

34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	301 *New Procedure
Committee:	SSCC/MMSR

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This Proposal provides language/guidance addressing the withdrawal of certification of a single-service containers and closures (SSCC) for milk and milk products manufacturer from the IMS List similar to what is already provided for Producer Dairies and Milk Plants, Receiving Stations and/or Transfer Station in *Procedures*.

It requests the NCIMS Chair to assign to the SSCC Committee and the Methods Committee to jointly develop IMS listing and withdrawal of IMS listing criteria for SSCC manufacturers. Consultants that currently have SSCC listings on the IMS List shall participate on these Committees.

Furthermore, it also requests the NCIMS Chair to assign to the SSCC Committee to develop qualifications, authorization, certification/recertification procedures, etc. for consultants that currently or wish to certify SSCC manufacturers located outside the geographical boundaries of NCIMS Member States. Consultants that currently have SSCC listings on the IMS List shall participate on this Committee.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

As stated in Appendix J-Standards for the Fabrication of Single-Service Containers and Closures for Milk and Milk Products of the PMO, the evaluation of the industry’s basic manufacturing and handling techniques and the establishment of sanitation criteria assure that single-service containers and closures and the materials from which they are formed are safe and in compliance with the bacteriological standards of the PMO.

Currently there is not any language contained in the *Procedures* that provides guidance to Sanitation Rating Officers, Private Consultants or FDA Regional Milk Specialists addressing the withdrawal of a single-service container/closure manufacturer from the IMS List when conducting an IMS listing certification or FDA audit.

By adding language to the *Procedures* addressing when the current status of a certified manufacturer of single-service containers and closures for milk and milk products changes due to a permit suspension and/or revocation or the withdrawal of their IMS listing based upon observed violations that cannot ensure the sanitary quality of their single-service containers and/or closures that may lead to a potential public health concern involving the contamination of milk and/or milk products packaged within them, this provides defined guidance and a protocol in order to sustain regulatory leveraging. This would be similar leveraging as is currently cited in the *Procedures* addressing Producer Dairies and Milk Plants, Receiving Stations and/or Transfer Station, with the exception that it currently does not provide for a sanitation and enforcement rating.

C. Proposed Solution

Changes to be made on page(s):	12 - 14 & 17	of the (X - one of the following):
<u> </u> 2011 PMO	<u> </u> 2011 EML	
<u> </u> 2011 MMSR	<u> </u> 2400 Forms	
<u> X </u> 2011 Procedures	<u> </u> 2011 Constitution and Bylaws	

MAKE THE FOLLOWING CHANGES TO THE 2011 PROCEDURES.

~~Strike through~~ text to be deleted and underline text to be added.

SECTION IV. OVERSIGHT AND RESPONSIBILITIES ...

B. STATE RESPONSIBILITIES

1. State Ratings and Single-Service Containers and Closures Manufacturer Listings

Page 12:

j. The Rating Agency shall certify U.S. manufacturers of single-service containers and closures in accordance with Appendix J. STANDARDS FOR THE FABRICATION OF SINGLE-SERVICE CONTAINERS AND CLOSURES FOR MILK AND MILK PRODUCTS ~~in~~ of the *Grade "A" PMO* for inclusion ~~in~~ on the *IMS List*.

k. When a certified manufacturer of Single-Service Containers and Closures for Milk and Milk Products changes status because of permit suspension and/or revocation or

the withdrawal of their listing based upon observed violations that cannot ensure the sanitary quality of their single-service containers and/or closures that may lead to a potential public health concern involving the contamination of milk and/or milk products packaged within them, the shipping State shall immediately notify all known receiving States and the appropriate PHS/FDA Regional Offices.

When an existing listing is no longer valid because a listed single-service containers and closures manufacturer's permit is revoked, the State shall within five (5) days request PHS/FDA to withdraw the shipper from the *IMS List*.

Receiving States shall notify shipping States of any irregularities in the single-service container and closure supply received. (Refer to Section IV., B., 7.)

The Rating Agency shall keep current the listings of all certified single-service containers and closures shippers within its State. ...

Page 13:

7. Challenges and Remedies

a. Complaints from Receiving States and Municipalities

1.) Complaints as to the sanitary quality of milk and/or milk products and/or single-service containers and closures being received and challenges ~~of~~ related to the validity of certified ratings and/or single-service containers and closures listings shall be made in writing by the receiving State or municipality to the Rating Agency of the shipping State, with a copy to the appropriate PHS/FDA Regional Office. ...

Page 14:

4.) After an investigation, and based on the facts disclosed, the shipping State shall:
...

C.) Make a new rating or listing for single-service containers and closures manufacturers within sixty (60) days, and with the written permission of the shipper, forward the new rating or listing, respectively, and a copy of the shipper's written permission to the appropriate PHS/FDA Regional Office for listing ~~in~~ on the *IMS List*. The receiving State(s) shall also be notified of the action being taken by the shipping State. ...

c. Action to be Taken if the PHS/FDA Check Rating or Single-Service Containers and Closures Manufacturer's Audit Indicates the Listed Rating is Not Justified: ...

3.) Single-Service Containers and Closures For Milk and Milk Products

A. Withdrawal of Certification

When PHS/FDA audit data indicates violations that cannot ensure the sanitary quality of single-service containers and/or closures that may lead to a potential public health concern involving the contamination of milk and/or milk products packaged within them requires a withdrawal of certification, the 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., 1k. In case of withdrawal, a new certification 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 certification 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.

34.) If a Rating Agency fails to take the required action outlined in Section IV., B., 7.c.1.)₂ ~~and 7.c.2.) and 7c.3.)~~, calling for immediate notification of all known receiving States when the current certification of a listed shipper is to be withdrawn as recommended by PHS/FDA, PHS/FDA after a reasonable lapse of time (not to exceed five (5) days), shall provide all participating States with the check rating scores or audit findings for single-service containers and closures listings. The State which failed to take the required action shall be identified in the next listing of the *IMS List* as not being in compliance with Section IV., B., 7.c.1.)₂ ~~and 7.c.2.) and 7c.3.)~~.

Page 17:

45.) ~~Should the~~ If a Rating Agency ~~indicate~~ indicates that it is not in a position to make a new rating or listing within a the sixty (60) day period or a reinspection within thirty (30) days, PHS/FDA shall identify those States in the next listing of the *IMS List* as not being in compliance with the provisions of this paragraph.

56.) If ~~the~~ a Rating Agency informs PHS/FDA that it is unable to make arrangements for PHS/FDA to check rate the sanitation compliance status of listed shippers or audit single-service containers and closures listed shippers, PHS/FDA shall identify those States in the next listing of the *IMS List* as not being in compliance with the provisions of this paragraph.

67.) If a Rating Agency fails to request the removal of a milk plant, receiving station and/or transfer station or single-service containers and closures manufacturer from the *IMS List* as provided for in Section IV., B., 1.f. and B., 1.k, respectively, PHS/FDA shall, after five (5) days, provide this information to all receiving states. ...

The following text is a part of the Proposal but will not be placed in an NCIMS document.

FDA requests the NCIMS Chair to assign the following charges to the identified NCIMS standing committee(s) and to report back to the 2015 NCIMS Conference:

- **SSCC and Methods Committees Jointly:** To develop listing and withdrawal of listing criteria for SSCC manufacturers. Consultants that currently have SSCC listings on the IMS List shall participate on these Committees.
- **SSCC Committee:** To develop qualifications, authorization, certification/recertification procedures, etc. for consultants that currently certify or wish to certify SSCC manufacturers located outside the geographical boundaries of NCIMS Member States. Consultants that currently have SSCC listings on the IMS List shall participate on this Committee.

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	302 *New Procedure
Committee:	Lab

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

All laboratory proposals requiring data shall be submitted with the data or said data shall be submitted to the NCIMS Laboratory Committee members at a minimum of 30 days before the first day of the Conference.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Many proposals submitted to the Conference require data in order to be considered for approval by the Laboratory Committee. While some data is included with the proposals, most is not and is either given at the Conference or never seen by the Laboratory Committee. The data that is not seen by Committee members is given a yea or nay by the FDA/LPET. The Committee then votes without a complete understanding of the data behind the study.

The members of the Laboratory Committee need more time to review the data along with the submitted proposal in order to make an informed decision and to be able to ask questions. This will help to move the process along more quickly during the Committee meetings at the Conference.

C. Proposed Solution

Changes to be made on page(s):		59	of the (X - one of the following):	
	2011 PMO		2011 EML	
	2011 MMSR		2400 Forms	
x	2011 Procedures		2011 Constitution and Bylaws	

ARTICLE V ----- DUTIES OF THE PROGRAM CHAIR AND COMMITTEE

SECTION 3. The Program Committee shall review and assign all Proposals received for Council and voting delegate deliberation. Proposal assignments shall be made in accordance with the subject matter outlined in Article VI, Sections 1., 2. and 3. of the *Bylaws* unless this will result in one Council being assigned more than 38% of all Proposals; in which case, the Program Committee may assign Proposals to the Councils without considering their subject matter for purposes of equalizing the distribution of Proposals between the three Councils.

Subd.1. Any laboratory method proposals submitted for consideration requiring data shall include the data points OR at a minimum the data shall be supplied to the Laboratory Committee at least 30 days prior to the beginning of the Conference.

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34th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #:	303 *Procedure Change
Committee:	Lab

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

The FDA 2400 Series Evaluation Forms being used as Conference documents should reflect the cooperative nature of the program. The forms are jointly worked on by the FDA/LPET and the NCIMS Laboratory Committee. A proposed name change would include NCIMS.

**B. Reason for the Submission and
Public Health Significance and/or Rationale Supporting the Submission**

There is no public health significance. Through a collaborative effort of the NCIMS Laboratory Committee's 2400 Sub-Committee and the FDA/LPET these forms are updated and new ones written. Naming them as FDA/NCIMS 2400 Series Evaluation Forms would reflect the cooperative program. The name is stated this way on page 27 of the 2011 Procedures document, under I. Laboratory Procedures.

C. Proposed Solution

Changes to be made on page(s):		various	of the (X - one of the following):
_____	2011 PMO	x	2011 EML
_____	2011 MMSR	_____	2400 Forms
x	2011 Procedures	_____	2011 Constitution and Bylaws

Page 8, 2011 Procedures:

4. Laboratory Evaluations

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

b. PHS/FDA shall periodically evaluate milk laboratories of participating States to assure compliance with FDA/NCIMS 2400 Series Evaluation Forms, and where appropriate, the current edition of *OMA*.

Page 27, 2011 Procedures:

I. LABORATORY PROCEDURES

Laboratory procedures used to examine milk and milk products of interstate milk shippers shall conform to the procedures in the current revisions of the ~~NCIMS/FDA~~ FDA/NCIMS 2400 Series Forms and the *OMA*, using only methods approved by the NCIMS.

Page 68, 2011 Procedures:

FDA/NCIMS 2400 Series Evaluation Forms, USPHS/FDA, U.S. Department of Health and Human Services, ~~Summit Argo~~ Bedford Park, Illinois 60501, Current Edition.

Page 1, paragraph 2, 2011 EML:

The State Laboratory Evaluation Officer (State LEO) will use the appropriate ~~FDA-~~ FDA/NCIMS 2400 Series Forms when evaluating official laboratories, officially designated laboratories, CIS, IS and IA. The Federal Laboratory Evaluation Officer (Federal LEO) will use the appropriate ~~FDA-~~ FDA/NCIMS 2400 Series Forms when evaluating State Central Milk Laboratories and State LEOs. Appropriate ~~FDA-~~ FDA/NCIMS 2400 Series Forms are those forms that have been approved by the NCIMS Laboratory Committee working cooperatively with the Food and Drug Administration (FDA) and the NCIMS Executive Board, and are effective 90 days after executive board approval. Approved forms shall be issued within 90 days of NCIMS Executive Board approval. If the FDA is unable to release the approved forms within the 90 day time frame, FDA/LPET shall issue a draft version of the 2400 series forms 90 days after NCIMS Executive Board approval.

Page 3, paragraph 1, 2011 EML:

The evaluation shall be made using the most recent approved Official Milk Laboratory

Evaluation Forms (~~FDA-~~ FDA/NCIMS 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-~~ FDA/NCIMS 2400 Series Forms.

Page 3, paragraph 3, 2011 EML:

The narrative report must be sufficiently detailed to allow readers to determine what is being cited without having to refer to the ~~FDA-~~ FDA/NCIMS 2400 Series Forms.

Page 3, paragraph 4, 2011 EML:

Reports to the Official Milk Laboratories-/CIS must include the narrative report and may include copies of the completed ~~FDA-~~ FDA/NCIMS 2400 Series Forms.

Page 4, item 3, 2011 EML:

3. The laboratory facilities, equipment and records shall meet the requirements stated on the ~~FDA-~~ FDA/NCIMS 2400 Series Forms, as determined by an on-site evaluation.

Page 4, item 4, 2011 EML:

4. Analyst performance is in compliance during an on-site evaluation, with procedures required by the ~~FDA-~~ FDA/NCIMS 2400 Series Forms and the PMO.

Page 5, item 1, 2011 EML:

1. The laboratory facilities, equipment, procedures and records must meet the requirements stated on the appropriate ~~FDA-~~ FDA/NCIMS 2400 Series Forms and for CIS, appropriate Appendix N 2400 Series Forms, as determined by an on-site evaluation.

Page 6, item 3, 2011 EML:

3. Analyst performance is in compliance with procedures required by the approved ~~FDA-~~ FDA/NCIMS 2400 Series Forms associated with the Appendix N program.

Page 8, item 2, 2011 EML:

2. The laboratory must maintain one certified BactoScan analyst (see current FDA/NCIMS 2400 series form) for training and ongoing oversight of the BIO.

Page 8, item 3, 2011 EML:

3. Refer to the BIO approved training procedures at the end of the BactoScan FDA/NCIMS 2400 series form.

Page 16, 2011 EML:

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-~~ FDA/NCIMS 2400 Series Forms when accompanied by a representative of the FDA/ LPET on an initial check laboratory survey.

Page 16, 2011 EML:

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-~~ FDA/NCIMS 2400 Series Forms when accompanied by a representative of the FDA/LPET on a check laboratory survey.

Page 21, 2011 EML:

1. Do the samples arrive at the laboratory as specified in the appropriate ~~FDA-~~ FDA/NCIMS 2400 Series Forms?

Page 23, 2011 EML:

~~FDA-~~ FDA/NCIMS 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 when the option to send them with the narrative report is used.

Page 23, 2011 EML:

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-~~ FDA/NCIMS 2400 Series Forms. Each form used shall have the revision date noted. Additional narrative reports, without ~~FDA-~~ FDA/NCIMS 2400 Series Forms, are to be sent to others that need to be informed as to the outcome of the laboratory survey.

Page 26, 2011 EML:

1. Copies of the ~~FDA-~~ FDA/NCIMS 2400 Series Forms can be obtained from Federal or State LEO(s).

Page 30, 2011 EML:

These are usually considered to be good laboratory practices but are not listed in the ~~FDA-~~ FDA/NCIMS 2400 Series Forms and are not debitible items.

Page 33, 2011 EML:

These are usually considered to be good laboratory practices but are not listed in the ~~FDA-~~ FDA/NCIMS 2400 Series Forms and are not debitible items.

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

JOINT COUNCILS	
Proposal #:	304 * Procedures Change & **Constitution & Bylaws Change
Committee:	Aseptic/ Lab/MMSR/ Constitution & Bylaws

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This Proposal contains modifications to the PMO, Methods, Procedures and Bylaws documents that address the regulation and rating of milk plants producing Grade “A” low-acid retort processed after packaging milk and/or milk products. It will incorporate the Aseptic Program Committee’s findings and determination for milk plants that produce Grade “A” low-acid retort processed after packaging milk and/or milk products into the NCIMS documents.

This Proposal also requests a two (2) year extension of the NCIMS Aseptic Pilot Program to specifically address Grade “A” acidified and fermented high-acid milk and/or milk products. The additional two (2) years will be utilized to evaluate the effectiveness of regulating and rating milk plants producing Grade “A” acidified and/or fermented high-acid milk an/or milk products.

This Proposal addresses the regulation of Grade “A” low-acid retort processed after packaging milk and/or milk products manufactured in accordance with the Low Acid Canned Foods (LACF) regulations contained in 21 CFR 108, 110, and 113 while regulating the areas of the milk plant that are outside the low-acid retort processed after packaging system (RPPS) in accordance with the PMO. It provides for a separate IMS listing for Grade “A” milk plants producing Grade “A” low-acid retort processed after packaging milk and/or milk products.

**B. Reason for the Submission and
Public Health Significance and/or Rationale Supporting the Submission**

This Proposal is based on the model that was established by the Aseptic Program Committee for low-acid aseptically processed and packaged milk and/or milk products. It provides a framework for the regulation of Grade "A" low-acid retort processed after packaged milk and/or milk products should a processor choose to label their retort processed after packaging milk and/or milk products Grade "A" or their retort processed after packaging milk and/or milk products are used as an ingredient in a defined Grade "A" milk and/or milk product.

This Proposal includes a request for a two (2) year extension of the NCIMS Aseptic Pilot Program (APP) to address Grade "A" acidified and fermented high-acid milk and/or milk products. The two (2) years will allow time to study, develop and evaluate the additional Grade "A" milk and/or milk product categories under a controlled pilot program and to develop a formal training program.

The APC shall be responsible for the oversight of the NCIMS Aseptic Program addressing low-acid aseptically processed and packaged Grade "A" milk and/or milk products, low-acid retort processed after packaging milk and/or milk products, as well as Grade "A" acidified and fermented high-acid milk and/or 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 technology and its application. The APC shall provide a report to the 2015 NCIMS.

C. Proposed Solution

Changes to be made on page(s):		<u>Entire Documents</u>		of the (X - one of the following):
<u>X</u>	2011 PMO	<u>X</u>	2011 EML	
<u>X</u>	2011 MMSR		2400 Forms	
<u>X</u>	2011 Procedures	<u>X</u>	2011 Constitution and Bylaws	

MAKE THE FOLLOWING CHANGES TO THE 2011 PMO:

~~Strikeout~~ text to be deleted and underlined text to be added.

Cover Page:

~~2011~~ 2013 Revision

Page iv:

PREFACE ...

This edition of the *Ordinance* contains sanitary standards for ~~only~~ Grade "A" raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging and Grade "A" milk and/or milk products defined in Section 1. ...

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

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STANDARDS FOR GRADE "A" PASTEURIZED, ULTRA-PASTEURIZED, AND ASEPTICALLY PROCESSED AND PACKAGED LOW-ACID MILK AND/OR MILK PRODUCTS AND RETORT PROCESSED AFTER PACKAGED LOW-ACID MILK AND/OR MILK PRODUCTS.....

ITEM 16P. PASTEURIZATION, ~~AND~~ ASEPTIC PROCESSING AND PACKAGING, AND RETORT PROCESSED AFTER PACKAGING.....

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

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APPENDIX S. ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM

Page 1:

**GRADE "A" PASTEURIZED MILK ORDINANCE
(*GRADE "A" PMO*)--~~2011~~ 2013 REVISION**

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

Be it ordained by the ... of ...¹ as follows:

SECTION 1. DEFINITIONS ...

B. ASEPTIC PROCESSING AND PACKAGING: The term "Aseptic Processing and Packaging", when used to describe a milk and/or milk product, means that the milk and/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 and to maintain the commercial sterility of the milk and/or milk 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 (APPS) in a milk plant is comprised of the processes and equipment used to process and package aseptic Grade "A" low-acid milk and/or milk products. The Aseptic Processing and Packaging System (APPS) shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. The Aseptic Processing and Packaging System (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 and/or equipment that are considered critical to the commercial sterility of the product. ...

Page 2:

F. **BULK MILK PICKUP TANKER:** A bulk milk pickup tanker is a vehicle, including the truck, tank and those appurtenances necessary for its use, used by a bulk milk hauler/sampler to transport bulk raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging from a dairy farm to a milk plant, receiving station, or transfer station. ...

Page 4:

S. **HACCP DEFINITIONS:** (For use in conjunction with Appendix K.)

S-1. **AUDIT:** An evaluation of the entire milk plant, receiving station, or transfer station facility, and NCIMS HACCP System to ensure compliance with the NCIMS HACCP System and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants and Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants, respectively. ...

Page 6:

V. **LOW-ACID ASEPTIC AND RETORT MILK AND/OR MILK PRODUCTS:** Milk and/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/or milk products and retort processed after packaging low-acid milk and/or milk products are stored under normal non-refrigerated conditions. Excluded from this definition are low-acid milk and/or milk products that are labeled for storage under refrigerated conditions. ...

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

Page 8:

GG. **OFFICIALLY DESIGNATED LABORATORY:** An officially designated laboratory is a commercial laboratory authorized to do official work by the Regulatory Agency, or a milk industry laboratory officially designated by the Regulatory Agency for the examination of producer samples of Grade "A" raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging and commingled milk tank truck samples of raw milk for drug residues and bacterial limits. ...

Page 9:

MM. **RETORT PROCESSED AFTER PACKAGING:** The term "Retort Processed after Packaging", when used to describe a milk and/or milk product, means that the milk and/or milk product has been subjected to sufficient retort heat processing after packaged

Parts 108, 110 and 113 and to maintain the commercial sterility of the milk and/or milk product under normal non-refrigerated conditions.

NN. RETORT PROCESSED AFTER PACKAGING SYSTEM (RPPS): For the purposes of this *Ordinance*, the Retort Processed after Packaging System (RPPS) in a milk plant is comprised of the processes and equipment used to retort process after packaging low-acid Grade "A" milk and/or milk products. The Retort Processed after Packaging System (RPPS) shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. The Retort Processed after Packaging System (RPPS) shall begin at the container filler and end at the palletizer, provided that the Process Authority may provide written documentation which will clearly define additional processes and/or equipment that are considered critical to the commercial sterility of the milk and/or milk product.

MMOO. SANITIZATION: Is the application of any effective method or substance to properly cleaned surfaces for the destruction of pathogens, and other microorganisms, as far as is practicable. Such treatment shall not adversely affect the equipment, the milk and/or milk product, or the health of consumers, and shall be acceptable to the Regulatory Agency. ...

Re-letter remaining DEFINITIONS accordingly.

OOQQ. TIME/TEMPERATURE CONTROL FOR SAFETY OF MILK AND/OR MILK PRODUCTS: Milk and/or milk products that require time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation includes: ...

Page 11:

QQSS. ULTRA-PASTEURIZATION (UP): The term "Ultra-Pasteurization", when used to describe a ~~dairy~~ milk and/or milk product, means that such milk and/or milk product shall have been thermally processed at or above 138°C (280°F) for at least two (2) seconds, either before or after packaging, so as to produce a milk and/or milk product, which has an extended shelf-life under refrigerated conditions. (Refer to 21 CFR 131.3.) ...

Re-letter remaining DEFINITIONS accordingly.

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SECTION 2. ADULTERATION OR MISBRANDED MILK AND/OR MILK PRODUCTS ...

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SECTION 4. LABELING ...

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, retort processed after packaging, condensed and/or dried.
2. The words "keep refrigerated after opening" in the case of aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaging low-acid milk and/or milk products. ...

Page 16:

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, retort processed after 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/or 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 (1) 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, retort processed after 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, retort processed after packaged, condensed and/or dried milk and/or milk products. The street address of the milk plant ~~need~~ does not need to be shown when only one (1) milk plant of a given name is located within the municipality.

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The identity labeling requirement may be interpreted as permitting milk plants and persons to purchase and distribute, under their own label, milk and/or milk products processed and packaged at another milk plant, provided, that the label reads, "Processed at ... (name and address)", or that the processing and packaging milk plant is identified by a proper code.

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~~ shall 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 low-acid milk and/or milk products, or retort processed after packaged low-acid milk and/or milk products when properly enforced, will ensure that this grade of milk and/or milk products will be as safe as they can practically be made. Descriptive labeling terms ~~must~~ shall not be used in conjunction with the Grade “A” designation or name of the milk and/or milk product and ~~must~~ shall not be false or misleading.

SECTION 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS

Each dairy farm, milk plant, receiving station, transfer station, milk tank truck cleaning facility whose milk and/or milk products are intended for consumption within ...of...¹ or it's jurisdiction, and each bulk milk hauler/sampler who collects samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging, for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station and each milk tank truck and its appurtenances shall be inspected/audited by the Regulatory Agency prior to the issuance of a permit. Following the issuance of a permit, the Regulatory Agency shall: ...

1. Inspect each milk tank truck and its appurtenances used by a bulk milk hauler/sampler who collects samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station, at least once every twelve (12) months. ...

3. Inspect each milk plant and receiving station at least once every three (3) months, provided that, for those milk plants and receiving stations that have HACCP Systems, which are regulated under the NCIMS voluntary 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 low-acid milk and/or milk products and/or retort processed after packaged low-acid milk and/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 and RPPS, respectively, 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. ...

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ADMINISTRATIVE PROCEDURES

INSPECTION FREQUENCY: For the purposes of determining the inspection frequency for dairy farms, transfer stations and milk plants or the portion of a milk plant that is IMS listed to produce aseptically processed and packaged low-acid milk and/or milk products

and/or retort processed after packaged low-acid milk and/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. ...

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~~ dairy farm, transfer station, milk plants or the portion of a milk plant that is IMS listed to produce aseptically processed and packaged low-acid milk and/or milk products and/or retort processed after packaged low-acid milk and/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/or milk products or receiving station inspection every three (3) months is not a desirable frequency, it is instead a legal minimum. Bulk milk hauler/samplers, industry plant samplers, milk tank trucks, milk tank truck cleaning facilities, dairy farms, milk plants, receiving stations and transfer stations experiencing difficulty meeting requirements should be visited more frequently. Milk plants that condense and/or dry milk and/or milk products and which operate for a short duration of time or intermittent periods of time should also be inspected more frequently. Inspections of dairy farms shall be made at milking time as often as possible and of milk plants at different times of the day in order to ascertain if the processes of equipment assembly, sanitizing, pasteurization, ultra-pasteurization, cleaning and other procedures comply with the requirements of this *Ordinance*. ...

Page 20:

ENFORCEMENT PROCEDURES - ASEPTIC PROCESSING AND PACKAGING MILK PLANTS AND/OR RETORT PROCESSED AFTER PACKAGING MILK PLANTS: 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/or Grade "A" retort milk plant and the ~~Grade "A"~~ aseptic Grade "A" low-acid milk and/or milk products and/or the retort processed Grade "A" low-acid milk and/or milk products, respectively, meet the applicable requirements of this *Ordinance*.

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SECTION 6. THE EXAMINATION OF MILK AND/OR MILK PRODUCTS ...

1. During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization, ultra-pasteurization, ~~or~~ aseptic processing and packaging, or retort processed after 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, or retort processed after 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, or retort processed after packaging.

3. 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 ultra-pasteurized milk and/or 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~~ that do not have validated and accepted methods are not required to be tested. Aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaged low-acid milk and/or milk products shall be exempt from the sampling and testing requirements of this Item. ...

Page 24:

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

All pasteurized and ultra-pasteurized milk and/or 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~~ not be a 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/or milk products defined in this *Ordinance* only when there are validated and accepted test methodology.

NOTE: When multiple samples of the same milk and/or milk products, except for aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaged low-acid milk and/or 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. ...

Page 25:

Assays of milk and/or milk products as defined in this *Ordinance*, including aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaged low-acid milk and/or 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. ...

Page 27:

SAMPLING PROCEDURES: *SMEDP* contains guidance for sampling of milk and milk products. Optionally, sample collection time may be identified in military time (24 hour clock). (Refer to Appendix G. for a reference to drug residues in milk and the conditions under which a positive phosphatase reaction may be encountered in properly pasteurized milk or cream. Refer to Appendix B. for reference to farm bulk milk hauling programs regarding training, licensing/permitting, routine inspection and the evaluation of sampling procedures.)

When samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging are taken at a milk plant prior to pasteurization, they shall be drawn following adequate agitation from randomly selected storage tanks. All counts and temperatures ~~should~~ shall be recorded on a milk-ledger form as soon as reported by the laboratory. A computer or other information retrieval system may be used. ...

SECTION 7. STANDARDS FOR GRADE "A" MILK AND/OR MILK PRODUCTS

All Grade "A" raw milk and/or milk products for pasteurization, ~~or~~ ultra-pasteurization, ~~or~~ aseptic processing and packaging, or retort processed after packaging and all Grade "A" pasteurized, ultra-pasteurized, ~~or~~ aseptically processed and packaged low-acid milk and/or milk products, or retort processed after packaged low-acid milk and/or milk products, shall be produced, processed, manufactured and pasteurized, ultra-pasteurized, ~~or~~ aseptically processed and packaged, or retort processed after 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, or retort processed after 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 bacto-fugation processes are performed in the milk plant in which the milk and/or milk product is pasteurized, ultra-pasteurized, ~~or~~ aseptically processed and packaged, or retort processed after 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 (1) time, to temperatures greater than 52°C (125°F) but less than 72°C (161°F), 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 75°C (166°F) in a continuing heating process and immediately cooled to 7°C (45°F) or less when necessary for enzyme deactivation (such as lipase reduction) for a functional reason. ...

Page 28:

Whey shall be from cheese made from Grade "A" raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging as provided in this *Ordinance*. ...

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Table 1. Chemical, Physical, Bacteriological, and Temperature Standards

GRADE "A" RAW MILK AND MILK PRODUCTS FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ~~OR~~ ASEPTIC PROCESSING AND ~~PACKGING~~ PACKAGING, OR RETORT PROCESSED AFTER PACKAGING

Page 31:

STANDARDS FOR GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ~~OR~~ ASEPTIC PROCESSING AND ~~PACKGING~~ PACKAGING OR RETORT PROCESSED AFTER PACKAGING ...

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ITEM 18r. RAW MILK COOLING

Raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging shall be cooled to 10°C (50°F) or less within four (4) hours or less, of the commencement of the first milking, and to 7°C (45°F) or less, within two (2) hours after the completion of milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10°C (50°F). ...

Page 55:

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging shall be cooled to 10°C (50°F) or less within four (4) hours or less, of the commencement of the first milking, and to 7°C (45°F) or less, within two (2) hours after the completion of milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10°C (50°F). ...

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STANDARDS FOR GRADE "A" PASTEURIZED, ULTRA-PASTEURIZED, ~~AND~~ ASEPTICALLY PROCESSED AND PACKAGED LOW-ACID MILK AND/OR

MILK PRODUCTS, AND RETORT PROCESSED AFTER PACKAGED LOW-ACID MILK AND/OR 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 low-acid milk and/or milk products and/or retort processed after packaging low-acid milk and/or milk products, the APPS or RPPS, respectively, 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 and RPPS, 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~~, and Retort Processed after 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. ...

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ITEM 1p. FLOORS – CONSTRUCTION ...

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when: ...

3. The floors are provided with trapped drains. Cold-storage rooms used for storing milk and/or milk products need not be provided with floor drains when the floors are sloped to drain to one (1) or more exits. Storage rooms for dry ingredients, dry packaged milk and/or milk products, ~~and~~ aseptically processed and packaged low-acid milk and/or milk products and/or packaging materials; and retort processed after packaged low-acid milk and/or milk products and/or packaging materials ~~need are not be~~ required to be provided with drains. ...

ITEM 2p. WALLS AND CEILINGS – CONSTRUCTION ...

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ADMINISTRATIVE PROCEDURES ...

This Item is deemed to be satisfied when: ...

NOTE: Refer to Item 11p for requirements for walls for drying chambers. Storage rooms used for the storage of packaged dry milk and/or milk products, ~~and~~ aseptically processed and packaged low-acid milk and/or milk products, and retort processed after packaged low-acid milk and/or milk products are exempt from the ceiling requirements of this Item.

...

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ITEM 5p. SEPARATE ROOMS

There shall be separate rooms for: ...

4. The fabrication of containers and closures for milk and/or milk products, except for aseptically processed and packaged low-acid milk and/or milk products and/or retort processed after packaged low-acid milk and/or milk products in which the containers and closures are fabricated within the APPS or RPPS, respectively. ...

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

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when: ...

Page 67:

12. Provided that all paper, plastics, foil, adhesives, and other components of containers and closures used in the packaging of milk and/or milk products that have been aseptically processed and packaged or retort processed after packaged are governed under the applicable provisions of 21 CFR Parts 110 and 113 and shall not be subject to this ~~Section~~ Item. ...

Page 82:

ITEM 16p. PASTEURIZATION, ~~AND~~ ASEPTIC PROCESSING AND PACKAGING, AND RETORT PROCESSED AFTER PACKAGING

Pasteurization shall be performed as defined in Section 1, Definition HH and Item 16p of this *Ordinance*. Aseptic processing and packaging and retort processed after packaging shall be performed in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. (Refer to Appendix L.) ...

PUBLIC HEALTH REASON ...

Page 83:

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/or milk products when certain staphylococci are present, as from udder infections, and when the milk and/or milk product is not properly refrigerated before pasteurization. Such toxins may cause severe illness. Aseptic processing and packaging and retort processed after packaging ~~has~~ have 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. ..

ITEM 17p. COOLING OF MILK AND/OR MILK PRODUCTS ...

Page 106:

Aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaged low-acid milk and/or milk products to be packaged in hermetically sealed containers shall be exempt from the cooling requirements of this Item. ...

Page 116:

SECTION 8. ANIMAL HEALTH

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

Page 117:

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

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SECTION 9. MILK AND/OR MILK PRODUCTS WHICH MAY BE SOLD

From and after twelve (12) months from the date on which this *Ordinance* is adopted, only Grade "A" pasteurized, ultra-pasteurized, ~~or~~ aseptically processed and packaged low-acid milk and/or milk products or retort processed after packaged low-acid milk and/or milk products shall be sold to the final consumer, to restaurants, soda fountains, grocery stores or similar establishments. Provided, only Grade "A" milk and/or milk products shall be sold to milk plants for use in the commercial preparation of Grade "A" milk and/or milk products. Provided further, that in an emergency, the sale of pasteurized, ultra-pasteurized, ~~or~~ aseptically processed and packaged low-acid milk and/or milk products or retort

_____, 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/or milk products shall be labeled "ungraded". ...

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

ADMINISTRATIVE PROCEDURES

Page 122:

11. Aseptically processed and packaged low-acid milk and/or milk products in Definition Z of this *Ordinance* shall be considered to be Grade "A" milk and/or milk products. The source(s) of the milk and/or milk products used to produce aseptically processed and packaged low-acid milk and/or milk products shall be IMS listed. Aseptically processed and packaged low-acid milk and/or 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 low-acid 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~~ shall occur within (6) months of this rating. Both the Milk Sanitation Compliance and Enforcement Ratings ~~must~~ shall 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/or milk products regulated under 21 CFR Parts 108, 110, and/or 114 ~~will~~ shall expire on December 31, ~~2013~~ 2015, unless extended by future conference action.

12. Retort processed after packaging low-acid milk and/or milk products as addressed in Definition Z of this *Ordinance* shall be considered to be Grade "A" milk and/or milk products if they are used as an ingredient to produce any milk and/or milk product defined in Definition Z of this *Ordinance*; or if they are labeled as Grade "A" as described in Section 4 of this *Ordinance*. Retort processed after packaging low-acid milk and/or milk products shall be labeled "Grade "A"" and meet Section 4 labeling requirements of this *Ordinance* whenever they meet the provisions cited within Definition Z of this *Ordinance*. The source(s) of the milk and/or milk products used to produce retort processed after packaging Grade "A" low-acid 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" low-acid 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~~ shall occur within (6) months of this rating. Both the Milk Sanitation Compliance and Enforcement Ratings ~~must~~ shall 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" low-acid milk and/or milk products and prior to the milk plant participating in the NCIMS Retort ~~Pilot~~ Processed after Packaging 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~~ Processed after Packaging 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. ...~~

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SECTION 13. PERSONNEL HEALTH

~~No persons~~ Persons affected with any disease capable of being transmitted to others through the contamination of food shall not work at a milk plant in any capacity which brings them into direct contact with pasteurized, ultra-pasteurized, ~~or~~ aseptically processed and packaged low-acid milk and/or milk products or retort processed after packaged low-acid milk and/or milk products or which brings them into direct contact with associated pasteurized, ultra-pasteurized, ~~or~~ aseptically processed and packaged milk and/or milk product-contact surfaces. ...

ADMINISTRATIVE PROCEDURES

Milk plant operators who have received reports, under this Section, from employees who have handled pasteurized, ultra-pasteurized, aseptically processed and packaged low-acid milk and/or milk products or retort processed after packaged low-acid milk and/or milk products or associated milk and/or milk product-contact surfaces shall immediately report these facts to the appropriate ~~Milk~~ Regulatory Agency. ...

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SECTION 14. PROCEDURE WHEN INFECTION OR HIGH RISK OF INFECTION IS DISCOVERED

When a person who may have handled pasteurized, ultra-pasteurized, ~~or~~ aseptically processed and packaged low-acid milk and/or milk products or retort processed after packaged low-acid milk and/or milk products or ~~pasteurized, ultra-pasteurized-aseptically processed and packaged~~ associated milk and/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 low-acid milk and/or milk products, or retort processed after packaged low-acid milk and/or milk products and associated milk and/or milk product-contact surfaces.

...

APPENDIX K. HACCP PROGRAM ...

II. IMPLEMENTATION OF A HACCP SYSTEM ...

Page 332:

VERIFICATION AND VALIDATION:

1. **Verification:** Every milk plant, receiving station or transfer station shall verify that the HACCP System is being implemented according to design, except that the milk plant's APPS or RPPS, respectively, as defined by this *Ordinance*, shall be managed separately from the NCIMS HACCP System, even if identified as a CCP in the hazard analysis. The milk plant's APPS or RPPS, respectively, 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 360:

APPENDIX Q. OPERATION OF AUTOMATIC MILKING INSTALLATIONS FOR THE PRODUCTION OF GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ~~OR~~ ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER 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 OR RETORT PROCESSED AFTER PACKAGING**. Both requirements and recommendations are discussed. ...

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ITEM 18r. RAW MILK COOLING

For AMIs the raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging shall be cooled to 10°C (50°F) within four

(4) hours or less after starting the milking operation and the milk shall be cooled within two (2) more hours to 7°C (45°F). The bulk milk storage tank temperature ~~should~~ shall not exceed 7°C (45°F) after that point. Bulk milk tank recording thermometers are recommended. ...

Page 362:

APPENDIX R. DETERMINATION OF TIME/TEMPERATURE CONTROL FOR SAFETY MILK AND/OR MILK PRODUCTS ...

Page 363:

Before using Tables A and B, which are included in Definition ~~OOOQ~~. TIME/TEMPERATURE CONTROL FOR SAFETY MILK AND/OR MILK PRODUCTS of this *Ordinance*, in determining whether a milk or milk product requires TCS, answers to the following questions should be considered: ...

5. Is the milk and/or milk product processed and packaged so that it ~~no longer~~ does not requires TCS; such as, ~~Grade "A"~~ aseptically processed and packaged Grade "A" low-acid milk and/or milk products and/or retort processed after packaged Grade "A" low-acid milk and/or milk products? ...

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APPENDIX S. ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM

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

The Retort Processed after Packaging Program is designed to include all Grade "A" low-acid (21 CFR Part 113) retort processed after packaged milk and/or milk products.

NOTE: Retort processed after packaging low-acid milk and/or milk products as addressed in Definition Z of the Grade "A" PMO shall be considered to be Grade "A" milk and/or milk products if they are used as an ingredient to produce any milk and/or milk product defined in Definition Z of this *Ordinance*; or if they are labeled as Grade "A" as described in Section 4 of this *Ordinance*.

Inspections of a milk plant or portion of a milk plant that is IMS listed to produce aseptically processed and packaged low-acid milk and/or milk products and/or retort processed after packaged low-acid milk and/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 milk plant's APPS or RPPS, respectively, 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 and/or RPPS, respectively, 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 low-acid milk and/or milk products and pasteurized and/or ultra-pasteurized 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 this *Ordinance*.

**ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT
PROCESSED AFTER PACKAGING PROGRAM
CFR/PMO COMPARISON SUMMARY REFERENCE**

PMO, Section 7 Items	<u>Aseptic Program/Retort Program</u>	Authority
1p. Floors – Construction	Floor drains are not required in storage rooms for aseptic processed and packaged <u>low-acid milk and/or milk products and retort processed after packaged low-acid milk and/or milk products.</u>	PMO
2p. Walls and Ceiling – Construction	Ceiling requirements are exempt in aseptically processed and packaged <u>low-acid milk and/or milk products and retort processed after packaged low-acid milk and/or milk products</u> dry storage rooms. (Same as for dry milk <u>and/or milk products.</u>)	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 <u>low-acid milk and/or milk products and retort processed after packaged low-acid milk and/or milk products</u> within the APPS <u>and/or RPPS, respectively, is exempt.</u>	PMO
6p. Toilet – Sewage Disposal Facilities	None	PMO
7p. Water Supply*	The APPS <u>and/or RPPS, respectively, is exempt, but shall comply with the CFR.</u>	PMO/CFR
8p. Handwashing Facilities	None	PMO
9p. Milk Plant Cleanliness	None	PMO
10p. Sanitary Piping*	The APPS <u>and/or RPPS, respectively, is exempt, but shall comply with the CFR.</u>	PMO/CFR
11p. Construction and Repair of	The APPS <u>and/or RPPS, respectively,</u>	PMO/CFR

PMO, Section 7 Items	Aseptic Program/ <u>Retort Program</u>	Authority
Containers and Equipment*	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 <u>and/or</u> milk products that have been aseptically processed and packaged <u>or retort processed after packaged</u> are not required to comply with Appendix J of the PMO; are not required to originate from an IMS Listed Source; and are subject to the requirements of the CFR.	
12p. Cleaning and Sanitizing of Containers and Equipment*	The APPS <u>and/or RPPS, respectively,</u> is exempt, but shall comply with the CFR.	PMO/CFR
13p. Storage of Cleaned Containers and Equipment*	The APPS <u>and/or RPPS, respectively,</u> 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 <u>and/or RPPS, respectively,</u> is exempt, but shall comply with the CFR.	PMO/CFR
15p.(B) Protection from Contamination - Cross Connections*	The APPS <u>and/or RPPS, respectively,</u> is exempt, but shall comply with the CFR. APPS <u>and/or RPPS</u> 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 <u>and/or RPPS, respectively,</u> 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 <u>and retort</u> 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 <u>and/or RPPS, respectively;</u> and aseptic processed and packaged	PMO/CFR

PMO, Section 7 Items	Aseptic Program/ <u>Retort Program</u>	Authority
	<u>low-acid milk and/or milk product storage; and retort processed after packed low-acid milk and/or milk product storage</u> is exempt, but shall comply with the CFR.	
18p. Bottling, Packaging and Container Filling*	The APPS <u>and/or RPPS, respectively,</u> is exempt, but shall comply with the CFR.	CFR
19p. Capping, Container Closure and Sealing and Dry Milk Product Storage*	The APPS <u>and/or RPPS, respectively,</u> 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 and/or RPPS, respectively, 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).

