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November 16, 2015

IMS-a-50

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

From: Milk and Milk Products Branch (HFS-316)

Subject: Actions of the 2015 National Conference on Interstate Milk Shipments

The 35th National Conference on Interstate Milk Shipments (NCIMS) was held in Portland, Oregon, April 24-29, 2015. A total of one hundred (100) Proposals were submitted and deliberated at the Conference. During the Conference, the State delegates approved several changes to the *Grade "A" Pasteurized Milk Ordinance* (PMO) and related NCIMS documents. Following is a table showing the Actions taken by the voting delegates:

COUNCIL	# OF PROPOSALS	NO ACTION	PASSED AS SUBMITTED	PASSED AS AMENDED	TABLED
I	37	26	2	9	0
II	46	22	8	16	0
III	9	0	4	5	0
JOINT COUNCIL	8	3	0	5	0
TOTAL	100	51	14	35	0

The following Proposals were passed and addressed changes to the PMO: 104, 105, 112, 114, 119, 121, 124, 126, 128, 133, 134, 203, 207, 208, 213, 216, 219 (FDA originally non-concurred), 224, 225, 226 (FDA originally non-concurred), 227 (FDA originally non-concurred), 229, 301, 306, 309, JC1, JC3, JC4, JC5 and JC7.

The following Proposals were passed and addressed changes to the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments* (Procedures): 306 and 309 (Identified as new Procedures) and 307 and 308 (Identified as Procedures changes).

The following Proposals were passed and addressed changes to the *Methods of Making Sanitation Ratings of Milk Shippers* (MMSR): 306 and 309.

The following Proposals were passed and addressed changes to the *Constitution* and/or the *Bylaws of the National Conference on Interstate Milk Shipments* (Constitution and Bylaws): 302, 303, 304 and 305.

The following Proposals were passed and addressed changes to the *Evaluation of Milk Laboratories* (EML): 221, 231, 232, 233 and 306.

The following Proposals were identified as FDA/NCIMS 2400 Forms and were voted on as a block to be handled by FDA and the NCIMS Laboratory Committee following the procedures for issuing and updating FDA/NCIMS 2400 Forms: 235, 237, 238, 241, and 245.

The following Proposals identified the development of new FDA/NCIMS 2400 Forms or changes to FDA/NCIMS 2400 Forms and were not voted on as a block to be handled by FDA and the NCIMS Laboratory Committee following the procedures for issuing and updating FDA 2400 Forms: 221, 222, 226 (FDA originally non-concurred), 239, and 246 (FDA non-concurred).

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

- FORM FDA 2359-MILK PLANT INSPECTION REPORT (10/11): JC3, JC4 and JC5.
- FORM FDA 2359c-MANUFACTURING PLANTS (*Single-Service Containers and/or Closures for Milk and/or Milk Products*) (10/11): 309
- FORM FDA 2359d-REPORT OF CERTIFICATION (*Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products*) (10/10): 309
- FORM FDA 2359e-STATUS OF MANUFACTURING PLANTS (*Single-Service Containers and/or Closures for Milk and/or Milk Products*): 309 (New Form)
- FORM FDA 2359h-INTERSTATE MILK SHIPPER'S CHECK RATING REPORT (10/11): JC3, JC4 and JC5.
- FORM FDA 2359L-STATUS OF MILK PLANTS (INCLUDING DRYING AND CONDENSING MILK PLANTS, RECEIVING STATIONS AND TRANSFER STATIONS) (10/11): JC3, JC4 and JC5

The following Proposals were passed and addressed the formation or continuation of Pilot Programs:

211: The Appendix N Modification Committee requests the Chair to assign this Proposal to an NCIMS standing committee, special committee, or ad hoc committee as approved by the NCIMS Executive Board.

The Appendix N Modification Committee is charged to develop a pilot program, establishing a regulatory framework by which testing raw milk for veterinary drugs would be *required for drugs other than beta-lactams*.

Note: The NCIMS Chair assigned this Proposal to the Appendix N Modification Committee.

301: The Aseptic Program Committee (APC) requests a two (2) year extension of the NCIMS Aseptic Pilot Program to specifically address aseptically processed and packaged Grade "A"

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 aseptically processed and packaged Grade “A” fermented high-acid milk and/or milk products under the provisions currently in place. The NCIMS Aseptic Program Committee is discontinuing their evaluation of aseptically processed and packaged Grade “A” acidified milk and/or milk products.

The NCIMS Aseptic Program Committee (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, retort processed after packaging low-acid Grade “A” milk and/or milk products, as well as aseptically processed and packaged Grade “A” 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 NCIMS APC shall provide a report to the 2017 NCIMS.

Note: The NCIMS Chair assigned this Proposal to the Aseptic Program Committee.

The following Proposal was passed and did not reference any documents or Forms: 211.

The following Proposals were passed and are of significance to the Grade “A” Milk Safety Program:

JC1, JC3, JC4, JC5 and JC7: All Proposals seek to align the PMO with the requirements of the Food Safety Modernization Act (FSMA) Proposed Rule for Prevention Controls for Human Foods.

- JC1 addresses the PMO, with Appendices, and the supporting milk plant-specific procedures required herein, shall constitute a milk plant’s food safety plan as required by 21 CFR 117.126 to the extent that the procedures address all the hazards identified by the milk plant as applicable for that milk plant. A milk plant shall have a written Hazard Analysis for each kind or group of milk and/or milk product processed.
- JC3 addresses food allergen control and a written food recall plan that shall include procedures as described in 21 CFR Part 7 (Subpart A and C).
- JC4 addresses environmental monitoring.
- JC5 addresses a supplier control program.
- JC7 addresses prerequisite and other program procedures as described in 21 CFR Part 7 (Subpart A and C) in Appendix K-HACCP Program of the PMO.

211, 213 and 216: Address testing for non-Beta lactam animal drugs on bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers.

- 211 charges the Appendix N Modification Committee to develop a pilot program, establishing a regulatory framework by which testing raw milk for veterinary drugs would be *required for drugs other than beta-lactams*.
- 213 establishes a protocol when utilizing a drug test method that has not been evaluated by FDA and accepted by the NCIMS for initial screening followed by a drug test method that has been evaluated by FDA and accepted by the NCIMS (M-a-85, latest revision, and

M-I-92-11) for determining a screening test positive (load and/or raw milk supply that has not been transported in bulk milk pickup tankers confirmation). It also established a protocol when utilizing a drug test method that has not been evaluated by FDA and accepted by the NCIMS for initial screening and determining a verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers when a drug test method that has been evaluated by FDA and accepted by the NCIMS (M-a-85, latest revision, and M-I-92-11) is not available.

- 216 identifies a “target testing” level instead of the previously used “safe” level for individual animal drugs. It also states that new drug test methods, which are submitted to NCIMS, from FDA, for acceptance, shall not detect drug residues at less than 50% of the tolerance level or 25% of the target testing level* for individual drugs, with the exception of penicillin G and tetracyclines.

*Target testing levels are set by FDA based on available science. They are not determined by the detection limits of commercially available test methods.

226: (FDA originally non-concurred) Changed the dairy farm, milk plant, receiving station, transfer station and milk tank truck cleaning facilities individual water supply PMO bacteriological standard from the MCL for Total Coliform to the implementation of the EPA MCL for E. coli.

NOTE: Pasteurized Equivalent Water treatment systems that have undergone the “Hazard Evaluation and Safety Assessment” of subpart d. of this section prior to December 31, 2015 shall review their assessment based on the new E. coli water standards and submit any revisions or a statement that no revisions were needed to the Regulatory Agency by April 1, 2016.

309: Contains modifications to the PMO, MMSR and Procedures documents that address the regulation and certification/listing of single-service containers and/or closures for milk and/or milk products manufacturing plants. It will incorporate the NCIMS Single-Service and Methods Committees’ findings and determination that for manufacturing plants that produce single-service containers and/or closures for milk and/or milk products to be certified and listing on the IMS List that they must obtain a Sanitation Compliance Rating of eighty (80) or above.

This Proposal also addresses the qualifications, authorization, certification/recertification procedures, etc. for single-service consultants (SSCs) that currently certify or wish to certify single-service containers and/or closures for milk and/or milk products manufacturers located outside the geographical boundaries of the NCIMS Member States.

FDA responded in writing to the NCIMS Conference Chair on August 11, 2015 and met with the NCIMS Executive Board on October 7-8, 2015 concerning the Proposals passed during the 2015 Conference. Within FDA’s letter dated August 11, 2015, FDA concurred with all of the passed Proposals with the exception of Proposals 219, 226, 227 and 246. During the October 7-8, 2015 NCIMS Executive Board meeting, FDA and the Executive Board did not reach mutual concurrence with Proposal 246; therefore, Proposal 246 in accordance with Section IX-

Application of Conference Agreements, A-Implementation of Changes, 4. of the *Procedures* will be referred to the next Conference for discussion.

219: (FDA originally non-concurred) During the October 7-8, 2015 NCIMS Executive Board meeting, FDA and the Executive Board reached mutual concurrence with Proposal 219. This provides for personnel approved by the Milk Laboratory Control Agency at an Official or Officially Designated Laboratory, with industry consent where applicable, to average the laboratory test results from multiple samples of the same milk and/or milk products collected from the same producer or processor on the same day.

***Note:** This Proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2015 National Conference on Interstate Milk Shipment following FDA's concurrence with the NCIMS Executive Board.*

226: (FDA originally non-concurred) During the October 7-8, 2015 NCIMS Executive Board meeting, FDA and the Executive Board reached mutual concurrence with Proposal 226. This changed the dairy farm, milk plant, receiving station and transfer station individual water supply PMO bacteriological standard from the MCL for Total Coliform to the implementation of the EPA MCL for E. coli.

227: (FDA originally non-concurred) During the October 7-8, 2015 NCIMS Executive Board meeting, FDA and the Executive Board reached mutual concurrence with Proposal 227. This provides for milk tank trucks to be inspected at least once every twenty-four (24) months plus the remaining days of the month in which the inspection is due.

***Note:** This Proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2015 National Conference on Interstate Milk Shipment following FDA's concurrence with the NCIMS Executive Board.*

The NCIMS Executive Board mutually concurred with FDA on all of the Proposals that were originally concurred with by FDA.

All Proposals that were passed and concurred with by FDA and the NCIMS Executive Board, with the exception of the Proposals noted below, will become effective within one (1) year of the electronic publication of the affected document(s); or by the official notification to the States through the transmittal of this IMS-a, as applicable, following the Conference at which the changes were passed. For States that can legally enforce the new regulations based on the issuance of this IMS-a, the effective date will be November 16, 2016.

The following Proposals are exceptions to the effective dates cited above:

JC3, JC4 and JC5: All Proposals seek to align the PMO with the requirements of the Food Safety Modernization Act (FSMA) Proposed Rule for Prevention Controls for Human Foods.

The NCIMS Liaison Committee requests an effective date for these Proposals to be August 30, 2016 – or one year after the final rule is published. If the final Preventive Controls for Human

Food Rule does not include mandatory provisions analogous to the allergen control plan and written recall plan (JC3); environmental monitoring requirements (JC4); and supplier verification requirements (JC5) in the Proposed Rule, these modification, respectively, will self-terminate and will be stricken from future versions of the PMO.

Note: *The final Preventive Controls for Human Food Rule was published September 17, 2015 and does include mandatory provisions analogous to the allergen control plan and written recall plan (JC3); environmental monitoring requirements (JC4); and supplier verification requirements (JC5) as cited in Proposal JC3, JC4 and JC5, respectively. Therefore, Proposals JC3, JC4 and JC5 become effective September 17, 2016.*

JC7: Addresses prerequisite and other program procedures as described in 21 CFR Part 7 (Subpart A and C) as cited in JC3, JC4 and JC5 in Appendix K-HACCP Program of the PMO.

The NCIMS HACCP Implementation Committee requests an effective date for this Proposal to be August 30, 2016 – or one year after the final rule is published.

Note: *The final Preventive Controls for Human Food Rule was published September 17, 2015. Therefore, Proposal JC7 becomes effective September 17, 2016.*

134: Adds wording to clarify the requirements for the operation of automatic milking installations (AMIs) addressing abnormal milk, computer system(s) verification and general computer functions related to Items 1r, 13r and 14r.

Note: *Implementation date will be one (1) year from the issuance of the 2015 version of the electronic PMO.*

211: Charges the Appendix N Modification Committee to develop a pilot program, establishing a regulatory framework by which testing raw milk for veterinary drugs would be *required for drugs other than beta-lactams*.

Note: *The Appendix N Modification Committee stands ready to begin work on the framework for this pilot program immediately and requests an effective date of the receipt and acceptance of FDA concurrence at the next NCIMS Executive Board meeting after the Conference.*

213: Establishes a protocol when utilizing a drug test method that has not been evaluated by FDA and accepted by the NCIMS for initial screening followed by a drug test method that has been evaluated by FDA and accepted by the NCIMS (M-a-85, latest revision, and M-I-92-11) for determining a screening test positive (load and/or raw milk supply that has not been transported in bulk milk pickup tankers confirmation). It also established a protocol when utilizing a drug test method that has not been evaluated by FDA and accepted by the NCIMS for initial screening and determining a verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers when a drug test method that has been evaluated by FDA and accepted by the NCIMS (M-a-85, latest revision, and M-I-92-11) is not available.

