***ITEM 16p. PASTEURIZATION AND ASEPTIC PROCESSING*** *on Pages 81 and 82:*

ITEM 16p. PASTEURIZATION AND ASEPTIC PROCESSING <u>AND PACKAGING</u>

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

A note of caution is in order. Although pasteurization destroys the organisms, it does not destroy the toxins that may be formed in milk and milk products when certain staphylococci are present, as from udder infections, and when the milk or milk product is not properly refrigerated before pasteurization. Such toxins may cause severe illness. Aseptic processing and packaging has also been conclusively demonstrated to be effective in preventing outbreaks from milkborne pathogens. Numerous studies and observations clearly prove that the food value of milk is not significantly impaired by pasteurization. …

Make the following changes to ***ITEM 16p. PASTEURIZATION AND ASEPTIC PROCESSING*** *on Page 84:*

ADMINSTRATIVE PROCEDURES

6. The design and operation of pasteurization equipment and all appurtenances thereto shall comply with the applicable specifications and operational procedures of Subitems (A), (B), (~~D~~C) and (~~E~~D).

Make the following changes to ***ITEM 16p.(A) BATCH PASTEURIZATION*** *on Page 88:*

ADMINISTRATIVE PROCEDURES

5. **RECORDING CHARTS:**
All recording thermometer charts shall comply with all the applicable requirements of Item 16p(~~E~~D)1.a.

Make the following changes to ***ITEM 16p.(B) HIGH-TEMPERATURE-SHORT-TIME (HTST) CONTINUOUS-FLOW PASTEURIZATION*** *on Page 92:*

ADMINISTRATIVE PROCEDURES

e. **Indicating and Recording Thermometers:** …
(3) The recorder/controller charts shall comply with the applicable provisions of Item 16p(~~E~~D)1.a.

Make the following changes to ***ITEM 16p.(C) ASEPTIC PROCESSING SYSTEMS*** *on Pages 95-98:*

~~**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 positive displacement type timing pump located upstream from the holding tube, or a magnetic flow meter based timing system, which complies with the specifications as outlined in Appendix H, shall be operated to maintain the required rate of milk or milk product flow. The motor of the timing pump shall be connected 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 speedup, of the pump. The 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 of an inch 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 66ºC (120ºF) 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.~~

Make the following changes to ***ITEM 16p.(D) PASTEURIZERS AND ASEPTIC PROCESSING SYSTYEMS EMPLOYING REGENERATIVE HEATING*** *on Pages 98-102:*

ITEM 16p.(~~D~~C) PASTEURIZERS ~~AND ASEPTIC PROCESSING SYSTYEMS~~ EMPLOYING REGENERATIVE HEATING

ADMINISTRATIVE PROCEDURES

This Item is deemed satisfied when: …

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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. …

4. 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.
5. 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.

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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 FF 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

Page 101:

OPTION II. 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:

1. A differential pressure controller shall be used to monitor pressures of the pasteurized milk or milk product and the heat-transfer-medium.
~~2. 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.~~
~~3. In either case, one~~ 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**.**
~~4~~2. The heat-transfer-medium pump shall be wired so that it cannot operate unless the timing pump is in operation.

Make the following changes to ***ITEM 16p.(E) PASTEURIZATION AND ASEPTIC PROCESSING RECORDS, EQUIPMENT TESTS AND EXAMINATIONS*** *on Pages 102-105:*

ITEM 16p.(~~E~~D) 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: …

Page 103:

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 (7) and in addition, shall include the following: …

~~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.~~

~~e~~d. **Electronic Data Collection, Storage and Reporting:** Electronic collection, storage and reporting of required pasteurization ~~and aseptic processing~~ records, with or without hard copy printouts, may be acceptable, provided, the electronically generated records are readily available at the milk plant for review by the Regulatory Agency and meet the criteria of this Section and Appendix H., V.

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

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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.

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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.

Make the following changes to ***TABLE 4. EQUIPMENT TESTS – BATCH, HTST, HHST and ASEPTIC PROCESSING SYSTEMS*** *on Page 106:*

Table 4. Equipment Tests - Batch Pasteurizers, and HTST, and HHST ~~and Aseptic Processing~~ Pasteurization Systems (Refer to Appendix I.)

1.	Vat, HTST~~,~~ and HHST~~, Aseptic~~ indicating and airspace thermometers	Temperature accuracy
2.	Vat, HTST~~,~~ and HHST~~, Aseptic~~ recording thermometer	Temperature accuracy
3.	Vat, HTST~~,~~ and HHST~~, Aseptic~~ recording thermometer	Time accuracy
4.	Vat, HTST~~,~~ and HHST~~, Aseptic~~ indicating and recording thermometer	Recording vs. Indicating thermometer
5.1	HTST~~,~~ and HHST FDD	Leakage pass FDD
5.2	HTST~~,~~ and HHST FDD	FDD freedom of movement
5.3	HTST~~,~~ and HHST FDD	Device assembly (single stem)
5.4	HTST~~,~~ and HHST FDD	Device assembly (dual stem)
5.5	HTST FDD	Manual diversion
5.6	HTST~~,~~ and HHST FDD	Response time
5.7	HTST~~,~~ and HHST FDD	Time delay (inspect)
5.8	HTST~~,~~ and 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~~,~~ and HHST, ~~Aseptic~~ differential pressure controllers	Calibration
9.2.2	HTST differential pressure controllers	Regenerator pressure
9.2.3	HTST*~~,~~ and HHST ~~and Aseptic~~ differential pressure controllers	Regenerator pressure
9.3.1	HTST booster pump/FDD	Inter-wiring check
9.3.2	HTST booster pump/timing pump	Inter-wiring check
10.1	HTST FDD	Temperature cut-in/cut-out
10.2	HTST*~~,~~ and HHST FDD~~, Aseptic~~ divert system (indirect heat)	Temperature cut-in/cut-out
10.3	HTST*~~,~~ and 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~~,~~ and HHST~~, Aseptic~~ MFMBTS	Flow alarm
11.2.c	HTST~~,~~ and 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*~~,~~ and HHST~~, Aseptic systems~~ indirect heating	Sequence logic
12.2	HTST*~~,~~ and HHST~~, Aseptic systems~~ direct heating	Sequence logic
13.	HHST~~, Aseptic systems~~	Pressure in the holding tube
14.	HTST*~~,~~ and HHST~~, Aseptic systems~~ using direct injection heating	Pressure differential across injector
15.	HTST~~,~~ and HHST~~, Aseptic~~ (all electronic controls)	Electro-Magnetic Interference

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

Make the following changes to ***ITEM 17p. COOLING OF MILK AND MILK PRODUCTS*** *on Page 109:*

ADMINISTRATIVE PROCEDURES

6. Each refrigerated room in which pasteurized 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.

Make the following changes to ***ITEM 18p. BOTTLING, PACKAGING AND CONTAINER FILLING*** *on Page 113:*

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 21 CFR Part 113.~~

Make the following changes to ***SECTION 8. ANIMAL HEALTH*** *on Pages 117-118:*

1. All milk for pasteurization, ultra-pasteurization or aseptic processing and packaging shall be from herds in Areas which have a Modified Accredited Advanced Tuberculosis (TB) status or higher as determined by the USDA. Provided, that in an Area which fails to maintain such status, any herd shall have been accredited by said Department as tuberculosis free, or shall have passed an annual tuberculosis test, or the Area shall have established a tuberculosis testing protocol for livestock that assures tuberculosis protection and surveillance of the dairy industry within the Area and that it is approved by FDA, USDA and the Regulatory Agency. …

2. All milk for pasteurization, ultra-pasteurization or aseptic processing and packaging shall be from herds under a brucellosis eradication program, which meets one (1) of the following conditions: …

Page 118:

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: …

Make the following changes to ***SECTION 9. MILK AND MILK PRODUCTS WHICH MAY BE SOLD*** *on Page 120:*

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, ultra-pasteurization or aseptic processed and packaged 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".

Make the following changes to ***SECTION 11. MILK AND MILK PRODUCTS FROM POINTS BEYOND THE LIMITS OF ROUTINE INSPECTION*** *on Pages 121-123:*

Milk and milk products, from points beyond the limits of routine inspection of the ... of... or its jurisdiction, shall be sold in…, [1] 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~~ an ~~satisfactory~~ acceptable 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.

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: …

Page 122:

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.

NOTE: Raw, ~~and~~ pasteurized and ultra-pasteurized milk and milk products beyond the limits of routine inspection shall be sampled as the Regulatory Agency requires. …

11. Aseptically processed and packaged milk and milk products in Definition X of this *Ordinance* shall be considered to be Grade "A" milk or milk products. The ~~source~~ source(s) of the milk and milk products used to produce aseptically processed and packaged 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~~. Aseptically processed and packaged milk and milk products shall be labeled "Grade "A"" and meet Section 4 labeling requirements of the PMO. The milk plant or portion of the milk plant that is producing aseptically processed and packaged milk and milk products shall be awarded a Milk Sanitation Compliance Rating of ~~a~~ at 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 and label its milk and milk products as "Grade "A""~~. an Enforcement Rating equal to the local supply, or

equal to ninety percent (90%) or higher, or if the Enforcement Rating is below ninety percent (90%) on a rating, a re-rating must occur within (6) months of this rating. Both the Milk Sanitation Compliance and Enforcement Ratings must be equal to ninety percent (90%) or higher on the re-rating or the supply is considered in violation of this Section. In the case of HACCP/Aseptic listings, an acceptable HACCP listing by a SRO is required. For milk plants that produce aseptically processed and packaged Grade "A" milk and/or milk products, prior to the milk plant participating in the NCIMS Aseptic Processing and Packaging Program, or the Aseptic Pilot Program, the State's regulatory and rating personnel shall have completed a training course that is acceptable to the NCIMS and FDA addressing the procedures for conducting regulatory inspections and ratings under the NCIMS Aseptic Processing and Packaging Program or Aseptic Pilot Program. The NCIMS Aseptic Pilot Program addressing aseptically processed and packaged acidified and fermented high acid milk and milk products regulated under 21 CFR Parts 108, 110, and/or 114 will expire on December 31, ~~2011~~ 2013, unless extended by future conference action.

Make the following changes to ***SECTION 13. PERSONNEL HEALTH*** *on Page 123:*

No persons affected with any disease capable of being transmitted to others through the contamination of food shall work at a milk plant in any capacity which brings them into direct contact with pasteurized, ultra-pasteurized or aseptically processed and packaged milk or milk products or which brings them into direct contact with associated pasteurized or aseptically processed and packaged milk or milk product-contact surfaces.

Make the following changes to ***SECTION 14. PROCEDURE WHEN INFECTION OR HIGH RISK OF INFECTION IS DISCOVERED*** *on Pages 124 and 125:*

When a person who may have handled pasteurized, ultra-pasteurized or aseptically processed and packaged milk or milk products or pasteurized, ultra-pasteurized or aseptically processed and packaged milk or milk product-contact surfaces meets one (1) or more of the conditions specified in the ADMINISTRATIVE PROCEDURES of Section 13, the Milk Regulatory Agency is authorized to require any or all of the following measures: …

Page 125:

NOTE: Persons at risk who decline to be examined may be reassigned to duties where they will not be required to handle pasteurized, ultra-pasteurized or aseptically processed and packaged milk or milk products and associated milk or milk product-contact surfaces.

Make the following changes to ***APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT*** *on Pages 216 and 217:*

I. HTST PASTEURIZATION

HTST PASTEURIZERS EMPLOYING MILK OR MILK PRODUCT-TO-MILK OR MILK PRODUCT REGENERATORS WITH BOTH SIDES CLOSED TO THE ATMOSPHERE

Item 16p(~~D~~C), of Section 7 establishes standards for regenerators. These standards insure that the raw milk or milk product will always be under less pressure than pasteurized milk or milk product in order to prevent contamination of the pasteurized milk or milk product in the event flaws should develop in the metal or joints separating it from the raw milk or milk product. An explanation of regenerator specifications is given below.

During normal operation, i.e., while the timing pump is operating, raw milk or milk product will be drawn through the regenerator at sub-atmospheric pressure. The pasteurized milk or milk product in the milk or milk product-to-milk or milk product regenerator will be above atmospheric pressure. The required pressure differential will be assured when there is no flow-promoting device downstream from the pasteurized milk or milk product side of the regenerator to draw the pasteurized milk or milk product through the regenerator, and the pasteurized milk or milk product downstream from the regenerator rises to at least 30.5 centimeters (12 inches) elevation above the highest raw milk or milk product level downstream from the constant-level tank, and is open to the atmosphere at this or a higher elevation, as required in Item 16p(~~D~~C), ADMINISTRATIVE PROCEDURES #2.

During a shutdown, i.e., when the timing pump stops, the raw milk or milk product in the regenerator will be retained under suction, except this suction may be gradually relieved by possible entrance of air drawn through the regenerator plate gaskets from the higher outside atmospheric pressure. With a free draining regenerator, as required under Item 16p(~~D~~C), ADMINISTRATIVE PROCEDURES #8, the raw milk or milk product level in the regenerator may drop slowly, depending on the tightness of the gaskets, ultimately falling below the level of the plates to the milk or milk product level in the constant-level tank. However, under these conditions, as long as any raw milk or milk product remains in the regenerator, it will be at sub-atmospheric pressure.

During shutdown, the pasteurized milk or milk product in the regenerator is maintained at atmospheric pressure or above by meeting the elevation requirement of Item 16p(~~D~~C), ADMINISTRATIVE PROCEDURES #2. Pressure greater than atmospheric is maintained when the level of pasteurized milk or milk product is at or above the required elevation and loss of pressure, due to suction, is prevented by prohibiting a downstream pump.

Any backflow of milk or milk product through the FDD would lower the pasteurized milk or milk product level, during pump shutdowns, thus tending to reduce the pressure on the pasteurized milk or milk product side of the regenerator. A FDD cannot be relied upon to prevent backflow in such instances, because during the first few minutes following a pump shutdown, the milk or milk product is still at a sufficiently high temperature to keep the FDD in the forward-flow position. Compliance with the provisions of Item 16p(~~D~~C), ADMINISTRATIVE PROCEDURES #2 and #3; however, will insure a proper pressure differential in the regenerator.

Page 217:

At the beginning of a run, from the time raw milk or milk product or water is drawn through the regenerator, until the pasteurized milk or milk product or water has risen to the elevation specified in Item 16p(~~D~~C), ADMINISTRATIVE PROCEDURES #2, the pasteurized milk or milk product side of the regenerator is at atmospheric pressure or higher. Even if the timing pump should stop during this period, the pressure on the pasteurized milk or milk product side of the regenerator will be greater than the sub-atmospheric pressure on the raw milk or milk product

side. This will be assured by compliance with Item 16p(~~D~~C), ADMINISTRATIVE PROCEDURES #2 and #3, as long as any raw milk or milk product remains in the regenerator. When a raw milk or milk product booster pump is incorporated into the HTST pasteurization system, Item 16p(~~D~~C), ADMINISTRATIVE PROCEDURES #5 requires, in part, that automatic means shall be provided to assure, at all times, the required pressure differential between raw and pasteurized milk or milk product in the regenerator, before the booster pump can operate.

Make the following changes to ***APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT*** *on Pages 219 and 220:*

I. HTST PASTEURIZATION

PRESSURE RELIEF VALVES LOCATED WITHIN HTST PASTEURIZATION SYSTEMS

OPTION I: …

c. The system is designed and operated so that loss of pressure from the pasteurized side of the regenerator cannot occur if the system flow-promoting devices stop while the FDD is in the forward-flow position. A system not protected against this potential pressure loss is considered a violation of Item 16p(~~D~~C) of this *Ordinance*.

Page 220:

OPTION II. The pressure relief valve is spring-loaded and plumbed so that it cannot be opened or forced open in any mode, "Product", "CIP" or "Inspect", without the assistance of pressure from the liquid flowing through the system. In this case, a leaking pressure relief valve can cause an unacceptable loss of pressure in the pasteurized side of the regenerator if the system flow-promoting devices stop while the FDD is in the forward-flow position. This is considered a violation of Item 16p(~~D~~C) of this *Ordinance*. Any leakage from this pressure relief valve must be readily visible. This may be accomplished by opening the pressure relief valve vent directly to the floor or by providing sanitary piping from the pressure relief valve vent to the constant-level tank. If the later option is utilized, the piping shall be properly sloped to assure drainage to the constant-level tank and shall be provided with a properly located and installed sight-glass.

2. **Downstream from the Holding Tube:** The pressures in the pasteurized side of the regenerator must be protected from falling within 6.9 kPa (1 psi) of the pressures in the raw side of the regenerator at all times, including during shut down. A relief valve and line on the pasteurized side of the FDD can meet this criterion if: …

c. The pressure relief valve is spring-loaded and plumbed so that it cannot be opened or forced open in any mode, "Product", "CIP" or "Inspect", without the assistance of pressure from the liquid flowing through the system. In this case, a leaking pressure relief valve can cause an unacceptable loss of pressure in the pasteurized side of the regenerator during a shut down and is considered a violation of Item 16p(~~D~~C) of this *Ordinance*. Any leakage from this pressure relief valve must be readily visible. This may be accomplished by opening the

pressure relief valve vent directly to the floor or by providing sanitary piping from the pressure relief valve vent to the constant-level tank. If the later option is utilized, the piping shall be properly sloped to assure drainage to the constant-level tank and shall be provided with a properly located and installed sight-glass.

Make the following changes to ***APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT*** *on Pages 221 and 222:*

MAGNETIC FLOW METER BASED TIMING SYSTEMS ~~FOR~~ WITHIN ~~HTST~~ CONTINUOUS FLOW ~~PASTEURIZERS~~ SYSTEMS

Components: …

Page 222:

10. All systems shall be designed, installed and operated so that all applicable tests required by Section 7, Item 16p(~~E~~D) can be performed by the Regulatory Agency, at the frequency specified. (Refer to Appendix I.) Where adjustment or changes can be made to these devices or controls, appropriate seals shall be applied by the Regulatory Agency after testing, so that changes cannot be made without detection.

Make the following changes to ***APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT*** *on Pages 251-253:*

V. CRITERIA FOR THE EVALUATION OF ELECTRONIC DATA COLLECTION, STORAGE AND REPORTING CRITERIA

The following criteria are to be used for the evaluation of electronic collection, storage and recording or reporting of any information required within Items 12p and 16p(~~E~~D). of Section 7 of this *Ordinance*.

Page 252:

5. In the case of pasteurization ~~and aseptic processing~~ records, data shall be stored no less than every five (5) seconds for each required variable. Any event required to be recorded in manual reporting, such as a divert condition; will be recorded no matter how short the duration. Provisions will be made to allow operators to report additional events electronically, such as a record of unusual occurrences. The data for the reporting system shall be backed up at least once every twenty-four (24) hours. Alternatively, the final reports may be stored and backed up at least once every twenty-four (24) hours. …

Page 253:

NOTE: While electronic and computerized systems can furnish a wide range of process validation and anomaly reporting, these criteria only require appended reporting of data loss that

affects the reports that are required to comply with this Appendix and Items 12p and 16p(~~E~~D) or other required reporting contained in this *Ordinance*. …

Make the following changes to ***APPENDIX I. PASTEURIZATION EQUIPMENT AND CONTROLS - TESTS*** *on Pages 273-276, 281-291, 295-297, 299, and 305-311:*

II. TEST PROCEDURES

TEST 1.

INDICATING THERMOMETERS - TEMPERATURE ACCURACY

Reference: Item 16p. (A), (B)~~, (C)~~ and (~~E~~D)
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 ± 0.25ºC (± 0.5ºF) for pasteurization and ~~aseptic processing~~ ultra-pasteurization thermometers and ± 0.5ºC (± 1ºF) 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°C (160°F), indicating thermometers shall be accurate to within ± 0.5°C (± 1°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 2ºC (3ºF) of the appropriate pasteurization~~,~~ or airspace temperature~~, or aseptic processing temperature~~.

Page 274:

TEST 2.

RECORDING THERMOMETERS - TEMPERATURE ACCURACY

Reference: Item 16p.(A), (B)~~, (C)~~ and (~~E~~D)
Application: To all mercury-actuated 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 mercury-actuated 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~~ pasteurization 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~~ pasteurization systems into the media bath described above, for not less than five (5) minutes. …

Page 275:

TEST 3.
RECORDING THERMOMETERS - TIME ACCURACY

Reference: Item 16p.(A), (B)~~, (C)~~ and (~~E~~D)
Application: To all recording and recorder-controller thermometers used to record the time of pasteurization ~~or aseptic processing~~. …

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

Page 276:

TEST 4.

RECORDING THERMOMETERS - CHECK AGAINST INDICATING THERMOMETERS

Reference: Item 16p.(A), (B)~~, (C)~~ and (~~E~~D)
Application: To all recording and recorder-controller thermometers used to record milk or milk product temperatures during pasteurization ~~or aseptic processing~~.
Frequency: Upon installation and at least once each three (3) months by the Regulatory Agency, or HACCP qualified industry person, acceptable to the Regulatory Agency, qualified under Item 16p(~~E~~D)2; and daily by the milk plant operator. …

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. …

TEST 5.

FDD - PROPER ASSEMBLY AND FUNCTION

Reference: Item 16p.(B)~~, (C)~~ and (~~E~~D)
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 281:

TEST 6.

LEAK-PROTECTOR VALVE

Reference: Item 16p.(A) and (~~E~~D) …

Page 282:

TEST 7.

INDICATING THERMOMETERS ON PIPELINES - THERMOMETRIC RESPONSE

Reference: Item 16p.(B) and (~~E~~D) …

Page 283:

TEST 8.

RECORDER/CONTROLLER - THERMOMETRIC RESPONSE

Reference: Item 16p.(B) and (~~E~~D) …

Page 284:

TEST 9.

REGENERATOR PRESSURE CONTROLS

Reference: Item 16p.(~~D~~C) and (~~E~~D) …

Page 285:

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 pasteurization systems or used to control the operation of

FDDs on HHST and HTST ~~Pasteurization~~ pasteurization systems with the FDD located downstream of the pasteurized regenerator and/or final cooler ~~and aseptic processing systems~~. … 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.~~ …

Page 286:

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~~ pasteurization 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 287:

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: …
2. To all differential pressure controllers used to control the operation of FDDs, milk or milk product divert systems, or 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: …

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.

Page 288:

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 289:

TEST 10.

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

References: Item 16p.(B)~~, (C)~~ and (~~E~~D) …

10.1 HTST PASTEURIZERS

Frequency: Upon installation; at least once each three (3) months thereafter by the Regulatory Agency, or HACCP qualified industry person, acceptable to the Regulatory Agency, qualified under Item 16p(~~E~~D)2; daily by the milk plant operator; or when a regulatory seal has been broken. …

Page 290:

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

Application: All HHST and HTST ~~pasteurizers~~ pasteurization systems 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 0.5ºC (1ºF) 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 291:

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

Application: All HHST and HTST ~~pasteurizers~~ pasteurization systems 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 0.5ºC (1ºF) 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 292:

TEST 11.

CONTINUOUS-FLOW HOLDING TUBES - HOLDING TIME

Reference: Item 16p.(B)~~, (C)~~ and (~~E~~D) …

Page 295:

11.2A MAGNETIC FLOW METER BASED TIMING SYSTEMS CONTINUOUS-FLOW HOLDING TIME

TEST OPTION I

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.

Page 296:

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, below the high flow alarm, 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. …

Page 297:

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 299:

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).
2. Mark the recorder chart with the high flow alarm set point.

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 305:

TEST 12.

THERMAL-LIMIT-CONTROLLER FOR CONTROL - SEQUENCE LOGIC

References: Items 16p.(B) and (~~E~~D)

Thermal-limit-controllers used with HHST and HTST ~~pasteurizers~~ pasteurization systems 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:

Page 306:

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

Application: To all HHST and HTST ~~pasteurizers~~ pasteurization systems 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 307:

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

Application: To all HHST and HTST ~~pasteurizers~~ pasteurization systems 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 308:

TEST 13.

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

Reference: Item 16p.(B) and (~~E~~D)
Application: To all HHST ~~pasteurizers and aseptic processing~~ pasteurization 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: …

Page 309:

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

TEST 14.

SETTING OF CONTROL SWITCHES FOR DIFFERENTIAL PRESSURE ACROSS THE INJECTOR

Reference: Item 16p.(B) and (~~E~~D)
Application: To all continuous flow ~~pasteurizers~~ pasteurization systems ~~and aseptic processing systems~~ using direct injection 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). …

Page 310:

TEST 15.

ELECTRO-MAGNETIC INTERFERENCE FROM HAND-HELD COMMUNICATION DEVICES

Application: To all electronic control~~s~~ devices used to assure compliance with public health safeguards on continuous flow pasteurization ~~and aseptic processing~~ equipment that are installed in milk plants. …

Page 311:

Procedure: …
5. Repeat the Test for each electronic control device used to regulate a pasteurization ~~or aseptic processing~~ system's public health safeguard(s).

For Example: For the temperature set point, operate the pasteurization ~~or aseptic processing~~ equipment on water in diverted-flow in the "Product" mode, at a steady temperature within 3ºC (5ºF) of the lowest cut-in temperature. In this example, an adverse effect is defined as the forward-flow movement of the FDD or any artificial increase in temperature. …

Make the following changes to ***APPENDIX K. HACCP PROGRAM*** *on Page 328:*

II. IMPLEMENTATION OF A HACCP SYSTEM

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 ~~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 Part 113~~ the APPS, as defined by this *Ordinance*, 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 Part 113 shall satisfy the requirements of this Section, regardless of whether a critical factor has also been designated as a CCP.~~ The milk plant's APPS shall be inspected by FDA, or the State Regulatory Agency when designated by FDA, in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113 at a frequency determined by FDA. …

Make the following change to ***APPENDIX L. APPLICABLE REGULATIONS, STANDARDS OF IDENTITY FOR MILK AND MILK PRODUCTS AND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT*** *on Page 335:*

21 CFR PART 113 - THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS
21 CFR PART 114 – ACIDIFIED FOODS
21 CFR 130.10 - Requirements for foods named by use of a nutrient content claim and a standardized term …

Within the Forms cited in APPENDIX M-REPORTS AND RECORDS on page 337, the following changes to FORM FDA 2359-MILK PLANT INSPECTION REPORT and FORM FDA 2359b-MILK PLANT EQUIPMENT TEST REPORT shall be made.

Department of Health and Human Services Public Health Service Food and Drug Administration	**MILK PLANT INSPECTION REPORT** (Includes Dry Milk/Condensing Plants, Receiving Stations, Transfer Stations, and Milk Tank Truck Cleaning Facilities)	INSPECTING AGENCY

NAME AND LOCATION OF PLANT	Pounds Sold Daily	Milk _____ Other Milk Products _____ Total _____ Permit No. _____

Inspection of your plant today showed violations existing in the Items checked below. You are further notified that this inspection report serves as notification of the intent to suspend your permit if the violations noted are not in compliance at the time of the next inspection. (Refer to Sections 3 and 5 of the *Grade "A" Pasteurized Milk Ordinance*.)

1. FLOORS:
Smooth; impervious; no pools; good repair; trapped drains ..... (a) ☐
2. WALLS AND CEILINGS:
Smooth; washable; light-colored; good repair ..... (a) ☐
3. DOORS AND WINDOWS:
All outer openings effectively protected against entry of flies and rodents ..... (a) ☐
Outer doors self-closing; screen doors open outward ..... (b) ☐
4. LIGHTING AND VENTILATION:
Adequate light in all rooms ..... (a) ☐
Well ventilated to preclude odors and condensation; filtered air with pressure systems ..... (b) ☐
5. SEPARATE ROOMS:
Separate rooms as required; adequate size ..... (a) ☐
No direct opening to barn or living quarters ..... (b) ☐
Storage tanks properly vented ..... (c) ☐
6. TOILET FACILITIES:
Complies with local Ordinances ..... (a) ☐
No direct opening to processing rooms; self-closing doors ..... (b) ☐
Clean; well-lighted and ventilated; proper facilities ..... (c) ☐
Sewage and other liquid wastes disposed of in sanitary manner ..... (d) ☐
7. WATER SUPPLY:
Constructed and operated in accordance with Ordinance ..... (a) ☐
No direct or indirect connection between safe and unsafe water ..... (b) ☐
Condensing water and vacuum water in compliance with Ordinance requirements ..... (c) ☐
Reclaim water complies with Ordinance ..... (d) ☐
Complies with bacteriological standards ..... (e) ☐
8. HANDWASHING FACILITIES:
Located and equipped as required; clean and in good repair; improper facilities not used ..... (a) ☐
9. MILK PLANT CLEANLINESS:
Neat; clean; no evidence of insects or rodents; trash properly handled ..... (a) ☐
No unnecessary equipment ..... (b) ☐
10. SANITARY PIPING:
Smooth; impervious, corrosion-resistant, non-toxic, easily cleanable materials; good repair; accessible for inspection ..... (a) ☐
Mechanically cleaned lines meet Ordinance specs ..... (b) ☐
Pasteurized products conducted in sanitary piping, except as permitted by Ordinance ..... (c) ☐
11. CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT:
Smooth, impervious, corrosion-resistant, non-toxic, easily cleanable materials; good repair; accessible for Inspection ..... (a) ☐
Self-draining; strainers of approved design ..... (b) ☐
Approved single-service articles; not reused ..... (c) ☐
12. CLEANING AND SANITIZING OF CONTAINERS/ EQUIPMENT:
Containers, utensils, and equipment effectively cleaned ..... (a) ☐
Mechanical cleaning requirements of Ordinance in Compliance; records complete ..... (b) ☐
Approved sanitization process applied prior to use of product-contact surfaces ..... (c) ☐
Required efficiency tests in compliance ..... (d) ☐
Multi-use plastic containers in compliance ..... (e) ☐

~~Aseptic system sterilized ..... (f) ☐~~
13. STORAGE OF CLEANED CONTAINERS AND EQUIPMENT:
Stored to assure drainage and protected from contamination ..... (a) ☐
14. STORAGE OF SINGLE-SERVICE ARTICLES:
Received, stored and handled in a sanitary manner; paperboard containers not reused except as permitted by the Ordinance ..... (a) ☐
15a. PROTECTION FROM CONTAMINATION:
Operations conducted and located so as to preclude contamination of milk, milk products, ingredients, containers, equipment, and utensils ..... (a) ☐
Air and steam used to process products in compliance with Ordinance ..... (b) ☐
Approved pesticides, safely used ..... (c) ☐
15b. CROSS CONNECTIONS:
No direct connections between pasteurized and raw milk or milk products ..... (a) ☐
Overflow, spilled and leaked products or ingredients discarded ..... (b) ☐
No direct connections between milk or milk products and cleaning and/or sanitizing solutions ..... (c) ☐
16a. PASTEURIZATION-BATCH:
(1) INDICATING AND RECORDING THERMOMETERS:
Comply with Ordinance Specifications ..... (a) ☐
(2) TIME AND TEMPERATURE CONTROLS :
Adequate agitation throughout holding; agitator sufficiently submerged ..... (a) ☐
Each pasteurizer equipped with indicating and recording thermometer; bulb submerged ..... (b) ☐
Recording thermometer reads no higher than indicating thermometer(c) ..... ☐
Product held minimum pasteurization temperature continuously for 30 minutes, plus filling time if product preheated before entering vat, plus emptying time, if cooling is begun after opening outlet ..... (d) ☐
No product added after holding begun ..... (e) ☐
Airspace above product maintained at not less than 5.0° F higher than minimum required pasteurization temperature during holding ..... (f) ☐
Approved airspace thermometer; bulb not less than 1 inch above product level ..... (g) ☐
Inlet and outlet valves and connections in compliance with Ordinance ..... (h) ☐
16b. PASTEURIZATION-HIGH TEMPERATURE:
(1) INDICATING AND RECORDING THERMOMETERS:
Comply with Ordinance specifications ..... (a) ☐
(2) TIME AND TEMPERATURE CONTROLS:
Flow-diversion device complies with Ordinance requirements ..... (a) ☐
Recorder controller complies with Ordinance requirements ..... (b) ☐
Holding tube complies with Ordinance requirements ..... (c) ☐
Flow promoting devices comply with Ordinance requirements ..... (d) ☐
(3) ADULTERATION CONTROLS: Satisfactory means to prevent adulteration with added water ..... (a) ☐
~~16c. ASEPTIC PROCESSING:~~
~~(1) INDICATING AND RECORDING THERMOMETERS:~~
~~Comply with Ordinance Specifications ..... (a) ☐~~

~~(2) TIME AND TEMPERATURE CONTROLS:~~
~~Flow-diversion device complies with Ordinance requirements ..... (a) ☐~~
~~Recorder controller complies with Ordinance requirements ..... (b) ☐~~
~~Holding tube complies with Ordinance requirements ..... (c) ☐~~
~~Flow promoting devices comply with Ordinance requirements ..... (d) ☐~~
~~(3) ADULTERATION CONTROLS:~~
~~Satisfactory means to prevent adulteration with added water ..... (a) ☐~~
16~~d~~c. REGENERATIVE HEATING:
Pasteurized ~~or aseptic~~ product in regenerator automatically under greater pressure than raw product in regenerator at all times ..... (a) ☐
Accurate pressure gauges installed as required; booster pump properly identified and installed ..... (b) ☐
Regenerator pressures meet Ordinance Requirements ..... (c) ☐
16~~e~~d. RECORDING CHARTS:
Batch pasteurizer charts comply with applicable Ordinance Requirements ..... (a) ☐
HTST and HHST pasteurizer charts comply with applicable Ordinance Requirements ..... (b) ☐
~~Aseptic charts comply with applicable Ordinance Requirements ..... (c) ☐~~
17. COOLING OF MILK:
Raw milk maintained at 45° F or less until processed ..... (a) ☐
Pasteurized milk and milk products, except those to be cultured, cooled immediately to 45° F or less in approved equipment; all milk and milk products stored there until delivered ..... (b) ☐
Approved thermometer properly located in all refrigeration rooms and storage tanks ..... (c) ☐
Recirculated cooling water from safe source and properly protected; complies with bacteriological standards ..... (d) ☐
18. BOTTLING AND PACKAGING:
Performed in a plant where contents finally pasteurized ..... (a) ☐
Performed in a sanitary manner by approved mechanical equipment ..... (b) ☐
~~Aseptic filling in compliance ..... (c) ☐~~
19. CAPPING:
Capping and/or closing performed in sanitary manner by approved mechanical equipment ..... (a) ☐
Imperfectly capped/closed products properly handled ..... (b) ☐
Caps and/or closures comply with Ordinance ..... (c) ☐
20. PERSONNEL CLEANLINESS:
Hands washed clean before performing plant functions; rewashed when contaminated ..... (a) ☐
Clean outer garments and hair covering worn ..... (b) ☐
No use of tobacco in processing areas ..... (c) ☐
21. VEHICLES:
Vehicles clean; constructed to protect milk ..... (a) ☐
No contaminating substances transported ..... (b) ☐
22. SURROUNDINGS:
Neat and clean; free of pooled water, harborages and breeding areas ..... (a) ☐
Tank unloading areas properly constructed ..... (b) ☐
Approved pesticides, used properly ..... (c) ☐

REMARKS

1. A receiving station shall comply with Items 1 to 15, inclusive, and 17, 20, and 22. Separation requirements of Item 5 do not apply.
2. A transfer station shall comply with Items 1, 4, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 20, 22 and as climatic and operating conditions require, applicable provisions of Items 2 and 3. In every case, overhead protection shall be required.
3. Facilities for the cleaning and sanitizing of milk tank trucks shall comply with the same requirements for transfer stations.
4. In areas of the milk plant where Items 7, 10, 11, 12, 13, 15, 17, 18 and 19 are dedicated only to the Aseptic Processing and Packaging System, as defined by the PMO, these Items shall be inspected and regulated in accordance with the applicable requirements of 21 CFR Parts 108,110 and113.