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MAKE THE FOLLOWING CHANGES TO THE 2011 PROCEDURES DOCUMENT:

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SECTION II. SCOPE

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 low-acid milk and/or milk products, and retort processed after packaged low-acid milk and/or milk products, condensed and dry milk products, and whey and whey products produced under the NCIMS program. ...

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SECTION III. DEFINITIONS

B. AREA RATING: An area rating, if used, shall apply to raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging and retort processed after packaging ~~only~~. An area rating consists of more than one (1) producer group operating under the supervision of a single Regulatory Agency and which is rated as a single entity. An individual dairy farm shall only be included in one (1) IMS Listing.

C. ASEPTIC PROCESSING AND PACKAGING SYSTEM (APPS): For the purposes of this document, the Aseptic Processing and Packaging System (APPS) in a milk plant is comprised of the processes and equipment used to process and package aseptic Grade "A" low-acid milk and/or milk products. The Aseptic Processing and Packaging System (APPS) shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. The Aseptic Processing and Packaging System (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 and/or equipment that are considered critical to the commercial sterility of the product. ...

- D. **BULK TANK UNIT (BTU):** A dairy farm or group of dairy farms from which raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging is collected under the routine supervision of one (1) Regulatory Agency and rated as a single entity and given a Sanitation Compliance and Enforcement Rating. An individual dairy farm shall only be included in one (1) IMS Listing.

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- 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 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" low-acid milk and/or milk products and/or retort processed after packaged Grade "A" low-acid milk and/or milk products, prior to the milk plant participating in the NCIMS Aseptic Processing and Packaging Program and/or Retort Processed after Packaging Program, respectively, 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 and/or the Retort Processed after Packaging Program.

- 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 and/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 and/or milk products, provided each listing holds a separate permit. Milk plants that produce ~~both~~ aseptically processed and packaged Grade "A" low-acid milk and/or milk products, and/or retort processed after packaged Grade "A" low-acid 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" low-acid milk and/or milk products and/or retort processed after packaged Grade "A" low-acid 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. ...

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- P. **MILK PLANT:** A milk plant is any place, premises, or establishment where milk and/or milk products are collected, handled, processed, stored, pasteurized, ultra-

pasteurized, aseptically processed and packaged, retort processed after packaged, condensed, dried, packaged, or prepared for distribution. ...

T. **RETORT PROCESSED AFTER PACKAGING SYSTEM (RPPS):** For the purposes of this document, the Retort Processed after Packaging System (RPPS) in a milk plant is comprised of the processes and equipment used to retort process after packaging low-acid Grade "A" milk and/or milk products. The Retort Processed after Packaging System (RPPS) shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. The Retort Processed after Packaging System (RPPS) shall begin at the container filler and end at the palletizer, provided that the Process Authority may provide written documentation which will clearly define additional processes and/or equipment that are considered critical to the commercial sterility of the milk and/or milk product.

U. **STATE PROGRAM EVALUATION:** An evaluation of a State program by PHS/FDA. This shall include check ratings of IMS Listed Shippers, an assessment of State administrative procedures and records, adoption of the *Grade "A" PMO* (or equivalent laws and regulations), and compliance with *NCIMS Procedures*.

V. **TRANSFER STATION:** A transfer station is any place, premises, or establishment where milk or milk products are transferred directly from one (1) milk tank truck to another. ...

SECTION IV. OVERSIGHT AND RESPONSIBILITIES

A. PHS/FDA RESPONSIBILITIES ...

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8. Check Ratings of the Sanitation Compliance Status of Listed Interstate 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 or retort 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 or the NCIMS Retort Processed after Packaging Program, respectively. Within a State, check ratings ~~will~~ shall be ~~made~~ conducted of a representative number of IMS Listed shippers. The selection of shippers ~~for~~ to be check rating rated in a given State ~~will~~ shall be made randomly. ...

B. STATE RESPONSIBILITIES ...

7. Challenges and Remedies ...

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

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

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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 or retort 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 AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) following the procedures cited above. ...

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D. MILK SANITATION RATING PERSONNEL ...

2. Have been ~~standardized~~ certified 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, and/or retort processed after packaging, if appropriate, dairy farms and transfer/receiving stations, including HACCP if appropriate. The PHS/FDA ~~will~~ shall 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~~ SRO's certification is valid.

3. A SRO applicant for initial ~~standardization~~ certification shall be evaluated by PHS/FDA personnel in an independent side-by-side comparison of dairy facilities using the items listed on the appropriate inspection or evaluation report form. The applicant and PHS/FDA personnel shall be in agreement at least eighty percent (80%) of the time on each listed item. Comparison evaluations shall be performed on at least the following number of dairy facilities: ...

b. Five (5) pasteurization milk plants. Milk plants of varying sizes using, vat, HTST, and HHST pasteurization; ultra-pasteurization; and/or aseptic processing and packaging; and/or retort processed after 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. ...

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6. To conduct ratings of aseptic processing and packaging milk plants and/or retort processed after 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 or the NCIMS Retort Processed after Packaging Program, respectively. ...

8. A certified SRO shall be ~~re-standardized~~ re-certified once each three (3) years by PHS/FDA personnel in an independent side-by-side comparison of dairy facilities using the items listed on the appropriate inspection or evaluation report form. The applicant and PHS/FDA personnel shall be in agreement at least eighty percent (80%) of the time on each listed item. Comparison evaluations shall be performed on at least the following number of dairy facilities: ...

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

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5. The SSO may delegate the inspection of bulk milk hauler/samplers, who collect samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging from individual producers, to other qualified State, Regional or Local Regulatory Agency personnel or certified industry personnel as outlined in Section 5 of the *Grade "A" PMO*. ...

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J. INDIVIDUAL RATINGS ...

3. If an aseptic or retort 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 AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products), the listing shall be immediately denied or withdrawn. ...

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

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 low-acid milk and/or milk products, and retort processed after packaging low-acid milk and/or milk products, condensed and dry milk products, and whey and whey products produced under the NCIMS program. Listings made under the NCIMS 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 NCIMS HACCP System to ensure compliance with the NCIMS HACCP System and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants and Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants, respectively. ...
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 NCIMS HACCP System and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants and Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants, respectively.. ...
7. **LISTING AUDIT:** An evaluation conducted by a Milk Sanitation Rating Officer (SRO) of the entire milk plant, receiving station or transfer station facility to ensure compliance with the NCIMS voluntary HACCP Program and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants and Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants, respectively. ...

C. PHS/FDA HACCP RESPONSIBILITIES

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8. PHS/FDA Audits of HACCP Listings

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 and/or retort processed after 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 and/or the NCIMS Retort Processed after Packaging Program, respectively. Within a State conducting the NCIMS HACCP Program, PHS/FDA audits ~~will~~ shall be ~~made~~ conducted of a representative number of IMS HACCP listed shippers. The selection of shippers ~~for auditing~~ to be audited in a given State ~~will~~ shall be made randomly. ...

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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~~ shall be used in the overall State Program Evaluation. Provided, that for NCIMS HACCP listed milk plants producing aseptically processed and packaged Grade "A" low-acid milk and/or milk products and/or retort processed after packaged Grade "A" low-acid milk and/or milk products, PHS/FDA HACCP audits shall be conducted using the procedures identified in the NCIMS Aseptic Processing and Packaging Program or the NCIMS Retort Processed after Packaging Program, respectively, related to the inspection/auditing and regulation of the APPS and RPPS, respectively, as described in the *Grade "A" PMO* and *MMSR*, along with the completion of FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products). ...

D. STATE HACCP RESPONSIBILITIES

1. State HACCP Listings for Milk Plants, Receiving Stations and Transfer Stations Section IV., B. 1.) shall apply as written, except that for purposes of this Section: ...

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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 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” low-acid milk and/or milk products and/or retort processed after packaged Grade “A” low-acid milk and/or milk products, FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) shall also be completed and submitted to PHS/FDA. ...

7. Challenges and Remedies ...

c. Action to be Taken if the PHS/FDA HACCP Audit Indicates the Listing is Not Justified: ...

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

C.) Withdrawal of Certification ...

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3.) A HACCP/ aseptic listing that includes an aseptically processed and packaged Grade “A” low-acid milk and/or milk products ~~plants~~ plant and/or a HACCP retort listing that includes a retort processed after packaged Grade “A” low-acid milk and/or milk products plant, 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 AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products). ...

E. QUALIFICATIONS AND CERTIFICATIONS

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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” low-acid milk and/or milk products and/or retort processed after packaged Grade “A” low-acid milk and/or milk products, FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) shall be completed as a part of all HACCP/ aseptic and/or HACCP retort listing audits. ...

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

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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” low-acid milk and/or milk products and/or retort processed after packaged Grade “A” low-acid milk and/or milk products, FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) shall also be completed and submitted for quality assurance review.

MAKE THE FOLLOWING CHANGES TO THE 2011 BYLAWS OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS:

~~Strikeout~~ text to be deleted and underlined text to be added.

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ARTICLE VI ----- DUTIES OF THE PROGRAM OF COUNCILS ...

SECTION 3. Council III shall deal with Proposals submitted to the Conference regarding Sections 11, 17, and 18 and ~~Appendix~~ Appendices K and S of the *Grade “A” Pasteurized Milk Ordinance*; the *Constitution and Bylaws*; the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the*

National Conference on Interstate Milk Shipments; issues of reciprocity; and Proposals assigned from the Program Committee.

MAKE THE FOLLOWING CHANGES TO THE MMSR:

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Cover Page:

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PREFACE ...

The rating method for evaluating the sanitary quality of milk measures the extent to which a shipper complies with the standards contained in the *Grade "A" PMO*. These nationally recognized standards, rather than local requirements, are used as a yardstick in order that ratings of individual Bulk Tank Units (BTUs) or attached shippers and milk plants may be comparable to each other, both interstate and intrastate. Ratings are expressed in terms of percentage compliance. For example, if the milk plant and dairy farms comply with all of the requirements of the *Grade "A" PMO*, the Sanitation Compliance Rating of the pasteurized milk supply would be one hundred percent (100%); whereas, if the plant or some of the dairy farms fail to satisfy one (1) or more of these requirements, the Sanitation Compliance Rating would be reduced in proportion to the amount of milk and milk products involved in the violation and to the relative public health significance of the violated Item(s). Procedures for collection of data, computation of Sanitation Compliance Ratings for raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging and pasteurized milk, and computation of the Enforcement Rating of the Regulatory Agency, responsible for administering milk sanitation regulations, are described in the following Sections. ...

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- 4. PREPARATION OF THE "INTERSTATE MILK SHIPPER'S REPORT" FOR ASEPTIC PROCESSING AND ~~PACKAGING~~ PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM LISTINGS

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- G. EXAMPLES OF RATING, NCIMS HACCP LISTING, ~~AND~~ ASEPTIC PROCESSING AND PACKAGING PROGRAM, AND RETORT PROCESSED AFTER PACKAGING PROGRAM LISTING FORMS
- 6. FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING.....

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- 13. FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ~~ELEMENTS~~ ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products).....
- H. EXAMPLES OF HOW TO PROPERLY COMPLETE RATING, NCIMS HACCP LISTING, ~~AND~~ ASEPTIC PROCESSING AND PACKAGING PROGRAM, AND RETORT PROCESSED AFTER PACKAGING PROGRAM LISTING FORMS

13. FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING.....

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

Page 1:

A. DEFINITIONS

- 1. **AREA RATING:** An area rating, if used, shall apply to raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging and retort processed after packaging only. An area rating consists of more than one (1) producer group operating under the supervision of a single Regulatory Agency and which is rated as a single entity. An individual dairy farm shall only be included in one (1) IMS Listing.

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

- 3. **ASEPTIC OR RETORT MILK PLANT RATING:** A rating of a milk plant or portion of a milk plant that produces aseptically processed and packaged Grade “A” low-acid milk and/or milk products and/or retort processed after packaged Grade “A” low-acid milk and/or milk products that is rated separately from the rating of pasteurized and/or ultra-pasteurized Grade “A” milk and/or milk products produced in the milk plant. This rating shall be made for all milk plants producing aseptically processed and packaged Grade “A” low-acid milk and/or milk products and/or retort processed after packaged Grade “A” low-acid 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” low-acid milk and/or milk products and/or retort processed after packaged Grade “A” low-acid milk and/or milk products shall have only an NCIMS HACCP listing.

NOTE: The raw milk receiving area may be rated with the aseptic or retort 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 (APPS) in a milk plant is comprised of the processes and equipment used to process and package aseptic Grade "A" low-acid milk and/or milk products. The Aseptic Processing and Packaging System (APPS) shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. The Aseptic Processing and Packaging System (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 and/or equipment that are considered critical to the commercial sterility of the product.

5. AUDIT: An evaluation of the entire milk plant, receiving station, or transfer station facility, and NCIMS HACCP System to ensure compliance with the NCIMS HACCP System and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants and Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants, respectively.

Page 2:

6. BULK TANK UNIT (BTU): A dairy farm or group of dairy farms from which raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging is collected under the routine supervision of one (1) Regulatory Agency and rated as a single entity and given a Sanitation Compliance and Enforcement Rating. An individual dairy farm shall only be included in one (1) IMS Listing. ...

11. FDA AUDIT: An evaluation conducted by FDA of the entire milk plant, receiving station, or transfer station facility to ensure compliance with the NCIMS HACCP System and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants and Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants, respectively. ...

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 and/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 and/or milk products, provided each listing holds a separate permit. Milk plants that produce ~~both~~ aseptically processed and packaged Grade "A" low-acid milk and/or milk products, and/or retort processed after packaged Grade "A" low-acid 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” low-acid milk and/or milk products and/or retort processed after packaged Grade “A” low-acid 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.
...

Page 3:

14. **LISTING AUDIT:** An evaluation conducted by a Milk Sanitation Rating Officer (SRO) of the entire milk plant, receiving station or transfer station facility to ensure compliance with the NCIMS voluntary HACCP Program and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants and the Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants, respectively.

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

19. **RETORT PROCESSED AFTER PACKAGING SYSTEM (RPPS):** For the purposes of this document, the Retort Processed after Packaging System (RPPS) in a milk plant is comprised of the processes and equipment used to retort process after packaging low-acid Grade "A" milk and/or milk products. The Retort Processed after Packaging System (RPPS) shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. The Retort Processed after Packaging System (RPPS) shall begin at the container filler and end at the palletizer, provided that the Process Authority may provide written documentation which will clearly define additional processes and/or equipment that are considered critical to the commercial sterility of the milk and/or milk product.

19 20. **TRANSFER STATION:** A transfer station is any place, premises, or establishment where milk or milk products are transferred directly from one (1) milk tank truck to another.

B. RATING METHODS FOR RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING ...

Page 7:

3. COMPUTATION OF SANITATION COMPLIANCE RATINGS

a. Rating results are transferred to FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING. This Form

<http://www.fda.gov/aboutfda/reportsmanualsforms/forms/default.htm>. The Form is sufficiently flexible to permit various combinations of pages to be used for reporting ratings of area or individual shippers.

Page 8:

b. The identity of each dairy farm, included in the rating, and the total pounds of milk sold daily, expressed to the nearest 100 pound unit (cwt.), are entered in the first, "Name of Dairy Farm", and second, "Pounds Sold Daily (100# Units)", columns, respectively, of FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING ...

NOTE: Item 8-Water Supply on FORM FDA 2359a-DAIRY FARM INSPECTION REPORT has been divided into two (2) point and five (5) point violations/debits. The maximum point value for the entire Item 8r cannot exceed five (5) points on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING. (Refer to Appendix B. TABLE OF FARM WATER SUPPLY VIOLATIONS, which provides guidance, which may be used to differentiate between two (2) point (minor) and five (5) point (major) violations of Section 7, Item 8r of the *Grade "A" PMO* during State Ratings and FDA Check Ratings.)

Non-compliance with Item 15r-DRUG AND CHEMICAL CONTROL, Administrative Procedures #s 5, 6 and 7 of the *Grade "A" PMO* (debited under Item 15r(d) and (e) on FORM FDA 2359a-DAIRY FARM INSPECTION REPORT), would constitute a five (5) point debit, not to exceed a total of seven (7) points for the entire Item 15-Drugs on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING.

Non-compliance with Item 18r-RAW MILK COOLING, Administrative Procedure #3 of the *Grade "A" PMO*, would constitute a one (1) point debit, not to exceed a total of five (5) points for the entire Item 18-Cooling on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING.

c. The Sanitation Compliance Rating is Derived from the Following Formula: ...

This rating figure is entered in the appropriate space in the upper right hand corner of FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING. It is also entered on FORM FDA 2359j-MILK

SANITATION RATING REPORT-SECTION A. REPORT OF THE MILK SANITATION RATING (PAGE 1), in the appropriate location.

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

2. COLLECTION OF DATA ...

Page 11:

b. Recording of Laboratory and Other Test Data ...

2.) Compliance with bacterial, coliform and cooling temperature requirements is based on whether, at the time of the rating, a milk plant's Grade "A" milk and/or milk products meet the standards of Section 7 of the *Grade "A" PMO*. Each milk and/or milk product, including commingled raw milk prior to pasteurization, ultra-pasteurization, aseptic processing and packaging and retort processed after packaging for each of the above applicable requirements, shall be debited if two (2) of the last four (4) sample results exceed the limit(s), and the last sample result is in violation. A debit shall be given when less than the required number of samples has been examined during the preceding six (6) months. For rating purposes, the preceding six (6) months is considered to be the elapsed period for the month in which the rating is made and the preceding six (6) months. Milk plants which have had a permit for less than six (6) months at the time of the rating or which do not operate on a year round basis and for which the Regulatory Agency has not yet examined the required number of samples shall not be debited. Provided, that the last sample result is within the limit(s).

3.) The SRO may utilize Regulatory Agency's records in determining ...

NOTE: The sampling and testing of aseptically processed and packaged Grade "A" milk and/or milk products and retort processed after packaged Grade "A" low-acid 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 and retort processed after packaging is required.

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

4.) Criteria and Procedures for Denial or Withdrawal of a 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 and/or HACCP retort listed milk plant, the identification of any ACLE element on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or 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.

Page 14:

d. Recording of Data for Milk Plants and Receiving Stations Being Listed Under the NCIMS Aseptic Processing and Packaging Program and/or the NCIMS Retort Processed after 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.) The NCIMS Retort Processed after Packaging Program includes all low-acid retort processed after packaging Grade "A" milk and/or milk products as defined in the *Grade "A" PMO*.

NOTE: Retort processed after packaging low-acid milk and/or milk products as addressed in Definition Z of the *Grade "A" PMO* shall be considered to be Grade "A" milk and/or milk products if they are used as an ingredient to produce any milk and/or milk product defined in Definition Z of the *Grade "A" PMO*; or if they are labeled as Grade "A" as described in Section 4 of this *Ordinance*.

~~(B.C.)~~ 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 and/or retort processed after packaged Grade "A" low-acid 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 and/or RPPS, respectively, 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.D.)~~ For milk plants or portions of milk plants that are listed to produce aseptically processed and packaged Grade "A" milk and/or milk products and/or retort processed after packaged Grade "A" low-acid milk and/or milk

_____, the APPS and/or RPPS, respectively, 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~~ Items, which are dedicated only to the APPS or RPPS, respectively, 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 and Retort Processed after Packaging Program of the *Grade “A” PMO*).

(~~D~~E.) 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~~F.) NCIMS HACCP listed aseptic and/or retort milk plants shall be inspected/audited and regulated under the NCIMS voluntary HACCP Program with the exception of the APPS or RPPS, respectively, which shall be inspected and regulated under the NCIMS Aseptic Processing and Packaging Program and/or Retort Processed after Packaging Program, respectively. Provided that FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or 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 AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or 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

Page 16:

f. If, upon receipt, one (1) or more shipper(s) of unattached raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging violates the bacterial and/or cooling temperature standards, the violations are debited against the rating of the receiving station(s) and/or transfer station(s) shipping the milk, prior to combining the ratings in accordance with the methods described above.

Page 17:

D. COMPUTATION OF ENFORCEMENT RATINGS

For all NCIMS HACCP listings, including aseptic and/or retort 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, ultra-pasteurization, aseptic processed and packaging and retort processed after packaging addressed in 2. of this Section. ...

Page 18:

2. RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING ONLY

a. When an individual shipper offers for sale only raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging directly from dairy farms, known as a BTU, and there are ~~no~~ not any milk plant(s), receiving and/or transfer station(s) involved, all Items in Part I-DAIRY FARMS, FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) shall be evaluated. The total of the credit column of Part I will be the Enforcement Rating and ~~should~~ shall be recorded on Page 1 of this Form, in the appropriate location. (Refer to Section H, #s 1, 9 and 11 for examples.) ...

3. RECEIVING STATION OR TRANSFER STATION

a. When an individual shipper offers for sale raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging, which is shipped from a receiving station or transfer station, with one (1) or more dairy farms rated with it, all Items in Part II-MILK PLANTS, except Numbers 5 and 7, 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. When a receiving station and/or transfer station receives and trans-ships raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging from one (1) or more rated and listed BTUs and wishes a separate listing for its facilities, all Items in Part II, except Numbers 5 and 7, and all Items in Part III, except Number 1 shall be evaluated. The procedures outlined in D., 3., b and D., 4., a.3.) ~~should~~ shall be followed in computing the Enforcement Rating of the receiving station and/or transfer station.

Page 19:

4. MILK PLANTS

a. For NCIMS aseptic milk plants and retort 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~~ shall be divided by eighty-five (85) and multiplied by 100. ...

Page 20:

b. Milk Plant with an Unattached Supply of Raw Milk

1.) When an individual shipper of pasteurized milk and/or milk products imports all raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging from outside the jurisdiction of the Regulatory Agency in which the milk plant is located, only Parts II and III of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), shall be evaluated. If an Item requires more than one (1) test or determination, i.e., Part II, Numbers 2, 4, 5, 6, 7, 8, 9, and 10, then compliance is also based on the proportion of tests or determinations, which according to the Regulatory Agency's records, were made at the required frequency. ...

Page 21:

c. Milk Plant with an Attached Supply of Raw Milk

1.) When an individual shipper of pasteurized milk and/or milk products receives raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging from an attached supply(ies) within the jurisdiction of the Regulatory Agency in which the plant is located, Parts I, II, and III, on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) shall be evaluated. If raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging is received from both attached and unattached supplies, only those sources from attached supplies ~~will~~ shall be evaluated in Part I. If an Item requires more than one (1) test or determination, i.e., Part II, Numbers 2, 4, 5, 6, 7, 8, 9, and 10, then compliance is also based on the proportion of tests or determinations, which according to the Regulatory Agency's records, were made at the required frequency. ...

E. PREPARATION OF THE SROs REPORT ...

2. SUMMARY OF RATING RESULTS

Sanitation Compliance Ratings computed in accordance with procedures previously described and other data pertinent to the shipper are entered in the SUMMARY OF RATING RESULTS on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION A. REPORT OF MILK SANITATION RATING (PAGE 1). When the Sanitation Compliance Rating of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging has been combined with the rating(s) of unattached supplies in accordance with the conditions and procedures found under F. PUBLICATION OF THE “INTERSTATE MILK SHIPPER’S REPORTS”, Sections 2., c., 2.) or 2., c., 3.)B.); the combined rating, rather than the rating of the attached supply is entered in the summary.

4. RECOMMENDATIONS OF THE SRO ...

Page 23:

For all NCIMS HACCP listings, including aseptic and/or retort 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.) ...

b. Milk plant, receiving station or transfer station audited by ~~the~~ a HACCP trained State Regulatory Agency auditor at the minimum required frequency, and follow-up conducted as required; ...

d. Pasteurization equipment tested at required frequency (~~not~~ Not applicable to receiving stations ~~and~~ /transfer stations, aseptic and retort milk plants); ...

f. Samples of milk plant’s milk and/or milk products collected at the required frequency and all necessary laboratory examinations made (~~not~~ Not applicable to receiving stations ~~and~~ /transfer stations); ...

F. PUBLICATION OF THE “INTERSTATE MILK SHIPPER’S REPORT” ...

Page 24:

2. PREPARATION OF THE “INTERSTATE MILK SHIPPER’S REPORT”

a. Individual Shipper of Raw Milk for Pasteurization, Ultra-Pasteurization, Aseptic Processing and Packaging or Retort Processed after Packaging ...

This shipper is commonly referred to as a BTU. Following the computation of the Sanitation Compliance Rating on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING and Part I of

FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the resultant data ~~will~~ shall be transferred to FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT. The earliest rating date shall be the date of the first day of the rating. (Refer to Section H, #s 16 and 17 for examples.) ...

b. Receiving Station or Transfer Station

Following the computation of the Sanitation Compliance Rating on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING, FORM FDA 2359L-STATUS OF MILK PLANTS, and Parts I, II and III of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the resultant data ~~will~~ shall be transferred to FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT. The earliest rating date shall be the date of the first day of the rating. When receiving and/or transfer stations wish a separate listing and receive raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging from one (1) or more rated and listed BTUs for trans-shipment, the procedures to be followed shall be that of Section F. PUBLICATION OF THE "INTERSTATE MILK SHIPPER's REPORT, 2., c.2) or 2., c.3). ...

Page 27:

4. PREPARATION OF THE "INTERSTATE MILK SHIPPER's REPORT" FOR ASEPTIC PROCESSING AND PACKAGING PROGRAM AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM LISTINGS

The provisions of this Section apply to milk plants and receiving stations listed under the NCIMS Aseptic Processing and Packaging Program and/or the NCIMS Retort Processed after Packaging Program listing procedure, except that FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or 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. ...

Page 29:

G. EXAMPLES OF RATING, NCIMS HACCP LISTING, AND ASEPTIC PROCESSING AND PACKAGING PROGRAM, AND RETORT PROCESSED AFTER PACKAGING PROGRAM LISTING FORMS ...

6. FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING.....

13. FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products)

Pages 31, 50, 53, 57 and 59:

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

MILK PLANT-PART II

Item 2: Milk plant and receiving station(s) inspected once every three (3) months; aseptic and retort milk plant and transfer station(s) once every six (6) months

Item 5: Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants)

INDIVIDUAL SHIPPER RATING-PART III

Individual Shipper of Pasteurized Milk and Milk Products:
Aseptic and Retort Milk Plants

(10/4413)

Pages 35, 36, 61 and 62:

FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION

FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING

(10/4413) PAGE 1

(10/4413) PAGE 2

Pages 44 and 71:

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

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

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

6. Samples of milk plant's milk and/or milk products collected at the required frequency and all necessary laboratory examinations made. (Not applicable to receiving/transfer stations.) ...

(10/1113)

Pages 46 and 76:

Department of Health and Human Services Food and Drug Administration	NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic Milk and/or Milk Products)	
<i>(To be included with all NCIMS Aseptic Processing and Packaging Program and Retort Processed after Packaging Program State Ratings/HACCP Listings and FDA Check Ratings/HACCP Audits.)</i>		
MILK PLANT	DATE OF RATING	
ADDRESS	LICENSE/PERMIT NO.	
RATING AGENCY		
EXPLANATION OF CONCERNS NOTED REGARDING CRITICAL LISTING ELEMENTS UNDER THE NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM. <i>(Use additional sheets as necessary.)</i>		
A narrative description shall be provided as a part of all NCIMS Aseptic Processing and Packaging Program <u>and Retort Processed after Packaging Program</u> 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 <u>and/or retort processed</u> Grade "A" milk <u>and/or</u> 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 <u>and/or retort processed</u> Grade "A" milk <u>and/or</u> 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 <u>and/or retort processed after packaging systems</u> 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?		

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

Page 48:

6. FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING.....

23. FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS ~~for~~ (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products).....

24. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (*EXAMPLE: ASEPTIC AND/OR RETORT MILK PLANT*)

Page 77:

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

(Example: Aseptic or Retort Milk Plant)

SHIPPER ASEPTIC OR RETORT DAIRY

DATE OF RATING 10/8-9/~~2012~~ 2014

MILK PLANT-PART II

Item 2: Milk plant and receiving station(s) inspected once every three (3) months; aseptic and retort milk plant and transfer station(s) once every six (6) months

Item 5: Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants)

INDIVIDUAL SHIPPER RATING-PART III

Individual Shipper of Pasteurized Milk and Milk Products:
Aseptic and Retort Milk Plants

REMARKS

#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 (or RPPS) room was in very poor condition. All existed but were not debited on the last inspection.

#7-Aseptic (or Retort) 2% chocolate milk, with vitamins A & D added, did not have a vitamin assay conducted during ~~2011~~ 2013.

#3-Aseptic (or Retort) nonfat milk was not labeled as Grade “A” and “Keep Refrigerated After Opening”.

(10/4413) ...

APPENDIX A.

GUIDELINES FOR COMPUTING ENFORCEMENT RATINGS

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

Page 85:

PART II. MILK PLANTS ...

2. Milk plants and receiving stations inspected at least once every three (3) months (transfer stations, ~~and~~ aseptic milk plants and retort 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. ...

Page 86:

b. Transfer stations, ~~and~~ aseptic milk plants and retort milk plants inspected at least once every six (6) months. ...

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 and retort 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 Pasteurizers, plus the number of HTST Pasteurizers, plus the number of HHST Pasteurizers, plus the number of APPS APPSs, if applicable as cited above, at the milk plant.

...

Page 88:

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 and retort milk plants, shall be collected, prior to pasteurization, ultra-pasteurization, ~~or~~ aseptic processing and packaging, or retort processed after 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. ...

d. Assays of Vitamin A, D, and/or A and D fortified milk and milk products, including aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaging low-acid milk and/or 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.

MAKE THE FOLLOWING CHANGES TO THE 2011 EML:

~~Strikeout~~ text to be deleted and underlined text to be added.

Page 1:

State Central Milk Laboratory: A State owned and operated Official Laboratory with analysts employed by the State working in conjunction with the State Regulatory Agency designated as the primary State laboratory for the examination of producer samples of Grade 'A' raw and commingled raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging, pasteurized milk and/or milk products, and dairy waters, as necessary.

Officially Designated Laboratory: An officially designated laboratory is a commercial laboratory authorized to do official work by the Regulatory Agency, or a milk industry laboratory officially designated by the Regulatory Agency for the examination of producer samples of Grade 'A' raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging and commingled milk tank truck samples of raw milk for drug residues. ...

Page 9:

An acceptable annual proficiency testing program shall meet the following applicable criteria:

1. When an analyst examines both raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging and pasteurized milk and/or milk products, a minimum of twenty-two (22) samples shall be examined by the analyst using those procedures for which the analyst has been approved unless excused for due cause. The laboratory tests, categories, types and recommended duplicates of milk products are shown in Table 1, page 27.
2. When an analyst examines only raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging, a minimum of fourteen (14)

samples shall be examined by the analyst using those procedures for which the analyst has been approved unless excused for due cause. The laboratory tests and recommended duplicates of samples are shown in Table 1, page 27. ...

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

NOTE: This Proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2013 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/or milk products and retort processed after packaged Grade "A" low-acid milk and/or milk products; and the Aseptic Pilot Program addressing aseptically processed and packaged Grade "A" acidified and fermented high-acid milk and/or 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/or milk products and retort processed after packaged Grade "A" low-acid milk and/or milk products; and the Aseptic Pilot Program addressing aseptically processed and packaged Grade "A" acidified and fermented high-acid milk and/or 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 2013 NCIMS Conference, and concurred with by FDA, related to the wording addressing aseptically processed and packaged Grade "A" low-acid milk and/or milk products and retort processed after packaged Grade "A" low-acid milk and/or milk products.

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

Name:	Mary Wodtke; Sia Economides: Co-Chairs, NCIMS Aseptic Program Committee		
Agency/Organization:	Indiana State Board of Animal Health		
Address:	Discovery Hall, Suite 100, 1202 East 38 th Street		
City/State/Zip:	Indianapolis, IN 46205		
Telephone No.:	317-544-2400	E-mail Address:	mwodtke@boah.IN.gov ; Sia.economides@us.nestle.com

134th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

JOINT COUNCILS	
	305 * Procedures
Proposal #:	Change & **Constitution & Bylaws Change
Committee:	ICPPC/Hauling/ MMSR/Constitution & Bylaws/Lab/SSCC

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This Proposal contains modifications to the PMO, MMSR, Procedures, and the EML documents that the International Certification Pilot Program Committee (ICPPC) deemed necessary for the regulatory oversight, rating and IMS listing of milk shippers and milk laboratories located outside the geographic boundaries of the National Conference on Interstate Milk Shipments (NCIMS) Member States.

This Proposal incorporates the findings of the ICPPC into the NCIMS documents and transform the International Certification Pilot Program (ICPP) into the International Certification Program (ICP) making it a permanent part of the NCIMS Grade “A” Milk Safety Program.

The program will utilize Third Party Certifiers (TPCs) who will act as regulatory, rating, and laboratory evaluation agencies in the regulation of foreign milk companies (MCs) and their associated farms, haulers, receiving stations, transfer stations, laboratories etc. FDA will conduct check ratings, laboratory evaluations and program evaluations in accordance with “Methods” and “Procedures”.

The ICPPC has concluded that TPCs have the capability to operate as the regulatory, rating, and laboratory evaluation agencies as required to comply with the PMO and related NCIMS documents.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

The ICPP was established by Proposal #316 from the 2005 NCIMS Conference and has been extended at each subsequent NCIMS Conference. This pilot program provided an additional option to M-I-00-4 and addressed the issue of imported Grade “A” milk and milk products by establishing a third party regulatory and rating program designed to follow and comply with all of the applicable NCIMS Grade “A” Milk Safety Program requirements. The ICPP is limited to three (3) Third Party Certifiers (TPC), and was expanded to a maximum of eighteen (18) foreign milk companies (six (6) per TPC) at the 2011 Conference. The ICPP has had one (1) TPC withdraw from the program leaving two (2) TPCs and currently a total of ten (10) foreign milk companies participating in the ICPP. Two (2) additional foreign milk companies achieved an IMS Listing under the ICPP but have since withdrawn from the program.

The NCIMS ICPPC was charged, under Proposal #316, to implement, evaluate, monitor and enforce the ICPP.

The NCIMS ICPP has fulfilled it’s objectives as outlined in the original Proposal and has demonstrated the effectiveness of utilizing TPCs in the regulation and rating of foreign milk companies and the evaluation and certification of their associated laboratories assuring milk and milk product safety for Grade “A” milk and milk products and that:

- TPCs are capable of functioning in foreign countries as regulatory, rating and laboratory evaluation agencies enforcing the PMO and associated documents;
- Utilizing TPCs provides another means for foreign milk companies to become NCIMS IMS Listed; and
- Utilizing TPCs provides an effective utilization of resources.

In addition to the changes to the PMO, MMSR, Procedures, and EML, the ICPPC is also requesting the following:

- A standing committee shall be formed to conduct the oversight of the ICP.
- The NCIMS Chair to assign to the SSCC Committee to develop qualifications, authorizations, certification/recertification procedures, etc. for consultation that currently or wish to wish to certify SSCC manufacturers located outside the geographical boundaries of NCIMS Member States and report back to the 2015 NCIMS Conference. Consultants that currently have SSCC listings on the IMS List shall participate on this Committee.

C. Proposed Solution

Changes to be made on page(s): Entire Documents of the (X - one of the following):

- | | | | |
|---|----------|---|----------|
| X | 2011 PMO | X | 2011 EML |
|---|----------|---|----------|

X	2011 MMSR		2400 Forms
X	2011 Procedures	X	2011 Constitution and Bylaws

MAKE THE FOLLOWING CHANGES TO THE 2011 PMO:

~~Strikeout~~ text will be deleted and underlined text will be added.

Cover Page:

~~2011~~ 2013 Revision

Page ii:

2013. Grade "A" Pasteurized Milk Ordinance, Including Provisions from the Grade "A" Condensed and Dry Milk Products and Condensed and Dry Whey--Supplement I to the Grade "A" Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration.

PREFACE ...

Page iv:

To assist States and Municipalities in initiating and maintaining effective programs for the prevention of milkborne disease, the USPHS, in 1924, developed a model regulation known as the *Standard Milk Ordinance* for voluntary adoption by State and Local Milk Control Agencies. To provide for the uniform interpretation of this *Ordinance*, an accompanying *Code* was published in 1927, which provided administrative and technical details as to satisfactory compliance. This model milk regulation, now titled the *Grade "A" Pasteurized Milk Ordinance* (Grade "A" PMO), ~~2011~~ 2013 Revision, incorporates the provisions governing the processing, packaging, and sale of Grade "A" milk and milk products, including buttermilk and buttermilk products, whey and whey products, and condensed and dry milk products and represents the 29th revision and incorporates new knowledge into public health practice. ...

The USPHS/FDA's recommended *Grade "A" PMO* is the basic standard used in the voluntary Cooperative State-USPHS/FDA Program for the Certification of Interstate Milk Shippers, a program participated in by all fifty (50) States, the District of Columbia and U.S. Trust Territories. The National Conference on Interstate Milk Shipments (NCIMS) in accordance with the Memorandum of Understanding with the Food and Drug Administration (FDA) has at its biennial conferences recommended changes and modifications to the *Grade "A" PMO*. These changes have been incorporated into this ~~2011~~ 2013 revision. The counsel and guidance rendered by the Conference in preparation of this edition of the *Grade "A" PMO* is deeply appreciated. ...

Page v:

Within the ~~2011~~ 2013 *Grade "A" PMO*, the administrative and technical requirements for the manufacture of condensed and dry milk products and condensed and dry whey included in the *Grade "A" Condensed and Dry Milk Ordinance--Supplement I to the Grade "A" Pasteurized*

Milk Ordinance have been incorporated as directed by the 2001 NCIMS.

Page vi:

INTRODUCTION

The following *Grade "A" PMO*, with Appendices, is recommended for legal adoption by States, ~~Counties, and Municipalities~~, in order to encourage a greater uniformity and a higher level of excellence of milk sanitation practice in the United States. An important purpose of this recommended standard is to facilitate the shipment and acceptance of milk and milk products of high sanitary quality in interstate and intrastate commerce. ...

The following form is suggested for adoption by States, ~~Counties, and Municipalities~~ subject to the approval of the appropriate legal authority. Adoption of this form will reduce the cost of publishing and printing, and will enable the *Grade "A" PMO* to be easily kept current. The adoption of this form is considered legal in many States and has been so adopted. The Council of State Governments has prepared a model State law, *Milk and Food Codes Adoption-by-Reference Act*,¹ which is recommended for enactment by States to enable communities to adopt milk and food ordinances by reference.

Page vii:

The USPHS/FDA does not have legal jurisdiction in the enforcement of milk sanitation standards, except on interstate carriers and milk and milk products shipped in interstate commerce. It serves solely in an advisory and stimulative capacity and its program is designed primarily to assist ~~State and Local~~ Regulatory Agencies. Its aim is to promote the establishment of effective and well-balanced milk sanitation programs in each State; to stimulate the adoption of adequate and uniform ~~State and Local~~ milk control legislation; and to encourage the application of uniform enforcement procedures through appropriate legal and educational measures.

Page viii:

When this *Ordinance* is adopted ~~locally~~, its enforcement becomes a function of the ~~Local or State authorities~~ Regulatory Agencies. Consequently, the *Ordinance* should be adopted only if adequate provisions can be made for qualified personnel and for suitable laboratory facilities. ~~Small Municipalities which cannot afford to provide these services should arrange for supervision by the County or State Health Department, or seek cooperation with neighboring Municipalities in organizing a milk control district or area.~~

Adoption: In the interest of national uniformity, it is recommended that ~~no~~ not any changes be made in this *Ordinance* when adopted by a State ~~or Local community~~, unless changes are necessary to avoid conflict with State law. Modifications should be contemplated with extreme caution so as not to render the *Ordinance* unenforceable. In order to promote uniformity, it is recommended that all of the **ADMINISTRATIVE PROCEDURES** be adopted as well.

Amendment of Existing Regulations: States ~~and Communities~~ that have adopted the 2009

2011 or earlier editions of the USPHS/FDA recommended *Grade "A" PMO* are urged to bring such *Ordinance* up-to-date in order to take advantage of the most current developments in milk sanitation and administration. States ~~and Communities~~ whose milk sanitation law or regulations are not based on a previous USPHS/FDA recommended *Grade "A" PMO* are urged to consider the attendant public health benefits, as well as those economic in nature, which can accrue upon the adoption and implementation of the *Grade "A" PMO*. ...

Page 1:

**GRADE "A" PASTEURIZED MILK ORDINANCE
(GRADE "A" PMO)--2011 2013 REVISION ...**

Page 2:

D. **AUTOMATIC MILKING INSTALLATION (AMI):** The term ~~automatic milking installation~~ Automatic Milking Installation (AMI) covers the entire installation of one (1) or more automatic milking units, including the hardware and software utilized in the operation of individual automatic milking units, the animal selection system, the automatic milking machine, the milk cooling system, the system for cleaning and sanitizing the automatic milking unit, the teat cleaning system, and the alarm systems associated with the process of milking, cooling, cleaning and sanitation.

E. **BULK MILK HAULER/SAMPLER:** A bulk milk hauler/sampler is any person who collects official samples and may transport raw milk from a farm and/or raw milk products to or from a milk plant, receiving station or transfer station and has in their possession a permit from any State Regulatory Agency to sample such products. ...