Note: *This Proposal shall take effect one (1) year from the issuance of the IMS-a, Actions from the 2015 National Conference on Interstate Milk Shipment following FDA's concurrence with the NCIMS Executive Board.*

219: (FDA originally non-concurred) During the October 7-8, 2015 NCIMS Executive Board meeting, FDA and the Executive Board reached mutual concurrence with Proposal 219. This provides for personnel approved by the Milk Laboratory Control Agency at an Official or Officially Designated Laboratory, with industry consent where applicable, to average the laboratory test results from multiple samples of the same milk and/or milk products collected from the same producer or processor on the same day.

Note: *This Proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2015 National Conference on Interstate Milk Shipment following FDA's concurrence with the NCIMS Executive Board.*

227: (FDA originally non-concurred) During the October 7-8, 2015 NCIMS Executive Board meeting, FDA and the Executive Board reached mutual concurrence with Proposal 227. This provides for milk tank trucks to be inspected at least once every twenty-four (24) months plus the remaining days of the month in which the inspection is due.

Note: *This Proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2015 National Conference on Interstate Milk Shipment following FDA's concurrence with the NCIMS Executive Board.*

302, 303, 304 and 305: Made changes to the *Constitution* and/or *Bylaws* of the NCIMS.

Note: *Amendments to the Constitution and Bylaws shall become effective at the close of the Conference at which they are adopted.*

309: Establishes certification/listing criteria for single-service containers and/or closures for milk and/or milk products manufacturing plants. It also addresses the qualifications, authorization, certification/recertification procedures, etc. for single-service consultants (SSCs) that currently certify or wish to certify single-service containers and/or closures for milk and/or milk products manufacturers located outside the geographical boundaries of the NCIMS Member States.

Note: *This Proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2015 National Conference on Interstate Milk Shipments, following FDA concurrence with the NCIMS Executive Board.*

Some of the language as adopted by the delegates was editorialized in order to maintain continuity with the present language and to ensure compatibility with existing sections of the affected NCIMS document(s). The edits have not changed the intent of the voted actions. Deletions to the current document's language are identified by ~~strikeout~~ and additions are identified by underlined text, unless otherwise noted.

Proposal: 306
Document: 2013 PMO
Pages: ix and xviii

Make the following changes to the 2013 PMO:

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ABBREVIATIONS AND ACRONYMS

3-A SSI (3-A Sanitary Standards, Inc.)

°C (Degrees Celsius)

°F (Degrees Fahrenheit)

+ (Positive)

- (Negative)

+/- (Plus or Minus)

AC (Air Cleaner or Alternating Current)

AISI (American Iron and Steel Institute)

AMI (Automatic Milking Installation)

AOAC (Association of Official Analytical Chemists)

APA (Administrative Procedures Act)

APHIS (Animal and Plant Health Inspection Service)

APPS (Aseptic Processing and Packaging System)

AR (Audit Reports)

ASHRAE (American Society of Heating, Refrigeration and Air-Conditioning Engineers)

ASME (American Society of Mechanical Engineers)

ASTM (American Society of Testing and Materials)

AUX STL (Auxiliary Safety Thermal Limit Recorder-Controller)

AVIC (Area Veterinarian-in-Charge)

a_w (Water Activity)

BTU (Bulk Tank Unit)

CCP (Critical Control Point)
cfm (Cubic Feet per Minute)
CFR (Code of Federal Regulations)
CFSAN (Center for Food Safety and Applied Nutrition)
cfu (Colony Forming Units)
CG (Confluent Growth)
CIP (Clean-in-Place)
CL (Critical Limit)
CLE (Critical Listing Element)
CLT (Constant-Level Tanks)
cm (Centimeter)
cm² (Square Centimeter)
CMR (Cooling Media Return)
CMS (Cooling Media Supply)
Condensed (Concentrated Milk and/or Milk Products)
COP (Cleaned-out-of-Place)
CPG (Compliance Policy Guide)
CTLR (Controller)

DIS/TSS 4 (Disinfectant/Technical Science Section-EPA Sanitizer Test for Inanimate Surfaces:
Efficacy Data Requirements)

DMSCC (Direct Microscopic Somatic Cell Count)
DNA (Deoxyribonucleic Acid)
DOP (Dioctylphthalate Fog Method)
DPC (Dairy Practices Council)
DPLI (Differential Pressure Limit Indicator)
DRT (Digital Reference Thermometer)
dSSO (delegated Sampling Surveillance Regulatory Agency Official)

EAPROM (Electrically Alterable, Programmable, Read-Only Memory)
EC (Electrical Conductivity)
ECA (Electro-Chemical Activation)
EEPROM (Electrically Erasable, Programmable, Read-Only Memory)
EML (*Evaluation of Milk Laboratories*)
EPA (Environmental Protection Agency)
EPROM (Erasable, Programmable, Read-Only Memory)
ESCC (Electronic Somatic Cell Count)

FAC (Free Available Chlorine)
FAO (Food and Agriculture Organization)
FC (Fail Closed)
FDA (Food and Drug Administration)
FFD (Flow-Diversion Device)
FFD&CA (*Federal Food, Drug, and Cosmetic Act*)
FIPS (Federal Information Processing Standard)
FR (Federal Register)

FRC (Flow Recorder/Controller)

GLP (Good Laboratory Practice)

gm (Gram)

GMP (Good Manufacturing Practice)

GRAS (Generally Recognized as Safe)

H (Height)

HACCP (Hazard Analysis Critical Control Point)

HFA (High Flow Alarm)

HHS (Health and Human Services)

HHST (Higher-Heat-Shorter-Time)

HMR (Heating Media Return)

HMS (Heating Media Supply)

HPC (Heterotrophic Plate Count)

HSCC (High Sensitivity Coliform Count)

HTST (High-Temperature-Short-Time)

ICP (International Certification Program)

IFT (The Institute of Food Technologists)

IMS (Interstate Milk Shipper)

in. (Inch)

I.U. (International Units)

kg (Kilogram)

kPa (Kilo Pascal)

L (Length or Liter)

LACF (Low Acid Canned Food)

LEO (Laboratory Evaluation Officer)

LOI (Letter of Intent)

LOSA (Loss of Signal/Low Flow Alarm)

LOU (Letter of Understanding)

LPET (Laboratory Proficiency Evaluation Team)

LS (Level Sensor)

lux (Unit of Illuminance and Luminous Emittance)

M (Meter)

M-a (Memorandum of Interpretation)

M-b (Memorandum of Milk Ordinance Equipment Compliance)

MBTS (Meter Based Timing System)

MC (Milk Company)

MF (Membrane Filtration or Micro-Filtration)

MFMBTS (Magnetic Flow Meter Based Timing System)

mg/L (Milligrams per Liter)

M-I (Memorandum of Information)

MIL-STD (Military Standard)
mL (Milliliter)
mm (Millimeter)
MMSR (*Methods of Making Sanitation Ratings of Milk Shippers*)
MOA (Memorandum of Agreement)
MOU (Memorandum of Understanding)
MPN (Most Probable Number)
MSDS (Material Safety Data Sheet)
MST (Milk Safety Team)
MTF (Multiple Tube Fermentation)

NA (Not Applicable)
NACMCF (National Advisory Committee on Microbiological Criteria for Foods)
NASA (National Aeronautics and Space Administration)
NCIMS (National Conference on Interstate Milk Shipments)
NIST (National Institute of Standards and Technology)
NLEA (Nutrition Labeling and Education Act)
NMC (National Mastitis Council)
NSDA (National Soft Drink Association)

OMA (*Official Methods of Analysis*)
OSHA (Occupational Safety and Health Administration)
OTC (Over-the-Counter)

P (Pasteurized)
PA (Product Assessment)
P/A (Presence/Absence)
PAC (Petrifilm Aerobic Count)
PAM (Pesticide Analytical Manual)
PC (Pressure Controller)
PCC (Petrifilm Coliform Count)
PDD (Position Detection Device)
pH (Potential Hydrogen-acid/alkaline balance of a solution)
PHF (Potentially Hazardous Food)
PI (Pressure Indicator)
PLC (Plate Loop Count or Programmable Logic Controller)
PLI (Pressure Limit Instrument)
PMO (*Pasteurized Milk Ordinance*)
PP (Prerequisite Program)
ppm (Parts per Million)
Procedures (*Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments*)
psi (Pounds per Square Inch)
psig (Pounds per Square Inch Gauge)
PT (Pressure Transmitter)
PVC (Polyvinyl Chloride)

R (Raw)
RAM (Random Access Memory)
RBPC (Regenerator Back Pressure Controller)
RC (Ratio Controller)
RDPS (Regenerator Differential Pressure Sensor)
RO (Reverse Osmosis)
ROM (Read-Only Memory)
RPPS (Retort Processed after Packaging System)
RTD (Resistance Temperature Detector)
Rx (Prescription)

SAE (Society of Automotive Engineers)
sec. (Second)
skim (Nonfat)
SMEDP (*Standard Methods for the Examination of Dairy Products*)
SMEWW (*Standard Methods for the Evaluation of Water and Wastewater*)
SOP (Standard Operating Procedure)
SPC (Standard Plate Count)
SRO (Sanitation Rating Officer)
SCC (Somatic Cell Count)
SSCC (Single-Service Containers and Closures)
SSO (Sampling Surveillance Officer)
SSOP (Sanitary Standard Operating Procedure)
STLR (Safety Thermal Limit Recorder-Controller)

t (Time)
T (Temperature)
TB (Tuberculosis)
TC (Temperature Controller)
TCS (Time/Temperature Control for Safety)
TKN (Total Kjeldahl Nitrogen)
TNTC (Too Numerous To Count)
TPC (Third Party Certifier)
TV (Throttling Valve)

UF (Ultra-Filtration)
UP (Ultra-Pasteurization)
UPS (Uninterruptible Power Supply)
USDA (United States Department of Agriculture)
USP (United States Pharmacopeia)
USPHS (United States Public Health Service)
USPHS/FDA (United States Public Health Service/Food and Drug Administration)
UV (Ultraviolet Light)
UVT (Ultraviolet Light Transmissivity)

Vat (Batch Pasteurizer/Pasteurization)

W (Width)
WHO (World Health Organization)
WORM (Write Once, Read Many)

Document: 2013 MMSR
Pages: ii and vi

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ABBREVIATIONS AND ACRONYMS

ACLE (Aseptic Critical Listing Element)
APPS (Aseptic Processing and Packaging System)
AR (Audit Report)

BTU (Bulk Tank Unit)

CCP (Critical Control Point)
CFR (Code of Federal Regulations)
CIP (Clean-in-Place)
CL (Critical Limit)
CLE (Critical Listing Element)
cwt. (100 Pounds Weight Unit)

dSSO (delegated Sampling Surveillance Regulatory Agency Official)

EML (Evaluation of Milk Laboratories)
EPA (Environmental Protection Agency)

FDA (Food and Drug Administration)
FFD&CA (Federal Food, Drug, and Cosmetic Act)

HACCP (Hazard Analysis Critical Control Point)

ICP (International Certification Program)
IMS (Interstate Milk Shipper)

LACF (Low Acid Canned Food)
LEO (Laboratory Evaluation Officer)
LOI (Letter of Intent)
LOU (Letter of Understanding)
LPET (Laboratory Proficiency Evaluation Team)

M-a (Memorandum of Interpretation)
MC (Milk Company)
M-I (Memorandum of Information)
MMSR (*Methods of Making Sanitation Ratings of Milk Shippers*)
MOA (Memorandum of Agreement)
MST (Milk Safety Team)

NCIMS (National Conference on Interstate Milk Shipments)

pH (Potential Hydrogen-acid/alkaline balance of a solution)
PHS (Public Health Service)
PHS/FDA (Public Health Service/Food and Drug Administration)
PMO (*Pasteurized Milk Ordinance*)
PP (Prerequisite Program)
Procedures (*Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments*)

RPPS (Retort Processed after Packaging System)

SMEDP (*Standard Methods for the Examination of Dairy Products*)
SRO (Sanitation Rating Officer)
SSO (Sampling Surveillance Officer)

TPC (Third Party Certifier)

USDA (United States Department of Agriculture)

Document: 2013 PROCEDURES

Pages: ii and iv

NEW PROCEDURE

Make the following changes to the 2013 PROCEDURES:

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ABBREVIATIONS AND ACRONYMS

ACLE (Aseptic Critical Listing Element)
AOAC (Association of Official Analytical Chemists)

BTU (Bulk Tank Unit)

CCP (Critical Control Point)
CFR (Code of Federal Regulations)
CIS (Certified Industry Supervisor)
CL (Critical Limit)
CLE (Critical Listing Element)