DATE	SANITARIAN

NOTE – Item numbers correspond to required sanitation Items for Grade "A" pasteurized milk in the *Grade "A" Pasteurized Milk Ordinance.*

FORM FDA 2359 (~~10/08~~ 10/12)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			MILK PLANT EQUIPMENT TEST REPORT		
TEST NO.	**TEST**		**TEST FREQUENCY**	**TESTED (X or NA)**	**RESULTS OF TEST** *(See Reverse for Working Notes)*
1.	Indicating Thermometers (including air space): Temperature Accuracy		3 months		
2.	Recording Thermometers: Temperature Accuracy		3 months		
3.	Recording Thermometers: Time Accuracy		3 months		
4.	Recording Thermometers: Checked against Indicating Thermometer		3 months		Daily by operator
5.	Flow-Diversion Device (FDD): Proper Assembly and Function (HTST and HHST)				
	5.1	Leakage Past Valve Seat(s)	3 months		
	5.2	Operation of Valve Stem(s)	3 months		
	5.3	Device Assembly (micro-switch) Single Stem	3 months		
	5.4	Device Assembly (micro-switches) Dual Stem	3 months		
	5.5	Manual Diversion - Parts (A, B, and C) (HTST only)	3 months		
	5.6	Response Time	3 months		
	5.7	Time Delay Interlock (dual stem devices) (Inspect)	3 months		
	5.8	Time Delay Interlock (dual stem devices) (CIP)	3 months		
	5.9	Leak Detect Flush Time Delay (HTST only as applicable)	3 months		
6.	Leak-Protect Valves: Leakage (Vats only)		3 months		
7.	Indicating Thermometers on Pipelines: Thermometric Response (HTST only)		3 months		
8.	Recorder-Controller: Thermometric Response (HTST only)		3 months		
9.	Regenerator Pressure Controls				
	9.1	Pressure Switches (HTST only)	3 months		
	9.2	Differential Pressure Controllers			
	9.2.1	Calibration	3 months		
	9.2.2	Interwiring Booster Pump (HTST only)	3 months		
	9.2.3	Interwiring FDD (HTST*~~,~~ and HHST ~~and Aseptic~~)	3 months		
	9.3	Additional Booster Pump Interwiring (HTST only)			
	9.3.1	With FDD	3 months		
	9.3.2	With Metering Pump	3 months		
10.	Milk-Flow Controls: Cut-in and Cut-out Temperatures (10.1, 10.2* or 10.3*)		3 months		Daily by operator (HTST)
11.	Timing System Controls				
	11.1	Holding time (HTST, except Magnetic Flow Meters)	6 months		Adjusted product holding time if applicable
	11.2.a	Magnetic Flow Meters (HTST only)	6 months		
	11.2.b	Flow Alarm (HTST~~,~~ and HHST ~~and Aseptic~~)	6 months		
	11.2.c	Loss of Signal Alarm (HTST~~,~~ and HHST ~~and Aseptic~~)	6 months		
	11.2.d	Flow Cut-in/Cut-out (HTST only)	6 months		
	11.2.e	Time Delay (after divert) (HTST with a FDD located at the end of the holding tube)	6 months		
	11.2.f	High Flow Alarm Response Time (All Magnetic Flow Meter Systems)	6 months		
	11.3	HHST Indirect Heating	6 months		
	11.4	HHST Direct Injection Heating	6 months		
	11.5	HHST Direct Infusion Heating	6 months		
12.	Controller: Sequence Logic (HHST ~~and Aseptic~~) (12.1* or 12.2*)		3 months		
13.	Product Pressure-Control Switch Setting (HHST ~~and Aseptic~~)		3 months		
14.	Injector Differential Pressure Injection Heating (HTST*~~,~~ and HHST ~~and Aseptic~~)		3 months		
15.	Electro-Magnetic Interference from Hand-Held Communication Devices (HTST~~,~~ and HHST ~~and Aseptic~~)		3 months		
	*For HTST systems with the FDD located downstream of the regenerator and/or cooler section.				

REMARKS *(If additional space is required please place information on the back of this form or on a separate page.)*

PLANT	IDENTITY OF EQUIPMENT	LOCATION	DATE	SANITARIAN

NOTE: This Form is a supplement to the Milk Plant Inspection Report, FORM FDA 2359, and these tests are in addition to the equipment requirements for which compliance is determined by inspection. (Refer to Appendix I of the *Grade "A" Pasteurized Milk Ordinance*.)

FORM FDA 2359b (~~10/08~~ 10/12) (PREVIOUS EDITIONS ARE OBSOLETE)

Make the following change to ***APPENDIX Q. OPERATION OF AUTOMATIC MILKING INSTALLATIONS FOR THE PRODUCTION OF GRADE "A" RAW MILK FOR PASTEURIZATION*** *on Page 356:*

APPENDIX Q. OPERATION OF AUTOMATIC MILKING INSTALLATIONS FOR THE PRODUCTION OF GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING AND PACKAGING

This Appendix is intended to clarify how AMIs are to perform to be considered in compliance with the *Grade "A" PMO*. It is formatted to follow the Items as outlined in Section 7. STANDARDS FOR GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING AND PACKAGING. Both requirements and recommendations are discussed.

Make the following change to ***APPENDIX R. DETERMINATION OF TIME/ TEMPERATURE CONTROL FOR SAFETY MILK AND MILK PRODUCTS*** *on Page 359:*

5. Is the milk or milk product processed and packaged so that it no longer requires TCS; such as, Grade "A" aseptically processed and packaged milk and milk products? …

Add a new ***APPENDIX S. ASEPTIC PROCESSING AND PACKAGING PROGRAM*** *on Page 362:*

APPENDIX S. ASEPTIC PROCESSING AND PACKAGING PROGRAM

The Aseptic Processing and Packaging Program is designed to include all low-acid (21 CFR Part 113) Grade "A" aseptic processed and packaged milk and milk products.

Inspections of a milk plant or portion of a milk plant that is IMS listed to produce aseptically processed and packaged milk or milk products shall be conducted by the Regulatory Agency in accordance with this *Ordinance* and the information provided below at least once every six (6) months. The APPS, 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 Parts 108, 110 and 113. The milk plant's APPS shall be inspected by FDA, or the State Regulatory Agency when designated by FDA, in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113 at a frequency determined by FDA.

When the APPS, as defined by this *Ordinance*, is utilized to produce aseptically processed and packaged milk or milk products and pasteurized and/or ultra-pasteurized milk and milk products, the APPS shall be inspected and tested by the Regulatory Agency in accordance with the requirements cited in Section 7 of this *Ordinance*.

ASEPTIC PROCESSING AND PACKAGING PROGRAM CFR/PMO COMPARISON SUMMARY REFERENCE

PMO, Section 7 Items	Aseptic Program	Authority
1p. Floors – Construction	Floor drains are not required in storage rooms for aseptic processed and packaged milk or milk products.	PMO
2p. Walls and Ceiling – Construction	Ceiling requirements are exempt in aseptically processed and packaged milk or milk products dry storage rooms. (Same as for dry milk or milk products.)	PMO
3p. Doors and Windows	None	PMO
4p. Lighting and Ventilation	None	PMO
5p. Separate Rooms	Fabrication of containers and closures for aseptic processed and packaged milk and milk products within the APPS is exempt.	PMO
6p. Toilet – Sewage Disposal Facilities	None	PMO
7p. Water Supply*	The APPS is exempt, but shall comply with the CFR.	PMO/CFR
8p. Handwashing Facilities	None	PMO
9p. Milk Plant Cleanliness	None	PMO
10p. Sanitary Piping*	The APPS is exempt, but shall comply with the CFR.	PMO/CFR
11p. Construction and Repair of Containers and Equipment*	The APPS is exempt, but shall comply with the CFR. 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 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.	PMO/CFR
12p. Cleaning and Sanitizing of Containers and Equipment*	The APPS is exempt, but shall comply with the CFR.	PMO/CFR
13p. Storage of Cleaned Containers and Equipment*	The APPS is exempt, but shall comply with the CFR.	PMO/CFR
14p. Storage of Single- Service Containers, Utensils and Materials	None	PMO
15p.(A) Protection from Contamination*	The APPS is exempt, but shall comply with the CFR.	PMO/CFR

PMO, Section 7 Items	Aseptic Program	Authority
15p.(B) Protection from Contamination - Cross Connections*	The APPS is exempt, but shall comply with the CFR. APPS equipment is exempt from the separation requirements of the PMO in relationship to instrumented steam blocks between milk and milk products and cleaning and/or chemical sanitizing solutions.	PMO/CFR
16p. Pasteurization and Aseptic Processing and Packaging (A) through (D)*	The APPS 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.	CFR
17p. Cooling of Milk and Milk Products*	The APPS and aseptic processed and packaged product storage is exempt, but shall comply with the CFR.	PMO/CFR
18p. Bottling, Packaging and Container Filling*	The APPS is exempt, but shall comply with the CFR.	CFR
19p. Capping, Container Closure and Sealing and Dry Milk Product Storage*	The APPS is exempt, but shall comply with the CFR.	CFR
20p. Personnel - Cleanliness	None	PMO
21p. Vehicles	None	PMO
22p. Surroundings	None	PMO

* **NOTE:** In areas of the milk plant where these Items are dedicated only to the APPS, as defined by this *Ordinance*, these Items shall be inspected and regulated in accordance with the applicable FDA regulations (21 CFR Parts 108, 110 and 113).

*Make the following change to the **INDEX** on Pages 362-379:*

Aseptic
- ~~aseptically processed~~ processing and packaging, definition ….
- ~~aseptic~~ processing and packaging ~~systems~~ system, definition ….
- ~~controlling added water ….~~
- ~~cooling exemption ….~~
- ~~examination of ….~~
- ~~imminent hazard ….~~
- labeling ….
- process authority ….

~~resterilized after contamination ….~~
sampler-milk tank truck ….

Page 368:

Flow diversion device
~~aseptic systems ….~~
leak escape ….

Page 369:

Indicating thermometer
airspace ….
~~aseptic system ….~~

Page 370:

Industry
~~aseptic processing records ….~~
certified farm inspection ….

~~records for aseptically packaged products ….~~
records, drug residue testing ….

Low-acid aseptic milk and milk products, definition

Page 371:

Milk
acidified, definition ….
adulterated ….
~~aseptically processed~~ aseptic processing and packaging, definition ….

flavored ….

low-acid aseptic, definition ….
lowfat ….

Page 372:

Packaging
~~aseptic ….~~
equipment ….

Page 373:

Pasteurization, definition
milk or milk product-to-water-to-milk or milk product regenerative heating ….
pasteurization ~~and aseptic processing~~ records, equipment tests and examination ….
pressure relief valves ….

Page 374:

Recording thermometer
~~aseptic system ….~~
~~aseptic system, chart reviewed by management ….~~
batch pasteurization ….

Page 375:

Records
access to industry ….
~~aseptic processing ….~~
batch pasteurizers ….

Page 377:

Storage
aseptically processed <u>and packaged</u> milk ….

Page 378:

Temperature
~~aseptic milk storage ….~~
charts ….

Tests
airspace thermometer ….
~~aseptic processing equipment ….~~
~~aseptically packaged milk and milk products ….~~
booster pump ….

Page 379:

airspace ….
~~aseptic system ….~~
batch pasteurization ….

Document: 2009 PROCEDURES (Table of Contents; and Sections II, III, IV, V, VI and VIII)
Pages: 1-3, 8, 10, 11, 16-19, 22, 23, 25, 27-29, 32, 33, 37, 39, 40 and 43

*Make the following changes to **SECTION II. SCOPE** on Page 1:*

A. **PRODUCTS COVERED**
Agreements adopted by the NCIMS shall apply to Grade "A" raw milk and milk products for pasteurization, heat-treated products, pasteurized, ultra-pasteurized, and aseptically processed and packaged milk and milk products, condensed and dry milk products, and whey and whey products produced under the NCIMS program.

*Make the following changes to **SECTION III. DEFINITIONS** on Pages 2 and 3:*

C. **ASEPTIC PROCESSING AND PACKAGING SYSTEM (APPS)**: For the purposes of this document, the Aseptic Processing and Packaging System in a milk plant is comprised of the processes and equipment used to process and package aseptic Grade "A" milk or milk products. The APPS shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. The APPS shall begin at the constant level tank and end at the discharge of the packaging machine, provided that the Process Authority may provide written documentation which will clearly define additional processes or equipment that are considered critical to the commercial sterility of the product.

~~C~~D. **BULK TANK UNIT (BTU):** …

Re-letter the remaining Definitions accordingly.

Page 3:

~~I~~.J **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*. 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). For milk plants that produce aseptically processed and packaged Grade "A" milk and/or milk products, prior to the milk plant participating in the NCIMS Aseptic Processing and Packaging Program, the State's regulatory and rating personnel shall have completed a training course that is acceptable to the NCIMS and PHS/FDA addressing the procedures for conducting regulatory inspections and ratings under the NCIMS Aseptic Processing and Packaging Program.

~~J~~K. **INDIVIDUAL RATING:** An individual rating is the rating of a single producer group, milk plant, receiving station, and/or transfer station under the supervision of a single Regulatory Agency. Milk plants producing Grade "A" condensed or dried milk and milk products and/or Grade "A" condensed or dry whey and whey products may be rated separately from the same milk plant producing other Grade "A" milk or milk products, provided each listing holds a

separate permit. Milk plants that produce both aseptically processed and packaged Grade "A" milk and/or milk products and pasteurized and/or ultra-pasteurized Grade "A" milk and/or milk products shall be rated separately. Provided that an NCIMS HACCP milk plant listing that produces aseptically processed and packaged Grade "A" milk and/or milk products shall have only an NCIMS HACCP listing. An individual dairy farm shall only be included in one (1) IMS Listing.

Re-letter the remaining Definitions accordingly.

~~O~~P. **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.

Re-letter the remaining Definitions accordingly.

Make the following changes to ***SECTION IV. OVERSIGHT AND RESPONSIBITIES*** *on Pages 8, 10, 11 and 16:*

A. **PHS/FDA RESPONSIBILITIES**

Page 8:

5. Electronic Publication of Sanitation Compliance and Enforcement Ratings

   a. PHS/FDA shall provide an electronic publication of the *IMS List* on their web site. The electronic *IMS List* is available at http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/FederalStatePrograms/InterstateMilkShippersList/default.htm. The Sanitation Compliance and Enforcement Ratings of Regulatory Agencies and the IMS Listed shippers' expiration rating dates contained in the electronic publication are certified by the State Rating Agency to be those established by ratings conducted in accordance with the *MMSR* by certified SROs when ~~the~~ FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT is signed and submitted to the PHS/FDA Regional Office for publication.

   ~~Transfer stations, receiving stations and milk plants~~ Milk plants, receiving stations and transfer stations must achieve a Sanitation Compliance Rating of 90 percent (90%) or higher, except as cited in Section VIII., C.,5. for HACCP listings, in order to be eligible for a listing in the *IMS List*. Sanitation Compliance Rating scores for transfer and receiving stations and milk plants will not be identified in the *IMS List*.
   PHS/FDA shall update the *IMS List* not less than monthly.

Page 10:

7. Interpretations and Editorial Updates

b. After each Conference and/or request by the NCIMS Executive Board, PHS/FDA shall incorporate editorial updates into the *Constitution of the National Conference on Interstate Milk Shipment, Bylaws of the National Conference on Interstate Milk Shipment, Grade "A" PMO*, the *MMSR*, the *Procedures* and the *EML* in accordance with the guidelines ~~to be~~ developed jointly by PHS/FDA and the NCIMS Executive Board.

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

a. PHS/FDA shall conduct, each year, check ratings of the Sanitation Compliance status of listed interstate milk shippers. To conduct check ratings of aseptic milk plants, the PHS/FDA Regional Milk Specialist shall have completed a training course that is acceptable to the NCIMS and PHS/FDA addressing the procedures for conducting check ratings under the NCIMS Aseptic Processing and Packaging 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 11:

g. Enforcement Ratings ~~will~~ shall be ~~made~~ conducted as part of check ratings.

B. **STATE RESPONSIBILITIES**

Page 16:

7. Challenges and Remedies

c. Action to be Taken if the PHS/FDA Check Rating Indicates the Listed Rating is Not Justified:

2.) Milk Plants, Receiving Stations and/or Transfer Stations

C.) Withdrawal of Certification

When check rating data indicates that the Sanitation Compliance Rating of a milk plant, receiving station and/or transfer station requires a withdrawal of certification, the State Rating Agency, upon written recommendation of PHS/FDA, shall immediately withdraw the current certification of the shipper and notify such shipper, PHS/FDA, and all known receiving States thereof, in accordance with Section IV., B., 1.d. In case of withdrawal, a new rating shall be made in not less than thirty (30) days and not to exceed sixty (60) days, unless the State Rating Agency has reason to believe a new rating within a lesser time period would result in an acceptable rating. The effective date for action shall be determined from the date of the letter of notification by the State Rating Agency. Such letter shall be dated within five (5) working days following the date of the official notification. A withdrawal of certification is also required if an aseptic milk plant has any Aseptic Critical Listing Element (ACLE) identified as not

being in compliance on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products following the procedures cited above.

Make the following changes to ***SECTION V. QUALIFICATIONS AND CERTIFICATIONS*** *on Pages 17, 18, 19, 22, 23 and 25:*

A. **SUPERVISION REQUIREMENTS**

3. Sampling procedures and laboratory examinations are a fundamental and basic component of supervision. The surveillance of sample collection procedures shall be conducted as prescribed in the ~~*EML*~~ *Grade "A" PMO*. Samples from each dairy farm and each pasteurization milk plant shall be examined for the prescribed tests at the frequency prescribed in the PHS/FDA recommended *Grade "A" PMO*.

C. **SANITATION COMPLIANCE AND ENFORCEMENT RATINGS REQUIRED**

D. **MILK SANITATION RATING PERSONNEL**

2. Have been standardized by PHS/FDA as a SRO and hold a valid certificate of qualification in one (1) or any combination of the following categories: milk pasteurization plants, including HACCP and/or aseptic processing and packaging if appropriate, dairy farms and transfer/receiving stations, including HACCP if appropriate. The PHS/FDA will issue a certificate, valid for three (3) years, to each individual who meets the criteria listed below, as applicable. Certification of a SRO shall qualify that SRO to perform ratings or HACCP listings, if applicable, in any State, upon the request of that State's Regulatory/Rating Agency as long as the Officer's certification is valid.

Page 18:

3. A SRO applicant for initial standardization … following number of dairy facilities:

b. Five (5) pasteurization milk plants. Milk ~~Plants~~ plants of varying sizes using, vat, HTST, HHST pasteurization and/or aseptic processing and packaging, if applicable, should be included in these evaluations. One (1) transfer or receiving station may also be included as one (1) of the required five (5) pasteurization milk plants. …

6. To conduct ratings of aseptic processing and packaging milk plants, the applicant shall have completed a training course that is acceptable to the NCIMS and PHS/FDA addressing the procedures for conducting the rating and the implementation of the NCIMS Aseptic Processing and Packaging Program.

~~6~~7. Applicants must demonstrate the ability to conduct and compute ~~Milk~~ Sanitation Compliance and Enforcement Ratings by completing all of the necessary forms.

Re-number all remaining Items accordingly.

Page 19:

~~7~~8. A certified SRO shall be re-standardized once three (3) years … number of dairy farms.

b. Three (3) pasteurization milk plants. Milk ~~Plants~~ plants of varying sizes using, vat, HTST, HHST pasteurization and/or aseptic processing and packaging, if applicable, should be included in these evaluations.

c. One (1) dry milk plant, if applicable. The dry milk plant may be used as one (1) of the required three (3) pasteurization milk plants.

d. If HACCP certified for milk plants, receiving or transfer stations, in addition to meeting the requirements listed above for pasteurization milk plants for a SRO, one (1) recertification audit is required. The recertification audit can be done independent as a mock-listing audit or as part of an official HACCP listing audit, at the discretion of the PHS/FDA ~~REGIONAL MILK SPECIALIST~~ Regional Milk Specialist and SRO. (Refer to Section VIII., E.6. for additional HACCP certification procedures.)

Page 22:

H. **THE HEARING PROCEDURE FOR REVOKING THE CERTIFICATION OF A SRO, SSO, OR LEO**

1. Certification Hearing Panel Members

c. The Director of the Division of ~~Cooperative Programs~~ Plant and Dairy Food Safety or designee. …

Page 23:

3. Request for a Hearing

The SRO, SSO, or LEO, after being notified of PHS/FDA's intent to revoke his or her certification, may request a hearing. This request must be received by the Director of the Division of ~~Cooperative Programs~~ Plant and Dairy Food Safety within fifteen (15) days of the date the SRO, SSO, or LEO receives written notification of the intent to revoke his or her certification. The hearing request must identify one (1) or more substantial issues of fact for which a hearing is requested. …

If the Certification Hearing Panel determines that the material submitted by the SRO, SSO, or LEO does not raise any genuine and substantial issue of fact, the request for the hearing will be denied. The Certification Hearing Panel will notify the SRO, SSO, or LEO of the decision in writing, and the revocation of the certification shall be effective immediately. If the Certification Hearing Panel determine that the material submitted by

the SRO, SSO, or LEO raises one (1) or more genuine and substantial issues of fact, the Certification Hearing Panel will notify the SRO, SSO, or LEO and the PHS/FDA Standard in writing that a hearing will be held…

Page 25:

J. **INDIVIDUAL RATINGS**

3. If an aseptic milk plant has any ACLE identified by a SRO or PHS/FDA Regional Milk Specialist as not being in compliance on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Milk and/or Milk Products, the listing shall be immediately denied or withdrawn.
~~3~~4. If an IMS listed shipper receives an Enforcement Rating of less than ninety percent …

*Make the following changes to **SECTION VI. STANDARDS** on Page 27:*

I. **LABORATORY PROCEDURES**

Laboratory procedures used to examine milk and milk products of interstate milk shippers shall conform to the procedures in the current edition of *SMEDP*, published by the American Public Health Association, and the *OMA*. Vitamin testing shall be performed in a laboratory which has been accredited by PHS/FDA and which is acceptable to the Regulatory Agency using test methods acceptable to PHS/FDA and other official methodologies that give statistically equivalent results to the PHS/FDA methods.

*Make the following changes to **SECTION VIII. PROCEDURES GOVERNING THE CERTIFICATION OF MILK PLANT, RECEIVING STATION AND TRANSFER STATION NCIMS HACCP SYSTEMS FOR IMS LISTED SHIPPERS** on Pages 28, 29, 32, 33, 37, 39, 40 and 43:*

A. **PURPOSE AND SCOPE**

2. Products Covered Under HACCP Listings

Agreements adopted by the NCIMS shall apply to Grade "A" raw milk and milk products for pasteurization, heat-treated products, pasteurized, ultra-pasteurized, and aseptically processed and packaged milk and milk products, condensed and dry milk products, and whey and whey products produced under the NCIMS program. Listings made under the voluntary HACCP listing system described in this Section, may be made for milk plants, receiving stations and transfer stations.

B. **HACCP DEFINITIONS:**

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

regulatory requirements, with the exception of the APPS for aseptic processing and packaging milk plants.

Page 29:

4. **PHS/FDA AUDIT:** An evaluation conducted by PHS/FDA of the entire milk plant, receiving station, or transfer station facility to ensure compliance with the HACCP System and other NCIMS regulatory requirements, with the exception of the APPS for aseptic processing and packaging milk plants.

7. **LISTING AUDIT:** An evaluation conducted by a SRO of the entire milk plant, receiving station or transfer station facility to ensure compliance with the NCIMS HACCP Program and other NCIMS regulatory requirements, with the exception of the APPS for aseptic processing and packaging milk plants.

8. **STATE PROGRAM EVALUATION:** Definition ~~S~~T. in Section III shall apply as written, except that for purposes of this Section the words "check ratings of IMS Listed Shippers" shall include "PHS/FDA audits of IMS Listed Shippers".

Page 32 :

C. **PHS/FDA RESPONSIBILITIES**

8. PHS/FDA Audits of HACCP Listing

a. PHS/FDA shall conduct, each year, PHS/FDA audits of HACCP listed shippers. To conduct audits of HACCP/aseptic processing and packaging milk plants, the PHS/FDA Regional Milk Specialist shall have completed a training course that is acceptable to the NCIMS and PHS/FDA addressing the procedures for conducting the audit and the implementation of the NCIMS Aseptic Processing and Packaging Program. Within a State conducting the NCIMS HACCP Program, PHS/FDA audits will be made of a representative number of IMS HACCP listed shippers. The selection of shippers for auditing in a given State will be made randomly. …

h. PHS/FDA shall conduct on-site milk plant, receiving station and transfer station audits of the HACCP compliance status of listed interstate milk shippers. These PHS/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 listed milk plants producing aseptically processed and packaged Grade "A" milk and milk products, PHS/FDA HACCP audits shall be conducted using the procedures identified in the NCIMS Aseptic Processing and Packaging Program related to the inspection/auditing and regulation of the APPS, as described in the *Grade "A" PMO* and *MMSR*, along with the completion of FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Milk and Milk Products.

i. PHS/FDA shall review the Regulatory Agency records for the milk plant, receiving station or transfer station being audited. In the event that there is reason to doubt the safety of any State's milk or milk products that are HACCP listed, PHS/FDA shall immediately investigate the State's Milk Safety Program and may evaluate/audit the milk plants, receiving stations or transfer stations affected. This applies even if the HACCP listing of the milk plant, receiving station or transfer station being audited is sustained.

Page 33:

Based on this investigation, if there are substantial milk or milk product safety program weaknesses, PHS/FDA shall send a written notice requiring corrections to the State Regulatory Agency with a copy to the Rating Agency. If after thirty (30) days, PHS/FDA determines that the corrections were not made, PHS/FDA shall notify the affected industry and receiving States.

If after this investigation of HACCP listings in the State, PHS/FDA determines that the State is not able to fulfill its obligations under the NCIMS HACCP Program and milk or milk products safety remains in doubt, PHS/FDA shall provide written notification to the State specifying the reasons this determination was made.

This written notification will specify that the State has 180 days from the date of the written notification to show to PHS/FDA's satisfaction that the State has made appropriate corrections and is once again able to fulfill its obligations under the NCIMS HACCP Program. …

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 FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT and the FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT, shall apply and shall be submitted to PHS/FDA. Provided that for NCIMS HACCP listed milk plants producing aseptically processed and packaged Grade "A" milk and milk products, FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM MILK PLANT CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products shall also be completed and submitted to PHS/FDA.

Page 37:

C.) Withdrawal of Certification

1.) A HACCP listing shall be requested to be withdrawn when CLE's have been noted on FORM FDA 2359m-MILK PLANT, RECEIVING STATION

OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT indicating that the milk plant, receiving station or transfer station has failed to recognize or correct a deficiency(ies) or nonconformity(ies) indicating: …

Page 39:

8. **HACCP SYSTEM AUDIT FOLLOW-UP ACTIONS:** …

3.) A HACCP/aseptic listing that includes aseptically processed and packaged Grade "A" milk and/or milk products shall be requested to be withdrawn when any ACLE is identified as not being in compliance on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products.

~~3~~4.) When PHS/FDA audit data indicates that the milk plant, receiving station and/or transfer station requires a withdrawal of certification, the Rating Agency, upon written recommendation of the PHS/FDA, shall immediately withdraw the current certification of the shipper and notify such shipper, PHS/FDA, and all known receiving States thereof. In case of withdrawal, a new listing shall be made in not less than thirty (30) days and not to exceed sixty (60) days, unless the Rating Agency has reason to believe a new listing within a lesser time period would result in an acceptable listing. The effective date for action shall be determined from the date of the letter of notification by the Rating Agency. Such letter shall be dated within five (5) working days following the date of the official notification.

Re-number remaining Items accordingly.

Page 40:

E. **QUALIFICATIONS AND CERTIFICATIONS**

3. HACCP Listing

a. An acceptable HACCP listing shall be substituted for an acceptable Sanitation Compliance and Enforcement Rating for a milk plant, receiving station or transfer station participating in the NCIMS HACCP Program. FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT and FORM FDA 2359n-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 listed milk plants producing aseptically processed and packaged Grade "A" milk and/or milk products, FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM MILK PLANT CRITICAL LISTING ELEMENTS for Low-Acid (pH

greater than 4.6) Aseptic Milk and Milk Products shall be completed as a part of all HACCP/aseptic listing audits.

Page 43:

6. Certification Procedure for SROs Who Will Conduct HACCP Listing Audits

   d. Paperwork Review

   FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT, with attachments, FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT, and FORM FDA 2359o-PERMISSION FOR PUBLICATION (*Interstate Milk Shipper's Listing*) shall be submitted with FORM FDA 2359i for each NCIMS HACCP Listing Audit to the PHS/FDA Regional Office for quality assurance review. Provided that for NCIMS HACCP listed milk plants producing aseptically processed and packaged Grade "A" milk and/or milk products, FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM MILK PLANT CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products shall also be completed and submitted for quality assurance review.

   These reviews will be used to enhance uniformity and strengthen each individual's skills and will be used to assist in identifying needs for future training. …

Document: 2009 MMSR (Table of Contents; Sections A, C, D, E, F, G and H; Appendix A; and FORMS 2359j-Section B, 2359n and a new 2359p)
Pages: ii-iv, 1, 2, 9, 10, 13, 15, 18, 21, 25, 26, 28, 41, 43, 44, 46, 49, 53, 55, 67, 79, 80 and 82

*Make the following changes to the **TABLE OF CONTENTS** on Pages ii through iv:*

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

2. COLLECTION OF DATA …….

   d. Recording of Data for Milk Plants and Receiving Stations Being Listed Under the NCIMS Aseptic Processing and Packaging Program…….
3. COMPUTATION OF SANITATION COMPLIANCE RATINGS……..

D. **COMPUTATION OF ENFORCEMENT RATINGS**……

4. MILK PLANTS……..
   a. Aseptic Milk Plant…….
   ~~a~~b. Milk Plant with an Unattached Supply of Raw Milk……
   ~~b~~c. Milk Plant with an Attached Supply of Raw Milk……

E. PREPARATION OF THE SROs REPORT……

Page iii:

F. **PUBLICATION OF THE "INTERSTATE MILK SHIPPER's REPORT"**…

4. PREPARATION OF THE "INTERSTATE MILK SHIPPER's REPORT" FOR ASEPTIC PROCESSING AND PACKAGING PROGRAM LISTINGS…….

G. **EXAMPLES OF RATING, ~~AND~~ NCIMS HACCP LISTING, AND ASEPTIC PROCESSING AND PACKAGING PROGRAM LISTING FORMS** ……..
13. FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products……

H. **EXAMPLES OF HOW TO PROPERLY COMPLETE RATING, ~~AND~~ NCIMS HACCP LISTING, AND ASEPTIC PROCESSING AND PACKAGING PROGRAM LISTING FORMS**…….

Page iv:

23. FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products ……..…….
24. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (*EXAMPLE: ASEPTIC MILK PLANT*)……

Make the following changes to ***A. DEFINITIONS*** *on Pages 1 and 2:*

2. **ASEPTIC CRITICAL LISTING ELEMENT (ACLE):** An item on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products. The identification of any ACLE element by a SRO or FDA Regional Milk Specialist as not being in compliance, whereby a listing shall be immediately denied or withdrawn.

3. **ASEPTIC MILK PLANT RATING:** A rating of a milk plant or portion of a milk plant that produces aseptically processed and packaged Grade "A" milk and/or milk products that is rated separately from the rating of pasteurized and/or ultra-pasteurized Grade "A" milk and milk products produced in the milk plant. This rating shall be made for all milk plants producing aseptically processed and packaged milk and/or milk products as defined in the *Grade "A" PMO*. An NCIMS HACCP milk plant listing that produces aseptically processed and packaged Grade "A" milk and/or milk products shall have only an NCIMS HACCP listing. **NOTE:** The raw milk receiving area may be rated with the aseptic milk plant, or with a separately-listed pasteurization and/or ultra-pasteurized milk plant, or separately as a receiving station.

4. **ASEPTIC PROCESSING AND PACKAGING SYSTEM (APPS)**: For the purposes of this document, the Aseptic Processing and Packaging System in a milk plant is comprised of the processes and equipment used to process and package aseptic Grade "A" milk or milk products. The APPS shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. The APPS shall begin at the constant level tank and end at the discharge of the packaging machine, provided that the Process Authority may provide written documentation which will clearly define additional processes or equipment that are considered critical to the commercial sterility of the product.

~~2~~5. **AUDIT:** An evaluation of the entire milk plant, receiving station, or transfer station facility, and HACCP System to ensure compliance with the HACCP System and other NCIMS regulatory requirements, with the exception of the APPS for aseptic processing and packaging milk plants.

Renumber remaining Definitions accordingly.

Page 2:

~~8~~11. **FDA AUDIT:** An evaluation conducted by FDA of the entire milk plant, receiving station, or transfer station facility to ensure compliance with the HACCP System and other NCIMS regulatory requirements, with the exception of the APPS for aseptic processing and packaging milk plants.

Renumber remaining Definitions accordingly.

~~10~~13. **INDIVIDUAL RATING:** An individual rating is the rating of a single producer group, milk plant, receiving station, and/or transfer station under the supervision of a single Regulatory Agency. Milk plants producing Grade "A" condensed or dried milk and milk products and/or Grade "A" condensed or dry whey and whey products may be rated separately from the same milk plant producing other Grade "A" milk or milk products, provided each listing holds a separate permit. Milk plants that produce both aseptically processed and packaged Grade "A" milk and/or milk products and pasteurized and/or ultra-pasteurized Grade "A" milk and/or milk products shall be rated separately. Provided, that an NCIMS HACCP milk plant listing that produces aseptically processed and packaged Grade "A" milk and/or milk products shall have only an NCIMS HACCP listing. An individual dairy farm shall only be included in one (1) IMS Listing.

~~11~~14. **LISTING AUDIT:** An evaluation conducted by a SRO of the entire milk plant, receiving station or transfer station facility to ensure compliance with the NCIMS HACCP Program and other NCIMS regulatory requirements, with the exception of the APPS for aseptic processing and packaging milk plants.

~~12~~15. **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.

~~13~~16. **RECEIVING STATION:** …

Renumber remaining Definitions accordingly.

Make the following changes to ***C. RATING METHODS FOR MILK PLANTS, RECEIVING STATIONS AND TRANSFER STATIONS*** *on Pages 9, 10 and 13:*

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~~,~~ <u>or</u> 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 …

Page 10:

b. Recording of Laboratory and Other Test Data

(3) The SRO may utilize Regulatory Agency's records in … *Grade "A" PMO.*

<u>**NOTE:** The sampling and testing of aseptically processed and packaged Grade "A" milk and/or milk products is not required, with the exception of the annual vitamin assay analysis to which vitamin(s) A and/or D have been added for fortification purposes. The sampling and testing requirements of Section 6 of the *Grade "A" PMO* for raw milk for aseptic processing and packaging is required.</u>

c. Recording of Data for Milk Plants, Receiving Stations and Transfer Stations Being Listed Under the NCIMS HACCP Listing Procedure …

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. …

Page 13:

(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.

NOTE: In the case of a HACCP/aseptic listed milk plant, the identification of any ACLE element on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products by a SRO or FDA Regional Milk Specialist as not being in compliance shall also constitute an ACLE deficiency under the NCIMS HACCP System, whereby a listing shall be immediately denied or withdrawn.

d. Recording of Data for Milk Plants and Receiving Stations Being Listed Under the NCIMS Aseptic Processing and Packaging Program

1.) Inspection Criteria

(A.) The NCIMS Aseptic Processing and Packaging Program includes all low-acid aseptically processed and packaged Grade "A" milk and/or milk products as defined in the *Grade "A" PMO.*

(B.) State Regulatory inspections of a milk plant or portion of a milk plant that is listed to produce aseptically processed and packaged Grade "A" milk and/or milk products shall be conducted in accordance with the *Grade "A" PMO* at least once every six (6) months. The milk plant's APPS, as defined by the *Grade "A" PMO,* shall be inspected by FDA, or the State Regulatory Agency when designated by FDA, in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113 at a frequency determined by FDA.