I. **CLEAN-IN-PLACE (CIP) CLEANING:** The removal of soil from product contact surfaces in their process position by circulating, spraying, or flowing chemical solutions and water rinses onto and over the surfaces to be cleaned. Components of the equipment, which are not designed to be cleaned-in-place, are removed from the equipment to be ~~cleaned-out-of-place~~ Cleaned-Out-Of-Place (COP) or manually cleaned. Product contact surfaces shall be inspectable, except when the cleanability by Cleaned-In-Place (CIP) has been documented and accepted by the Regulatory Agency. In such accepted equipment, all product and solution contact surfaces do not have to be readily accessible for inspection, i.e., permanently installed pipelines and silo tanks. ...

Page 3:

N. **DAIRY PLANT SAMPLER:** A person responsible for the collection of official samples for regulatory purposes outlined in Section 6 of this *Ordinance*. This person is an employee of the Regulatory Agency and is evaluated at least once every two (2)-year period by a State Sampling Surveillance Officer (SSO) or a properly delegated Sampling Surveillance Regulatory Agency Official (dSSO). Sampling Surveillance Officers (SSOs) or properly delegated Sampling Surveillance Regulatory Agency Officials (dSSO) are not required to be evaluated for sampling collection procedures. ...

Page 4:

S. **HACCP DEFINITIONS:** (For use in conjunction with Appendix K.)

S-2. **CENTRALIZED DEVIATION LOG:** A centralized log or file identifying data detailing any deviation of ~~critical limits~~ Critical Limits (CLs) and the corrective actions taken as required in Appendix K. ...

S-4. **CONTROL MEASURE:** Any action or activity that can be used to prevent, eliminate, or reduce a significant hazard that is managed at a Critical Control Point (CCP).
...

S-6. **CRITICAL CONTROL POINT (CCP):** A step at which control can be applied and is essential to prevent or eliminate a milk and/or milk product safety hazard or reduce it to an acceptable level.

S-7. **CRITICAL LIMIT (CL):** A maximum and/or minimum value to which a biological, chemical, or physical parameter ~~must~~ shall be controlled at a ~~CCP~~ Critical Control Point (CCP) to prevent, eliminate, or reduce to an acceptable level the occurrence of a milk and/or milk product safety hazard.

S-8. **CRITICAL LISTING ELEMENT (CLE):** An item on FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT identified with a double star (**). The marking of a CLE by a ~~State~~ Milk Sanitation Rating Officer (SRO) or FDA auditor, indicates a condition that constitutes a major dysfunction likely to result in a potential compromise to milk and/or milk product safety, or that ~~violate~~ violates NCIMS requirements regarding drug residue testing and trace back and/or raw milk sources, whereby a listing may be denied or withdrawn. ...

Page 5:

S-11. **DEVIATION:** A failure to meet a ~~CL~~ Critical Limit (CL).

S-12. **HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP):** A systematic approach to the identification, evaluation, and control of significant milk and/or milk product safety hazards. ...

S-14. **HACCP SYSTEM:** The implemented HACCP Plan and Prerequisite ~~Program~~ Programs (PPs), including other applicable NCIMS requirements. ...

S-16. **HAZARD:** A biological, chemical, and/or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

S-17. **HAZARD ANALYSIS:** The process of collecting and evaluating information on hazards associated with the milk and/or milk product under consideration, to decide which are reasonably likely to occur and ~~must~~ shall be addressed in the HACCP Plan.

S-18. **MONITOR:** To conduct a planned sequence of observations or measurements to assess whether a ~~CCP~~ Critical Control Point (CCP) is under control or to assess the conditions and practices of all required Prerequisite Programs (PPs). ...

S-21. **PREREQUISITE PROGRAMS (PPs):** Procedures, including Good Manufacturing Practices (GMPs), which address operational conditions that provide the foundation for the HACCP System. The required ~~PPs~~ Prerequisite Programs (PPs) specified in Appendix K.

are sometimes called Sanitary Standard Operating Procedures (SSOPs) in other HACCP Systems. ...

U. **INDUSTRY PLANT SAMPLER:** A person responsible for the collection of official samples for regulatory purposes at a milk plant, receiving station or transfer station as outlined in Appendix N. This person is an employee of the milk plant, receiving station or transfer station and is evaluated at least once every two (2) year period by a State Sampling Surveillance Officer (SSO) or a properly delegated Sampling Surveillance Regulatory Agency Official (dSSO).

Page 6:

V. **INTERNATIONAL CERTIFICATION PROGRAM (ICP):** The International Certification Program (ICP) means the NCIMS voluntary program designed to utilize Third Party Certifiers (TPCs) authorized by the NCIMS Executive Board in applying the requirements of the NCIMS Grade “A” Milk Safety Program for Milk Companies (MCs) located outside the geographic boundaries of NCIMS Member States that desire to produce and process Grade “A” milk and/or milk products for importation into the United States.

W. **LETTER OF INTENT (LOI):** A formal written signed agreement between a Third Party Certifier (TPC), authorized under the NCIMS voluntary International Certification Program (ICP), and a Milk Company (MC) that intends to be certified and IMS Listed under the NCIMS voluntary International Certification Program (ICP). A copy of each written signed agreement shall be immediately submitted to the International Certification Program (ICP) Committee following the signing by the Third Party Certifier (TPC) and Milk Company (MC).

X. **LETTER OF UNDERSTANDING (LOU):** A formal written signed agreement between a Third Party Certifier (TPC) and the NCIMS Executive Board that acknowledges the NCIMS’ authorization of the Third Party Certifier (TPC) to operate under the NCIMS voluntary International Certification Program (ICP). It also states the Third Party Certifier’s (TPC’s) responsibilities under the NCIMS voluntary International Certification Program (ICP); their agreement to execute them accordingly; and their understanding of the consequences for failing to do so. The Letter of Understanding (LOU) shall include, but is not limited to, the issues and concerns addressed in all documents involved in the NCIMS voluntary International Certification Program (ICP).

∇Y. **LOW-ACID ASEPTIC MILK AND MILK PRODUCTS: ...**

Z. **MEMORANDUM OF AGREEMENT (MOA):** A formal written signed memorandum that states the requirements and responsibilities of each party (Third Party Certifier (TPC) and Milk Company (MC)) to participate and execute the NCIMS voluntary International Certification Program (ICP). The Memorandum of Agreement (MOA) shall include, but is not limited to, the issues and concerns addressed in all documents involved in the NCIMS voluntary International Certification Program (ICP). This agreement shall be considered the Milk Company’s (MC’s) permit to operate in the context of the NCIMS Grade “A” Milk Safety Program and shall be renewed (signed and dated) on an annual basis.

AA. **MILK COMPANY (MC):** A Milk Company (MC) is a private entity that is listed on the

IMS List by a Third Party Certifier (TPC) including all associated dairy farms, bulk milk haulers/samplers, milk tank trucks, milk transportation companies, milk plants, receiving stations, transfer stations, dairy plant samplers, industry plant samplers, milk distributors, etc. and their servicing milk and/or water laboratories, as defined in the Grade "A" PMO, located outside the geographic boundaries of NCIMS Member States.

WBB. MILK DISTRIBUTOR: ...

Re-letter the remaining DEFINITIONS accordingly.

Page 9:

OO. RATING AGENCY: A Rating Agency shall mean a State Agency, which certifies interstate milk shippers (BTUs, receiving stations, transfer stations, and milk plants) as having attained the Sanitation Compliance and Enforcement Ratings necessary for inclusion on the IMS List. The ratings are based on compliance with the requirements of the Grade "A" PMO and were conducted in accordance with the procedures set forth in the Methods of Making Sanitation Ratings of Milk Shippers (MMSR). Ratings are conducted by FDA certified Milk Sanitation Rating Officers (SROs). They also certify single-service containers and closures for milk and/or milk products manufacturers for inclusion on the IMS List. The certifications are based on compliance with the requirements of the Grade "A" PMO and were conducted in accordance with the procedures set forth in the Methods of Making Sanitation Ratings of Milk Shippers (MMSR). The definition of a Rating Agency also includes a Third Party Certifier (TPC) that conducts ratings and certifications of Milk Companies (MCs) located outside the geographic boundaries of NCIMS Member States that desire to produce and process Grade "A" milk and/or milk products for importation into the United States. ...

Re-letter the remaining DEFINITIONS accordingly.

LLRR. REGULATORY AGENCY: The Regulatory Agency shall mean the ... of the ...¹ or their authorized representative. The term, "Regulatory Agency", whenever it appears in the Ordinance shall mean the appropriate agency, including a Third Party Certifier (TPC) authorized under the NCIMS voluntary International Certification Program (ICP), having jurisdiction and control over the matters embraced within this Ordinance. ...

Re-letter the remaining DEFINITIONS accordingly.

UU. THIRD PARTY CERTIFER (TPC): A Third Party Certifier (TPC) is a non-governmental individual(s) or organization authorized under the NCIMS voluntary International Certification Program (ICP) that is qualified to conduct the routine regulatory functions and enforcement requirements of the Grade "A" PMO in relationship to milk plants, receiving stations, transfer stations, associated dairy farms, bulk milk hauler/samplers, milk tank trucks, milk transportation companies, dairy plant samplers, industry plant samplers, milk distributors, etc. participating in the NCIMS voluntary International Certification Program (ICP). The Third Party Certifier (TPC) provides the means for the rating and listing of milk plants, receiving stations, transfer stations and their related raw milk sources. They also conduct the certification and IMS listing of related milk and/or water laboratories and related single-service container and closure manufacturers on the Sanitation Compliance and

Enforcement Ratings of Interstate Milk Shippers (IMS) List. To be authorized under the NCIMS voluntary International Certification Program (ICP), a valid Letter of Understanding (LOU) shall be signed between the NCIMS Executive Board and the Third Party Certifier (TPC). ...

Re-letter the remaining DEFINITIONS accordingly.

Page 11:

SECTION 2. ADULTERATED OR MISBRANDED MILK AND/OR MILK PRODUCTS

Not any person shall, within the ... of ...¹, or its jurisdiction, produce, provide, sell, offer, or expose for sale or have in possession with intent to sell any milk or milk product, which is adulterated or misbranded. Provided, that in an emergency, the sale of pasteurized milk and/or milk products, which do not fully meet the requirements of this *Ordinance*, may be authorized by the Regulatory Agency.

NOTE: The option for the emergency sale of pasteurized milk and/or milk products as cited above, shall not be applicable to a Milk Company (MC) IMS listed under the NCIMS voluntary International Certification Program (ICP).

Any adulterated and/or misbranded milk and/or milk products may be impounded by the Regulatory Agency and disposed of in accordance with applicable laws or regulations.

NOTE: Adulterated and/or misbranded milk and/or milk products from MCs IMS listed under the ICP shall not gain entry into the U.S.

Page 12:

ADMINISTRATIVE PROCEDURES

This Section of the *Ordinance* shall be used in impounding the milk and/or milk products of, or preferring charges against, persons who adulterate and/or misbrand their milk and/or milk products; or label them with any grade designation not authorized by the Regulatory Agency under the terms of this *Ordinance*; or who sell or deliver ungraded milk and/or milk products, except as may be permitted under this Section in an emergency. An emergency is defined as a general and acute shortage in the milk shed, not simply one (1) distributor's shortage.

NOTE: The option for the emergency sale of pasteurized milk and/or milk products as cited above, shall not be applicable to a MC IMS listed under the ICP.

SECTION 3. PERMITS ...

The term “permit”, whenever it appears in this *Ordinance* shall also mean a MC operating under the ICP possessing a valid Memorandum of Agreement (MOA) with a Third Party Certifier (TPC).

It shall be unlawful for any person who does not possess a permit from the Regulatory Agency of the ... of ...¹ to manufacture, bring into, send into or receive into the ... of ...¹ or its jurisdiction, for sale, or to sell, or offer for sale therein or to have in storage any milk and/or milk products, defined in this *Ordinance*. Provided, that grocery stores, restaurants, soda fountains and similar establishments where milk and/or milk products are served or sold at retail, but not processed may be exempt from the requirements of this Section. Provided further, that brokers, agents, and distributors representing, buying from, and/or selling condensed and dry milk products from or to a milk plant having a valid permit are not required to have a permit. ...

It shall be unlawful for any person to manufacture in a milk plant under a permit for Grade "A" condensed or dry milk products in the...of...¹ or its jurisdiction any condensed and dry milk products which do not meet the requirements of this *Ordinance* for Grade "A" condensed or dry milk products without a permit from the Regulatory ~~Authority~~ Agency who shall require that such condensed and dry milk products be processed, packaged and stored separately from Grade "A" condensed or dry milk products and that each container of such products be plainly marked in such a manner as to prevent confusion of the product with Grade "A" condensed or dry milk products. ...

SUSPENSION OF PERMIT: When any requirement(s) of this *Ordinance* is violated, the permit holder is subject to the suspension of their permit.

Page 14:

The Regulatory Agency may forego suspension of the permit, provided the milk and/or milk product in violation is not sold or offered for sale as a Grade "A" milk and/or milk product. A Regulatory Agency may allow the imposition of a monetary penalty in lieu of a permit suspension, provided the milk and/or milk product in violation is not sold or offered for sale as a Grade "A" milk and/or milk product. Except, that a milk producer may be assessed a monetary penalty in lieu of permit suspension for violative counts provided:

1. If the monetary penalty is due to a violation of the bacterial or cooling temperature standards, the Regulatory Agency shall conduct an inspection of the facility and operating methods and make the determination that the conditions responsible for the violation have been corrected. Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3) week period in order to determine compliance with the appropriate standard as determined in accordance with Section 6 of this *Ordinance*.
2. If the monetary penalty is due to a violation of the somatic cell count standard, the Regulatory Agency shall verify that the milk supply is within acceptable limits as prescribed in Section 7 of this *Ordinance*. Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3) week period in order to determine compliance with the appropriate standard as determined in accordance with Section 6 of this *Ordinance*.

NOTE: The option to issue a monetary penalty in lieu of a permit suspension as cited above, shall not be applicable to a TPC authorized under the ICP.

HEARINGS: If a State's Administrative Procedure Act (APA), which provides procedures for

administrative hearings and judicial review of administrative determinations, is available, the APA shall be made applicable by reference to the hearings provided for in the *Ordinance*. If such APA is not available, appropriate procedures, including provision for notice, hearing officer, their authority, record of hearing, rules of evidence and court review shall be established by the appropriate authority.

NOTE: TPCs authorized under the ICP shall follow the hearing procedures and process addressed in this *Ordinance*.

SECTION 4. LABELING

Page 16:

ADMINISTRATIVE PROCEDURES ...

LABELING OF EMERGENCY SUPPLIES: When the sale of ungraded milk or milk products is authorized during emergencies, under the terms of Section 2, the label ~~must~~ shall bear the designation "ungraded". When such labeling is not available, the Regulatory Agency shall take immediate steps to inform the public that the particular supply is "ungraded" and that the supply will be properly labeled as soon as the distributor can obtain the required labels.

NOTE: The option for the sale of "ungraded" milk and/or milk products as cited above, shall not be applicable to a MC IMS listed under the ICP. ...

Page 17:

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

3. Inspect each milk plant and receiving station at least once every three (3) months, provided that, for those milk plants and receiving stations that have HACCP Systems, which are regulated under the NCIMS voluntary 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~~ a Regulatory Agency ~~when~~ designated by FDA under the FDA LACF Program, in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113 at a frequency determined by FDA.

...

Page 20:

ENFORCEMENT PROCEDURES - ASEPTIC PROCESSING AND PACKAGING MILK PLANTS: 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. ...

Page 22:

INSPECTION/AUDIT REPORTS: A copy of the inspection/audit report shall be filed as directed by the Regulatory Agency and retained for at least twenty-four (24) months. The results shall be entered on appropriate ledger forms. The use of a computer or other information retrieval system may be used. Examples of field inspection/audit forms are identified in Appendix M.

NOTE: The option to use Certified Industry Inspection as cited in this Section, shall not be applicable to a TPC authorized under the ICP.

SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS

Page 23:

Samples of milk and/or milk products shall be taken while in the possession of the producer, milk plant or distributor at any time prior to delivery to the store or consumer.

Samples of milk and/or milk products from dairy retail stores, food service establishments, grocery stores and other places where milk and/or milk products are sold shall be examined periodically as determined by the Regulatory Agency and the results of such examination shall be used to determine compliance with Sections 2, 4 and 10. Proprietors of such establishments shall furnish the Regulatory Agency, upon request, with the names of all distributors from whom milk and/or milk products are obtained.

NOTE: The sampling of milk and/or milk products from locations where milk and/or milk products are sold as cited above, shall not be applicable to a TPC authorized under the ICP. ...

ITEM 7r. TOILET ...

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

Page 42:

1. There is at least one (1) flush toilet connected to a public sewer system, or to an individual sewage-disposal system, or a chemical toilet, earth pit privy or other type of privy. Such sewage systems shall be constructed and operated in accordance with the standards outlined in Appendix C., or when a Regulatory Agency has more effective standards designed specifically for that region, these standards may apply, provided, there is ~~no~~ not any mixing of animal and human waste.

NOTE: The text “or when a Regulatory Agency has more effective standards designed specifically for that region, these standards may apply” as cited in 1. above, shall not be applicable to a TPC authorized under the ICP. ...

ITEM 8r. WATER SUPPLY ...

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. The water supply for milkhouse and milking operations is approved as safe by the State applicable Government Water Control Authority and, in the case of individual water systems, complies with the specifications outlined in Appendix D, and the Bacteriological Standards outlined in Appendix G. ...

ITEM 10r. UTENSIL AND EQUIPMENT – CLEANING ...

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

Page 46:

3. There shall ~~be no~~ not be any partial removal of milk from milk storage/holding tanks by the bulk milk hauler/sampler, except partial pickups may be permitted when the milk storage/holding tank is equipped with a seven (7) day recording device complying with the specifications of Appendix H. or other recording device acceptable to the Regulatory Agency, provided the milk storage/holding tank shall be clean and sanitized when empty and shall be emptied at least every seventy-two (72) hours. In the absence of a temperature-recording device, partial pickups may be permitted as long as the milk storage/holding tank is completely empty, clean and sanitized prior to the next milking. In the event of an emergency situation, such as inclement weather, natural disaster, etc., a variance may be permitted at the discretion of the Regulatory Agency.

NOTE: The text "In the event of an emergency situation" as cited in 3. above, shall not be applicable to a TPC authorized under the ICP. ...

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

Page 61:

ITEM 7p. WATER SUPPLY

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when: ...

2. The water supply is approved as safe by the State applicable Government Water Control Authority and, in the case of individual water systems, complies with the specification outlined in Appendix D. and the Bacteriological Standards outlined in Appendix G. ...

ITEM 11p. CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

Page 66:

11. The manufacture, packing, transportation and handling of single-service containers, closures, caps, gaskets and similar articles comply with the requirements of Appendix J. Standards for the Fabrication of Single-Service Containers and Closures for Milk and Milk Products. Provided, that all paper, plastics, foil, adhesives, and other components of containers used in the packaging of milk and/or milk products that have been condensed and/or dried shall be free from deleterious substances and comply with the requirements of the *FFD&CA*.

Inspections and tests shall be made by the Regulatory Agency or any Agency authorized by them.

NOTE: The option for “Inspections and tests” as cited in 11. above, shall only be made by a TPC authorized under the ICP. ...

ITEM 12p. CLEANING AND SANTIZING OF CONTAINERS AND EQUIPMENT

ADMINISTRATIVE PROCEDURES

Page 71:

6. a. The residual bacteria count of multi-use containers and closures shall be conducted as ...

c. When single-service containers or closures are fabricated in another plant that conforms to the Standards of Appendix J. and the Regulatory Agency has information that they do comply, the Regulatory Agency may accept the containers as being in conformance without additional testing. If there is reason to believe that containers do not conform to the bacteriological standards, additional testing may be required. If containers are fabricated in the milk plant, the Regulatory Agency shall collect, during any consecutive six (6) months, at least four (4) sample sets of containers, as defined in Appendix J., from each manufacturing line, as defined in Appendix J., 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, and analyze the sample sets at an Official, Commercial or Industry Laboratory, approved by the ~~State Milk Laboratory~~ Certifying Control Agency specifically for the examinations required under Appendix J. ...

ITEM 15p. PROTECTION FROM CONTAMINATION

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

Page 75:

15p.(A) ...

2. Packaged milk and/or milk products, which have physically left the premises or the processing milk plant are not re-pasteurized for Grade “A” use. The Regulatory Agency may, on a specific individual request, authorize reprocessing of packaged milk and/or milk products, provided all other aspects of this Item, including proper storage temperature and container integrity are complied with. Provided, that the re-pasteurization of milk and/or milk products shipped in milk tank trucks, which have been pasteurized at another Grade “A” milk plant and have been handled in a sanitary manner and maintained at 7°C (45°F) or less is permitted. Equipment, designated areas or rooms utilized for handling, processing and storage of returned packaged milk and/or milk products are maintained, operated, cleaned and sanitized so as to preclude the contamination of Grade “A” milk and/or products and equipment and the Grade “A” operations.

NOTE: The option for the authorizing of the reprocessing of packaged milk and/or milk products on an individual request, as cited in 2. above, shall not be applicable to a TPC authorized under the ICP. ...

ITEM 16p.(D) PASTEURIZATION RECORDS, EQUIPMENT TESTS AND EXAMINATIONS

1. PASTEURIZATION RECORDS: ...

Page 100:

a. Batch Pasteurizers: ...

(5) Reading of the 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; ...

Page 101:

2. EQUIPMENT TESTS AND EXAMINATIONS:

The Regulatory Agency shall perform the indicated tests on the following instruments and devices initially on installation; and at least once each three (3) months, including the remaining days of the month in which the equipment tests are due; and whenever any alteration or replacement is made which may affect the proper operation of the instrument or device. Provided, that the holding time test shall be conducted at least every six (6) months, including the remaining days of the month in which the equipment check is due.

NOTE: A TPC authorized under the ICP may utilize appropriately trained and TPC authorized in-country regulatory personnel to comply with 2. as cited above.

On an emergency basis, pasteurization equipment may be tested and temporarily sealed by a milk plant employee provided the following conditions are met: ...

a. The individual applying the seal(s) ~~is~~ shall be employed by the milk plant in which the ~~seal~~ seal(s) was removed; ...

d. The individual ~~is~~ shall be in possession of authorization from the Regulatory Agency to perform these tests;

e. The individual ~~will~~ shall immediately notify the Regulatory Agency of the time of the shutdown that would necessitate the breaking and removal of the regulatory seal(s). Permission to test and ~~seal~~ reseal the equipment ~~must~~ shall be obtained for each specific incident. The individual ~~will~~ shall also notify the Regulatory Agency of the identity of the controls affected, the cause, if known, of the equipment failure, the repairs made and the results of the testing. Test results for Pasteurization Equipment Testing shall be recorded on a similar document for all milk plants. (Refer to the reference in Appendix M. for an example.) The individual ~~will~~ shall provide to the Regulatory Agency the identity and volume of milk and/or milk products processed during the period that the temporary seals ~~were~~ seal(s) was applied ~~to the Regulatory Agency~~;

f. If regulatory ~~tests reveal~~ testing reveals that the equipment or controls are not in compliance with the provisions of this *Ordinance*, all milk and/or milk products that were processed during ~~that~~ this period may be recalled by the Regulatory Agency;

g. The Regulatory Agency or a properly trained regulatory official, commissioned by the responsible ~~State~~ Regulatory Agency, of each participating non-U.S. country or political subdivision thereof, ~~will~~ shall remove the temporary seal(s), retest the equipment and apply the regulatory seal(s) within ten (10) working days of the notification by ~~industry~~ the milk plant; and

h. ~~No~~ Grade "A" milk and/or milk products ~~will~~ shall not be processed after ten (10) working days of the notification by the milk plant without the affected equipment being tested and sealed by the Regulatory Agency or a properly trained regulatory official, commissioned by the responsible ~~State~~ Regulatory Agency, of each participating non-U.S. country or political subdivision thereof. ...

Page 116:

SECTION 8. ANIMAL HEALTH ...

Page 118:

5. Records supporting the tests required in this Section shall be available to the Regulatory Agency and be validated with the signature of a licensed and accredited veterinarian or an accredited veterinarian in the employ of an official Agency.

NOTE: For the ICP, references to USDA and/or State in Items 1 through 5 above, shall mean the Government Agency responsible for animal disease control in the Country or region of that Country. The term "accredited veterinarian" shall mean an individual veterinarian authorized for those activities in said Country or region of that Country. ...

AMINISTRATIVE PROCEDURES

BOVINE TUBERCULOSIS: All tuberculin tests and retests shall be made, and any reactors

disposed of, in accordance with the current edition of *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*, as published by USDA. For tuberculosis test purposes, the herd is defined as all adult cattle twenty-four (24) months of age and over, including any commingled beef animals. Dairy cattle less than two (2) years of age and already milking shall be included in the herd test. A letter or other official correspondence attesting to the accreditation status of the locality in which the herd is located, including the date of accreditation, or a certificate identifying the animals tested, the date of injection, the date of reading of the test and the results of the test signed by a USDA accredited veterinarian, shall be evidence of compliance with the above requirements and shall be filed with the Regulatory Agency. (Refer to Appendix A.)

NOTE: For the ICP, an official letter or other official correspondence attesting to the accreditation status of the locality in which the herd is located, including the date of accreditation or recertification, or certificate identifying the animals tested, the date of injection, the date of the reading of the test and the results of the test signed by the Country's Veterinary Services shall be provided as directed by the TPC.

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BOVINE BRUCELLOSIS: All brucellosis tests, retests, disposal of reactors, vaccination of calves and certification of herds and areas shall be in accordance with the current edition of *Brucellosis Eradication, Recommended Uniform Methods and Rules*, as published by USDA. All reactors disclosed on blood agglutination tests shall be separated immediately from the milking herd and the milk of these reactors shall not be used for human consumption.

A certificate identifying each animal, signed by the veterinarian and the director of the laboratory making the test, shall be filed as directed by the Regulatory Agency. Provided, that in the event the herd is subject to the milk ring test, the record shall be required to show only the date and results of such test. Within thirty (30) days following the expiration of an official milk ring testing program, or in the case of a herd subject to annual blood tests, thirteen (13) months following the last annual blood tests, the Regulatory Agency shall notify the herd owner or operator of the necessity to comply with the brucellosis requirements. The failure of the herd owner or operator to comply with the brucellosis requirements within thirty (30) days of written notice shall result in immediate suspension of the permit. (Refer to Appendix A.)

NOTE: For the ICP, a certificate identifying each animal signed by the Country's Veterinary Services and director of the laboratory conducting the testing, shall be provided as directed by the TPC.

SECTION 9. MILK AND MILK PRODUCTS WHICH MAY BE SOLD

From and after twelve (12) months from the date on which this *Ordinance* is adopted, only Grade "A" pasteurized, ultra-pasteurized, or aseptically processed and packaged milk and milk products shall be sold to the final consumer, to restaurants, soda fountains, grocery stores or similar establishments. Provided, only Grade "A" milk and milk products shall be sold to milk plants for use in the commercial preparation of Grade "A" milk and milk products. Provided further, that in an emergency, the sale of pasteurized, ultra-pasteurized 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".

NOTE: The option for the sale of “ungraded” milk and/or milk products as cited above, shall not be applicable to a MC IMS listed under the ICP. ...

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

Page 121:

ADMINISTRATIVE PROCEDURES ...

7. All ratings are made on the basis of procedures outlined in the *Methods of Making Sanitation Ratings of Milk Shippers* (MMSR).

NOTE: Names of interstate milk shippers and their ratings, as reported by ~~State~~ Rating Agencies, are contained in the *IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers* (IMS List), issued electronically by FDA. This list may be obtained from the FDA web site at www.fda.gov.

8. The supplies have been awarded, by a SRO, certified by FDA, a satisfactory listing under the NCIMS voluntary HACCP Program as specified in Appendix K. of this *Ordinance*.

9. The foreign supplies have been awarded a satisfactory listing, by ~~an NCIMS Certified Third Party~~ a TPC Rating Officer ~~standardized~~ certified by the FDA, under the ~~NCIMS International Certification Pilot Program ICP~~. ~~This provision will expire December 31, 2013, unless extended by future conference action.~~

Page 122:

11. Aseptically processed and packaged milk and milk products in Definition Z of this *Ordinance* shall be considered to be Grade "A" milk or milk products. The source(s) of the milk and milk products used to produce aseptically processed and packaged milk and milk products 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~~ Grade "A" 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 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~~ shall occur within (6) months of this rating. Both the Milk Sanitation Compliance and Enforcement Ratings ~~must~~ shall 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~~ Regulatory Agency's and ~~rating~~ Rating Agency's 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, 2013, unless extended by future conference action.

12. Retort processed after packaging milk and milk products as addressed in Definition Z 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 Z 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 Z 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~~ shall occur within (6) months of this rating. Both the Milk Sanitation Compliance and Enforcement Ratings ~~must~~ shall 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~~ Regulatory Agency's and ~~rating~~ Rating Agency's 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.

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SECTION 13. PERSONNEL HEALTH ...

ADMINISTRATIVE PROCEDURES

Milk plant operators who have received reports, under this Section, from employees who have handled pasteurized milk or milk products or associated milk or milk product-contact surfaces shall immediately report these facts to the appropriate ~~Milk~~ Regulatory Agency. ...

Page 124:

SECTION 14. PROCEDURE WHEN INFECTION OR HIGH RISK OF INFECTION IS DISCOVERED

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:

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FOOTNOTES

4. Where State law does not permit the sale of reconstituted or recombined milk and/or milk products, Definition ~~KKQQ~~ and other corresponding references ~~should~~ shall be omitted.

NOTE: This option, as cited in 4. above, shall not be applicable to a TPC authorized under the ICP. ...

Page 128:

16. A certified copy may be secured from the Food and Drug Administration, HFS-626, 5100 Paint Branch Parkway, College Park, MD 20740-3835.

NOTE: In reference to Footnotes 2, 7, 8, 9, 10, 11, 12, and 13, for the purposes of the ICP, cottage cheese, dry curd cottage cheese and reduced fat or low fat cottage cheese shall be Grade "A" and shall be regulated under the terms of this Ordinance. ...

Page 130:

APPENDIX B. MILK SAMPLING, HAULING AND TRANSPORTATION

I. MILK SAMPLING AND HAULING PROCEDURES ...

The bulk milk hauler/sampler is any person who collects official samples and may transport raw milk from a farm and/or raw milk products to or from a milk plant, receiving station or transfer station and has in their possession a permit from any ~~State~~ Regulatory Agency to sample such products. The bulk milk hauler/sampler occupies a unique position making this individual a critical factor in the current structure of milk marketing.

Page 131:

EVALUATION OF BULK MILK HAULER/SAMPLER PROCEDURES: ...

The bulk milk hauler/sampler's technique is best determined when the regulatory agent is able to observe the bulk milk hauler/sampler at one (1) or more farms. Each bulk milk hauler/sampler ~~must~~ shall be inspected by the Regulatory Agency prior to the issuance of a permit and at least once every twenty-four (24) months thereafter as referenced in Section 5 of this *Ordinance*. The bulk milk hauler/sampler ~~must~~ shall hold a valid permit prior to the collection of official samples. ~~States~~ Regulatory Agencies may use inspections from any Regulatory Agency as a means of maintaining record requirements and enforcement.

NOTE: The option to utilize inspections of bulk haulers/samplers conducted by other Regulatory Agencies, as cited above, shall not be applicable to a TPC authorized under the ICP. ...

Page 132:

5. **Universal Sampling System:** The following are sampling procedures: ...

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

Page 135:

V. MILK TANK TRUCK PERMITTING AND INSPECTION ...

PERMITTING: Each milk tank truck shall bear a permit for the purpose of transporting milk and/or milk products. (Refer to Section 3 of this *Ordinance*.) The permit shall be issued to the owner of each milk tank truck by an authorized Regulatory Agency. The permit identification and ~~State~~ Regulatory Agency issuing the permit shall be displayed on the milk tank truck. It is recommended that this permit be renewed each year pending satisfactory completion of an inspection as outlined in the following **INSPECTION** Section. ...

Page 136:

INSPECTION: ...

When significant defects or violations are encountered by a Regulatory Agency, a copy of the report shall be forwarded to the permitting ~~agency~~ Regulatory Agency and also carried on the milk tank truck until the violations are corrected. ...

Page 137:

5. **Wash and Sanitize Record:**

a. The bulk milk hauler/sampler shall be responsible for assuring that the milk tank truck has been properly cleaned and sanitized at a permitted milk plant, receiving station, transfer station, or milk tank truck cleaning facility. A milk tank truck without proper cleaning and sanitizing documentation shall not be loaded or unloaded until the proper cleaning and sanitization can be verified.

NOTE: The option to use non-IMS listed milk tank truck cleaning facilities, as cited in a. above, shall not be applicable to a TPC authorized under the ICP. ...

Page 138:

e. ~~State will~~ States shall submit to the NCIMS Executive Secretary an updated list of all currently permitted non-IMS listed milk tank truck cleaning facilities. The list is to be submitted for publication on the NCIMS ~~or other easily accessible~~ web site.

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APPENDIX C. DAIRY FARM CONSTRUCTION STANDARDS AND MILK PRODUCTION

I. TOILET AND SEWAGE DISPOSAL FACILITIES

FLUSH TOILETS

Flush toilets are preferable to pit privies, earth closets or chemical toilets at both dairy farms and milk plants. Their installation shall conform to the ~~Local or State~~ applicable Government plumbing regulations. Toilets shall be located in a well-lighted and well-ventilated room. Fixtures shall be protected against freezing. The following shall be considered defects in flush-toilet installations: ...

SEPTIC TANKS

Disposal of the wastes from toilets should preferably be into a sanitary-sewer system. Where such systems are not available to a dairy farm or milk plant, the minimum satisfactory method should include treatment in a septic tank, with the effluent discharged into the soil. Where soil of satisfactory permeability is not available, the effluent shall be disposed of in accordance with the rules of the ~~Local or State Health~~ applicable Government Authority. It is preferable to treat floor drainage, wastes from washing of utensils, etc., in separate systems. When such wastes are combined with toilet wastes in the septic tank system, careful consideration ~~must~~ shall be given to the expected flow in the design of both the septic tank and the leaching system. ...

Page 141:

DISPOSAL FIELDS FOR SEPTIC TANKS ...

Information as to methods of making percolation tests to determine absorptive quality of the soil may be obtained from ~~Local and/or State Health Departments~~ applicable Government Agencies. From the same sources, advice may be obtained as to trench areas needed for various numbers of users, in relation to observed percolation rates. In view of their close knowledge of local conditions, it is recommended that such assistance be requested before an absorption system is constructed. ...

EARTH-PIT PRIVY ...

Page 141:

4. **Floor and Riser:** Impervious materials, such as concrete, are believed to be most suitable for the floor and riser. Because privy units are commonly used as urinals, the use of impervious materials for risers is desirable in the interest of cleanliness. In cold climates, wood treated with a preservative, such as creosote, has been found to be durable and to reduce the problem of condensation. Therefore, in some sections of the country, wood may be used if approved by the ~~Local or State Health~~ applicable Government Authority

Page 145:

CONSTRUCTION PLANS

Detailed construction drawings for septic tanks, pit privies, masonry-vault privies and chemical toilets complying with ~~State~~ applicable Government regulations may be secured from the ~~Local and State Health~~ applicable Government Authority. ...

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APPENDIX D. STANDARDS FOR WATER SOURCES

The *Grade "A" PMO*, formal FDA interpretations of the *Grade "A" PMO* and other written USPHS/FDA opinions ~~will~~ shall be used in evaluating the acceptability of individual water supplies and water system construction requirements at dairy farms, milk plants, and single-service container manufacturing facilities.

~~State~~ The applicable Government Water Control Authority requirements, which are less stringent than the *Grade "A" PMO*, shall be superseded by the *Grade "A" PMO*. ~~State~~ The applicable Government Water Control Authority requirements, which are more strict than the *Grade "A" PMO*, shall not be considered in determining the acceptability of water supplies during ratings, check ratings, single-service listing evaluations and audits. For example, the *Grade "A" PMO* requires a satisfactory farm water sample every three (3) years. If State law required such samples to be taken annually, a SRO conducting a sanitation rating, which includes that farm, ~~will~~ shall give that farm full credit for water sample frequency, if the *Grade "A" PMO* three (3) year requirement is met, even though, the State required annual frequency is not met.

Supplies other than individual water supplies, which have been approved as safe by the ~~State~~ applicable Government State Water Control Authority, shall be considered to be acceptable sources as provided in Section 7 of this *Ordinance* for Grade "A" inspections, as well as for all other IMS purposes without further inspection of the spring, well or reservoir treatment facility(ies), testing records, etc.

I. LOCATION OF WATER SOURCES

DISTANCE FROM SOURCES OF CONTAMINATION ...

When a properly constructed well penetrates an unconsolidated formation, with good filtering properties, and when the aquifer itself is separated from sources of contamination by similar materials, research and experience have demonstrated that 15 meters (50 feet) is an adequate distance separating the two. Lesser distances should be accepted, only after a comprehensive sanitary survey, conducted by qualified ~~Local or State Agency~~ applicable Government Water Control Authority Officials, has determined such lesser distances are both necessary and safe.

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If it is proposed to install a properly constructed well in formations of unknown character, the ~~State or U.S. Geological Survey and the Local or State Health~~ applicable Government Agency should be consulted.

When wells must be constructed in consolidated formations, extra care should always be taken in the location of the well and in setting "safe" distances, since pollutants have been known to travel great distances in such formations. The owner should request assistance from the ~~Local or State Health~~ applicable Government Agency ...

II. CONSTRUCTION

SANITARY CONSTRUCTION OF WELLS ...

Page 165:

Well Pits and Drainage: Because of the pollution hazards involved, the well head, well casing, pump, pumping machinery, valve connected with the suction pump or exposed suction pipe shall not be permitted in any pit, room or space extending below ground level, or in any room or space above the ground, which is walled-in or otherwise enclosed, so that it does not have free drainage by gravity to the surface of the ground. Provided, that a dug well properly constructed, lined and covered, as herein prescribed, shall not be construed to be a pit. Provided further, that pumping equipment and appurtenances may be located in a residential basement, which is not subject to flooding. And provided further, that in the case of existing water supplies which otherwise comply with the applicable requirements of this Appendix, pit installations may be accepted, under the following conditions, when permitted by the State applicable Government Water Control Authority: ...

Page 168:

SURFACE WATER ...

The milk producer and/or milk plant operator, who is considering surface sources of water for milking, milkhouse and milk plant, receiving station and/or transfer station operations shall receive the advance approval of the Regulatory Agency and shall comply with all applicable requirements of the State applicable Government Water Control Authority on the construction, protection and treatment of the chosen supply. ...

APPENDIX E. EXAMPLES OF 3-OUT-OF-5 COMPLIANCE ENFORCEMENT PROCEDURES ...

Page 203:

Table 12. Example of Enforcement Procedures for Raw Milk Laboratory Examinations

11/14/2011	1,200,000	Violative (3 of last 5 counts exceed the standard); Required Regulatory Actions: 3. Impose monetary penalty in lieu of permit suspension, provided ... Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3) week period in order to determine compliance with the appropriate standard as determined in accordance with Section 6 of this <i>Ordinance</i> . (Refer to Section 3.) NOTE: <u>The option to issue a monetary penalty in</u>
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		<u>lieu of a permit suspension, as cited in 3. above, shall not be applicable to a TPC authorized under the ICP.</u>
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...

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

CRITERIA ...

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9. The public health computer program access ~~must~~ shall be sealed. ... Public health controls in pasteurizers that may be compromised by such a challenge, ~~must~~ shall be altered or re-programmed so this compromise is prevented and the access to this computer program ~~must~~ shall be sealed by the Regulatory ~~Authority~~ Agency. Similar challenges may be performed on other required public health functions that are computer controlled. ...

14. When the public health computer prints the holding tube temperature trace at specific intervals, rather than a continuously changing line, temperature readings shall be printed not less than once every five (5) seconds. In addition, during the recorder/controller thermometric response test, the temperature shall be printed or indicated at a time rate sufficient to allow the Regulatory Agency ~~official~~ to measure the 7°C (12°F) rise in temperature as described in TEST 8. RECORDER/CONTROLLER-THERMOMETRIC RESPONSE. ...

Page 276:

APPENDIX I. PASTEURIZATION EQUIPMENT AND CONTROLS - TESTS

**I. TESTING APPARATUS SPECIFICATIONS
TEST THERMOMETER ...**

2. **Digital Test Thermometer:** Hand-held; high accuracy digital thermometer; and battery or AC line powered. Calibration is protected from unauthorized changes. ...

Accuracy: System accuracy of: ... This calibration shall be performed annually by a properly trained representative of an "Official Laboratory" or an "Officially Designated Laboratory"; or by a qualified representative of a thermometer manufacturer; or by a properly trained State Regulatory Agency representative. The calibration protocol/SOP shall be developed by the Regulatory Agency in cooperation with the thermometer manufacturer and FDA. Documentation of the identity of the properly trained State Regulatory Agency representative shall be maintained by the ~~State~~ Regulatory Authority Agency. A signed certificate of calibration for the digital thermometer shall be maintained with the unit. ...

Page 318:

C. BACTERIAL STANDARDS AND EXAMINATION OF SINGLE-SERVICE CONTAINERS AND CLOSURES ...

3. During any consecutive six (6) months, at least four (4) sample sets 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, and analyzed at an Official, Commercial or Industry Laboratory approved by the ~~State Milk Laboratory~~ Certifying Control Agency specifically for the examinations required under these Standards. (Refer to Item 12p of this *Ordinance* for sampling of containers and closures in milk plants.) ...

D. FABRICATION PLANT STANDARDS ...

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6. TOILET FACILITIES - SEWAGE DISPOSAL

- a. Disposal of sewage and other wastes shall be in a public sewage system or in a manner in compliance with ~~Local and State~~ applicable Government regulations.
- b. All plumbing shall comply with the ~~Local and State~~ applicable Government plumbing regulations. ...