EML (Evaluation of Milk Laboratories)

FDA (Food and Drug Administration)
FFD&CA (Federal Food, Drug, and Cosmetic Act)
FIMA (Federal Import Milk Act)
FR (Federal Register)

HACCP (Hazard Analysis Critical Control Point)
HHST (Higher-Heat-Shorter-Time)
HTST (High-Temperature-Short-Time)

ICP (International Certification Program)
IMS (Interstate Milk Shipper)
IDFA (International Dairy Foods Association)
IMS-a (Memorandum of Conference Actions)

LEO (Laboratory Evaluation Officer)
LOI (Letter of Intent)
LOU (Letter of Understanding)
LPET (Laboratory Proficiency Evaluation Team)

M-a (Memorandum of Interpretation)
M-b (Memorandum of Milk Ordinance Equipment Compliance)
MC (Milk Company)
M-I (Memorandum of Information)
MMSR (*Methods of Making Sanitation Ratings of Milk Shippers*)
MOA (Memorandum of Agreement)
MOU (Memorandum of Understanding)
MST (Milk Safety Team)

NACMCF (National Advisory Committee on Microbiological Criteria for Foods)
NCIMS (National Conference on Interstate Milk Shipments)
NMPF (National Milk Producers Federation)

OMA (*Official Methods of Analysis*)

pH (Potential Hydrogen-acid/alkaline balance of a solution)
PHS (Public Health Service)
PHS/FDA (Public Health Service/Food and Drug Administration)
PMO (*Pasteurized Milk Ordinance*)
Procedures (*Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments*)

RPPS (Retort Processed after Packaging System)

SMEDP (*Standard Methods for the Examination of Dairy Products*)
SRO (Sanitation Rating Officer)
SCC (Somatic Cell Count)
SSO (Sampling Surveillance Officer)

TPC (Third Party Certifier)

U.S.C. (United States Code)
USDA (United States Department of Agriculture)

Document: 2013 EML
Pages: i and iii

Make the following changes to the 2013 EML:

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ABBREVIATIONS AND ACRONYMS

* (Repeat Violation as Used on Evaluation Reports)

°C (Degrees Celsius)

AOAC (Association of Official Analytical Chemists)

ASTM (American Society of Testing and Materials)

BIO (BactoScan Industry Operator)

BSC (BactoScan FC Count)

C (Conditional Certification as Used on Evaluation Reports)

CFSAN (Center for Food Safety and Applied Nutrition)

CIS (Certified Industry Supervisor)

cm (Centimeter)

DMSCC (Direct Microscopic Somatic Cell Count)

EML (Evaluation of Milk Laboratories)

EPA (Environmental Protection Agency)

EPC (Electronic Phosphatase Count)

ESCC (Electronic Somatic Cell Count)

FDA (Food and Drug Administration)

FDA/NCIMS 2400 Forms (Official Milk Laboratory Evaluation Forms)

ft (Foot/Feet)

ft-candles (Foot Candles)

HVD (Homogenized Vitamin D Milk)

IA (Industry Analyst)

IMS (Interstate Milk Shipper)

IS (Industry Supervisor)

L (Limit)

LEO (Laboratory Evaluation Officer)

LPET (Laboratory Proficiency Evaluation Team)

MRT (Maximum Registering Thermometer)
mU (milliUnits)

N (Number of Results per Test or Not Certified as Used on Evaluation Reports)
NA (Not Applicable)
NCIMS (National Conference on Interstate Milk Shipments)

O (Unused Laboratory Procedures or Equipment as Used on Evaluation Reports)

P (Provisional Certification as Used on Evaluation Report)
PAC (Petrifilm Aerobic Count)
PLC (Plate Loop Count)
PMO (*Pasteurized Milk Ordinance*)
Procedures (*Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments*)

QA (Quality Assurance)
QC (Quality Control)

REV (Revision)

SPC (Standard Plate Count)
SPLC (Spiral Plate Loop Count)

TC (Temperature Control)

U (Undetermined as Used on Evaluation Reports)

X (Deviated Item or Full Certification as Used on Evaluation Reports)

Note: Grant FDA the editorial license to add additional abbreviations and acronyms to these individual lists that are added to the individual NCIMS documents through Proposals that are passed and concurred with from the 2015 NCIMS Conference.

Proposal: 309
Document: 2013 PMO
Pages: Cover, x, xiii, 73, 78, 80, 169, 337-346 and 362

Make the following changes to the 2013 PMO:

Cover:

2013 2015

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PREFACE

STANDARDS FOR THE FABRICATION OF SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS

C. BACTERIAL STANDARDS AND EXAMINATIONS OF SINGLE-SERVICE CONTAINERS AND/OR CLOSURES

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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~~ of this Ordinance. 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*. ...

ITEM 12p. CLEANING AND SANITIZING OF CONTAINERS AND EQUIPMENT ...

ADMINISTRATIVE PROCEDURES ...

6. a. ...

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c. When single-service containers and/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 and/or closures as being in conformance without additional testing. If there is reason to believe that containers and/or closures do not conform to the bacteriological standards, additional testing may be required. If containers and/or closures 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 with applied closures, 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 Milk Laboratory Control Agency specifically for the examinations required under Appendix J. ...

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ITEM 14p. STORAGE OF SINGLE-SERVICE CONTAINERS ARTICLES, UTENSILS AND MATERIALS

Single-service ~~eaps closures~~, ~~eap closure~~ stock, parchment paper, containers, gaskets, liners, bags and other single-service articles for use in contact with milk and/or milk products shall be purchased and stored in sanitary tubes, wrappings or cartons; shall be kept therein in a clean, dry place until used; and shall be handled in a sanitary manner.

PUBLIC HEALTH REASON

Soiled or contaminated ~~eaps closures~~, parchment paper, gaskets and single-service containers nullify the benefits of the safeguards prescribed throughout this *Ordinance*. Packing the ~~eaps closures~~ in sanitary tubes, wrappings or cartons, which remain unbroken until they are placed in the bottling machine, is the best method of assuring ~~eap closure~~ cleanliness.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Single-service ~~eaps closures~~, ~~eap closure~~ stock, parchment paper, containers, gaskets, liners, bags and other single-service articles for use in contact with milk and/or milk products are purchased and stored in sanitary tubes, wrappings or cartons; are kept in a clean, dry place until used; and are handled in a sanitary manner. ...

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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 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~~ containers and/or closures manufacturing facilities.

The applicable Government Water Control Authority requirements, which are less stringent than the *Grade "A" PMO*, shall be superseded by the *Grade "A" PMO*. 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~~ certifications 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 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. ...

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APPENDIX J. STANDARDS FOR THE FABRICATION OF SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS ...

PREFACE ...

Within recent years, single-service ~~container~~ containers and/or closures manufacturers have introduced new materials, equipment, and design concepts for these containers and closures. Evaluation of the industry's basic manufacturing and handling techniques and establishment of sanitation criteria assure that single-service containers and/or closures and the materials from which they are formed are safe and in compliance with bacteriological standards of Item 12p of this *Ordinance*.

STANDARDS FOR THE FABRICATION OF SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS ...

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B. DEFINITIONS

The following definitions shall be employed in the application of these sanitation Standards: ...

2. "Certified Single-Service Consultant (SSC)" shall mean an individual who has been certified by the Public Health Service/Food and Drug Administration (PHS/FDA), has a valid certificate of qualification to conduct the certification and listing of foreign single-service containers and/or closures for milk and/or milk products manufacturers on the *IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS List)* and does not have direct responsibility for the routine regulatory inspection and enforcement or regulatory auditing of the foreign single-service containers and/or closures manufacturer to be certified.

Re-number the remaining DEFINITIONS accordingly.

45. "**Component Part**" shall mean any item that by itself, does not perform any function, but when assembled with one (1) or more component parts or closures, becomes a part of the single-service container or closure. These may include, but are not limited to blanks, sheeting, valves and valve parts, tubes, dispensing devices and sampling containers. All material used for the fabrication of a component part shall meet the requirements of the *FFD&CA* as amended.

56. "**Manufacturer**" shall mean any person or company in the business of manufacturing a single-service container and/or closure for the packaging or sampling of a Grade "A" milk and/or milk product.

Re-number the remaining DEFINITIONS accordingly.

1314. "**Production Scrap**" shall mean material which remains from the manufacture of single-service containers or closures, that has been handled or treated in such a manner that it does not comply with the definition for "broke and trim" or "regrind", but may be collected for recycling. It may contain material such as containers, closures or trim that have fallen on the floor.

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1415. "**Regrind**" shall mean clean plastic material that is trimmed from the container and/or closure, and imperfectly formed containers and/or closures, which result from the manufacture of single-service containers and/or closures, provided it is handled in a clean, sanitary manner. This may be in its trimmed or molded form and ground in a suitable grinder within the plant. It shall not include any material, container and/or closure which comes from an unapproved source or whose source, chemical content or treatment is unknown, or which may have poisonous or deleterious material retained in the plastic, which migrates to the food at levels exceeding regulatory levels. Regrind, when transported from one (1) approved plant to another, shall be shipped in suitable, clean, sealed, properly labeled containers. This definition shall not preclude the use of regrind plastic material when it complies with a protocol that has been reviewed and accepted by FDA.

1516. "**Sample Set**" shall mean:

- a. For the rinse test, a minimum of four (4) containers shall be tested.
- b. For the swab test, a minimum of four (4), 50 square centimeter areas of surface from separate containers or closures shall be tested. In the case of containers or closures with a product-contact surface area smaller than 50 square centimeters, more than four (4) containers or closures to equal at least 50 square centimeters times four (4) shall be required to be swabbed. ...

1718. "**Single-Service Articles**" shall mean articles that are constructed wholly, in part, or in combination from paper, paperboard, molded pulp, plastic, metals, glass, rubber, ceramic, coatings or similar materials and intended by the manufacturer for one (1) usage only. ...

Re-number the remaining DEFINITIONS accordingly.

20. "**Single-Service Containers and/or Closures Manufacturer Certification**" shall mean the certification conducted by a Milk Sanitation Rating Officer (SRO) for U.S. manufacturers of single-service containers and/or closures for milk and/or milk products; or a Third Party Certifier's (TPC's) Milk Sanitation Rating Officer (SRO); or a Certified Single-Service

Consultant (SSC) for foreign manufacturers of single-service containers and/or closures for milk and/or milk products, which measures the degree to which the provisions of Appendix J. of this Ordinance are being complied with by the single-service containers and/or closures manufacturer for inclusion on the IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS List). The certification is based on compliance with the requirements of Appendix J. of this Ordinance and is conducted in accordance with the procedures set forth in the Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers (MMSR).

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

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5. A sample set from each manufacturing line, as defined in these Standards, shall consist of a minimum of four (4) containers and/or closures, when the rinse test is used, or a minimum of four (4) 50 square centimeters (cm²) areas of surface, when the swab test is used. ...

D. FABRICATION PLANT STANDARDS

NOTE: To be used in conjunction with FORM FDA 2359c-MANUFACTURING PLANT INSPECTION REPORT (Single-Service ~~Milk~~ Containers and/or Closures for Milk and/or Milk Products). (Refer to Appendix M.) ...

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5. SEPARATE ROOMS

a. All fabricating areas shall be separate from non-fabricating areas to protect against contamination. Provided, that if the entire plant meets all sanitation requirements and ~~is~~ a source of cross contamination does not exist, separation between areas is not required. ...

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13. PROTECTION FROM CONTAMINATION ...

e. Pesticides shall be used in accordance with the manufacturer's directions and used so as to preclude the contamination of containers and/or closures. ...

g. Single-service containers and/or closures for milk and/or milk products shall not be fabricated on equipment used for the manufacture of products made of non-food-grade materials, unless such equipment has been thoroughly cleaned and/or purged of all non-food-grade material by a process that will not contaminate the food-grade material.

h. The manufacture of single-service containers and/or closures for milk and/or milk products shall be carried on in such a manner that there shall not be ~~no~~ any cross contamination of raw material or regrind with non-food-grade materials. ...

14. STORAGE OF MATERIALS AND FINISHED PRODUCT ...

- c. Where containers and/or closures are pre-formed in plants other than the original fabricating facility:
- (1) Containers, blanks and closures shall be stored in the original cartons and sealed until used; and
 - (2) Partially used cartons of containers, blanks and closures shall be resealed until used. ...

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e. In-process storage bins that touch the product-contact surface of containers and/or closures shall be constructed of cleanable, nonabsorbent material and kept clean.

15. FABRICATING EQUIPMENT

The requirements of this Section pertain to all equipment and processes used in the fabrication of containers and/or closures, irrespective of the materials used and whether or not mentioned herein. Some of this equipment includes grinders, rollers, reamers and cutters, molders and fittings, extruders, silos, resin bins and hoppers, printing equipment, blanking equipment and sealing equipment. ...

c. Take-off tables and other container and/or closure contact surfaces shall be constructed of cleanable material, kept clean and in good repair. ...