(C.) For milk plants or portions of milk plants that are listed to produce aseptically processed and packaged Grade "A" milk and/or milk products, the APPS, as defined by the *Grade "A" PMO*, shall be exempt from Items 7p, 10p, 11p, 12p, 13p, 15p, 16p, 17p, 18p, and 19p of the *Grade "A" PMO*. These items which are dedicated only to the APPS shall comply with the applicable portions of 21 CFR Parts 108, 110 and 113. The rest of the milk plant, including the receiving area, shall be inspected in accordance with the *Grade "A" PMO* and rated and listed in accordance with the current NCIMS requirements. (Refer to Appendix S. Aseptic Processing and Packaging Program of the *Grade "A" PMO).*

(D.) When the APPS is utilized to produce aseptically processed and packaged Grade "A" milk and/or milk products and pasteurized and/or ultra-pasteurized Grade "A" milk and/or milk products, the APPS shall be inspected and tested by the Regulatory Agency in accordance with the requirements cited in Section 7 of the *Grade "A" PMO.*

(E.) NCIMS HACCP listed aseptic milk plants shall be inspected/audited and regulated under the NCIMS HACCP Program with the exception of the APPS which shall be inspected and regulated under the NCIMS Aseptic Processing and Packaging Program. Provided that FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM MILK PLANT CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products shall also be completed and submitted.

2.) Criteria and Procedures for Denial or Withdrawal of a Listing

In addition to the current NCIMS requirements for a listing, the identification of any ACLE element on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products by a SRO or FDA Regional Milk Specialist as not being in compliance, requires that a listing shall be immediately denied or withdrawn.

3. COMPUTATION OF SANITATION COMPLIANCE RATINGS

Make the following changes to ***D. COMPUTATION OF ENFORCEMENT RATINGS*** *on Pages 15 and 18:*

For all NCIMS HACCP listings, including aseptic milk plants, complete FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT. (Refer to Section H, # 19 for an example.) 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.

Page 18:

4. MILK PLANTS

a. For NCIMS aseptic milk plants, all Items in Part II-MILK PLANTS, except Number 5, and all Items on Part III-INDIVIDUAL SHIPPER RATING on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), shall be evaluated. The total weight, which can be earned in Part II, is eighty-five (85). Therefore, the sum of the total credits earned in Part II should be divided by eighty-five (85) and multiplied by 100.

~~a~~b. Milk Plant with an Unattached Supply of Milk …

Note: Re-letter remaining sub items.

Make the following changes to ***E. PREPARATION OF THE SROs REPORT*** *on Page 21:*

4. RECOMMENDATIONS OF THE SRO

For all NCIMS HACCP listings, including aseptic milk plants, complete FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT, which includes an evaluation of the following: (Refer to Section H, #19 for an example.) …

Make the following changes to ***F. PUBLICATION OF THE "INTERSTATE MILK SHIPPER's REPORT*** *on Page 25:*

b. FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT and FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT shall be submitted with all FORM FDA 2359i's.

4. PREPARATION OF THE "INTERSTATE MILK SHIPPER's REPORT" FOR ASEPTIC PROCESSING AND PACKAGING PROGRAM LISTINGS

The provisions of this Section apply to milk plants and receiving stations listed under the NCIMS Aseptic Processing and Packaging Program listing procedure, except that FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products shall be submitted with FORM FDA 2359i for each NCIMS aseptic milk plant listing to the PHS/FDA Regional Office for quality assurance review.

Make the following changes to ***G. EXAMPLES OF RATING AND NCIMS HACCP LISTING FORMS*** *on Page 26:*

G. EXAMPLES OF RATING, ~~AND~~ NCIMS HACCP LISTING, AND ASEPTIC PROCESSING AND PACKAGING PROGRAM LISTING FORMS

2. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2)…….

NOTE: Update this FORM as indicated below:

MILK PLANT
PART II

2 Milk plant and receiving station(s) inspected ~~at least~~ once every three (3) months; aseptic milk plant and transfer station(s) once every six (6) months

5 Pasteurization equipment tested at required frequency (Not required for aseptic milk plants.)

INDIVIDUAL SHIPPER RATING
PART III

INDIVIDUAL SHIPPER ENFORCEMENT RATINGS

Individual Shipper of Raw Milk for Pasteurization:

- Without Milk Plant, Receiving Station~~,~~ or Transfer Station ~~or Plant~~:

Individual Shipper of Pasteurized Milk and Milk Products:

- Aseptic Milk Plants:
  - Evaluate all Items PART II., except Number 5. Divide by 85.

- With Attached Raw Supply: …

FORM FDA 2359j (~~10/08~~ 10/11) (PAGE 2)

Refer to FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) on the next page.

NOTE: *Also make these same changes on Pages 28, 46, 49, 53, and 55.*

MILK SANITATION RATING REPORT

SHIPPER _____

DATE OF RATING _____

ENFORCEMENT RATING _____

DAIRY FARMS PART I

Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	3	All dairy farmers hold a valid permit				5	
2	5	All dairy farms inspected at least once every six (6) months or as required in Appendix "P"				15	
3	5	Inspection sheet posted or available				5	
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				10	
5	8	TB & Brucellosis Certification on file as required				10	
6	7	Water samples tested and reports on file as required				5	
7	5	Milking time inspection program established				5	
8	6	At least four (4) samples collected from each dairy farm's supply every six (6) months and all necessary laboratory examinations made				10	
9	6 App B	Sampling procedures approved by PHS/FDA evaluation methods				10	
10	3, 5 6, 16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required				15	
11		Records systematically maintained and current				10	
		TOTAL CREDIT, PART I ➡					

REMARKS

MILK PLANT PART II

Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	3	All milk plant, receiving station and transfer station operators hold a valid permit				5	
2	5	Milk plant and receiving station(s) inspected ~~at least~~ once every three (3) months; aseptic milk plant and transfer station(s) once every six (6) months				15	
3	5	Inspection sheet posted or available				5	
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				10	
5	7 App I	Pasteurization equipment tested at required frequency (Not required for aseptic milk plants.)				15	
6	7	Individual and cooling water samples tested and reports on file as required				5	
7	6	Samples of each plant's milk and milk products collected at required frequency and all necessary laboratory examinations made				10	
8	6 App B	Sampling procedures approved by PHS/FDA evaluation methods				10	
9	3, 5 6, 16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required				15	
10		Records systematically maintained and current				10	
		TOTAL CREDIT, PART II ➡					

REMARKS

INDIVIDUAL SHIPPER RATING PART III

Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1		Enter TOTAL CREDIT from PART I under Percent Complying				47	
2		Enter TOTAL CREDIT from PART II under Percent Complying				47 / 94	
3	4	All milk and milk products properly labeled				6	
		TOTAL CREDIT, PART III ➡					

INDIVIDUAL SHIPPER ENFORCEMENT RATINGS

INDIVIDUAL SHIPPER OF RAW MILK FOR PASTEURIZATION:

- Without Milk Plant, Receiving Station~~,~~ or Transfer Station ~~or Plant~~:
  - Evaluate all Items PART I. and record.
- With Receiving Station(s) or Transfer Station(s):
  - Evaluate all Items PART I.
  - Evaluate all Items PART II., except Numbers 5 and 7. Divide by 75.
  - Evaluate all Items PART III.

INDIVIDUAL SHIPPER OF PASTEURIZED MILK AND MILK PRODUCTS:

- Aseptic Milk Plants:
  - Evaluate all Items PART II., except Number 5. Divide by 85.
- With Attached Raw Supply:
  - Evaluate all Items PART I.
  - Evaluate all Items PART II., use 47 Weight.
  - Evaluate all Items PART III.
- With Unattached Raw Supply:
  - Evaluate all Items PART II., use 94 Weight.
  - Evaluate all Items PART III., except Number 1.

REMARKS

FORM FDA 2359j (~~10/08~~ 10/11) (PAGE 69) (PREVIOUS EDITIONS ARE OBSOLETE)

11. FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT……

NOTE: *Update this FORM as indicated below:*

A narrative description shall be provided as a part of all NCIMS HACCP Listings and FDA Audits, including aseptic milk plants with NCIMS HACCP Listings. This report shall include an evaluation of the following requirements:

4. Pasteurization equipment tested as required frequency. (Not applicable to receiving and transfer stations and aseptic milk plants.)

FORM FDA 2359n (~~10/10~~ 10/11)

Refer to FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT on the next page.

NOTE: *Also make these same changes on Pages 41 and 67.*

Department of Health and Human Services Food and Drug Administration	**NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT** **(To be included with all NCIMS HACCP Listings and FDA Audits)**	
STATE REGULATORY AGENCY		DATE OF EVALUATION
FIRM NAME	LICENSE/PERMIT NO.	IMS PLANT NO.
ADDRESS		

EXPLANATION OF CONCERNS NOTED REGARDING REGULATORY AGENCY OBLIGATIONS UNDER THE NCIMS HACCP SYSTEM

(Use additional sheets if necessary.)

A narrative description shall be provided as a part of all NCIMS HACCP Listings and FDA Audits, including aseptic milk plants with NCIMS HACCP Listings. This report shall include an evaluation of the following requirements:

1. Milk plant, receiving station or transfer station holds a valid permit.
2. Milk plant, receiving station or transfer station audited by the Regulatory Agency at the minimum required frequency.
3. Requirements interpreted in accordance with the *Grade "A" PMO* as indicated by past audits.
4. Pasteurization equipment tested at required frequency. (Not applicable to receiving and transfer stations and aseptic milk plants.)
5. Individual and cooling water samples tested and reports on file as required.
6. Samples of milk plant's milk and milk products collected at the required frequency and all necessary laboratory examinations made. (Not applicable to receiving and transfer stations.)
7. Sampling procedures approved by PHS/FDA evaluation methods.
8. Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required.
9. Records systematically maintained and current.

FORM FDA 2359n (~~10/10~~ 10/11)

13. FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products ……

NOTE: *Add this new FORM after Page 42 of this Section.*

NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM
CRITICAL LISTING ELEMENTS
(Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products)

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

MILK PLANT _____ **DATE OF RATING** _____

ADDRESS _____ **LICENSE PERMIT NUMBER** _____

RATING AGENCY _____

EXPLANATION OF CONCERNS NOTED REGARDING CRITICAL LISTING ELEMENTS UNDER THE NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM
(Use additional sheets as necessary.)

A narrative description shall be provided as a part of all NCIMS Aseptic Processing and Packaging Program State Ratings/HACCP Listings and FDA Check Ratings/HACCP Audits. This report shall include an evaluation of the following requirements:

1. Is the milk plant registered with FDA LACF and are all of the milk plant's low-acid 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 low-acid 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 an "Order of Determination of Need" for an Emergency Permit?

FORM FDA 2359p (10/11)

Make the following changes to ***H. EXAMPLES OF HOW TO PROPERLY COMPLETE RATING AND NCIMS HACCP LISTING FORMS*** *on Pages 43 and 44:*

H. EXAMPLES OF HOW TO PROPERLY COMPLETE RATING, ~~AND~~ NCIMS HACCP LISTING, AND ASEPTIC PROCESSING AND PACKAGING PROGRAM LISTING FORMS

Page 44:

23. FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products ……..……..
24. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (EXAMPLE: ASEPTIC MILK PLANT)……

Add the following two (2) new completed FORMS after Page 71 of this Section.

NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM
MILK PLANT CRITICAL LISTING ELEMENTS
(Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products)

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

MILK PLANT _ASEPTIC DAIRY_____ **DATE OF RATING** 10/8-9/2012 _

ADDRESS _1000 PLANT DRIVE_ _____ **LICENSE PERMIT NUMBER** 80-001 _

RATING AGENCY _USA MILK CONTROL AGENCY_ _ _____

EXPLANATION OF CONCERNS NOTED REGARDING CRITICAL LISTING ELEMENTS UNDER THE NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM
(Use additional sheets as necessary.)

A narrative description shall be provided as a part of all NCIMS Aseptic Processing and Packaging Program State Ratings/HACCP Listings and FDA Check Ratings/HACCP Audits. This report shall include an evaluation of the following requirements:

1. Is the milk plant registered with FDA LACF and are all of the milk plant's low-acid aseptic Grade "A" milk and milk products covered by a filing with the FDA LACF using Form FDA 2541c or equivalent electronic filing?

Yes – FCE number 000000; Grade "A" Products: White Milks (Whole, 2%, 1% and Skim), Flavored Milk, including chocolate (Whole, 2% and Skim)
SID 2005-01-12/001 indirect UHT processor. SUP SID 2005-01-12/003 Tetra Pak A3/Flex. (Or refer to attached list of additional SIDs and SUP SIDs.)

2. Are the milk plant's filed scheduled processes for all of its low-acid aseptic Grade "A" milk and milk products developed by a recognized Process Authority qualified as having expert knowledge of thermal processing requirements?

YES-Sterilization Processing System #1 and 2: Processing Authorities, Inc., 400 SE 1st, Aseptic, State 00000 (George reviewer); Aseptic Fillers #3 and 4: Good Packaging, LLC, 1111 Filler Lane, Bottle, State 00000 (Johnny B. Sterile)

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)?

YES-Supervisors on site are: Jeff Plant-Better Processing Control School-Purdue University (10/2011); Robert Fixer-Better Processing Control School-WA State University (6/2005); and Jamie Boss-Better Processing Control School-University of Arkansas (8/2010).

4. Is the milk plant currently under an "Order of Determination of Need" for an Emergency Permit?

NO.

FORM FDA 2359p (10/11)

MILK SANITATION RATING REPORT (Example: Aseptic Milk Plant)

SECTION B. REPORT OF ENFORCEMENT METHODS

SHIPPER ASEPTIC DAIRY

DATE OF RATING 10/8-9/2012

ENFORCEMENT RATING 91

DAIRY FARMS PART I

Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	3	All dairy farmers hold a valid permit				5	
2	5	All dairy farms inspected at least once every six (6) months or as required in Appendix "P"				15	
3	5	Inspection sheet posted or available				5	
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				10	
5	8	TB & Brucellosis Certification on file as required				10	
6	7	Water samples tested and reports on file as required				5	
7	5	Milking time inspection program established				5	
8	6	At least four (4) samples collected from each dairy farm's supply every six (6) months and all necessary laboratory examinations made				10	
9	6 App B	Sampling procedures approved by PHS/FDA evaluation methods				10	
10	3, 5 6, 16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required				15	
11		Records systematically maintained and current				10	
		TOTAL CREDIT, PART I ➡					

REMARKS

#2-One (1) of the required six (6) month inspections was missed (12/2011).

#4-Violation of Item 7(b) (4 pts)-Submerged water inlet in the CIP make-up tank; Item 15b(c) (5 pts)-Cross connection between the raw milk storage silo #2 and the CIP system in the receiving area; and Item 1(a) (1 pt)-The flooring in the APPS room was in very poor condition, existed but were not debited on the last inspection.

MILK PLANT PART II

Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	3	All milk plant, receiving station and transfer station operators hold a valid permit				5	5
2	5	Milk plant and receiving station(s) inspected once every three (3) months; aseptic milk plant and transfer station(s) once every six (6) months	4	3	75	15	11.25
3	5	Inspection sheet posted or available				5	5
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections	1	.90	90	10	9.00
5	7 App I	Pasteurization equipment tested at required frequency (Not required for aseptic milk plants.)	NA	NA	NA	15	NA
6	7	Individual and cooling water samples tested and reports on file as required	6	6	100	5	5
7	6	Samples of each plant's milk and milk products collected at required frequency and all necessary laboratory examinations made	5	4	80	10	8.00
8	6 App B	Sampling procedures approved by PHS/FDA evaluation methods	1	1	1	10	10
9	3, 5 6, 16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required	1	1	100	15	15
10		Records systematically maintained and current	1	1	100	10	10
		TOTAL CREDIT, PART II ➡					92.06

REMARKS

#7-Aseptic 2% chocolate milk, with vitamins A & D added, did not have a vitamin assay conducted during 2011.

78.25/85 = 92.06

INDIVIDUAL SHIPPER RATING PART III

Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1		Enter TOTAL CREDIT from PART I under Percent Complying			NA	47	NA
2		Enter TOTAL CREDIT from PART II under Percent Complying			92.06	47 / 94	86.54
3	4	All milk and milk products properly labeled	5	4	80	6	4.80
		TOTAL CREDIT, PART III ➡					91.34

INDIVIDUAL SHIPPER ENFORCEMENT RATINGS

INDIVIDUAL SHIPPER OF RAW MILK FOR PASTEURIZATION:

- Without Milk Plant, Receiving Station or Transfer Station:
  - Evaluate all Items PART I. and record.
- With Receiving Station(s) or Transfer Station(s):
  - Evaluate all Items PART I.
  - Evaluate all Items PART II., except Numbers 5 and 7. Divide by 75.
  - Evaluate all Items PART III.

INDIVIDUAL SHIPPER OF PASTEURIZED MILK AND MILK PRODUCTS:

- Aseptic Milk Plants:
  - Evaluate all Items PART II., except Number 5. Divide by 85.
- With Attached Raw Supply:
  - Evaluate all Items PART I.
  - Evaluate all Items PART II., use 47 Weight.
  - Evaluate all Items PART III.
- With Unattached Raw Supply:
  - Evaluate all Items PART II., use 94 Weight.
  - Evaluate all Items PART III., except Number 1.

REMARKS

#3-Aseptic nonfat milk was not labeled as Grade "A" and "Keep Refrigerated After Opening".

FORM FDA 2359j (~~10/08~~ 10/11) (PAGE 2) (PREVIOUS EDITIONS ARE OBSOLETE)

Make the following changes to ***APPENDIX A. GUIDELINES FOR COMPUTING ENFORCEMENT RATINGS*** *on Pages 79, 80 and 82:*

PART II. MILK PLANTS

2. Milk plants and receiving stations inspected at least once every three (3) months (transfer stations and aseptic milk plants once every six (6) months) (*Grade "A" PMO*, Section 5 - INSPECTION OF MILK PLANTS). Prorate by number of inspections in compliance with the required frequency.

For Example:

$$= \frac{\text{\# of three (3) or six (6) month periods with an inspection conducted}}{\text{Total \# of three (3) or six (6) month periods in rating period}}$$

a. Milk plants and receiving stations inspected at least once every three (3) months.
b. Transfer stations and aseptic milk plants inspected at least once every six (6) months.

NOTE: Use *Methods*, Section D., 1., e. as a guide: "…the interval shall include the designated period plus the remaining days of the month in which the inspection is due."

Page 80:

5. Pasteurization equipment tested at required frequency (*Grade "A" PMO*, Section 7 - STANDARDS FOR MILK AND MILK PRODUCTS and APPENDIX I. - PASTEURIZATION EQUIPMENT AND CONTROLS-TESTS). Prorate by number of units per quarter that were correctly tested within the required testing frequency vs. total number of units.

NOTE: Not required for aseptic milk plants, except when the APPS is utilized to produce aseptically processed and packaged Grade "A" milk and/or milk products and pasteurized and/or ultra-pasteurized Grade "A" milk and/or milk products. The APPS shall then be tested by the Regulatory Agency in accordance with the requirements cited in Section 7 of the *Grade "A" PMO.*

a. Total required tests performed based on pasteurization system(s)~~:~~ equals the ~~(~~# number of Vat ~~Past.~~ Pasteurizers~~.~~, ~~+ #~~ plus the number of HTST ~~Past.~~ Pasteurizers~~.~~, ~~+ #~~ plus the number of HHST ~~Past.~~ Pasteurizers~~.~~, ~~+ #~~ plus the number of ~~Aseptic Systems~~ APPS, if applicable as cited above, at the milk plant.

For Example: …

Page 82:

7. Samples of each milk plant's milk and milk products collected at the required frequency and all necessary laboratory examinations made (*Grade "A" PMO,* Section 6 - THE EXAMINATION OF MILK AND MILK PRODUCTS). Prorate by number of products in compliance.

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

e. Assays of Vitamin A, D, and/or A and D fortified milk and milk products, including aseptically processed and packaged milk and milk products, made at least annually in an IMS Listed Laboratory. Credit for vitamin-fortified products is not given unless vitamin analysis is completed and records are available. Each fortified product is evaluated separately.

Document: No Document Referenced

The following text is a mandatory part of this solution but will not be placed in an NCIMS document.

NOTE: *This provision shall take immediate effect upon the issuance of the IMS-a, Actions from the 2011 National Conference on Interstate Milk Shipments, following FDA's concurrence with the NCIMS Executive Board.*

As part of the NCIMS Aseptic Program addressing aseptically processed and packaged Grade "A" low acid milk and milk products and the Aseptic Pilot Program addressing aseptically processed and packaged Grade "A" acidified and fermented high acid milk and milk products, an NCIMS Aseptic Program Committee (APC) shall be formed in accordance with NCIMS *Procedures*. The APC shall be responsible for the oversight of the NCIMS Aseptic Program addressing aseptically processed and packaged Grade "A" low acid milk and milk products as well as aseptically processed and packaged Grade "A" acidified and fermented high acid milk and milk products in consultation with FDA, including the development of forms, documents and guidance necessary to implement, evaluate and provide training as well as study current and new aseptic technology and its application. The APC shall provide a report to the 2013 NCIMS.

This Proposal also authorizes FDA to make appropriate editorial changes to the NCIMS documents as needed, in accordance with NCIMS *Procedures*, resulting from Proposals that are passed at the 2011 NCIMS Conference, and concurred with by FDA, related to the wording addressing aseptic processing and packaging systems.

All milk plants producing aseptically processed and packaged Grade "A" acidified and fermented high acid milk and milk products, as defined by the PMO and regulated under the NCIMS program will participate in the Aseptic Pilot Program for those milk and milk products.

- - - -

Proposal: 208
Document: 2009 PMO (Table of Contents; Section 6; Appendixes B and M; and FORM 2399a)
Pages: x, 22, 24, 26, 130, 132-135 and 337

*Make the following changes to the **TABLE OF CONTENTS** on Page x:*

APPENDIX B. MILK SAMPLING, HAULING, AND RANSPORTATION……~~130~~

I. MILK SAMPLING AND HAULING PROCEDURES……..……...~~130~~
II. REQUIREMENTS FOR USING AN APPROVED IN-LINE SAMPLER……..…..~~134~~
III. REQUIREMENTS FOR USING AN APPROVED ASEPTIC SAMPLER FOR MILK TANK TRUCKS……..……...~~134~~
IV. REQUIREMENTS FOR USING AN APPROVED ASEPTIC SAMPLER FOR FARM BULK MILK TANKS AND SILOS….……..~~135~~
~~IV~~V. MILK TANK TRUCK PERMITTING AND INSPECTION……..……....~~136~~

*Make the following changes to the **SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS** on Pages 22, 24-26:*

It shall be the responsibility of the bulk milk hauler/sampler to collect a representative sample of milk from each farm bulk tank and/or silo or from a properly installed and operated in-line-sampler or aseptic sampler, that is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring or as transferring milk utilizing an aseptic sampler from a farm bulk tank or silo, truck or other container. All samples shall be collected and delivered to a milk plant, receiving station, transfer station or other location approved by the Regulatory Agency. …

Pages 24-25:

Samples shall be analyzed at an appropriate official or officially designated laboratory. All sampling procedures, including the use of approved in-line samplers and approved aseptic samplers for milk tank trucks or for farm bulk milk tanks and silos, 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 *Procedures*. Aseptically processed milk and milk products packaged in hermetically sealed containers shall be tested in accordance with FDA's *Bacteriological Analytical Manual* (BAM). …

Page 26:

LABORATORY TECHNIQUES: Procedures for the collection, including the use of approved in-line samplers and approved aseptic samplers for milk tank trucks or for farm bulk milk tanks and silos, and the holding of samples; the selection and preparation of apparatus, media and reagents; and the analytical procedures, incubation, reading and reporting of results, shall be in

substantial compliance with the FDA 2400 Series Forms, *SMEDP* and *OMA*. The procedures shall be those specified therein for: …

Make the following changes to the ***APPENDIX B. MILK SAMPLING, HAULING AND TRANSPORTATION*** *on Pages 130 and 132-135:*

TRAINING: To understand the importance of bulk milk collection and the techniques of sampling, including the use of an approved in-line sampler and approved aseptic samplers for milk tank trucks or for farm bulk milk tanks and silos, all bulk milk hauler/samplers and industry plant samplers must be told why, and instructed how, in the proper procedures of picking up milk and the collection of samples. The Regulatory Agency, dairy field person, route supervisors or any appropriate person whose techniques and practices are known to meet the requirements can conduct this training. If the Regulatory Agency does not conduct the training, the training must be approved by or conducted under the supervision of the Regulatory Agency. …

Pages 132-133:

2. **Equipment Requirements:**

…

c. Sample dipper or other approved aseptic sampling devices of sanitary design and material approved by the Regulatory Agency; clean and in good repair. …

5. **Universal Sampling System:**

…

b. The milk must be agitated a sufficient time to obtain a homogeneous blend. Follow the State and/or manufacturer's guidelines or when using an approved aseptic sampling device, follow the specified protocol and SOP for that device.

c. While the ~~tank~~ farm bulk milk tank or silo is being agitated, bring the sample container, dipper, dipper container and sanitizing agent for the outlet valve, or single-service sampling tubes into the milkhouse aseptically. Remove the cap from the ~~tank~~ farm bulk milk tank or silo outlet valve and examine the outlet valve for milk deposits or foreign matter and then sanitize if necessary. Protect the hose cap from contamination when removing it from the transfer hose and during storage.

d. The sample may only be collected after the milk has been properly agitated or when using an approved aseptic sampling device, follow the specified protocol and SOP for that device. Remove the dipper or sampling device from the sanitizing solution or sterile container and rinse at least twice in the milk.

e. Collect a representative sample or samples from the farm bulk milk tank or silo by using a sample dipper or other approved aseptic sampling device. Refer to Section IV. Requirements for Using an Approved Aseptic Sampler for Farm Bulk Milk Tanks and Silos of Appendix B. of this *Ordinance* for the specific protocol for the use of approved aseptic sampling devices**.** When transferring milk from the sampling equipment, caution should be used to assure that ~~no~~ milk is not spilled back into the ~~tank~~ farm bulk milk tank or silo. Do not fill the sampling container more than ¾ full. Close the cover on the sample container.

f. The sample dipper shall be rinsed free of milk and placed in its carrying container.

g. Close the cover or lid of the farm bulk milk tank. …

Page 135:

IV. REQUIREMENTS FOR USING AN APPROVED ASEPTIC SAMPLER FOR FARM BULK MILK TANKS AND SILOS

A protocol specific to each milk producer in which the milk producer, who transports milk only from his/her own dairy farm, or bulk milk hauler/samplers utilize an approved aseptic sampler shall be developed by the Regulatory Agency in cooperation with the sampling equipment manufacturer, the milk producer and FDA. As a minimum, the protocol should include the following:

1. A description of how the milk sample is to be collected, identified, handled and stored.
   a. The aseptic sampler fitting must be installed according to the manufacturer's recommendations and in a manner that is compatible with its intended use and does not create a dead end.
   b. The aseptic sampler septum must be installed according to the manufacturer's instructions.
   c. Transfer of milk is achieved using a Standard Operating Procedure (SOP) specific to the aseptic sampler.
2. A description of how and when the aseptic sampler is to be cleaned and sanitized, if not of a single use design, as per the manufacturer's instructions.
3. A listing of the milk producer, who transports milk only from his/her own dairy farm, and/or licensed bulk milk hauler/samplers who have been trained to maintain, operate, clean and sanitize the aseptic sampling device as well as collect, identify, handle and store the milk sample.

~~IV~~V. MILK TANK TRUCK PERMITTING AND INSPECTION

*Make the following changes to the **APPENDIX M. REPORTS AND RECORDS** on Page 337:*

Within the Forms cited in APPENDIX M-REPORTS AND RECORDS, the following changes to FORM FDA 2399a-BULK MILK HAULER/SAMPLER EVALUATION REPORT shall be made:

BULK TANK SAMPLING PROCEDURES

10. Sample Transfer Instrument …
    c. Or an approved in-line sampler……□
    d. Or an approved aseptic sampler …..□
    ~~d~~e. Or a sanitized sampling cock …….□

……..

FORM FDA 2399a (~~10/08~~ 10/12**) FRONT (PREVIOUS EDITIONS ARE OBSOLETE**

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **BULK MILK HAULER/SAMPLER EVALUATION REPORT**	BULK MILK HAULER/SAMPLER PERMIT NO.	TANKER PERMIT NO.
	BULK MILK HAULER/SAMPLER	DAILY PICKUP NO.

ADDRESS OF BULK MILK HAULER/SAMPLER	NAME AND ADDRESS OF INSPECTION LOCATION
OWNER	NAME AND ADDRESS OF RECEIVING PLANT
ADDRESS OF OWNER	

An evaluation of your sampling procedures showed violations existing in the Items checked below. You are further notified that this evalua- tion report serves as notification of the intent to suspend your permit if the violations noted are not in compliance at the time of the next inspection. (Refer to Sections 3 and 5 of the Grade "A" Pasteurized Milk Ordinance.)

HAULER SANITATION PROCEDURES

1. Pickup practices conducted to preclude contamination of milk contact surfaces ☐
2. Hands clean and dry, no infections ☐
3. Clean outer clothing, no use of tobacco ☐
4. Hose port used, tank lids closed during completion of pickup ☐
5. Hose properly capped between milk pickup operations, hose cap protected during milk pickup ☐
6. Hose disconnected before tank rinsed ☐
7. Observations made for sediment/abnormalities ☐
8. Sample collected from each producer's bulk tank picked up ☐

BULK TANK SAMPLING PROCEDURES

9. Thermometer – Approved Type ☐
   a. Accuracy – Checked against standard thermometer every 6 months – accuracy (+) (-) 1 division ☐
   b. Date checked and checker's initials attached to case ☐
10. Sample Transfer Instrument
   a. Clean, sanitized or sterilized and of proper construction and repair ☐
   b. Sterile needle for aseptically dispensing a milk sample from the bulk tank sample septum into a sample container (i.e., vial) ☐
   c. Or an approved in-line sampler ☐
   d. Or an approved aseptic sampler ☐
   ~~d~~e. Or a sanitized sampling cock ☐
11. Sampling Instrument Container
   a. Proper design, construction and repair for storing sample dipper in sanitizer ☐
   b. Applicable test kit for checking strength of sanitizer (200 ppm chlorine or equivalent) ☐
12. Sample Containers
   a. Clean, properly sanitized or sterilized ☐
   b. Adequate supply, properly stored or handled ☐
13. Sample Storage Case
   a. Rigid construction, suitable design to maintain samples at 0°C - 4.4°C (32°F - 40°F), protected from contamination ☐
   b. Ample space for refrigerant, racks provided as necessary ☐
14. Sample Collection – Precautions and Procedures
   a. Sampling instrument and container(s) properly carried into and aseptically handled in milkhouse ☐
   b. Bulk tank milk outlet valve sanitized before connecting transfer hose ☐
   c. Smell milk through tank port hole ☐
   d. Observe milk in a quiescent state with lid wide open and lights on when necessary ☐
   e. Test thermometer sanitized (1 min. contact time) ☐
   f. Non-acceptable milk rejected ☐
   g. Dry measuring stick with single-service paper towel ☐
   h. Measure milk only when quiescent ☐
   i. Do not contaminate milk during the measuring process ☐
   j. Agitate milk before sampling at least 5 min. or longer as may be required by tank specifications, or follow approved aseptic sampling device protocol and SOP ☐
   k. Do not open bulk tank valve until milk is measured and sampled ☐
   l. Temperature of milk, time, date of pickup and bulk milk hauler/sampler name and license or permit no. recorded on each farm weight ticket ☐
   m. Tank thermometer accuracy
      1. Tank thermometer accuracy checked monthly and recorded when used as test thermometer ☐
      2. Accuracy of required recording thermometer checked monthly against standardized thermometer and recorded ☐
   n. Temperature control sample provided at first sampling location for each rack of samples ☐
   o. Temperature control sample properly labeled with time, date, temperature, producer ID and bulk milk hauler/sampler identification ☐
   p. Sample containers legibly identified at collection points ☐
   q. Sample dipper rinsed at least two times in the milk before transferring sample ☐
   r. Dipper should be extended 6-8 inches into the milk to obtain representative sample ☐
   s. Sample cock properly sanitized and flushed prior to sampling ☐
   t. Septum surface properly sanitized and single service sterile needle used (Follow approved aseptic sampling device SOP for sample transfer) ☐
   u. Do not hold sample container over the milk when transferring sample into the container ☐
   v. Fill sample container no more than ¾ full ☐
   w. Rinse sample dipper in safe tap water, return to storage container, open tank valve, start milk transfer pump ☐
   x. Immediately place milk sample in the sample case ☐
15. Sample Collection – Storage and Transportation
   a. Sample storage – refrigerant maintained no higher than milk level in sample containers – maintain sample temperature 0ºC – 4.4ºC (32ºF- 40ºF), do not bury tops of containers in ice, protect from contamination ☐
   b. Deliver samples to laboratory promptly ☐
   c. Samples and sample data – submitted to laboratory – if by common carrier, use tamper proof shipping case with top labeled "This Side Up". ☐

REMARKS *(If additional space is required, please place information on the back of this Form or on a separate page.)*

DATE	SANITARIAN	AGENCY

FORM FDA 2399a (~~10/08~~ 10/12) FRONT (PREVIOUS EDITIONS ARE OBSOLETE)

PSC Graphics: (301) 443-1090 EF

NOTE: *An M-I shall be developed and issued addressing the Standard Operating Procedure (SOP) for this approved aseptic sampler for farm bulk milk tanks and silos.*

- - - -

II. CRITERIA FOR THE ONSITE PRODUCTION AND USE OF ELECTRO-CHEMICAL ACTIVATION (ECA) GENERATED HYPOCHLOROUS ACID FOR THE SANITIZATION OF MULTI-USE CONTAINERS, UTENSILS, AND EQUIPMENT

The following is a list of criteria that are required for on-site generation of ECA generated hypochlorous acid that was produced onsite and used as a sanitizer for the sanitization of multi-use containers, utensils and equipment.

1. The ECA device manufacturer shall be registered with the EPA as a pesticidal device establishment pursuant to 40 CFR 152.500 and shall comply with the labeling requirements outlined in 40 CFR 156.10.
2. The minimum dilution percentage of the sanitizer shall be 50 parts per million (ppm) free available chlorine (FAC) with a minimum contact time of 30 seconds pursuant to the efficacy requirements for EPA DIS/TSS 4 Sanitizer rinses, for previously cleaned milk-contact surfaces, and less than 200 ppm FAC. The sanitizer produced shall meet the data requirements of 40 CFR Part 158 Data Requirements for Registration, Pesticide Assessment Guidelines – Subdivision G, 91-2(f), and its test documents shall be pursuant to Good Laboratory Practices (GLP's).
3. The salt used to generate the sanitizer shall be of food-grade quality rated at a minimum of 99.6% purity, and potable water shall be used to ensure quality and consistency of the sanitizer generated.
4. The ECA device and its solution concentrate storage containers shall be constructed of materials that do not impart toxic materials into the sanitizing solution either as a result of the presence of toxic constituents in the materials of construction or as a result of physical or chemical changes that may occur during the ECA process.
5. The ECA solution concentrate storage containers shall be labeled with the following:
   a. Contents;
   b. EPA Establishment Number for the ECA device manufacturer;
   c. Dilution percentage instructions for use and storage conditions, including the shelf-life;
   d. A list of its active and inert ingredients; and
   e. Other required standard safety data disclosures, formerly referred to as Material Safety Data Sheet (MSDS).
6. The ECA device used to produce the hypochlorous sanitizer shall control and record the parameters to ensure that the ECA device is operating within its design limits and provides an effective real time notification or alarm and will shut down when it falls out of the required range as recommended by the ECA device manufacturer.
7. Standard measurement methods such as FAC titration or chlorine test strips shall be used to verify that the concentration of the ready to use sanitizer being applied is in a range between 50 ppm and 200 ppm. Measurement equipment shall be checked, calibrated and measurements recorded. All records shall be accessible to the Regulatory Agency for inspection. Electronically generated records for FAC concentrations, if used, shall meet the criteria specified in Appendix H., Section V.