7. WATER SUPPLY

- a. The water supply, if from a public system, shall be approved as safe by the ~~State~~ applicable Government Water Control Authority responsible for water quality, and in the case of individual water systems, comply with at least the specifications outlined in Appendix D. and the bacteriological standards outlined in Appendix G. of this *Ordinance*. ...

Page 320:

E. CRITERIA FOR LISTING CERTIFIED SINGLE-SERVICE MANUFACTURERS IN THE IMS LIST ...

Page 326:

The following procedures shall be followed for listing certified single-service manufacturers in the *IMS List*:

1. ~~For domestic firms, Triplicate~~ triplicate copies or PHS/FDA's electronic version (transmitted via computer) of FORM FDA 2359d-REPORT OF CERTIFICATION (*Fabrication of Single-Service Containers and Closures for Milk and Milk Products*) shall be submitted by the ~~State Rating Officer~~ SRO to the appropriate Regional Office of the PHS/FDA for single-service manufacturers who desire to be listed ~~in~~ on the *IMS List*.
2. For foreign firms, duplicate copies or PHS/FDA's electronic version (transmitted via computer) of FORM FDA 2359d-REPORT OF CERTIFICATION (*Fabrication of Single-Service Containers and Closures for Milk and Milk Products*) shall be submitted by the TPC or private consultant conducting the certification to CFSAN's Milk Safety Team (HFS-316), Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740-3835 for single-service manufacturers who desire to be listed ~~in~~ on the *IMS List*.
3. The Certified Single-Service Manufacturer is not listed ~~in~~ on the *IMS List* unless the "PERMISSION TO PUBLISH" SECTION of FORM FDA 2359d is signed by an officer of the firm authorizing the release.
 - a. For the submission of PHS/FDA's electronic version, a signed copy of FORM FDA 2359d, including Section 12, shall be maintained on file by the Rating Agency and ~~will~~ shall be reviewed as part of the Single-Service Listing Audit and/or the ~~State~~

4. The Certified Single-Service Manufacturer may be listed ~~in~~ on the *IMS List* as a "PARTIAL" listing. A "PARTIAL" listing shall mean that only specific production rooms, or fabrication lines or machines have been evaluated in regard to specific containers or closures or specific size of containers or closures and conform to the specifications contained within Appendix J.

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APPENDIX K. HACCP PROGRAM

I. THE HACCP SYSTEM INTRODUCTION ...

VOLUNTARY PARTICIPATION: This Appendix describes a ~~voluntary~~, NCIMS voluntary HACCP Program alternative to the traditional inspection system. ~~No~~ A milk plant, receiving station or transfer station may not participate in the ~~voluntary~~ NCIMS voluntary HACCP Program unless the Regulatory Agency responsible for the oversight of the facility agrees to participate with the ~~dairy~~ milk plant(s), receiving station(s) and transfer station(s) in the NCIMS voluntary HACCP Program. Both parties ~~must~~ shall provide written commitment to each other that the necessary resources to support participation in the NCIMS voluntary HACCP Program ~~will~~ shall be made available. Management responsible for both the State Regulatory Agency and milk plant, receiving station and/or transfer station ~~must~~ shall be willing to provide the resources ~~needed~~ required to develop and implement a successful HACCP System. ...

Page 335:

IV. TRAINING AND STANDARDIZATION ...

Industry, State Regulatory Agency, Rating Agency and ~~Federal regulatory and listing~~ FDA personnel should be trained together. ...

Page 336:

V. HACCP AUDITS AND FOLLOW-UP ACTIONS

~~STATE REGULATORY AGENCY~~ AUDITS, ENFORCEMENT AUDITS, ACTIONS AND FOLLOW-UP: Audits shall be conducted of the milk plant, receiving station, or transfer station facility, and the NCIMS voluntary HACCP Program to ensure compliance with the HACCP System and other associated NCIMS regulatory requirements. ...

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~~STATE REGULATORY AGENCY~~ ENFORCEMENT ACTION/FOLLOW-UP: The State Regulatory Agency shall: ...

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APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

I. INDUSTRY RESPONSIBILITIES

MONITORING AND SURVEILLANCE: ...

The bulk milk pickup tanker shall be sampled after the last producer has been picked up and before any additional commingling. ... All presumptive positive test results for drug residues from analysis done on commingled raw milk tanks, bulk milk pickup tankers, farm raw milk tanks (only milk offered for sale) or finished milk or milk product samples ~~must~~ shall be reported to the Regulatory Agency ~~of the State~~ in which the testing was conducted.

REPORTING AND FARM TRACE BACK:

When a bulk milk pickup tanker is found to be positive for drug residues, the Regulatory Agency ~~of the State~~ in which the testing was conducted, shall be immediately notified of the results and the ultimate disposition of the raw milk. ...

Page 343:

II. REGULATORY AGENCY RESPONSIBILITIES

Upon receipt of notification from industry of a bulk milk pickup tanker, which contains milk from another ~~State(s)~~ Regulatory Agency's jurisdiction, is found to be presumptive positive for drug residues it is the responsibility of the receiving Regulatory Agency ~~of the receiving State~~ to notify the Regulatory Agency(ies) ~~of all States of origin~~ from which the milk originated. ...

Page 346:

2. **Screening Test Positive (Load Confirmation):** A screening test positive result is obtained when the presumptive positive sample is tested in duplicate, using the same or equivalent (M-I-96-10, latest revision) test as that used for the presumptive positive, with a positive and negative control, and either or both of the duplicates are positive and the controls give the proper results. A screening test positive (load confirmation) is to be performed by an Official ~~State~~ Laboratory, Officially Designated Laboratory or Certified Industry Supervisor using the same or an equivalent test (M-I-96-10, latest revision).

3. **Producer Trace Back/Permit Action:** A producer trace back/permit action test is performed after a screening test positive load is identified by an Official ~~State~~ Laboratory, Officially Designated Laboratory or Certified Industry Supervisor using the same or an equivalent (M-I-96-10, latest revision) test as was used to obtain the screening test positive (load confirmation). ...

7. **Certified Industry Supervisor:** An Industry Supervisor who is evaluated and listed by a ~~State~~ LEO as certified to conduct drug residue screening tests at industry drug residue screening sites for *Grade "A" PMO*, Appendix N. regulatory actions (confirmation of tankers, producer trace back and/or permit actions).

CERTIFIED INDUSTRY SUPERVISORS; EVALUATION AND RECORDS:

Reference: *EML*

1. **Certified Industry Supervisors/Industry Supervisors/Industry Analysts:** Regulatory Agencies may choose to allow Industry Supervisors to be certified. Under this program, these Certified Industry Supervisors may officially confirm presumptive positive tanker loads and confirm producer milk for regulatory purposes (producer trace back/permit action). In the implementation of Appendix N. of this *Ordinance*, the LEO ~~will~~ shall use the appropriate Appendix N. FDA 2400 Series Form when evaluating Official ~~State~~ Laboratories, Officially Designated Laboratories or Certified Industry Supervisors, Industry Supervisors and Industry Analysts.

The Certified Industry Supervisor/Industry Supervisor shall report to the LEO the result of all competency evaluations performed on Industry Analysts. The names of all Certified Industry Supervisors, Industry Supervisors and Industry Analysts, as well as their training and evaluation status, shall be maintained by the ~~State~~ LEO and updated as replacement, additions and/or removals occur. The ~~State~~ LEO shall verify (document) that each Certified Industry Supervisor and/or Industry Supervisor has established a program that ensures the proficiency of the Industry Analysts they supervise. The ~~State~~ LEO shall also verify that each Industry Supervisor and Industry Analyst has demonstrated proficiency in performing drug residue analysis at least biennially. Verification may include an analysis of split samples and/or an on-site performance evaluation or another proficiency determination that the ~~State~~ LEO and the Laboratory Proficiency Evaluation Team (LPET) agree is appropriate. ...

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BULK MILK PICKUP TANKER SCREENING TEST: ...

2. **Initial Drug Testing Procedures: ...**

a. Industry Presumptive Positive Options: There are two (2) industry options for the milk represented by a presumptive positive sample:

(1) The Regulatory Agency involved (origin and receipt) shall be notified. ... Testing for confirmation of that presumptive positive load shall be in an Official ~~State~~ Laboratory, Officially Designated Laboratory or by a Certified Industry Supervisor at a location acceptable to the Regulatory Agency. Documentation of prior testing shall be provided to the analyst performing the load confirmation. ...

Page 348:

4. **Producer Trace Back:** All screening test positive (confirmed) loads ~~must~~ shall be broken down (producer trace back) using the same or an equivalent test method (M-I-96-10, latest revision). Confirmation tests (load and producer trace back/permit action) shall be performed in an Official ~~State~~ Laboratory, or Officially Designated Laboratory or by a Certified Industry Supervisor. Positive producers shall be handled in accordance with this Appendix. ...

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SCREENING TESTS NECESSARY TO IMPLEMENT THE PROVISIONS OF APPENDIX N. FOR BULK MILK PICKUP TANKERS:

1. Performance Tests/Controls (+/-): ...

c. All NCIMS Approved Bulk Milk Pickup Tanker Screening Tests Include The Following Format: All presumptive positive test results ~~are to~~ shall be repeated in duplicate as soon as possible at the direction of the Regulatory Agency on the same sample with single positive (+) and negative (-) controls by a certified analyst (Official ~~State~~ Laboratory, Officially Designated Laboratory or Certified Industry Supervisor) using the same or equivalent test (M-I-96-10, latest revision). If the duplicate tests, with appropriate control (+/-) results are negative (-), the tanker is reported as negative. If one or both duplicate test(s) is positive (+), the test result is reported to the Regulatory Agency ~~of the State~~ in which the testing was conducted, as a screening positive. ...

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7. Screening Test Volumetric Measuring Devices: ...

b. NCIMS Certified Laboratories require calibrated pipetting/dispensing devices. These devices may be calibrated at another location acceptable to the ~~State~~ LEO. ...

IV. ESTABLISHED TOLERANCES AND/OR SAFE LEVELS OF DRUG RESIDUES

"Safe levels" are used by FDA as guides for prosecutorial discretion. They do not legalize residues found in milk that are below the safe level. In short, FDA uses the "safe levels" as ~~prosecutorial~~ prosecutorial guidelines and in full consistency with CNI v. Young stating, in direct and unequivocal language, that the "safe levels" are not binding. They do not dictate any result; they do not limit ~~the Agency's~~ FDA's discretion in any way; and they do not protect milk producers, or milk from court enforcement action.

"Safe levels" are not and cannot be transformed into tolerances that are established for animal drugs under Section 512 (b) of the *FFD&CA* as amended . "Safe levels" do not:

1. Bind the courts, the public, including milk producers, or ~~the Agency~~ FDA, including individual FDA employees; and ...

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APPENDIX P. PERFORMANCE-BASED DAIRY FARM INSPECTION SYSTEM

PREFACE

A performance-based inspection system is an option to the traditional routine inspection frequency of at least once every six (6) months on Grade "A" dairy farms. This option provides ~~States~~ Regulatory Agencies with a choice. For some ~~States~~ Regulatory Agencies, inspecting every farm routinely twice a year may provide effective regulatory oversight and make efficient use of inspection resources. ~~In other States, however~~ For other Regulatory Agencies, an optional system, which determines routine farm inspection frequency based on producer milk quality and inspection performance may be more desirable, equally effective, and make the most efficient use of limited inspection resources. The overall inspection effort devoted to a performance-based farm inspection system may be more or less than the

traditional inspection system, which requires a routine inspection at least once every six (6) months per farm. ...

APPENDIX R. DETERMINATION OF TIME/TEMPERATURE CONTROL FOR SAFETY MILK AND MILK PRODUCTS

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A milk or milk product designated PA (further product assessment required) in either Table A or B should be considered TCS until sufficient information is provided to demonstrate the safety of the product. The PA ~~will~~ shall be an evaluation of the ~~product~~ milk or milk product group’s ability to not support pathogenic growth. Means to evaluate this assessment include (but are not limited to): literature review of similar milk products, inoculation studies, expert risk assessment, and/or ~~state regulatory~~ Regulatory Agency assessment.

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APPENDIX S. ASEPTIC PROCESSING AND PACKAGING PROGRAM ... ASEPTIC PROCESSING AND PACKAGING PROGRAM CFR/GRADE “A” PMO COMPARISON SUMMARY REFERENCE ...

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
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MAKE THE FOLLOWING CHANGES TO THE 2011 PROCEDURES:

~~Strike through~~ text to be deleted and underline text to be added.

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APPENDIX A. OFFICIAL AGREEMENTS UTILIZED IN THE NCIMS VOLUNTARY INTERNATIONAL CERTIFICATION PROGRAM

LETTER OF INTENT
MEMORANDUM OF AGREEMENT

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SECTION III. DEFINITIONS ...

- E. **CERTIFIED MILK LABORATORY EVALUATION OFFICER (LEO):** A Regulatory Agency or Milk Laboratory Control Agency employee who has been certified by the Public Health Service/Food and Drug Administration (PHS/FDA) Laboratory Proficiency Evaluation Team (LPET) using the Evaluation of Milk Laboratories (EML) to evaluate milk laboratories for the purpose of accrediting or approving laboratories that conduct official NCIMS milk testing and has a valid certificate of qualification.
- EF. **CERTIFIED MILK SANITATION RATING OFFICER (SRO):** ~~A State~~ Regulatory Agency employee who has been ~~standardized~~ certified by the Public Health Service/Food and Drug Administration (PHS/FDA), has a valid certificate of qualification; and does not have direct responsibility for the routine regulatory inspection and enforcement or regulatory auditing of the shipper to be rated or listed. Directors, administrators, supervisors, etc. may be certified as Milk Sanitation Rating Officers (SROs). A Milk Sanitation Rating Officer (SRO) may be certified to make HACCP milk plant, receiving station or transfer station listings.
- EG. **CERTIFIED SAMPLING SURVEILLANCE OFFICER (SSO):** ~~A State~~ Regulatory Agency employee who has been ~~standardized~~ certified by the Public Health Service/Food and Drug Administration (PHS/FDA) and has a valid certificate of qualification. Directors, administrators, supervisors, etc., Milk Sanitation Rating Officers (SROs), Laboratory Evaluation Officers (LEOs), etc. may be certified as Sampling Surveillance Officers (SSOs).

Page 3:

- GH. **CHECK RATING:** The designated PHS/FDA and NCIMS *Procedures* method to ensure that the published ~~State~~ rating of a milk shipper on the *IMS LIST-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS List)* is valid and maintained during the interval between ~~State~~ ratings. ...

Re-Letter remaining DEFINITIONS accordingly.

- JK. **IMS LISTED SHIPPER:** An interstate milk shipper (BTU, receiving station, transfer station, or milk plant), which has been certified by ~~the State~~ a Rating Agency as having attained the Sanitation Compliance and Enforcement Ratings necessary for inclusion ~~in~~ on 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 Agency's regulatory and Rating Agency's 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.

- L. **INTERNATIONAL CERTIFICATION PROGRAM (ICP):** The International

Certification Program (ICP) means the NCIMS voluntary program designed to utilize Third Party Certifiers (TPCs) authorized by the NCIMS Executive Board in applying the requirements of the NCIMS Grade “A” Milk Safety Program for Milk Companies (MCs) located outside the geographic boundaries of NCIMS Member States that desire to produce and process Grade “A” milk and/or milk products for importation into the United States.

- M. **LETTER OF INTENT (LOI):** A formal written signed agreement between a Third Party Certifier (TPC), authorized under the NCIMS voluntary International Certification Program (ICP), and a Milk Company (MC) that intends to be certified and IMS Listed under the NCIMS voluntary International Certification Program (ICP). A copy of each written signed agreement shall be immediately submitted to the International Certification Program (ICP) Committee following the signing by the Third Party Certifier (TPC) and Milk Company (MC).
- N. **LETTER OF UNDERSTANDING (LOU):** A formal written signed agreement between a Third Party Certifier (TPC) and the NCIMS Executive Board that acknowledges the NCIMS’ authorization of the Third Party Certifier (TPC) to operate under the NCIMS voluntary International Certification Program (ICP). It also states the Third Party Certifier’s (TPC’s) responsibilities under the NCIMS voluntary International Certification Program (ICP); their agreement to execute them accordingly; and their understanding of the consequences for failing to do so. The Letter of Understanding (LOU) shall include, but is not limited to, the issues and concerns addressed in all documents involved in the NCIMS voluntary International Certification Program (ICP).

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- O. **MEMORANDUM OF AGREEMENT (MOA):** A formal written signed memorandum that states the requirements and responsibilities of each party (Third Party Certifier (TPC) and Milk Company (MC)) to participate and execute the NCIMS voluntary International Certification Program (ICP). The Memorandum of Agreement (MOA) shall include, but is not limited to, the issues and concerns addressed in all documents involved in the NCIMS voluntary International Certification Program (ICP). This agreement shall be considered the Milk Company’s (MC’s) permit to operate in the context of the NCIMS Grade “A” Milk Safety Program and shall be renewed (signed and dated) on an annual basis.
- ~~LP~~ **MEMORANDUM OF CONFERENCE ACTIONS (IMS-a):** A memorandum issued by PHS/FDA providing the transmittal of information related to the actions taken at NCIMS Conferences and between PHS/FDA and the NCIMS Executive Board ~~FDA~~ to PHS/FDA Regional staff and Regulatory/Rating Agencies.
- ~~MQ~~ **MEMORANDUM OF INFORMATION (M-I):** A memorandum issued by PHS/FDA providing the transmittal of administrative and miscellaneous information by PHS/FDA to PHS/FDA Regional staff and ~~State~~ Regulatory/Rating Agencies.
- ~~NR~~ **MEMORANDUM OF INTERPRETATION (M-a):** A memorandum issued by PHS/FDA, following the *Procedures* document, providing clarification of the intent or meaning of wording related to the *Grade “A” PMO* and the *Evaluation of Milk Laboratories (EML)* to PHS/FDA Regional staff and Regulatory/Rating Agencies.

~~OS~~. **MEMORANDUM OF MILK ORDINANCE EQUIPMENT COMPLIANCE (M-b):**
A memorandum issued by PHS/FDA that provides a notice of PHS/FDA's review of equipment related to compliance with the *Grade "A" PMO* to PHS/FDA Regional staff and Regulatory/Rating Agencies.

T. **MILK COMPANY (MC):** A Milk Company (MC) is a private entity that is listed on the *IMS List* by a Third Party Certifier (TPC) including all associated dairy farms, bulk milk haulers/samplers, milk tank trucks, milk transportation companies, milk plants, receiving stations, transfer stations, dairy plant samplers, industry plant samplers, milk distributor, etc., and their servicing milk and/or water laboratories, as defined in the *Grade "A" PMO*, located outside the geographic boundaries of NCIMS Member States.

U. **RATING AGENCY:** A Rating Agency shall mean a State Agency, which certifies interstate milk shippers (BTUs, receiving stations, transfer stations, and milk plants) as having attained the Sanitation Compliance and Enforcement Ratings necessary for inclusion on the *IMS List*. The ratings are based on compliance with the requirements of the *Grade "A" PMO* and were conducted in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers (MMSR)*. Ratings are conducted by FDA certified Milk Sanitation Rating Officers (SROs). They also certify single-service containers and closures for milk and/or milk products manufacturers for inclusion on the *IMS List*. The certifications are based on compliance with the requirements of the *Grade "A" PMO* and were conducted in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers (MMSR)*. The definition of a Rating Agency also includes a Third Party Certifier (TPC) that conducts ratings and certifications of Milk Companies (MCs) located outside the geographic boundaries of NCIMS Member States that desire to produce and process Grade "A" milk and/or milk products for importation into the United States.

Re-letter remaining DEFINITIONS accordingly.

~~SX~~. **REGULATORY AGENCY:** A Regulatory Agency shall mean an agency which has adopted an ordinance, rule or regulation in substantial compliance with the current edition of the *Grade "A" PMO* ~~or two (2) agencies which have mutually agreed to share the~~ and is responsible responsible for the enforcement of ~~an~~ such ordinance, rule or regulation, which is in substantial compliance with the *Grade "A" PMO* for a listed interstate milk shipper. ~~The mutual agreement shall specify the details of how the rating will be made so long as the details do not conflict with the basic intent of this document.~~ The term, "Regulatory Agency", whenever it appears in the *Procedures* shall also mean the appropriate Third Party Certifier (TPC) having jurisdiction and control over the matters cited within these *Procedures*.

~~FY~~. **STATE REGULATORY/RATING AGENCY PROGRAM EVALUATION:** An evaluation of a State Regulatory/Rating Agency's program by PHS/FDA. This shall include check ratings of IMS Listed Shippers, an assessment of a State Regulatory/Rating Agency's administrative procedures and records, adoption of the *Grade "A" PMO* (or equivalent laws and regulations), and compliance with NCIMS *Procedures*.

Z. **THIRD PARTY CERTIFER (TPC):** A Third Party Certifier (TPC) is a non-governmental individual(s) or organization authorized under the NCIMS voluntary

International Certification Program (ICP) that is qualified to conduct the routine regulatory functions and enforcement requirements of the Grade "A" PMO in relationship to milk plants, receiving stations, transfer stations, associated dairy farms, bulk milk hauler/samplers, milk tank trucks, milk transportation companies, dairy plant samplers, industry plant samplers, milk distributors, etc. participating in the NCIMS voluntary International Certification Program (ICP). The Third Party Certifier (TPC) provides the means for the rating and listing of milk plants, receiving stations, transfer stations and their related raw milk sources. They also conduct the certification and IMS listing of related milk and/or water laboratories and related single-service container and closure manufacturers on the Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS) List. To be authorized under the NCIMS voluntary International Certification Program (ICP), a valid Letter of Understanding (LOU) shall be signed between the NCIMS Executive Board and the Third Party Certifier (TPC).

Re-letter remaining DEFINITIONS accordingly.

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SECTION IV. OVERSIGHT AND RESPONSIBILITIES

A. PHS/FDA RESPONSIBILITIES

1. Standardization of Personnel ...
 - a. PHS/FDA Regional personnel who: ...
 - 2.) Comply with the directives of the PHS/FDA Milk Safety Program as administered by the PHS/FDA Milk Safety Team (MST); and ...
 - c. PHS/FDA shall standardize, in accordance with Section V., F. and G., the evaluation procedures of ~~State Milk~~ LEOs and SSOs.
2. Training
 - a. PHS/FDA shall extend to ~~State~~ Regulatory and Rating Agencies and educational institutions assistance in the training of ~~representatives of State, Regional and Local Governmental Units personnel~~, including ~~Milk~~ SROs, ~~Milk~~ LEOs, SSOs and dairy industry personnel.
 - b. In order to coordinate ratings and evaluation procedures and interpretations, PHS/FDA shall sponsor seminars annually or biennially for the ~~state~~ milk rating and milk laboratory personnel in each of its regions. The content and agenda of the seminar shall be mutually concurred with by PHS/FDA MST and appropriate PHS/FDA Regional Milk Specialist. Each seminar shall be open to representatives of ~~State, Regional and Local Government Units~~ Regulatory/Rating Agencies, including SROs, LEOs and SSOs. Dairy industry personnel ~~should~~ shall be permitted to attend appropriate sessions of such seminars.
 - c. PHS/FDA ~~should~~ shall provide consultation and training in order to correct any

deficiency in ~~State~~ Regulatory/Rating Agency's programs. Reasonable action shall be taken to resolve any dispute between PHS/FDA and the ~~State~~ Regulatory/Rating Agency over interpretations and implementation of any program components.

3. State Regulatory/Rating Agency Program Evaluations

a. A PHS/FDA Regional Milk Specialist or PHS/FDA MST personnel shall conduct a triennial written program evaluation of the IMS program administered by each Member State and TPC, respectively. This triennial written program evaluation ~~will~~ shall be submitted to the ~~State Milk~~ Regulatory Agency, the ~~State Milk~~ Rating Agency, if applicable, and PHS/FDA MST. The evaluation shall concentrate on the following areas: ...

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3.) ~~State laws~~ Laws and regulations to include a review of ~~State~~ laws and regulations with an explanation of any areas not compatible with the *Grade "A" PMO*. ...

5.) Regulatory compliance with Appendix N. of the *Grade "A" PMO* ~~will~~ shall be determined by the PHS/FDA Regional Milk Specialist and/or PHS/FDA MST personnel for TPCs through check ratings or the triennial evaluation and will be reported as part of the written triennial evaluation. The review shall include: ...

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6.) Regulatory compliance with Appendix B. and other *Grade "A" PMO* milk sampling, hauling, and transportation requirements ~~will~~ shall be determined by the PHS/FDA Regional Milk Specialist and/or PHS/FDA MST personnel for TPCs and ~~will~~ shall be reported as part of the written triennial evaluation. This portion of the evaluation shall include a review of: ...

b. Any State or TPC in substantial non-compliance as determined by PHS/FDA ~~will~~ shall be referred to the NCIMS Executive Board for determination of listing on a separate page ~~in~~ on the *IMS List*. The State or TPC, upon notification of PHS/FDA and the Executive Board ~~will~~ shall have an opportunity to address the Executive Board to explain why they believe they should not be so listed. If such listing is required, annual evaluations shall be conducted until substantial compliance, as determined by PHS/FDA, is achieved. Any State or TPC not in substantial compliance a second consecutive year ~~will~~ shall be notified by PHS/FDA and provided an opportunity for a hearing by the NCIMS Executive Board. The NCIMS Executive Board, as a result of the hearing, may determine that the State or TPC ~~should~~ shall not be an active participant in future NCIMS Conferences until substantial compliance is achieved.

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4. Laboratory Evaluations

- a. PHS/FDA shall evaluate and approve the laboratory facilities and procedures of State Milk Laboratory Approval Control Agencies and TPCs to assure compliance with FDA 2400 Series Evaluation Forms and, where appropriate, the current edition of *Official Methods of Analysis of AOAC INTERNATIONAL (OMA)*.
 - b. PHS/FDA shall periodically evaluate milk laboratories of participating States and TPCs to assure compliance with FDA 2400 Series Evaluation Forms, and where appropriate, the current edition of *OMA*. Evaluations conducted during the 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.
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/Food Safety/Product-SpecificInformation/MilkSafety/FederalStatePrograms/InterstateMilkShippersList/default.htm](http://www.fda.gov/Food/Food%20Safety/Product-SpecificInformation/MilkSafety/FederalStatePrograms/InterstateMilkShippersList/default.htm). The Sanitation Compliance Ratings of IMS listed milk shippers, and the 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 FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT is signed and submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs for publication.
 - b. PHS/FDA shall list ratings only from States Rating Agencies, and/or shippers, which are in substantial compliance with the *Procedures*. ...
 - d. PHS/FDA shall identify ~~in~~ on the *IMS List* milk laboratories approved by PHS/FDA Laboratory Proficiency Evaluation Team (LPET), ~~or State Milk Laboratory Control Agencies or TPCs~~ to perform official examinations of Grade "A" raw milk and milk products, pasteurized milk and milk products, condensed and dry milk products, and whey and whey products; as well as milk containers and closures.

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6. Electronic Publication of Qualified PHS/FDA Regional Milk Specialists, ~~and State and TPC Personnel~~ ...
7. Interpretations and Editorial Updates
 - a. Interpretations of the PHS/FDA recommended *Grade "A" PMO* and related documents as referenced in Section VI. of these *Procedures* shall be issued to the State Milk Regulatory and Rating Agencies in accordance with the following procedure:

**Procedure for Issuing Interpretations of the *Grade "A" PMO*
and Related Documents**

3. PHS/FDA disseminates the draft M-a to all ~~State-Milk~~ Regulatory and Rating Agencies and the Executive Board with provisions for a thirty (30) day written comment period from the date of dissemination. The date the draft M-a was actually distributed by PHS/FDA to all ~~State-Milk~~ Regulatory and Rating Agencies and the Executive Board shall be the date of dissemination from which all timelines are calculated. When calculating the timelines, the date of dissemination is not counted as one (1) of the days. ...

5. The Executive Secretary shall forward comments to PHS/FDA, MST, and the Executive Board within fifteen (15) days of the end of the comment period. ...

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9. ~~No~~ An M-a shall not become effective unless it receives the approval from a simple majority of the returned ballots of the NCIMS voting delegates. ...

8. PHS/FDA Check Ratings of the Sanitation Compliance Status of Listed Interstate 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 and/or PHS/FDA MST personnel for TPCs 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 or a TPC's jurisdiction, check ratings ~~will~~ shall be ~~made~~ conducted of a representative number of IMS Listed shippers. The selection of shippers ~~for to be check rating rated~~ in a given State or a TPC's jurisdiction, ~~will~~ shall be made randomly.

b. In order to make effective use of PHS/FDA Regional Office personnel, the random selection of shippers to be check rated ~~will~~ shall be selected in advance and assignments scheduled in each State and/or TPC's jurisdiction. Selection of dairy farms ~~will~~ shall be made from records provided at the time of the check rating.

c. The number of shippers selected ~~for to be check rating rated~~ will shall be based on consideration of the number of shippers in the State or TPC's jurisdiction, as well as the demonstrated validity of the State or TPC program. Validity ~~will~~ shall be measured by estimating the number of adverse actions (re-inspections, re-ratings, or withdrawals of certification) in the ~~States~~ State or a TPC's jurisdiction based on the results of previous check ratings. This approach ~~will~~ shall shift attention from States or TPCs with demonstrated validity to problem States or TPCs, while still preserving an adequate level of monitoring.

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d. In ~~no~~ any case ~~can~~ a check rating cannot be ~~made~~ conducted with a greater frequency than the official rating or listing.

e. For action to be taken if the PHS/FDA check rating indicates the listed rating is not justified, refer to Section IV., B., 7.c. For the purpose of these *Procedures* and all related forms, the terms “listed rating”, “official rating” and “published rating” shall mean the most recent rating, which is accompanied by written permission ~~by~~ from the shipper to publish, and submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs by the ~~State~~ Rating Agency.

f. Except as provided in Section IV., B., 7.c., PHS/FDA shall release the detailed results of its check ratings of listed individual interstate shippers only to the Rating Agency, which originally certified the shipper for listing, and the shipper's ~~State~~ Regulatory Agency. ...

B. STATE AND TPC RESPONSIBILITIES

State Ratings

a. The ~~State~~ Rating Agency of the shipping State or TPC shall certify the results of ratings of each interstate milk shipper to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs, which, in turn, ~~will~~ shall transmit the ratings to the PHS/FDA Headquarters Office for inclusion ~~in~~ on the *IMS List*. (Refer to Section IV., A., 5) The rating results, together with other pertinent information, shall be forwarded on an appropriate form (FORM FDA 2359i).

b. If both an area and individual rating are available on an individual supply of milk, the most recent rating of the two (2) shall be reported. The Rating Agency shall immediately send a completed copy of FORM FDA 2359i and all applicable rating/listing Forms used to complete the rating/listing to the ~~State~~ Regulatory Agency upon completion of any ~~Milk Sanitation Rating~~ rating. ...

d. When a certified interstate milk shipper's supply, raw or pasteurized, changes status because of degrading, permit revocation, significant change in the number of producers dairy farms, or change in the Sanitation Compliance or Enforcement Rating to less than ninety percent (90%), the shipping State or TPC shall immediately notify all known receiving States and/or TPCs and the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

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e. When a certified interstate milk shipper's supply, raw or pasteurized, receives an Enforcement Rating of less than ninety percent (90%), the State or TPC shall re-rate the supply within six (6) months of that rating. Should this re-rating result in either a Sanitation Compliance and/or Enforcement Rating of less than ninety percent (90%), the shipping State or TPC shall immediately withdraw the shipper from the IMS List and notify all known receiving States and/or TPCs and the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs. If a re-rating of the original rating is not requested and conducted within six (6) months of the earliest rating date of the rating with the Enforcement Rating not equal to ninety percent (90%) or greater, the shipper shall be immediately withdrawn from the IMS List and the shipping State or TPC shall

immediately notify all receiving States and/or TPCs and the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

f. When an existing rating is no longer valid because a listed milk plant, receiving station and/or transfer station's permit is revoked, the State or TPC shall within five (5) days request PHS/FDA to withdraw the shipper from the IMS List.

g. Receiving States or TPCs shall notify shipping States and/or TPCs of any irregularities in the supply received. (Refer to Section IV., B., 7.)

h. The Rating Agency shall furnish their Regulatory ~~Agencies~~ Agency with copies of coded memoranda, including interpretations of the PHS/FDA recommended *Grade "A" PMO* and HACCP listing procedures received from PHS/FDA.

i. The Rating Agency shall keep current the ratings of all certified shippers within its State or a TPC's jurisdiction.

j. The State Rating Agency shall certify U.S. manufacturers of containers and closures in accordance with Appendix J. STANDARDS FOR THE FABRICATION OF SINGLE-SERVICE CONTAINERS AND CLOSURES FOR MILK AND MILK PRODUCTS in the *Grade "A" PMO* for inclusion ~~in~~ on the IMS List. ...

3. Lab Evaluation

a. If written split sample results of the laboratories/Certified Industry Supervisor (CIS) used by certified interstate milk shippers are not received by PHS/FDA LPET within sixteen (16) months of the last previous split sample date, PHS/FDA LPET ~~will~~ shall notify the appropriate PHS/FDA Regional Office in writing to send a written withdrawal of the accreditation of the laboratory(ies) concerned. A copy of the PHS/FDA Regional Office notice or PHS/FDA LPET notice for TPCs to the ~~State~~ Milk Laboratory Control Agency to withdraw accreditation shall be sent to the ~~State~~ Regulatory and/or Rating Agency. The ~~State~~ Milk Laboratory Control Agency shall then inform the laboratory(ies), ~~and~~ the Regulatory Agency and/or Rating Agency in writing of the action.

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b. If written results of the official evaluations are not received by PHS/FDA LPET within twenty-six (26) months of the previous evaluation date, PHS/FDA LPET ~~will~~ shall notify the appropriate PHS/FDA Regional Office, in writing, to inform the ~~State~~ Milk Laboratory Control Agency to send a written withdrawal of accreditation of the laboratory(ies) concerned. A copy of the PHS/FDA Regional Office notice or PHS/FDA LPET notice for TPCs to the ~~State~~ Milk Laboratory Control Agency to withdraw accreditation shall be sent to the Regulatory Agency and/or Rating Agency. The ~~State~~ Milk Laboratory Control Agency shall then inform the laboratory(ies), ~~and~~ the Regulatory Agency and/or Rating Agency in writing, of the action.

4. Response to State Regulatory/Rating Agency Program Evaluations

The State or TPC shall cooperate with PHS/FDA in order to correct any deficiencies identified in the State or TPC Milk Safety programs Program, including regulatory, rating and laboratory.

5. Request for Emergency Consideration

In the event of a declared public health emergency or natural or man made disaster, including the activation of the State Emergency Response Plan, if the State is not in a position to operate the program in full compliance with NCIMS program requirements, the State shall immediately contact PHS/FDA. PHS/FDA shall immediately conduct discussions with the State to reach a mutually acceptable resolution.

NOTE: This request for emergency consideration is not applicable to TPCs. ...

7. Challenges and Remedies

a. Complaints from Receiving States ~~and Municipalities~~ or TPCs

1.) Complaints as to the sanitary quality of milk and/or milk products being received and challenges of the validity of certified ratings shall be made in writing by the receiving State ~~or municipality~~ and/or TPC to the Rating Agency of the shipping State or TPC, with a copy to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs. ...

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3.) The Rating Agency of the shipping State or TPC shall make a preliminary investigation of the complaints within fifteen (15) days and notify the receiving State and/or TPC in writing of the action being taken, with a copy to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

4.) After an investigation, and based on the facts disclosed, the shipping State or TPC shall:

A.) Notify the receiving State(s) and/or TPC and appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs that the complaint ~~was~~ has been resolved;

B.) Withdraw the certification of the shipper and notify the receiving State(s) and/or TPC and appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs of such action; or

C.) Make a new rating within sixty (60) days, and with the written permission of the shipper, forward the new rating and a copy of the shipper's written permission to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs for listing ~~in~~ on the *IMS List*. The receiving State(s) and/or TPC(s) shall also be notified of the action being taken by the shipping State or TPC.

5.) If the Rating Agency of the shipping State or TPC for any reason cannot make a prompt investigation called for in 7.a.3.) above, or the new rating called for in 7.a.4.) above, it shall:

A.) Notify PHS/FDA, ~~and~~ the State and/or TPC making the complaint. Such notification shall be considered by PHS/FDA as tantamount to the withdrawal of the present ~~State~~ certification of the interstate shipper involved.

B.) Notify the shipper involved, and any other interested parties, that in accordance with Conference agreements, the current ~~State~~ certification is being withdrawn until such time as the complaint may be investigated or a new rating made.

b. Complaints from Shipping States ~~and Municipalities~~ and/or TPCs

1.) Complaints from shipping States ~~and municipalities~~ and/or TPCs shall be made in writing to the Rating Agency of the receiving State(s) and/or TPC(s) with a copy to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

2.) The Rating Agency of the receiving State(s) and/or TPC(s) ~~will~~ shall make a preliminary investigation of the complaint(s) within fifteen (15) days and notify the shipping State or TPC in writing of the action being taken, with a copy to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

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

1.) ~~Producer Dairies~~ Dairy Farms (Raw Milk) ...

A.) Action to be Taken

The following table shall be used to determine action to be taken if the ~~PHS/FDA raw milk~~ Sanitation Compliance Rating from a check rating of a listed shipper's dairy farms indicates the listed ~~raw milk rating~~ Sanitation Compliance Rating is not justified:

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~~PRODUCER DAIRIES~~ DAIRY FARMS (RAW MILK) ...

B.) Re-Rating

When check rating data indicates that the Sanitation Compliance Rating of a listed shipper's ~~producer dairies~~ dairy farms requires a re-rating, PHS/FDA shall formally notify the ~~State~~ Rating Agency that a re-rating of the ~~producer dairies~~ dairy farms ~~will~~ shall be required within sixty (60) days.

C.) Withdrawal of Certification

When check rating data indicates that the Sanitation Compliance Rating of a listed shipper's ~~producer dairies~~ dairy farms 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 and/or TPCs 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.

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

A.) Action to be Taken

The following table shall be used to determine action to be taken if the ~~PHS/FDA~~ Sanitation Compliance Rating from a check rating of a milk plant, receiving station and/or transfer station indicates the listed ~~rating~~ Sanitation Compliance Rating is not justified: ...

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B.) Reinspection

When check rating data indicates that the Sanitation Compliance Rating of the milk plant, receiving station and/or transfer station requires a reinspection, PHS/FDA shall formally notify the ~~State~~ Rating Agency that a reinspection of the milk plant, receiving station and/or transfer station ~~will~~ shall be required within thirty (30) days. If the reinspection indicates a level of sanitation compliance below that of the published rating, the ~~State~~ Rating Agency shall submit such new rating for publication, provided that if the reinspection indicates a level of sanitation compliance equal to or better than the published rating, the PHS/FDA Regional Office or PHS/FDA MST for TPCs shall be so advised by the ~~State~~ Rating Agency and no further action ~~will~~ shall be necessary.

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 and/or TPCs 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.

3.) If a Rating Agency fails to take the required action outlined in Section IV., B., 7.c.1.) and 7.c.2.), calling for immediate notification of all known receiving States and/or TPCs when the current certification of a listed shipper is to be withdrawn as recommended by PHS/FDA, PHS/FDA after a reasonable lapse of time (not to exceed five (5) days), shall provide all participating States and TPCs with the check rating ~~scores~~ results. The State or TPC which failed to take the required action shall be identified in the next listing of the *IMS List* as not being in compliance with Section IV., B., 7.c.1.) and 7.c.2.).

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4.) Should ~~the~~ a Rating Agency indicate that it is not in a position to make a new rating within a sixty (60) day period or a reinspection within thirty (30) days, PHS/FDA shall identify those States or TPCs in the next listing of the *IMS List* as not being in compliance with the provisions of this paragraph.

5.) If ~~the~~ a Rating Agency informs PHS/FDA that it is unable to make arrangements for PHS/FDA to check rate the sanitation compliance status of listed shippers, PHS/FDA shall identify those States or TPCs in the next listing of the *IMS List* as not being in compliance with the provisions of this paragraph.

6.) If a Rating Agency fails to request removal of a milk plant, receiving station and/or transfer station from the *IMS List* as provided for in Section IV., B., 1.f., PHS/FDA shall, after five (5) days, provide this information to all receiving ~~states~~ States and/or TPCs.

SECTION V. QUALIFICATIONS AND CERTIFICATIONS

A. SUPERVISION REQUIREMENTS ...

2. The shipper to be rated shall be under the full-time supervision of a State or TPC ~~Regional or Local Milk~~ Regulatory Agency. ...

B. PROCEDURES FOR REQUESTING A MILK SANITATION RATING

A shipper desiring a rating of their supply for the purpose of interstate certification shall submit a request to the Rating Agency in their own State or to their TPC. ...

C. SANITATION COMPLIANCE AND ENFORCEMENT RATINGS REQUIRED

Ratings to be made on each shipper who desires certification shall include:

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1. Sanitation Compliance Rating on ~~producer~~ dairy farms, transfer stations, receiving stations, pasteurization plants, condensed and dry milk plants and whey plants. ...

D. MILK SANITATION RATING PERSONNEL

~~Milk~~ Sanitation Compliance and Enforcement Ratings shall be made by certified SROs and the certification of U.S. manufacturers of containers and closures for milk and/or milk products shall be made by certified State SROs who meet the following requirements: ...

2. Have been ~~standardized~~ certified 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~~ shall 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 or TPC's Regulatory/Rating Agency as long as the ~~Officer's~~ SRO's certification is valid.

3. A SRO applicant for initial ~~standardization~~ certification shall be evaluated by PHS/FDA personnel in an independent side-by-side comparison of dairy facilities using the items listed on the appropriate inspection or evaluation report form. The applicant and PHS/FDA personnel shall be in agreement at least eighty percent (80%) of the time on each listed item. Comparison evaluations shall be performed on at least the following number of dairy facilities: ...