16. MATERIALS FOR THE CONSTRUCTION OF CONTAINERS AND/OR CLOSURES

a. Only resin from a manufacturing plant in compliance with 21 CFR Parts 174-178 shall be used for the construction of containers and/or closures. Only plastic sheeting and extrusions, plastic laminated paper, roll stock, component part(s), molded or formed parts, metal and paperboard blanks, or combinations thereof, from a manufacturing and/or fabricating plant conforming to these Standards, shall be used. Fabricating plants listed in the current *IMS List* shall be considered in compliance with this Item.

b. Only food-grade, non-toxic lubricants shall be used on container and/or closure-contact surfaces. Excess lubricant shall be removed from surfaces close to shafts, rollers, bearing sleeves and mandrels. These lubricants shall be handled and stored in a manner that shall prevent cross contamination with non-food-grade lubricants. Such storage areas shall be clean and adequately ventilated.

c. Containers, closures, resin and flashing on the floor, floor sweepings of production materials and production scrap are prohibited from being reused. This shall not preclude the use of these materials when they comply with a recycling protocol that has been reviewed and accepted by FDA.

17. WAXES, ADHESIVES, SEALANTS, COATINGS AND INKS

- a. Waxes, adhesives, sealants, coatings and inks used for containers and/or closures shall be handled and stored in a manner that shall prevent cross contamination with similar non-food-grade materials. Such storage areas shall be clean and adequately ventilated. ...

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- e. Waxing shall be performed so as to assure that containers and/or closures are completely coated and the wax shall be kept at a temperature of 60°C (140°F) or higher.

18. HANDLING OF CONTAINERS, CLOSURES AND EQUIPMENT

- a. Handling container and/or closure surfaces shall be kept to a minimum. ...

19. WRAPPING AND SHIPPING ...

- c. Transportation vehicles used to ship finished materials from the single-service container and/or closure plant or within the plant shall be clean and in good repair and shall not have been used for the transportation of garbage, waste or toxic materials.

- d. Paperboard containers, wrappers, and dividers that contact the surface of the container and/or closure shall not be reused for this purpose.

- e. All packaging materials that contact the product-contact surface of the container and/or closure shall comply with the requirements of 21 CFR Parts 174-178 and the bacteriological standards of Section C of these Standards, but the materials do not have to be manufactured at a listed single-service plant. Some outer packaging material such as corrugated cardboard boxes used for the packaging of milk carton flats, are exempt from this bacteriological standard. The edges of these flats are subject to heat during the forming and sealing of the container. There are not any specifications for the bacteriological sampling frequency. The Regulatory Agency may choose to collect samples of packaging materials to determine compliance with the bacteriological standards of this Section.

20. IDENTIFICATION AND RECORDS

- a. Outer wrappings shall be identified with the name, ~~and~~ city and State of the plant where the contents are fabricated, except those manufactured in, and which are only for use in the same facility. For foreign manufacturing plants, the outer wrap shall also be identified with the country. Where several plants are operated by one (1) firm, the common firm name may be utilized, provided that the location of the plant at which the contents were fabricated is also shown either directly or by the Federal Information Processing Standards (FIPS) numerical code on the outer wrapper. ...

- c. Records of all required bacteriological tests of containers and/or closures shall be maintained at the plant of manufacture for two (2) years and results shall be in compliance with Section C of these Standards. ...

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

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

~~E. CRITERIA FOR LISTING CERTIFIED SINGLE SERVICE MANUFACTURERS ON THE IMS LIST~~

~~The following criteria have been developed to allow Rating and/or Regulatory Agencies flexibility in evaluating and listing single service manufacturing plants. Rating and/or Regulatory Agencies may choose from the following list of criteria for listing certified single-service manufacturers:~~

- ~~1. Single service manufacturers that operate in conjunction with an IMS Listed milk plant may be listed for twenty four (24) months, if the single service plant is inspected at least quarterly, using FORM FDA 2359c MANUFACTURING PLANT INSPECTION REPORT (Single-Service Milk Containers and Closures), and records of such inspections and all required tests are maintained by the Regulatory Agency. Provided that, single-service manufacturers that operate in conjunction with an IMS HACCP listed milk plant may be listed for twenty four (24) months, if the single service plant is integrated into the milk plant's NCIMS HACCP system and if the single service plant is inspected at the minimum milk plant audit frequency specified in Appendix K, using FORM FDA 2359c MANUFACTURING PLANT INSPECTION REPORT (Single-Service Milk Containers and Closures), and records of such inspections and all required tests are maintained by the Regulatory Agency. The permit for the milk plant shall also include the inspection of the single service manufacturing areas.~~
- ~~2. Single service manufacturers that operate in conjunction with an IMS listed milk plant and are not inspected at least quarterly and/or are not included under a permit system may be optionally listed for twelve (12) months.~~
- ~~3. Single service manufacturers that operate as a separate entity may be listed for twenty four (24) months, if the Regulatory Agency has a permit system and inspects the plant using FORM FDA 2359c MANUFACTURING PLANT INSPECTION REPORT (Single-Service Milk Containers and Closures) at least quarterly. All testing of containers and individual water supplies shall be under the direction of the Regulatory Agency and kept on file.~~
- ~~4. Single service manufacturers that operate as a separate entity and are not inspected by Regulatory Agency personnel at least quarterly and/or do not have a permit system may be optionally listed for twelve (12) months.~~
- ~~5. Certification of single service manufacturing plants may be valid for a period not to exceed one (1) or two (2) years from the earliest survey date, based on the criteria above. The expiration date is one (1) or two (2) years from the earliest survey date. In the case of a one (1) year certification with the earliest survey date of 6/15/2013, the expiration date would be 6/14/2014.~~

~~The following procedures shall be followed for listing certified single service manufacturers on the IMS List:~~

1. ~~For domestic firms, triplicate copies or USPHS/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 SRO to the appropriate Regional Office of the USPHS/FDA for single-service manufacturers who desire to be listed on the *IMS List*.~~
2. ~~For foreign firms, duplicate copies or USUSPHS/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 on the *IMS List*.~~
3. ~~The Certified Single Service Manufacturer is not listed 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 USPHS/FDA's electronic version, a signed copy of FORM FDA 2359d, including Section 12, shall be maintained on file by the Rating Agency and shall be reviewed as part of the Single Service Listing Audit and/or the Regulatory/Rating Agency Program Evaluation.~~
 - b. ~~For the submission of USPHS/FDA's electronic version, a signed copy of FORM FDA 2359d, including Section 12, shall be maintained on file by the private consulting firm.~~
4. ~~The Certified Single Service Manufacturer may be listed 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 of this Ordinance.~~

APPENDIX K. HACCP PROGRAM ...

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APPENDIX M. REPORTS AND RECORDS ..

FORM FDA 2359c	MANUFACTURING PLANT INSPECTION REPORT (<i>Single-Service Milk Containers and/or Closures for Milk and/or Milk Products</i>)
FORM FDA 2359d	REPORT OF CERTIFICATION (<i>Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products</i>)

Make the following changes to:

FORM FDA 2359c-MANUFACTURING PLANT INSPECTION REPORT (*Single-Service ~~Milk~~ Containers and/or Closures for Milk and/or Milk Products*)

**MANUFACTURING PLANT
INSPECTION REPORT**
*(Single-Service Milk Containers and/or Closures
for Milk and/or Milk Products)*

NAME AND LOCATION OF PLANT

<p>1. FLOORS Smooth; impervious; in good repair.....(a) <input type="checkbox"/> Joints between walls and floors tight; impervious.....(b) <input type="checkbox"/> Floor drains properly trapped; sloped to drain.....(c) <input type="checkbox"/></p> <p>2. WALLS AND CEILINGS In fabrication areas—smooth; cleanable; light-colored.....(a) <input type="checkbox"/> In fabrication and storage areas—good repair.....(b) <input type="checkbox"/> Openings in walls and ceilings effectively sealed.....(c) <input type="checkbox"/></p> <p>3. DOORS AND WINDOWS All outside openings protected against entrance of insects, rodents, dust, and airborne contamination.....(a) <input type="checkbox"/> Outer doors tight, self-closing.....(b) <input type="checkbox"/></p> <p>4. LIGHTING AND VENTILATION Adequate light in all rooms.....(a) <input type="checkbox"/> Ventilation sufficient.....(b) <input type="checkbox"/> Pressure ventilation systems properly filtered.....(c) <input type="checkbox"/></p> <p>5. SEPARATE ROOMS Fabrication areas separate from non-fabrication areas when required.....(a) <input type="checkbox"/> Regrinding plastic and paper trim shredding, packaging and baling conducted in separate room(s) from fabrication areas or as Appendix J permits.....(b) <input type="checkbox"/></p> <p>6. TOILET FACILITIES-SEWAGE DISPOSAL Disposal of sewage; other waste; in public sewage system or in compliance with Local and State Regulations.....(a) <input type="checkbox"/> All plumbing complies with Local and State plumbing Regulations.....(b) <input type="checkbox"/> Solid, tight-fitting, self-closing doors.....(c) <input type="checkbox"/> Toilet rooms and fixtures clean; in good repair.....(d) <input type="checkbox"/> Adequate light and ventilation; ducts vented to the outside.....(e) <input type="checkbox"/> Proper handwashing facilities.....(f) <input type="checkbox"/> Open windows effectively screened.....(g) <input type="checkbox"/> Employee handwashing signs posted.....(h) <input type="checkbox"/> Eating/food storage prohibited.....(i) <input type="checkbox"/></p> <p>7. WATER SUPPLY Safe; complies with bacteriological and construction requirements.....(a) <input type="checkbox"/> No direct or indirect connection between safe and unsafe water.....(b) <input type="checkbox"/> Sampled and examined as required.....(c) <input type="checkbox"/> Recirculated cooling water <u>used in water baths</u> complies with bacteriological standards, tested semi-annually.....(d) <input type="checkbox"/> Testing records maintained as required.....(e) <input type="checkbox"/></p> <p>8. HANDWASHING FACILITIES Hot and cold and/or warm running water, soap, individual towels or air dryers convenient to fabrication areas; covered trash containers when required; hand sanitizers used as Appendix J permits.....(a) <input type="checkbox"/> Handwashing facilities clean.....(b) <input type="checkbox"/></p> <p>9. PLANT CLEANLINESS Floors, walls, ceilings, overhead beams, fixtures, pipes and ducts clean in rooms as required.....(a) <input type="checkbox"/> Plant free of evidence of insects, rodents and birds.....(b) <input type="checkbox"/> Machines and appurtenances clean.....(c) <input type="checkbox"/></p>	<p>10. LOCKERS AND LUNCHROOMS Separate from plant operation; self-closing doors.....(a) <input type="checkbox"/> Eating/storage of food prohibited in fabrication and storage areas.....(b) <input type="checkbox"/> Locker and lunchrooms clean.....(c) <input type="checkbox"/> Cleanable trash containers provided; properly labeled, covered.....(d) <input type="checkbox"/> Handwashing facilities convenient.....(e) <input type="checkbox"/> Employee handwashing signs posted.....(f) <input type="checkbox"/></p> <p>11. DISPOSAL OF WASTES Stored in covered, impervious, leak-proof containers; does not apply to production scrap.....(a) <input type="checkbox"/> Waste containers properly identified.....(b) <input type="checkbox"/> Storage of garbage/rubbish meets requirements.....(c) <input type="checkbox"/></p> <p>12. PERSONNEL - PRACTICES Hands washed as required.....(a) <input type="checkbox"/> Clean outer garments; hair restraints.....(b) <input type="checkbox"/> No person affected by disease in communicable form; while a carrier of such disease; or with inadequately protected wounds or lesions shall work in the fabrication areas.....(c) <input type="checkbox"/> Tobacco use in authorized areas only.....(d) <input type="checkbox"/> Insecured jewelry not permitted in fabrication areas.....(e) <input type="checkbox"/></p> <p>13. PROTECTION FROM CONTAMINATION Product contact surfaces protected; all materials in process properly protected.....(a) <input type="checkbox"/> Air under pressure directed at materials or product contact surfaces in compliance.....(b) <input type="checkbox"/> Air directed at materials or product contact surfaces by fans or blowers in compliance.....(c) <input type="checkbox"/> Pesticides approved; EPA registered.....(d) <input type="checkbox"/> Pesticides used in accordance with directions; precludes contamination of containers/closures.....(e) <input type="checkbox"/> Single-service articles in process protected from contamination.....(f) <input type="checkbox"/> Equipment cleaned after use of non-food-grade materials.....(g) <input type="checkbox"/> Cross contamination with non-food-grade material prevented.....(h) <input type="checkbox"/> No overcrowding of equipment and operations.....(i) <input type="checkbox"/> Toxic chemicals separated from raw materials and finished products.....(j) <input type="checkbox"/> Food containers manufactured by facility not used for storage of miscellaneous items or chemicals.....(k) <input type="checkbox"/></p> <p>14. STORAGE OF MATERIALS AND FINISHED PRODUCT Away from any wall; soiled outer turns or edges discarded.....(a) <input type="checkbox"/> Stored in clean, dry place, protected from splash, insects, and dust.....(b) <input type="checkbox"/> Containers and closures stored in original cartons and sealed until used; partially used cartons resealed during storage.....(c) <input type="checkbox"/> Containers for storage of resin, raw and reuse materials are covered, clean, impervious and properly identified.....(d) <input type="checkbox"/> In-process storage bins that touch the product contact surface constructed of cleanable, nonabsorbent material; clean.....(e) <input type="checkbox"/></p> <p>15. FABRICATING EQUIPMENT Contact surfaces clean; milk plant equipment utilized for preforming containers clean and sanitized prior to operation.....(a) <input type="checkbox"/></p>	<p>Makeshift devices not used; fasteners, guides, hangers, supports and baffles properly constructed; good repair.....(b) <input type="checkbox"/> Take-off tables and other container contact surfaces properly constructed; clean; in good repair.....(c) <input type="checkbox"/> Grinders, shredders and similar equipment properly installed; protected from contamination.....(d) <input type="checkbox"/> Resin storage silos, other containers, constructed to protect resin from contamination; air vents filtered; air tubes good repair and properly protected.....(e) <input type="checkbox"/></p> <p>16. MATERIALS FOR CONSTRUCTION OF CONTAINERS AND/OR CLOSURES Materials from approved source.....(a) <input type="checkbox"/> Food-grade lubricants used on contact surfaces; stored to prevent cross contamination; storage clean and ventilated.....(b) <input type="checkbox"/> Containers, closures or materials on floor not used.....(c) <input type="checkbox"/></p> <p>17. WAXES, ADHESIVES, SEALANTS, COATING AND INKS Handled and stored to prevent cross contamination with non-food-grade materials; storage areas clean and ventilated.....(a) <input type="checkbox"/> Unused materials covered, labeled and properly stored.....(b) <input type="checkbox"/> Nontoxic; imparts no flavor or odor; non-contaminating; complies with 21 CFR Parts 175-174-178.....(c) <input type="checkbox"/> Transfer containers clean; covered, properly identified.....(d) <input type="checkbox"/> Waxing, when used, performed as required; wax kept at proper temperature.....(e) <input type="checkbox"/></p> <p>18. HANDLING OF CONTAINERS, CLOSURES AND EQUIPMENT Handling of container and closure surfaces minimized.....(a) <input type="checkbox"/> Hands sanitized frequently or clean, single-use gloves worn; sanitizing dispensers convenient.....(b) <input type="checkbox"/></p> <p>19. WRAPPING AND SHIPPING Single-service articles properly containerized prior to shipping.....(a) <input type="checkbox"/> Packaged contents protected from contamination.....(b) <input type="checkbox"/> Transportation vehicles clean; in good repair; not used for unapproved uses.....(c) <input type="checkbox"/> Paperboard containers, wrappers and dividers not reused.....(d) <input type="checkbox"/> Packaging materials in compliance.....(e) <input type="checkbox"/></p> <p>20. IDENTIFICATION AND RECORDS Plant identification on outer wrapping as required.....(a) <input type="checkbox"/> Glass containers properly labeled.....(b) <input type="checkbox"/> Required bacteriological tests on file; maintained as required; and in compliance.....(c) <input type="checkbox"/> Required bacteriological and chemical test records for all component parts used in final assembled product on file.....(d) <input type="checkbox"/> Information on file from suppliers of raw materials, waxes, adhesives, sealants, coatings and inks indicating compliance.....(e) <input type="checkbox"/> Information on file from suppliers of packaging materials indicating compliance.....(f) <input type="checkbox"/></p> <p>21. SURROUNDINGS Surroundings neat and clean and free of breeding areas, conditions attracting or harboring flies, insects or rodents.....(a) <input type="checkbox"/> Driveways graded; no standing water.....(b) <input type="checkbox"/></p>
<p>REMARKS (If additional space is required, please place information on the back of this Form or on a separate page.)</p>		
<p>DATE</p>	<p>SANITARIAN/CONSULTANT/SRO/SSC/RMS</p>	
<p>NOTE: This Form has been developed for use with Appendix J of the <i>Grade "A" Pasteurized Milk Ordinance</i>.</p>		