III. EVAPORATING, DRYING AND DRY PRODUCT EQUIPMENT CLEANING

Make the following changes to ***APPENDIX L. APPLICABLE REGULATIONS, STANDARDS OF IDENTITY FOR MILK AND MILK PRODUCTS AND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT*** *on Pages 335 and 336:*

APPENDIX L. APPLICABLE REGULATIONS, STANDARDS OF IDENTITY FOR MILK AND MILK PRODUCTS AND THE *FEDERAL FOOD, DRUG, AND COSMETIC ACT* AND THE *FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT*

Page 336:

40 CFR PART 141- NATIONAL PRIMARY DRINKING WATER REGULATIONS
40 CFR 152.500 Requirements for Devices
40 CFR 156.10 Labeling Requirements for Devices and Their Products
40 CFR 158 Data Requirements for Registration, Pesticide Assessment Guidelines
40 CFR 180.940 Tolerance Exemptions for Active and Inert Ingredients for Use in Antimicrobial Formulations, Food-Contact Surface Sanitizing Solutions …

Proposal: 205
Document: 2009 PMO (Section 6)
Pages: 23 and 29-31

Make the following changes to ***SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS*** *on Page 23:*

It shall be the responsibility of the bulk milk hauler/sampler to collect a representative …

~~3. During any consecutive six (6) months, at least four (4) samples of heat-treated milk products, from milk plants offering such products for sale, 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.~~

~~4~~3. During any consecutive six (6) months, at least four (4) samples of pasteurized milk, …

Make the following changes to ***SECTION 7. STANDARDS FOR GRADE "A" MILK AND MILK PRODUCTS, Table 1. Chemical, Physical, Bacteriological, and Temperature Standards*** *on Pages 29-31:*

Table 1. Chemical, Physical, Bacteriological, and Temperature Standards		
GRADE "A" RAW MILK AND MILK PRODUCTS FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING	Temperature.....	Cooled to 10ºC (50ºF) or less within four (4) hours or less, of the commencement of the first milking, and to 7°C (45ºF) 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 10ºC (50ºF). **NOTE:** Milk sample submitted for testing cooled and maintained at 0ºC (32ºF) to 4.4ºC (40ºF), where sample temperature is >4.4ºC (40ºF), but ≤7.0ºC (45ºF) 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. **NOTE:** 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 7ºC (45ºF) or less and maintained thereat. **NOTE:** Milk sample submitted for testing cooled and maintained at 0ºC (32ºF) to 4.4ºC (40ºF), where sample temperature is >4.4ºC (40ºF), but ≤7.0ºC (45ºF) and less than three (3) hours after collection has not increased in temperature.
	Bacterial Limits**…...	Not to exceed 20,000 per mL, or gm.*** **NOTE:** 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. **NOTE:** 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.

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. *Provided,* 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 7ºC (45ºF) or less and maintained thereat.
	Bacterial Limits**…...	Not to exceed 20,000 per mL, or gm.***
	Coliform****	Not to exceed 10 per mL. Provided, 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 MILK AND MILK PRODUCTS	Temperature.....	None.
	Bacterial Limits.....	Refer to 21 CFR 113. 3(e)(1)*****
	Drugs**.....	There are no validated and accepted drug residue tests for Aseptically Processed Milk and Milk Products.

* Goat Milk 1,500,000/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°C (280°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".

Document: 2009 MMSR (Appendix A)
Page: 82

Make the following changes to ***APPENDIX A. GUIDELINES FOR COMPUTING ENFORCDEMENT RATINGS*** *on Page 82:*

PART II. MILK PLANTS

7. Samples of each milk plant's milk and milk products collected at the required frequency and all necessary laboratory examinations made (*Grade "A" PMO,* Section 6 - THE EXAMINATION OF MILK AND MILK PRODUCTS). Prorate by number of products in compliance.

b. During any consecutive six (6) months, at least four (4) samples of each milk product processed, as defined in Sections 1 and 6 of the *Grade "A" PMO* shall be collected in four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. However, if the production of any Grade "A" condensed or dry milk product, as defined in the *Grade "A" PMO*, is not on a yearly basis, at least five (5) samples shall be taken within a continuous production period.
~~c. During any consecutive six (6) months, at least four (4) samples of heat-treated products 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.~~
~~d~~c. All required examinations performed on each sample (bacterial, coliform, drug residue, phosphatase, and cooling temperature) in an official or officially designated laboratory.
~~e~~d. Assays of Vitamin A, D, and/or A and D fortified milk and milk products made at least annually in an IMS Listed Laboratory. Credit for vitamin-fortified products is not given unless vitamin analysis is completed and records are available. Each fortified product is evaluated separately. …

Proposal: 209
Document: 2009 PMO (Section 6)
Page: 25

Make the following changes to ***SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS*** *on Page 25****:***

… The determination of a problem is to be based upon:

1. Sample survey results;
2. USDA tissue residue data from cull ~~and veal~~ dairy animals;
3. Animal drug disappearance and sales data;
4. State feed back; and
5. Other relevant information. …

FDA DID NOT CONCUR WITH THIS PROPOSAL AS CITED IN THEIR LETTER TO THE NCIMS CHAIR DATED 8/29/2011.

FDA maintains that the FDA Commissioner will make the final decision on which information and data will be used to determine if a problem exists with animal drug residues or other contaminants in the nation's milk supply.

Proposal: 103
Document: 2009 PMO (Section 7-Table 1)
Page: 30

Make the following changes to ***SECTION 7. STANDARDS FOR GRADE "A" MILK AND MILK PRODUCTS, Table 1. Chemical, Physical, Bacteriological, and Temperature Standards*** *on Page 30****:***

GRADE "A" NONFAT DRY MILK AND DRY MILK AND MILK PRODUCTS		~~No More Than~~ Not to Exceed:
	~~Butterfat……~~	~~1.25%~~
	~~Moisture……~~	~~4.00%~~
	~~Titratable Acidity……~~	~~0.15%~~
	~~Solubility Index……~~	~~1.25 mL~~
	Bacterial Limit…….	~~30,0000~~ 10,000 per gram
	Coliform……..	10 per gram
	~~Scorched Particles disc B……..~~	~~15.0 per gram~~

Proposal: 106
Document: 2009 PMO (Section 7-Item 5r; Appendix M; and FORM 2359a)
Pages: 36-40 and 337

Make the following changes to ***SECTION 7, ITEM 5r*** *on Pages 36-40:*

When the Regulatory Agency determines conditions exist whereby the direct loading of a milk tank truck (through by-passing the use of a farm bulk tank(s) or silo(s)) can be adequately protected and sampled without contamination, a shelter need not be provided if the following minimum criteria are met:

1. The milk hose connection is accessible to, and made from within, the milkhouse. The milk hose connection to the milk tank truck is completely protected from the outside environment at all times. Provided, based on Regulatory Agency acceptance, the direct loading of milk from the milkhouse to the milk tank truck may be conducted through a properly designed hose port that adequately protects the milkhouse opening or by stubbing the milk transfer and associated CIP cleaned lines outside the milkhouse wall in accordance with Item 5r, ADMINISTRATIVE PROCEDURES #15. …

8. When direct loading of a milk tank truck using either a hose port, as addressed above, or stubbing the milk transfer and associated CIP cleaned lines outside the milkhouse wall in accordance with Item 5r, ADMINISTRATIVE PROCEDURES #15, overhead protection of the milk hose connection to the milk tank truck shall be provided. …

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:
…
~~13~~12. Water under pressure is piped into the milkhouse.
~~14~~13. Each milkhouse is provided with facilities for heating…
~~15~~14. The milkhouse is equipped with a wash-and-rinse vat…

~~12~~15. The transfer of milk from a bulk milk tank to a bulk milk pickup tanker is through a hose port located in the milkhouse wall. The hose port shall be fitted with a tight door, which shall be in good repair. It shall be kept closed except when the hose port is in use. An easily cleanable surface shall be constructed under the hose port, adjacent to the outside wall and sufficiently large to protect the milk hose from contamination. …

16. A transportation tank, with or without, …

When the Regulatory Agency determines conditions exist whereby the direct loading of a milk tank truck (through by-passing the use of a farm bulk tank(s) or silo(s)) can be adequately protected and sampled without contamination, a shelter need not be provided if the following minimum criteria are met:

a. The milk hose connection is accessible to, and made from within, the milkhouse. The milk hose connection to the milk tank truck is completely protected from the outside environment at all times. Provided, based on Regulatory Agency acceptance, the direct loading of milk from the milkhouse to the milk tank truck may be conducted through a properly designed hose port that adequately protects the milkhouse opening or by stubbing the milk transfer and associated CIP cleaned lines outside the milkhouse wall in accordance with Item 5r, ADMINISTRATIVE PROCEDURES #15. ...

h. When direct loading of a milk tank truck using either a hose port, as addressed above, or stubbing the milk transfer and associated CIP cleaned lines outside the milkhouse wall in accordance with Item 5r, ADMINISTRATIVE PROCEDURES #15, overhead protection of the milk hose connection to the milk tank truck shall be provided.

Make the following changes to ***APPENDIX M. REPORTS AND RECORDS*** *on Page, 337:*

Within the Forms cited in APPENDIX M-REPORTS AND RECORDS, the following changes to FORM 2359a-DAIRY FARM INSPECTION REPORT shall be made:

MILKHOUSE OR ROOM

5. Construction and Facilities:

Miscellaneous Requirements

…

Suitable shelter or direct load for transportation truck as required ……. (f) ☐

FORM FDA 2359a (~~10/08~~ 10/12) Edition

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	**DAIRY FARM INSPECTION REPORT**	INSPECTING AGENCY
NAME AND LOCATION OF DAIRY FARM		POUNDS SOLD DAILY
		PLANT
		PERMIT NO.

Inspection of your dairy farm today showed violations existing in the Items checked below. You are further notified that this inspection report serves as notification of the intent to suspend your permit if the violations noted are not in compliance at the time of the next inspection. (Refer to Sections 3 and 5 of the **Grade "A" Pasteurized Milk Ordinance**.)

COWS

1. Abnormal Milk:

Cows secreting abnormal milk milked last or in separate equipment ..... (a) ☐
Abnormal milk properly handled and disposed of ..... (b) ☐
Proper care of abnormal milk handling equipment ..... (c) ☐

MILKING BARN, STABLE, OR PARLOR

2. Construction:

Floors, gutters, and feed troughs of concrete or equally impervious materials; in good repair ..... (a) ☐
Walls and ceilings smooth, painted or finished adequately; in good repair; ceiling dust-tight ..... (b) ☐
Separate stalls or pens for horses, calves, and bulls; no overcrowding ..... (c) ☐
Adequate natural and/or artificial light; well distributed ..... (d) ☐
Properly ventilated ..... (e) ☐

3. Cleanliness:

Clean and free of litter ..... (a) ☐
No swine or fowl ..... (b) ☐

4. Cowyard:

Graded to drain; no pooled water or wastes ..... (a) ☐
Cowyard clean; cattle housing areas and manure packs properly maintained ..... (b) ☐
No swine ..... (c) ☐
Manure stored inaccessible to cows ..... (d) ☐

MILKHOUSE OR ROOM

5. Construction and Facilities:

Floors
Smooth; concrete or other impervious material; in good repair ..... (a) ☐
Graded to drain ..... (b) ☐
Drains trapped, if connected to sanitary system ..... (c) ☐

Walls and Ceilings
Approved material and finish ..... (a) ☐
Good repair (windows, doors, and hoseport included) ..... (b) ☐

Lighting and Ventilation
Adequate natural and/or artificial light; properly distributed ..... (a) ☐
Adequate ventilation ..... (b) ☐
Doors and windows closed during dusty weather ..... (c) ☐
Vents and lighting fixtures properly installed ..... (d) ☐

Miscellaneous Requirements
Used for milkhouse operations only; sufficient size ..... (a) ☐
No direct opening into living quarters or barn, except as permitted by *Ordinance* ..... (b) ☐
Liquid wastes properly disposed of ..... (c) ☐
Proper hoseport where required ..... (d) ☐
Acceptable surface under hoseport ..... (e) ☐
Suitable shelter or direct load for transport truck as required ..... (f) ☐

Cleaning Facilities
Two-compartment wash and rinse vat of adequate size ..... (a) ☐
Suitable water heating facilities ..... (b) ☐
Water under pressure piped to milkhouse ..... (c) ☐

6. Cleanliness:

Floors, walls, windows, tables and similar non-product contact surfaces clean ..... (a) ☐
No trash, unnecessary articles, animals or fowl ..... (b) ☐

TOILET AND WATER SUPPLY

7. Toilet:

Provided; conveniently located ..... (a) ☐
Constructed and operated according to *Ordinance* ..... (b) ☐
No evidence of human wastes about premises ..... (c) ☐
Toilet room in compliance with *Ordinance* ..... (d) ☐

8. Water Supply:

Constructed and operated according to *Ordinance* ..... (a) ☐
Complies with bacteriological standards ..... (b) ☐
No connection between safe and unsafe supplies; no improper submerged inlets ..... (c) ☐

UTENSILS AND EQUIPMENT

9. Construction:

Smooth, impervious, nonabsorbent, safe materials; easily cleanable ..... (a) ☐
In good repair; accessible for inspection ..... (b) ☐
Approved single-service articles; not reused ..... (c) ☐
Utensils and equipment of proper design ..... (d) ☐
Approved CIP cleaned milk pipeline system ..... (e) ☐

10. Cleaning:

Utensils and equipment clean ..... (a) ☐

11. Sanitization:

All multi-use containers and equipment subjected to approved sanitization process (Refer to *Ordinance*) ..... (a) ☐

12. Storage:

All multi-use containers and equipment properly stored ..... (a) ☐
Stored to assure complete drainage, where applicable ..... (b) ☐
Single-service articles properly stored ..... (c) ☐

MILKING

13. Flanks, Udders, and Teats:

Milking done in barn, stable, or parlor ..... (a) ☐
Brushing completed before milking begun ..... (b) ☐
Flanks, bellies, udders, and tails of cows clean at time of milking; clipped when required ..... (c) ☐
Teats cleaned, treated with sanitizing solution (if required) and dried, just prior to milking ..... (d) ☐
No wet hand milking ..... (e) ☐

TRANSFER/PROTECTION OF MILK

14. Protection From Contamination:

No overcrowding ..... (a) ☐
Product and CIP cleaning circuits separated ..... (b) ☐
Improperly handled milk discarded ..... (c) ☐
Immediate removal of milk ..... (d) ☐
Milk and equipment properly protected ..... (e) ☐
Sanitized milk surfaces not exposed to contamination ..... (f) ☐
Air under pressure of proper quality ..... (g) ☐

15. Drug and Chemical Control:

Cleaners and sanitizers properly identified ..... (a) ☐
Drug administration equipment properly handled and stored ..... (b) ☐
Drugs properly labeled (name and address) and stored ..... (c) ☐
Drugs properly labeled (directions for use, cautionary statements, active ingredient(s)) ..... (d) ☐
Drugs properly used and stored to preclude contamination of milk or milk product-contact surfaces ..... (e) ☐

PERSONNEL

16. Handwashing Facilities:

Proper handwashing facilities convenient to milking operations ..... (a) ☐
Wash and rinse vats not used as handwashing facilities ..... (b) ☐

17. Personnel Cleanliness:

Hands washed clean and dried before milking, or performing milkhouse functions; rewashed when contaminated ..... (a) ☐
Clean outer garments worn ..... (b) ☐

COOLING

18. Cooling:

Milk cooled to 45°F (7°C) or less within 2 hours after milking, except as permitted by *Ordinance* ..... (a) ☐
Recirculated cooling water from a safe source and properly protected; complies with bacteriological standards ..... (b) ☐
An acceptable recording device shall be installed and maintained when required ..... (c) ☐

PEST CONTROL

19. Insect and Rodent Control:

Fly breeding minimized by approved manure disposal methods (Refer to *Ordinance*) ..... (a) ☐
Manure packs properly maintained ..... (b) ☐
All milkhouse openings effectively screened or otherwise protected; doors tight and self-closing; screen doors open outward ..... (c) ☐
Milkhouse free of insects and rodents ..... (d) ☐
Approved pesticides; used properly ..... (e) ☐
Equipment and utensils not exposed to pesticide contamination ..... (f) ☐
Surroundings neat and clean; free of harborages and breeding areas ..... (g) ☐
Feed storage not attraction for birds, rodents or insects ..... (h) ☐

REMARKS

DATE	SANITARIAN

NOTE: Item numbers correspond to required sanitation Items for Grade "A" raw milk for pasteurization in the **Grade "A" Pasteurized Milk Ordinance**.

FORM FDA 2359a (~~10/08~~ 10/12) Edition

Proposal: 214
Document: 2009 PMO (Section 7-Item 11r; and Appendixes F, J and L)
Pages: 46, 202, 319-321, 335 and 336

Make the following changes to ***SECTION 7, ITEM 11r-UTENSILS AND EQUIPMENT – SANITIZATION*** *on Page 46:*

ADMINISTRATIVE PROCEDURES

2. Certain chemical compounds are effective for the sanitization of milk utensils, containers, and equipment. These are contained in ~~21 CFR 178.1010~~ 40 CFR 180.940 and shall be used in accordance with label directions. (Refer to Appendix F. for further discussion of approved sanitizing procedures.)

Make the following changes to ***APPENDIX F. SANITIZATION*** *on Page 202:*

II. METHODS OF SANITIZATION

CHEMICAL

Certain chemical compounds are effective for the sanitization of milk containers, utensils and equipment. These are contained in ~~21 CFR 178.1010~~ 40 CFR 180.940 and shall be used in accordance with label directions.

Make the following changes to ***APPENDIX J. STANDARDS FOR THE FABRICATION OF SINGLE SERVICE CONTAINERS AND CLOSURES FOR MILK AND MILK PRODUCTS*** *on Pages 319-321:*

D. FABRICATION PLANT STANDARDS

17. WAXES, ADHESIVES, SEALANTS, COATINGS AND INKS

c. Waxes, adhesives, sealants, coatings and inks shall not impart odor or taste to the milk or milk products and shall not contaminate the product with microorganisms or toxic or injurious substances. All materials that are applied to the product-contact surface shall comply with the requirements of 21 CFR Parts ~~175~~ 174-178. …

19. **WRAPPING AND SHIPPING**

e. All packaging materials that contact the product-contact surface of the container or closure shall comply with the requirements of 21 CFR Parts ~~175~~ 174-178 and the bacteriological standards of Section C of these Standards, but the materials do not have to be manufactured at a listed single-service plant. Some outer packaging material such as corrugated cardboard boxes used for the packaging of milk carton flats, are exempt from this bacteriological

standard. The edges of these flats are subject to heat during the forming and sealing of the container.

20. **IDENTIFICATION AND RECORDS**

e. The fabricating plant shall have on file information from suppliers of raw material, waxes, adhesives, sealants, coatings and inks indicating that the material complies with the requirements of 21 CFR Parts ~~175~~ 174-178.

f. The fabricating plant shall have on file information from the suppliers of packaging materials specified in these Standards indicating that the material complies with the requirements of 21 CFR Parts ~~175~~ 174-178 and the bacteriological standards of Section C. of these Standards. There are no specifications for sampling frequency. The Regulatory Agency may choose to collect samples of packaging materials to determine compliance with bacteriological standards of this Section. …

Make the following changes to ***APPENDIX L. APPLICABLE REGULATIONS, STANDARDS OF IDENTITY FOR MILK AND MILK PRODUCTS AND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT*** *on Pages 335 and 336:*

21 CFR 173.310 Boiler Water Additives
21 CFR 174 - INDIRECT FOOD ADDITIVES: GENERAL
21 CFR PART 175 - INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS…

40 CFR PART 141 – NATIONAL PRIMARY DRINKING WATER REGULATIONS
40 CFR 180.940 – Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food contact surface sanitizing solutions)

- - - -

single-bodied double seat mixproof valve, with a drainable opening to the atmosphere between the seats, if:

(1) The drainable opening to the atmosphere (vent) is equal to the largest pipeline ~~feeding the valve(s)~~ connected to the mixproof valve or one (1) of the following exceptions:

i) If the cross sectional area of the vent opening is less than that of the largest pipe diameter for the double seat valve, the maximum pressure in the space between the two (2) valve seats for the double seat valve shall be equivalent to or less than the maximum pressure in the space between the two (2) blocking seats of two (2) automatically controlled compression type valves (three (3)-way valve to the drain and a two (2)-way valve separating product lines from cleaning and sanitizing solution lines); or

ii) In low pressure, gravity drain applications, i.e., cheese curd transfer lines from cheese process vats where the product line is the same size or larger than the cleaning or sanitizing solution line, the vent may be the size of the solution line and the valves or valve seats need not be position detectable. In order to accept this variation, the valve(s) must fail to the blocked position upon loss of air or power, and there shall not be any pumps capable of pushing milk or milk product, cleaning solutions, or sanitizing solutions into this valve arrangement.

(2) Both valves, and valve seats in the case of single-bodied double seat valves, are position detectable and capable of providing an electronic signal when not properly seated in the blocked position. (Refer to Appendix H., I., Position Detection Devices.) …

(6) The vent is not cleaned until milk and milk products have been removed or isolated, except in the case of a properly designed and operated single-bodied double seat valve, in which case, the vent may be cleaned while milk or milk products are present in one (1) of the valve housings. A properly designed and operated single-bodied double-seat valve will incorporate the following:

i) There shall not be any impingement of cleaning liquid on the opposite valve seat gasket during seat lifting, even in the case of damaged or missing gaskets, and

ii) The pressure in the critical seat area of the valve vent cavity, even in the case of damaged or missing gaskets, shall be demonstrated to be atmospheric or less at all times, and

iii) During a seat-lift operation, the position of the seat opposite to the seat being lifted shall be monitored by a proximity switch that is interlocked with the cleaning pump or source of the CIP cleaning solution pressure such that if this opposite seat is determined to be other than fully closed, the cleaning pump …

Page 78:

(7) Variations from the above specifications may be individually evaluated and found to also be acceptable if the level of protection is not compromised.

~~**For Example:** In low pressure, gravity drain applications where the product line is the same size or larger than the cleaning or sanitizing solution line, the vent may be the size of the solution line and the valves or valve seats need not be position detectable. If a common drain line is used to connect vent lines from more than one (1) block-and-bleed~~

~~vent, such as in the case of drain lines from a series of cheese vats with a common drain for the block-and-bleed vent lines, the cross sectional area of the common drain line must be at least equal to the total cross sectional area of the lines connected to the header. Or, a common drain line of the same size as the vent may be used, if provisions are included in a fail-safe control system to sequence the use and cleaning of the vats to assure that no more than one (1) vat attached to that drain can be washed at the same time. All other criteria still apply. In order to accept this variation, the valve(s) must fail to the blocked position upon loss of air or power, and there must be no pumps capable of pushing milk or milk product, cleaning solutions, or sanitizing solutions into this valve arrangement.~~

Proposal: 114
Document: 2009 PMO (Section 7-Item 15p; and Appendix D)
Pages: 81 and 176

Make the following changes to ***SECTION 7, ITEM 15p.(B)-PROTECTION FROM CONTAMINATION*** *on Page 81:*

10. Raw milk or milk product-to-water-to-pasteurized milk or milk product plate or double/triple tube type heat exchangers may be used for heat-exchange purposes, other than legal pasteurization, when constructed, installed and operated in accordance with the following:

a. Plate or double/triple tube type heat exchangers, as described above, shall be constructed, installed and operated so that pasteurized milk or milk product in the plate or double/triple tube type heat exchanger will automatically be under greater pressure than the heat-transfer water in the plate or double/triple tube type heat exchanger at all times.

b. The pasteurized milk or milk product, between the outlet of the last flow promoting device and the entrance to the plate or double/triple tube type heat exchanger, shall rise to a vertical elevation of 30.5 centimeters (12 inches) above the highest heat-transfer water level, downstream from the water supply tank, and shall be open to the atmosphere at this or a higher elevation.

c. The pasteurized milk or milk product, between its outlet from the plate or double/triple tube type heat exchanger and the nearest point downstream open to the atmosphere, shall rise to a vertical elevation of 30.5 centimeters (12 inches) above the highest heat-transfer water level, downstream from the water supply tank, and shall be open to the atmosphere at this or a higher elevation.

d. The overflow of the top rim of the water supply tank shall always be lower than the lowest heat-transfer water level in the plate or double/triple tube type heat exchanger.

e. A pump(s) or flow-promoting device(s), which can affect the proper pressure relationships within the plate or double/triple tube type heat exchanger, shall not be located between the pasteurized milk or milk product outlet from the plate or double/triple tube type heat exchanger and the nearest downstream point open to the atmosphere.

f. A pump(s) shall not be located between the heat-transfer water inlet to the plate or double/triple tube type heat exchanger and the water supply tank, unless it is designed and installed to operate only when pasteurized milk or milk product is flowing through the pasteurized milk or milk product side of the plate or double/triple tube type heat exchanger and when the pressure of the pasteurized milk or milk product is higher than the maximum

pressure produced by the pump(s). This may be accomplished by wiring the heat-transfer water pump(s) so that it cannot operate unless:

(1) Pasteurized milk or milk product is flowing through the pasteurized milk or milk product side of the plate or double/triple tube type heat exchanger; and

(2) The pasteurized milk or milk product pressure exceeds, by at least 6.9 kPa (1 psi), the maximum pressure developed by the heat-transfer water pump. A pressure differential controller shall be installed with a sensor located at the heat-transfer water inlet to the plate or double/triple tube type heat exchanger and the pasteurized milk or milk product outlet of the plate or double/triple tube type heat exchanger. The differential set point of this pressure differential controller shall tested~~,~~ by the Regulatory Agency upon installation; at least once every three (3) months thereafter; whenever the regulatory seal has been broken; and following any repair or replacement. Accuracy shall be determined by utilizing testing procedures as outlined in Appendix I, Test 9.2.1 to assure that the pressure differential controller probes are accurately calibrated. Also, the applicable procedures cited in Appendix I, Test 9.2.2 shall be utilized to assure that the pressure differential controller is accurately calibrated and will de-energize the heat-transfer water pump at the required differential pressure set point.

g. All heat-transfer water in the plate or double/triple tube type heat exchanger will automatically drain freely back to the water supply tank or to the floor when the heat transfer water pump(s) are shut down and the heat-transfer water connection(s) at the plate or double/triple tube type heat exchanger is disconnected.

Make the following changes to ***APPENDIX D. STANDARDS FOR WATER SOURCES*** *on Page 176:*

CATEGORY II. USED FOR LIMITED PURPOSES

Reclaimed water may be used for the following limited purposes ~~including:~~

1. Production of culinary steam.
2. Pre-rinsing of the product surfaces where pre-rinses will not be used in milk or milk products.
3. Cleaning solution make-up water.
4. Non-recirculated heat exchange media used against unpasteurized milk or milk products or acid whey provided it complies with Item 1. as cited below.
5. Non-recirculated heat exchange media used against pasteurized milk and milk products with the plate or double/triple tube type heat exchanger designed and operated in accordance with Item 15p.(B)10.

Proposal: 115
Document: 2009 PMO (Section 7-Item 16p)
Page: 84

Make the following changes to ***SECTION 7, ITEM 16p. PASTEURIZATION AND ASEPTIC PROCESSING*** *on Page 84:*

4. Milk and/or milk products for pasteurization may be processed by micro-filtration (MF) systems prior to pasteurization for the sole purpose of the removal of micro-organisms, provided that:

a. Prior to processing, all raw milk supplies are sampled and tested for antibiotic residues in accordance with the provisions of Appendix N.;

b. If there is a continuous, circulating retentate loop with a feed and bleed system, the following design, installation and operational criteria shall be complied with:

(1) The MF system is designed and operated to assure that milk or milk product temperature in the circulating retentate loop is maintained at or below 18.3ºC (65ºF), or at or above 51.7°C (125°F) throughout the process. Provided that the product temperature may rise above 18.3ºC (65ºF) or fall below 51.7°C (125°F) for a period of not more than fifteen (15) minutes, further provided that should the product temperature rise above 21.1ºC (70ºF) or fall below 48.9°C (120°F), the product shall be either immediately diverted to the system's balance tank until the product is again below 18.3ºC (65ºF) or above 51.7°C (125°F), or be diverted to exit the system entirely. Diverted product that has exited the system shall be either discarded, immediately cooled to below 7°C (45°F), or immediately pasteurized;

(2) The MF system must be equipped with temperature monitoring and recording devices that comply with the applicable specifications outlined in Appendix H. of this *Ordinance*. At a minimum, milk or milk product temperature shall be monitored and recorded prior to entering the MF system and within the circulating retentate loop of each module just prior to the circulation pump;

(3) The permeate from the MF system is either immediately cooled to below 7°C (45°F), or immediately pasteurized.

45. All condensed milk and milk products transported to a milk plant for drying shall be re-pasteurized at the milk plant where it is dried.

(Renumber the remaining Items accordingly.)

Proposal: 116
Document: 2009 PMO (Section 7-Item 16p; and Appendix I)
Pages: 102 and 276

Make the following changes to ***SECTION 7, ITEM 16p.(E.) PASTEURIZATION AND ASEPTIC PROCESSING RECORDS, EQUIPMENT TESTS AND EXAMINATIONS*** *on Page 102:*

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

a. **Batch Pasteurizers**:
(1) Date;
(2) Number or location of recording thermometer when more than one is used;
(3) A continuous record of the product temperature;

(4) Extent of holding period, including filling and emptying times when required;
(5) Reading of airspace thermometer, at the start of the holding period and at the end of the holding period, at a given time or reference point as indicated on the chart; provided, if the airspace thermometer is a digital combination airspace/recording thermometer, which provides a continuous recording of the airspace temperature and has been calibrated by the State Regulatory Agency in accordance with Appendix I, Test 4, the recording of the airspace temperature on the chart shall only be required at the start of the holding period; …

Make the following changes to ***APPENDIX I. PASTEURIZATION EQUIPMENT AND CONTROLS – TESTS, II. TEST PROCEDURES*** *on Page 276:*

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 and for batch pasteurizer digital combination airspace/recording thermometers with a continuous recording of the airspace temperature and where the airspace temperature is read and recorded on the recording chart only at the start of the holding period.

Frequency: Upon installation and at least once each three (3) months by the Regulatory Agency, or HACCP qualified industry person, acceptable to the Regulatory Agency, qualified under Item 16p(E)2; whenever the regulatory seal is broken; and daily by the milk plant ~~operator~~ personnel for the HTST and HHST pasteurization systems.

Criteria: The recording thermometer and recorder-controller thermometer shall not read higher than the indicating or airspace thermometer.

Apparatus: No supplementary materials required.

Method: This Test requires only that the reading of the recording thermometer, ~~or the~~ recorder-controller thermometer or airspace recording thermometer be compared with the indicating thermometer at a time when both are exposed to ~~milk or milk product at~~ a stabilized temperature at or above the minimum legal 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.
2. For batch pasteurizers, while the airspace indicating and recording temperatures are stabilized at or above the minimum legal pasteurization temperature, read the airspace thermometer.

~~2~~3. Immediately record and identify on the recording thermometer chart, the observed indicating and/or airspace thermometer temperature reading and the time at which this comparison was made. This may be accomplished by inscribing a line intersecting the recorded temperature arc at the pen location or other methods acceptable to the Regulatory Agency. …

- - - -

Proposal: 118
Document: 2009 PMO (Section 7-Item 16p)
Page: 103

Make the following changes to ***SECTION 7, ITEM 16p.(E.) PASTEURIZATION AND ASEPTIC PROCESSING RECORDS, EQUIPMENT TESTS AND EXAMINATIONS*** *on Page 103:*

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 (7), 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.

Proposal: 117
Document: 2009 PMO (Section 7-Item 17p)
Pages: 107-111

Make the following changes to ***SECTION 7, ITEM 17p-COOLING OF MILK AND MILK PRODUCTS*** *on Pages 107-111:*

SUBSTITUTE SOLUTION

HHS:PHS:FDA:CFSAN:OFS:DPDFS:DEB:MST

5100 Paint Branch Parkway
College Park, MD 20740-3835

June ??, 2011

IMS-a-45
Supplement 2

To: All Regional Food and Drug Directors
Attn: Regional Milk Specialists

From: Dairy and Egg Branch (HFS-316)

Subject: Additional Action from the 2005 National Conference on Interstate Milk Shipments Related to Proposal 126

The 30th National Conference on Interstate Milk Shipments (NCIMS) was held in Columbus, Ohio, May 12-17, 2005. FDA responded in writing to the NCIMS Conference Chair on

September 2, 2005 and met with the NCIMS Executive Board on September 27, 2005 concerning all of the Proposals passed during the 2005 Conference. FDA did not concur with Proposals 126, 127 and 128 relating to Item 17p-Cooling of Milk and Milk Products of the Grade "A" PMO. FDA and the Executive Board mutually concurred with all of the other Proposals and changes cited in IMS-a-45, which was issued October 1, 2005.

IMS-a-45, page 39, states:

"FDA NON-CONCURRED WITH THIS PROPOSAL

Proposal: 126
Document: 2003 PMO (Section 7-Item 17p)
Page: 102

NOTE: THE NON-CONCURRENCE WITH PROPOSALS 126 AND 127 IS BASED ON THE LACK OF CONCLUSIVE EVIDENCE TO SUPPORT THESE PROPOSALS AT THIS TIME, AFTER A REVIEW OF THE SPECIFIC DATA SUBMITTED TO FDA. INDUSTRY DATA DEVELOPMENT AND FDA REVIEW IS CONTINUING ON THESE PROPOSALS AND IN THE FUTURE ADDITIONAL INFORMATION MAY BE PRESENTED TO THE NCIMS EXECUTIVE BOARD FOR RECONSIDERATION OF THESE PROPOSALS.

Make the following changes to ***SECTION 7. STANDARDS FOR GRADE "A' MILK AND MILK PRODUCTS*** *on Page 102:*

ITEM 17p. COOLING OF MILK AND MILK PRODUCTS

All pasteurized milk and milk products, except those to be cultured and cottage cheese with a pH of 5.3 or less, shall be cooled immediately prior to filling or packaging, in approved equipment, to a temperature of 7ºC (45ºF) or less, unless drying is commenced immediately after condensing. All condensed whey and whey products shall be cooled during the crystallization process to 7°C (45°F) or less within 48 hours of condensing, including the filling and emptying time, unless filling occurs above 57°C (135°F), in which case, the 48 hour time period begins when cooling is started.
All pasteurized milk and milk products, except for cottage cheese with a pH of 5.3 or less, shall be stored at a temperature of 7ºC (45ºF) or less and maintained thereat until further processed.

PUBLIC HEALTH REASON

When milk and milk products are not cooled within a reasonable time, after being received at the milk plant, its bacterial content will be materially increased. The same reasoning applies to cooling the milk and milk products after pasteurization, unless drying is commenced immediately after condensing, or the product is inherently safe and does not support the growth of pathogenic organisms.

ADMINISTRATIVE PROCEDURES

3. All pasteurized milk and milk products, except those to be cultured and cottage cheese with a pH of 5.3 or below*, are cooled immediately in approved equipment prior to filling or packaging

to a temperature of 7ºC (45ºF) or less, unless drying is commenced immediately after condensing.
4. All pasteurized milk and milk products shall be stored at a temperature of 7ºC (45ºF) or less and be maintained thereat until further processed. Provided that cottage cheese (except hot packed cottage cheese) with a pH of 5.3 or below shall be packaged at 13ºC (55ºF) or less and cooled to a temperature of 7ºC (45ºF) or less 72 hours of packaging*. If surge tanks or balance tanks are used between the evaporator and the drier, such tanks shall hold the product at a temperature of 66°C (150°F) or more, or shall be completely emptied and cleaned after each 4 hours of operation or less.