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

8. A certified SRO shall be ~~re-standardized~~ re-certified once each three (3) years by PHS/FDA personnel in an independent side-by-side comparison of dairy facilities using the items listed on the appropriate inspection or evaluation report form. The applicant and PHS/FDA personnel shall be in agreement at least eighty percent (80%) of the time on each listed item. Comparison evaluations shall be performed on at least the following number of dairy facilities: ...

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~~ personnel and SRO. (Refer to Section VIII., E.6. for additional HACCP certification procedures.) ...

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10. To be ~~re-standardized~~ re-certified, a certified SRO shall have during the three (3) year period attended at least one (1) PHS/FDA Regional Milk Seminar, attended at least one (1)

training course, which includes the auditing of milk plant HACCP Systems and NCIMS listing, if applicable, and attended at least one (1) PHS/FDA training course on “Special Problems in Milk Protection” or other training judged by PHS/FDA to be equivalent and appropriate.

11. Should PHS/FDA determine that a certified SRO has failed to demonstrate proficiency in the above ~~re-standardization~~ re-certification procedures; PHS/FDA may require the certified SRO to perform the initial ~~standardization~~ certification procedures. ...

F. SAMPLING SURVEILLANCE PERSONNEL ...

Have been ~~standardized~~ certified by PHS/FDA as a SSO and hold a valid certificate of qualification. The PHS/FDA ~~will~~ shall issue a certificate, valid for three (3) years, to each individual who meets the criteria listed in 3. and 4. below.

3. A SSO applicant for initial ~~standardization~~ certification shall be evaluated by PHS/FDA personnel in an independent side-by-side comparison of sampling procedure observations using the items listed on the appropriate inspection or evaluation report form. The applicant and PHS/FDA personnel shall be in agreement at least eighty percent (80%) of the time on each listed item. Comparison evaluations shall be performed on at least the following number of bulk milk hauler/samplers and plant samplers at dairy facilities: ...

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d. Hold a valid certificate of qualification ~~for~~ as a SRO, LEO, or, in the case of a State or TPC Regulatory Supervisor, hold a valid certificate as a SSO.

4. A certified SSO shall be ~~re-standardized~~ re-certified once each three (3) years by PHS/FDA personnel in an independent side-by-side comparison of sampling procedure observations using the items listed on the appropriate inspection or evaluation report form. The applicant and PHS/FDA personnel shall be in agreement at least eighty percent (80%) of the time on each listed item. Comparison evaluations shall be performed in accordance with 3. above.

5. The SSO may delegate the inspection of bulk milk hauler/samplers, who collect samples of raw milk for pasteurization from individual ~~producers~~ dairy farms, to other qualified State, or TPC ~~Regional or Local~~ Regulatory Agency personnel or certified industry personnel as outlined in Section 5 of the *Grade “A” PMO*.

NOTE: The delegation to industry certified personnel is not applicable to TPCs.

The SSO may delegate the inspection of Dairy Plant Samplers and Industry Plant Samplers to other qualified State, or TPC ~~Regional or Local~~ Regulatory Agency personnel. ...

a. Initial ~~Standardization~~ Certification: ...

Page 22:

c. ~~Re-standardization~~ Re-certification: A certified applicant for the delegation of sampling surveillance responsibilities shall be ~~re-standardization~~ re-certification once each three (3) years by a PHS/FDA certified SSO in an independent side-by-side comparison of sampling procedure observations using the items listed on the appropriate inspection or evaluation report form. The applicant and SSO shall be in agreement at least eighty percent (80%) of the time on each listed item. Comparison evaluations shall be performed on at least the following number of bulk milk hauler/samplers and plant samplers at dairy facilities: ...

G. MILK LABORATORY EVALUATION PERSONNEL

Milk laboratory evaluations may be made ~~in any State~~, upon the request of that State's or TPC's Regulatory Agency, and shall be made by certified LEOs who:

1. Have been ~~standardized~~ certified and approved by PHS/FDA as a LEO per the requirements and criteria listed in the most recent edition of the *EML*. (Refer to Section 3 of the *EML*.) ...

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

Page 23:

2. Notification of Intent to Revoke PHS/FDA Certification and an Opportunity for a Hearing

If the PHS/FDA Standard (Regional Milk Specialist, or MST personnel, or member of LPET, respectively) makes an initial determination to revoke certification, PHS/FDA ~~will~~ shall notify the SRO, SSO, or LEO in writing of its intent to revoke his or her certification. The notification shall specify: ...

Page 24:

I. AREA RATING ...

2. If a shipper's supply is included in an area rating which has received a Sanitation Compliance Rating of ninety percent (90%) or more, the shipper may be listed without an individual rating, provided that an individual rating shall be furnished upon request of the receiving State(s) ~~or Local jurisdiction(s)~~ and/or TPC(s). ...

Page 25:

J. INDIVIDUAL RATINGS ...

3. If an aseptic milk plant has any ACLE identified by a SRO, ~~or~~ PHS/FDA Regional Milk Specialist, or PHS/FDA MST personnel 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 Milk Products, the

listing shall be immediately denied or withdrawn.

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SECTION VI. STANDARDS

A. POINTS BEYOND THE LIMITS OF THE ROUTINE INSPECTION

Milk and/or milk products from points beyond the limits of the routine inspection shall be acceptable under the principles of reciprocity ~~for sale in the State or Local area concerned,~~ provided they are produced and pasteurized under regulations which are substantially equivalent to the current edition of the *Grade "A" PMO* and have been awarded an acceptable Milk Sanitation Compliance and Enforcement Rating by a SRO certified by PHS/FDA. ...

E. MILK SANITATION STANDARDS

The current edition of the *Grade "A" PMO* shall be used as the basic sanitation standards in making Milk Sanitation Compliance Ratings of interstate milk shippers. ...

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SECTION VII. PROCEDURES GOVERNING A STATE'S OR THIRD PARTY CERTIFIER'S PARTICIPATION IN THE COOPERATIVE PROGRAM FOR THE CERTIFICATION OF IMS LISTED SHIPPERS

STATE REGULATORY/RATING AGENCY PROGRAM EVALUATIONS ...

- B. Any State or TPC in substantial non-compliance as determined by PHS/FDA ~~will~~ shall be referred to the NCIMS Executive Board for determination of listing on a separate page ~~in~~ on the *IMS List*. The State or TPC upon notification of PHS/FDA and the NCIMS Executive Board ~~will~~ shall have an opportunity to address the NCIMS Executive Board to explain why they believe they ~~should~~ shall not be so listed. If such listing is required, annual evaluations shall be conducted until substantial compliance as determined by PHS/FDA is achieved. Any State or TPC not in substantial compliance a second consecutive year ~~will~~ shall be notified by PHS/FDA and provided an opportunity for a hearing by the NCIMS Executive Board. The NCIMS Executive Board, as a result of the hearing, may determine that the State or TPC ~~should~~ shall not be an active participant in future NCIMS Conferences until substantial compliance is achieved. ...

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

Page 29:

8. **STATE REGULATORY/RATING AGENCY PROGRAM EVALUATION:** Definition ~~FY~~ 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".

C. PHS/FDA HACCP RESPONSIBILITIES ...

Page 30:

- a. PHS/FDA Regional personnel who: ...
 - 2.) Comply with the directives of the PHS/FDA Milk Safety Program as administered by the PHS/FDA MST; and ...
 - 4.) PHS/FDA personnel responsible for PHS/FDA HACCP audits and State Regulatory/Rating Agency Program Evaluations in States and TPCs participating in the NCIMS HACCP Program shall, at a minimum, be required to meet the same level of training and ~~standardization~~ certification required for SROs who make HACCP listing audits. ...
2. HACCP Training ...
 - b. Regulatory Agency ~~Personnel~~ personnel responsible for the evaluation, licensing and regulatory auditing of facilities using the ~~voluntary~~ NCIMS voluntary HACCP Program ~~will~~ shall have equivalent training to the training required to perform traditional NCIMS functions. They shall also have specialized training in conducting HACCP System audits. ...

Page 31:

3 State Regulatory/Rating Agency Program Evaluations

In the event a State or TPC has a participating HACCP milk plant, receiving station, or transfer station, PHS/FDA shall conduct an evaluation of ~~the State's~~ their NCIMS HACCP Program, as a part of the State Regulatory/Rating Agency Program Evaluation. ...

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/Food Safety/Product-SpecificInformation/MilkSafety/FederalStatePrograms/InterstateMilkShippersList/default.htm](http://www.fda.gov/Food/Food%20Safety/Product-SpecificInformation/MilkSafety/FederalStatePrograms/InterstateMilkShippersList/default.htm). The HACCP listings and IMS Listed shippers' expiration listing dates contained in the electronic publication are certified by the State Rating Agency to be those established by HACCP audits conducted in accordance with the *MMSR* by certified SROs when FORM FDA 2359i-INTERSTATE MILK SHIPPER'S REPORT is signed and submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs for electronic publication. ...
- b. PHS/FDA shall identify listings only from ~~States~~ Rating Agencies, and/or shippers, which are in substantial compliance with the *Procedures*.

6. Electronic Publication of Qualified PHS/FDA Regional Milk Specialists, ~~and~~ State and TPC Personnel ...

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8. PHS/FDA Audits of HACCP Listings
 - 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 and/or PHS/FDA MST personnel for TPCs shall have completed a training course that is acceptable to the NCIMS and PHS/FDA addressing the procedures for conducting ~~the audit~~ audits and the implementation of the NCIMS Aseptic Processing and Packaging Program. Within a State or a TPC conducting the NCIMS voluntary HACCP Program, PHS/FDA audits ~~will~~ shall be ~~made~~ conducted of a representative number of IMS HACCP listed shippers. The selection of shippers ~~for auditing~~ to be audited in a given State or a TPC's jurisdiction ~~will~~ shall be made randomly.
 - b. In order to make effective use of PHS/FDA Regional Office personnel, the random selection of shippers to be audited ~~will~~ shall be selected in advance and assignments scheduled in each State and/or TPC's jurisdiction.
 - c. The number of shippers selected ~~for~~ to be PHS/FDA ~~audit~~ audited ~~will~~ shall be based on consideration of the number of shippers in the State or TPC's jurisdiction as well as the demonstrated validity of the State or TPC program. Validity ~~will~~ shall be measured by estimating the number of adverse actions (re-audits or withdrawals of certification) in the State or a TPC's jurisdiction based on the results of previous PHS/FDA audits. This approach ~~will~~ shall shift attention from States or TPCs with demonstrated validity, to problem States or TPCs, while still preserving an adequate level of monitoring.
 - d. Except as provided for in Sections VIII., C. 8. i., VIII., D. 2., and VIII., D. 7. c.2.)A.) ~~an~~ a PHS/FDA HACCP audit ~~will~~ shall not be ~~made~~ conducted with a greater frequency than the official HACCP listing.
 - e. For action to be taken when a PHS/FDA audit indicated that a HACCP listing is not justified, refer to Section VIII., D. 7.c. For the purpose of these *Procedures* and all related forms, the terms "listed/listing", "official listing" and "published listing" shall mean the most recent listing, which is accompanied by written permission ~~by~~ from the shipper to publish, and submitted to the PHS/FDA Regional Office or PHS/FDA MST for TPCs by the ~~State~~-Rating Agency.
 - f. Except as provided in Sections VIII., C.8.i., VIII., D.2., and VIII., D.7.c.2.), PHS/FDA shall release the detailed results of its ~~check ratings~~ or PHS/FDA HACCP audits of listed individual interstate shippers only to the Rating Agency, which originally certified the shipper for listing, and the State shipper's Regulatory Agency.

...

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~~ shall be used in the overall ~~State~~ Regulatory/Rating Agency Program Evaluation. ...

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~~ Regulatory Agency's milk and/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.

Based on this investigation, if there are substantial milk and/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 and/or TPCs.

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

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

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

D. **STATE NCIMS HACCP RESPONSIBILITIES**

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

Section IV., B. 1.) shall apply as written, except that for purposes of this Section:

a. The Rating Agency of the shipping State or TPC shall certify the results of

HACCP listing audits of each interstate milk shipper to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs, which in turn, ~~will~~ shall transmit the HACCP listing audits to the PHS/FDA Headquarters Office for inclusion ~~in~~ on the *IMS List*. (Refer to Section IV., A., 5.) The HACCP listing audit results, together with other pertinent information, shall be forwarded on an appropriate form (FORM FDA 2359i). ...

d. When a certified interstate milk shipper's supply, raw or pasteurized, changes status because of degrading, permit revocation, significant change in the number of ~~producers~~ dairy farms, change in the Sanitation Compliance or Enforcement Rating to less than ninety percent (90%), or a change in HACCP listing status, the shipping State or TPC shall immediately notify all known receiving States and/or TPCs and the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

f. When a HACCP listing is no longer valid because a listed milk plant, receiving station and/or transfer station's permit is revoked, the State or TPC shall within five (5) days request PHS/FDA to withdraw the shipper from the *IMS List*.

h. The Rating Agency shall furnish their Regulatory ~~Agencies~~ Agency with copies of coded memoranda, including interpretations of the PHS/FDA recommended *Grade "A" PMO* and HACCP listing procedures received from PHS/FDA.

i. The Rating Agency shall keep current the HACCP listings of all certified shippers within its State or TPC's jurisdiction

2. NCIMS HACCP Enforcement Responsibilities ...

Based on this report, if PHS/FDA finds there may be reason to doubt the safety of the State's or TPC's milk and/or milk products that are NCIMS HACCP listed, PHS/FDA shall immediately investigate the State's or TPC's Milk Safety Program and may evaluate/audit the milk plants, receiving stations or transfer stations affected. This applies even if FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT finds that the listing of the milk plant, receiving station or transfer station is satisfactory.

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If there are substantial milk and/or milk product safety program weaknesses, PHS/FDA shall send a notice requiring corrections to the ~~State~~ Regulatory Agency with a copy to the ~~State~~ 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 and/or TPCs.

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

This notification ~~will~~ shall specify that the State or TPC has 180 days from the date of the notification to show to PHS/FDA's satisfaction that the State or TPC has made appropriate corrections and is once again able to fulfill its obligations under the NCIMS voluntary HACCP Program. After the 180 days, if the State or TPC is still unable to fulfill its obligations under the NCIMS voluntary HACCP Program and milk and/or milk product safety remains in doubt PHS/FDA ~~will~~ shall not accept new HACCP listings from the State or TPC and PHS/FDA may audit the existing listings as necessary to protect the public health. ...

4. Response to ~~State~~ Regulatory/Rating Agency Program Evaluations

The State or TPC shall cooperate with PHS/FDA in order to correct any deficiencies identified in the State or TPC Milk Safety Programs Program, including regulatory, rating and laboratory. ...

7. Challenges and Remedies

a. Complaints from Receiving States and/or TPCs ~~and Municipalities~~

Section IV., B. 7.a. shall apply as written, except that for purposes of this Section:

1.) Complaints as to the sanitary quality of milk and/or milk products being received and challenges of the validity of certified HACCP listing audits shall be made in writing by the receiving State ~~or municipality~~ and/or TPC to the Rating Agency of the shipping State or TPC, with a copy to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

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3.) The Rating Agency of the shipping State or TPC shall make a preliminary investigation of the complaints within fifteen (15) days and notify the receiving State and/or TPC in writing of the action being taken, with a copy to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

4.) After an investigation, and based on the facts disclosed, the shipping State or TPC shall:

C.) Make a new listing audit within sixty (60) days and, with the written permission of the shipper, forward the new listing audit and a copy of the shipper's written permission to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs for publication ~~in~~ on the *IMS List*. The receiving State(s) and/or TPC(s) shall also be notified of the action being taken by the shipping State or TPC.

5.) If the Rating Agency of the shipping State or TPC for any reason cannot make a prompt investigation called for in 7.a.3.) above, or the new listing called for in 7.a.4.) above, it shall:

B.) Notify the shipper involved, and any other interested parties, that in accordance with Conference agreements, the current ~~State~~ certification is being withdrawn until such time as the complaint may be investigated or a new listing audit is made.

b. Complaints from Shipping States ~~and Municipalities~~ and/or TPCs

1.) Complaints from shipping States ~~and municipalities~~ and/or TPCs shall be made in writing to the Rating Agency of the receiving State(s) and/or TPC(s), with a copy to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

2.) The Rating Agency of the receiving State(s) and/or TPC(s) ~~will~~ shall make a preliminary investigation of the complaint(s) within fifteen (15) days and notify the shipping State or TPC in writing of the action being taken, with a copy to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

c. Action to be Taken if the PHS/FDA HACCP Audit Indicates the Listing is Not Justified: ...

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

A.) Action to be Taken

Should a milk plant, receiving station or transfer station's HACCP System be found to be either invalid or improperly verified, PHS/FDA shall request that the State or TPC initiate regulatory action. In addition, PHS/FDA may request a re-audit or withdrawal of certification. When milk and/or milk product safety is in doubt, based on Regulatory Agency practices or concerns, PHS/FDA shall immediately investigate and may audit other milk plants, receiving stations and transfer stations affected.

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Based on this investigation, if there are substantial milk and/or milk product safety program weaknesses, PHS/FDA shall send a notice requiring corrections to the 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 and/or TPCs.

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

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

After the 180 days, if the State or TPC is still unable to fulfill its obligations

under the NCIMS voluntary HACCP Program and milk and/or milk product safety remains in doubt, PHS/FDA ~~will~~ shall not accept new HACCP listings from the State or TPC and PHS/FDA may audit the existing listings as necessary to protect the public health.

B.) Re-Audit

If deficiencies and/or non-conformities are significant to the point that timely correction is necessary, but do not require an immediate withdrawal of certification, the deficiencies and/or non-conformities shall be corrected and the correction confirmed by a re-audit by an appropriate listing official. The period of time allowed to correct the HACCP System deficiencies and/or non-conformities shall be specified by the PHS/FDA Regional Milk Specialist and/or PHS/FDA MST personnel for TPCs in writing to the State or TPC. ~~No~~ A re-audit is not required if the deficiencies and/or non-conformities are immediately corrected, or are minor and can be corrected within a time period, which will neither present a risk to the public health nor result in milk and/or milk product adulteration.

If after notice, as specified by PHS/FDA, the HACCP System deficiencies and/or non-conformities have not been corrected, the milk plant's, receiving station's or transfer station's listing shall be withdrawn by the State or TPC.

If the HACCP System deficiencies and/or non-conformities have been corrected, the Rating Agency shall notify the Regional Office of PHS/FDA or PHS/FDA MST for TPCs and ~~no~~ further action ~~will~~ shall not be necessary.

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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) and/or nonconformity(ies) indicating:

i.) A major HACCP System dysfunction that is reasonably likely to result in a milk and/or milk product safety hazard or an adverse health consequence;

NOTE: A milk and/or milk product safety hazard that is reasonably likely to occur is one for which a prudent milk plant, receiving station or transfer station operator would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable likelihood that, in the absence of those controls, the milk and/or milk product hazard will occur in the particular type of milk and/or milk product being processed.

ii.) Series of observations that leads to a finding of a potential HACCP System failure that is likely to result in a compromise to milk and/or milk product safety; ...

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1. **HAZARD ANALYSIS:** Flow Diagram and Hazard Analysis conducted and written for each kind or group of milk and/or milk products processed.
2. **HACCP PLAN:** HACCP Plan prepared for each kind or group of milk and/or milk products processed. ...
4. **HACCP PLAN CORRECTIVE ACTION:** Corrective action taken for milk and/or milk products produced during a deviation from CL's defined in the HACCP Plan. ...
8. **HACCP SYSTEM AUDIT FOLLOW-UP ACTIONS:** 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 and/or milk product safety. ...

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 and/or TPCs thereof. ...

5.) If a Rating Agency fails to immediately notify all known receiving States and/or TPCs when the current certification of a listed shipper is to be withdrawn as recommended by PHS/FDA, the PHS/FDA, after a reasonable lapse of time, not to exceed five (5) days, shall provide all participating States and/or TPCs with the PHS/FDA audit conclusion. The State or TPC, which failed to take the required action, shall be identified in the next listing of the *IMS List* as not being in compliance with the provisions of this paragraph.

6.) If a Rating Agency informs PHS/FDA that it is unable to make arrangements for PHS/FDA to audit HACCP listed shippers, PHS/FDA shall identify those States or TPCs in the next listing of the *IMS List* as not being in compliance with the provisions of this paragraph.

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7.) If a Rating Agency fails to request removal of a milk plant, receiving station and/or transfer station from the *IMS List* as provided for in this Section, PHS/FDA shall, after five (5) days, provide this information to all receiving States and/or TPCs.

D.) Imminent Health Hazard

1.) When an imminent health hazard is observed, PHS/FDA shall request the Regulatory Agency to take immediate action to prevent any further movement of such milk and/or milk products until such hazard(s) has been eliminated. If such a violation results in a milk and/or milk product that presents a public health risk, the Regulatory Agency shall take immediate action against all milk and/or milk products produced and/or processed that have already entered the distribution system. ...

4.) If the Regulatory Agency fails to take immediate action to correct the identified hazard(s), or fails to notify PHS/FDA concerning actions taken within five (5) working days, PHS/FDA shall provide this information to all receiving States and/or TPCs.

I. **QUALIFICATIONS AND CERTIFICATIONS**

1. Supervision Requirements

Section V., A. shall apply as written, except that for purposes of this Section: ...

b. The shipper to be audited shall be under the full-time supervision of a State or TPC; ~~Regional or Local Milk~~ Regulatory Agency.

2. Procedure for Requesting a HACCP Listing

A shipper desiring a HACCP listing of their supply for the purpose of interstate certification shall submit a request to the ~~State Milk Rating~~/Rating Agency in their own State or to their TPC. ...

Page 41:

3. HACCP Listing

b. Milk plants, receiving stations or transfer stations participating in the NCIMS voluntary HACCP Program shall receive dairy ingredients, including raw milk and/or milk products, for use in listed products only from IMS listed sources that have been awarded an acceptable HACCP listing or acceptable Sanitation Compliance and Enforcement Ratings.

4. HACCP Listing Personnel

HACCP listings shall be made by qualified SROs who:

a. Have been ~~standardized~~ certified by PHS/FDA as a SRO and hold a valid ~~SRO~~ certification of qualification to perform HACCP listing audits. ...

c. Have, during the three (3) year period for which ~~standardized~~ certified, participated in at least one (1) Regional Milk Seminar and, in addition, attended at least one (1) training course on "Special Problems in Milk Protection" or other training course

judged by the PHS/FDA to be equivalent. ...

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NOTE: The cause shall be documented and provided to the Candidate and the State Rating Agency.

c. Continuous Certification

After the initial successful ~~Conditional~~ HACCP Certification, subsequent certification of a SRO to make NCIMS HACCP Listing Audits ~~will~~ shall be valid for three (3) years unless revoked for cause.

1.) Milk Plant Technical Knowledge ...

During the three (3) year certification period, the SRO, certified to conduct NCIMS HACCP listings, ~~will~~ shall complete the minimum training requirements established to maintain proficiency regarding the NCIMS voluntary HACCP Program including having attended at least one (1) training course in the auditing of milk plant HACCP Systems and NCIMS listing for the period of qualification. The NCIMS HACCP Implementation Committee has developed and accepted for this required training both a comprehensive multi-day course presented by members of the NCIMS HACCP Implementation Committee and an abbreviated individual instruction that may be presented to individuals or small groups by any of the HACCP Certified FDA Regional Milk Specialists.

Small group training with practical exercises and other appropriate training that may include written examinations ~~will~~ shall be used to evaluate the SROs technical knowledge for continuing certification. ...

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NOTE: The cause shall be documented and provided to the Candidate and the State Rating Agency.

d. Paperwork Review ...

9. Milk Plant, Receiving Station and Transfer Station HACCP Listings ...

b. If an audit for a HACCP listing is unsatisfactory, another audit shall be conducted after written notification from an authorized representative of the IMS Listed shipper to the State Rating Agency that the IMS Listed shipper is in substantial compliance. The audit shall be completed in ~~no~~ not more than fifteen (15) days from the date of receipt of the notification, unless the Rating Agency has a reason to believe a new listing within a lesser time would result in an acceptable listing. ...

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F. STANDARDS TO BE USED FOR THE NCIMS VOLUNTARY HACCP PROGRAM

Section VI. shall apply as written, except that for purposes of this Section:

1. Points Beyond the Limits of Routine Inspection

Milk and/or milk products from points beyond the limits of the routine inspection shall be acceptable under the principles of reciprocity ~~for sale in the State or Local area concerned~~, provided they are produced and pasteurized under regulations which are substantially equivalent to the current edition of the *Grade "A" PMO* and have been awarded an acceptable HACCP listing by a SRO certified by PHS/FDA. ...

G. PROCEDURES GOVERNING A STATE'S OR THIRD PARTY CERTIFIER'S PARTICIPATION IN THE NCIMS HACCP PROGRAM FOR THE CERTIFICATION OF IMS LISTED SHIPPERS

Section VII. shall apply as written, except that for purposes of this Section:

1. State Regulatory/Rating Agency Program Evaluations ...

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SECTION IX. APPLICATION OF CONFERENCE AGREEMENTS PROCEDURES GOVERNING THE NCIMS VOLUNTARY INTERNATIONAL CERTIFICATION PROGRAM

In addition to complying with all of the other Sections of the *Procedures*, the following shall apply to the NCIMS voluntary International Certification Program (ICP):

A. PURPOSE AND SCOPE

This Section outlines the policies and procedures for the implementation, operation and maintenance of the NCIMS voluntary ICP. The NCIMS voluntary ICP is intended to provide an additional certification option for Milk Companies (MCs) located outside the United States seeking participation in the NCIMS Grade "A" Milk Safety Program and a listing on the *IMS List*. Previous to this additional option, MCs located outside the United States wishing to import Grade "A" milk and/or milk products, as defined in the *Grade "A" PMO*, into the United States were required to pursue one (1) of the three (3) options identified in M-I-00-4.

This additional option involves using Third Party Certifiers (TPCs) who are authorized by the NCIMS to offer regulatory and rating services to dairy and laboratory facilities in accordance with all of the procedures and requirements of the NCIMS Grade "A" Milk Safety Program. This Section defines the responsibilities and requirements of NCIMS voluntary ICP participants, including prospective TPCs, participating MCs and associated dairy farms, receiving stations, transfer stations, official laboratories, official designated laboratories, etc., the NCIMS and PHS/FDA. This Section also outlines the conditions under which the NCIMS voluntary ICP shall satisfy the requirements for obtaining and maintaining the IMS listing of dairy and laboratory facilities located outside of the geographic boundaries of the NCIMS

Member States.

An NCIMS ICP Committee shall be responsible for the implementation, operation and maintaining the oversight of the NCIMS voluntary ICP.

The policies and procedures contained in this Section apply only to TPCs and MCs that are authorized by a signed and dated Letter of Understanding (LOU) with the NCIMS as participants in the NCIMS voluntary ICP. This Section does not apply to Member State and U.S. trust territory regulatory and rating programs that operate under the requirements of the NCIMS, nor does it apply to dairy facilities located within the geographic boundaries of those Member States and trust territories. The NCIMS voluntary ICP does not establish requirements for regulatory programs operated by any governmental agency within or outside of the United States.

TPCs authorized by the NCIMS for participation are required to conform to all of the policies and procedures of the NCIMS voluntary ICP and all of the applicable NCIMS Grade “A” Milk Safety Program requirements when providing regulatory and/or rating services to MCs that produce and process Grade “A” milk and/or milk products for importation into the United States. This includes related services provided to dairy farms, bulk milk hauler/samplers, milk tank trucks, milk transportation companies, milk plants, receiving stations, transfer stations, dairy plant samplers, industry plant samplers, distributors and servicing laboratories located outside the geographic boundaries of the NCIMS Member States that are a part of or serve a MC that desires to produce and process Grade “A” milk and/or milk products for importation into the United States.

B. PROCEDURES

1. Operation of the NCIMS voluntary ICP

The NCIMS voluntary ICP is to be implemented, operated and maintained so as to:

- a. Comply with all of the applicable requirements of the *Grade “A” PMO* and related NCIMS documents. The regulation and rating of MCs shall be in accordance with the applicable requirements of the NCIMS Grade “A” Milk Safety Program for the purpose of listing those complying on the *IMS List*.
- b. Continue to assure the same level of milk safety provided within the NCIMS Grade “A” Milk Safety Program.
- c. Provide a means for NCIMS Member States to accept Grade “A” milk and/or milk products from NCIMS voluntary ICP IMS Listings.

2. Application by Prospective TPCs

- a. The NCIMS Executive Board shall make an initial announcement seeking applications from non-governmental individuals or organizations wishing to participate in the NCIMS voluntary ICP as a TPC. Prospective TPCs shall complete and submit the official NCIMS voluntary ICP application form along with all of the appropriate

documentation to the ICP Committee. The ICP Committee shall confirm with each applicant, the receipt of the application form and whether it is complete enough to be warranted for consideration as submitted or if additional information shall be required.

b. All documents that are utilized and exchanged within the NCIMS voluntary ICP shall be in English or translated into English by the submitter.

3. Review of Applications, Selection and Official Notification of TPCs

a. The ICP Committee is responsible to review all valid application forms from qualified prospective TPCs. This review shall evaluate the quality and strength of each application on the basis of the applicant's response to the requests for information on the application form. This review shall also evaluate each application based on the TPC identified personnel's knowledge and experience with the requirements of the NCIMS Grade "A" Milk Safety Program and the responsibilities and duties of a Regulatory/Rating/Laboratory Control Agencies providing the regulatory, rating and laboratory functions within the NCIMS Grade "A" Milk Safety Program. The ICP Committee shall make recommendations to the NCIMS Executive Board of qualified applicants for participation in the NCIMS voluntary ICP.

b. The NCIMS Executive Board may request additional information concerning the ICP Committee's recommendations. If the NCIMS Executive Board has a reason to dispute any of the ICP Committee's recommendations, they may request that the ICP Committee reconvene to consider additional information that may be relevant to their recommendations.

c. All applicants shall be notified in writing, which may include mail, facsimile, email or other electronic means, by the Chair of the NCIMS Executive Board as to the status of their application and whether or not they have been selected to participate as a TPC in the NCIMS voluntary ICP.

d. If an applicant is not selected to participate as a TPC in the NCIMS voluntary ICP, included within the written NCIMS Executive Board notification, they shall be provided an opportunity to request a meeting with the NCIMS Executive Board and members of the ICP Committee to appeal the decision and present any additional information. This meeting request shall be received by the Chair of the NCIMS Executive Board within fifteen (15) days of the date of receipt of their official written notification that the applicant has not been selected to participate as a TPC in the NCIMS voluntary ICP. If a meeting request is received within this fifteen (15) day time period, the meeting shall take place at a time, location and manner (in person or via teleconference) agreed upon by the Chair of the NCIMS Executive Board and the applicant. If an agreement cannot be reached, the meeting shall take place at a reasonable time, location and manner as determined by the Chair of the NCIMS Executive Board.

e. If the applicant is selected to participate as a TPC in the NCIMS voluntary ICP, they shall be provided a Letter of Understanding (LOU), signed and dated by the Chair of the NCIMS Executive Board, and the TPC shall be provided fifteen (15) days from

the date of receipt of their official notification of selection as a TPC to sign, date and return the LOU to the Chair of the NCIMS Executive Board.

f. If the LOU is not signed and dated by the TPC and returned to the Chair of the NCIMS Executive Board within this fifteen (15) day time period, the TPC has been determined to decline their selection as a TPC in the NCIMS voluntary ICP. If they wish to seek selection as a TPC in the NCIMS voluntary ICP at a later date, they shall complete and submit a new official NCIMS voluntary ICP application form along with all of the appropriate documentation to the ICP Committee.

g. Once the signed and dated LOU has been received by the Chair of the NCIMS Executive Board, within the time period as cited in 3.e. above, a copy of the signed and dated LOU shall be provided to the ICP Committee Chair and PHS/FDA MST.

h. PHS/FDA MST upon receipt of the signed and dated LOU shall issue an M-I officially announcing the selection of the TPC to participate in the NCIMS voluntary ICP and include the TPC on the *IMS List*.

i. If a TPC has not IMS listed any milk shippers within two (2) years of the signed and dated LOU, the ICP Committee Chair shall request a meeting with the TPC to discuss why their LOU shall continue to remain valid. The meeting shall take place at a time, location and manner (in person or via teleconference) agreed upon by the ICP Committee Chair and the TPC. If an agreement cannot be reached, the meeting shall take place at a reasonable time, location and manner as determined by the ICP Committee Chair.

Following the meeting, the ICP Committee Chair shall make a recommendation to the NCIMS Executive Board that the LOU remain valid or that the LOU shall be suspended. If the NCIMS Executive Board agrees with the recommendation from the ICP Committee Chair, then the Chair of the NCIMS Executive Board shall provide written notification to the TPC of their findings, with a copy to the ICP Committee Chair and to PHS/FDA MST.

If the agreed upon recommendation is for the suspension of the LOU, a TPC meeting request and the process as cited in 3.d. above shall be followed. Following this meeting, if the ICP Committee recommendation is still agreed to by the NCIMS Executive Board, then the Chair of the NCIMS Executive Board shall provide written notification to the TPC of their official LOU suspension, with a copy to the ICP Committee Chair and to PHS/FDA MST.

PHS/FDA MST, upon receipt of the written notification to officially suspend the TPC's LOU, shall issue an M-I officially announcing the suspension of the TPC to participate in the NCIMS voluntary ICP and immediately withdraw the TPC from the *IMS List*.

C. THIRD PARTY CERTIFER (TPC) RESPONSIBILITIES

1. Required Signed and Dated Agreements/Commitments

The following written agreements are required of TPCs with their MCs participating in the NCIMS voluntary ICP:

a. **Letter of Intent (LOI):** A TPC shall sign and date a formal written agreement with a MC that it intends to certify and IMS list under the NCIMS voluntary ICP. A copy of each agreement, signed and dated by the TPC and the MC selected to participate in the NCIMS voluntary ICP, shall be immediately submitted to the ICP Committee Chair and PHS/FDA MST. A copy of the official LOI for the NCIMS voluntary ICP may be obtained from the NCIMS Executive Secretary or the ICP Committee Chair. A copy is included in Appendix A. of this document.

b. **Memorandum of Agreement (MOA):** This formal written, signed and dated memorandum states the requirements and responsibilities of each party (TPC and MC) to participate and execute the NCIMS voluntary ICP. The MOA shall include, but is not limited to, the issues and concerns addressed in all documents involved in the NCIMS voluntary ICP and NCIMS documents. This agreement shall be considered the MC's permit to operate in the context of the NCIMS Grade "A" Milk Safety Program and shall be renewed (signed and dated) on an annual basis. A copy of the official MOA for the NCIMS voluntary ICP may be obtained from the NCIMS Executive Secretary or the ICP Committee Chair. A copy is included in Appendix A. of this document.

A signed and dated MOA shall be submitted to the ICP Committee Chair and PHS/FDA MST prior to the initial rating/certification of any milk shipper, or official laboratory, or official designated laboratory, respectively. The MOA shall be reviewed by the ICP Committee and PHS/FDA MST and LPET to determine that it contains all the provisions set forth herein. PHS/FDA MST and LPET shall provide comments to the ICP Committee concerning the MOA. There shall not be any ratings/certifications conducted of any milk shipper, or official laboratory, or official designated laboratory, respectively, of the MC until the ICP Committee has indicated in writing, which may include mail, facsimile, email or other electronic means, to the TPC that the signed and dated MOA complies with the requirements herein stated.

All annual renewed (signed and dated) MOAs shall be immediately submitted to the ICP Committee Chair and PHS/FDA MST.

Either party (TPC or MC) may terminate an MOA upon the MOA's required specified number of days notice by registered or certified mail, return receipt requested, addressed to the other party. If either party (TPC or MC) terminates a MOA, both the TPC and the MC shall immediately notify the ICP Committee Chair and PHS/FDA MST. Upon the TPC ceasing to provide oversight of the MC, the MC shall be immediately withdrawn from the *IMS List* and removed from the NCIMS voluntary ICP. Within fifteen (15) days of the TPC ceasing to provide oversight, they shall forward all related records, including, but not limited to: sample results, equipment tests, plant inspection notes and reports, etc. to PHS/FDA MST in a manner acceptable to PHS/FDA MST. PHS/FDA MST shall retain such records until such time as a suitable replacement TPC, authorized under the NCIMS voluntary ICP, has been hired and a signed and dated LOI has been submitted to the ICP Committee Chair and PHS/FDA MST to fulfill the obligations of the NCIMS voluntary ICP.

2. Qualifications of TPC Personnel

a. Regulatory Personnel

The TPC's regulatory personnel performing the routine required inspections of dairy farms, milk plants, transfer/receiving stations, etc. and the required pasteurization equipment testing shall be adequately trained to perform these duties and shall have had previous work experience in the NCIMS Grade "A" Milk Safety Program.

NOTE: All regulated MCs shall provide an interpreter during all official inspections, ratings/listings, training, and accreditation/certification activities.

b. Milk Sanitation Rating Personnel

TPC personnel conducting rating/listing activities shall meet the qualification and certification requirements set forth in Section V, D, and Section VIII, E. 4, if applicable, of this document. SROs cannot have direct responsibility for the routine inspection and enforcement or regulatory auditing of the milk shipper to be rated or listed.

c. Sampling Surveillance Personnel

TPC personnel conducting sampling surveillance activities shall meet the qualification and certification requirements set forth in Section V, F, and Section VIII, E.7, if applicable, of this document.

d. Milk Laboratory Evaluation Personnel

TPC personnel conducting milk laboratory evaluation activities shall meet the qualification and certification requirements set forth in Section V, G, and Section VIII, E. 8, if applicable, of this document and those of the *EML*.

e. NCIMS HACCP Program Personnel

Before a milk plant, receiving station or transfer station may be regulated under the requirements of the NCIMS voluntary HACCP Program, all relevant industry personnel and TPC regulatory and rating personnel shall complete all of the required NCIMS HACCP Program training as required in this document. Before a MC is allowed to begin the NCIMS voluntary HACCP Program there shall be a mutual agreement between the milk plant, receiving station or transfer station and the TPC. A TPC's NCIMS HACCP Program shall be evaluated as a part of the required triennial Regulatory/Rating Agency Program Evaluation completed by FDA.

f. NCIMS Aseptic Program Personnel

Before a milk plant may be regulated under the requirements of the NCIMS

Aseptic Program, all relevant TPC regulatory and rating personnel shall successfully complete the mandatory NCIMS Aseptic Program training developed and offered by the NCIMS Aseptic Program Committee.

NOTE: Any change in TPC personnel shall be immediately reported to the ICP Committee Chair and PHS/FDA MST.

3. Code of Ethics

The TPC, its personnel and contractors, if any, are obligated to abide by the following Code of Ethics:

The TPC:

- a. Shall not be owned, operated or controlled by a manufacturer, supplier or vendor of milk and/or milk products regulated under the NCIMS;
- b. Shall not be financially affiliated with a manufacturer, supplier or vendor of milk and/or milk products regulated under the NCIMS;
- c. Shall not charge fees contingent or based upon results from the TPC inspection, rating and certification activities; and
- d. Shall hold all personnel, including contractors, to the same conflict of interest standards.

The TPC and its personnel:

- a. Shall act with honesty and integrity;
- b. Shall act impartially and shall not give preferential treatment to any organization(s) or individual(s);
- c. Shall not discriminate because of race, religion, national origin or gender;
- d. Shall not hold financial interest(s) that conflict with the conscientious and impartial performance of their duties;
- e. Shall not engage in financial transactions using Regulatory/Rating derived information or allow the improper use of such information to further any private interest;
- f. Shall not disclose or use confidential or privileged information for personal benefit or for financial gain. The TPC and its personnel shall maintain strict confidentiality of proprietary information learned through their Regulatory/Rating oversight activities;
- g. Shall avoid conflicts of interest or the appearance of a conflict of interest. The TPC and its personnel shall not participate in any matter in which they, or their spouse or

dependents, have a private interest which may directly or indirectly affect or influence the performance of their duties.

h. Shall perform only the activities within the scope of their responsibilities, training and/or certification within the context of the NCIMS Grade “A” Milk Safety Program;

i. Shall endeavor to avoid any actions creating the appearance that they are violating the ethical tenets set forth in this Section. Whether particular circumstances create an appearance that these tenets have been violated shall be determined from the perspective of a reasonable person with the knowledge of the relevant facts; and

j. The TPC, TPC personnel, their spouses and dependants shall not solicit or accept any gift or other items of monetary value for their duties beyond the agreed upon contract value from the regulated industry or entity seeking Regulatory/Rating activities whose interests may be substantially affected by the performance or nonperformance of their duties.

Violators of any of the Code of Ethics’ tenets shall be subject to removal from participation in the NCIMS voluntary ICP.

4. Performance of Duties and Responsibilities

a. TPCs shall furnish all required services and activities as an independent contractor and not as an employee of the MC or of any company affiliated with the MC. The TPC does not have any power to or authority to act for, represent, or bind the MC or any company affiliated with the MC in any manner.

b. TPCs shall conduct all services and activities required under the signed and dated MOA with integrity and impartiality. The TPC shall avoid all conflicts of interest or the appearance of a conflict of interest. During the term of the signed and dated MOA, TPCs shall not enter into any activity, employment, or business arrangement that conflicts with the MC’s interests or their own obligations to the MC under the signed and dated MOA, except that the TPC may sign an MOA with and provide Regulatory/Rating services to other MCs as allowed under the NCIMS voluntary ICP. The TPC shall advise the MC of any activity, employment or business arrangement contemplated by the TPC that may be relevant to this paragraph.

c. TPCs shall treat all proprietary or privileged information obtained during the course of their services with the MC with strict confidentiality.

d. TPCs shall submit all required rating/listing paperwork and forms to PHS/FDA MST upon the completion of all ratings/listings conducted by the TPC.

D. MILK COMPANY (MC) RESPONSIBILITIES

1. Required Signed and Dated Agreements/Commitments

The following agreements are required of a MC with their TPC for participating in the

NCIMS voluntary ICP:

a. **Letter of Intent (LOI)**

b. **Memorandum of Agreement (MOA)**

A MC shall have the option of terminating a signed and dated MOA if, at any time, in the MC's sole judgment, a conflict of interest exists or is imminent. Termination shall be in accordance with the notification requirements addressed in Item 8 of the signed and dated MOA. The MC shall be aware and fully understand that if a signed and dated MOA is terminated after they have been listed on the *IMS List* they shall be immediately withdrawn from the *IMS List* and removed from the NCIMS voluntary ICP.