Document: 2013 MMSR

Pages: Cover, i-v, 1, 2, 4-6, 20, 25, 27, 32, 50-53 and 81-82

Make the following changes to the 2013 MMSR:

Cover:

METHODS OF MAKING SANITATION RATINGS OF MILK SHIPPERS AND THE CERTIFICATIONS/LISTINGS OF SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS MANUFACTURERS

2013 2015 Revision

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I. PUBLICATION OF THE "REPORT OF CERTIFICATION (*Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products*)"

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HK. EXAMPLES OF HOW TO PROPERLY COMPLETE RATING, NCIMS HACCP LISTING, ASEPTIC PROCESSING AND PACKAGING PROGRAM, AND RETORT PROCESSED AFTER PACKAGING PROGRAM LISTING FORMS AND SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS MANUFACTURERS CERTIFICATION/LISTING FORMS.....

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25. FORM FDA 2359e-STATUS OF MANUFACTURING PLANTS (Single-Service Containers and/or Closures for Milk and/or Milk Products)

26. FORM FDA 2359d-REPORT OF CERTIFICATION (Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products)

Page 1:

METHODS OF MAKING SANITATION RATINGS OF MILK SHIPPERS AND THE CERTIFICATIONS/LISTINGS OF SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS MANUFACTURERS

A. DEFINITIONS ...

Page 2:

10. CERTIFIED SINGLE-SERVICE CONSULTANT (SSC): An individual who has been certified by the Public Health Service/Food and Drug Administration (PHS/FDA), has a valid certificate of qualification to conduct the certification and listing of foreign single-service containers and/or closures for milk and/or milk products manufacturers on the *IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS List)* and does not have direct responsibility for the routine regulatory inspection and enforcement or regulatory auditing of the foreign single-service containers and/or closures manufacturer to be certified.

Re-number the remaining DEFINITIONS accordingly.

Page 4:

2324. 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 and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers (MMSR)*. Ratings are conducted by FDA certified Milk Sanitation Rating Officers (SROs). They also certify single-service containers and/or 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 and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers (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-number the remaining DEFINITIONS accordingly.

Page 5:

28. RETORT PROCESSED AFTER PACKAGING SYSTEM (RPPS) ..

Page 6:

29. SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURER: A single-service containers and/or closures manufacturer shall mean any person or company in the business of manufacturing a single-service container and/or closure for the packaging or sampling of Grade “A” milk and/or milk products in accordance with Appendix J. Standards for the Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products of the *Grade “A” PMO*.

30. SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURER AUDIT: The designated PHS/FDA and NCIMS *Procedures* method to ensure that the published certification/listing of a single-service containers and/or closures for milk and/or milk products manufacturer on the *IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS List)* is valid and maintained during the interval between certifications.

31. SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURER CERTIFICATION: This is the certification conducted by a Milk Sanitation Rating Officer (SRO) for U.S. manufacturers of single-service containers and/or closures for milk and/or milk products; or a Third Party Certifier’s (TPC’s) Milk Sanitation Rating Officer (SRO); or a Certified Single-Service Consultant (SSC) for foreign manufacturers of single-service containers

and/or closures for milk and/or milk products, which measures the degree to which the provisions of Appendix J. Standards for the Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products of the *Grade "A" PMO* are being complied with by the single-service containers and/or closures manufacturer for inclusion on the *IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS List)*. The certification is based on compliance with the requirements of Appendix J. of the *Grade "A" PMO* and is conducted in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers (MMSR)*.

27-32. THIRD PARTY CERTIFIER (TPC): ...

29-33. TRANSFER STATION: ...

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D. CERTIFICATION/LISTING METHODS FOR SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS MANUFACTURERS

The State Rating Agency shall certify U.S. manufacturers of single-service containers and/or closures for milk and/or milk products based on compliance with Appendix J. of the *Grade "A" PMO* and in accordance with the *MMSR* for inclusion on the *IMS List*.

A TPC's SRO or a SSC shall certify foreign manufacturers of single-service containers and/or closures for milk and/or milk products based on compliance with Appendix J. of the *Grade "A" PMO* and in accordance with the *MMSR* for inclusion on the *IMS List*.

1. COLLECTION OF DATA

Data from which certifications for U.S. manufacturers of single-service containers and/or closures for milk and/or milk products are determined shall be obtained by State Rating Agency SROs from the records on file with the Regulatory Agency and from the evaluation of sanitary practices and facilities at the single-service containers and/or closures manufacturer.

Data from which certifications for foreign manufacturers of single-service containers and/or closures for milk and/or milk products are determined shall be obtained by a TPC's SRO or a SSC from the records on file with the Regulatory Agency, SSC or single-service containers and/or closures manufacturer, respectively, and from the evaluation of sanitary practices and facilities at the single-service containers and/or closures manufacturer.

a. Recording of Inspection Data

1.) During a certification, inspection data are recorded on FORM FDA 2359c-MANUFACTURING PLANT INSPECTION REPORT (*Single-Service Containers and/or Closures for Milk and/or Milk Products*), the Items of which correspond to the Items of sanitation in Appendix J. of the *Grade "A" PMO*.

2.) Sanitary conditions are evaluated in terms of the requirements of Appendix J. of the Grade "A" PMO. Professional judgment alone shall dictate whether an observed deficiency is representative of significant day-to-day sanitary conditions or is an anomaly. When significant violations of any given requirement are noted, the corresponding Item(s) or sub-item(s) on the individual FORM FDA 2359c-MANUFACTURING PLANT INSPECTION REPORT (Single-Service Containers and/or Closures for Milk and/or Milk Products) are marked with an "X". Each sub-item found in violation should be carefully considered before marking with an "X", as this affects the computation of the Sanitation Compliance Rating.

b. Recording of Laboratory and Other Test Data

1.) Regulatory Agency, SSC and/or single-service containers and/or closures manufactures, as applicable, records are used in determining compliance with bacterial, coliform and chemical, as applicable, 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 Milk Laboratory Control Agency or for the SSC that certified the single-service containers and/or closures manufacturer that both sampling and laboratory procedures have been approved in accordance with the methods of the current edition of the EML. Certifications shall not be conducted when an approved laboratory has not been utilized by the Regulatory Agency, SSC or single-service containers and/or closures manufacturers, as applicable, for the necessary tests.

2.) Compliance with bacterial and coliform requirements is based on whether, at the time of the certification, a single-service containers and/or closures manufacturer's containers and/or closures meet the standards of Appendix J. of the Grade "A" PMO. Each manufacturing line of containers and/or closures for each of the above applicable requirements, shall be debited if two (2) of the last four (4) sample set results exceed the limit(s), and the last sample set result is in violation. A debit shall be given when less than the required number of sample sets has been examined during the preceding six (6) months. For certification purposes, the preceding six (6) months is considered to be the elapsed period for the month in which the certification is made and the preceding six (6) months. Single-service containers and/or closures manufactures which have had a permit, if applicable, for less than six (6) months at the time of the certification or which do not operate on a year round basis and for which the Regulatory Agency, SSC and/or single-service containers and/or closures manufacturer, as applicable, has not yet examined the required number of sample sets shall not be debited. Provided, that the last sample set result is within the limit(s).

2. COMPUTATION OF SANITATION COMPLIANCE RATINGS

Sanitation Compliance Ratings shall be made of single-service containers and/or closures for milk and/or milk products manufacturers.

a. Certification results are transferred to FORM FDA 2359e-STATUS OF MANUFACTURING PLANTS (Single-Service Containers and/or Closures for Milk and/or

Milk Products). This Form may be obtained from the Regional Offices of the PHS/FDA or at the following FDA website: <http://www.fda.gov/aboutfda/reportsmanualsforms/forms/default.htm>.

b. The identity of each single-service containers and/or closures manufacturer is entered in the first column, "Name of Plant" on FORM FDA 2359e-STATUS OF MANUFACTURING PLANTS (Single-Service Containers and/or Closures for Milk and/or Milk Products).

Violations of Items are indicated by an "X" or by inserting the point value of the violation in the appropriate column(s). The sum of the weights of all Items found violated at the single-service containers and/or closures manufacturer is entered in the "Total Debits" column. (Refer to Section K, #25, for an example.)

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

Sanitation Compliance Rating = 100 – (The Sum of the "Total Debits")

This Sanitation Compliance Rating is entered in the appropriate space in the upper right hand corner of FORM FDA 2359e-STATUS OF MANUFACTURING PLANTS (Single-Service Containers and/or Closures for Milk and/or Milk Products). (Refer to Section K, #25, for an example.)

DE. COMPUTATION OF ENFORCEMENT RATINGS ...

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EF. PREPARATION OF THE SROs SRO's REPORT FOR MILK SHIPPERS ...

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G. PREPARATION OF THE SRO's or SSC's REPORT FOR SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURERS

1. PURPOSE

Certifications made by the methods described measure the degree to which the single-service containers and/or closures manufacturer conforms to the standards and procedures contained in Appendix J. of the Grade "A" PMO.