*The following ****Note** is not intended for placement in any NCIMS document.*

***Note: The dairy industry will be responsible for providing FDA with scientific information for evaluation on cottage cheese product.**

Since the September 27, 2005 NCIMS Executive Board meeting, the Dairy Industry has submitted scientific data to FDA addressing Proposal 126 (Cold Filled Cottage Cheese with a pH of 5.3 or below, packaged at a temperature of 13ºC (55 ºF) or less and cooled to a temperature of 7ºC (45ºF) or less within seventy-two (72) hours of packaging).

FDA's Center for Food Safety and Applied Nutrition's (CFSAN) staff has reviewed the Dairy Industry's submitted scientific data and has reached the following conclusions based on the specific scientific data submitted. Those conclusions are identified by the specific criteria and parameters cited below. They address the appropriate changes to be incorporated into Item 17p-Cooling of Milk and Milk Products within the 2011 Grade "A" Pasteurized Milk Ordinance (Grade "A" PMO), which are warranted to address FDA's consensus conclusions from their review of the specific scientific data submitted. Additions are identified as being underlined and deletions are identified as being ~~struck through~~.

CHANGES TO ITEM 17p.-COOLING OF MILK AND MILK PRODUCTS OF THE 2009 GRADE "A" PASTEURIZED MILK ORDINANCE (PMO) PAGES 107-112

ITEM 17p. COOLING OF MILK AND MILK PRODUCTS

All raw milk and milk products shall be maintained at 7ºC (45ºF) or less until processed. All whey and whey products for condensing and/or drying shall be maintained at a temperature of 7°C (45°F) or less; or 57°C (135°F) or greater until processed, except that acid-type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below, is exempted from these temperature requirements.
All pasteurized milk and milk products, except the following, shall be cooled immediately prior to filling or packaging, in approved equipment, to a temperature of 7ºC (45ºF) or less, unless drying is commenced immediately after condensing:

1. Those to be cultured;
2. Cultured sour cream at all milkfat levels with a pH of 4.70 or below*;

3. Acidified sour cream at all milkfat levels with a pH of 4.60 or below*;
4. All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling;
5. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below*;

[6.] NOTE: IMS-a-45 (Supplement 1) approved language as of March 10, 2011 (effective date of April 1, 2011) is identified in [red and in backets] throughout this document.

[Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below* and:

a. Filled at 63°C (145°F) or above* for containers of four (4) ounces (118 ml) or larger, or

b. Filled at 69°C (155°F) or above* for containers of 2.9 ounces (85.6 ml), and

c. The additional] applicable [critical factors*, as cited below, shall also be utilized for either] hot [fill temperature to determine the acceptability of filling at these temperatures~~;~~, ~~and~~] or

d. The addition of potassium sorbate at a minimum concentration of 0.06% and filled at 13ºC (55°F) or less*, or

e. The addition of one (1) of the specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97, and filled at 13ºC (55°F) or less*; and

[~~6~~7]. All condensed whey and whey products shall be cooled during the crystallization process to 10°C (50°F) or less within seventy-two (72) hours of condensing, including the filling and emptying time, unless filling occurs above 57°C (135°F), in which case, the seventy-two (72) hour time period begins when cooling is started.

*Critical factors including, but not limited to, pH, [filling temperature, ~~and~~] cooling [times] and [temperatures,] and potassium sorbate concentration or specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97, if applicable, shall be monitored and documented by the processing facility for verification by the Regulatory Agency. pH limit with a pH variance of + 0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the Regulatory Agency.

NOTE: Microbial inhibitors and/or preservatives and/or all of their individual components shall have GRAS status; and their pathogen inhibition shall be supported by documented challenge study results that are acceptable to the Regulatory Agency and FDA.

All pasteurized milk and milk products, except the following, shall be stored at a temperature of 7ºC (45ºF) or less and maintained thereat following filling or until further processed:

1. Cultured sour cream at all milkfat levels with a pH of 4.70 or below* and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of filling**;
2. Acidified sour cream at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of filling**;
3. All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling, with a pH of 4.60 or below within twenty-four (24) hours of filling* and cooled to 7°C (45°F) or less within ninety-six (96) hours of filling**;
4. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**; and

[5. Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below* and:

a. Filled at 63°C (145°F) or above* for containers of four (4) ounces (118 ml) or larger; cooled to 15°C (59°F) or less within ten (10) hours of filling**; and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**; or

b. Filled at 69°C (155°F) or above* for containers of 2.9 ounces (85.6 ml); cooled to 15°C (59°F) or less within ten (10) hours of filling**; and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**~~.~~]; or

c. The addition of potassium sorbate at a minimum concentration of 0.06% and filled at 13ºC (55°F) or less*; cooled to 10ºC (50°F) or less within twenty-four (24) hours of filling**; and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling**; or

d. The addition of one (1) of the specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97; filled at 13ºC (55°F) or less*; cooled to 10ºC (50°F) or less with twenty-four (24) hours of filling**; and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling**.

*Critical factors including, but not limited to, pH, [filling temperature, ~~and~~] cooling [times] and [temperatures], and potassium sorbate concentration or specified microbial inhibitors and/or preservative, at the specified concentration as addressed in M-a-97, if applicable, shall be monitored and documented by the processing facility for verification by the Regulatory Agency. pH limit with a pH variance of + 0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the Regulatory Agency.

NOTE: Microbial inhibitors and/or preservatives and/or all of their individual components shall have GRAS status; and pathogen inhibition shall be supported by documented challenge study results that are acceptable to the Regulatory Agency and FDA.

** [Cooling temperatures] monitored at the slowest cooling portion, i.e., [in the] middle of the container, of the slowest cooling container, i.e., in the middle of the pallet.

All pasteurized milk and milk products to be condensed and/or dried, shall be stored at a temperature of 10°C (50ºF) or less and be maintained thereat until further processed.

Every refrigerated room or tank, in which milk or milk products, whey and whey products, and condensed milk and milk products are stored, shall be equipped with an accurate indicating thermometer.

On delivery vehicles, the temperature of milk and milk products shall not exceed 7ºC (45ºF).

Aseptically processed milk and milk products to be packaged in hermetically sealed containers shall be exempt from the cooling requirements of this Item.

Electronic Data Collection, Storage and Reporting: The electronic storage of required cleaning records and product storage temperature records, with or without hard copy printouts, shall be acceptable, provided, the electronically generated records are readily available at the milk plant for review by the Regulatory Agency. Electronic records that comply with the applicable provisions of Appendix H., IV and V, with or without hard copy, may be used in place of the cleaning records.

PUBLIC HEALTH REASON

When milk and milk products are not cooled within a reasonable time, after being received at the milk plant, its bacterial content will be materially increased. The same reasoning applies to cooling the milk and milk products after pasteurization, unless drying is commenced immediately after condensing.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. All raw milk and milk products shall be maintained at 7ºC (45ºF) or less until processed, except that acid-type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below, is exempted from these temperature requirements. Provided, that all balance or surge tanks (continuous flow with a retention time not to exceed one (1) hour) for raw milk and milk products, pasteurized milk and milk products and whey and whey products may be maintained at any temperature for up to twenty-four (24) hours.
2. All whey and whey products for condensing and/or drying are maintained at a temperature of 7°C (45°F) or less; or 57°C (135°F) or greater until processed. Storage tanks containing whey and whey product above 7°C (45°F) and below 57°C (135°F) shall be emptied, cleaned and sanitized after each four (4) hours of use or less. ***
3. All pasteurized milk and milk products, except the following, are cooled immediately in approved equipment prior to filling or packaging to a temperature of 7ºC (45ºF) or less, unless drying is commenced immediately after condensing:
   a. Those to be cultured;
   b. Cultured sour cream at all milkfat levels with a pH of 4.70 or below*;
   c. Acidified sour cream at all milkfat levels with a pH of 4.60 or below*;
   d. All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling;
   e. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below*;
   [f. Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below* and:
      (1) Filled at 63°C (145°F) or above* for containers of four (4) ounces (118 ml) or larger, or
      (2) Filled at 69°C (155°F) or above* for containers of 2.9 ounces (85.6 ml), and
      (3) The additional] applicable [critical factors*, as cited below, shall also be utilized for either] hot [fill temperature to determine the acceptability of filling at these temperatures~~;~~, ~~and~~] or
      (4) The addition of potassium sorbate at a minimum concentration of 0.06% and filled at 13ºC (55°F) or less*, or
      (5) The addition of one (1) of the specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97, and filled at 13ºC (55°F) or less*; and

   [~~f~~g]. All condensed whey and whey products shall be cooled during the crystallization process to 10°C (50°F) or less within seventy-two (72) hours of condensing, including the filling and emptying time, unless filling occurs above 57°C (135°F), in which case, the seventy-two (72) hour time period begins when cooling is started. ***

*Critical factors including, but not limited to, pH, [filling temperature, ~~and~~] cooling [times] and [temperatures], and potassium sorbate concentration or specified microbial inhibitors and/or preservative, at the specified concentration as addressed in M-a-97, if applicable, shall be monitored and documented by the processing facility for verification by the Regulatory Agency. pH limit with a pH variance of + 0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the Regulatory Agency.

NOTE: Microbial inhibitors and/or preservatives and/or all of their individual components shall have GRAS status; and pathogen inhibition shall be supported by documented challenge study results that are acceptable to the Regulatory Agency and FDA.

4. All pasteurized milk and milk products, except the following, shall be stored at a temperature of 7°C (45ºF) or less and be maintained thereat following filling or until further processed:

a. Cultured sour cream at all milkfat levels with a pH of 4.70 or below* and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of filling**;

b. Acidified sour cream at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of filling**;

c. All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling, with a pH of 4.60 or below within twenty-four (24) hours of filling* and cooled to 7°C (45°F) or less within ninety-six (96) hours of filling**;

d. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**; and

[e. Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below* and:

(1) Filled at 63°C (145°F) or above* for containers of four (4) ounces (118 ml) or larger; cooled to 15°C (59°F) or less within ten (10) hours of filling**; and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**; or

(2) Filled at 69°C (155°F) or above* for containers of 2.9 ounces (85.6 ml); cooled to 15°C (59°F) or less within ten (10) hours of filling**; and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**~~.~~]; or

(3) The addition of potassium sorbate at a minimum concentration of 0.06% and filled at 13ºC (55°F) or less*, cooled to 10ºC (50°F) or less within twenty-four (24) hours of filling**; and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling**; or

(4) The addition of one (1) of the specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97; filled at 13ºC (55°F) or less*; cooled to 10ºC (50°F) or less with twenty-four (24) hours of filling**; and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling**.

*Critical factors including, but not limited to, pH, [filling temperature, ~~and~~] cooling [times] and [temperatures], and potassium sorbate concentration or specified microbial inhibitors and/or preservative, at the specified concentration as addressed in M-a-97, if applicable, shall be monitored and documented by the processing facility for verification by the Regulatory Agency. pH limit with a pH variance of + 0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the Regulatory Agency.

NOTE: Microbial inhibitors and/or preservatives and/or all of their individual components shall have GRAS status; and pathogen inhibition shall be supported by documented challenge study results that are acceptable to the Regulatory Agency and FDA.

** [Cooling temperatures] monitored at the slowest cooling portion, i.e., [in the] middle of the container, of the slowest cooling container, i.e., in the middle of the pallet.

5. All pasteurized milk and milk products to be condensed and/or dried, shall be stored at a temperature of 10ºC (50ºF) or less and be maintained thereat until further processed. If storage tanks are used between the condenser and dryer, any such storage tank(s) containing pasteurized milk or milk products stored above 10°C (50°F) and below 57°C (135°F) shall be completely emptied and cleaned after each six (6) hours of operation or less. ***

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.

7. Each storage tank shall be equipped with an indicating thermometer, the sensor of which shall be located to permit the registering of the temperature of the contents when the tank contains no more than twenty percent (20%) of its calibrated capacity. Such thermometer shall comply with the applicable specifications of Appendix H.

8. On delivery vehicles, the temperature of milk and milk products shall not exceed 7ºC (45ºF).

9. All surface coolers comply with the following specifications:

a. The sections of open-surface coolers shall be so installed as to leave a gap of at least 6.4 millimeters (0.25 of an inch) between the header sections to permit easy cleaning.

b. Where header ends are not completely enclosed within the cooler covers, condensation or leakage from the headers shall be prevented from entering the milk or milk product by so shaping the exposed header faces, above and below all gaps, that condensation is directed away from the tubes, and by using deflectors at the bottom of the headers; or by shortening the bottom of the headers; or by shortening the bottom trough; or by some other approved method.

c. The location of supports of cooler sections shall prevent condensation and leakage from entering the milk or milk product.

d. All open-surface coolers shall be provided with tight-fitting shields that protect the milk and milk product from contamination by insects, dust, drip, splash or manual contact.

10. Recirculated cooling water, which is used in coolers and heat exchangers, including those systems in which a freezing point depressant is used, is from a safe source and protected from contamination. Such water shall be tested semiannually and shall comply with the Bacteriological Standards of Appendix G. Samples shall be taken by the Regulatory Agency and examination shall be conducted in an Official Laboratory. Recirculated cooling water systems, which become contaminated through repair work or otherwise, shall be properly treated and tested before being returned to use. Freezing point depressants and other chemical additives, when used in recirculating systems, shall be non-toxic under conditions of use.

11. Recirculated cooling water contained in corrosion resistant, continuous piping, with no joints or welds, which fail to meet applicable ASME or equivalent standards in the non-potable water contact areas, may be considered to be protected from contamination, as required above, when cooled by non-potable water flowing over the exterior of the piping, within open evaporative

type cooling tower. In these systems, the recirculated cooling water piping shall be properly maintained and shall be installed so that it is at least two (2) pipe diameters above the flood rim of the cooling tower.

12. Water from an open**,** evaporative cooling tower may be used to cool water in an intermediate cooling media loop that will subsequently be used to cool product, provided that the water in the intermediate cooling media loop is effectively protected against infiltration and contamination by tower water at all times.

If a plate type or double/triple tube type heat exchanger is used to exchange heat between the water from the open tower and the water in the intermediate cooling media loop it must be protected by an Isolation System to assure that there is no possibility of contamination of the intermediate cooling media loop water by the tower water. The Isolation System shall include:

a. Tower water heat exchangers shall be constructed, installed and operated so that the intermediate cooling media water in the heat exchanger will automatically be under greater pressure than the open tower water in the heat exchanger at all times.

b. The tower water heat exchanger shall be effectively isolated from the tower water system and the tower water side of the heat exchanger shall drain during shut down.

c. The Isolation System shall be controlled with a pressure differential controller set to a minimum of 6.9 kPa (1 psi). Pressure sensors shall be installed at the tower water inlet to the heat exchanger and intermediate cooling water outlet of the heat exchanger. The differential pressure controller will be interwired with the related supply valves and/or pumps to automatically shut down all supply pumps and return valves in the Isolation System to a fail-safe position to isolate the heat exchanger from the open tower water system, as would occur in a shut down or power failure.

d. The intermediate cooling water shall rise to a vertical elevation of at least 30.5 centimeters (12 inches) above the highest tower water in the tower water heat exchanger Isolation System, and shall be open to the atmosphere at this elevation. During a shut down the intermediate cooling water shall not drain from the tower water heat exchanger.

e. The Isolation System shall meet one (1) of the following:

(1) In a system with tower water supplied directly from the tower water distribution line without a balance tank, or with a balance tank higher than the lowest water level in the tower water heat exchanger. (Refer to Figures 8, 9, and 10 in Appendix D., VII.)

In this application, the Isolation System shall begin at the normally closed tower water supply stop "block" valve and ends at the check-valve in the line returning to the open cooling tower.

Isolation is accomplished by meeting all of the following:

i) Closing the tower water supply valve. This tower water supply valve shall be a normally closed (spring-to-close) valve;

ii) Opening a full port vent valve on the supply side of the tower water heat exchanger and a full port drain valve prior to a check-valve in the tower water return line. This drain valve shall be normally open (spring-to-open);

iii) The drain valve and any pipes or pumps located between the drain valve and the heat exchanger must be lower than the lowest liquid level in the heat exchanger;

iv) De-energize any dedicated tower water supply pump, if present, located between the tower water reservoir and the tower water heat exchanger; and

v) If a tower water return pump is used, a bypass line may be used to flood the dry pump at start up.

(2) In a system with the overflow of an atmospheric balance tank lower than the lowest water level in the heat exchanger. (Refer to Figures 11 and 12 in Appendix D., VII.)
In this application, the Isolation System shall begin at the tower water balance tank and end at the check-valve in the line returning to the open cooling tower.
Isolation is accomplished by meeting all of the following:

i) De-energizing the "local tower water supply pump", if present. (Refer to Figure 11 in Appendix D., VII.);

ii) Opening a full port vent valve on the supply side of the tower water heat exchanger;

iii) Open a full port drain valve prior to a check-valve in the tower water return line. This drain valve must be normally open (spring-to-open); and

iv) The drain valve and any pipes or pumps located between it and the heat exchanger must be lower than the lowest liquid level in the heat exchanger.

(3) Variations from the above Isolation Systems may be individually evaluated and found to also be acceptable by the Regulatory Agency, if the level of protection required by this ADMINISTRATIVE PROCEDURE is not compromised.
TESTING: A means to test the response of this Isolation System must be developed and available at the milk plant. The accuracy of the required differential pressure controller shall be checked by the Regulatory Agency on installation; every six (6) months thereafter; and following repair or replacement.

*** **NOTE:** Nothing shall be construed as barring other time and temperature relationships, which have been recognized by FDA to be equally efficient and which are approved by the Regulatory Agency.

SECTION IX. APPLICATION OF CONFERENCE AGREEMENTS, A. IMPLEMENTATION OF CHANGES, Items 3. and 4. of the 2009 Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments states:

"3. Those issues with which PHS/FDA does not concur will be referred to the NCIMS Executive Board for further discussion (within thirty (30) days if possible). If mutual concurrence is obtained, the changes shall be effective within one (1) year of the electronic publication of the affected documents or notification to the States by IMS-a, following the Conference at which the changes were approved, unless otherwise mutually agreed upon by PHS/FDA and the NCIMS Executive Board.
4. If mutual concurrence cannot be reached, the matter will be referred to the next Conference for further discussion. In the interim period between the PHS/FDA-NCIMS Executive Board Meeting (referred to in 3. above) and the next NCIMS Conference, PHS/FDA will consider additional information that becomes available concerning Proposals for which there was not mutual concurrence. If review of this additional information causes PHS/FDA to reconsider its position, PHS/FDA may bring Proposals back to the NCIMS Executive Board for reconsideration and the establishment of an alternative effective date."

Based on FDA's review of the additional submitted scientific data from the Dairy Industry related to Proposal 126, since the September 27, 2005 NCIMS Executive Board/FDA meeting to discuss Actions taken at the 2005 Conference, FDA has elected to reconsider its original position of non-concurrence with Proposal 126. FDA brought Proposal 126, with their documented changes to Item 17p-Cooling of Milk and Milk Products of the Grade "A" PMO back to the Executive Board on April 30, 2011 for their reconsideration. During that NCIMS Executive Board meeting the Executive Board concurred with the findings of FDA as cited in this IMS-a and has established an alternative effective date for Proposal 126 to be June 15, 2011.
The specific wording cited within Item 17p, contained within this IMS-a, will be incorporated into the 2011 Grade "A" PMO when it is updated. Copies of this memorandum are enclosed for distribution to Regional Milk Specialists, State Milk Regulatory and Rating Agencies, State Laboratory Evaluation Officers, and State Milk Rating Officers in your region. This memorandum should be widely distributed to representatives of the milk industry and other interested parties, and will be available on the FDA Web Site at http://www.fda.gov at a later date.

Robert F. Hennes, RS, MPH
CAPT, US Public Health Service
Dairy and Egg Branch

HHS:PHS:FDA:CFSAN:OFS:DPDFS:DEB:MST

5100 Paint Branch Parkway

College Park, MD 20740-3835

DRAFT M-a-97

June ??, 2011

Implementation Date: June 15, 2011

TO: All Regional Food and Drug Directors
Attn: Regional Milk Specialists

FROM: Dairy and Egg Branch (HFS-316)

SUBJECT: Specified Microbial Inhibitors and/or Preservatives Accepted By FDA For Use In The Production Of Cottage Cheese That Will Be Filled At 13ºC (55°F) Or Less, Cooled To 10ºC (50°F) Or Less Within Twenty-Four (24) Hours Of Filling, And Cooled To 7°C (45°F) Or Less Within Seventy-Two (72) Hours Of Filling

This is the accompanying document as referenced in IMS-a-45 (Supplement 2)-Additional Action from the 2005 National Conference on Interstate Milk Shipments Related to Proposal 126, dated June ??, 2011, with an effective/implementation date of June 15, 2011 as passed in Proposal 117 from the 2011 NCIMS Conference.

The 30th National Conference on Interstate Milk Shipments (NCIMS) was held in Columbus, Ohio, May 12-17, 2005. FDA responded in writing to the NCIMS Conference Chair on September 2, 2005 and met with the NCIMS Executive Board on September 27, 2005 concerning all of the Proposals passed during the 2005 Conference. FDA did not concur with Proposals 126, 127 and 128 relating to Item 17p-Cooling of Milk and Milk Products of the Grade "A" PMO. FDA and the Executive Board mutually concurred with all of the other Proposals and changes cited in IMS-a-45, which was issued October 1, 2005.

Since the September 27, 2005 NCIMS Executive Board meeting, the Dairy Industry has submitted scientific data to FDA addressing Proposal 126 (Cold Filled Cottage Cheese with a pH of 5.3 or below, packaged at a temperature of 13ºC (55 ºF) or less and cooled to a temperature of 7ºC (45ºF) or less within seventy-two (72) hours of packaging).

FDA's Center for Food Safety and Applied Nutrition's (CFSAN) staff has reviewed the Dairy Industry's submitted scientific data and has reached the following conclusions based on the specific scientific data submitted. Those conclusions are identified by the specific criteria and parameters cited below. They address the appropriate changes to be incorporated into Item 17p-Cooling of Milk and Milk Products within the 2011 Grade "A" Pasteurized Milk Ordinance (Grade "A" PMO), which are warranted to address FDA's consensus conclusions from their review of the specific scientific data submitted.

Following are CFSAN's conclusions based on the specific scientific data submitted for review and the specific criteria and parameters for the cold filled packaging of cottage cheese at a temperature of 13ºC (55 ºF) or less; cooled to 10ºC (50°F) or less within twenty-four (24) hours of filling; and cooled to a temperature of 7ºC (45ºF) or less within seventy-two (72) hours of filling as cited in the Grade "A" PMO:

"ITEM 17p. COOLING OF MILK AND MILK PRODUCTS

ADMINISTRATIVE PROCEDURES

All pasteurized milk and milk products, except the following, shall be stored at a temperature of 7ºC (45ºF) or less and maintained thereat following filling or until further processed:
…

5. Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below* and: …

   c. The addition of potassium sorbate at a minimum concentration of 0.06% and filled at 13ºC (55°F) or less*; cooled to 10ºC (50°F) or less within twenty-four (24) hours of filling**; and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling**; or
   d. The addition of one (1) of the specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97; filled at 13ºC (55°F) or less*; cooled to 10ºC

(50°F) or less with twenty-four (24) hours of filling**; and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling**.
*Critical factors including, but not limited to, pH, filling temperature, cooling times and temperatures, and potassium sorbate concentration or specified microbial inhibitors and/or preservative, at the specified concentration as addressed in M-a-97, if applicable, shall be monitored and documented by the processing facility for verification by the Regulatory Agency. pH limit with a pH variance of + 0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the Regulatory Agency.

NOTE: Microbial inhibitors and/or preservatives and/or all of their individual components shall have GRAS status; and pathogen inhibition shall be supported by documented challenge study results that are acceptable to the Regulatory Agency and FDA.

** Cooling temperatures monitored at the slowest cooling portion, i.e., in the middle of the container, of the slowest cooling container, i.e., in the middle of the pallet."

The following Table includes the FDA accepted specified microbial inhibitors and/or preservatives, at the specified concentration, for use in the production of cottage cheese that will be cold filled packaged at 13ºC (55°F) or less; cooled to 10ºC (50°F) or less within twenty-four (24) hours of filling; and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling at the time of the issuance of this M-a:

PRODUCT BRAND NAME	FOOD INGREDIENTS	SPECIFIED CONCENTRATION TO BE USED	MANUFACTURER
Sea-i®	Glucose (common name is corn sugar, also call *D*-glucose), Glucose Oxidase, Whey (Lactperoxidase, Lactose, and Casein)	0.03% Bioactive Protein I Or 0.04% Bioactive Protein I	Bienca Products
MicroGARD 430	Cultured Skim Milk Blend, NFDM and Maltodextrin	0.15% Fermentate D	Danisco
DURAFresh™ 5015 And DURAFresh™ 5015 +	Cultured Skim Milk and Skim Milk Powder Cultured Skim Milk and Skim Milk	0.1% Fermentate E 0.1% Fermentate E +	Kerry Ingredients

Fargo 763	Powder and Lactic Acid Starter Culture or Starter Culture	Live Culture	
Pura Q™ Safe-RS20P	Cultured Whey and Calcium Lactate	0.15% To 0.5% Fermentate	Purac

NOTE: Proposal 117 as passed at the 2011 NCIMS Conference provided for the issuance of IMS-a-45 (Supplement 2) and accompanying M-a-97 with an effective/implementation date of June 15, 2011. It also provided that future updates to M-a-97 that add, delete or revise the listing of FDA acceptable specified microbial inhibitors and/or preservatives for use in the production of cottage cheese that will be filled at 13ºC (55°F) or less; cooled to 10ºC (50°F) or less within twenty-four (24) hours of filling; and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling will not require a public comment period or follow the protocol established in the *Procedures* document for the issuance of M-a's.

An electronic version of this memorandum is available for distribution to Regional Milk Specialists, State Milk Regulatory Agencies, State Laboratory Evaluation Officers and State Milk Sanitation Rating Officers in your region. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties and will also be available on the FDA Web Site at http://www.fda.gov at a later date.

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to Robert.Hennes@fda.hhs.gov.

Robert F. Hennes, RS, MPH
CAPT, U.S. Public health Service
Dairy and Egg Branch

Proposal: 119
Document: 2009 PMO (Section 7-Item 17p; and Appendix H)
Pages: 107-110 and 219

Make the following changes to ***SECTION 7, ITEM 17p-COOLING OF MILK AND MILK PRODUCTS*** *on Pages 107-110:*

All raw milk and milk products shall be maintained at 7ºC (45ºF) or less until processed. All whey and whey products for condensing and/or drying shall be maintained at a temperature of 7ºC (45ºF) or less; or 57°C (135°F) or greater until processed, except that acid-type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below, is exempted from these temperature requirements.

For a milk or milk product flavoring slurry that contains milk and/or milk products and is not intended to be injected within a HTST pasteurization system as a part of a liquid ingredient injection system as outlined in Appendix H., the tanks and/or vessels used to blend and hold the slurry shall be completely emptied and cleaned after each four (4) hours of operation or less, unless the slurry is stored at a temperature of 7ºC (45ºF) or less, or at a temperature of 66ºC (150ºF) or greater and maintained thereat.
All pasteurized milk and milk products, …

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. All raw milk and milk products shall …
2. All whey and whey products…
3. For a milk or milk product flavoring slurry that contains milk and/or milk products and is not to be injected within a HTST pasteurization system as a part of a liquid ingredient injection system as outlined in Appendix H., the tanks and/or vessels used to blend and hold the slurry shall be completely emptied and cleaned after each four (4) hours of operation or less, unless the slurry is stored at a temperature of 7ºC (45ºF) or less, or at a temperature of 66ºC (150ºF) or greater and maintained thereat.
~~3~~4. All pasteurized milk and milk products ...
~~4~~5. All pasteurized milk and milk products ...
~~5~~6. All pasteurized milk and milk products …
~~6~~7. Each refrigerated room …
~~7~~8. Each storage tank shall …
~~8~~9. On delivery vehicles ...
~~9~~10. All surface coolers ...
~~10~~11. Recirculated cooling water ...
~~11~~12. Recirculated cooling water ...
~~12~~13. Water from an open …

Make the following changes to ***APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT*** *on Page 219:*

THE USE OF LIQUID INGREDIENT INJECTION WITHIN HTST SYSTEMS

6. ~~If the slurry contains milk and/or milk products, tanks used to blend and hold such slurry shall be completely emptied and cleaned after each four (4) hours of operation or less, unless it shall be stored at a temperature of 7ºC (45ºF) or less, or at a temperature of 66ºC (150ºF) or more and be maintained thereat until the time of injection.~~ For a milk or milk product flavoring slurry that contains milk and/or milk products the tanks and/or vessels used to blend and hold the slurry shall be completely emptied and cleaned after each four (4) hours of operation or less, unless the slurry is stored at a temperature of 7ºC (45ºF) or less, or at a temperature of 66ºC (150ºF) or greater and maintained thereat until the time of injection.

- - - -

Proposal: 120
Document: 2009 PMO (Section 8; and Appendix A)
Pages: 117, 118 and 129

Make the following changes to ***SECTION 8. ANIMAL HEALTH*** *on Pages 117 and 118:*

1. All milk for pasteurization shall be from herds ~~in Areas which have Modified Accredited Advanced Tuberculosis (TB) status or higher as determined by the USDA. Provided, that in an Area which fails to maintain such status, any herd shall have been accredited by said Department as tuberculosis free, or shall have passed an annual tuberculosis test, or the Area shall have established a tuberculosis testing protocol for livestock that assures tuberculosis protection and surveillance of the dairy industry within the Area and that is approved by FDA, USDA and the Regulatory Agency.~~ under a tuberculosis eradication program, which meets one (1) of the following conditions:
   a. Areas which have Modified Accredited Advanced Tuberculosis (TB) status or higher as determined by the USDA; or
   b. An Area which fails to maintain such status:
      (1) Any herd shall have been accredited by USDA; or
      (2) Shall have passed an annual tuberculosis test; or
      (3) The Area shall have established a tuberculosis testing protocol for livestock that assures tuberculosis protection and surveillance of the dairy industry within the Area and that is approved by FDA, USDA and the Regulatory Agency.

~~**NOTE:** Under the Federal USDA TB Eradication Program, cattle and other hooved mammals (goats, sheep, water buffalo, etc.) are covered within the USDA State TB status determination.~~

2. All milk for pasteurization shall be from herds under a brucellosis eradication program, which meets one (1) of the following conditions:
   a. Located in a Certified Brucellosis-Free Area as defined by USDA and enrolled in the testing program for such areas; or
   b. Meet USDA requirements for ~~an individually certified herd~~ a Certified Brucellosis-Free Herd; or
   c. Participating in a milk ring testing program at least two (2) times per year at approximately one hundred eighty (180) day intervals and all herds with positive milk ring results shall have the entire herd blood tested within thirty (30) days from the date of the laboratory ring tests; or
   d. Have an individual blood agglutination test on all cattle or bison six (6) months of age or older, except steers and spayed heifers, annually with an allowable maximum grace period not exceeding two (2) months.

NOTE: Under the Federal USDA Brucellosis Eradication Program…

Make the following changes to ***APPENDIX A. ANIMAL DISEASE CONTROL*** *on Page 129:*

Copies of the ~~*Uniform Methods and Rules; Bovine Tuberculosis Eradication, Uniform Methods and Rules for Establishment and Maintenance of Tuberculosis-Free Accredited Herds of Cattle,*~~

~~*Modified Accredited Areas and Areas Accredited Free of Bovine Tuberculosis in the Domestic Bovine*~~ *Bovine Tuberculosis Eradication: Uniform Methods and Rules (available at http://www.aphis.usda.gov/animal_health/animal_diseases/tuberculosis/downloads/tb-umr.pdf)*, and ~~recommended~~ *Brucellosis Eradication*~~,~~: ~~*Recommended*~~ *Uniform Methods and Rules, (available at http://www.aphis.usda.gov/animal_health/animal_diseases/brucellosis/downloads/umr_bovine_bruc.pdf)*, current at the time of the adoption of this *Ordinance* are available electronically using the hyperlinks above or may be obtained from your State Veterinarian or:

Veterinary Services
Animal and Plant Health Inspection Service
U. S. Department of Agriculture
~~Federal Center Building~~
~~Hyattsville, MD 20782~~
4700 River Road, Unit 43
Riverdale, MD 20737
http://www.aphis.usda.gov/animal_health/ …

Document: No Document Referenced

The Other Species committee recommends that the Conference Chair assign an ad-hoc committee to develop acceptable program options for the control of tuberculosis and brucellosis for hooved mammals not covered by the USDA Bovine Tuberculosis and Brucellosis Eradication Programs.

Proposal: 210
Document: 2009 PMO (Appendix B)
Pages: 135

Make the following changes to ***APPENDIX B. MILK SAMPLING, HAULING AND TRANSPORTATION*** *on pages 135:*

IV. MILK TANK TRUCK PERMITTING AND INSPECTION

INSPECTION: Each milk tank truck shall be inspected at least once each year by a Regulatory Agency. (Refer to Section 5 of this *Ordinance.*) A copy of the current inspection report shall accompany the milk tank truck at all times, or the tank shall bear an affixed label, which identifies the Regulatory Agency with the month and year of inspection. The affixed label shall be located near the tank outlet valve or on the front left side of the milk tank truck bulkhead.

Proposal: 121
Document: 2009 PMO (Appendix D)
Pages: 174-177

Make the following changes to ***APPENDIX D. STANDARDS FOR WATER SOURCES*** *on Pages 174-177:*

IV. CONTINUOUS WATER DISINFECTION

ULTRAVIOLET DISINFECTION OF WATER

7. The materials of construction shall not impart toxic materials into the water either as a result of the presence of toxic constituents in the materials of construction or as a result of physical or chemical changes resulting from exposure to UV energy.

Criteria for the Acceptability of a UV Disinfection Unit for Farm Water Supplies with a Flow Rate Less than Twenty (20) Gallons Per Minute:

1. When used to disinfect water to potable drinking water standards, UV light shall be applied so that the entire volume of water receives at least a minimum reduction equivalent does of UV at 2,537 Angstrom (254 nanometers) of 40,000 microwatt-seconds per square centimeter.
2. A flow or time delay mechanism shall be provided so that all water moving past the flow stop or divert valve receives the minimum dose required above.
3. The unit shall be designed to permit the frequent cleaning of the system without disassembly of the unit and shall be cleaned often enough to ensure that the system will provide the required dose at all times.
4. An accurately calibrated UV intensity sensor, properly filtered to restrict its sensitivity to the 2,500-2,800 Angstrom (250-280 nanometers) germicidal spectrum, shall measure the UV energy from the lamps. There shall be one (1) sensor for each UV lamp.
5. A flow-diversion valve or automatic shut-off valve shall be installed which will permit flow into the potable water lines only when at least the minimum required UV dosage is applied. When power is not being supplied to the unit, the valve shall be in a closed (fail-safe) position which will prevent the flow of water into the potable water lines.
6. An automatic flow control valve, accurate within the expected pressure range, shall be installed to restrict flow to the maximum design flow of the treatment unit so that the entire volume of water receives the minimum dose required above.
7. The materials of construction shall not impart toxic materials into the water either as a result of the presence of toxic constituents in the materials of construction or as a result of physical or chemical changes resulting from exposure to UV energy.

NOTE: Existing water supplies which otherwise comply with the applicable requirements of this Appendix may continue to use UV disinfection systems that were accepted under M-a-18 (Use of Ultraviolet Process for Disinfection of Water). Replacement systems must comply with this *Ordinance*.