2. The MC shall comply with the signed and dated MOA and all applicable requirements of the NCIMS Grade "A" Milk Safety Program and the NCIMS voluntary ICP.

3. The MC shall allow unannounced inspections, during reasonable working hours, of all facilities included in the NCIMS voluntary ICP.

4. The MC shall provide access to the TPC of all required records relating to the provisions and requirements of the NCIMS Grade "A" Milk Safety Program and the NCIMS voluntary ICP. They shall also provide access to the TPC for all required pasteurization equipment testing and the collection of all required milk and/or milk products and milk containers, if applicable, and the required sampling of all applicable water system(s), including recirculated water systems.

5. Along with all of the other requirements as cited in the NCIMS documents, a MC seeking listing on the *IMS List*, shall provide documentation, acceptable to the TPC, the ICP Committee, and PHS/FDA MST, that demonstrates their compliance with the provisions of Section 8. Animal Health and Appendix A. Animal Disease Control of the *Grade "A" PMO* and the relevant USDA/APHIS requirements for tuberculosis and brucellosis.

6. All documents that are utilized and exchanged within the NCIMS voluntary ICP shall be in English or translated into English by the MC. These documents include all forms, contracts and written communication between the TPC and the regulated MC. The MC shall provide an interpreter during all official inspections, ratings/listings, training, and accreditation/certification activities.

C. COMPLIANCE WITH THE NCIMS VOLUNTARY INTERNATIONAL CERTIFICATION PROGRAM (ICP)

1. Third Party Certifier (TPC)

Compliance with the requirements of the NCIMS voluntary ICP shall be determined by PHS/FDA MST and LPET. Failure to adequately comply with the regulatory and enforcement provisions of the NCIMS Grade "A" Milk Safety Program; the requirements of the NCIMS

voluntary ICP; requirements for IMS listing; Code of Ethics; etc. can result in the removal of the TPC from the NCIMS voluntary ICP.

Reasons for the removal of a TPC from the NCIMS voluntary ICP and subsequent withdrawal of MCs and certified laboratories from the *IMS List* include, but are not limited to, the following:

a. If a TPC is found to be in non-compliance with the requirements set forth in the documents of the NCIMS Grade “A” Milk Safety Program by PHS/FDA MST and/or LPET, the TPC shall be subject to procedures addressing their removal from the NCIMS voluntary ICP.

b. If a TPC ceases to provide oversight of all of their IMS listed MCs for purposes of the NCIMS voluntary ICP, both the TPC and the MCs shall immediately notify the ICP Committee Chair and PHS/FDA MST and/or LPET. Both the TPC and MCs shall immediately be removed from the NCIMS voluntary ICP and the MCs shall immediately be withdrawn from the *IMS List* by PHS/FDA MST and/or LPET. Within fifteen (15) days of a TPC ceasing to provide this required MC oversight, the TPC shall transfer all existing records to PHS/FDA MST in a manner acceptable to PHS/FDA MST.

c. When there is evidence, found during PHS/FDA check ratings or a triennial Regulatory/Rating Agency Program Evaluation, that the TPC is in non-compliance with the applicable requirements set forth in the documents of the NCIMS Grade “A” Milk Safety Program, the TPC shall be referred to the NCIMS Executive Board in accordance with Section IV, A. 3. b of this document. The TPC and MC(s) listed by the TPC can be subject to withdrawal by PHS/FDA MST and/or LPET from the *IMS List*.

d. Violators of any of the required Code of Ethics’ tenets by a TPC or their personnel shall be subject to removal from participation in the NCIMS voluntary ICP by the Executive Board.

2. Milk Company (MC)

Compliance with the requirements of the NCIMS voluntary ICP shall be determined by PHS/FDA MST and LPET. Failure to adequately comply with the sanitation requirements and provisions of the NCIMS Grade “A” Milk Safety Program; the requirements of the NCIMS voluntary ICP; requirements for IMS listing; etc. can result in the removal of the MC from the NCIMS voluntary ICP.

Reasons for the removal of a MC from the NCIMS voluntary ICP and subsequent withdrawal of MCs and certified laboratories from the *IMS List* include, but are not limited to, the following:

a. If a MC’s IMS listed milk shipper changes status due to non-compliance or a change in the Sanitation Compliance Rating to less than ninety percent (90%), the TPC shall immediately notify the PHS/FDA MST and all known receiving Member States and/or TPCs. The MC’s IMS listed milk shipper shall immediately be withdrawn from the *IMS List* by PHS/FDA MST.

b. If a TPC ceases to provide the required oversight of an IMS listed MC for purposes of the NCIMS voluntary ICP, both the TPC and the MC shall immediately notify the ICP Committee Chair and PHS/FDA MST and/or LPET. The MC, including all associated facilities, shall immediately be removed from the NCIMS voluntary ICP and the MC shall also immediately be withdrawn from the IMS List by PHS/FDA MST and/or LPET. Within fifteen (15) days of a TPC ceasing to provide this required MC oversight, the TPC shall transfer all existing records to PHS/FDA MST in a manner acceptable to PHS/FDA MST.

c. When there is evidence that the MC or its servicing laboratory is not meeting the applicable requirements of the Grade "A" PMO and/or the EML, respectively, as determined by the TPC, or the ICP Committee, and/or PHS/FDA MST and/or LPET, the MC's IMS listing(s) is subject to withdrawal from the IMS List. The TPC or the ICP Committee shall immediately notify PHS/FDA MST and/or LPET, respectively. In the case that PHS/FDA MST and/or LPET makes this determination based upon the results of a check rating or a laboratory evaluation, the MC is subject to suspension and/or removal from the NCIMS voluntary ICP until compliance, as determined by PHS/FDA MST and/or LPET, is achieved. With this determination, PHS/FDA MST and/or LPET, respectively, shall notify all known receiving Member States.

D. CONFIDENTIALITY

The Member States of the NCIMS, the ICP Committee, and the PHS/FDA are obligated to operate under rules and regulations pursuant to the Freedom of Information Act that may require disclosure of information related to a TPC and the rating and certification of MCs and their related facilities.

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SECTION IXX. APPLICATION OF CONFERENCE AGREEMENTS

A. IMPLEMENTATION OF CHANGES ...

2. PHS/FDA ~~will~~ shall review the transcript and within ninety (90) days of receipt, notify the Conference Chair of those issues with which they do or do not concur. The changes involved, that have been concurred with shall be effective within one (1) year of the electronic publication of the affected documents or notification to the States and TPCs by IMS-a, following the Conference at which the changes were approved.

3. Those issues with which PHS/FDA does not concur ~~will~~ shall 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 and TPCs 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~~ shall 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~~ shall consider additional information that becomes available concerning Proposals for which there was not mutual concurrence. If following the 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. ...

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APPENDIX A. OFFICIAL AGREEMENTS UTILIZED IN THE NCIMS VOLUNTARY INTERNATIONAL CERTIFICATION PROGRAM

LETTER OF INTENT (LOI):

LETTER OF INTENT TO PARTICIPATE IN THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS VOLUNTARY INTERNATIONAL CERTIFICATION PROGRAM

It is necessary to comply with all applicable requirements of the Grade "A" Pasteurized Milk Ordinance (PMO) in order to properly produce and/or process and label our Grade "A" milk and/or milk products for distribution in the United States of America. We hereby confirm our intent to review through inspection our milk production (dairy farms), transportation, bulk milk hauler/samplers, processing, industry plant samplers, laboratory facilities, etc. in order to prepare them for compliance with the Grade "A" PMO. We understand that our facilities shall also meet the rating and certification requirements of the National Conference on Interstate Milk Shipments (NCIMS) Grade "A" Milk Safety Program.

Milk Company

Signature of Most Responsible Party

Name

Title

Date

We hereby confirm our intent to provide _____ (Milk Company) _____ with routine regulatory inspections, laboratory services and other obligations under the NCIMS voluntary International Certification Program to determine if your milk production (dairy farms), transportation, bulk milk hauler/samplers, processing, industry plant samplers, laboratory facilities, etc. comply with the Grade "A" PMO and the NCIMS Grade "A" Milk Safety Program. Once compliance is determined, your milk production (dairy farms), transportation, bulk milk hauler/samplers, processing, industry plant samplers, laboratory facilities, etc. shall be rated and potentially certified in accordance with the provisions of the NCIMS Grade "A" Milk Safety Program. Upon an acceptable rating and certification of your milk production (dairy farms), transportation, bulk milk hauler/samplers, processing, industry plant samplers, laboratory facilities, etc. and you having signed a "Permission to Publish" release form, you

shall be granted a listing on the Interstate Milk Shipper's List of Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS List).

Third Party Certifier

Signature of Most Responsible Party

Name

Title

Date

{TPC and MC} hereby agree to indemnify and hold harmless all members of the National Conference on Interstate Milk Shipments (NCIMS), including, but not limited to, all members of the NCIMS International Certification Program Committee, all federal regulatory agencies including the U.S. Food and Drug Administration, all State Regulatory Agencies, all trade associations including the International Dairy Foods Association and the National Milk Producers Federation, and all private entities including companies and consultants, and their respective members, agents, officers, directors and employees, against any and all losses, liabilities, costs, actions, claims and other obligations and proceedings, including any reasonable attorney's fees incurred in connection with, or which may arise or result in any way from the operation of the NCIMS voluntary International Certification Program.

MEMORANDUM OF AGREEMENT (MOA)

**NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS
VOLUNTARY INTERNATIONAL CERTIFICATION PROGRAM**

**MEMORANDUM OF AGREEMENT
BETWEEN A
THIRD PARTY CERTIFIER
AND
A MILK COMPANY**

1) Introduction. This Memorandum of Agreement (MOA) is entered into on {date} by and between {Third Party Certifier} with offices at {address}, and {Milk Company} with principal offices at {address}.

2) Retention and Description of Services. During the term of this MOA, {Third Party Certifier} shall furnish regulatory, rating, laboratory, etc. services and activities related to the regulatory compliance of {Milk Company} with the National Conference on Interstate Milk Shipments (NCIMS) voluntary International Certification Program (ICP). These services and activities shall be within the area of their technical competence and shall include, but are not limited to, the following:

- All required regulatory inspections and related enforcement;
- All required pasteurization system equipment testing;
- All required sampling and analysis of Grade “A” raw, pasteurized, ultra-pasteurized and/or aseptically processed milk and/or milk products, and milk containers, if applicable;
- All ratings/listings of shippers of Grade “A” milk and/or milk products; and
- Laboratory certification/approval program activities required for compliance with all applicable NCIMS Grade “A” Milk Safety Program requirements.

For purposes of this NCIMS voluntary ICP, the Third Party Certifier (TPC) shall have similar authority and responsibilities as State Regulatory Agencies, State Rating Agencies, State Laboratory Control Agencies and/or Officially Designated Laboratories, if applicable, as identified in the NCIMS Grade “A” Milk Safety Program. A detailed explanation of each service and activity can be found in the NCIMS documents (Grade “A” Pasteurized Milk Ordinance (PMO), Methods of Making Sanitation Ratings of Milk Shippers (MMSR), Procedures Governing the Cooperative State Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (Procedures), and Evaluation of Milk Laboratories (EML)).

During the term of this MOA, {Milk Company} shall comply with all applicable requirements of the NCIMS Grade “A” Milk Safety Program and the NCIMS voluntary ICP. They shall allow unannounced inspections, during reasonable working hours, of all facilities identified in Item 4. below. They shall provide access to the TPC of all required records relating to the provisions and requirements of the NCIMS Grade “A” Milk Safety Program and the NCIMS voluntary ICP. They shall provide access to the TPC for all required pasteurization equipment testing and the collection of all required milk and/or milk products and milk containers, if applicable, and the required sampling of all applicable water system(s), including recirculated water systems.

The MC shall provide written evidence acceptable to the TPC, the ICP Committee, and the U.S. Food and Drug Administration Milk Safety Team and Laboratory Proficiency Evaluation Team (FDA MST and LPET) that the milk and/or milk products used to produce Grade “A” milk and/or milk products for importation into the U.S. are from sources that comply with the provisions of Section 8 and Appendix A of the PMO and U.S. Department of Agriculture (USDA) regulations for tuberculosis and brucellosis testing and control.

All documents that are utilized and exchanged within the NCIMS voluntary ICP shall be in English or translated into English by the MC. These documents include all forms, contracts and written communication between the TPC and the regulated MC. The MC shall provide an interpreter during all official inspections, ratings/listings, training and accreditation/certification activities.

3) Term of the Memorandum Of Agreement (MOA). This formal written, signed and dated memorandum states the requirements and responsibilities of each party (TPC and MC) to participate and execute the NCIMS voluntary ICP. The MOA shall include, but is not limited to, the issues and concerns addressed in all documents involved in the NCIMS voluntary ICP and NCIMS documents. This agreement shall be considered the MC’s permit to operate in the context of the NCIMS Grade “A” Milk Safety Program and shall be renewed (signed and

dated) on an annual basis.

This signed and dated MOA shall be submitted to the ICP Committee Chair and FDA MST and shall be reviewed by the NCIMS ICP Committee and FDA MST and LPET to determine that it contains all provisions set forth within the NCIMS voluntary ICP. There shall not be any ratings/listings/certifications conducted of any MC's milk shipper or official laboratory or official designated laboratory, respectively, until the ICP Committee has indicated in writing that this MOA complies with the requirements of the Grade "A" Milk Safety Program and the NCIMS voluntary ICP.

Compliance with the requirements of the NCIMS voluntary ICP shall be determined by the FDA MST and LPET. Failure to adequately comply with the regulatory and enforcement provisions of the Grade "A" Milk Safety Program; the requirements of the NCIMS voluntary ICP; requirements for IMS listing; the required Code of Ethics; etc. may result in the removal of {Third Party Certifier} from the NCIMS voluntary ICP.

Reasons for the removal of TPCs or MCs from the NCIMS voluntary ICP and withdrawal of MCs from the Interstate Milk Shippers (IMS) List include, but are not limited to, the following:

- a. If a TPC is found to be in non-compliance with the requirements set forth in the documents of the NCIMS Grade "A" Milk Safety Program by PHS/FDA MST and/or LPET, the TPC shall be subject to procedures addressing their removal from the NCIMS voluntary ICP.
- b. If a TPC ceases to provide the required oversight of an IMS listed MC for purposes of the NCIMS voluntary ICP, both the TPC and the MC shall immediately notify the ICP Committee Chair and PHS/FDA MST and/or LPET. The MC, including all associated facilities, shall immediately be removed from the NCIMS voluntary ICP and the MC shall also immediately be withdrawn from the IMS List by PHS/FDA MST and/or LPET. Within fifteen (15) days of a TPC ceasing to provide this required MC oversight, the TPC shall transfer all existing records to PHS/FDA MST in a manner acceptable to PHS/FDA MST.
- c. If a TPC ceases to provide oversight of all of their IMS listed MCs for purposes of the NCIMS voluntary ICP, both the TPC and the MCs shall immediately notify the ICP Committee Chair and PHS/FDA MST and/or LPET. Both the TPC and MCs shall immediately be removed from the NCIMS voluntary ICP and the MCs shall immediately be withdrawn from the *IMS List* by PHS/FDA MST and/or LPET. Within fifteen (15) days of a TPC ceasing to provide this required MC oversight, the TPC shall transfer all existing records to PHS/FDA MST in a manner acceptable to PHS/FDA MST.
- d. When there is evidence, found during PHS/FDA check ratings or a triennial Regulatory/Rating Agency Program Evaluation, that the TPC is in non-compliance with the applicable requirements set forth in the documents of the NCIMS Grade "A" Milk Safety Program, the TPC shall be referred to the NCIMS Executive Board in accordance with Section IV, A. 3. b of this document. The TPC and MC(s) listed by the TPC can be subject to withdrawal by PHS/FDA MST and/or LPET from the *IMS List*.

- e. If a MC's IMS listed milk shipper changes status due to non-compliance or a change in the Sanitation Compliance Rating to less than ninety percent (90%), the TPC shall immediately notify the PHS/FDA MST and all known receiving Member States and/or TPCs. The MC's IMS listed milk shipper shall immediately be withdrawn from the IMS List by PHS/FDA MST.
- f. When there is evidence that the MC or its servicing laboratory is not meeting the applicable requirements of the Grade "A" PMO and/or the EML, respectively, as determined by the TPC, or the ICP Committee, and/or PHS/FDA MST and/or LPET, the MC's IMS listing(s) is subject to withdrawal from the IMS List. The TPC or the ICP Committee shall immediately notify PHS/FDA MST and/or LPET, respectively. In the case that PHS/FDA MST and/or LPET makes this determination based upon the results of a check rating or a laboratory evaluation, the MC is subject to suspension and/or removal from the NCIMS voluntary ICP until compliance, as determined by PHS/FDA MST and/or LPET, is achieved. With this determination, PHS/FDA MST and/or LPET, respectively, shall notify all known receiving Member States.
- g. Violators of any of the required Code of Ethics' tenets by a TPC or their personnel shall be subject to removal from participation in the NCIMS voluntary ICP by the Executive Board.

4) Where Services Are To Be Performed. {Third Party Certifiers} services and activities shall be performed at the {Milk Company's} facilities located at [address] and at such other locations that are appropriate and required to fulfill the requirements of the NCIMS voluntary ICP.

5) Third Party Certifier as an Independent Contractor. {Third Party Certifier} shall furnish all required services and activities as an independent contractor and not as an employee of {Milk Company} or of any company affiliated with {Milk Company}. The TPC does not have any power to or authority to act for, represent, or bind the MC or any company affiliated with the MC in any manner.

6) Third Party Certifier is not to Engage in Conflicting Activities. {Third Party Certifier} shall conduct all services and activities required under this MOA with integrity and impartiality. The TPC shall avoid all conflicts of interest or the appearance of a conflict of interest. During the term of this MOA, {Third Party Certifier} shall not enter into any activity, employment, or business arrangement that conflicts with the MC's interests or their own obligations to {Milk Company} under this MOA, except that the TPC may sign an MOA with and provide regulatory and rating services to another MC as allowed under the NCIMS voluntary ICP.

The MC shall have the option of terminating this MOA if, at any time, in the MC's sole judgment, a conflict of interest exists or is imminent. The TPC shall advise the MC of any activity, employment or business arrangement contemplated by the TPC that may be relevant to this Paragraph. Termination shall be in accordance with the notification requirements in Item 8. of this Agreement. The MC understands that if this MOA is terminated after they have been listed on the IMS List that their IMS Listings shall be immediately withdrawn from the IMS List and the MC shall be immediately removed from the NCIMS voluntary ICP.

Name: _____

Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

Expiration Date: _____

**MAKE THE FOLLOWING CHANGES TO THE 2011
CONSTITUTION OF THE NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS:**

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ARTICLE II ----- MISSION

The mission of the Conference shall be to "Assure the Safest Possible Milk Supply for all the People" by:

SECTION 1. Adopting sound, uniform procedures, which will be accepted by participating ~~State Milk~~ Rating and ~~State Milk~~ Regulatory Agencies.

SECTION 2. Promoting mutual respect and trust between ~~State Milk~~ Rating and ~~State Milk~~ Regulatory Agencies of producing and receiving States and Third Party Certifiers.

SECTION 3. Utilizing Public Health Service/Food and Drug Administration (PHS/FDA) personnel for training programs and using that Agency as a channel for the dissemination of information among ~~State Milk~~ Rating and ~~State Milk~~ Regulatory Agencies for the objective of promoting uniformity among the States and ~~regions~~ Third Party Certifiers.

SECTION 4. Acquainting producers, processors, and consumers with the purpose of the Conference through the media of meetings, conferences, workshops, press releases, publications, and by utilization of facilities and personnel of educational institutions, trade associations, ~~State Milk~~ Rating and ~~State Milk~~ Regulatory Agencies and other groups that are willing to assist in the dissemination of such information.

**ARTICLE IV ----- VOTING DELEGATES, EXECUTIVE BOARD, OFFICERS,
EXECUTIVE SECRETARY, COMMITTEES, COUNCILS,
AND PROGRAM CHAIR**

SECTION 1. The voting delegates, of the Conference, are representatives of the State Milk Rating Agencies, State Milk Regulatory Agencies, and like representatives from the District of Columbia, participating U.S. Trust Territories and each participating non-U.S. country or political subdivisions thereof, as identified in Article VII, Section 4., Subdivision 3. of the *Bylaws*.

SECTION 4. The Board shall be composed up to ~~twenty-five (25)~~ twenty-six (26) members as follows:

Four (4) members from Group I (Eastern States); Six (6) members from Group II (Central States) (two (2) at large); Four (4) members from Group III (Western States); all to be elected by the General Assembly by majority vote (General Assembly is defined as qualified voting delegates, assembled at a biennial or special meeting of the Conference); plus one (1) member at large from each of Groups I (PHS/FDA) and III (United States Department of Agriculture (USDA)), appointed as outlined in the following Section; plus one (1) non-voting member at large representing consumers, appointed by the Chair and confirmed by the Board; plus one (1) non-voting representative from the Third Party Certifiers, appointed by the Chair and confirmed by the Board; plus the immediate Past Chair, the Program Chair, Chair of the NCIMS Liaison Committee, and the three (3) Council Chairs who are appointed by the Chair and confirmed by the Board; and one (1) representative each from the International Dairy Foods Association (IDFA) and the National Milk Producers Federation (NMPF). The Program Chair, Chair of the NCIMS Liaison Committee, the three (3) Council Chairs, the immediate Past Chair and the representatives from IDFA and NMPF, except as otherwise provided, shall serve on the Board as non-voting members. Each elected member of the Board shall serve through three (3) biennial meetings of the Conference. Full term Board members may succeed themselves, unless re-election would extend the total terms of consecutive service to more than twelve (12) years.

SECTION 5. The membership of the Board shall be selected as follows:

Subd. 1. Group I -- Eastern States

The Eastern States are Connecticut, Delaware, Florida, Georgia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York,

North Carolina, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, Vermont, Virginia, West Virginia and the District of Columbia. A total of four (4) members shall be selected for election from this area (one (1) member from a State ~~Milk~~ Rating Agency, one (1) member from industry, one (1) member from a State ~~Milk~~ Regulatory Agency, plus one (1) member from either a ~~Local Health Authority~~, a State ~~Milk~~ Rating or State ~~Milk~~ Regulatory Agency), plus one (1) member (at large) from the PHS/FDA to be appointed by the Commissioner of FDA.

Subd. 2. Group II -- Central States

The Central States are Alabama, Arkansas, Illinois, Indiana, Iowa, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Ohio, Tennessee, and Wisconsin. A total of four (4) members shall be selected for election from this area (one (1) member from a State ~~Milk~~ Rating Agency, one (1) member from industry, one (1) member from a State ~~Milk~~ Regulatory Agency, plus one (1) member from either a ~~Local Health Authority~~, a State ~~Milk~~ Rating or State ~~Milk~~ Regulatory Agency), plus one (1) member (at-large) from an educational institution and one (1) member (at-large) from a laboratory. The at-large members need not live or be employed in Group II.

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Subd. 3. Group III -- Western States

The Western States are Alaska, Arizona, California, Colorado, Hawaii, Idaho, Kansas, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Texas, Utah, Washington and Wyoming. A total of four (4) members shall be selected for election from this area (one (1) member from a State ~~Milk~~ Rating Agency, one (1) member from industry, one (1) member from a State ~~Milk~~ Regulatory Agency, plus one (1) member from either a ~~Local Health Authority~~, a State ~~Milk~~ Rating Agency or State ~~Milk~~ Regulatory Agency), plus one (1) member (at-large) from USDA to be appointed by the Secretary of Agriculture. ...

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SECTION 6. The Board shall elect a Chair and a Vice Chair from its membership after each biennial meeting of the Conference and they may retain their position at the pleasure of the Board as long as they are officially members of the Board. If the Chair cannot perform the duties, the Board shall again elect a Chair. The Board shall retain the services of an Executive Secretary. The Executive Secretary shall be bonded, shall not have ~~no a~~ vote on the Board, ~~shall have no vote and~~ in biennial or special meetings of the Conference; but shall perform all duties required

in Article IV of the *Bylaws*. The compensation of the Executive Secretary shall be set by the Board. ...

SECTION 10. Each Council shall have a voting membership of twenty (20) members to be appointed by the Chair with the approval of the Board.

Subd. 1. Each Council shall have ten (10) representatives from ~~State Milk Rating~~ and/or ~~State Milk~~ Regulatory Agencies and ten (10) representatives from industry. ...

SECTION 11. Each Council shall have a Council Chair and a Vice Chair ...

Subd. 2. If the Council Chair represents a ~~State Milk~~ Rating and/or ~~State Milk~~ Regulatory Agency, the Vice Chair shall represent industry. If the Council Chair represents industry, the Vice Chair shall represent a ~~State Milk~~ Rating and/or ~~State Milk~~ Regulatory Agency.

MAKE THE FOLLOWING CHANGES TO THE 2011 BYLAWS OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS:

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ARTICLE I ----- DUTIES OF THE BOARD ...

SECTION 5. The Board shall have the right of approval of the Nominating Committee appointed by the Chair at each Conference for the purpose of nominating registrants to be elected to the Board by the voting delegates. The Nominating Committee shall be composed of six (6) members, one (1) each from State ~~Milk~~ Rating and State ~~Milk~~ Regulatory Agencies in each of the three (3) geographical groups of States. ...

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SECTION 14. The Board shall, after written notification of PHS/FDA recommendations, within 120 days, rule on the matter of non-compliance with ~~State~~ Regulatory/Rating Agency Program Evaluations, including Regulatory, Rating and Laboratory as required by Section IV., A. 3.b. and VII., B. of the *Procedures*. ...

ARTICLE II ----- DUTIES OF THE CHAIR ...

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SECTION 3. The Chair, with the approval of the Board, shall appoint qualified Conference registrants to Standing Committees, including the Constitution and Bylaws, Documents Review Committee, HACCP Implementation Committee, Laboratory, Methods of Making Sanitation Ratings, Liaison, Single-Service Container and Closure, Technical Engineering Review, Scientific Advisory, Hauling Procedures, ~~and~~ Other Species and International Certification Program Committees, and Councils as is necessary to carry out the mission of the Conference.

SECTION 5. The Chair shall assure that at least one half (1/2) the voting membership of Standing Committees, Ad hoc Committees and Study Committees as set forth in Article II, Sections 3. and 4. of the *Bylaws*, shall be composed of ~~State Milk~~ Rating and ~~State Milk~~ Regulatory Agencies, provided the membership of the Nominating Committee, Resolutions Committee and Constitution and Bylaws Committee shall consist in whole from State ~~Milk~~ Rating and State ~~Milk~~ Regulatory Agencies. The Nominating Committee shall be composed as set forth in Article I, Section 5. of the *Bylaws*. ...

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ARTICLE IV ----- DUTIES OF THE EXECUTIVE SECRETARY ...

SECTION 3. At least sixty (60) days prior to a biennial meeting, or as soon as possible for a special meeting of the Conference, the Executive Secretary shall notify the office or offices of the ~~State Milk~~ Rating and/or ~~State Milk~~ Regulatory Agency or Agencies in each participating State and Third Party Certifier, or a like representative from the District of Columbia, participating U.S. Trust Territories and each participating non-U.S. country or political subdivision thereof, of the time and place of the next Conference, and the issues which are to be voted on in the General Assembly of the Conference under the heading of unfinished business. ...

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ARTICLE VI ----- DUTIES AND RESPONSIBILITIES OF COUNCILS ...

SECTION 3. Council III shall deal with Proposals submitted to the Conference regarding Sections 11, 17, and 18 and Appendix K of the *Grade "A" Pasteurized Milk Ordinance*; the *Constitution and Bylaws*; the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments*; issues of reciprocity; Proposals addressing the International Certification Program; and Proposals assigned from the Program Committee. ...

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SECTION 5. The Chair of each Council shall appoint four (4) alternate Council members representing a dairy processor, a dairy producer, a ~~State Milk~~ Regulatory Agency and a ~~State Milk~~ Rating Agency for review and approval by the NCIMS Executive Board prior to each Conference. Alternate Council members shall be seated to cast votes during periods of temporary absence of Council members and shall be designated to replace Council members for the entire Conference if they cannot attend. ...

ARTICLE VII ----- RULES OF THE CONFERENCE ...

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SECTION 4. Rules of the delegate business meeting. ...

Subd. 3. Only a registrant at the Conference, who is a representative of a State ~~Milk~~ Rating Agency or a State ~~Milk~~ Regulatory Agency responsible for the enforcement of sanitation laws for Grade "A" milk and milk products, Grade "A" condensed and dry milk products and Grade "A" whey and whey products, or a like representative from the District of Columbia, or a participating U.S. Trust Territory, or a participating non-U.S. country or political subdivision thereof, is entitled to be a voting delegate. When any State is represented by both ~~Milk~~ Rating and ~~Milk~~ Regulatory Agencies, the vote may be cast together as one (1) vote or separately as one-half (1/2) vote each, provided that any State represented by both ~~Milk~~ Rating and ~~Milk~~ Regulatory delegates certified in compliance with the provisions of Subdivision 4. of this Section may during any delegate business meeting, reassign its one-half (1/2) vote privilege to the other duly certified State delegate by giving written notice of such action to the Chair. ...

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Subd. 4. Ninety (90) days prior to the biennial meeting of the Conference, or as soon as possible for a special meeting of the Conference, the Executive Secretary shall send to the office, or offices, of the State ~~Milk~~ Rating or State ~~Milk~~ Regulatory Agency or Agencies in each participating State, the District of Columbia, participating U.S. Trust Territories and each participating non-U.S. country or political subdivision thereof, notice of the forthcoming meeting. Each notice shall include a copy of Article VII, Section 4., Subdivisions 3. and 4. of the *Bylaws* that outlines the designation of voting delegates and their privileges.

Each Agency shall report to the Executive Secretary, in writing on forms provided, within thirty (30) days of the Conference, or a date determined by the Chair for a special meeting, the following:

- a. Its officially designated responsibility whether as State ~~Milk~~ Rating Agency only, or as State ~~Milk~~ Regulatory Agency only, or both as identified in Article VII, Section 4., Subdivision 3. of the *Bylaws*. ...

MAKE THE FOLLOWING CHANGES TO THE 2011 MMSR:

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Cover:

~~2011~~ 2013 Revision

Page 1:

PREFACE

The objective of a rating is to provide an assessment of ~~State and Local~~ the Regulatory Agency's sanitation activities regarding public health protection and milk quality control. This is accomplished by evaluating sanitation compliance and enforcement standards of the current edition of the *Grade "A" Pasteurized Milk Ordinance (Grade "A" PMO)* and Related Documents as listed in the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (Procedures)*. Rating results are used for the purpose of evaluating the sanitation compliance and enforcement requirements of shippers to determine the degree of compliance with public health standards as expressed in the *Grade "A" PMO*. Rating results are further utilized as a means of uniform education and interpretation, in addition to providing a basis for the acceptance/rejection of shippers by Regulatory ~~Officials~~ Agencies beyond the limits of routine inspection. Rating results are intended to establish uniform reciprocity between ~~States~~ Regulatory Agencies to prevent unnecessary restrictions of the interstate flow of milk and/or milk products, yet assure public health protection.

The rating method for evaluating the sanitary quality of milk and/or milk products measures the extent to which a shipper complies with the standards contained in the *Grade "A" PMO*. These nationally recognized standards, rather than local requirements, are used as a yardstick in order that ratings of individual Bulk Tank Units (BTUs) or attached shippers and milk plants, receiving stations and/or transfer stations may be comparable to each other, both interstate and intrastate. Ratings are expressed in terms of percentage compliance. For example, if the milk plant, receiving station, transfer station and/or dairy farms comply with all of the requirements of the *Grade "A" PMO*, the Sanitation Compliance Rating of the pasteurized milk supply and/or raw milk supply, respectively would be one hundred percent (100%); whereas, if the milk plant, receiving station, transfer station or some of the dairy farms fail to satisfy one (1) or more of these requirements, the Sanitation Compliance Rating would be reduced in proportion to the amount of milk and/or milk products involved in the violation and to the relative public health significance of the violated Item(s). Procedures for the collection of data, the computation of Sanitation Compliance Ratings for raw milk for pasteurization and pasteurized milk, and the computation of the Enforcement Rating of the

Regulatory Agency, responsible for administering milk sanitation regulations, are described in the following Sections. ...

Page ii:

A. DEFINITIONS

Page 2:

7. **CERTIFIED MILK LABORATORY EVALUATION OFFICER (LEO):** A Regulatory Agency or Milk Laboratory Control Agency employee who has been certified by the Public Health Service/Food and Drug Administration (PHS/FDA) Laboratory Proficiency Evaluation team (LPET) using the Evaluation of Milk Laboratories (EML) to evaluate milk laboratories for the purpose of accrediting or approving laboratories that conduct official NCIMS milk testing and has a valid certificate of qualification.

78. **CERTIFIED MILK SANITATION RATING OFFICER (SRO):** A State Regulatory Agency employee who has been standardized certified by the Public Health Service/Food and Drug Administration (PHS/FDA), has a valid certificate of qualification and does not have direct responsibility for the routine regulatory inspection and enforcement or regulatory auditing of the shipper to be rated or listed. Directors, administrators, supervisors, etc. may be certified as Milk Sanitation Rating Officers (SROs). A Milk Sanitation Rating Officer (SRO) may be certified to make HACCP milk plant, receiving station or transfer station listings.

9. **CERTIFIED SAMPLING SURVEILLANCE OFFICER (SSO):** A Regulatory Agency employee who has been certified by the Public Health Service/Food and Drug Administration (PHS/FDA) and has a valid certificate of qualification. Directors, administrators, supervisors, etc., Milk Sanitation Rating Officers (SROs), Laboratory Evaluation Officers (LEOs), etc. may be certified as Sampling Surveillance Officers (SSOs).

§10. **CRITICAL LISTING ELEMENT (CLE):** An item on FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT identified with a double star (**). The marking of a CLE by a Milk Sanitation Rating Officer (SRO) or FDA auditor, indicates a condition that constitutes a major dysfunction likely to result in a potential compromise to milk and/or milk product safety, or that violates NCIMS requirements regarding drug residue testing and trace back and/or raw milk sources, whereby a listing may be denied or withdrawn.

Renumber remaining DEFINITIONS accordingly.

1214. **HACCP LISTING:** An inclusion in on the IMS List—Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS List) based on a SROs Milk Sanitation Rating Officer's (SRO's) evaluation of a milk plant's, receiving station's or transfer station's NCIMS voluntary HACCP Program and other applicable NCIMS requirements.

1315. **INDIVIDUAL RATING:** ...

Page 3:

16. **INTERNATIONAL CERTIFICATION PROGRAM (ICP):** The International Certification Program (ICP) means the NCIMS voluntary program designed to utilize Third Party Certifiers (TPCs) authorized by the NCIMS Executive Board in applying the requirements of the NCIMS Grade “A” Milk Safety Program for Milk Companies (MCs) located outside the geographic boundaries of NCIMS Member States that desire to produce and process Grade “A” milk and/or milk products for importation into the United States.

17. **LETTER OF INTENT (LOI):** A formal written signed agreement between a Third Party Certifier (TPC), authorized under the NCIMS voluntary International Certification Program (ICP), and a Milk Company (MC) that intends to be certified and IMS Listed under the NCIMS voluntary International Certification Program (ICP). A copy of each written signed agreement shall be immediately submitted to the International Certification Program (ICP) Committee following the signing by the Third Party Certifier (TPC) and Milk Company (MC).

18. **LETTER OF UNDERSTANDING (LOU):** A formal written signed agreement between a Third Party Certifier (TPC) and the NCIMS Executive Board that acknowledges the NCIMS’ authorization of the Third Party Certifier (TPC) to operate under the NCIMS voluntary International Certification Program (ICP). It also states the Third Party Certifier’s (TPC’s) responsibilities under the NCIMS voluntary International Certification Program (ICP); their agreement to execute them accordingly; and their understanding of the consequences for failing to do so. The Letter of Understanding (LOU) shall include, but is not limited to, the issues and concerns addressed in all documents involved in the NCIMS voluntary International Certification Program (ICP).

1419. **LISTING AUDIT:** ...

20. **MEMORANDUM OF AGREEMENT (MOA):** A formal written signed memorandum that states the requirements and responsibilities of each party (Third Party Certifier (TPC) and Milk Company (MC)) to participate and execute the NCIMS voluntary International Certification Program (ICP). The Memorandum of Agreement (MOA) shall include, but is not limited to, the issues and concerns addressed in all documents involved in the NCIMS voluntary International Certification Program (ICP). This agreement shall be considered the Milk Company’s (MC’s) permit to operate in the context of the NCIMS Grade “A” Milk Safety Program and shall be renewed (signed and dated) on an annual basis.

21. **MILK COMPANY (MC):** A Milk Company (MC) is a private entity that is listed on the IMS List by a Third Party Certifier (TPC) including all associated dairy farms, bulk milk haulers/samplers, milk tank trucks, milk transportation companies, milk plants, receiving stations, transfer stations, dairy plant samplers, industry plant samplers, milk distributors, etc. and their servicing milk and/or water laboratories, as defined in the *Grade “A” PMO*, located outside the geographic boundaries of NCIMS Member States.

1422. **MILK PLANT**

23. **RATING AGENCY:** A Rating Agency shall mean a State Agency, which certifies interstate milk shippers (BTUs, receiving stations, transfer stations, and milk plants) as having attained the Sanitation Compliance and Enforcement Ratings necessary for inclusion on the *IMS List*. The ratings are based on compliance with the requirements of the *Grade “A” PMO*

and were conducted in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers (MMSR)*. Ratings are conducted by FDA certified Milk Sanitation Rating Officers (SROs). They also certify single-service containers and closures for milk and/or milk products manufacturers for inclusion on the *IMS List*. The certifications are based on compliance with the requirements of the *Grade "A" PMO* and were conducted in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers (MMSR)*. The definition of a Rating Agency also includes a Third Party Certifier (TPC) that conducts ratings and certifications of Milk Companies (MCs) located outside the geographic boundaries of NCIMS Member States that desire to produce and process Grade "A" milk and/or milk products for importation into the United States. ...

4624. **RECEIVING STATION:** ...

4725. **RECIPROCITY:** For the purposes of the *National Conference on Interstate Milk Shipments* (NCIMS) agreements, reciprocity shall mean no any action or requirements on the part of any Regulatory Agency will not cause or require any action in excess of the requirements of the current edition of the *Grade "A" PMO* and Related Documents of the NCIMS agreements.

4826. **REGULATORY AGENCY:** A Regulatory Agency shall mean an agency which has adopted an ordinance, rule or regulation in substantial compliance with the current edition of the *Grade "A" PMO* ~~or two (2) agencies which have mutually agreed to share the~~ and is ~~responsibilities~~ responsible for the enforcement of ~~an~~ such ordinance, rule or regulation, which is in substantial compliance with the *Grade "A" PMO* for a listed interstate milk shipper. ~~The mutual agreement shall specify the details of how the rating will be made so long as the details do not conflict with the basic intent of this document. The term, "Regulatory Agency", whenever it appears in the MMSR shall also mean the appropriate Third Party Certifier (TPC) having jurisdiction and control over the matters cited within this MMSR.~~

27. **THIRD PARTY CERTIFER (TPC):** A Third Party Certifier (TPC) is a non-governmental individual(s) or organization authorized under the NCIMS voluntary International Certification Program (ICP) that is qualified to conduct the routine regulatory functions and enforcement requirements of the *Grade "A" PMO* in relationship to milk plants, receiving stations, transfer stations, associated dairy farms, bulk milk hauler/samplers, milk tank trucks, milk transportation companies, dairy plant samplers, industry plant samplers, milk distributors, etc. participating in the NCIMS voluntary International Certification Program (ICP). The Third Party Certifier (TPC) provides the means for the rating and listing of milk plants, receiving stations, transfer stations and their related raw milk sources. They also conduct the certification and IMS listing of related milk and/or water laboratories and related single-service container and closure manufacturers on the *Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS) List*. To be authorized under the NCIMS voluntary International Certification Program (ICP), a valid Letter of Understanding (LOU) shall be signed between the NCIMS Executive Board and the Third Party Certifier (TPC).

4928. **TRANSFER STATION:** ...

B. RATING METHODS FOR RAW MILK FOR PASTEURIZATION ...

2. COLLECTION OF DATA ...

Page 6:

c. Number of Bulk Milk Hauler/Samplers to be Evaluated

At each ~~producer~~ dairy farm, during the rating or check rating of a BTU, determine the identification of the bulk milk hauler/sampler(s), from at least the previous thirty (30) days, to be used when computing FORM FDA 2359j-MILK SANITATION RATING REPORT, SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3). Obtaining records on bulk milk hauler/samplers from other ~~States~~ Regulatory Agencies may be necessary, depending on the Regulatory Agency, which issued the permit(s). ...

Page 7:

e. Recording of Laboratory and Other Test Data

1.) Regulatory Agency records are used in determining compliance with bacterial, drug residue, somatic cell, and cooling temperature requirements. The acceptance of data from official and/or officially designated laboratories is contingent upon the utilization of standard procedures by the laboratories concerned. Accordingly, it is necessary for the SRO to determine from the official ~~State~~ Milk Laboratory Certifying Control Agency that both sampling and laboratory procedures have been approved in accordance with the methods of the current edition of the *Evaluation of Milk Laboratories (EML)*. Ratings shall not be conducted when an approved laboratory is not utilized by the Regulatory Agency for the necessary tests. ...

3.) The SRO ~~may~~ shall utilize the Regulatory Agency's records in determining compliance with those Items of sanitation which require laboratory tests to complete the evaluation. ...

Page 8:

NOTE: Item 8-Water Supply on FORM FDA 2359a-DAIRY FARM INSPECTION REPORT has been divided into two (2) point and five (5) point violations/debits. The maximum point value for the entire Item 8r cannot exceed five (5) points on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION. (Refer to Appendix B. TABLE OF FARM WATER SUPPLY VIOLATIONS, which provides guidance, which may be used to differentiate between two (2) point (minor) and five (5) point (major) violations of Section 7, Item 8r of the *Grade "A" PMO* during ~~State~~ Ratings and FDA Check Ratings.) ...