2. SUMMARY OF CERTIFICATION RESULTS

The following FORM shall be provided in the summary report provided to the Regulatory Agency and/or single-service containers and/or closures manufacturer, as applicable:

FORM FDA 2359c-MANUFACTURING PLANT INSPECTION REPORT (Single-Service Containers and/or Closures for Milk and/or Milk Products) shall be used. Under "REMARKS"

an explanation of the observations per debited Item shall be included. During the certification, additional facts may become apparent. These facts, if provided, would be valuable information to the Regulatory Agency and/or single-service containers and/or closures manufacturer in directing the Regulatory Agency program and/or single-service containers and/or closures manufacturer to be utilized for improvement. Specific measures that give guidance on how improvements may be made shall be included. The full report shall be discussed in detail with the appropriate officials of the Regulatory Agency and/or the appropriate personnel responsible for the management of the single-service containers and/or closures manufacturer. These discussions will contribute to a better understanding of the problems present and provide an opportunity for communicating a means of implementing the SRO's or SSC's recommendations.

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

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I. PUBLICATION OF THE “REPORT OF CERTIFICATION (Fabrication of Single-Service Containers and/or Closure for Milk and/or Milk Products)”

1. PURPOSE

a. Criteria for Listing Certified Single-Service Containers and/or Closures Manufacturers on the *IMS LIST*

The following criteria have been developed to allow Rating and/or Regulatory Agencies flexibility in evaluating and listing single-service containers and/or closures manufacturing plants. Rating and/or Regulatory Agencies shall choose from the following list of criteria for listing certified single-service containers and/or closures manufacturers:

1.) Single-service containers and/or closures manufacturers that operate in conjunction with an IMS Listed milk plant may be listed for twenty-four (24) months, if the single-service containers and/or closures manufacturing plant is inspected at least quarterly, using FORM FDA 2359c-MANUFACTURING PLANT INSPECTION REPORT (Single-Service Containers and/or Closures for Milk and/or Milk Products), and records of such inspections and all required tests are maintained by the Regulatory Agency. Provided that, single-service containers and/or closures manufacturers that operate in conjunction with an IMS HACCP listed milk plant may be listed for twenty-four (24) months, if the single-service containers and/or closures manufacturing plant is integrated into the milk plant's NCIMS HACCP system and if the single-service containers and/or closures manufacturing plant is inspected at the minimum milk plant audit frequency specified in Appendix K. of the *Grade “A” PMO*, using FORM FDA 2359c-MANUFACTURING PLANT INSPECTION REPORT (Single-Service Containers and/or Closures for Milk and/or Milk Products), and records of such inspections and all required tests are maintained by the Regulatory Agency. The permit for the milk plant shall also include the inspection of the single-service containers and/or closures manufacturing areas.

2.) Single-service containers and/or closures manufacturers that operate in conjunction with an IMS listed milk plant and are not inspected at least quarterly and/or are not included under a permit system may be optionally listed for twelve (12) months.

3.) Single-service containers and/or closures manufacturers that operate as a separate entity may be listed for twenty-four (24) months, if the Regulatory Agency has a permit system and inspects the single-service containers and/or closures manufacturing plant using FORM FDA 2359c–MANUFACTURING PLANT INSPECTION REPORT (Single-Service Containers and/or Closures for Milk and/or Milk Products) at least quarterly. All testing of containers, closures and individual water supplies shall be under the direction of the Regulatory Agency and kept on file.

4.) Single-service containers and/or closures manufacturers that operate as a separate entity and are not inspected by Regulatory Agency personnel at least quarterly and/or do not have a permit system may be optionally listed for twelve (12) months.

NOTE: This criterion is the only option available for use by a SSC when certifying foreign manufacturers of single-service containers and/or closures for milk and/or milk products.

5.) Certification of single-service containers and/or closures manufacturing plants may be valid for a period not to exceed one (1) or two (2) years from the earliest certification date, based on the criteria above. The expiration date is one (1) or two (2) years from the earliest certification date. In the case of a one (1) year certification with the earliest certification date of 6/15/2015, the expiration date would be 6/14/2016.

b. Procedures for Certifying/Listing Single-Service Containers and/or Closures Manufacturers

The following procedures shall be followed for certifying/listing single-service containers and/or closures manufacturers on the *IMS List*:

1.) For domestic firms, triplicate copies or PHS/FDA’s electronic version (transmitted via computer) of FORM FDA 2359d-REPORT OF CERTIFICATION (*Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products*) shall be submitted by the SRO to the appropriate Regional Office of the PHS/FDA for single-service containers and/or closures manufacturers who desire to be listed 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/or Closures for Milk and/or Milk Products*) shall be submitted by the TPC or SSC 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 containers and/or closures manufacturers who desire to be listed on the *IMS List*.

3.) The certified single-service containers and/or closures manufacturer is not listed on the *IMS List* unless the “PERMISSION TO PUBLISH” SECTION of FORM FDA 2359d-REPORT OF CERTIFICATION (*Fabrication of Single-Service Containers*

and/or Closures for Milk and/or Milk Products) 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-REPORT OF CERTIFICATION (Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products), including Section 12, shall be maintained on file by the Rating Agency and shall be reviewed as part of the single-service containers and/or closures manufacturer’s listing audit and/or the Regulatory/Rating Agency Program Evaluation.

B.) For the submission of PHS/FDA’s electronic version, a signed copy of FORM FDA 2359d-REPORT OF CERTIFICATION (Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products), including Section 12, shall be maintained on file by the SSC.

4.) The certified single-service containers and/or closures manufacturer may be listed 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 and/or closures or specific size of containers and/or closures and conform to the specifications contained within Appendix J. of the Grade “A” PMO.

2. PREPARATION OF THE “REPORT OF CERTIFICATION”

Following the computation of the Sanitation Compliance Rating on FORM FDA 2359e-STATUS OF MANUFACTURING PLANTS (Single-Service Containers and/or Closures for Milk and/or Milk Products), the resultant rating shall be transferred to FORM FDA 2359d-REPORT OF CERTIFICATION (Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products). The earliest certification date shall be the date of the first day of the certification.

NOTE: Certification of single-service containers and/or closures for milk and/or milk products manufacturers conducted by SSCs may be valid for a period not to exceed one (1) year from the earliest certification date. The expiration date is one (1) year from the earliest certification date. For this one (1) year certification, with the earliest certification date of 6/15/2015, the expiration date would be 6/14/2016.

GJ. EXAMPLES OF RATING, NCIMS HACCP LISTING, ASEPTIC PROCESSING AND PACKAGING PROGRAM, AND RETORT PROCESSED AFTER PACKAGING PROGRAM LISTING FORMS AND SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCT MANUFACTURERS CERTIFICATION/LISTING FORMS ...

- 14. FORM FDA 2359e-STATUS OF MANUFACTURING PLANTS (Single-Service Containers and/or Closures for Milk and/or Milk Products)
- 15. FORM FDA 2359d-REPORT OF CERTIFICATION (Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products)

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HK. EXAMPLES OF HOW TO PROPERLY COMPLETE RATING, NCIMS HACCP LISTING, ASEPTIC PROCESSING AND PACKAGING PROGRAM, AND RETORT PROCESSED AFTER PACKAGING PROGRAM LISTING FORMS AND SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCT MANUFACTURERS CERTIFICATION/LISTING FORMS ...

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- 25. FORM FDA 2359e-STATUS OF MANUFACTURING PLANTS (Single-Service Containers and/or Closures for Milk and/or Milk Products)
- 26. FORM FDA 2359d-REPORT OF CERTIFICATION (Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products)

Note: Grant FDA editorial license to add the new titles for these FORMS to the NCIMS documents where appropriate.

Add the following FDA Forms to the MMSR:

Pages 52-53 and 81-82:

STATUS OF MANUFACTURING PLANTS

(SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS)

Plant _____

Date of Certification _____

Sanitation Compliance Rating¹ _____

NAME OF PLANT	ITEMS OF SANITATION																				REMARKS								
	Floors	Walls and Ceilings	Doors and Windows	Lighting and Ventilation	Separate Rooms	Toilet/Facilities- Sewage Disposal	Water Supply	Handwashing Facilities	Plant Cleanliness	Lockers and Lunchrooms	Disposal of Wastes	Personnel - Practices	Protection From Contamination	Storage of Materials and Finished Product	Fabrication Equipment	Materials for Construction of Containers and/or Closures	Waxes, Adhesives, Sealants, Coating and Inks	Handling of Containers, Closures and Equipment	Wrapping and Shipping	Identification and Records		Surroundings	Bacterial Count*	Colliform Count*	Total Debits ²				
ITEM	1	2	3	4	5	6	7	8	9	10	11	12	13 a,b,c,f f,g,i,k	13 d,e,h,j	14	15	16 a	16 b,c	17 a,b,c d,e	17 f	18	19	20 a,b,f	20 c,d,e	21				
WEIGHT	1	1	2	2	3	3	4	2	3	2	2	3	3	11	3	5	11	3	3	11	2	4	3	11	2	5	10		
TOTALS																													

Footnotes:
¹Sanitation Compliance Rating = 100 – Total Debits
²Total Debits for each manufacturing plant are the sum of the weights of the items violated. (NOTE: Any item or sub-item violated, indicate by placing the debit value (weight) of that item or an "X" under that item.)
*Used only when not in compliance.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	REPORT OF CERTIFICATION <i>(Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products)</i>	FOR FDA USE ONLY				
		1	2	3	4	5

IDENTIFICATION

1. NAME OF SINGLE-SERVICE FABRICATING PLANT			2. CITY			3. STATE/COUNTRY																							
4. STREET						5. MFG. CODE NO			6. CODE																				
7. AGENCY PROVIDING ROUTINE INSPECTION						56			57			58			59			60		61		62							
						7.a. RATING/CERTIFICATION AGENCY PERSONNEL <input type="checkbox"/> SHD <input type="checkbox"/> Other <input type="checkbox"/> SHA <input type="checkbox"/> TPC <input type="checkbox"/> SDL <input type="checkbox"/> SSC						7.b. DATE OF INSPECTION PLANT CERTIFICATION MONTH DAY YEAR 67 68 69 70 72 72 20						7.c. SANITATION COMPLIANCE RATING						PRODUCT CODE (60) 1. Containers 2. Closures 3. Other products 4. Containers and closures 5. Containers and other products 6. Closures and other products 7. Containers, closures and other products					
*EXPIRATION DATE Certification of single-service manufacturing plants may be valid for a period not to exceed one (1) or two (2) years from the earliest survey certification date. The expiration date is one (1) or two (2) years from the earliest survey certification date. NOTE: Certifications conducted by SSCs shall only be valid for a period not to exceed one (1) year from the earliest certification date.						8. SANITARIAN <u>SRO</u> OR CONSULTANT <u>SSC</u>						9. CERTIFICATION RECOMMENDED <input type="checkbox"/> YES <input type="checkbox"/> NO						9a. LISTING TYPE <input type="checkbox"/> FULL <input type="checkbox"/> PARTIAL											

LABORATORY CONTROL

10. NAME AND ADDRESS (OR CODE) OF APPROVED LABORATORY

11. INSPECTION RESULTS (Place an "X" under Items involved ~~debited~~)

1	2	3	4	5	6	7	8	9	10	11	12	13 a,b,c,f g,i,k	13 d,e h,j	14	15	16 a	16 b,c	17 a,b d,e	17 c	18	19	20 a,b,f	20 c,d,e	21

12. PERMISSION TO PUBLISH

Permission is hereby granted to release and publish the above-stated certification for use by ~~State and local milk control authorities~~ Regulatory/Rating Agencies and prospective purchasers.

It is understood and agreed by the undersigned that the official Rating Agency or SSC, as applicable, may review and appraise the single-service fabricating plant at any time during the period of time the above certification is in effect. It is further understood that failure to maintain the above certification will subject this plant to withdrawal from the IMS Listing. We will notify the Rating Agency or SSC, as applicable, of any significant changes made in the operation of this plant.