V. WATER RECLAIMED FROM MILK AND MILK PRODUCTS AND FROM HEAT EXCHANGERS IN MILK PLANTS

CATEGORY I. USED FOR POTABLE WATER PURPOSES

Page 175:

7. Approved chemicals, such as chlorine, with a suitable detention period, or UV disinfection that complies with the criteria in Appendix D. may be used to suppress the development of bacterial growth and prevent the development of tastes and odors.
8. ~~The addition of chemicals shall be~~ When chemicals are added, they shall be added by an automatic proportioning device, prior to the water entering the storage vessel, to assure satisfactory quality water in the storage vessel at all times. …

Page 176:

CATEGORY II. USED FOR LIMITED PURPOSES

1. There is no carry-over of water from one (1) day to the next, and any water collected is used promptly; or …

b. The water is treated with a suitable, approved chemical to suppress bacterial propagation by means of an automatic proportioning device, or UV disinfection that complies with the criteria in Appendix D., prior to the water entering the storage tank; or …

Page 177:

VI. WATER RECLAIMED FROM HEAT EXCHANGER PROCESSES OR COMPRESSORS ON GRADE "A" DAIRY FARMS

8. Approved chemicals, such as chlorine, with a suitable retention period, or UV disinfection that complies with the criteria in Appendix D. may be used to suppress the development of bacterial growth and prevent the development of tastes and odors. …

Proposal: 215
Document: 2009 PMO (Appendix G)
Page: 211

Make the following changes to ***APPENDIX G. CHEMICAL AND BACTERIOLOGICAL TESTS*** *on Page 211:*

I. PRIVATE WATER SUPPLIES AND RECIRCULATED WATER - BACTERIOLOGICAL

…
Criteria: A Most Probable Number (MPN) of coliform organisms of less than 1.1 per 100 mL, when ten (10) replicate tubes containing 10 mL, or when five (5) replicate tubes containing 20 mL are tested using the Multiple Tube Fermentation (MTF) technique, or one of the Chromogenic Substrate ~~techniques~~ multiple tube procedures; a direct count of less than 1 per 100 mL using the Membrane Filter (MF) technique; or a presence/absence (P/A) determination indicating less than 1 per 100 mL when one vessel containing 100 mL ~~are~~ is tested using the MTF technique or one of the Chromogenic Substrate ~~techniques~~ procedures. The Chromogenic

~~s~~Substrate ~~techniques~~ procedures are not acceptable for recirculated cooling water. Any sample producing a bacteriological result of Too Numerous To Count (TNTC)~~, greater than 200 total bacteria colonies per 100 mL,~~ or Confluent Growth (CG)~~, bacterial growth covering the entire filtration area or a portion thereof and colonies are not discrete~~ by the MF technique; or turbidity in a presumptive test with no gas production and ~~without~~ with no gas production in confirmation (optional test) by the MTF technique (both MPN and P/A format) shall be considered invalid and shall have a Heterotrophic Plate Count (HPC)~~,~~ from the same sample or subsequent resample~~,~~ of less than 500 ~~colonies~~ colony forming units (CFU) per mL in order to be deemed satisfactory. Findings by HPC shall be reported as Positive or Not-Found. …

Proposal: 123
Document: 2009 PMO (Appendix H)
Page: 218

Make the following changes to ***APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT*** *on Page 218:*

I. HTST PASTEURIZATION

THE USE OF LIQUID INGREDIENT INJECTION WITHIN HTST SYSTEMS

Milk or milk product flavoring slurries, condensed milk or milk products, and cream or skim for standardization and similar ingredients may be injected at a point after the last regenerator and before the timing pump, if all of the following conditions are met:

1. The slurry injection valve(s) is (are) closed and the slurry pump is de-energized:
   a. When the FDD is in the ~~inspect~~ "Inspect" mode;
   b. When the timing pump is not in operation; and
   c. When the temperature is below the required minimum legal pasteurization temperature and the FDD is not in the fully diverted position.

   NOTE: The slurry pump may remain energized provided:

   A spring-to-close and air-to-open blocking valve is located between the slurry injection pump and the slurry injection valve(s) described in 2 below.
   All valves shall be inter-wired to assure they fully isolate the slurry pump from the pasteurization system when the FDD is not in the forward-flow position or whenever any flow-promoting device(s), which is (are) upstream of the FDD and are capable of generating flow through the FDD, is (are) not in operation.

2. The slurry injection valve(s) is (are) of the fail-safe type, spring-to-close and air-to-open, …

Proposal: 124
Document: 2009 PMO (Appendix H)
Pages: 221 and 222

Make the following changes to ***APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT*** *on Pages 221 and 222:*

I. HTST PASTEURIZATION

MAGNETIC FLOW METER BASED TIMING SYSTEMS ~~FOR~~ WITHIN ~~HTST~~ CONTINUOUS FLOW ~~PASTEURIZERS~~ PASTEURIZATION SYSTEMS

Many ~~HTST~~ ~~pasteurizing system~~ pasteurization systems use magnetic flow meter based timing systems (MBTS). The flow through these timing systems is developed by a combination of flow promoting devices including booster and stuffer pumps, separators and clarifiers, homogenizers and positive displacement pumps.

Item 16p(B)2(f) of Section 7 provides for their use, provided they meet the following specifications for design, installation and use.
Components: Magnetic flow meter based timing systems shall consist of the following components:

1. A ~~sanitary~~ magnetic flow meter which has been reviewed by FDA or one (1) which ~~is equally accurate, reliable and will produce six (6) consecutive measurements of holding time within 0.5 seconds of each other~~ meets the following criteria for accuracy and reliability:
   a. Self-diagnostic circuitry that provides constant monitoring of all sensing, input and conditioning circuits. The diagnostic circuitry shall be capable of detecting "open" circuits, "short" circuits, poor connections and faulty components. Upon the detection of a failure of any component, the magnetic flow meter read-out shall blank or become unreadable.
   b. The electro-magnetic compatibility of the magnetic flow meter shall be documented and available to the Regulatory Agency. The magnetic flow meter shall be tested to determine the effects of electrostatic discharge, power fluctuation, conductive emission and susceptibility, and radiative emission and susceptibility.
   c. The effect of exposure to specific environmental conditions shall be documented. The magnetic flow meter shall be tested to determine the effects of low and high temperatures, thermal shock, humidity, physical shock and salt fog.
   d. The magnetic flow meter converter or transmitter and flow sensor, for those magnetic flow meters in which flow sensor sealing is required, shall be constructed so that they can be sealed by the Regulatory Agency.
   e. The calibration of the magnetic flow meter shall be protected against unauthorized changes.
   f. The magnetic flow meter shall be protected against unauthorized converter or transmitter replacement. If flow tubes are replaced, the Regulatory Agency shall be notified and such replacement shall be regarded as a replacement of the magnetic flow meter and subject to Regulatory Agency inspection and all applicable tests under Appendix I. of this *Ordinance*.

g. The flow tube shall be encased in appropriate material and constructed in such a manner that the final assembly complies with the conditions cited within Item 11p of this *Ordinance*.

Calibration: The calibration shall be based on multiple points for the entire range of the magnetic flow meter for MBTS application. The magnetic flow meter shall be tested against a traceable NIST standard. The procedure(s) used for the magnetic flow meter calibration is documented and available to the Regulatory Agency.

Accuracy: At mid range, six (6) consecutive flow measurements are taken at the same flow setting. From these six (6) measurements, the standard deviation is calculated. The standard deviation for these measurements shall be less than 0.5%. Compliance of the magnetic flow meter would be determined through the actual installation field-testing of the magnetic flow meter.

2. Suitable converters for conversion of electric and/or air signals to the proper mode for the operation of the system.

3. A suitable flow recorder capable of recording flow at the flow alarm set point and also at least 19 liters (5 gallons) per minute higher than the flow alarm setting. The flow recorder shall have an event pen that shall indicate the status of the flow alarm with respect to flow rate.

4. A flow alarm, with an adjustable set point, shall be installed within the system which will automatically cause the FDD to be moved to the divert position whenever excessive flow rate causes the milk or milk product holding time to be less than the legal holding time for the pasteurization process being used. The flow alarm shall be tested by the Regulatory Agency in accordance with the procedures of Appendix I, Test 11, 2.A and B at the frequency specified. The flow alarm adjustment shall be sealed. **NOTE:** Test 11, 2.A is not applicable to HHST systems.

5. A low-flow or loss-of-signal alarm shall be installed with the system, which will automatically cause the FDD to be moved to the divert position whenever there is a low-flow or loss-of-signal from the magnetic flow meter. The low-flow or loss-of-signal provision shall be tested by the Regulatory Agency in accordance with Appendix I, Test 11, 2.C at the frequency specified. The low-flow or loss-of-signal provision shall be sealed.

6. For HTST systems, ~~When~~ when the legal flow rate has been reestablished, following an excessive flow rate, a time delay ~~must~~ shall be instituted, which will prevent the FDD from assuming the forward-flow position ~~until~~ for at least a minimum of fifteen (15) ~~seconds, for milk or milk product,~~ or twenty-five (25) seconds ~~for eggnog and similar products, of continuous legal flow has been re-established~~ depending upon the product being pasteurized and the temperature being utilized. The time delay ~~must~~ shall be tested and sealed by the Regulatory Agency ~~and if it is of the adjustable type shall be sealed~~.

For HHST systems, when the legal holding time has been reestablished, following an excessive flow rate, a time delay at least as long as the legal flow rate shall be instituted, which will prevent the FDD from assuming the forward-flow position until at least the legal holding time within the holding tube has been reestablished. This time delay shall be built into the sequence logic that requires all conditions for legal pasteurization to be satisfied and that legal pasteurization temperature exists from the holding tube to the FDD, before the FDD can assume the forward-flow position.

7. For HTST systems, ~~A~~ a sanitary check valve or normally closed automatically controlled sanitary valve shall be installed with the magnetic flow meter to prevent a positive pressure in

the raw milk or milk product side of the regenerator whenever a power failure, shutdown or flow-diversion occurs. **NOTE:** This provision is not applicable to HHST systems.
8. For HTST systems, ~~When~~ when a regenerator is used with large systems, it will be necessary to bypass the regenerator during start-up and when the FDD is in the diverted-flow position. Care ~~should~~ shall be taken in the design of such bypass systems to assure that a dead-end does not exist. A dead-end could allow milk or milk product to remain at ambient temperature for long periods of time and allow bacterial growth in the milk or milk product. Caution ~~should~~ shall also be observed with such bypass systems and any valves used in them so that raw milk or milk product will not be trapped, under pressure in the raw regenerator plates, and not have free drainage back to the constant-level tank when shutdown occurs. **NOTE:** This provision is not applicable to HHST systems.
9. ~~Most systems will utilize a dual stem FDD and will be using the timing pump during the CIP cleaning cycle. All public health controls, required of such systems, must be applicable.~~ When switching to the "CIP" position, the FDD ~~must~~ shall move to the divert position and ~~must~~ shall remain in the diverted-flow position for at least ten (10) minutes, regardless of temperature, and for HTST systems the booster pump cannot run during this ten (10) minute time delay.
10. All MBTS pasteurization systems shall be designed, installed and operated so that all applicable tests required by Section 7, Item 16p(E) can be performed by the Regulatory Agency, at the frequency specified. (Refer to Appendix I.) Where adjustment or changes can be made to these devices or controls, appropriate seals shall be applied by the Regulatory Agency after testing, so that changes cannot be made without detection.
11. Except for those requirements directly related to the physical presence of the timing pump, all other requirements of the most recent edition of this *Ordinance* are applicable.

Placement of Components: Individual components in ~~the~~ a magnetic flow ~~meter based timing systems~~ MBTS shall comply with the following placement conditions:

1. The timing ~~pump~~ system's flow promoting device(s) shall be located ~~downstream~~ upstream from the ~~raw milk or milk product regenerator section, if a regenerator is used~~ magnetic flow meter.
2. The magnetic flow meter shall be placed ~~before the holding tube and~~ after ~~any bypassed regenerator(s)~~ the last raw product regenerator outlet and upstream of the holding tube ~~any bypassed regenerator(s)~~. There shall be no intervening flow-promoting components between the magnetic flow meter and the holding tube.
3. For HTST systems, ~~The~~ when a ~~control valve~~ sanitary check valve or normally closed automatically controlled sanitary valve, as described in #7 above, is used with ~~the~~ a variable or constant speed flow promoting device, ~~may~~ it shall be located downstream ~~of the magnetic flow meter~~ of the last regenerator outlet and upstream of the holding tube. **NOTE:** This provision is not applicable to HHST systems.
~~4. The magnetic flow meter, the sanitary check valve or normally closed control valve, shall all be located upstream from the start of the holding tube.~~
~~5~~4. All flow-promoting devices, which are upstream of the FDD~~, such as booster and stuffer pumps, separators and clarifiers, homogenizers and positive displacement pumps~~ and which are capable of generating flow through the FDD, shall be properly interwired with the FDD so that they may run and produce flow through the system at sub-legal temperatures, only when the FDD is in the fully diverted position and ~~when~~ in "Product" run mode, or "CIP" mode after the

ten (10) minute time delay has timed out. Such flow promoting devices shall be de-energized in "Inspect" mode. Separators or clarifiers that continue to run, after they are de-energized ~~must~~ shall be automatically valved-out of the system, with fail-safe valves, so that they are incapable of producing flow.

~~6~~5. There shall be no product entering or leaving the system, i.e., cream or skim milk from a separator or other product components, between the magnetic flow meter and the ~~FDD~~ holding tube.

~~7~~6. The magnetic flow meter shall be so installed that the milk or milk product has contact with both electrodes at all times when there is flow through the system. This is most easily accomplished by mounting the flow tube of the magnetic flow meter in a vertical position with the direction of flow from the bottom to the top. However, horizontal mounting is acceptable when other precautions are taken to assure that both electrodes are in contact with the product and the horizontal line shall remain full of liquid during operation. ~~They should~~ Magnetic flow meters shall not be mounted on a ~~high~~ horizontal line that may be only partially full and thereby trap air.

~~8~~7. The magnetic flow meter shall be piped in such a manner that at least ten (10) pipe diameters of straight pipe exists, upstream and downstream from the center of the magnetic flow meter, before any elbow or change of direction takes place. Except that other piping configurations upstream and downstream of the magnetic flow meter may also be used if they have been reviewed and found acceptable to FDA and the Regulatory Agency.

Proposal: 126
Document: 2009 PMO (Appendix H)
Pages: 252 and 253

Make the following changes to ***APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT*** *on Pages 252 and 253:*

V. CRITERIA FOR THE EVALUATION OF ELECTRONIC DATA COLLECTION, STORAGE AND REPORTING

CRITERIA

8. The electronic computerized data collection, storage, and reporting system shall provide for any signatures or initials required by this *Ordinance*. Acceptable operator signatures or initials, captured electronically, may be any combination of alpha and/or numeric characters that identify the individual performing the test or operation. Input of this signature or initials may be done by any means, including, but not limited to, a biometric reader, a card or radio frequency device, or by simple direct entry that provides a unique identifier directly associated with a specific person. Input of this signature or initials must occur each time it is required by this *Ordinance*. ~~A login~~ Except that in the case of pasteurization and aseptic processing records, the operator's signature or initials must occur whenever an operator changes and at a minimum frequency of once every twenty-four (24) hours. …

Proposal: 127
Document: 2009 PMO (Appendix H)
Page: 256

Make the following changes to ***APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT*** *on Page 256:*

VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED CONTROLS FOR GRADE "A" PUBLIC HEALTH CONTROLS

CRITERIA

4. The status of the inputs and outputs of the public health computer may be provided as inputs only to other computer systems and all public health outputs or devices shall be controlled by direct hard-wiring from the output terminal bus of the computer to the device. This includes solenoids, motor speed controls, such as frequency drives, and motors located within the HTST or HHST system. The wiring connections must be provided with isolation protection such as relays, diodes, or optical-coupling devices to prevent the public health outputs from being driven by the other computer system. Digital outputs from another computer may be connected to an input of the public health computer in order to request the operation of a device controlled by the public health computer. This section shall not be interpreted to prohibit control of the motor speed controls, such as frequency drives, by non-public health computer systems provided that the regulatory limits cannot be altered or disabled.

Proposal: 128
Document: 2009 PMO (Appendix H)
Page: 258

Make the following changes to ***APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT*** *on Page 258:*

VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED CONTROLS FOR GRADE "A" PUBLIC HEALTH CONTROLS

17. Computers require high quality; clean, well-regulated power supplies to operate reliably and safely. Spurious voltage spikes can cause unwanted changes in public health computer RAM. To assure the public health computer will execute its functions error free the following items parameters must be considered:

a. A "clean" power source that is relatively free of spikes, interference and other irregularities shall be supplied to the public health computer.

b. The correct program should be confirmed at the time of sealing. (Refer to the criteria cited within #9 of this Section).

c. The output bus "last state" switch should be in the "off" or "fail-safe" position which will stop all functions of the HTST or HHST pasteurizer in case of a spurious program error.

d. All public health computer outputs shall not have any operator override switches and must be wired in a manner that only allows the public health PLC complete control.

~~Some mechanical and electrical components also deteriorate with age. One (1) solution is to have two (2) permanent programs in the public health computer; one (1) in RAM and one (1) in ROM. Through a self-diagnostic test, these two (2) programs could be compared routinely. If there were differences in the programs, the public health computer would go into default mode. Another solution would be to download the program from ROM to RAM at every start-up. A third solution could be to have the public health computer read the program directly from unchangeable ROM. However, this approach is practical only in large volume (home appliances, etc.) applications. For most small volume applications, the ROM's are field alterable, such as EPROMS, EEPROMS and EAPROMS. These types of computer programs cannot be relied upon to maintain a permanent record.~~ It is necessary that the installer or designer for the public health PLC ensure that the proper program is in the public health computer memory before the Regulatory Agency seals the computer. It is also necessary that any program changes be written to the public health computer's back-up chip if one exists. …

Proposal: 129
Document: 2009 PMO (Appendix H)
Page: 267

Make the following changes to ***APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT*** *on Page 267:*

VIII. MILK AND MILK PRODUCTS HACCP CCP MODELS FOR PASTEURIZATION EQUIPMENT

MILK AND MILK PRODUCT CONTINUOUS-FLOW (HTST AND HHST) PASTEURIZATION --- CCP MODEL HACCP PLAN SUMMARY

(Modify the footnote at the bottom of the model table on page 267 of the 2009 PMO to read as below):

**Every particle of milk or milk product is heated, in a properly designed, calibrated and operated pasteurizer, to one of the temperature and time combinations specified in the current *Grade "A" PMO*.

Proposal: 308
Document: 2007 PMO (Section 11)
Pages: 121 and 122

Make the following change to ***SECTION 11. MILK AND MILK PRODUCTS FROM POINTS BEYOND THE LIMITS OF ROUTINE INSPECTION*** *on Pages 112 and 122:*

Milk and milk products, from points beyond the limits of routine inspection of the ... of... or its jurisdiction, shall be sold in…, [1] or its jurisdiction provided they are produced and pasteurized, ultra-pasteurized, aseptically processed, retort processed after packaging, 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~~ an ~~satisfactory~~ acceptable 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 the 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.

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: …

Page 122:

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

12. Retort processed after packaging milk and milk products as addressed in Definition X of this *Ordinance* shall be considered to be Grade "A" milk or milk products if they are used as an ingredient to produce any milk or milk product defined in Definition X of this *Ordinance*; or if they are labeled as Grade "A" as described in Section 4 of this *Ordinance*. Retort processed after packaging milk and milk products shall be labeled "Grade "A"" and meet Section 4 labeling requirements of this *Ordinance* whenever they meet the provisions cited within Definition X of this *Ordinance*. The source(s) of the milk and/or milk products used to produce retort processed after packaging Grade "A" milk and/or milk products shall be IMS listed. The milk plant or portion of the milk plant that is producing retort processed after packaging Grade "A" milk and/or milk products shall be awarded a Milk Sanitation Compliance Rating of at least ninety percent (90%) and an Enforcement Rating equal to the local supply, or equal to ninety percent (90%) or higher; or if the Enforcement Rating is below ninety percent (90%) on a rating, a re-rating must occur within (6) months of this rating. Both the Milk Sanitation Compliance and Enforcement Ratings must be equal to ninety percent (90%) or higher on the re-rating; or the supply is considered in violation of this Section. In the case of HACCP/Retort listings, an acceptable HACCP listing by a SRO is required. For milk plants that produce retort processed after packaging Grade "A" milk and/or milk products and prior to the milk plant participating in the NCIMS Retort Pilot Program, the State's regulatory and rating personnel shall have completed a training course that is acceptable to the NCIMS and FDA addressing the procedures for conducting regulatory inspections and ratings under the NCIMS Retort Pilot Program. The NCIMS Retort Pilot Program addressing retort processed after packaging Grade

"A" milk and milk products regulated under 21 CFR Parts 108, 110, and 113 will expire on December 31, 2013, unless extended by future conference action.

The following text is a mandatory part of this solution but will not be placed in an NCIMS document:

NOTE: *This provision shall take immediate effect upon the issuance of the IMS-a, Actions from the 2011 National Conference on Interstate Milk Shipments, following FDA's concurrence with the NCIMS Executive Board.*

This NCIMS Retort Pilot Program shall be assigned as a part of the NCIMS Aseptic Pilot Program Implementation Committee's (APPIC) current charge that addresses aseptically processed and packaged Grade "A" low acid milk and milk products. The APPIC shall also be responsible for the oversight of the NCIMS Retort Pilot Program addressing retort processed after packaging Grade "A" milk and milk products in consultation with FDA; and shall include the development of required forms, documents and guidance necessary to implement, evaluate and provide training, as well as study current and new retort technology and its application. The APPIC shall provide a report to the 2013 NCIMS.

All milk plants producing retort processed after packaging Grade "A" milk and/or milk products, as defined by the PMO and regulated under the NCIMS program shall participate in the NCIMS Retort Pilot Program for those milk and/or milk products.

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Make the following change to ***SECTION IV. OVERSIGHT AND RESPONSIBILITIES*** *on Page 7:*

A. **PHS/FDA RESPONSIBILITES**

4. Laboratory Evaluation

a. PHS/FDA shall evaluate and approve the laboratory facilities and procedures of State Laboratory Approval Agencies to assure compliance with FDA 2400 Series Evaluation Forms and, where appropriate, the current edition of ~~*Standard Methods for the Examination of Dairy Products* (*SMEDP*) and~~ *Official Methods of Analysis of AOAC INTERNATIONAL (OMA).*

b. PHS/FDA shall periodically evaluate milk laboratories of participating States to assure compliance with FDA 2400 Series Evaluation Forms, and where appropriate, the current edition of ~~*SMEDP* and~~ *OMA*. Evaluations conducted during recertification of LEOs shall be submitted, but it shall be the option of the LEO as to whether or not the evaluation is submitted for official action regarding laboratory status~~.~~, except when the LEO is conditionally approved. All laboratory evaluations conducted by conditionally approved LEOs are official.

Make the following change to ***SECTION VI. STANDARDS*** *on Page 27:*

I. **LABORATORY PROCEDURES**

Laboratory procedures used to examine milk and milk products of interstate milk shippers shall conform to the procedures in the current ~~edition of *SMEDP*, published by the American Public Health Association,~~ revisions of the NCIMS/FDA 2400 Series Forms and the *OMA* using only methods approved by the NCIMS. Vitamin testing shall be performed using test methods acceptable to PHS/FDA and other official methodologies that give statistically equivalent results to the PHS/FDA methods.

Proposal: 216
Document: 2009 MMSR (Section G; Appendix A; and FORM FDA 2359j-Section D-and Section E)
Pages: 30, 31, 48, 51, 52, 54, 56, 76, 77 and 82-84

Make the following change to ***SECTION G. EXAMPLES OF RATING AND NCIMS HACCP LISTING FORMS*** *on Pages 30 and 31 and* ***SECTION H. EXAMPLES OF HOW TO PROPERLY COMPLETE RATING AND NCIMS HACCP FORMS*** *on Pages, 48, 51, 52, 54 and 56:*

4. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4)……..

5. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 5)…….

NOTE: *Update the FORMs cited above as indicated below:*

Page 30:

SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS

For the Calculation of
DAIRY FARM ENFORCEMENT
PROCEDURES
(Refer to PART I, Item 10 on PAGE 2 of this Form)

1 Category I-Permit Issuance ~~(PI)~~
2 Category II-Permit Suspension ~~(PS)~~
3 Category III-Permit Revocation ~~(PR)~~
4 Category IV-Permit Reinstatement ~~(PRI)~~
5 Category V-Hearing/Court Action ~~(H/CA)~~

FORM FDA 2359j (~~10/09~~ 10/12) (PAGE 4) (PREVIOUS EDITIONS ARE OBSOLETE)

Refer to the actual FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4) on Page 65.

NOTE: *Also make these same changes on Pages 51, 54 and 56 of the 2009 MMSR.*

Page 31:

SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS

For the Calculation of
MILK PLANT ENFORCEMENT
PROCEDURES
(Refer to PART II, Item 9 on PAGE 2 of this Form)

1 Category I-Permit Issuance ~~(PI)~~
2 Category II-Permit Suspension ~~(PS)~~
3 Category III-Permit Revocation ~~(PR)~~
4 Category IV-Permit Reinstatement ~~(PRI)~~
5 Category V-Hearing/Court Action ~~(H/CA)~~

FORM FDA 2359j (~~10/09~~ 10/12) (PAGE 5) (PREVIOUS EDITIONS ARE OBSOLETE)

Refer to the actual FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 5) on Page 66.

NOTE: *Also make these same changes on Pages 48 and 52 of the 2009 MMSR.*

MILK SANITATION RATING REPORT

SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS

SHIPPER
LOCATION
BTU NUMBER
INSPECTING AGENCY
DATE(S)

The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on PAGE 2 of this Form.

For the Calculation of DAIRY FARM ENFORCEMENT PROCEDURES

(Refer to PART I, ITEM 10 on PAGE 2 of this Form)

Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I-Permit Issuance ~~(PI)~~				20	
2	Category II-Permit Suspension ~~(PS)~~				20	
3	Category III-Permit Revocation ~~(PR)~~				20	
4	Category IV-Permit Reinstatement ~~(PRI)~~				20	
5	Category V-Hearing/Court Action ~~(H/CA)~~				20	
					100	

TOTAL CREDIT ➡

TOTAL CREDIT to be entered into PART I, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.

REMARKS

For the Calculation of DAIRY FARM RECORDS

(Refer to PART I, ITEM 11 on PAGE 2 of this Form)

Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I-Permit Records				25	
2	Category II-Inspection Records				25	
3	Category III-Laboratory Records				25	
4	Category IV-Plan Review File (Within Rating Period)				25	
					100	

TOTAL CREDIT ➡

TOTAL CREDIT to be entered into PART I, Item 11 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.

REMARKS

FORM FDA 2359j (~~10/09~~ 10/12) (PAGE 4) (PREVIOUS EDITIONS ARE OBSOLETE)

SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS

SHIPPER
LOCATION
PLANT NUMBER
INSPECTING AGENCY
DATE(S)

The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on PAGE 2 of this Form.

For the Calculation of MILK PLANT ENFORCEMENT PROCEDURES

(Refer to PART II, ITEM 9 on PAGE 2 of this Form)

Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I-Permit Issuance ~~(PI)~~				20	
2	Category II-Permit Suspension ~~(PS)~~				20	
3	Category III-Permit Revocation ~~(PR)~~				20	
4	Category IV-Permit Reinstatement ~~(PRI)~~				20	
5	Category V-Hearing/Court Action ~~(H/CA)~~				20	
					100	

TOTAL CREDIT ➡

TOTAL CREDIT to be entered into PART II, Item 9 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.

REMARKS

For the Calculation of MILK PLANT RECORDS

(Refer to PART II, ITEM 10 on PAGE 2 of this Form)

Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I-Permit Records				25	
2	Category II-Inspection/Equipment Records				25	
3	Category III-Laboratory Records (Also Containers/Vitamin Volume Control)				25	
4	Category IV-Plan Review File (Within Rating Period)				25	
					100	

TOTAL CREDIT ➡

TOTAL CREDIT to be entered into PART II, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.

REMARKS

FORM FDA 2359j (~~10/09~~ 10/12) (PAGE 5) (PREVIOUS EDITIONS ARE OBSOLETE)

Make the following changes to ***APPENDIX A. GUIDELINES FOR COMPUTING ENFORCEMENT RATINGS*** *on Pages 76-77 and 82-84:*

PART I. DAIRY FARMS

10. Permit issuance, suspension, revocation, reinstatement, hearings and/or court action taken as required (*Grade "A" PMO*, Section 3 - PERMITS, Section 5 - INSPECTION OF DAIRY FARMS, Section 6 - EXAMINATION OF MILK AND MILK PRODUCTS and Section 16 - PENALTY). The BTU will be prorated by enforcement action(s) in compliance per farm. Five (5) Categories (a-e) will be utilized for determining compliance with this Item and each will possess a value of twenty percent (20%) compliance. The Categories are as follows:

a. Category I: Permit Issuance ~~(PI)~~;
b. Category II: Permit Suspension ~~(PS)~~;
c. Category III: Permit Revocation ~~(PR)~~;
d. Category IV: Permit Reinstatement ~~(PRI)~~; and
e. Category V: Hearing/Court Action ~~(H/CA)~~.

The Categories relate to the following Sanitation Requirements and Product Compliance~~, which are identified with an *~~. Compliance will be prorated based on **full** compliance with each of the five (5) Categories. **NOTE:** Use FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4). (Refer to Section G, #4 for an example of the Form.)

SANITATION REQUIREMENTS

Category I: Permit Issuance

a. Inspected prior to the issuance of a permit. ~~(PI*)~~
b. Permit issuance based on compliance. ~~(PI*)~~

Category II: Permit Suspension

~~e~~a. Notice issued for intent to suspend permit if an inspection(s) discloses a violation of a *Grade "A" PMO* requirement(s). Reinspection(s) made as required. ~~(PS*)~~
~~d~~b. Permit suspension upon violation of:

1.) Section 3 for a serious health hazard or interference by the permit holder in the performance of the Regulatory Agency's duties; or
2.) Section 5 for consecutive violation(s) of the same requirements of Section 7. ~~(PS*)~~

c. Milk produced during suspension or while a monetary penalty is imposed for repeated inspection violations is not eligible for sale as Grade "A". ~~(PS*)~~

NOTE: *Grade "A" PMO*, Section 3 states: "The Regulatory Agency may forego suspension of the permit, provided the milk or milk product in violation is not sold or offered for sale as

a Grade "A" milk or milk product. A Regulatory Agency may allow the imposition of a monetary penalty in lieu of a permit suspension, provided the milk or milk product in violation is not sold or offered for sale as a Grade "A" milk or milk product. Except, that a milk producer may be assessed a monetary penalty in lieu of permit suspension for violative counts provided …"

Category III: Permit Revocation

~~e.~~ Action to revoke a permit taken upon multiple suspensions. ~~(PR*)~~
~~f. Hearings provided for as required. (H*)~~

Category IV: Permit Reinstatement

~~g.~~ Reinstatement procedures followed. ~~(PRI*)~~

NOTE: *Grade "A" PMO*, Section 3 states: "Within one (1) week of the receipt of such notification {of correction}, the Regulatory Agency shall make an inspection/audit of the applicant's facility and as many additional inspections/audits thereafter as are deemed necessary to determine that the applicant's facility is complying with the requirements."

~~h. Milk produced during suspension or while a monetary penalty is imposed for repeated inspection violations is not eligible for sale as Grade "A". (PS*)~~

Category V: Hearing/Court Action

Hearings provided for as required.

PRODUCT COMPLIANCE

Category II: Permit Suspension

a. All milk produced during suspension or while a monetary penalty is imposed for bacterial, somatic cell, cooling temperature or drug residue violation is not eligible for sale as Grade "A". ~~(PS*)~~
b. When two (2) out of the last four (4) samples exceed the standards, a written notice is sent, and an additional sample is taken within twenty-one (21) days of the date of the notice, but not before three (3) days. ~~(PS*)~~
c. Permit suspension; stop sale; or imposition of a monetary penalty upon violation of:

1.) Section 3 for serious health hazard; or
2.) Section 6 for:
   i. Three (3) out of the last five (5) samples exceeding the bacterial, somatic cell, or cooling temperature standards; or
   ii. "Four (4) in six (6) months" positive antibiotic (not of Appendix N. origin); or
   iii. If pesticide contaminated milk is not withheld from sale. ~~(PS*)~~

Category IV: Permit Reinstatement

~~d~~a. Temporary permit issued as required on reinstatement(s) following somatic cell count resampling, which indicates the milk supply to be within acceptable limits; or reinspection (bacterial or cooling temperature standards violation) made within one (1) week following proper notification, except after reinstatement for a drug residue or with resampling for somatic cell standard. ~~(PRI*)~~

~~e~~b. "Reinstating accelerated sample(s)" for bacterial, cooling temperature, or somatic cell counts taken at a rate of not more than two (2) per week on separate days within a three (3) week period. ~~(PRI*)~~

For Example: FORM FDA 2359j-PART I, Item 10 Calculation (Use FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4). (Refer to Section G, #4 for an example of the Form.): …

PART II. MILK PLANTS

Pages 82-84:

9. Permit issuance, suspension, revocation, reinstatement, hearings and/or court action taken as required (*Grade "A" PMO*, Section 3 - PERMITS, Section 5 - INSPECTION OF MILK PLANTS, Section 6 - EXAMINATION OF MILK AND MILK PRODUCTS and Section 16 - PENALTIES). Prorate by enforcement action(s) in compliance. **NOTE:** A milk plant will be prorated by enforcement action(s) in compliance. Five (5) Categories will be utilized for determining compliance with this Item and each will possess a value of twenty percent (20%) compliance. The Categories are as follows:

a. Category I: Permit Issuance ~~(PI)~~;
b. Category II: Permit Suspension ~~(PS)~~;
c. Category III: Permit Revocation ~~(PR)~~;
d. Category IV: Permit Reinstatement ~~(PRI)~~; and
e. Category V: Hearing/Court Action ~~(H/CA~~).

The Categories relate to the following Sanitation Requirements and Product Compliance~~, which are identified with an *~~. Compliance will be prorated based on **full** compliance with each of the five (5) Categories. **NOTE:** Use FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 5). (Refer to Section G, #5 for an example of the Form.)

SANITATION REQUIREMENTS

Category I: Permit Issuance

a. Inspected prior to the issuance of a permit. ~~(PI)*~~
b. Permit issuance based on compliance. ~~(PI)*~~

Category II: Permit Suspension

~~c.~~a. Notice issued for intent to suspend permit if an inspection(s) discloses a violation of a *Grade "A" PMO* requirement(s). Reinspection(s) made as required. ~~(PS)*~~
~~d.~~b. Permit suspension upon violation of:

1.) Section 3 for a serious health hazard or interference by the permit holder in the performance of the Regulatory Agency's duties; or
2.) Section 5 for sanitation and/or uncorrected critical processing elements; or
3.) Section 5 for consecutive violation(s) of the same requirements of Section 7. ~~(PS)*~~

c. Milk products processed during suspension or while a monetary penalty is imposed for repeated inspection violations is not eligible for sale as Grade "A". ~~(PS)*~~

NOTE: *Grade "A" PMO*, Section 3 states: "The Regulatory Agency may forego suspension of the permit, provided the milk or milk product in violation is not sold or offered for sale as a Grade "A" milk or milk product. A Regulatory Agency may allow the imposition of a monetary penalty in lieu of a permit suspension, provided the milk or milk product in violation is not sold or offered for sale as a Grade "A" milk or milk product. Except, that a milk producer may be assessed a monetary penalty in lieu of permit suspension for violative counts provided …"

Category III: Permit Revocation

~~e.~~ Action to revoke a permit taken upon multiple suspensions. ~~(PR)*~~

Category IV: Permit Reinstatement

~~f. Hearings provided for as required. (H/CA)*~~
~~g.~~ Reinstatement procedures followed. ~~(PRI)*~~

NOTE: *Grade "A" PMO*, Section 3 states: "Within one (1) week of the receipt of such notification {of correction}, the Regulatory Agency shall make an inspection/audit of the applicant's facility and as many additional inspections/audits thereafter as are deemed necessary, to determine that the applicant's facility is complying with the requirements."