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

2. COLLECTION OF DATA ...

Page 11:

b. Recording of Laboratory and Other Test Data

1.) Regulatory Agency records are used in determining compliance with bacterial, coliform, phosphatase, drug residue, and cooling temperature requirements. The acceptance of data from official and/or officially designated laboratories is contingent upon the utilization of standard procedures by the laboratories concerned. Accordingly, it is necessary for the SRO to determine from the official State Milk Laboratory Certifying Control Agency that both sampling and laboratory procedures have been approved in accordance with the methods of the current edition of the *EML*. Ratings and HACCP listing audits shall not be conducted when an approved laboratory has not been utilized by the Regulatory Agency for the necessary tests. ...

3.) The SRO ~~may~~ shall utilize Regulatory Agency's records in determining compliance with those Items of sanitation, which require laboratory tests to complete the evaluation. Official records of Equipment Tests may also be used in lieu of performing such Equipment Tests during the rating. Provided, that the SRO is satisfied as to the competency of the Regulatory Agency's personnel to perform these Equipment Tests as described in Appendix I. of the *Grade "A" PMO*. ...

Page 14:

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

1.) Inspection Criteria ...

(B.) State Regulatory Agency 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~~ a Regulatory Agency ~~when~~ designated by FDA under the FDA LACE, in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113 at a frequency determined by FDA.

...

4. MILK PLANTS ...

Page 20:

b. Milk Plant with an Unattached Supply of Raw Milk ...

3.) The utilization of milk from a separately rated source, which has a Milk Sanitation Compliance Rating, which is not equal to ninety percent (90%) or greater, or is from an unlisted source, would initiate an immediate withdrawal of the shipper from the *IMS List*. ...

Page 21:

c. Milk Plant with an Attached Supply of Raw Milk ...

3.) The utilization of milk from a separately rated source, which has a ~~Milk~~ Sanitation Compliance Rating, which is not equal to ninety percent (90%) or greater, or is from an unlisted source, would initiate an immediate withdrawal of the shipper from the *IMS List*. ...

Page 23:

F. PUBLICATION OF THE “INTERSTATE MILK SHIPPER’S REPORT”

1. PURPOSE

a. The *IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS List)* is an electronic publication of CFSAN’s Milk Safety ~~Branch~~ Team (HFS-316), Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740-3835. This is a part of the activities of the PHS/FDA in cooperation with the States Regulatory Agencies in the cooperative program for the certification of interstate milk shippers. ...

b. Triplicate copies or PHS/FDA’s electronic version (transmitted via computer) of FORM FDA 2359i-INTERSTATE MILK SHIPPER’S REPORT shall be submitted by the ~~State Rating Officer~~ SRO to the appropriate PHS/FDA Regional Office ~~of the PHS/FDA or PHS/FDA MST for TPCs~~ for shippers who desire to be listed ~~in~~ on the *IMS List*. (Refer to Section G, #s 8 and 9 for a copy of the Form.)

A signed copy of a written FORM FDA 2359o-PERMISSION FOR PUBLICATION - INTERSTATE MILK SHIPPER’S LISTING shall accompany each triplicate set of FORM FDA 2359i-INTERSTATE MILK SHIPPER’S REPORT, submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs for publication ~~in~~ on the *IMS List*. For the submission of PHS/FDA’s electronic version, a signed copy of the written FORM FDA 2359o-PERMISSION FOR PUBLICATION - INTERSTATE MILK SHIPPER’S LISTING shall be maintained on file by the Rating Agency for publication ~~in~~ on the *IMS List* and ~~will~~ shall be reviewed as part of the check rating and/or State Regulatory/Rating Agency Program Evaluation. Once a shipper has been listed, all new ratings shall be submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs even though the shipper has refused to sign a written FORM FDA 2359o-PERMISSION FOR PUBLICATION - INTERSTATE MILK SHIPPER’S LISTING. Supporting sampling and laboratory certification reports, as specified in the *Procedures*, are also necessary for inclusion and retention of the shipper on the list. (Refer to Section G, #12 for a copy of the Form.)

Page 24:

The Sanitation Compliance Rating of a shipper is not published unless the written and signed FORM FDA 2359o-“PERMISSION FOR PUBLICATION - INTERSTATE MILK SHIPPER’S LISTING” of the shipper concerned has been obtained by the ~~State Milk Sanitation~~ Rating Agency. Milk plants, receiving stations and transfer stations shall

achieve a Sanitation Compliance Rating of ninety percent (90%) or greater in order to be eligible for a listing ~~in~~ on the *IMS List*. The Sanitation Compliance Rating ~~score~~ for milk plants, receiving stations and transfer stations will not be printed ~~in~~ on the *IMS List*.

2. PREPARATION OF THE “INTERSTATE MILK SHIPPER’S REPORT” ...

Page 25:

c. Milk Plant

1.) Attached Supply Only: A milk plant with a single source of raw milk, both under the jurisdiction of the same Regulatory Agency. ...

Following the computation of the Sanitation Compliance Rating on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, FORM FDA 2359L-STATUS OF MILK PLANTS, and Parts I, II and III of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the resultant data ~~will~~ shall be transferred to FORM FDA 2359i-INTERSTATE MILK SHIPPER’S REPORT. The earliest rating date shall be the date of the first day of the rating of the dairy farms (BTU) or milk plant, whichever is earliest in time. ...

2.) Attached Supply and Unattached Supplies: A milk plant with a source of raw milk ~~for pasteurization~~ under the jurisdiction of the same Regulatory Agency as the milk plant and one (1) or more sources of raw milk ~~for pasteurization~~ from other separate rated and listed sources.

Following the computation of the Sanitation Compliance Rating on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, FORM FDA 2359L-STATUS OF MILK PLANTS, and Parts I, II and III of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the resultant data ~~will~~ shall be transferred to FORM FDA 2359i-INTERSTATE MILK SHIPPER’S REPORT. The earliest rating date and the Raw Milk Sanitation Compliance Rating shall be computed by the following methods:

All unattached supplies shall have a Sanitation Compliance Rating of ninety percent (90%) or greater. The Sanitation Compliance Rating of the attached supply shall be reported as the Raw Milk Sanitation Compliance Rating for the milk plant. The earliest rating date shall be reported on FORM FDA 2359i-INTERSTATE MILK SHIPPER’S REPORT. In addition, the name of each unattached shipper, during the thirty (30) days preceding the rating, along with the Sanitation Compliance Rating and Date of Rating of each shipper shall be listed on the reverse side of FORM FDA 2359i-INTERSTATE MILK SHIPPER’S REPORT. If milk is received from an unlisted source or from a source having a Raw Milk Sanitation Compliance Rating of less than ninety percent (90%), the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs shall be notified and the milk plant shall be immediately withdrawn from the *IMS List*...

Page 26:

3.) Unattached Supplies Only: A milk plant with one (1) or more sources of raw milk received from other rated and listed sources.

Following the computation of the Sanitation Compliance Rating on FORM FDA 2359L-STATUS OF MILK PLANTS and Parts II and III of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the resultant data ~~will~~ shall be transferred to FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT. The earliest rating date and the ~~Milk~~ Sanitation Compliance Rating shall be computed by one (1) of the following two (2) options: ...

A.) **Option 1:** If all raw milk sources have a published, or submitted for publication, Sanitation Compliance Rating of ninety percent (90%) or greater and the milk plant desires to be listed with the milk plant rating date, the raw milk ~~will~~ shall be reported as ninety percent (90%) or listed with an asterisk (*), which denotes all supplies are ninety percent (90%) or greater. This ~~will~~ shall eliminate the need for frequent updating of FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT by the ~~State Milk Sanitation~~ Rating Agency. Certain precautions shall be taken to ensure that the raw supply remains at or above the required listed ninety percent (90%) Sanitation Compliance Rating. The name of each shipper of raw milk for the thirty (30) days preceding the rating shall be listed on the reverse side of FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT, along with their Sanitation Compliance Rating and the Expiration Rating Date of Rating. The milk plant shall be immediately withdrawn from the *IMS List* when milk is received from an unlisted source or from a source having a Raw Milk Sanitation Compliance Rating of less than ninety percent (90%). The appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs shall be immediately notified ~~should~~ shall either of the above events occur.

B.) **Option 2:** If the milk plant desires to be listed with the actual Sanitation Compliance Rating of the raw milk, a weighted average of all raw milk sources, the requirements of the preceding **Option** shall also apply except that:

- (i) The earliest rating date of any of the raw milk sources or the milk plant, whichever is earliest in time, ~~will~~ shall be shown as the earliest rating date on FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT.
- (ii) The Raw Milk Sanitation Compliance Rating ~~will~~ shall be prorated on a weighted basis as follows: ...

Page 27:

The SRO shall re-compute the Raw Milk Sanitation Compliance Rating whenever any of the raw milk sources is re-rated and a new FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT shall be submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

NOTE: The acceptance of milk, which has a Sanitation Compliance Rating ~~score~~ of less than ninety percent (90%), or is from an unlisted source, is a violation of the agreed upon provisions of **Options 1 and 2** and ~~would~~ shall initiate an immediate withdrawal of

the shipper from the *IMS List*.

The utilization of milk from a separately rated source which has an Enforcement Rating of less than ninety percent (90%) for longer than six (6) months, or which has been re-rated and received an Enforcement Rating of less than ninety percent (90%), following a rating with an Enforcement Rating of less than ninety percent (90%), is considered a violation of Section 11 of the *Grade "A" PMO* and ~~would~~ shall initiate an immediate withdrawal of the shipper from the ~~IMS list~~ *IMS List*.

3. PREPARATION OF THE "INTERSTATE MILK SHIPPER'S REPORT" FOR HACCP LISTINGS ...

a. A statement regarding the acceptability, or unacceptability of the HACCP System ~~will~~ shall be substituted on FORM FDA 2359i-INTERSTATE MILK SHIPPER'S REPORT for the Sanitation Compliance and Enforcement ~~Rating Scores~~ Ratings; and

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 to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs for quality assurance reviews with all FORM FDA 2359i's.

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

Page 38:

FORM FDA 2359i-INTERSTATE MILK SHIPPER'S REPORT

FRONT

STATE/COUNTRY

(10/4413)

Page 39

BACK

CITY AND STATE/COUNTRY

(10/4413)

Page 41:

FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT PAGE 1

TYPE OF AUDIT

STATE REGULATORY* STATE REGULATORY FOLLOW-UP STATE LISTING FDA AUDIT OF LISTING

STATE/COUNTRY

(10/4413)

Page 42:

PAGE 2

(10/4413)

Page 43:

PAGE 3

(10/4413)

Page 44:

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

2. Milk plant, receiving station or transfer station audited by a HACCP trained ~~State~~ Regulatory Agency auditor at the minimum required frequency and follow-ups conducted as required.

(10/4413)

Page 45:

FORM FDA 2359o-PERMISSION FOR PUBLICATION-*Interstate Milk Shipper's Listing*

Publication Permission Section

Permission is hereby granted to release and publish the above-stated Rating or HACCP Listing for use by ~~State and Territorial Milk Control Authorities~~ Regulatory Agencies and prospective purchasers. ...

(10/4413)

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

Pages 65 and 72:

FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT

FRONT

STATE/COUNTRY

(10/4413)

Pages 66 and 73:

BACK

CITY AND STATE/COUNTRY

Page 66:

ABC BTU	Bulls Role, State/Country
Udderly Delightful BTU	Tootle Town, State/Country
GMI Good Dairy	Paradise, State/Country

(10/4413)

Page 73:

Cows BTU #1	Midtown, State/Country
Udderly Delightful BTU #2	Tootle Town, State/Country
Moosville BTU	Cow Palace, State/Country

Page 68:

FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT

PAGE 1

TYPE OF AUDIT

STATE REGULATORY* STATE REGULATORY FOLLOW-UP STATE LISTING FDA AUDIT OF LISTING

STATE/COUNTRY

(10/4413)

Page 69:

PAGE 2

(10/4413)

Page 70:

PAGE 3

(10/4413)

Page 71:

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

2. Milk plant, receiving station or transfer station audited by a HACCP trained State Regulatory Agency auditor at the minimum required frequency and follow-ups conducted as required.

(10/4413)

Pages 74 and 75:

FORM FDA 2359o-PERMISSION FOR PUBLICATION-*Interstate Milk Shipper's Listing*

Publication Permission Section

Permission is hereby granted to release and publish the above-stated Rating or HACCP Listing for use by ~~State and Territorial Milk Control Authorities~~ Regulatory Agencies and prospective purchasers. ...

(10/4413)

Page 79:

APPENDIX A.

GUIDELINES FOR COMPUTING ENFORCEMENT RATINGS

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

PART I. DAIRY FARMS

NOTE: Enforcement evaluation is based on NCIMS requirements, not on individual State's and/or Country's laws or regulations.

The term "permit", whenever it appears in this document shall also mean a MC operating under the ICP possessing a valid MOA with a TPC.

1. All dairy ~~farms~~ farm operators hold valid permits (*Grade "A" PMO*, Section 3 - PERMITS). Prorate by the number of dairy farms in compliance.

Page 80:

5. Tuberculosis and Brucellosis Certification on file as required (*Grade "A" PMO*, Section 8 - ANIMAL HEALTH and APPENDIX A. - ANIMAL DISEASE CONTROL). All or nothing Item based on record verification.

a. Located in a Certified Brucellosis - Free Area as defined by USDA and enrolled in the testing program for such areas; or

- 1.) Meet USDA requirements for an individually certified herd; or
- 2.) Participate in an approved milk ring testing program; or
- 3.) Have individual blood agglutination testing done annually; or
- 4.) For goat, sheep, water buffalo, or any other hooved mammal herds/flocks, excluding cattle and bison, they are included in an official annual written certification from the State Veterinarian documenting their brucellosis-free status.

b. Located in an Area, which has a Modified Accredited Advanced Tuberculosis status or greater as determined by USDA. Other Areas or herds shall have passed an annual tuberculosis test or the Area has established a tuberculosis testing protocol that assures tuberculosis protection and surveillance of the dairy industry and is approved by FDA, USDA and the State Regulatory Agency....

e. Milk from Brucellosis reactor animals withheld as required.

NOTE: For the ICP, references to USDA and/or State within 5 above, shall mean the Government Agency responsible for animal disease control in the Country or region of that Country. The term "State Veterinarian" shall mean an individual veterinarian authorized for those activities in said Country or region of that Country.

6. Water samples tested and reports on file as required (*Grade "A" PMO*, Section 7 - STANDARDS FOR MILK AND MILK PRODUCTS, APPENDIX D. - STANDARDS FOR WATER SOURCES and APPENDIX G. - CHEMICAL AND BACTERIOLOGICAL TESTS). Prorate by number of dairy farms in compliance. A dairy farm missing one (1) water sample during a required time period ~~will~~ shall not receive any credit for this Item.

NOTE: A single dairy farm BTU ~~will~~ shall be prorated by the number of water samples tested during the required time period vs. the total number of water tests due per water system. ...

Page 81:

f. ~~No sampling~~ Sampling is not required for public, community, or rural water system(s), which are under EPA/~~State~~ applicable Government Water Control Authority and in compliance with their requirements. ...

NOTE: ~~State~~ Applicable Government Water Control Authority requirements, which are less stringent than the *Grade "A" PMO*, shall be superseded by the *Grade "A" PMO*. ~~State~~ Applicable Government Water Control Authority requirements, which are more strict than the *Grade "A" PMO*, shall not be considered in determining the acceptability of water supplies during ratings, check ratings, single-service listing evaluations and audits.

For Example: If the State applicable Government Water Control Authority's law required more frequent individual water supply samples to be taken, a SRO conducting a ~~sanitation~~ rating, which includes that dairy farm or milk plant, ~~will now shall~~ give that dairy farm or milk plant full credit for water sample frequency, if the *Grade "A" PMO* minimum sampling frequency requirement is met, even though, the State applicable Government Water Control Authority's frequency is not met.

Supplies other than individual water supplies, which have been approved as safe by the State applicable Government Water Control Authority, shall be considered to be acceptable sources, as provided in Section 7 of the *Grade "A" PMO*, for Grade "A" inspections, as well as for all other IMS purposes, without further inspection of the spring, well or reservoir treatment facility(ies), testing records, etc. ...

Page 82:

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 shall~~ be prorated by enforcement action(s) in compliance per dairy farm. Five (5) Categories (a-e) ~~will shall~~ be utilized for determining compliance with this Item and each ~~will shall~~ possess a value of twenty percent (20%) compliance. The Categories are as follows: ...

e. Category V: Hearing/Court Action

The Categories relate to the following Sanitation Requirements and Product Compliance. Compliance ~~will shall~~ be prorated based on **full** compliance with each of the five (5) Categories. ...

SANITATION REQUIREMENTS ...

Category II: Permit Suspension ...

c. Milk produced during suspension or while a monetary penalty is imposed for repeated inspection violations is not eligible for sale as Grade "A".

Page 83:

NOTE: *Grade "A" PMO*, Section 3 states: "The Regulatory Agency may forego suspension of the permit, provided the milk and/or milk product in violation is not sold or offered for sale as a Grade "A" milk and/or milk product. A Regulatory Agency may allow the imposition of a monetary penalty in lieu of a permit suspension, provided the milk and/or milk product in violation is not sold or offered for sale as a Grade "A" milk and/or milk product. Except, that a milk producer may be assessed a monetary penalty in lieu of permit suspension for violative counts provided"

The option to issue a monetary penalty in lieu of a permit suspension as cited above, shall not be applicable to a TPC authorized under the ICP. ...

PRODUCT COMPLIANCE ...

Category II: Permit Suspension

- a. All milk produced during a permit 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". ...

- 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.

NOTE: The option to issue a monetary penalty in lieu of a permit suspension as cited above, shall not be applicable to a TPC authorized under the ICP. ...

Page 84:

11. Records systematically maintained and current (*Grade "A" PMO*, Section 3 - PERMITS, Section 5 - INSPECTION OF DAIRY FARMS, Section 6 - EXAMINATION OF MILK AND MILK PRODUCTS, and Section 7 - STANDARDS FOR MILK AND MILK PRODUCTS). Make use of both general record-keeping deficiencies and record keeping by dairy farm to determine the value. The BTU ~~will~~ shall be prorated by the number of identified record-keeping deficiencies per dairy farm. The four (4) Categories (a-d) listed below ~~will~~ shall be utilized for determining compliance with this Item and each ~~will~~ shall possess a value of twenty-five percent (25%) compliance. Compliance ~~will~~ shall be prorated based on **full** compliance with each of the four (4) 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.)

- a. Category I: Permit records available, accurate and current, including permit suspension, impositions of a monetary penalty, notices, reinstatement, etc. The results shall be entered on appropriate ledger forms. The use of a computer or other information retrieval system may be used.

NOTE: The option to issue a monetary penalty in lieu of a permit suspension as cited above, shall not be applicable to a TPC authorized under the ICP. ...

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PART II. MILK PLANTS

NOTE: Enforcement evaluation is based on NCIMS requirements, not on individual State's and/or Country's laws or regulations.

The term "permit", whenever it appears in this document shall also mean a MC operating under the ICP possessing a valid MOA with a TPC. ...

Page 87:

6. Individual and cooling water samples tested and reports on file as required (*Grade "A" PMO*, ...

c. ~~No sampling~~ Sampling is not required for public, community, or rural water system(s), which are under EPA/~~State~~ applicable Government Water Control Authority and in compliance with their requirements. ...

Page 88:

j. Current records of sample results on file at the Regulatory Agency, back to the last rating.

NOTE: ~~State~~ Applicable Government Water Control Authority requirements, which are less stringent than the *Grade "A" PMO*, shall be superseded by the *Grade "A" PMO*. ~~State~~ Applicable Government Water Control Authority requirements, which are more strict than the *Grade "A" PMO*, shall not be considered in determining the acceptability of water supplies during ratings, check ratings, single-service listing evaluations and audits.

For Example: If the ~~State~~ applicable Government Water Control Authority's law required more frequent individual water supply samples to be taken, a SRO conducting a ~~sanitation~~ rating, which includes that ~~farm or~~ milk plant, ~~will now~~ shall give that ~~farm or~~ milk plant full credit for water sample frequency, if the *Grade "A" PMO* minimum sampling frequency requirement is met, even though, the ~~State~~ applicable Government Water Control Authority's frequency is not met.

Supplies other than individual water supplies, which have been approved as safe by the ~~State~~ applicable Government Water Control Authority, shall be considered to be acceptable sources, as provided in Section 7 of the *Grade "A" PMO*, for Grade "A" inspections, as well as for all other IMS purposes, without further inspection of the spring, well or reservoir treatment facility(ies), testing records, etc. ...

Page 89:

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~~ shall be prorated by enforcement action(s) in compliance. Five (5)

Categories ~~will~~ shall be utilized for determining compliance with this Item and each ~~will~~ shall possess a value of twenty percent (20%) compliance. The Categories are as follows: ...

The Categories relate to the following Sanitation Requirements and Product Compliance. Compliance ~~will~~ shall be prorated based on **full** compliance with each of the five (5) Categories. ...

SANITATION REQUIREMENTS ...

Category II: Permit Suspension ...

Page 90:

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”.

NOTE: *Grade “A” PMO*, Section 3 states: “The Regulatory Agency may forego suspension of the permit, provided the milk and/or milk product in violation is not sold or offered for sale as a Grade “A” milk and/or milk product. A Regulatory Agency may allow the imposition of a monetary penalty in lieu of a permit suspension, provided the milk and/or milk product in violation is not sold or offered for sale as a Grade “A” milk and/or milk product. ~~Except, that a milk producer may be assessed a monetary penalty in lieu of permit suspension for violative counts provided~~”

The option to issue a monetary penalty in lieu of a permit suspension as cited above, shall not be applicable to a TPC authorized under the ICP. ...

PRODUCT COMPLIANCE

Category II: Permit Suspension

a. All milk produced during a permit 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”.

NOTE: The option to issue a monetary penalty in lieu of a permit suspension as cited above, shall not be applicable to a TPC authorized under the ICP. ...

Page 91:

Category IV: Permit Reinstatement

a. All milk and/or milk product violations followed promptly by an inspection to determine the cause(s).

10. Records systematically maintained and current (*Grade “A” PMO*, Section 3 - PERMITS, Section 4 - LABELING, Section 5 - INSPECTION OF MILK PLANTS, Section 6 - EXAMINATION OF MILK AND MILK PRODUCTS, and Section 7 - STANDARDS FOR

MILK AND MILK PRODUCTS.) Make use of both general and specific record-keeping deficiencies to determine the value. The four (4) Categories (I-IV) listed below ~~will~~ shall be utilized for determining compliance with this Item and each ~~will~~ shall possess a value of twenty-five percent (25%) compliance. Compliance ~~will~~ shall be prorated based on **full** compliance with each of the four (4) 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.)

a. Category I: Permit records available, accurate and current, including permit suspension, imposition of a monetary penalty, notices, reinstatement, etc. The results shall be entered on appropriate ledger forms. The use of a computer or other information retrieval system may be used.

NOTE: The option to issue a monetary penalty in lieu of a permit suspension as cited above, shall not be applicable to a TPC authorized under the ICP. ...

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PART III. INDIVIDUAL SHIPPER RATING ...

NOTE: All records shall be summarized in ledger form. Computer ledgers are acceptable. Records include:

- a. Inspections of dairy farms, milk plants, receiving and transfer stations, samplers, ~~vehicles~~ milk tank trucks, etc.;
- b. Laboratory information, i.e., raw milk, ~~heat-treated milk~~, finished milk and/or milk products, vitamin assays, water, cooling media, etc.); and ...

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GUIDANCE FOR COMPUTING ENFORCEMENT CREDIT FOR PART I, ITEM 9 AND/OR PART II, ITEM 8 OF FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2)

FORM FDA 2359j-MILK SANITATION RATING REPORT- SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3) is shall be used to determine enforcement credit for Part I, Item 9, FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (Dairy Farms), and Part II, Item 8, FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (Milk Plant). Items 4 and 7 on FORM FDA 2359j-MILK SANITATION RATING REPORT- SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3) do not apply when calculating Enforcement Ratings for milk plants, receiving and transfer stations for FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), Part II, Item

8.

Item 1. Sampling Surveillance Officers (SSOs) Properly Certified

- a. All SSOs are certified by FDA.
- b. Certification is currently valid (three years).
- c. SSOs shall be a certified SRO, LEO or ~~State~~ Regulatory Supervisor per "Procedures" Section V., F. ...

Item 3. Sampling Surveillance Authority Properly Delegated ...

- c. Initial Delegation: Comparison evaluations shall be performed on at least five (5) bulk milk hauler/samplers during a routine milk pick-up at a ~~producer~~ dairy farm; one (1) plant sampler that collects raw and finished milk and/or milk product samples and single-service container/closures at one (1) milk plant, if applicable; and one (1) industry plant sampler that collects a raw milk sample from a milk tank truck at one (1) milk plant, if applicable, with at least eighty percent (80%) agreement on each listed Item.
- d. Re-delegation conducted at least each three (3) years. Comparison evaluations shall be performed on at least two (2) bulk milk hauler/samplers during a routine milk pick-up at a ~~producer~~ dairy farm; one (1) plant sampler that collects raw and finished milk and/or milk product samples and single-service containers/closures at one (1) milk plant, if applicable; and one (1) industry plant sampler that collects a raw milk sample from a milk tank truck at one (1) milk plant, if applicable, with at least eighty percent (80%) agreement on each listed Item.

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- e. Proper certification of industry field ~~person~~ personnel when applicable.

Item 4. Permit Issuance (Applies to Part 1-DAIRY Farms only.) ...

Item 5. Sampler (Including Dairy Plant and Industry Plant Samplers at the Receiving Site) Evaluated Every Two (2) Years and Reports Properly Filed

- a. Samplers shall have their sampling collection procedures evaluated by a certified SSO or a properly delegated Sampling Surveillance Regulatory Agency Official (dSSO) every two (2) years. SSOs or ~~properly delegated Sampling Surveillance Regulatory Officials~~ dSSOs are not required to be evaluated for sampling collection procedures. ...

Item 7. Permit Suspension, Revocation, Reinstatement, Hearings and/or Court Actions Ta as Required (Applies to Part 1-DAIRY FARMS only.) ...

Item 8. Records Systematically Maintained and Current

- a. Records of the delegation of sampling evaluation authority to other ~~State, Local,~~ Regulatory Agency or industry individuals on file and available for review with the ~~producer~~ dairy farm or milk plant records.
- b. Records of each sampler evaluation on file and available for review with the ~~producer~~ dairy farm or milk or plant records. ...

APPENDIX B ...

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Major (5 point)

2. Permanent in-line high pressure pump (power washer): Without acceptable protection, such as:

- a. Properly functioning low-pressure cut-off switch with a properly located test valve; and
b. Other methods acceptable to the State applicable Government Water Control Authority.

Minor (2 point)

2. Portable high pressure water pump (power washer): Without acceptable protection, such as:

- a. Separate water supply or reservoir;
b. Properly functioning low-pressure cut-off switch with a properly located test valve; and
C. Other methods acceptable to the State applicable Government Water Control Authority.
D.

MAKE THE FOLLOWING CHANGES TO THE 2011 EML:

Strike through text to be deleted and underline text to be added.

Cover:

2011 2013 Revision

Page ii:

TABLE OF CONTENTS

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SECTION 1: DEFINITIONS
SECTION 12: LABORATORY EVALUATION PROGRAMS
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SECTION 34: CERTIFICATION OF MILK LABORATORY CONTROL AGENCY MILK LABORATORY EVALUATION OFFICERS
SECTION 45: EQUIPMENT AND APPARATUS OF AID TO MILK LABORATORY EVALUATION OFFICERS

Re-number the remaining SECTIONS within the TABLE OF CONTENTS accordingly.

EVALUATION OF MILK LABORATORIES 2011 2013 Revision

INTRODUCTION

Official accreditation of milk laboratories and Certified Industry Supervisors (~~CIS~~ CISs) requires that the appropriate Federal or State milk laboratory control agency FDA/LPET or the appropriate Milk Laboratory Control Agency conduct an on-site survey to determine satisfactory performance of analysis in milk laboratories and performance of analysis by ~~CIS~~ CISs in facilities where the examinations, required by the *Grade 'A' "A" Pasteurized Milk Ordinance (Grade "A" PMO)*, are performed. In addition, satisfactory performance in the analysis of annual proficiency test samples ~~must~~ shall be demonstrated. An accredited milk laboratory may be an approved official or officially designated milk laboratory under the administrative control of a ~~federal, state or local~~ Regulatory authority Agency. Approval of Industry Supervisors (~~IS~~ ISs) and Industry Analysts (~~IA~~ IAs) requires verification of proficiency in performing drug residue analysis at least biennially, through on-site performance evaluation and/or analysis of split samples or by other means as noted in SECTION ~~42~~ below.

~~The State~~ A certified Laboratory Evaluation Officer (~~State~~ LEO) ~~will~~ shall use the appropriate FDA-2400 Series Forms when evaluating official laboratories, officially designated laboratories, ~~CIS, IS~~ CISs, ISs and ~~IA~~ IAs. The ~~Federal~~ FDA/LPET Laboratory Evaluation Officer (~~Federal~~ FDA/LPET LEO) ~~will~~ shall use the appropriate FDA-2400 Series Forms when evaluating State Central Milk Laboratories and ~~State~~ LEOs. Appropriate FDA-2400 Series Forms are those forms that have been approved by the NCIMS Laboratory Committee working cooperatively with the ~~Food and Drug Administration (FDA)~~ and the NCIMS Executive Board, and are effective 90 days after executive board approval. Approved forms shall be issued within 90 days of NCIMS Executive Board approval. If the FDA is unable to release the approved forms within the 90 day time frame, FDA/LPET shall issue a draft version of the 2400 series forms 90 days after NCIMS Executive Board approval.

~~Official Laboratory: An official laboratory is a biological, chemical or physical laboratory which is under direct supervision of the state or a local regulatory agency.~~

~~State Central Milk Laboratory: A State owned and operated Official Laboratory with analysts employed by the State working in conjunction with the State Regulatory Agency designated as the primary State laboratory for the examination of producer samples of Grade 'A' raw and commingled raw milk for pasteurization, pasteurized milk and milk products, and dairy waters, as necessary.~~

~~Officially Designated Laboratory: An officially designated laboratory is a commercial laboratory authorized to do official work by the regulatory agency, or a milk industry laboratory officially designated by the regulatory agency for the examination of producer samples of Grade 'A' raw milk for pasteurization and commingled milk tank truck samples of~~

raw milk for drug residues.

~~Certified Industry Supervisor (CIS): An industry supervisor who is evaluated and listed by a State LEO as certified to conduct drug residue screening tests at industry drug residue screening sites for PMO, Appendix N regulatory actions (confirmation of tankers, producer trace back and/or permit actions).~~

Page 2:

~~Industry Supervisors (IS): An individual trained by the State LEO who is responsible for the supervision and training of industry analysts who test milk tank trucks for Appendix N drug residue requirements.~~

~~Industry Analyst (IA): A person under the supervision of the CIS or IS who is assigned to conduct screening of milk tank trucks for Appendix N drug residue requirements.~~

~~BactoScan Industry Operator (BIO): A person who operates a BactoScan FC under the supervision of a certified BactoScan analyst and analyzes samples for regulatory compliance.~~

~~Food and Drug Administration (FDA) laboratory accreditation procedures provide a national base for the uniform collection and examination of milk, in compliance with the sanitation standards of the Grade "A" PMO.~~

Uniform accreditation of milk laboratories is maintained by the following two (2) functions:

1. FDA accreditation of ~~state~~ State central milk laboratories and certification of analysts is based on:
 - ~~(a)a. satisfactory~~ Satisfactory triennial on-site evaluations of laboratory facilities, equipment, records, and analyst performance of techniques, and
 - ~~(b)b. satisfactory~~ Satisfactory annual proficiency testing (the examination of split milk samples) to continuously appraise analyst performance.

2. FDA certification of State LEOs who:
 - ~~(1)a. accredit~~ Accredit local laboratories and certify analysts and ~~CIS~~ CISs based on:
 - ~~(a1) satisfactory~~ Satisfactory biennial on-site evaluations of laboratory facilities, equipment, records and analyses and
 - ~~(b2) satisfactory~~ Satisfactory annual proficiency testing which meets established national standards ~~and~~.
 - ~~(2)b. approve IS and IA~~ Approve ISs and IAs (who only screen for drugs) based on:
 - ~~(a1) verification~~ Verification that each IS has been trained (by conducting required workshops for all industry supervisors) and has established a program that ensures the proficiency of the IA they supervise; ~~and~~
 - ~~(b2) verification~~ Verification that each IS and IA has demonstrated proficiency in performing drug residue analysis at least biennially. Verification of proficiency may include an analysis of split samples and/or an on-site performance evaluation or another proficiency determination that the State LEO and the FDA/LPET agree is appropriate. (Grade "A" PMO, Appendix N)

SECTION 1: DEFINITIONS

1. BACTOSCAN INDUSTRY OPERATOR (BIO): A person who operates a BactoScan FC under the supervision of a certified BactoScan analyst and analyzes samples for regulatory compliance.

2. CERTIFIED INDUSTRY SUPERVISOR (CIS): An industry supervisor who is evaluated and listed by a LEO as certified to conduct drug residue screening tests at industry drug residue screening sites for *Grade “A” PMO*, Appendix N regulatory actions (confirmation of tankers milk tank trucks, producer trace back and/or permit actions).

3. CERTIFIED MILK LABORATORY EVALUATION OFFICER (LEO): A Regulatory Agency or Milk Laboratory Control Agency employee who has been certified by the Food and Drug Administration (FDA) Laboratory Proficiency Evaluation Team (LPET), using the Evaluation of Milk Laboratories (EML) to evaluate milk laboratories for the purpose of accrediting or approving laboratories that conduct official NCIMS milk testing has a valid certificate of qualification.

4. FOOD AND DRUG ADMINISTRATION/LABORATORY PROFICIENCY EVALUATION TEAM LABORATORY EVALUATION OFFICER (FDA/LPET LEO): A Food and Drug Administration (FDA) employee that has been internally standardized to evaluate State Central Milk Laboratories for the purpose of accreditation to conduct official NCIMS milk testing. They are standardized to evaluate and certify milk laboratory evaluation officers (LEOs) working for a Regulatory Agency or Milk Laboratory Control Agency for the purpose of accrediting other official and officially designated laboratories participating in the NCIMS Grade “A” Milk Safety Program.

5. INDUSTRY ANALYST (IA): A person under the supervision of the a CIS or IS who is assigned to conduct screening of milk tank trucks for Appendix N drug residue requirements.

6. INDUSTRY SUPERVISORS (IS): An individual trained by the LEO who is responsible for the supervision and training of industry analysts who test milk tank trucks for Appendix N drug residue requirements.

7. INTERNATIONAL CERTIFICATION PROGRAM (ICP): The International Certification Program (ICP) means the NCIMS voluntary program designed to utilize Third Party Certifiers (TPCs) authorized by the NCIMS Executive Board in applying the requirements of the NCIMS Grade “A” Milk Safety Program for Milk Companies (MCs) located outside the geographic boundaries of NCIMS Member States that desire to produce and process Grade “A” milk and/or milk products for importation into the United States.

8. MILK LABORATORY CONTROL AGENCY: A Milk Laboratory Control Agency shall mean a governmental or other Regulatory Agency body which has adopted an ordinance, rule or regulation in substantial compliance with the current edition of the *Evaluation of Milk Laboratories (EML)* and is responsible for the enforcement of such ordinance, rule or regulation in substantial compliance with the Grade “A” Milk Safety Program for a listed milk laboratory. The Milk Laboratory Control Agency has authority, recognized by the National Conference on Interstate Milk Shipments (NCIMS), to oversee and control the activities of

milk laboratories and/or personnel involved with official NCIMS Grade “A” milk testing. The term, “Milk Laboratory Control Agency”, whenever it appears in the *EML* shall also mean the appropriate Third Party Certifier (TPC) having jurisdiction and control over the matters cited within this *EML*.

9. OFFICIAL LABORATORY: An official laboratory is a biological, chemical or physical laboratory which is under the direct supervision of the Regulatory Agency or Milk Laboratory Control Agency.

10. OFFICIALLY DESIGNATED LABORATORY: An officially designated laboratory is a commercial laboratory authorized to do official work by the Regulatory Agency, or a milk industry laboratory officially designated by the Regulatory Agency or Milk Laboratory Control Agency for the examination of producer samples of Grade 'A' raw milk for pasteurization and commingled milk tank truck samples of raw milk for drug residues.

11. RATING AGENCY: A Rating Agency shall mean a State Agency, which certifies interstate milk shippers (BTUs, receiving stations, transfer stations, and milk plants) as having attained the Sanitation Compliance and Enforcement Ratings necessary for inclusion on the *IMS List*. The ratings are based on compliance with the requirements of the *Grade “A” PMO* and were conducted in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers (MMSR)*. Ratings are conducted by FDA certified Milk Sanitation Rating Officers (SROs). They also certify single-service containers and closures for milk and/or milk products manufacturers for inclusion on the *IMS List*. The certifications are based on compliance with the requirements of the *Grade “A” PMO* and were conducted in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers (MMSR)*. The definition of a Rating Agency also includes a Third Party Certifier (TPC) that conducts ratings and certifications of Milk Companies (MCs) located outside the geographic boundaries of NCIMS member States that desire to produce and process Grade “A” milk and/or milk products for importation into the United States.

12. REGULATORY AGENCY: A Regulatory Agency shall mean an agency which has adopted an ordinance, rule or regulation in substantial compliance with the current edition of the *Grade “A” PMO* and is responsible for the enforcement of such ordinance, rule or regulation, which is in substantial compliance with the *Grade “A” PMO* for a listed interstate milk shipper and milk laboratory. The term "Regulatory Agency", whenever it appears in the *EML* shall also mean the appropriate Third Party Certifier (TPC) having jurisdiction and control over the matters cited within this *EML*.

13. STATE CENTRAL MILK LABORATORY: A State owned and operated Official Laboratory with analysts employed by the State working in conjunction with the State Regulatory Agency designated as the primary State laboratory for the examination of producer samples of Grade ‘A’ raw and commingled raw milk for pasteurization, pasteurized milk and milk products, and dairy waters, as necessary.

14. THIRD PARTY CERTIFIER (TPC): A Third Party Certifier (TPC) is a non-governmental individual(s) or organization authorized under the NCIMS voluntary International Certification Program (ICP) that is qualified to conduct the routine regulatory functions and enforcement requirements of the *Grade “A” PMO* in relationship to milk plants.

receiving stations, transfer stations, associated dairy farms, bulk milk hauler/samplers, milk tank trucks, milk transportation companies, dairy plant samplers, industry plant samplers, milk distributors, etc. participating in the NCIMS voluntary International Certification Program (ICP). The Third Party Certifier (TPC) provides the means for the rating and listing of milk plants, receiving stations, transfer stations and their related raw milk sources. They also conduct the certification and IMS listing of related milk and/or water laboratories and related single-service container and closure manufacturers on the *Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS) List*. To be authorized under the NCIMS voluntary International Certification Program (ICP), a valid Letter of Understanding (LOU) shall be signed between the NCIMS Executive Board and the Third Party Certifier (TPC).

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SECTION 12: LABORATORY EVALUATION PROGRAMS

An evaluation of a milk laboratory ~~must~~ shall 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~~ FDA/LPET LEO or LEO shall determine if the laboratory facilities, equipment, records and techniques of analysts are in compliance with the FDA-2400 Series Forms.

A copy of the “Grade ~~‘A’~~ ‘A’ Milk Laboratory Evaluation Request and Agreement Form” (see page 20) ~~must~~ shall be signed by a representative of the facility prior to the initiation of the survey. This document ~~must~~ shall be maintained on file by the ~~Federal or State~~ FDA/LPET LEO or LEO.

A set of completed evaluation forms 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~~ shall 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 sixty (60) days of the initial, biennial/triennial anniversary or supplemental date of the laboratory evaluation to the Official Milk Laboratory/CIS, the appropriate ~~Food and Drug Administration~~ FDA 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~~ shall include the narrative report and may include copies of the completed FDA-2400 Series Forms. Reports to the FDA Regional Office and FDA/LPET shall be sent electronically and shall include the narrative report and appropriate, completed FDA summary template only (see page pages 37 – 40). ...

CERTIFICATION/APPROVAL OF MILK LABORATORY ANALYSTS

Certification of milk laboratory analysts by ~~the Federal or State~~ a FDA/LPET LEO or LEO shall be based on the following criteria:

1. Evaluations of State central milk laboratories' Central Milk Laboratory 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 ~~Federal~~ FDA/LPET LEO shall schedule a mutually agreeable date within thirty (30) days of the request for an evaluation.
2. Evaluations of other milk laboratories ~~within a state~~ shall be scheduled and performed by their biennial expiration date. Milk laboratories ~~within a state~~ shall submit requests, in writing, for on-site evaluation of new analyst(s) performance of techniques, new methods and/or new facilities to the ~~State~~ LEO. The ~~State~~ LEO shall schedule a mutually agreeable date within 30 days of the receipt of the request for an evaluation. ...

Page 4:

5. Analysts meet the performance levels of the proficiency testing program (SECTION 23). The ~~State~~ LEO may issue a certificate of approval to each laboratory analyst who meets the stated criteria in numbers 3 and 4 above.
6. Vitamin testing laboratories have submitted satisfactory quality control information, use methods acceptable to the FDA or other official methodologies which give statistically equivalent results to the FDA methods, have one or more certified analysts who have satisfactorily participated in the vitamin split sample program and have met performance levels of the proficiency testing program (SECTION 23).

Analysts seeking certification or approval who are employed in laboratories not previously approved, or laboratories that have lost accreditation or approval and are seeking Recertification, may be approved to conduct official examinations only if criteria 3 and 4 above are met. When such analysts successfully complete the next official proficiency tests administered by the ~~State~~ LEO, a certificate of approval may be issued to such analyst. If such analyst does not successfully meet the performance levels of the proficiency testing program, the approval to conduct official examinations shall be withdrawn. ...