12.a. NAME OF PLANT

12.b. OFFICER AUTHORIZING RELEASE

12.c. TITLE

13. SUBMISSION OF REPORT BY STATE MILK SANITATION RATING AGENCY OR SSC, AS APPLICABLE

13.a. DATE OF REPORT

13.b. RECOMMENDED CLASSIFICATION ACCEPTED
 YES NO

13.c. SUBMITTED BY (Signature and Title)

FOR FDA USE ONLY

14. DATE RECEIVED

15. PUBLICATION OF RATING RECOMMENDED YES NO (If "NO", indicate why.)

16. DATE TRANSMITTED

17. SIGNATURE (FDA Regional Milk Specialist)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	REPORT OF CERTIFICATION <i>(Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products)</i>	FOR FDA USE ONLY																
		1	2	3	4	5												
IDENTIFICATION																		
1. NAME OF SINGLE-SERVICE FABRICATING PLANT Blow Mold Plastics			2. CITY Container		3. STATE/COUNTRY Country													
4. STREET 4200 Injection Point			5. MFG CODE NO		6. CODE													
7. AGENCY PROVIDING ROUTINE INSPECTION Resin Single-Service Consultants 2100 Injection Point Nozzle, State 00000			56 XX	57 XX	58 0	59 1												
7.a. RATING/CERTIFICATION AGENCY PERSONNEL			7.b. DATE OF INSPECTION PLANT CERTIFICATION 6/21/2016		7.e.g. EXPIRATION DATE*													
<input type="checkbox"/> SHD <input type="checkbox"/> Other <input type="checkbox"/> SDA <input type="checkbox"/> TPC <input type="checkbox"/> SDL <input checked="" type="checkbox"/> SSC			7.c. SANITATION COMPLIANCE RATING 85		<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th colspan="2">MONTH</th> <th colspan="2">DAY</th> <th colspan="2">YEAR</th> </tr> <tr> <td style="text-align: center;">67 0</td> <td style="text-align: center;">68 6</td> <td style="text-align: center;">69 2</td> <td style="text-align: center;">70 0</td> <td style="text-align: center;">72 20</td> <td style="text-align: center;">72 17</td> </tr> </table>		MONTH		DAY		YEAR		67 0	68 6	69 2	70 0	72 20	72 17
MONTH		DAY		YEAR														
67 0	68 6	69 2	70 0	72 20	72 17													
*EXPIRATION DATE <small>Certification of single-service manufacturing plants may be valid for a period not to exceed one (1) or two (2) years from the earliest survey certification date. The expiration date is one (1) or two (2) years from the earliest survey certification date. NOTE: Certifications conducted by SSCs shall only be valid for a period not to exceed one (1) year from the earliest certification date.</small>			8. SANITARIAN SRO OR CONSULTANT SSC Hammer Down, SSC		9a. LISTING TYPE <input checked="" type="checkbox"/> FULL <input type="checkbox"/> PARTIAL													
			9. CERTIFICATION RECOMMENDED <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO															
LABORATORY CONTROL																		
10. NAME AND ADDRESS (OR CODE) OF APPROVED LABORATORY XX-XX-100																		
11. INSPECTION RESULTS (Place an "X" under Items involved-debited)																		
1	2	3	4	5	6	7												
8	9	10	11	12	13 <small>a.b.c.f. g.i.k</small>	13 <small>d.e. h.j</small>												
14	15	16 <small>a</small>	16 <small>b.c</small>	17 <small>a.b. d.e</small>	17 <small>c</small>	18												
19	20 <small>a.b.f.</small>	20 <small>c.d.e</small>	21															
X						E												
12. PERMISSION TO PUBLISH																		
Permission is hereby granted to release and publish the above-stated certification for use by State and local milk control authorities <u>Regulatory/Rating Agencies</u> and prospective purchasers. It is understood and agreed by the undersigned that the official Rating Agency or <u>SSC, as applicable</u> , may review and appraise the single-service fabricating plant at any time during the period of time the above certification is in effect. It is further understood that failure to maintain the above certification will subject this plant to withdrawal from the IMS Listing. We will notify the Rating Agency or <u>SSC, as applicable</u> , of any significant changes made in the operation of this plant.																		
12.a. NAME OF PLANT Blow Mold Plastics																		
12.b. OFFICER AUTHORIZING RELEASE Single Service				12.c. TITLE Owner														
13. SUBMISSION OF REPORT BY STATE MILK SANITATION RATING AGENCY OR SSC, AS APPLICABLE																		
13.a. DATE OF REPORT 6/22/2016		13.b. RECOMMENDED CLASSIFICATION ACCEPTED <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO		13.c. SUBMITTED BY (Signature and Title) Hammer Down, SSC														
FOR FDA USE ONLY																		
14. DATE RECEIVED		15. PUBLICATION OF RATING RECOMMENDED <input type="checkbox"/> YES <input type="checkbox"/> NO (If "NO", indicate why.)																
16. DATE TRANSMITTED		17. SIGNATURE (FDA Regional Milk Specialist)																

FORM FDA 2359d (10/4015)

Document: 2013 PROCEDURES

Pages: Cover, 1-3, 6, 7, 11, 13-22, 24 and 27-31

Make the following changes to the 2013 PROCEDURES:

Cover:

~~2013~~ 2015

SECTION II. SCOPE

Page 1:

A. PRODUCTS COVERED

Agreements adopted by the NCIMS shall apply to Grade “A” raw milk and/or milk products for pasteurization, heat-treated products, pasteurized, ultra-pasteurized, aseptically processed and packaged low-acid milk and/or milk products, and/or retort processed after packaged low-acid milk and/or milk products, condensed and dry milk products, ~~and~~ whey and/or whey products, and single-service containers and/or closures for milk and/or milk products produced under the NCIMS program. ...

SECTION III. DEFINITIONS

Page 2:

A. ADVERSE ACTION: A re-inspection, re-rating or withdrawal of ~~certification~~ the IMS Listing of an individual IMS listed milk shipper or the withdrawal of the certification of an individual IMS listed single-service containers and/or closures manufacturer. ...

Page 3:

H. CERTIFIED SINGLE-SERVICE CONSULTANT (SSC): An individual who has been certified by the Public Health Service/Food and Drug Administration (PHS/FDA), has a valid certificate of qualification to conduct the certification and listing of foreign single-service containers and/or closures for milk and/or milk products manufacturers on the IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS List) and does not have direct responsibility for the routine regulatory inspection and enforcement or regulatory auditing of the foreign single-service containers and/or closures manufacturer to be certified.

Re-letter the remaining DEFINITIONS accordingly.

Page 6:

DD. SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURER: A single-service containers and/or closures manufacturer shall mean any person or company in the business of manufacturing a single-service container and/or closure for the packaging or

sampling of Grade “A” milk and/or milk products in accordance with Appendix J. STANDARDS FOR THE FABRICATION OF SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS of the Grade “A” PMO.

EE. SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURER AUDIT: The designated PHS/FDA and NCIMS Procedures method to ensure that the published certification/listing of a single-service containers and/or closures for milk and/or milk products manufacturer on the IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS List) is valid and maintained during the interval between certifications.

FF. SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURER CERTIFICATION: This is the certification conducted by a Milk Sanitation Rating Officer (SRO) for U.S. manufacturers of single-service containers and/or closures for milk and/or milk products; or a Third Party Certifier’s (TPC’s) Milk Sanitation Rating Officer (SRO); or a Certified Single-Service Consultant (SSC) for foreign manufacturers of single-service containers and/or closures for milk and/or milk products, which measures the degree to which the provisions of Appendix J. STANDARDS FOR THE FABRICATION OF SINGLE-SERVICE CONTAINERS AND CLOSURES FOR MILK AND/OR MILK PRODUCTS of the Grade “A” PMO are being complied with by the single-service containers and/or closures manufacturer for inclusion on the IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS List). The certification is based on compliance with the requirements of Appendix J. of the Grade “A” PMO and is conducted in accordance with the procedures set forth in the Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers (MMSR).

GG. THIRD PARTY CERTIFIER (TPC): ...

HH. TRANSFER STATIONS: ...

SECTION IV. OVERSIGHT AND RESPONSIBILITIES

Page 7:

A. PHS/FDA RESPONSIBILITIES

1. Standardization of Personnel ...

d. PHS/FDA shall standardize, in accordance with Section V, H., the certification procedures of SSCs. ...

5. Electronic Publication of Sanitation Compliance and Enforcement Ratings ...

Page 11:

b. PHS/FDA shall list ratings only from Rating Agencies, and/or milk shippers, which are in substantial compliance with the *Procedures*. ...

e. PHS/FDA shall identify on the *IMS List*, certified IMS listed single-service containers and/or closures manufacturers and their certification's expiration dates contained on the electronic publication as certified by the Rating Agency or SSC, as applicable, to be those established by certifications conducted in accordance with the *MMSR* by certified SROs or SSCs, as applicable, when FORM FDA 2359d-REPORT OF CERTIFICATION (*Fabrication of Single-Service Containers and/or Closures for Milk and Milk Products*) is signed and submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs and SSCs for publication.

Single-service containers and/or closures manufacturers shall achieve a Sanitation Compliance Rating of 80 percent (80%) or higher in order to be eligible for a listing on the *IMS List*. Sanitation Compliance Ratings for single-service containers and/or closures manufacturers will not be identified on the *IMS List*.

PHS/FDA shall list certifications only from Rating Agencies, SSCs, and/or single-service containers and/or closures manufacturers, which are in substantial compliance with the *Procedures*.

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

d. PHS/FDA shall provide a list of SSCs whose certification methods and interpretations of Appendix J. of the *Grade "A" PMO* have been evaluated and certified by PHS/FDA on the *IMS List*. ...

Page 13:

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

a. PHS/FDA shall conduct, each year, check ratings of the Sanitation Compliance status of listed interstate milk shippers. To conduct check ratings of aseptic or retort 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 or the NCIMS Retort Processed after Packaging Program, respectively. Within a State or a TPC's jurisdiction, check ratings shall be conducted of a representative number of IMS Listed milk shippers. The selection of milk shippers to be check rated in a given State or a TPC's jurisdiction shall be made randomly.

b. In order to make effective use of PHS/FDA Regional Office personnel, the random selection of milk shippers to be check rated shall be selected in advance and assignments

scheduled in each State and/or TPC's jurisdiction. Selection of dairy farms shall be made from records provided at the time of the check rating.

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

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 from the milk shipper to publish, and submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs by the 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 milk shippers only to the Rating Agency, which originally certified the milk shipper for listing, and the milk shipper's Regulatory Agency. ...

Page 14:

9. PHS/FDA Audits of the Sanitation Compliance Status of SRO Listed Single-Service Containers and/or Closures Manufacturers

a. PHS/FDA shall conduct, each year, audits of the Sanitation Compliance status of SRO certified/listed single-service containers and/or closures manufacturers. Within a State or a TPC's jurisdiction, audits shall be conducted of a representative number of IMS listed single-service containers and/or closures manufacturers. The selection of single-service containers and/or closures manufacturers to be audited in a given State or a TPC's jurisdiction shall be made randomly.

b. In order to make effective use of PHS/FDA Regional Office or MST personnel, the random selection of single-service containers and/or closures manufacturers to be audited shall be selected in advance and assignments scheduled in each State and/or TPC's jurisdiction.

c. The number of single-service containers and/or closures manufacturers selected to be audited shall be based on consideration of the number of single-service containers and/or closures manufacturers in the State or TPC's jurisdiction as well as the demonstrated validity of the State or TPC program. Validity shall be measured by estimating the number of adverse actions (withdrawals of certification) in the State or TPC's jurisdiction

based on the results of previous audits. This approach shall shift attention from States or TPCs with demonstrated validity to problem States or TPCs while still preserving an adequate level of monitoring.

d. In any case an audit cannot be conducted with a greater frequency than the official certification listing.

e. For action to be taken if the PHS/FDA audit indicates the listed certification is not justified, refer to Section IV., B., 7.c. For the purpose of these *Procedures* and all related forms, the terms “listed certification”, “official certification” and “published certification” relating to single-service containers and/or closures manufacturers shall mean the most recent certification, which is accompanied by written permission from the single-service containers and/or closures manufacturer to publish, and submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs by the Rating Agency.

f. Except as provided in Section IV., B., 7.c., PHS/FDA shall release the detailed results of its audits of certified/listed individual single-service containers and/or closures manufacturers only to the Rating Agency, which originally certified the single-service containers and/or closures manufacturer for listing, and the single-service containers and/or closures manufacturer’s Regulatory Agency.

B. STATE, AND TPC, AND SSC RESPONSIBILITIES

1. Ratings of Milk Shippers and Single-Service Containers and/or Closures Manufacturer Certification Listings ...

c. When the Sanitation Compliance status of a listed milk shipper's supply changes as a result of a new rating made within the twenty-four (24) month eligibility period, the most recent rating, including Enforcement Rating, shall apply and shall be submitted to PHS/FDA. ...

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 milk 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 milk 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 Office or PHS/FDA MST for TPCs.

Page 15:

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 milk shipper from the *IMS List*. ...

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

j. The State Rating Agency shall certify U.S. manufacturers of single-service containers and/or closures for milk and/or milk products in accordance based on compliance with Appendix J. of the Grade "A" PMO and in accordance with the MMSR for inclusion on the *IMS List*.

k. A TPC's SRO or a SSC shall certify foreign manufacturers of single-service containers and/or closures for milk and/or milk products based on compliance with Appendix J. of the Grade "A" PMO and in accordance with the MMSR for inclusion on the IMS List.

~~k.~~ When a certified manufacturer of Single-Service Containers and Closures for Milk and Milk Products single-service containers and/or closures for milk and/or milk products changes status because of permit suspension and/or revocation or the withdrawal of their certification/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, on a change in the Sanitation Compliance Rating to less than eighty percent (80%), the shipping State, or TPC or SSC, as applicable, shall immediately notify all known receiving States and/or TPCs and the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs and SSCs.