Category V: Hearing/Court Action

Hearings provided for as required.

~~h. Milk products processed during suspension or while a monetary penalty is imposed for repeated inspection violations are not eligible for sale as Grade "A". (PS)*~~

PRODUCT COMPLIANCE

Category II: Permit Suspension

a. All milk and milk products produced during suspension or while a monetary penalty is imposed for bacterial count, coliform count, cooling temperature or drug residue violations are not eligible for sale as Grade "A". ~~(PS)*~~
~~b. All product violations followed promptly by an inspection to determine the cause(s). (PRI)*~~
~~c.~~b. When two (2) out of the last four (4) samples exceed the limits, a written notice is sent, and an additional sample is taken within twenty-one (21) days of the date of the notice, but not before three (3) days. ~~(PS)*~~
~~d.~~c. When three (3) out of the last five (5) samples exceed the standards; or a positive drug residue or pesticide residue, the permit is immediately suspended. ~~(PS)*~~
~~e. Temporary permit issued as required on reinstatement(s) and reinspection made within one (1) week following proper notification (except for drug residues). (PRI)*~~
~~f. "Reinstating accelerated samples" for bacterial, cooling temperature, or coliform counts taken at a rate of not more than two (2) per week, on separate days, within a three (3) week period. (PRI)*~~
~~g.~~d. Violation of Vitamin Fortification Levels (Refer to M-I-92-13): Determine the cause and re-sample or withhold product from the market. ~~(PS)*~~
~~h.~~e. Positive Phosphatase: Determine the probable cause and if the cause is improper pasteurization it shall be corrected before further sale of milk is allowed. ~~(PS)*~~
~~i.~~f. Positive Drug Residues or Pesticide Test: Investigate, determine the probable cause and correct before further sale of milk is allowed. ~~(PS)*~~
~~j.~~g. Permit suspension upon violation of:

1.) Section 3 for serious health hazard; or
2.) Section 6 for bacterial counts, coliform counts and cooling temperature violations if the product is not otherwise withheld. ~~(PS)*~~

h. All permits suspended as required by the *Grade "A" PMO*.

Category IV: Permit Reinstatement

a. All product violations followed promptly by an inspection to determine the cause(s).
b. Temporary permit issued as required on reinstatement(s) and reinspection made within one (1) week following proper notification (except for drug residues).
c. "Reinstating accelerated samples" for bacterial, cooling temperature, or coliform counts taken at a rate of not more than two (2) per week, on separate days, within a three (3) week period.
d. All permits reinstated as required by the *Grade "A" PMO*.
~~k. All permit issuance, suspension, revocation, etc., as required by the *Grade "A" PMO*.~~

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Proposal: 217
Document: 2009 MMSR (Sections G and H; and FORM FDA 2359m)
Pages: 39 and 65

Make the following change to ***SECTION G. EXAMPLES OF RATING AND NCIMS HACCP LISTING FORMS*** *on Page 39 and* ***SECTION H. EXAMPLES OF HOW TO PROPERLY COMPLETE RATING AND NCIMS HACCP FORMS*** *on Page 65:*

Modify Section 11 of **FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT (10/10)** as follows:

Section 11 **HACCP SYSTEM TRAINING** (Individuals trained according to Appendix K or alternatively, have equivalent job experience.)

~~A. Employees trained in monitoring operations.~~
~~B. HACCP Plan reassessment performed by trained individual.~~
~~C. Records review performed by trained individual.~~
~~D. Employees trained in PP operations.~~

A. PPs developed by trained personnel.
B. Hazard Analysis developed by trained personnel.
C. HACCP Plan developed by trained personnel.
D. HACCP Plan validation, modification or reassessment performed by trained personnel.
E. HACCP Plan records review performed by trained individual.
F. Employees trained in monitoring operations.
G. Employees trained in PP operation**s**

FORM FDA 2359m (10/12) **PAGE 2**

Proposal: 218
Document: 2009 MMSR (Sections G and H; and FORM FDA 2359n)
Pages: 41 and 67

Make the following change to ***SECTION G. EXAMPLES OF RATING AND NCIMS HACCP LISTING FORMS*** *on Page 41 and* ***SECTION H. EXAMPLES OF HOW TO PROPERLY COMPLETE RATING AND NCIMS HACCP FORMS*** *on Page 67:*

Modify the **NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT (Form FDA 2359n)** Item #2 as follows:

2. Milk plant, receiving station or transfer station audited by a HACCP trained State Regulatory auditor ~~the Regulatory Agency~~ at the minimum required frequency, and follow-ups conducted as required.

…

FORM FDA 2359n (10/12)

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Page 5:

ACCREDITATION/APPROVAL OF MILK LABORATORIES

When a certified analyst or CIS leaves an accredited laboratory, the laboratory/facility manager must notify the State or Federal LEO immediately since the loss of a certified analyst may result in the loss of certification for one or more procedures, or may result in the loss of the laboratory's accreditation. For example, a laboratory having only one certified analyst will lose accreditation.

Page 6:

Laboratories requesting withdrawal of accreditation shall notify the State LEO in writing. Upon receipt of the written request, the State LEO shall …

State Central Milk Laboratories requesting withdrawal of accreditation shall notify the FDA/LPET in writing and shall notify the appropriate FDA Regional Office in writing within 5 working days of FDA/LPET's receipt of the written request. …

Make the following change to ***SECTION 3: CERTIFICATION OF LABORATORY EVALUATION OFFICERS*** *on Pages 16 and 17:*

SECTION 3: CERTIFICATION OF STATE LABORATORY EVALUATION OFFICERS

Initial certification of a State LEO shall be based on meeting the following criteria:

1. The individual must be a State government employee and demonstrate competence in evaluating milk testing laboratories and analysts' performance of milk laboratory test methods or Appendix N procedures as stated on the FDA-2400 Series Forms, and where appropriate, as described in SMEDP when accompanied by a representative of the FDA/LPET on an initial check laboratory ~~evaluation~~ survey. The Federal LEO shall accompany the State LEO to not more than two laboratories/facilities during an initial check survey for initial certification purposes. Initial check evaluation surveys (for certification) should not be conducted at sites that have been evaluated within the past 90 days. …

3. The individual must attend the Milk Laboratory Evaluation Officers Workshop (FDA Course #373) conducted by the FDA/LPET in conjunction with the Food and Drug Administration, State Training Team. Note: It is recommended that the individual attend the Milk Laboratory Evaluation Officers Workshop prior to step 1 above. If the individual does not have experience in the examination of dairy products, they must attend Course FD374 (formerly STT 300) "Laboratory Examination of Dairy Products" prior to or within the year of attending the Milk Laboratory Evaluation Officers Workshop.

Laboratory evaluations conducted by conditionally approved State LEOs ~~are~~ will be considered official.

Conditional certification of a State LEO can occur following the initial check ~~evaluation~~ survey described above. Full certification will be granted after the State LEO attends the next scheduled Milk Laboratory Evaluation Officers Workshop. Failure of a conditionally certified State LEO to attend the next scheduled Workshop, unless excused with cause by FDA/LPET, will require that the State LEO must restart the process. The State LEO candidate would then be required to participate in another check ~~evaluation~~ survey with a representative of the FDA/LPET, and then attend the next scheduled Workshop.

Recertification of the State LEO will occur triennially, and will be based on satisfactorily meeting the following criteria:

1. The individual must be a State government employee and demonstrate continued competence in evaluating milk testing laboratories and analysts' performance of milk laboratory test methods or Appendix N procedures as stated on the FDA-2400 Series Forms, and where appropriate, as described in SMEDP when accompanied by a representative of the FDA/ LPET on a check laboratory evaluation. The Federal LEO shall accompany the State LEO to not more than two laboratories/facilities during a check survey for recertification purposes. ...

Page 17:

Laboratory evaluations conducted by provisionally approved State-LEOs ~~are~~ will be considered official.

Make the following change to ***SECTION 4: EQUIPMENT AND APPARATUS OF AID TO EVALUATION OFFICERS*** *on Page 18:*

While conducting laboratory evaluations, the State or Federal LEO may find it extremely useful to have in his/her possession different types of equipment which will enable them to examine the apparatus in use and judge the proficiency of laboratory procedures in use for the examination of milk products. Some evaluation officers currently use a large percentage of the equipment and apparatus listed below. Equipment should be maintained in proper working conditions to assure accuracy.

Make the following change to ***SECTION 5: GUIDELINES FOR LABORATORY EVALUATIONS*** *on Pages 19-21:*

The evaluations of laboratories by a State or Federal LEO should be systematic. These guidelines are recommended to enable complete evaluation of the laboratory facilities, equipment and records and of analyst technique.

Upon initial evaluation and/or renewal, the laboratory, must make application for an evaluation provided by the State or Federal LEO. The application will include the statement: …..

In preparation for the laboratory evaluation, normally the laboratory director or supervisor should be notified in advance to insure the presence of analysts and the availability of samples for laboratory examination. In arranging for an initial evaluation, laboratory officials should be

told that all tests must be set up and that during the evaluation the work of all analysts, who may perform any official methods must be observed. If laboratory evaluations are conducted on days when procedures, e.g. the SPC, are not normally performed, advance arrangements should be made to have samples on hand in order to observe the SPC procedure and the laboratory personnel should be requested to save countable plates from the previous day. Where the latter is not feasible, previously prepared and incubated plates may be brought to the laboratory by the State or Federal LEO to permit observations of counting procedures. …

After entering the laboratory, the State or Federal LEO should note the names of all analysts in the laboratory as/or after they are introduced and record procedures performed by each.

Before beginning the survey, the State or Federal LEO should discuss the "ground rules" for the survey. Rules should be established for procedural evaluations (e.g. whether an analyst can restart a procedure if the analyst notices that he/she make an error, how many times may an analyst restart...).

During an evaluation of a large laboratory, various analysts may be performing different examinations which may make a comprehensive evaluation difficult, particularly since all analysts are to be observed for each bacteriological and chemical procedure for which certification is requested. It is recommended that the officer establish a schedule so as to be in a position to evaluate apparatus and procedures used in the laboratory without disrupting, as far as possible, the routine examination of samples. Since it is expected that various portions of the evaluation forms will be used at separate times, it is advisable to note observed items of the various procedures on the left hand margins of the evaluation forms. By frequent referral to the noted items, the State or Federal LEO will be reminded to observe all laboratory procedures in use and avoid misuse of the phrase "undetermined" (U) when procedures were actually in use but were not observed.

While observations of procedures are being made and the evaluation forms completed, certain precautions should be taken by the State or Federal LEO: …

During the laboratory evaluation it is probable that some items pertinent to receiving samples will not be observed. However, the State or Federal LEO should determine from consultation with the laboratory supervisor the procedures used in receiving samples from the sample collectors: …

Deviations are to be discussed with the analysts at some time after it has been observed and properly recorded. This discussion should include the nature of the deviation, any effect on validity of results, remedial action suggested and reasons justifying the change. All interested personnel should have an opportunity to look over the completed evaluation form and each major deviation should be discussed by the officer with interested staff. At that time comments should be invited from the staff concerning the evaluation. The State or Federal LEO should make suggestions concerning any needed improvement of laboratory techniques. Following the discussion of procedures and competence of analysts, past split sample results of the laboratory should be discussed, suggestions made for improvement, and/or commendations made for superior performance.

In addition to a regularly scheduled visit, some State or Federal LEOs find that an occasional unannounced visit to an accredited laboratory provides them with supporting information concerning laboratory practices. Information generated on all surveys (unannounced, scheduled, check surveys) must be evaluated by the State or Federal LEO and used to determine compliance ~~to~~ with the NCIMS Milk Laboratory Program.

If at any time during any ~~evaluation~~ survey there is interference with or willful refusal to permit ~~evaluation~~ survey, the State or Federal LEO will serve notice that the laboratory will not be certified or will be decertified until such time as the laboratory agrees to abide by the voluntary certification program. The laboratory may make reapplication by completing the application form and stipulating that future interference or refusals will result in non-certification or decertification for thirty days (30). Or, if at any time before or during any ~~evaluation~~ survey the State or Federal LEO feels their safety is in jeopardy or determines extensive non-compliance, they may terminate the ~~evaluation~~ survey. The State or Federal LEO must indicate to the laboratory management why the ~~evaluation~~ survey was terminated and must indicate what steps must be taken before a ~~re-evaluation~~ resurvey will be scheduled. The laboratory may make reapplication by addressing the concerns that led to the termination of the ~~evaluation~~ survey and by completing the application form and stipulating that the safety concerns and/or non compliance issues have been addressed.

Make the following change to ***SECTION 6: LABORATORY EVALUATION REPORTS*** *on Pages 22-24:*

EVALUATION FORMS

Copies of the evaluation forms are to be prepared for the laboratory evaluated. The State or Federal LEO must maintain a complete copy of the ~~evaluation~~ survey report, including forms. The laboratory/facility and State or Federal LEO must maintain, at minimum, copies of the last two biennial/triennial ~~evaluations~~ surveys, subject to verification by the State LEO and the FDA/LPET. In marking the official copies of the completed evaluation forms, leave items in compliance blank. When typing copies for transmittal to others, do not include check marks in the margin which were made at the time of the actual evaluation for the convenience of the evaluating official.

NARRATIVE REPORT

The set of completed ~~evaluation~~ survey forms for the laboratory must be accompanied by a narrative report giving the conclusions of the State or Federal LEO as to whether or not the laboratory is doing acceptable work. Additional narrative reports, without FDA-2400 Series Forms, are to be sent to others that need to be informed as to the outcome of the laboratory evaluation. State LEOs may submit reports by email, however, they must receive verification of receipt by return email and must maintain a copy of the verification in their records. The narrative report must identify the laboratory, give the laboratory number, show the date of the evaluation, who made the evaluation, list the prior status, list the date of the last on-site evaluation, indicate the present status, what recommendations were made to correct any deviations, what test were approved, and who was certified to do them. …

Page 23:

CONCLUSIONS

2. …

Explanation: A qualified acceptance where the State or Federal LEO believes that the deviations noted do not seriously affect the analytical results and that a letter explaining the corrective actions taken will be sufficient to ensure compliance. …

Page 24:

4. …

Explanation: Severe deficiencies in facilities, records, staff and/or procedural techniques exist which would result in unacceptable results. A new on-site ~~evaluation~~ survey shall be made when the State or Federal LEO has reason to believe that a rating would result in an acceptable rating. A new on-site evaluation would not be required for certified milk laboratories, CIS facility or screening facilities if the withdrawal was for facility deficiencies only. The laboratory, CIS facility or screening facility would be required to submit pictures, invoices, etc. to show compliance with the facility requirements noted in the last on-site evaluation.

Proposal: 235
Document: 2009 EML (Sections 1 and 6; Example and Example Report)
Pages: 3, 22, 27 and 29

Make the following change to ***SECTION 1: LABORATORY EVALUATION PROGRAM*** *on Page 3:*

A set of completed evaluation forms ~~shall~~ may accompany the narrative report which describes the degree of suitability of the laboratory facilities, equipment, records, the analysts' procedures, and a statement as to whether the results of the analyst or CIS examinations are acceptable for use in rating milk for interstate shipments. The narrative report must be sufficiently detailed to allow readers to determine what is being cited without having to refer to the FDA-2400 Series Forms.

Survey reports of on–site evaluations of Official Milk Laboratories and CISs shall be sent within 60 days of the initial, biennial anniversary or supplemental date of the laboratory evaluation to the Official Milk Laboratory/CIS, the appropriate Food and Drug Administration Regional Office and the FDA/LPET. Reports can be submitted by traditional fashion (mail, common courier) or electronically. Reports to the Official Milk Laboratories/CIS must include the narrative report and may include copies of the completed FDA-2400 Series Forms ~~and a copy of the narrative report~~. Reports to FDA Regional Office and FDA/LPET should only include the narrative report. …

Make the following change to ***SECTION 6: LABORATORY EVALUATION REPORTS*** *on Page 22:*

EVALUATION FORMS

FDA-2400 Series Forms shall be completely identified with the name of the laboratory, the laboratory number, its location, date and the name of the individual making the evaluation (even when pages are stapled together they may become separated during handling and filing) when the option to send them with the narrative report is used. Forms pertaining to procedures not used should not be returned with the report.

Copies of the evaluation forms ~~are to~~ may be prepared for the laboratory evaluated. The State LEO must maintain a complete copy of the evaluation report, including forms. The laboratory/facility and State LEO must maintain, at minimum, copies of the last two biennial/triennial evaluations, subject to verification by the State LEO and the FDA/LPET. In marking the official copies of the completed evaluation forms, leave items in compliance blank. When typing copies for transmittal to others, do not include check marks in the margin which were made at the time of the actual evaluation for the convenience of the evaluating official.

NARRATIVE REPORT

The set of completed evaluation forms for the laboratory ~~must~~ may be accompanied by ~~a~~ the narrative report giving the conclusions of the State LEO as to whether or not the laboratory is doing acceptable work. If the completed evaluation forms do not accompany the narrative report, the report must be sufficiently detailed to allow readers to determine what is being cited without having to refer to the FDA-2400 Series Forms. Each form used shall have the revision date noted. Additional narrative reports, without FDA-2400 Series Forms, are to be sent to others that need to be informed as to the outcome of the laboratory evaluation. State LEOs may submit reports by email, however, they must receive verification of receipt by return email and must maintain a copy of the verification in their records. The narrative report must identify the laboratory, give the laboratory number, show the date of the evaluation, who made the evaluation, list the prior status, list the date of the last on-site evaluation, indicate the present status, what recommendations were made to correct any deviations, what test were approved, and who was certified to do them.

The report must be sufficiently detailed to allow readers to determine what is being cited without having to refer to the FDA-2400 Series Forms.

~~A form~~ Formats suitable for narrative reports ~~appears~~ appear on pages 27-32.

If choosing the option to send the narrative only via electronic submission, it will be necessary to summarize what each item is. Grouped under the title of each method observed (e.g., Standard Plate Count), list each major and/or minor deviation or omission numbered identically with the item number on the evaluation form and the corrective action necessary for compliance with standard procedures or good laboratory practices.

*Make the following change to the **EXAMPLE** on Page 27 and **EXAMPLE REPORT** on Page 29:*

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade 'A' PMO. If forms accompany the narrative report then, ~~Deviated~~ deviated items are marked with an "X" on the evaluation forms. Items marked "U" are undetermined because of local conditions at the time of the evaluation. Laboratory procedures and/or equipment marked "O" are not used. Items marked "NA" are optional procedural techniques and/or equipment not applicable to designated laboratory procedures. Repeat deviations are marked by an asterisk "*". Noted items are not considered deviations. They will be marked as deviations if not corrected by the next evaluation.

Proposal: 236
Document: 2009 EML (Sections 1, 3, and 6; and References)
Pages: 3, 5-7, 16, 22, 24 and new 33-xx

*Make the following change to **SECTION 1: LABORATORY EVALUATION PROGRAM** on Pages 3, 5, 6 and 7:*

Survey reports of on–site evaluations of Official Milk Laboratories and CISs shall be sent within 60 days of the initial, biennial anniversary or supplemental date of the laboratory evaluation to the Official Milk Laboratory/CIS, the appropriate Food and Drug Administration Regional Office and the FDA/LPET. Reports can be submitted by traditional fashion (mail, common courier) or electronically. Reports to the Official Milk Laboratories/CIS must include copies of the completed FDA-2400 Series Forms and a copy of the narrative report. Reports to FDA Regional Office and FDA/LPET ~~should~~ shall be sent electronically and shall ~~only~~ include the narrative report and appropriate, completed FDA summary template~~s~~ only (see page xx – xx). …

CERTIFICATION/APPROVAL OF MILK LABORATORY ANALYSTS

Page 5:

Copies of notices of changes of certification or revocation of certification shall be sent to the laboratory or facility involved, the milk regulatory agency, the state milk sanitation rating agency, the appropriate FDA Regional Office and the FDA/LPET. For FDA/LPET notification, changes in certification shall be indicated on the appropriate, completed FDA summary template and shall be submitted electronically. …

ACCREDITATION/APPROVAL OF MILK LABORATORIES

Page 6:

Official examinations cannot be conducted at non-accredited laboratories. When a laboratory or CIS facility loses its accreditation because of lack of certified analysts, or for some other reason, the Federal or State LEO shall immediately notify the milk laboratory involved, the state milk

regulatory agency, the state milk sanitation rating agency, any out-of-state milk regulatory agencies where known customers are located, the appropriate FDA Regional Office and the FDA/LPET, by a letter of notification to be dated within five (5) working days of the loss of accreditation. For FDA/LPET notification, changes in accreditation shall be indicated on the appropriate, completed FDA summary template and shall be submitted electronically.

Laboratories requesting withdrawal of accreditation shall notify the State LEO in writing. Upon receipt of the written request, the State LEO shall immediately notify the state milk regulatory agency, the state milk sanitation rating agency, any out-of-state milk regulatory agencies where known customers are located, the appropriate FDA Regional Office and the FDA/LPET by a letter of notification to be dated within five (5) working days of receipt of the written request. Upon notice of withdrawal of accreditation, the certificate, if issued, shall be returned to the issuing State LEO within 90 days. For FDA/LPET notification, changes in accreditation shall be indicated on the appropriate, completed FDA summary template and shall be submitted electronically. …

APPROVAL OF INDUSTRY ANALYSTS/INDUSTRY SUPERVISORS

Page 7:

When a screening facility loses its approval because of lack of approved IS or IA, or for some other reason, the State LEO shall immediately notify the screening facility involved, the state milk regulatory agency, the state milk sanitation rating agency, any out-of-state milk regulatory agencies where known customers are located, the appropriate FDA Regional Office and the FDA/LPET, by a letter of notification to be dated within five (5) working days of receipt of the loss of approval. For FDA/LPET notification, changes in approval shall be indicated on the appropriate, completed FDA summary template and shall be submitted by email.

Screening facilities requesting withdrawal of approval shall notify the State LEO in writing. Upon receipt of the written request, the State LEO shall immediately notify the state milk regulatory agency, the state milk sanitation rating agency, any out-of-state milk regulatory agencies where known customers are located, the appropriate FDA Regional Office and the FDA/LPET by a letter of notification to be dated within five (5) working days of receipt of the written request. For FDA/LPET notification, changes in approval shall be indicated on the appropriate, completed FDA summary template and shall be submitted by email. …

Make the following change to ***SECTION 3: CERTIFICATION OF LABORATORY EVALUATION OFFICERS*** *on Page 16:*

Initial certification of State LEO shall be based on meeting the following criteria: …

2. The individual must submit an acceptable written report of the milk laboratory initial check evaluation to the FDA/LPET within 60 days of the evaluation. Reports to FDA Regional Office and FDA/LPET shall be sent by email and shall include the narrative report and appropriate, completed FDA summary template only (see page xx – xx). …

Laboratory evaluations conducted by conditionally approved State LEOs are official. …

2. The individual must submit an acceptable written report of the milk laboratory check evaluation to the FDA/LPET within 60 days of the evaluation. Reports to FDA Regional Office and FDA/LPET shall be sent by email and shall include the narrative report and appropriate, completed FDA summary template only (see page xx – xx). …

Make the following change to ***SECTION 6: LABORATORY EVALUATION REPORTS*** *on Pages 22 and 24:*

NARRATIVE REPORTS

The set of completed evaluation forms for the laboratory must be accompanied by a narrative report giving the conclusions of the State LEO as to whether or not the laboratory is doing acceptable work. Additional narrative reports, without FDA-2400 Series Forms, are to be sent to others that need to be informed as to the outcome of the laboratory evaluation. The copy of the narrative report submitted by email to FDA/LPET must be accompanied by the appropriate, completed FDA summary template, both attached to the same email. The LEO must receive verification of receipt by return email and must maintain a copy of the verification in their records. State LEOs may submit reports by email~~,~~; however, they must receive verification of receipt by return email and must maintain a copy of the verification in their records. The narrative report must identify the laboratory, give the laboratory number, show the date of the evaluation, who made the evaluation, list the prior status, list the date of the last on-site evaluation, indicate the present status, what recommendations were made to correct any deviations, what test were approved, and who was certified to do them. …

Page 24:

…compliance with the facility requirements noted in the last on-site evaluation.

FDA SUMMARY TEMPLATES

The narrative report must be accompanied by the appropriate, completed FDA summary template for the laboratory, specifically representing the information required for verifying and updating the IMS List of accredited laboratories and CISs along with other useful information to be used by FDA/LPET. Only the current revision of the FDA summary templates, authored by FDA/LPET, may be used. There are two FDA summary templates: one for full service laboratories and one for Appendix N Screening Only facilities (CIS and IS). The information captured on the FDA summary template must match the information provided in the narrative report (i.e., IMS number, facility identification, accreditation and certification status, dates, procedures, conclusion, etc.). The information captured may also lend itself to analyst/laboratory tracking and filing by the State LEO.

The appropriate FDA summary template form must also be used for the notification of changes in accreditation and certification status, and must be submitted by email to FDA/LPET.

Directions for completing the FDA summary template, authored by LPET, will be updated with each revision of the FDA summary template, as necessary, and provided to the LEOs by email.

An example of a completed FDA summary template for each application appears on pages 33-xx.

*Make the following change to **REFERENCES** on New Pages 33-xx:*

New Page 33-xx:

NOTE: At the end of the EML document, add an example of a completed FDA summary template for each application on pages 33-xx.

Proposal: 246
Document: 2009 EML (Section 3)
Pages: 16

*Make the following change to the **SECTION 3: CERTIFICATION OF LABORATORY EVALUATION OFFICERS** on Page 16*:

3. The individual must attend the Milk Laboratory Evaluation Officers Workshop (FDA Course #373) conducted by the FDA/LPET in conjunction with the Food and Drug Administration, State Training Team. If the individual does not have experience in the examination of dairy products, they must attend Course FD374 (formerly STT 300) "Laboratory Examination of Dairy Products" prior to or within the year of attending the Milk Laboratory Evaluation Officers Workshop. Note: It is recommended that the individual attend the Milk Laboratory Evaluation Officers Workshop prior to step 1 above.

Proposal: 247
Document: 2009 EML (References)
Page: 24

*Make the following change to the **REFERENCES** on Page 24*:

2. Copies of the FDA-2400 Series Forms can be ~~downloaded from {http://www.fda.gov/opacom/morechoices/fdaforms/default.html}~~ obtained from your federal or state LEO.

   A list of federal or state LEO's can be found at the website: http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/FederalStatePrograms/InterstateMilkShippersList/default.htm.

   Once at that website:

For federal LEO's click on the link FDA CFSAN Personnel and scroll down to the Laboratory Proficiency and Evaluation Team.

For state LEO's click on the link State Grade A Milk Regulatory, Rating and Laboratory Personnel and them click on your state. The table is organized Regulatory, Rating, then Laboratory. Scroll down to the laboratory section to find the contact information for your state's LEO(s).

Proposal: 237
Document: 2009 EML (Example and Example Report)
Pages: 27-32

Make the following change to the ***EXAMPLE*** and ***EXAMPLE REPORT*** *on Pages 27-32*:

~~EXAMPLE~~

~~Report of a Biennial On-Site Evaluation~~
~~of~~

~~Certified Industry Supervisor~~
~~Name~~
~~Plant Manager~~

~~Laboratory Name~~
~~Laboratory number: 00600~~
~~Laboratory Street Address~~
~~City, State 00000~~

~~On~~

~~Evaluation Date~~

~~By~~

~~LEO Name~~
~~Laboratory Evaluation Officer~~

~~Last Certified: Date~~

~~A copy of the "Grade 'A' Milk Laboratory Evaluation Request and Agreement Form" is signed and is on file.~~
~~Previous Laboratory Status: Fully certified for [List Procedures].~~
~~Present Laboratory Status: Fully certified for [List Procedures] pending receipt within 60 days of correction of deviations resulting from on - site evaluation of [Date].~~
~~Other changes that need to be made to IMS list, etc: None or List Changes~~

~~The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade 'A' PMO. Deviated items are marked with an "X" on the evaluation forms. Items marked "U" are undetermined because of local conditions at the time of the evaluation. Laboratory procedures and/or equipment marked "O" are not used. Items marked "NA" are optional procedural techniques and/or equipment not applicable to designated laboratory procedures. Repeat deviations are marked by an asterisk "*". Noted items are not considered deviations. They will be marked as deviations if not corrected by the next evaluation.~~

~~Beta lactam Tests~~

~~DEVIATIONS AND CORRECTIONS~~
~~GENERAL REQUIREMENTS~~

~~3. Thermometers for use with Test Kits and Laboratory Equipment.~~
~~d. Calibrate your freezer thermometer against a traceable thermometer.~~
~~d2. Tag above calibrated thermometer with date, identification and correction (+0.0, if none) and record results.~~
~~6. Balance.~~
~~e. Note: Have your new balance calibrated annually by a qualified service representative.~~

~~TECHNIQUES~~

~~[Name Test]~~
~~No deviations were observed for the [Name Test].~~
~~[Name of Second Test]~~

~~15. Test Procedure.~~
~~p. Multiple tests were run at the same time. Start incubation timing immediately after the sample is added to the last test device. Analyst started timing too late.~~

~~CONCLUSIONS~~

~~[CIS Name] is certified as a Certified Industry Supervisor to perform the procedures as listed above pending correction of listed deviations and receipt of corrections in writing by the State LEO within sixty days of receipt of this evaluation. Contact me if there are questions.~~

~~Sincerely,~~

~~LEO Name~~
~~Laboratory Evaluation Officer~~

~~EXAMPLE REPORT~~

~~REPORT Of an On-Site Biennial/~~
~~Supplemental (analyst, procedure, walk-through)/~~
~~Unofficial~~

~~Certified Laboratory~~
~~NCIMS Lab ##~~

~~Certified Industry Supervisor~~
~~CIS ##~~

~~Appendix N Screening Site~~

~~NAME OF SITE~~
~~Address~~
~~Date of evaluation~~
~~By LEO's name~~

~~Previous Laboratory Status: Fully/provisionally/conditionally Certified until date~~
~~Previous Procedures: X, X, X~~
~~Present Laboratory Status: Fully/provisionally/conditionally Certified until date, pending acceptable response to this report~~
~~Procedures evaluated: X, X~~

~~A copy of the "Grade 'A' Milk Laboratory Evaluation Request and Agreement Form" is signed and is on file with LEO.~~
~~Other changes that need to be made to IMS list, etc: None~~
~~The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade 'A' PMO. Deviated items are marked with an "X" on the evaluation forms. Items marked "U" are undetermined because of local conditions at the time of the evaluation. Laboratory procedures and/or equipment marked "O" are not used. Items marked "NA" are optional procedural techniques and/or equipment not applicable to designated laboratory procedures. Repeat deviations are marked by an asterisk "*". Noted items are not considered deviations. They will be marked as deviations if not corrected by the next evaluation.~~

~~DEVIATIONS AND CORRECTIVE ACTIONS~~

~~ITEM METHOD~~

~~CULTURAL PROCEDURES FOR CERTIFIED LAB/~~
~~GENERAL REQUIREMENTS FOR APP N~~

~~CERTIFIED LAB~~

~~3d1.In the media section, calibration of thermometers was done but the calibration temperature was not always at temperature of use. Refrigerator was calibrated at 5C vs. 0.0C and hot air oven was calibrated at 65C vs. 170C. Send new/proper calibrations with response.~~

~~3d2a. The tags did not include correction factors in media area. Send verification.~~

~~APPENDIX N LAB~~

~~*1c. Adequate lighting, [NCIMS Certified Laboratories, and Certified Industry Supervisors >50 foot candles at the working surface (pref. 100].*~~

~~During the technique demonstration, the wall light was not used. The lighting measured 14-24 foot candles in the confirmation testing area. The confirmation testing area had 83-105 foot candles when the wall light was utilized. Whenever testing is being conducted the wall light must be utilized.~~

~~It was determined during the survey that the screening test area had 20-25 foot candles of light. Add additional lighting to the area to increase to >50 ft-candles and send verification.~~

~~ITEM METHOD~~

~~TESTS-LIST ALL TESTS OBSERVED and DEVIATIONS OF TECHNIQUES.~~

~~CERTIFIED LAB~~

~~Standard Plate Count, Coliform, and Simplified Count Methods~~

~~5b1/2.Proper mixing or shaking of samples, retail must have complete inversion top over bottom and raw is to be more vigorous than observed.~~

~~6d. Analysts are to avoid the foam of sample. The raw milk container may be tapped on the container on counter and tilted as to show clear spot on surface of milk. The pipet is not inserted more than 2.5 cm. Analysts may use the cap of retail containers or sterile Petri dish to adjust the pipet volume and not adjust pipet volume while pipet is still in liquid portion of sample.~~

~~APPENDIX N LAB~~

~~*3a1. Incubator level. Temperature checked daily (day of use), records maintained.*~~

~~The temperature is not being recorded to the tenth of a degree. Please instruct analysts to record the strip incubator to the tenth of a degree.~~

~~*10a. Reader tapes or computer printouts maintained for two years.*~~

~~Please remember that the kit number is the lot number. Please Note: Post the analyst codes in each testing area (confirmation testing area and screening testing area). This will eliminate any confusion as to which code belongs to which analyst.~~

~~Comments/Recommendations: Optional Areas that may need to be addressed or LEO has some concern.~~

~~PERSONNEL AND PROCEDURES CERTIFIED~~

~~LEO IS TO LIST ALL THE PERSONNEL AND PROCEDURES THAT WERE EVALUATED AT THIS AUDIT. INCLUDE A LETTER (X, C, N, ETC) THAT DENOTES THE STATUS OF ANALYSTS (REFERENCED AS BELOW) ON THE EVALUATION AND SPLIT SAMPLES.~~

~~CERTIFIED LAB~~

~~PERSONNEL AND PROCEDURES CERTIFIED~~

	SPC/PACCOLI/PCCPMC		D3	I1	C[3,9,10,12]	DMSCC	PHOS[28]
Name Analyst 1	X/N	X/X	X	C	X	X	X	X
Name Analyst 2	X/P	X/X	X	X	X	X	X	X

~~[X denotes full certification in the indicated procedures pending acceptable performance in the annual proficiency testing program (split sample) for all procedures for which certification has been granted. P denotes provisional certification pending acceptable performance in the annual proficiency testing program for all procedures for which certification has been granted. C denotes conditional certification pending acceptable performance in the annual proficiency testing program for all procedures for which certification has been granted. N denotes no certification status granted.].~~

~~APPENDIX N LAB~~

Certified Industry Analysts	2004 On-Site Evaluation TEST KIT	4/2004 Split Sample Survey TEST KIT
Name CIS 1	x (CIS)	x
Name CIS 2	x (CIS)	x
Name CIS 3	No Longer Employed	x

Industry Analysts	2004 On-Site Evaluation TEST KIT	6/2004 Split Sample Survey TEST KIT
Name IA 1	x	x
Name IA 2	x	x

~~CONCLUSION~~

~~Use the proper conclusion found on pages 23 & 24.~~

New example reports for the EML.

EXAMPLE REPORT #1

Report of a Biennial On-Site Evaluation

of

City Health Department Milk Laboratory

Accredited Laboratory
NCIMS LAB #####

100 South Main Street
City, State 78000

On

March 1, 2010

By

LEO Name
Laboratory Evaluation Officer
State Department of [Health, Agriculture}
100 Healthy Way
City, State 78000

Last Full Evaluation Date: March 19, 2008
Next Evaluation Due By: March 31, 2012

A copy of the "Grade 'A' Milk Laboratory Evaluation Request and Agreement Form" is signed and is on file.