When a new analyst is assigned to an accredited laboratory between on-site evaluations, conditional approval status ~~will~~ shall be provided to the new analyst upon satisfactory completion of criteria 4 or 5 above. Full certification ~~will~~ shall follow after acceptable completion of both criteria 4 and 5 above. Conditionally approved analysts failing to meet the established applicable criteria of laboratory performance during an on-site laboratory evaluation ~~will~~ shall have their conditionally approved status revoked.

The ~~CIS~~ CISs and certified analysts ~~must~~ shall participate, at least annually, in proficiency testing (the examination of milk split samples) for those specific procedures for which they are certified. Failure without cause to participate in the annual split sample evaluation or failure to meet established satisfactory performance criteria ~~will~~ shall result in the ~~CIS~~ CISs or certified analyst(s) having their certification status downgraded from full to provisional. Failure of a

provisionally certified analyst or ~~CIS~~ CISs to participate in the examination of or to meet established satisfactory performance levels on the next set of split samples ~~will~~ shall result in withdrawal of their certification.

A CIS or certified analyst that loses their certification for one (1) or more tests cannot examine official samples using a test for which their certification was withdrawn. Recertification procedures are shown in “SECTION 23: PROFICIENCY TESTING PROGRAMS”.

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~~ Regulatory Agency, the ~~state milk sanitation rating agency~~ 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.

Upon notice of revocation, the certificate, if issued, shall be returned to the issuing ~~State~~ LEO within ninety (90) days.

ACCREDITATION/APPROVAL OF MILK LABORATORIES

Accreditation or approval of milk laboratories by ~~Federal or State milk laboratory control agencies~~ FDA/LPET or Milk Laboratory Control Agencies shall be based on meeting the following requirements:

1. The laboratory facilities, equipment, procedures and records ~~must~~ shall meet the requirements stated on the appropriate FDA-2400 Series Forms and for ~~CIS~~ CISs, appropriate Appendix N 2400 Series Forms, as determined by an on-site evaluation.
2. All official examinations required by the Grade “A” PMO ~~must~~ shall only be performed by certified analysts or ~~CIS~~ CISs.
3. Vitamin testing laboratories have submitted satisfactory quality control information, use methods acceptable to the FDA or other official methodologies which give statistically equivalent results to the FDA methods, have one or more certified analysts who have satisfactorily participated in the vitamin split sample program and have met performance levels of the proficiency testing program (SECTION 23).

The ~~State~~ LEO may issue a certificate of accreditation or approval to each official, commercial, and industry laboratory meeting criteria 1 and 2 above.

When an accredited laboratory changes location or undergoes substantial remodeling, an evaluation of the new laboratory or screening facility is required within three (3) months. ~~No~~ An evaluation of personnel or procedures is not required at this time. ...

When a certified analyst or CIS leaves an accredited laboratory, the laboratory/facility manager ~~must~~ shall notify the ~~Federal or State~~ FDA/LPET LEO or 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~~ shall lose accreditation. Official examinations cannot be conducted at non-accredited laboratories. When a laboratory or CIS facility loses its accreditation because of a lack of certified analysts, or for some other reason, the ~~Federal or State~~ FDA/LPET LEO or LEO shall immediately notify the milk laboratory involved, the ~~state milk regulatory agency, the state milk sanitation rating agency~~ respective Regulatory/Rating Agency, any ~~out-of-state milk regulatory agencies~~ other Regulatory/Rating Agency that oversees locations where known customers of that laboratory 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 any FDA/LPET notification, changes in accreditation shall be indicated on the appropriate, completed FDA summary template and shall be submitted electronically.

Page 6:

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~~ respective Regulatory/Rating Agency, any ~~out-of-state milk regulatory agencies~~ other Regulatory/Rating Agency that oversees locations where known customers of that laboratory 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 ninety (90) days. ...

Additionally, the laboratory shall notify its customers in writing, that it has withdrawn or been decertified and shall not represent itself as an official laboratory or officially designated laboratory, for those decertified or unapproved procedures under the agreements of the NCIMS. A copy of the generic notification ~~must~~ shall be sent to the ~~State~~ LEO. Decertification ~~will~~ shall remain in effect until measures are taken by the laboratory to attain compliance and another survey is completed successfully.

APPROVAL OF INDUSTRY ANALYSTS/INDUSTRY SUPERVISORS

Approval of Industry Supervisors (~~IS~~ ISs) and Industry Analysts (~~IA~~ IAs) by the ~~State~~ LEOs shall be based on meeting all of the following requirements: ...

2. All screening tests required by the Grade "A" PMO, Appendix N ~~must~~ shall only be performed by approved ~~IS, IA~~ ISs, IAs or by a certified entity. ...

Page 7:

5. Approval of ~~IS and IA~~ ISs and IAs require verification of proficiency in performing drug residue analyses at least biennially, through on site performance evaluation and/or analysis of split samples, or another proficiency determination that the ~~State~~ LEO and the FDA/LPET agree is appropriate. (~~PMO, Refer to~~ Appendix N of the Grade "A" PMO.)
6. The IS has attended and received training by the ~~State~~ LEO. This training ~~must~~ shall be documented.

The IS shall report to the ~~State~~ LEO the result of all competency evaluations performed by ~~IA~~ IAs. The name of each IS and IA (as well as their training and evaluation status) shall be maintained by the ~~State~~ LEO and updated as replacement, additions and/or removals occur. The ~~State~~ LEO shall verify (document) that each IS has established a program that ensures the proficiency of the ~~IA~~ IAs they supervise. The ~~State~~ LEO shall also verify that each IS and IA has demonstrated proficiency in performing drug residue analysis at least biennially. Verification may include an analysis of split samples and/or an on-site performance evaluation or another proficiency determination that the ~~State~~ LEO and the FDA/LPET agree is appropriate. ...

Failure by the ~~IS~~ ISs or the ~~IA~~ IAs to demonstrate adequate proficiency to the ~~State~~ LEO shall lead to their removal from the ~~State~~ LEO list of ~~IS/IA~~ Approved ISs/IAs. Re-instatement of their testing status shall only be possible by completing retraining and/or successfully analyzing split samples and/or passing an on-site evaluation or otherwise demonstrating proficiency to the ~~State~~ LEO. Analysts not on the ~~State~~ LEO list of ~~Approved IS/IA~~ ISs/IAs are not approved to test bulk milk in the Appendix N program.

When a screening facility loses its approval because of a lack of approved ~~IS or IA~~ ISs or IAs, 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~~ respective Regulatory/Rating Agency, any ~~out-of-state milk regulatory agencies~~ other Regulatory/Rating Agency that oversees locations where known customers of that laboratory 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.

Page 8:

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~~ respective Regulatory/Rating Agency, any ~~out-of-state milk regulatory agencies~~ other Regulatory/Rating Agency that oversees locations where known customers of that laboratory 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.

Additionally, the screening facility shall notify its customers in writing that it has been withdrawn or has lost its approval and shall not represent itself as an approved screening facility under the agreements of the NCIMS. A copy of the generic notification ~~must~~ shall be sent to the ~~State~~ LEO. Loss of approval ~~will~~ shall remain in effect until measures are taken by the screening facility to attain compliance and another survey is completed successfully.

APPROVAL OF BACTOSCAN INDUSTRY OPERATORS

Approval of BactoScan Industry Operators (BIO) shall be based on meeting the following

requirements:

1. The industry operator ~~must~~ shall complete the BIO operating protocols, training and oversight specified in the training procedure document.
2. The laboratory ~~must~~ shall maintain one (1) certified BactoScan analyst (see current FDA 2400 series form) for training and ongoing oversight of the BIO. ...

Page 9:

SECTION 23: PROFICIENCY TESTING PROGRAMS

~~The Food and Drug Administration~~ FDA/LPET shall split samples annually with all ~~federally~~ FDA/LPET certified analysts of each ~~State/Territory (hereafter noted as State)~~ central ~~accredited milk laboratory~~ Milk Laboratory Control Agency's accredited Central Milk Laboratory. ~~State milk laboratory control agencies~~ Milk Laboratory Control Agencies shall split samples at least annually with all ~~state~~ certified analysts of each official, officially designated accredited milk laboratory, and all ~~CIS~~ CISs. ~~State milk laboratory control agencies~~ Milk Laboratory Control Agencies shall verify that each IS and IA has demonstrated proficiency in performing drug residue analysis at least biennially through on-site performance evaluation and/or analysis of split samples, or another proficiency determination that the ~~State~~ LEO and the FDA/LPET agree is appropriate.

~~State milk laboratory control agencies~~ Milk Laboratory Control Agencies having less than ten (10) analysts (total) in their milk laboratory program are to develop joint ~~state~~ proficiency testing programs with other ~~states~~ Milk Laboratory Control Agencies, which can meet the criteria for certification of analysts and accreditation of laboratories. In cases where a minimum number of analysts (\geq ten (10)) are not available, evaluation of proficiency ~~will~~ shall be made by a determination that the ~~State~~ LEO and the FDA/LPET agree is appropriate.

An acceptable annual proficiency testing program shall meet the following applicable criteria:
...

4. When a CIS examines bulk milk tanker milk or its equivalent for Appendix N purposes, a minimum of eight (8) samples shall be analyzed utilizing the test kit(s) for which that CIS is certified or approved, or for which the CIS is seeking certification. In general, the milk samples shall consist of the members of the beta-lactam family, at the safe/tolerance levels, which the test kit(s) is designed to detect as well as milk samples ~~containing no~~ that do not contain animal drug residues. The CIS may misidentify one (1) of the samples and maintain and/or gain certification. If more than one (1) sample is misidentified, the CIS falls one (1) level of certification. If this occurs twice consecutively, the CIS is no longer certified or approved (rules for Recertification of laboratories apply).

Page 10:

5. When an IS or an IA examines bulk milk tanker milk or its equivalent for Appendix N purposes, a minimum of eight (8) samples shall be analyzed utilizing the test kits for which that IS or IA is approved or for which the IS or IA is seeking approval. In general, the

milk samples shall consist of members of beta-lactam family, at the safe/tolerance levels, which the test kits are designed to detect as well as milk samples ~~containing no~~ that do not contain animal drug residues. The IS or IA may misidentify one (1) of the samples and maintain and/or gain approval. If more than one (1) sample is misidentified, the IS or IA falls one (1) level of approval. If this occurs twice consecutively, the IS or IA is no longer approved. Re-instatement of their testing status shall only be possible by completing retraining and/or successfully analyzing split samples and/or passing an on-site evaluation or otherwise demonstrating proficiency to the State LEO.

6. Each analyst certified to perform visual drug residue tests ~~will~~ shall participate in annual proficiency tests to demonstrate their ability to detect the beta-lactams at safe/tolerance level per kit label claim (Penicillin G, Cloxacillin, Cefotiofur, and Cephapirin) using blind samples with duplicate negatives. A minimum of six (6) samples may be used. However, with six (6) samples ALL results ~~must~~ shall be correct. If eight (8) samples are used, an analyst/CIS may miss one (1) and still pass the proficiency test. ...

SPLIT SAMPLE ANALYSIS ...

The Standard Plate Count (SPC), Petrifilm Aerobic Count (PAC), Plate Loop Count (PLC), BactoScan FC Count (BSC), Spiral Plate Count Method (SPLC), Direct Microscopic Somatic Cell Count (DMSCC), Electronic Somatic Cell Count (ESCC), Electronic Phosphatase Count and Vitamin A and D₃ result of each certified analyst shall fall within the limits shown in Table 2, page 28.

The steps for statistical analysis of split sample results are as follows: ...

2. Calculate the logarithmic mean for the ~~Standard Plate Count SPC, Petrifilm Aerobic Count PAC, Plate Loop Count PLC, BactoScan FC Count (BSC), Spiral Plate Count Method (SPLC), Direct Microscopic Somatic Cell Count DMSCC, Electronic Somatic Cell Count ESCC,~~ Electronic Phosphatase Count and Vitamin A and D₃ results of each test sample; using a table of common logarithms, list the logarithms of all analyst counts for a given sample. Calculate the mean of the logarithms for the sample. ...

Page 11:

ANALYST PERFORMANCE LEVEL

Analysts certified to perform the examinations required by the “Grade “A” PMO² shall meet the following performance levels on an annual basis.

1. Analysts certified to perform the ~~Standard Plate Count SPC, Petrifilm Aerobic Count PAC, Plate Loop Count PLC, BactoScan FC Count (BSC), Spiral Plate Count Method (SPLC), Direct Microscopic Somatic Cell Count DMSCC, Electronic Somatic Cell Count ESCC,~~ Electronic Phosphatase Count and Vitamin A and D₃ analysis, and BIOs approved to operate a BactoScan FC shall meet the acceptance limits and performance levels shown in Tables 2 and 3, page 28.

Page 12:

2. Analysts certified to perform inhibitor tests shall detect samples that contain beta-lactam or other animal drug residues detectable by the appropriate official test for the drug and product. If using a drug other than beta-lactam, samples ~~must~~ shall be spiked in duplicate. See Table 3, page 28. ...
5. ~~Certified Industry Supervisors~~ CISs certified to perform Appendix N test(s) for beta-lactam drugs shall detect members of the beta-lactam family, at the safe/tolerance levels, which the test kit(s) is designed to detect. See Table 3, page 28.

Fully certified analysts not meeting the described performance levels shall be provisionally certified for the test procedure(s) in which they exceed the maximum number of unacceptable results on samples. Provisionally certified analysts can regain full certification status by meeting satisfactory performance levels on the next set of split samples. If a provisionally certified analyst does not meet satisfactory performance levels on the next set of split samples, certification to perform the specific test(s) ~~will~~ shall be withdrawn. An analyst who has lost certification may be required to participate in a training program acceptable to the ~~milk laboratory certifying authority~~ Milk Laboratory Control Agency before requesting recertification. Recertification after training shall be based on the analyst meeting the certification criteria described in SECTION ~~42~~: LABORATORY EVALUATION PROGRAMS. A certified analyst may only become conditionally approved again by the route by which he/she lost certification, i.e. if the analyst lost certification due to failure on milk split samples then he/she can only become conditionally certified by passing the next set of milk split samples. If the analyst failed an on-site evaluation that leads to his/her loss of certification then he/she ~~must~~ shall pass the next on-site certification to become conditionally certified.

~~BactoScan Industry Operators~~ BIOs performance levels shall follow the performance procedures indicated above for fully certified analysts. ...

Page 13:

SPLIT SAMPLES – CHEMISTRY

VITAMINS

The Grade “A” Vitamin Proficiency Test Program is operated by the FDA/LPET. In order to be accredited and be listed, laboratories ~~must~~ shall have analysts who have satisfactorily participated in at least two (2) consecutive split sample analyses and ~~must~~ shall have submitted satisfactory method validation and quality control/quality assurance (QC/QA) information. Participation in proficiency testing alone does not satisfy the criteria for analyst certification and laboratory accreditation.

The Grade A “A” Vitamin Proficiency Testing Program involves the analysis of sets of four (4) samples sent to participating laboratories every four (4) months, i.e., three (3) times a year with a total of twelve (12) samples. Certification status is based in part on the ability of analysts to analyze samples and have their results fall within limits ($L_1=0.300$ and $L_2=0.200$, based on the statistical parameters set at the 1995 NCIMS Conference in St. Louis, MO).

Conditional certification is granted to an analyst (not to a laboratory) when the analyst has satisfactorily analyzed two (2) sets of samples (eight (8) samples in two (2) consecutive shipments). Analysts may have one (1) unsatisfactory result, i.e., miss (out of limits) one (1) sample, and still be considered as having satisfactory performance. After analyzing the next consecutive set of samples the analyst is considered fully certified if ~~no~~ not more than 2 two (2) samples have been missed over the course of a one (1) year period (twelve (12) consecutive samples analyzed).

Once fully certified, analysts maintain certification by satisfactorily analyzing all three (3) sets of split samples each year. During the course of the year full certification is maintained if ~~no~~ not more than two (2) samples (of twelve (12)) are missed. Failure without cause to analyze all twelve (12) samples during the course of the year ~~will~~ shall result in the down grading of an analyst's status. It is imperative that laboratory schedules be set up to allow for the analysis of these samples. If a fully certified analyst misses more than two (2) samples (of twelve (12)) then that analyst ~~will~~ shall be down graded to provisional certification. Full certification ~~will~~ shall be regained if that analyst misses ~~no~~ not more than one (1) sample of the next eight (8) that he/she analyzes. Provisionally or conditionally certified analysts that miss more than one (1) sample in the next eight (8) samples analyzed after receiving the respective status ~~will~~ shall have their certification/approval removed.

Once certification/approval is removed an analyst may only regain conditional certification by satisfactory performance on the next eight (8) samples, i.e., miss ~~no~~ not more than one (1) sample. Full certification requires that the analyst meet the criteria described above.

For split sample purposes each analyst ~~must~~ shall independently analyze the samples. Routine analysis may be performed by multiple analysts working together or by partitioning duties. Certified analysts are responsible for conducting official analysis. Non-certified analysts may assist in analysis but may not solely perform official analyses or report official results.

Re-entry of laboratories that have voluntarily withdrawn or laboratories that have had their accreditation removed ~~is~~ are subject to meeting all of the requirements needed from a new laboratory, including all quality control (QC) information. It is the responsibility of the laboratory to inform the FDA/LPET when a certified analyst is no longer employed at that laboratory. A laboratory that loses all of their certified analysts is no longer accredited to do official work and ~~must~~ shall seek new laboratory entry prior to resuming official analysis. ..

Page 14:

WATER MICROBIOLOGY

Laboratories using EPA or ~~State~~ other officially administrated programs for water analysis are not required to meet the intentions of this Section. ~~State administered programs~~ Programs administered by ~~laboratory control agencies~~ Milk Laboratory Control Agencies include central, official, officially designated and other water testing laboratories sanctioned by the ~~state~~ Milk Laboratory Control Agencies and participation in a split sample program is voluntary.

Each State central accredited milk laboratory, and all ~~State~~ official, officially designated

accredited milk laboratories not participating in an EPA or ~~State~~ other officially administered program for water analysis shall participate annually in a microbiological proficiency testing program for each water analysis methodology for which the laboratory is certified. The proficiency testing samples are to be provided by ~~State programs~~ Milk Laboratory Control Agencies or through private providers. ...

Page 15:

LABORATORY PERFORMANCE LEVEL ...

Fully accredited laboratories not meeting the described performance levels shall be provisionally accredited for the test procedure(s) in which they exceed the maximum number of unacceptable results on samples. Provisionally accredited laboratories can regain full accreditation status by meeting satisfactory performance levels on the next set of split samples. If a provisionally accredited laboratory does not meet satisfactory performance levels on the next set of split samples, accreditation to perform the specific test(s) ~~will~~ shall be withdrawn. A laboratory that has lost their accreditation ~~must~~ shall participate in a training program acceptable to the ~~milk laboratory certifying authority~~ Milk Laboratory Control Agency before requesting ~~reaccreditation~~ re-accreditation. Re-accreditation after training shall be based on the laboratory meeting the accreditation criteria described in SECTION ~~42~~: LABORATORY EVALUATION PROGRAMS.

Copies of the proficiency testing report, including tabulation of laboratory results, shall be sent within four (4) months of the split sample examination date to the participating laboratory, the appropriate ~~Food and Drug Administration~~ FDA Regional Office; and the FDA/LPET.

Page 16:

SECTION 34: CERTIFICATION OF MILK LABORATORY CONTROL AGENCY MILK LABORATORY EVALUATION OFFICERS

Initial certification of a ~~State~~ LEO shall be based on meeting the following criteria:

1. The individual ~~must~~ shall be a ~~State government~~ an employee of a Regulatory or a Milk Laboratory Control Agency 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 when accompanied by a representative of the ~~FDA/LPET~~ FDA/LPET on an initial check laboratory survey. The ~~Federal~~ FDA/LPET LEO shall accompany the ~~State~~ LEO to not more than two (2) laboratories/facilities during an initial check survey for initial certification purposes. Initial check surveys (for certification) should not be conducted at sites that have been evaluated within the past ninety (90) days.
2. The individual ~~must~~ shall submit an acceptable written report of the milk laboratory initial check survey to the FDA/LPET within sixty (60) days of the evaluation. Reports to the appropriate 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 pages 37 – 40).

3. The individual ~~must~~ shall attend the Milk Laboratory Evaluation Officers Workshop (FDA Course FD373) 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~~ shall attend Course FD374 “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 ~~will~~ shall be considered official.

Conditional certification of a new ~~State~~ LEO can occur following the initial check survey described above. Full certification ~~will~~ shall 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 Milk Laboratory Evaluation Officers Workshop, unless excused with cause by FDA/LPET, ~~will~~ shall require that the ~~State~~ LEO ~~must~~ restart the process. The ~~State~~-LEO candidate would then be required to participate in ~~another~~ a new check survey with a representative of the FDA/LPET, and then attend the next scheduled Milk Laboratory Evaluation Officers Workshop.

Recertification of the ~~State~~ LEO ~~will~~ shall occur triennially, and ~~will~~ shall be based on satisfactorily meeting the following criteria:

1. The individual ~~must~~ shall ~~be a State government~~ an employee of a Regulatory Agency or a Milk Laboratory Control Agency 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 when accompanied by a representative of the FDA/LPET on a check laboratory survey. The ~~Federal~~ FDA/LPET LEO shall accompany the ~~State~~ LEO to not more than two (2) laboratories/facilities during a check survey for recertification purposes.

Page 17:

2. The individual ~~must~~ shall submit an acceptable written report of the milk laboratory check survey to the FDA/LPET within sixty (60) days of the evaluation. Reports to the appropriate 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 37 – 40).
3. The individual ~~must~~ shall have all laboratory evaluations, proficiency test examinations, and reports current (in particular, biennial surveys ~~must~~ shall be performed within the month of their anniversary date).
4. The individual ~~must~~ shall have prepared and transmitted, at least annually, a summary list of certified and approved analysts and procedures by laboratory to the ~~state milk sanitation rating agency~~ Regulatory Agency and/or Rating Agency and the FDA/LPET.
5. The individual has met the responsibilities for the training of ~~Industry Supervisors~~ ISs.

6. The individual ~~must~~ shall attend the Milk Laboratory Evaluation Officers Workshop once every three (3) years.
7. The individual ~~must~~ shall not fail, without cause, to attend an FDA Regional Milk Seminar. If a region holds a FDA Regional Milk Seminar, then ~~State~~ LEOs in that region are obligated to attend. If another region holds their regional milk seminar in the same year the ~~State~~ LEO may opt to attend that regional milk seminar in lieu of attending the regional milk seminar held in their region and still meet the requirement.

Once an individual has become a ~~State~~ LEO and is therefore considered fully certified, if he/she fails to submit acceptable written reports of milk laboratory evaluations within sixty (60) days to the FDA/LPET or fails to comply with item 2 above for Recertification (or continued certification), the ~~State~~ LEO ~~will~~ shall have ~~their~~ his/her certification status downgraded from full to provisional. In addition, an action plan ~~will~~ shall be established that is mutually agreeable to the FDA/LPET and the ~~state~~ Milk Laboratory Control Agency. The ~~State~~ LEO ~~would~~ shall ~~have to~~ meet the action plan criteria in addition to continuing to meet all the criteria specified in items 1-7 above, to maintain provisional certification status.

Laboratory evaluations conducted by provisionally approved ~~State~~ LEOs ~~will~~ shall be considered official.

Should a provisionally certified ~~State~~ LEO meet the criteria specified by their action plan and EML, SECTION 34, their certification ~~will~~ shall be returned to full certification once they have successfully undergone their next LEO check evaluation with the FDA/LPET.

Should a provisionally certified ~~State~~ LEO fail to meet the criteria specified in the EML, SECTION 34 and/or follow the action plan, then their certification ~~would~~ shall be revoked.

Page 18:

The procedures for revocation ~~must~~ shall follow SECTION V. QUALIFICATIONS AND CERTIFICATIONS, Part H. of the *Procedures* Document.

~~State~~ LEOs who lose certification cannot be re-certified for a period of sixty (60) days from the date of the loss of their certification. Recertification ~~will~~ shall require meeting the requirements for initial certification.

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SECTION 45: EQUIPMENT AND APPARATUS OF AID TO MILK LABORATORY EVALUATION OFFICERS

While conducting laboratory evaluations, the ~~Federal or State~~ FDA/LPET LEO or LEO may find it extremely useful to have in his/her possession different types of equipment which ~~will~~ shall 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~~ LEOs currently use a large percentage of the equipment and apparatus listed below. Equipment

should be maintained in proper working conditions to assure accuracy.

Page 20:

SECTION 56: GUIDELINES FOR CONDUCTING LABORATORY EVALUATIONS

The evaluations of laboratories by a ~~Federal or State~~ FDA/LPET LEO or 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~~ shall make application for an evaluation upon a form provided by the ~~Federal or State~~ FDA/LPET LEO or LEO. The application ~~will~~ shall 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~~ shall be set up and that during the evaluation the work of all analysts, who may perform any official methods ~~must~~ shall 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 ~~Federal or State~~ FDA/LPET LEO or LEO to permit observations of counting procedures. ...

After entering the laboratory, the ~~Federal or State~~ FDA/LPET LEO or LEO should note the names of all analysts in the laboratory as/or after they are introduced and record the procedures performed by each.

Before beginning the survey, the ~~Federal or State~~ FDA/LPET LEO or 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~~ FDA/LPET LEO or LEO 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~~ shall 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 ~~Federal or State~~ FDA/LPET LEO or LEO ~~will~~ shall 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.

Page 21:

While observations of procedures are being made and the evaluation forms completed, certain precautions should be taken by the ~~Federal or State~~ FDA/LPET LEO or LEO: ...

During the laboratory evaluation it is probable that some items pertinent to receiving samples will not be observed. However, the ~~Federal or State~~ FDA/LPET LEO or 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 the validity of the 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~~ FDA/LPET LEO or LEO with interested staff. At that time comments should be invited from the staff concerning the evaluation. The ~~Federal or State~~ FDA/LPET LEO or 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.

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In addition to a regularly scheduled visit, some ~~Federal or State~~ FDA/LPET LEOs or 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~~ shall be evaluated by the ~~Federal or State~~ FDA/LPET LEO or LEO and used to determine compliance with the NCIMS Milk Laboratory Program.

If at any time during a survey there is interference with or willful refusal to permit the survey, the ~~Federal or State~~ FDA/LPET LEO or LEO ~~will~~ shall serve notice that the laboratory ~~will~~ shall not be certified or ~~will~~ shall 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~~ shall result in non-certification or decertification for thirty days (30). Or, if at any time before or during any survey the ~~Federal or State~~ FDA/LPET LEO or LEO feels their safety is in jeopardy or determines extensive non-compliance, they may terminate the survey. The ~~Federal or State~~ FDA/LPET LEO or LEO ~~must~~ shall indicate to the laboratory management the reason why the survey was terminated and ~~must~~ shall indicate what steps ~~must~~ shall be taken before a resurvey will be scheduled. The laboratory may make ~~reapplication~~ re-application by addressing the concerns that led to the termination of the survey and by completing the application form stipulating that the safety concerns and/or non compliance issues have been addressed.

Page 23:

SECTION 67: LABORATORY EVALUATION REPORTS

EVALUATION FORMS ...

Copies of the survey forms may be prepared for the laboratory evaluated. The ~~Federal or State~~ FDA/LPET LEO or LEO ~~must~~ shall maintain a complete copy of the survey report, including forms. The laboratory/facility and ~~Federal or State~~ FDA/LPET LEO or LEO ~~must~~ shall maintain, at a minimum, copies of the last two (2) biennial/triennial ~~surveys~~ survey reports, subject to verification by the ~~State~~ LEO and the FDA/LPET. In marking the official copies of the completed survey 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 survey for the convenience of the evaluating official.

NARRATIVE REPORT

The set of completed survey forms for the laboratory may accompany the narrative report which states the conclusions of the ~~Federal or State~~ FDA/LPET LEO or 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~~ shall 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 survey. The copy of the narrative report submitted by email to FDA/LPET ~~must~~ shall be accompanied by the appropriate, completed FDA summary template, both attached to the same email. The ~~State~~ LEO ~~must~~ shall receive verification of receipt by return email and ~~must~~ shall maintain a copy of the verification in their records. The narrative report ~~must~~ shall identify the laboratory, give the laboratory number, show the date of the survey, who made the survey, list the prior status, list the date of the last on-site survey, indicate the present status, what recommendations were made to correct any deviations, what test(s) were approved, and who was certified to do them. ...

A paragraph headed "Remarks" or "Recommendations" may be included if the ~~officer~~ FDA/LPET LEO or LEO wishes to comment on an item, e.g., one which could be improved by a change in procedure or by new equipment, or for any comment which is not appropriately covered in other Sections of the report.

Page 24:

After "Personnel and Procedures Certified" list the full name of all laboratory personnel qualified to make each individual test for which certification or approval is given. Include information on the analysts' last split sample performance. Also include a statement requiring participation in the Proficiency Testing Program to maintain certification (e.g., "To maintain certification, analysts ~~must~~ shall successfully participate in the Annual Proficiency Testing Program for all procedures for which certification has been granted"). ...

Under "Conclusion" give a descriptive statement of the degree of acceptability or rejection of the procedures used by the laboratory, including recommendations for approval or rejection of

the results of the laboratory. Some typical conclusions are given in the following text, and except in special circumstances, one of the conclusions listed ~~must~~ shall be used to indicate whether the results are (or are not) acceptable to ~~State authorities~~ the Milk Laboratory Control Agency for use in rating milk for interstate shipment, where this is the purpose of the evaluation.

CONCLUSIONS ...

2. Although the procedures, records, facilities and/or equipment in use at the time of the evaluation were in substantial compliance with the requirements of the *Grade 'A' "A" PMO* the analyst/facility/equipment/records deviations noted ~~must~~ shall be corrected. This laboratory is accredited/approved for thirty (30) – sixty (60) days pending correction of the deviations and receipt of a letter by the ~~evaluation officer~~ FDA/LPET LEO or LEO detailing the corrections made. Upon receipt of such letter, full accreditation/approval ~~will~~ shall be given.

Explanation: A qualified acceptance where the ~~Federal or State~~ FDA/LPET LEO or LEO believes that the deviations noted do not seriously affect the analytical results and that a letter explaining the corrective actions taken ~~will~~ shall be sufficient to ensure compliance.

3. Although the procedures, records, facilities and/or equipment in use at the time of the evaluation did not substantially comply with the requirements of the *Grade 'A' "A" PMO*, the analyst/facility/equipment/records deviations noted are readily correctable. This laboratory is accredited/approved for (___) days pending correction of the deviations. Corrections ~~must~~ shall be made and detailed in writing to the ~~evaluation officer~~ FDA/LPET LEO or LEO during this period. A new survey ~~will~~ shall be scheduled upon receipt of the letter to assure full compliance.

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Explanation: A qualified acceptance where procedural or technical errors or facilities which could have an effect on analytical results are noted but which are readily correctable by the analysts or management. Depending on the judgment of the ~~State~~ LEO, a period of ~~no~~ not more than sixty (60) days usually is given to make the required adjustments before another survey is made or specified criteria are met, record, new equipment, etc. (some things may not require a return visit) to fully accredit (or approve) the laboratory.

4. This laboratory is not accredited/approved as the procedures, records, facilities and/or equipment in use at the time of the survey did not comply with the requirements of the *Grade 'A' "A" PMO*.

Explanation: Severe deficiencies in facilities, records, staff and/or procedural techniques exist which would result in unacceptable results. A new on-site survey shall be made when the ~~Federal or State~~ FDA/LPET LEO or LEO has reason to believe that a rating would result in an acceptable rating. A new on-site survey 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.

FDA SUMMARY TEMPLATES

The narrative report sent to FDA/LPET ~~must~~ shall 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~~ shall be used. There are two (2) FDA summary templates: one (1) for full service laboratories and one (1) for Appendix N Screening Only facilities (~~CIS and IS~~ CISs and ISs). The information captured on the FDA summary template ~~must~~ shall 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~~ shall also be used for the notification of changes in accreditation and certification status, and ~~must~~ shall be submitted by email to FDA/LPET.

Directions for completing the FDA summary template, authored by LPET, ~~will~~ shall be updated with each revision of the FDA summary template, as necessary, and provided to the LEOs by email. ...

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REFERENCES

1. Copies of the FDA-2400 Series Forms can be obtained from ~~Federal or State~~ Federal or State ~~Federal or State~~ FDA/LPET LEOs or LEO(s)-.

A list of ~~Federal and State~~ FDA/LPET LEOs and LEOs can be found at the website: <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/FederalStatePrograms/InterstateMilkShippersList/default.htm>; and

<http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/FederalStatePrograms/InterstateMilkShippersList/ucm114736.htm#TPC>

For ~~Federal~~ FDA/LPET LEOs click on the link FDA CFSAN Personnel and scroll down to the Laboratory Proficiency and Evaluation Team.

For State LEOs click on the link State Grade A Milk Regulatory, Rating and Laboratory Personnel and then click on your ~~state~~ State. The table is organized by listing Regulatory personnel first, then Rating personnel, and finally Laboratory personnel. Scroll down to the laboratory section to find the contact information for your ~~state's~~ State's LEO(s).

For TPC LEOs click on the link [International Certification Program Third Party Certifiers](#). The table is organized by individual TPCs, listing Regulatory personnel first, then Rating personnel, and finally Laboratory personnel. Scroll down to the laboratory section to find the contact information for your TPC's LEO(s).

The following text is a part of the Proposal but will not be placed in an NCIMS document.

The ICPPC requests the NCIMS Chair to assign the following charge to the SSCC Committee and report back to the 2015 NCIMS Conference:

Develop qualifications, authorization, certification/recertification procedures, etc. for consultants that currently certify or wish to certify SSCC manufacturers located outside the geographical boundaries of NCIMS Member States. Consultants that currently have SSCC listings on the IMS List shall participate on this Committee.

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 2013 NCIMS Conference, and concurred with by FDA, related to the wording addressing references to State, Regulatory Agency, Milk Laboratory Control Agency, etc. as cited throughout this Proposal.

NOTE: *This Proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2013 National Conference on Interstate Milk Shipments, following FDA's concurrence with the NCIMS Executive Board.*

Name:	Tom Ford and Claudia Coles, Co-Chairs		
Agency/Organization:	NCIMS International Certification Pilot Program Committee		
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34th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 306
Committee: HACCP/Liaison

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This proposal is to authorize the NCIMS HACCP Implementation Committee to conduct an evaluation/comparison of the FDA Food Safety Modernization Act (FSMA) and the voluntary NCIMS HACCP plant program in cooperation with FDA. Based on such an evaluation/comparison, the NCIMS HACCP Implementation Committee will develop a pilot program that would test modifications to the voluntary NCIMS HACCP plant program to be consistent with applicable requirements found in the 2011 FDA Food Safety Modernization Act (FSMA) and its associated regulations. The pilot will run from June 1, 2013 until December 31, 2015 with progress reports made to the NCIMS Executive Board.

**B. Reason for the Submission and
Public Health Significance and/or Rationale Supporting the Submission**

The FDA Food Modernization Act (FSMA) became law on January 4, 2011. Many parts of the Act became enforceable by FDA on that date; however, some provisions required FDA to publish regulations to provide more details than found in the Act. In addition, FDA decided some parts of the Act that were enforceable still required more detailed regulatory information in order for these provisions to be enforced in a practical way by FDA field investigators and compliance officers.

On Monday, January 7, 2013, FDA published in the Federal Register the “Current Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventative Controls for Human Food” which contained substantive details regarding written and operational programs that will be required of all food processing plants including Grade “A” dairy plants. A short summary of these is listed in the “Proposed Solution” section of this proposal. These FSMA requirements need to be addressed in some manner within the voluntary NCIMS HACCP

program. However, since this FDA regulation was just published, there was no time for the NCIMS HACCP Implementation Committee to review the 608 page regulation, become familiar with it, consult with FDA and develop a meaningful proposal in time for the 2013 Conference.

In order for the NCIMS Program to be up-to-date and current with FSMA and its associated regulations, it is in the best interests of the entire NCIMS Conference to have its voluntary HACCP plant program. The NCIMS HACCP Implementation Committee has the most experience with the NCIMS program and would best equipped to conduct an evaluation/comparison of FSMA and the new Preventative Controls regulation, discuss this subject with FDA representatives, develop modifications to the voluntary NCIMS HACCP Program and work with existing NCIMS HACCP program plant participants to test modifications in order to develop successful approaches regarding FSMA Preventative Control integration into the voluntary NCIMS HACCP Program.

C. Proposed Solution

Changes to be made on page(s):		all pages applicable to the voluntary NCIMS	of the (X - one of the following):
X	2011 PMO		2011 EML
X	2011 MMSR		2400 Forms
X	2011 Procedures		2011 Constitution and Bylaws

This NCIMS HACCP Implementation Committee is authorized to conduct an evaluation/comparison between the voluntary NCIMS HACCP plant program and the FDA Food Safety Modernization Act (FSMA) and its associated regulations in cooperation with FDA. After completion of the evaluation/comparison, the NCIMS HACCP Implementation Committee is then authorized to develop a pilot program that would test modifications to the voluntary NCIMS HACCP plant program in order to be consistent with applicable requirements found in the 2011 FDA Food Safety Modernization Act (FSMA) and its associated regulations. The pilot will start June 1, 2013 and end December 31, 2015. Progress reports will be provided to the NCIMS Executive Board, with a final report and possible proposal submitted for consideration at the 2015 NCIMS Conference.

The modification list below is to serve as an example and not a final or complete list, which will be developed in cooperation between authorized FDA representatives and the NCIMS HACCP Implementation Committee. Add in some manner to the existing voluntary NCIMS HACCP Program:

1. Radiological” hazards in addition to existing requirements for biological, chemical and physical hazards in a Hazard Analysis	2. “Employee Training” to includes employee hygiene, overall food safety and food GMP training)”
3. “Written Allergens Controls” program	4. “Environmental Monitoring Program”
5. “Written Recall Plan”	6. “Process Controls” including rework program
7. “Written Traceability Plan”	8. “Foreign Material Management” (glass, metal)

9. "Written Sanitation Controls" for food contact surfaces (includes equipment, utensil and toxic material storage	10. "Temperature Management" of raw materials, in-process and finished products
11. "Written Sanitary Operations" program for maintenance and condition of the plant facility and grounds	12. "Supplier Management" of raw materials and primary-contact packaging

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34th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 307

Committee: Liaison

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This proposal is to authorize the NCIMS Liaison Committee to conduct an independent equivalency evaluation/comparison between the 2011 FDA Food Safety Modernization Act (FSMA) (including all applicable regulations) and the traditional NCIMS Grade “A” plant program. Based on such an equivalency evaluation/comparison, the NCIMS Liaison Committee shall provide a report to the NCIMS Executive Committee prior to the 2015 NCIMS Conference on equivalency GAPS between the two regulatory programs and make recommendations to close identified equivalency GAPS. Such recommendations could include proposals to the 2015 NCIMS Conference.

**B. Reason for the Submission and
Public Health Significance and/or Rationale Supporting the Submission**

The FSMA was signed into law on January 4, 2011. Many parts of the Act became enforceable by FDA on that date; however, some provisions required FDA to publish regulations to provide more details than found in the Act. In addition, FDA decided some parts of the Act that were enforceable still required more detailed regulatory information in order for these provisions to be enforced in a practical way by FDA field investigators and compliance officers.

On Monday, January 7, 2013, FDA published in the Federal Register the “Current Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventative Controls for Human Food” known as the proposed “Preventative Controls” regulation. This regulation contained substantive details regarding written and operational programs that will be required of all food processing plants including Grade “A” dairy plants. A short summary of these is listed in the “Proposed Solution” section of this proposal. These FSMA and Preventative

controls requirements need to be addressed in some manner within the traditional NCIMS Grade “A” plant program. However, since this FDA regulation was just published, there was no time for the NCIMS Liaison Committee or any other NCIMS Body to review the 608 page regulation, become familiar with it, consult with FDA and develop a meaningful proposal in time for the 2013 Conference.

In order for the NCIMS Program to be up-to-date and current with FSMA and its associated regulations, it is in the best interests of the entire NCIMS Conference to have its traditional Grade “A” plant program equivalent to this national food safety regulation. The NCIMS Liaison Committee is designated to represent the NCIMS on matters related to FSMA and would be equipped to conduct an equivalency evaluation/comparison of FSMA and the new Preventative Controls regulation, discuss this subject with FDA representatives on behalf of the entire NCIMS Conference, identify equivalency GAPS and develop recommendations or proposals to fill these GAPS.

C. Proposed Solution

Changes to be made on page(s):		All applicable pages of the following documents		of the (X - one of the following):
X	2011 PMO	X	2011 EML	
X	2011 MMSR		2400 Forms	
X	2011 Procedures	X	2011 Constitution and Bylaws	

This NCIMS Liaison Committee is authorized to conduct an equivalency evaluation/comparison between the traditional NCIMS Grade “A” plant program and the FDA Food Safety Modernization Act (FSMA) and its associated regulations. Based on identified equivalency GAPS, the NCIMS Liaison Committee shall submit a report of their findings to the NCIMS Executive Board prior to the 2015 NCIMS Conference and possibly develop proposals to address identified GAPS.

The list below is to serve as an example and not a final or complete list, which is intended to demonstrate a few potential equivalency GAPS between the 2011 Food Safety Modernization Act (FSMA), its associated regulations and the traditional NCIMS Grade “A” plant program.

1. “Written Sanitary Operations” for maintenance of the plant facility & grounds consistent with 21 CFR 117 (new food GMPs)	
2. “Written Sanitation Controls” for food contact surfaces (includes equipment, utensil and chemical storage) consistent with 21 CFR 117 (new food GMPs)	
3. “Employee Training” to including employee hygiene, overall food safety and food GMP training)”	
4. “Written Allergens Controls” program	5. “Environmental Monitoring Program”
6. “Written Recall Plan”	7. “Process Controls” including rework program
8. “Written Traceability Plan”	9. “Foreign Material Management” (glass, metal)

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