Previous Laboratory Status: Fully certified for [5, 9C13, 9C14, 9D3, 12, 20, 22, 24, 28]

Present Laboratory Status: Fully certified for [5, 9C13, 9D3, 12, 16, 20 22, 24, 28] pending receipt within 60 days of correction of deviations resulting from on - site evaluation of March 1, 2010.

Other changes that need to be made to IMS list, etc: Update Anniversary Date, drop procedure 9C14, add procedure 16.

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade 'A' PMO. If forms accompany the narrative then deviated items

are marked with an "X" on the evaluation forms. Items marked "U" are undetermined because of local conditions at the time of the evaluation. Laboratory procedures and/or
Page 2 / #####
3/1/2010

procedures equipment marked "O" are not used. Items marked "NA" are optional procedural techniques and/or equipment not applicable to designated laboratory procedures. Repeat deviations are marked by an asterisk "*". Noted items are not considered deviations. ~~They will be marked as deviations if not corrected by the next evaluation.~~ The phrase "Note" as used in these narrative reports is to suggest or remark upon items which would improve laboratory functions. These are usually considered to be good laboratory practices but are not listed in the FDA-2400 Series Forms and are not debitable items.

DEVIATIONS AND CORRECTIVE ACTIONS

ITEM **METHOD**

CULTURAL PROCEDURES - GENERAL REQUIREMENTS (rev. 2/10)

2. Records

2e Corrections to all records follow appropriate requirements

During the review of the autoclave records it was noticed that there were a number a items written over.

Analysts are to be reminded of the proper protocol for correcting mistakes. Cross out the error with one line, initial, date and write the correct information next to it.

Send copies of the March and April autoclave records.

3. Thermometers

3a NIST Thermometer

#NOTE: The graduations on the lower end of the NIST thermometer are so worn that it is difficult to read. It is suggested that a new thermometer be purchased.

The other option is to use the new NIST traceable unit that is available for use in the rest of the laboratory.

3c3 No tag was found on the freezer thermometer

Although the accuracy check was documented the unit was not tagged.

Tag the thermometer with the following: identification/location, date of check, temperature checked and the correction factor.

Send a copy of the tag.

5. Freezer

5b Maintains -15C or below

Over the past four months at least 50% of the days noted with the unit out of temperature range with no corrective action noted.

This is a serious violation and no controls or samples may be kept in the unit until it is proven that that the unit holds the proper temperature.

Send copies of the freezer temperature records for the next 4 months. If the unit cannot be maintained then a new one will need to be purchased.

Page 3 / #####
3/1/2010

13. Autoclave

13i Performance check
There were no thermometers for the incubation units for the spore check. There must be a way to check the appropriate temperature range for the test.
Please purchase thermometers for these units and send a copy of the purchase order, the temperature calibrations when received and the temperature records for the two months following.

TECHNIQUES

PETRIFILM AEROBIC AND COLIFORM COUNTS (IMS# 5,20 rev. 1/09)

No deviations noted. The analysts showed marked improvement over the last biennial on-site.

PASTEURIZED MILK CONTAINERS (IMS# 22 rev. 1/09)

10. Collection of Surface Rinse Samples

10b2 While adding the rinse solution to the container, do not touch the bottle of rinse solution to the container.
One analyst held the bottle against the container while adding the rinse solution.
Use aseptic technique when adding the rinse solution.

DELVOTEST P 5 PACK (IMS# 9D3 rev. 2/10)

No deviations noted.

DMSCC (IMS# 12 rev. 2/10)

21. Sample Measurement

21e Touch the slide with the tip and expel the test portion.
One analyst held the syringe above the slide and dripped the milk.
Take the syringe and hold it vertically against the slide, depress the plunger slowly allowing the milk to be expelled. Then touch off to a dry spot.

ESCC – BENTLEY 150 (IMS# 16 rev. 10/07)
No deviations noted.

FLUOROPHOS ALP (IMS# 28 rev. 6/05)

15. Instrument and Reagent Checks
Page 4 / #####
3/1/2010

15g2b Reconstituted Substrate / Buffer Stability Check A/D Value Recorded
The A/D value for this check was missing on several days of testing records during the period evaluated. While this may be from having to reconstitute a new bottle of substrate because the A/D value was greater than 1200, the corrective action must be noted with both the old *AND* new values recorded.

DAIRY WATERS (IMS# 24 rev. 1/09)

No deviations noted.

CHARM SL BETA LACTAM (IMS# 9C13 rev. 1/10)

No deviations noted.

PERSONNEL & PROCEDURES OBSERVED

Analyst	5	9C13	9D3	12	16	20	22	24	28	ON-SITE Last 2	SPLITS Last 2
Analyst 1	X	X	X	X	X	X	X	X	X	3/10, 3/08	10/09, 10/08
Analyst 2	X	X	X	X	X	X	X	X	X	3/10, 3/08	10/09, 10/08
Analyst 3	X	X	X	X	X	X	X	X	X	3/10, 3/08	10/09, 10/08
Analyst 4	X	X	X	X		X	X	X	X	3/10	10/09
Analyst 5*	X	X	X	X	X	X	X	X	X	3/08, 3/06	10/09, 10/08

X = Fully Certified
* = Analyst excused – on medical leave.
5 = Petrifilm Aerobic Count
9C13 = Charm SL Beta Lactam
9D3 = Delvotest 5 Pack
12 = DMSCC
16 = ESCC (Bentley 150)
20 = Petrifilm Coliform Count
22 = Pasteurized Milk Containers
24 = Dairy Waters
28 = Advanced Fluorometer

CONCLUSION

Although the procedures, records, facilities and equipment in use at the time of the evaluation were in substantial compliance with the requirements of the *Grade 'A' PMO* the analyst, equipment and record deviations noted must be corrected. This laboratory is accredited until May 1, 2010 pending correction of the deviations and receipt of a letter by the evaluation officer detailing the corrections made. Upon receipt of such letter, full accreditation will be given.

Sincerely,
LEO

EXAMPLE REPORT #2

REPORT Of an Biennial On-Site/
Supplemental (analyst, procedure, walk-through)/
Unofficial/Check

Certified Laboratory
NCIMS Lab #####

Certified Industry Supervisor
CIS #####

Appendix N Screening Site

NAME OF SITE
Address
Date of Evaluation
By LEO's name

Previous Laboratory Status: Fully/provisionally/conditionally Certified until [date]
Previous Procedures: X, X, X

Present Laboratory Status: Fully/provisionally/conditionally Certified until [date], pending acceptable response to this report
Procedures evaluated: X, X

A copy of the "Grade 'A' Milk Laboratory Evaluation Request and Agreement Form" is signed and is on file with LEO.

Other changes that need to be made to IMS list, etc: None or addition of analysts, change in procedures, etc.

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade 'A' PMO. Deviated items are marked with an "X" on the evaluation forms. Items marked "U" are undetermined because of local conditions at the time of the evaluation. Laboratory procedures and/or equipment marked "O" are not used. Items marked "NA" are optional procedural techniques and/or equipment not applicable to designated laboratory procedures. Repeat deviations are marked by an asterisk "*". Noted items are not considered deviations. The phrase "Note" as used in these narrative reports is to suggest or remark upon items which would improve laboratory functions. These are usually considered to be good laboratory practices but are not listed in the FDA-2400 Series Forms and are not debitable items.

Page 2 / #####
Date

DEVIATIONS AND CORRECTIVE ACTIONS

ITEM METHOD

CULTURAL PROCEDURES FOR CERTIFIED LAB [rev. 2/10] /
GENERAL REQUIREMENTS FOR APPENDIX N [rev. 2/10]

CERTIFIED LAB

3. Thermometers

3c2 All test temperature measuring devices are checked at temperature of use.
The thermometers in the media section were checked for accuracy but were not always done at the temperature of use as required. The hot air oven was checked at 65C vs. 170C.
Re-check the thermometer and send with the response.

3c3a Tags include correction factors on temperature measuring devices.
The tags did not include correction factors in media area.
Send copies of the tags.

APPENDIX N LAB

1c Adequate lighting, [NCIMS Certified Laboratories, and Certified Industry Supervisors >50 foot candles at the working surface (pref. 100)].

During the technique demonstration, the wall light was not used. The lighting measured 14-24 foot candles in the confirmation testing area. The confirmation testing area had 83-105 foot candles when the wall light was utilized. Whenever testing is being conducted the wall light must be utilized.

It was determined during the survey that the screening test area had 20-25 foot candles of light. Add additional lighting to the area to increase to >50 ft-candles and send verification.

ITEM METHOD

TESTS-LIST ALL TESTS OBSERVED and DEVIATIONS OF TECHNIQUES.

CERTIFIED LAB

Standard Plate Count, Coliform, and Simplified Count Methods (IMS#2 rev. 1/09)

5. Sample Agitation

5b1 Shake samples raw samples 25 times in 7 sec with 1 ft movement
All analysts did not shake quickly enough. Raw samples need to be shaken more vigorously.

Page 3 / #####
Date
5b2 Invert filled retail container 25 times, each inversion a complete down and up motion

All analysts did not complete the inversions.

6d Avoid foam if possible when pipet is inserted into sample.
All analysts did not avoid the foam. The raw milk container may be tapped on the container on counter and tilted as to show clear spot on surface of milk. The pipet is not inserted more than 2.5 cm. Analysts may use the cap of retail containers or sterile Petri dish to adjust the pipet volume and not adjust pipet volume while pipet is still in liquid portion of sample.

APPENDIX N LAB

CHARM SL BETA LACTAM (IMS# 9C13 rev 2/10)

3a1 Incubator level. Temperature checked daily (day of use), records maintained.
The temperature is not being recorded to the tenth of a degree.
Please instruct analysts to record the strip incubator to the tenth of a degree.
Send copies of the temperature record for the next two months.

14d Reader tapes or computer printouts maintained for two years.
It would be best to keep the printouts with the daily sheets as it is more difficult to look through separate stacks to match.the tankers tested.

Comments/Recommendations: Optional Areas that may need to be addressed or LEO has some concern.

PERSONNEL AND PROCEDURES CERTIFIED

LEO IS TO LIST ALL THE PERSONNEL AND PROCEDURES THAT WERE EVALUATED AT THIS AUDIT. INCLUDE A LETTER (X, C, N, ETC) THAT DENOTES THE STATUS OF ANALYSTS (REFERENCED AS BELOW) ON THE EVALUATION AND SPLIT SAMPLES.

CERTIFIED LAB

PERSONNEL AND PROCEDURES CERTIFIED

	SPC/PACCOLI/PCCPMC			D3	I1	C[3,9,10,12]	DMSCC	PHOS[28]
Name Analyst 1	X/N	X/X	X	C	X	X	X	X
Name Analyst 2	X/P	X/X	X	X	X	X	X	X

[X denotes full certification in the indicated procedures pending acceptable performance in the annual proficiency testing program (split sample) for all procedures for which certification has been granted. P denotes provisional certification pending acceptable performance in the annual proficiency testing program for all procedures for which certification has been granted. C denotes conditional certification pending acceptable performance in the annual proficiency testing program for all procedures for which certification has been granted. N denotes no certification status granted.].

APPENDIX N LAB

Certified Industry Analysts	2010 On-Site Evaluation TEST KIT	4/2010 Split Sample Survey TEST KIT
Name CIS 1	x (CIS)	x
Name CIS 2	x (CIS)	x
Name CIS 3	No Longer Employed	x

Industry Analysts	2010 On-Site Evaluation TEST KIT	6/2010 Split Sample Survey TEST KIT
Name IA 1	x	x
Name IA 2	x	x

CONCLUSION

Use the proper conclusion found on pages 23 & 24.

Proposal: 238
Document: 2009 EML (SECTION 1)
Pages: 3

*Make the following change to **SECTION 1: LABORATORY EVALUATION PROGRAM** on Page 3:*

CERTIFICATION/APPROVAL OF MILK LABORATORY ANALYSTS

Certification of milk laboratory analysts by the Federal or State LEO shall be based on the following criteria:

1. State central milk laboratories' evaluations shall be scheduled and performed by their triennial expiration date. State central milk laboratories shall submit requests, in writing, for on-site evaluation of new analyst(s) performance of techniques, new methods and/or new facilities to the FDA/LPET. ~~The FDA/LPET shall schedule a mutually agreeable date or a date within 60 days of the request for an evaluation.~~ The Federal LEO shall schedule a mutually agreeable date within 30 days of the request for evaluation.

Proposal: 241
Document: 2009 EML (Sections1, 3 and 4; and References)
Pages: 3, 4, 16, 18 and 24

Make the following change to ***SECTION 1: LABORATORY EVALUATION PROGRAM*** *on Pages 3 and 4:*

An evaluation of a milk laboratory must include an on-site visit to the laboratory, a review of the records, including training records of IAs, records of split sample performance, facilities, equipment, materials and procedures. The evaluation shall be made using the most recent approved Official Milk Laboratory Evaluation Forms (FDA-2400 Series Forms). The Federal or State LEO shall determine if the laboratory facilities, equipment, records and techniques of analysts are in compliance with the FDA-2400 Series Forms ~~and where appropriate the latest edition of *Standard Methods for the Examination of Dairy Products*[1] (SMEDP)~~.

CERTIFICATION/APPROVAL OF MILK LABORATORY ANALYSTS

Page 4:

3. The laboratory facilities, equipment and records shall meet the requirements stated on the FDA-2400 Series Forms~~, and where appropriate SMEDP,~~ as determined by an on-site evaluation.

4. Analyst performance is in compliance during an on-site evaluation, with procedures required by the FDA-2400 Series Forms~~,~~ and the PMO~~, and where appropriate SMEDP~~.

Make the following change to ***SECTION 3: CERTIFICATION OF LABORATORY EVALUATION OFFICERS*** *on Page 16:*

Initial certification of State LEO shall be based on meeting the following criteria:

1. The individual must be a State government employee and demonstrate competence in evaluating milk testing laboratories and analysts' performance of milk laboratory test methods or Appendix N procedures as stated on the FDA-2400 Series Forms~~, and where appropriate, as described in SMEDP~~ when accompanied by a representative of the FDA/ LPET on an initial check laboratory evaluation. Initial check evaluation surveys (for certification) should not be conducted at sites that have been evaluated within the past 90 days.

Make the following change to ***SECTION 4: EQUIPMENT AND APPARATUS OF AID TO EVALUATION OFFICERS*** *on Page 18:*

8. Reference books ~~– other than SMEDP~~. (e.g., AOAC Official Methods of Analysis, Standard Methods for the Examination of Water and Wastewater)

Make the following change to the ***RERENCES*** *on Page 24:*

~~1. Available from the American Public Health Association, 800 I St., N.W., Washington, D.C. 20001-3710, USA. {http://www.apha.org}~~

~~2~~1. Copies of the FDA-2400 Series Forms can be downloaded from {http://www.fda.gov/opacom/morechoices/fdaforms/default.html}

Proposals: 219, 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234, and 248
Document: FDA 2400 Series Forms

*All were referred to the Laboratory Committee to follow the **2400 Series Forms** protocol.*

Proposal: 219
Document: FDA 2400 Series Forms

Approve the Charm Beta lactam and Flunixin Test for screening under Appendix N and Section 6 of the PMO, develop a 2400 Series Form and add the test method to M-a-85-Beta lactam Test Methods For Use Under Appendix N And Section 6 Of The Grade "A" Pasteurized Milk Ordinance (PMO). Also, revise M-I-96-10 accordingly.

Proposal: 224
Document: FDA 2400 Series Forms

*Make the following change to the **FDA 2400 Series Forms**:*

Revise 2400 form Appendix N Bulk Milk Tanker Screening for Neogen BetaStar US to reflect specific changes to the new BetaStar Plus test, which has met the requirements of FDA/AOAC validation. The BetaStar Plus test will replace the BetaStar US test upon final FDA approval and the form must be revised to meet the new requirements.

Additional changes in formatting by the NCIMS Laboratory Committee to conform with new format for 2400 forms.

Proposal: 225
Document: FDA 2400 Series Forms
Pages: 15-20

*Make the following change to the **FDA 2400 Series Forms**:*

Milk Laboratory Evaluation Form 2400 (Rev. 1-09)

Add to page 15 "27. Media":

c. Easygel Aerobic Plate Count, Pectin Gel Method
1. Lot No. _____ Exp. Date _____

Rcd. Date _____ Date Opened _____

Re-letter c. – r., currently in Form 2400

Add to page 20 "29. Prepared Media Storage":

e. Easygel Aerobic Plate Count plate storage
1. Store at room temperature.
2. Use before expiration date on package.
3. Store Easygel pretreated petri dishes at room temperature. Reseal unused dishes in bag.

Re-letter e. – f., currently in Form 2400

Proposal: 226
Document: FDA 2400 Series Forms
Pages: 4 and 5

*Make the following change to the **FDA 2400 Series Form:***

Idexx SNAP 2400 Series Form

Starting at item 6q

q. At the end of incubation, visually inspect the control and test spot. The test is invalid and the same sample should be retested with a new SNAP device if:

1. The control spot fails to develop color.
2. Blue streaking occurs in the background or the background is the same color as the sample or control spots.
3. The sample or control spots are not uniform in color or exhibit poor spot quality.

~~q~~r. ~~Read~~ Insert only valid tests into the reader **IMMEDIATELY (no longer than 30 seconds)** ~~**after final incubation)**~~ after completion of incubation. ~~with IDEXX Reader for SNAP devices~~

s. Use the stylus to tap OK

7. Interpretation with Idexx Reader for SNAP Devices
~~a. The control spot is on the top and the test spot on the bottom~~
~~of the Results Window (Correct orientation is with activator button to right and sample well to left)~~
~~b. Negative result:~~
~~1. If test spot is darker than or equal to the control spot, sample is **Negative (NF)**~~
~~c. Positive result:~~
~~1. If test spot is lighter than control spot, sample is **Initial Positive**~~

~~d~~. a. IDEXX Reader for SNAP devices automatically prints results as **Positive** ~~(initial)~~ or **Negative (NF)**

- - - -

Charm 3 SL3 Beta-lactam Test shipping requirements in the 2400 form to allow non-refrigerated shipment.

- - - -

CERTIFIED INDUSTRY SUPERVISORS, 0.5C] Graduation/ recording interval not greater than 0.1C (electronic/digital) _____

c. Accuracy of all test temperature measuring devices checked before initial use and annually _____

1. Checked against NIST traceable thermometer to 0.1C _____

2. Accurate to ±1C when checked at temperature(s) of use _____

3. Results recorded/documented and individual devices tagged _____

a. Tag includes identification/location, date of check, temperature(s) checked and correction factor(s), as applicable _____

~~d. Temperature measuring devices are to be read to the nearest graduation/recording interval, optionally labs may interpolate between graduations~~ _____

~~e~~d. Temperature Monitoring Systems (wired/wireless) _____

1. The software must record temperature reading from each sensor/probe in the piece of equipment being monitored at the same or greater frequency as stipulated for MIG or AIG thermometers. Optionally, set to register an alert/alarm when out of the acceptable temperature range _____

a. When temperature(s) are out of acceptable range for greater than two hours, event must be documented and corrective action taken as necessary. Records maintained _____

2. Optionally, a minimum two-day backup power source (battery/electrical) for the temperature monitoring system and/or all required sensors/probes, remote signal device and monitor/controller may be employed in case of power failure _____

3. Temperature monitoring system records for each piece of equipment must be available/accessible for auditing as described in item 2c above _____

~~f~~e. Automatic temperature recording instruments, if used, compared weekly against an accurate thermometer, results recorded _____

~~g~~f. Temperature measuring device(s) calibrated at another location _____

1. Location calibrated: _____ _____
2. Calibrations current and acceptable _____

3. Copy of calibration record on-site _____

~~h~~g. Dial thermometers not used in the laboratory _____

Items 4.-8.

SAMPLES

9. Sample Requirements _____

a. Appendix N tanker sample(s) _____

1. Prevent contamination with disinfectants from hands or other sources _____

2. Ascertain temperature of bulk milk tanker, record maintained _____

3. Secure a representative sample for testing. Sample not over filled. If sample will not be tested without delay then a temperature control (TC) sample must be taken at the same time, transported, and maintained with the tanker sample(s) until it is tested _____

4. Transport sample(s) to the testing location promptly (preferably on ice if needed to maintain temperature) _____

5. Tanker sample(s) tested promptly upon arrival at the testing location _____

a. Determine sample temperature by inserting a pre-cooled thermometer (pre-cooling of electronic/digital thermometer probes is not necessary) into temperature control

b. Sample temperature must be 0.0-4.4C at testing _____

~~b~~c. Date, time and temperature of bulk milk tanker may be used for date, time and temperature as received and tested if sample testing begins without delay, record maintained _____

b. Appendix N Producer Trace Back Samples (Sample(s) not meeting the conditions outlined below may still be tested. The certified laboratory or CIS will document the condition of the samples(s)) _____

1. Samples should be accompanied by a temperature control (TC). If no TC, aliquot sample(s) for testing and measure temperature using one of the producer samples _____

2. Sample(s) should not be leaking _____

3. Tops of samples should be protected from direct contact with ice _____

4. Unprotected samples should not be submerged in water and/or ice or slush _____

Items 10.-15.

- - - -

INSTRUMENT AND REAGENT CHECKS

~~14.~~11. **Check Procedures** _____

e. Zero Check _____
   1. With no tube in the instrument, press "Start" key and take a reading _____
   2. A/D value _____ _____
   3. The reading must not exceed 314. If the reading exceeds 314, an instrument problem is indicated, call for technical assistance _____
   4. Record value ~~on printout and~~ in QC record _____

f. Calibrator C/Daily Instrument Control Check _____

…

   2. Place the cuvette with the warmed Calibrator C or Daily Instrument Control into the sample chamber and press "Start" key _____
      a. The A/D value should be 602±15 (maximum allowable drift _____
      b. A/D value _____ _____
      c. Record Lot # and value ~~on printout and~~ in QC record _____
   3. If the value does not fall within the acceptable range, then perform the following procedure (refer to manual, or contact manufacturer if unsure) _____

      …

      c. Record Lot # and value ~~on strip and~~ in QC record _____
   ~~4.~~ d. If the value does not fall within and stabilize at 602±2 seek technical assistance _____
   ~~5.~~ e. For older units requiring the instrument cover to be removed or if unsure seek technical assistance _____

g. Reconstituted Substrate/Buffer stability check _____

…

   2. Place the cuvette with the warmed working substrate into the sample chamber and press "Start" key _____
      a. The A/D value should be < 1,200 _____
      b. A/D value _____ _____
      c. Record Lot # and value ~~on printout and~~ in QC record _____

h. Reconstituted Substrate/Buffer contamination check _____

…

   4. The ALP value should be < 10 mU/L _____
      a. ALP value _____ _____
      b. Record Lot # and value ~~on printout and~~ in QC record _____

CALIBRATION
(Required at installation and after any instrument adjustments)

~~11.~~12. Calibration Procedure _____

a. Perform instrument and reagent checks (item ~~14~~ 11) prior to proceeding _____
   1. Readings from item ~~14~~ 11 are within specification, proceed with calibration _____
   2. If readings not within specification, do not proceed with calibration, make appropriate adjustments or seek technical assistance and re-check _____
   3. Record all values (initial and re-checks) ~~on tape and~~ in QC record _____

b. Check calibration ratio of Calibrators A, B and C, record Calibrator Lot # ~~on strip and~~ in QC record _____

c. Sample agitation
   1. Invert retail containers 25 times, each inversion a full cycle down and up _____

d. Remove test portions (avoiding foam) within 3 min of agitation _____

e. To each calibrator, add 75 µL (or 25 µL) of the well-mixed product being tested and immediately mix by vortexing _____
   1. For positive displacement pipettor with reusable tip _____
      ~~1.~~a. Prior to pipetting sample, draw up MS water once and expel to waste _____
      ~~2.~~b. Dry exterior of piston and tip _____
      ~~3.~~c. Place tip of pipettor into sample (no more than 1 cm) and draw up and expel several times _____
      ~~4.~~d. Draw sample into pipettor~~, touch off to side of container~~ _____
      ~~5.~~e. Holding pipettor at 90° to lab bench and with tip down and at eye level, dry exterior of tip by quickly wiping from the pipettor over the tip _____
      ~~a.~~f. Carefully inspect the pipettor tip to insure sample volume is flush with the tip _____
      ~~b.~~g. If concave, re-sample _____
      ~~c.~~h. If convex, re-wipe as above to achieve a flush sample volume (see Item 12e1e) _____
   2. For air displacement pipettor with new tip for each Sample _____
      a. Depress plunger and place tip into sample (avoiding foam or bubbles) _____
      b. Draw up test portion _____

c. Remove from sample, touch off to side of container _____

d. If excess product adheres to tip, wipe carefully without wicking sample _____

~~6.~~3. Dispel 75 µL (or 25 µL) of sample 1 cm below the surface of the calibrator (do not dispense down side of cuvette) _____

~~7.~~4. With tip still below surface depress plunger three times into calibrator to completely expel sample _____

~~8.~~5. With plunger still completely depressed, remove from tube _____

f. Add products to calibrators one tube at a time just prior to being tested _____

g. ~~Mix by vortexing~~ Run test within 20 sec of adding sample to calibrator _____

…

k. Record lot #'s of the calibrators used ~~on the tape printout and~~ in the QC record book _____

…

m. Re-calibration required if: _____

1. Controls out of limits _____

2. Adjustments made to bring A-D mode checks (item ~~14~~ 11) into specification _____

3. Any significant instrument service if performed, ex. lamp or filter replaced

…

CONTROLS

~~12.~~13. Negative Control _____

a. Use PhosphaCheck negative control from set in item 9c _____

b. Or, optionally heat a sample of product to 95±1C for 1 min with stirring (temperature control [TC] used) _____

1. Cool rapidly to 0-4.4C in an ice bath _____

2. If desired, ~~distribute~~ aliquot 1 mL quantities ~~in small tubes,~~ within 24 hours, seal and freeze at

-15C or colder in a non-frost-free freezer, or place in a Styrofoam container and place in the center of a frost-free freezer ~~for no more than~~ ,use within 2 months _____

~~c. Add 2.0 mL of working substrate (Reagent C) to cuvettes and heat to 38±1C for 20 min (use within 4 hours)~~ _____

~~d. Add 75 µL of well mixed control to cuvette and immediately vortex~~ _____

~~e. Once control is added to reagent test within 20 sec~~ _____

~~f. Place the cuvette in the Fluorometer, close the cuvette door and press the "TEST" key on the keypad~~ _____

c. Test control as a sample (see item 15 b-k) _____

~~g.~~d. Value less than (<) 20 mU/L _____ _____

e. Record lot # or identity and value in QC record _____

~~13.~~14. **Positive Control** _____

a. Use PhosphaCheck positive control from set in item 9c _____

b. Or, optionally to a portion of negative control (Item 13b), add ~~exactly~~ 0.1 mL of mixed-herd raw milk and bring up to ~~exactly~~ 100 mL with additional negative control ~~(as in item 12b)~~ _____

1. If desired, ~~distribute~~ aliquot 1 mL quantities ~~in small tubes,~~ within 24 hours, seal and freeze at -15C or colder in a non-frost-free freezer, or place in a Styrofoam container and place in the center of a frost-free freezer ~~for no more than~~ ,use within 2 months _____

c. Test ~~as in items 12 c-f~~ control as a sample (see item 15 b-k) _____

d. Value between 500±150 mU/L _____ _____

e. Record lot # or identity and value in QC record _____

TEST PROCEDURE

15. Test Procedure _____

a. Perform all instrument and reagent checks (item ~~14~~11), negative control test (item ~~12~~13) and positive control test (item ~~13~~14) prior to running analysis _____

…

e. Remove test portions (avoiding foam) within 3 min of agitation _____

…

h. Dispense 75 µL (or 25 µL) of the well-mixed sample into the warmed substrate and immediately mix by vortexing _____

1. For positive displacement pipettor with reusable tip _____

~~1.~~a. Prior to pipetting sample, draw up MS water once and expel to waste _____

~~2.~~b. Dry exterior of piston and tip _____

~~3.~~c. Place tip of pipettor into sample (no more than 1 cm) and draw up and expel several times _____

~~4.~~d. Draw sample into pipettor~~, touch off to side of container~~ _____

~~5.~~e. Holding pipettor at 90° to lab bench and with tip down and at eye level, dry exterior of tip by quickly wiping from the pipettor over the tip _____

~~a.~~f. Carefully inspect the pipettor tip to insure sample volume is flush with the tip _____

~~b.~~g. If concave, re-sample _____

~~c.~~h. If convex, re-wipe as above to achieve a flush sample volume (see Item 15h1e) _____

2. For air displacement pipettor with new tip for each Sample _____

a. Depress plunger and place tip into sample (avoiding foam or bubbles) _____

b. Draw up test portion _____

c. Remove from sample, touch off to side of container _____

d. If excess product adheres to tip, wipe carefully without wicking sample _____

~~6.~~3. Dispel 75 µL (or 25 µL) of sample 1 cm below the surface of the calibrator (do not dispense down side of cuvette) _____

~~7.~~4. With tip still below surface depress plunger three times into calibrator to completely expel sample _____

~~8.~~5. With plunger still completely depressed, remove from tube _____

i. Add products to substrate one tube at a time just prior to being tested _____

~~9.~~j. Run test within 20 sec of adding sample to reagent _____

~~i.~~k. Place the cuvette in the Fluorometer, close the cuvette door, and press the "START" key on the keypad _____

~~j.~~l. Results will display in 3 min., save tape print-out of results ~~in record book~~ and QC record _____

~~a.~~1. If a 25 µL sample volume was used multiply the displayed value by 3 _____

~~b.~~2. Record adjusted value on printout _____

~~k.~~m. Values of ≥ 350 mU/L or more of ALP activity are considered to contain approximately 0.1% (v/v) raw milk and must be confirmed _____

n. Record lot # of the substrate used in the QC record. _____

CONFIRMATION

16. Negative Control _____

a. Prepare separate negative control ~~for each product~~ from each suspect product _____

b. For preparation of control using the suspect product

1. Prepare by heating sample for at least 1 min after thermometer registers 95±1C, stirring or mixing as necessary (TC used) _____

~~c.~~2. Cool rapidly to 0-4.4C in an ice bath _____

~~d.~~c. This control must be less than 20 mU/L when tested _____

~~**17. Positive Control (See item 13)**~~ _____

~~a. Must be prepared from suspect product~~ _____

~~18.~~17. Microbial Phosphatase _____

…

~~19.~~18. Reactivated Phosphatase _____

a. Magnesium acetate solution _____

1. Dissolve 35.4g of $Mg(C_2H_30_2)_2 \cdot 4H_20$ in 25 mL MS water warming slightly to aid solution.
2. Pour solution into 100 mL volumetric flask, rinse original container several times and add rinses to flask.
3. After cooling, make up to 100 mL (stable for 1 year at 0-4.4C) _____

c. Interpretation _____

1. If the diluted aliquot containing magnesium (Test) has equal (±5%) or greater phosphatase activity than the undiluted aliquot containing no magnesium (Blank), the sample is regarded negative for residual phosphatase, and the phosphatase originally measured is of **reactivated** origin _____

   Diluted w/Mg (Test) ≥ Undiluted (Blank) = Reactivated

2. If the diluted aliquot (Test) contains less activity (< 5%) than the undiluted aliquot (Blank), the sample is considered positive for **residual phosphatase** _____

Diluted w/Mg (Test) < Undiluted (Blank) = Residual
…

RECORDING AND REPORTING

~~20.~~19. Confirmatory Interpretation _____

a. Report as positive for residual phosphatase if microbial phosphatase, and reactivatable phosphatase are not present _____
b. ~~Report~~ Record all values in mU/L _____
c. Report as **Not Found** for residual phosphatase if: _____
   l. If microbial phosphatase present _____
   ~~3.~~2. Or, if reactivatable phosphatase present _____
   ~~4.~~3. Or, if there is documentation that the product was treated such that reactivatable phosphatase may be present _____

Proposal: 232
Document: FDA 2400 Series Forms
Page: 1

*Make the following changes to the **FDA 2400 Series Forms**:*

Addition to Item 1 on the DMSCC form:

a. Un-preserved samples may be run up to 72 hours after initial collection.

Proposal: 233
Document: FDA 2400 Series Forms

*Make the following change to the **FDA 2400 Series Forms**:*

Request a study, after study review refer to 2400 form committee.

From A.Summary of Proposal:

To allow for beta lactam drug residue testing of sheep milk by the Charm SLBL method after a quantity of such milk has been frozen for up to 60 days and properly thawed. Subsequently the samples shall be held at 0-4.4°C and analyzed within 24 hours as per the instructions for frozen controls of the Charm SLBL test method as described in the Charm SL / SL6 / SL3 2400 form.

Proposal: 234
Document: FDA 2400 Series Forms
Pages: 15 and 20

*Make the following changes to the **FDA 2400 Series Forms**:*

Cultural Procedures – General Requirements form –

Item 13. Autoclave

i. Performance checked with full load and results recorded ~~weekly~~
quarterly at a minimum (preferably once during each week of use)
using spore (G. stearothermophilus) strips or suspensions,
include positive control check, results maintained _____

Proposal: 248
Document: FDA 2400 Series Forms

All sections listing control samples for instruments approved for testing somatic cells electronically for regulatory counts required under the PMO.

Proposal: 101
Document: No Document Referenced

SUBSTITUTE SOLUTION

Recommend that the NCIMS Chair establish a study committee to address the use of UV illumination as an adjunct to pasteurization. The study must be consistent with federal regulations and reviewed and accepted by FDA prior to implementation. Results will be reported back to the 2013 NCIMS Conference.

Proposal: 222
Document: No Document Referenced

The NCIMS Laboratory Committee is directed to develop a review/study committee, with the direction to report back to the 2013 NCIMS Conference, to review all uses and intended uses of references to the SMEDP as they are used in the PMO and related documents. Identify areas of duplication and where specific conference actions have eliminated the need to reference the SMEDP. The review committee is also charged to identify areas where, if any, the SMEDP reference needs to remain and recommend the specific targeted areas in SMEDP for intended conference use.

Proposal: 312
Document: No Document Referenced

Change the voluntary NCIMS International Certification Pilot Program (ICPP) as defined in IMS-a-45 and amended by IMS-a-47, that once a Third Party Certifier (TPC) has four (4) plants IMS listed and the completion and issuance of the equivalent of a State Program Evaluation, with a determination that the TPC is in **Compliance** with the PMO, the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments* (Procedures) and other NCIMS related documents, including the ICPP's Policies and Procedures, Letter of Intent (LOI) and Code of Ethics, the TPC may request from the ICPP Committee permission to add two (2) additional plants for a maximum of six (6) IMS listed plants.

The following text is a mandatory part of this solution but will not be placed in an NCIMS document:

NOTE: *This provision shall take immediate effect upon the issuance of the IMS-a, Actions from the 2011 National Conference on Interstate Milk Shipments, following FDA's concurrence with the NCIMS Executive Board.*

Proposal: 313
Document: No Document Referenced

To request that the NCIMS Executive Board request the Liaison Committee to study, provide comments and stakeholder outreach on the implications of the Food Safety Modernization Act on the Interstate Milk Shipments Program. The committee shall report back to the Executive Board with recommendations before the 2013 NCIMS Conference.

All Proposals that make changes to the NCIMS documents will be incorporated into the next edition of the affected document as they are updated. Copies of this memorandum are enclosed for distribution to Regional Milk Specialists, State Milk Regulatory Agencies, State Laboratory Evaluation Officers, and State Milk Rating Officers. This memorandum should be widely distributed to representatives of the milk industry and other interested parties, and will be available on the FDA Web Site at www..fda.gov at a later date.

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to Robert.Hennes@fda.hhs.gov.

Robert F. Hennes, RS, MPH
CAPT, US Public Health Service
Dairy and Egg Branch