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

Receiving States or TPCs shall notify shipping States, ~~and/or~~ TPCs and/or SSCs, as applicable, of any irregularities in the single-service ~~container and closure~~ containers and closures for milk and/or milk products supply received. (Refer to Section IV., B., 7.)

The Rating Agency shall keep current the listings of all certified single-service containers and/or closures shippers manufacturers within its State or a TPC's jurisdiction.

The SSC shall keep current the listings of all certified single-service containers and/or closures manufacturers that they have IMS Listed.

The Rating Agency or SSC, as applicable, shall submit all required certification/listing paperwork and forms to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs and SSCs upon the completion of all certifications/listings conducted by the Rating Agency or SSC, as applicable. ...

Page 16:

5. Request for Emergency Consideration ...

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

7. Challenges and Remedies

Page 17:

a. Complaints from Receiving States or TPCs

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

3.) The Rating Agency of the shipping State, ~~or~~ TPC, or SSC, as applicable, 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 and SSCs.

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

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

B.) Withdraw the certification of the milk shipper or single-service containers and/or closures manufacturer and notify the receiving State(s) and/or TPC(s) and the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs and SSCs of such action; or

C.) ~~Make~~ Conduct a new rating for milk shippers or new certification listing for single-service containers and/or closures manufacturers within sixty (60) days, and with the written permission of the milk shipper or single-service containers and/or closures manufacturer, forward the new rating or certification listing, respectively, and a copy of the milk shipper's or single-service containers and/or closures manufacturer's written permission to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs and SSCs for listing 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 or SSC, as applicable.

5.) If the Rating Agency of the shipping State, ~~or TPC or SSC~~, as applicable, 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 the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs and SSCs, the State and/or TPC making the complaint. Such notification shall be considered by PHS/FDA as tantamount to the withdrawal of the ~~present current rating~~ of the interstate milk shipper or certification listing of the single-service containers and/or closures manufacturer involved.

Page 18:

B.) Notify the milk shipper or the single-service containers and/or closures manufacturer involved, and any other interested parties, that in accordance with Conference agreements, the current rating or certification listing, respectively, is being withdrawn until such time as the complaint may be investigated or a new rating or certification listing is made conducted. ...

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

1.) Dairy Farms (Raw Milk) ...

DAIRY FARMS (RAW MILK)

LISTED RATING	RE-RATING	WITHDRAW CERTIFICATION IMS LISTING
100 to 90	84 to 80	79 or less
89 to 84	83 to 80	79 or less
83	82 to 80	79 or less
82	81 to 80	79 or less
81 or less	80	79 or less

...

Page 19:

C.) Withdrawal of ~~Certification~~ Listed Rating

When check rating data indicates that the Sanitation Compliance Rating of a listed shipper's dairy farms requires a withdrawal of ~~certification~~ their listed rating, the Rating Agency, upon written recommendation of PHS/FDA, shall immediately

withdraw the current ~~certification~~ listed rating of the milk shipper and notify such milk 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 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 Rating Agency. Such letter shall be dated within five (5) working days following the date of the official notification by PHS/FDA. ...

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

MILK PLANTS, RECEIVING STATIONS AND/OR TRANSFER STATIONS

LISTED RATING	REINSPECTION	WITHDRAW CERTIFICATION <u>IMS LISTING</u>
100 to 90	80	79 or less

...

Page 20:

C.) Withdrawal of ~~Certification~~ Listed Rating

When check rating data indicates that the Sanitation Compliance Rating of a milk plant, receiving station and/or transfer station requires a withdrawal of their listed rating, the Rating Agency, upon written recommendation of PHS/FDA, shall immediately withdraw the current ~~certification~~ listed rating of the milk shipper and notify such milk 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 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 Rating Agency. Such letter shall be dated within five (5) working days following the date of the official notification by PHS/FDA. A withdrawal of ~~certification~~ a listed rating 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/OR RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) following the procedures cited above.

3.) Single-Service Containers and/or Closures ~~For~~ for Milk and/or Milk Products

A.) Action to be Taken

The following table shall be used to determine action to be taken if the Sanitation Compliance Rating from an audit of a single-service containers and/or closures for milk and/or milk products manufacturer indicates the certification listing is not justified:

SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURERS

<u>LISTED CERTIFICATION</u>	<u>WITHDRAW IMS CERTIFICATION LISTING</u>
<u>100 to 80</u>	<u>79 or less</u>

AB.) Withdrawal of Certification Listing

~~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, that the Sanitation Compliance Rating of a single-service containers and/or closures manufacturer requires a withdrawal of their certification listing,~~ the Rating Agency upon written recommendation of PHS/FDA, shall immediately withdraw the current certification listing of the ~~shipper~~ single-service containers and/or closures manufacturer and notify such ~~shipper~~ single-service containers and/or closures manufacturer, PHS/FDA, and all known receiving States and TPCs thereof, in accordance with Section IV., B., 1.k]. In case of withdrawal, a new certification listing shall be made in not less than thirty (30) days and not to exceed sixty (60) days, unless the Rating Agency has reason to believe a new certification listing within a lesser time period, would result in an acceptable certification 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 from PHS/FDA.

4.) If a Rating Agency fails to take the required action outlined in Section IV., B., 7.c.1.), 7.c.2.) ~~and or~~ 7.c.3), calling for immediate notification of all known receiving States and/or TPCs when the current certification listing 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 or audit findings for single-service containers and/or closures manufacturer's listings. The State or TPC₂ 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.), 7.c.2.) ~~and or~~ 7.c.3).

Page 21:

5.) If a Rating Agency indicates that it is not in a position to make a new rating or certification listing within the 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.

6.) If 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 milk shippers or audit listed single-service containers and/or closures ~~listed shippers~~ manufacturers, 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.

7.) If a Rating Agency or SSC fails to request the removal of a milk plant, receiving station and/or transfer station or single-service containers and/or 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 and/or TPCs.

SECTION V. QUALIFICATIONS AND CERTIFICATIONS ...

A. SUPERVISION REQUIREMENTS

1. Supervision of the milk supply, dry milk products, whey and whey products to be rated for ~~interstate certification~~ IMS listing shall be based on the criteria and procedures for Grade “A” standards set forth in Section VI., and procedures for Grade “A” standards set forth in Section VI., E., or regulations pertaining to supervision substantially equivalent thereto.
2. The milk shipper to be rated shall be under the full-time supervision of a State or TPC Regulatory Agency. ...

B. PROCEDURES FOR REQUESTING A MILK SHIPPER SANITATION RATING OR SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS MANUFACTURER CERTIFICATION

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

A U.S. manufacturer of single-service containers and/or closures for milk and/or milk products desiring a certification of their single-service containers and/or closures for the purpose of interstate listing shall submit a request to the State Rating Agency in their own State.

A foreign manufacturer of single-service containers and/or closures for milk and/or milk products desiring a certification of their single-service containers and/or closures for the purpose of interstate listing shall submit a request to a TPC or SSC that is listed on *the IMS List*.

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C. SANITATION COMPLIANCE AND ENFORCEMENT RATINGS REQUIRED

Ratings to be made on each milk shipper or certifications on each single-service containers and/or closures for milk and/or milk products manufacturer, respectively who desires an IMS rating listing or certification listing shall include:

1. Sanitation Compliance Ratings on dairy farms, transfer stations, receiving stations, ~~pasteurization~~ milk plants, dry powder blending plants, condensed and dry milk and/or milk products plants, and whey and/or whey products plants and single-service containers and/or closures for milk and/or milk products manufacturers.
2. Enforcement Rating of the Regulatory Agency for dairy farms, transfer stations, receiving stations, milk plants, dry powder blending plants, condensed and dry milk and/or milk products plants and whey and/or whey products plants.

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E. DRUG RESIDUE COMPLIANCE

A milk shipper desiring a rating of their supply shall comply with Appendix N. of the *Grade "A" PMO*. ...

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H. SINGLE-SERVICE CONSULTANT PERSONNEL

1. The Sanitation Compliance Rating and certification of foreign manufacturers of single-service containers and/or closures for milk and/or milk products shall be conducted by certified Single-Service Consultants (SSCs) who meet one (1) of the following requirements:
 - a. Hold a current valid certification as a SRO, which includes the evaluation of single-service containers and/or closures manufacturers; or
 - b. Currently is listed under "Single-Service Consultants for Foreign Single-Service Manufacturer's Certification" on the IMS List and has been found to be acceptable by PHS/FDA; or
 - c. Have submitted to PHS/FDA a written request for certification including the following: applicant name and contact information, education, training, work experience, list of training courses attended, work with other SCCs; and has been certified by PHS/FDA as a SSC and hold a valid certificate of qualification for the certification of foreign manufacturers of containers and/or closures for milk and/or milk products. The PHS/FDA shall issue a certificate, valid for three (3) years, to each individual who meets the criteria listed below, as applicable:

1.) A SSC applicant for initial certification shall be evaluated by PHS/FDA personnel in an independent side-by-side comparison of five (5) single-service containers and/or closures for milk and/or milk products manufacturing plants using the items listed on FORM FDA 2359c-MANUFACTURING PLANT INSPECTION REPORT (*Single-Service Containers and/or Closures for Milk and/or Milk Products*). Single-service containers and/or closures for milk and/or milk products manufacturing plants shall be of varying sizes, manufacturing processing, such as injection molding, extrusion, blow-molding, paperboard, etc., and single-service containers/closures. The applicant and PHS/FDA personnel shall be in agreement at least eighty percent (80%) of the time on each listed item.

2.) Applicants shall demonstrate the ability to conduct and compute Sanitation Compliance Ratings and certification listings by completing FORM FDA 2359c-MANUFACTURING PLANT INSPECTION REPORT (*Single-Service Containers and/or Closures for Milk and/or Milk Products*), FORM FDA 2359e-STATUS OF MANUFACTURING PLANTS (*Single-Service Containers and/or Closures for Milk and/or Milk Products*) and FORM FDA 2359d-REPORT OF CERTIFICATION (*Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products*).

3.) A certified SSC shall be re-certified once each three (3) years by PHS/FDA personnel in an independent side-by-side comparison of at least two (2) single-service containers and/or closures manufacturing facilities using the items listed on FORM FDA 2359c-MANUFACTURING PLANT INSPECTION REPORT (*Single-Service Containers and/or Closures for Milk and/or Milk Products*). The applicant and PHS/FDA personnel shall be in agreement at least eighty percent (80%) of the time on each listed item.

4.) To be re-certified, a certified SSC during the three (3) year period shall also have certified/listed at least one (1) single-service containers and/or closures for milk and/or milk products manufacturer annually and attended at least one (1) PHS/FDA Regional Milk Seminar. If a SSC has not fulfilled the certification/listing of at least one (1) single-service containers and/or closures for milk and/or milk products manufacturer annual obligation, PHS/FDA MST shall request a meeting with the SSC to discuss why they should continue to be certified. The meeting shall take place at a time, location and manner (in person or via teleconference) agreed upon by PHS/FDA MST and the SSC. If an agreement cannot be reached, the meeting shall take place at a reasonable time, location and manner as determined by PHS/FDA MST.

If PHS/FDA MST's decision is to not re-certify the SSC that decision shall be provided through written notification to the SSC to officially notify the SSC that they will not be re-certified. PHS/FDA MST shall issue an M-I officially announcing the suspension of the SSC to participate in the NCIMS Grade "A" Milk Safety Program and immediately withdraw the SSC and any of the SSC's listed certified single-service containers and/or closures for milk and/or milk products manufacturer from the *IMS List*.

5.) Should PHS/FDA determine that a certified SSC has failed to demonstrate proficiency in the above re-certification procedures; PHS/FDA may require the certified SSC to perform the initial certification procedures.

6.) A SSC shall not have direct responsibility for the routine regulatory inspection and enforcement or regulatory auditing of the foreign single-service containers and/or closures manufacturer to be certified.

2. Code of Ethics

A SSC is obligated to abide by the following Code of Ethics:

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 Certification/Listing 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 SSC shall maintain strict confidentiality of proprietary information learned through their Certification/Listing oversight activities;

g. Shall avoid conflicts of interest or the appearance of a conflict of interest. The SSC 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 SSC, their spouses and dependents 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 Certification/Listing activities whose interests may be substantially affected by the performance or nonperformance of their duties.

3. The SSC's certification may be revoked by PHS/FDA upon findings that the SSC:
 - a. Fails to carry out the provisions of Appendix J. of the Grade "A" PMO and the MMSR;
 - b. Is in violation of any of the Code of Ethics tenets; or
 - c. Fails to meet the requirements specified for maintaining certification.

The hearing procedure for revoking the certification of a SSC shall follow Section V, I.

HI. THE HEARING PROCEDURE FOR REVOKING THE CERTIFICATION OF A SRO, SSO, ~~OR~~ LEO, OR SSC ...

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 shall notify the SRO, SSO, ~~or~~ LEO, or SSC in writing of its intent to revoke his or her certification. The notification shall specify: ...

3. Request for a Hearing

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

Within fifteen (15) days after the receipt of a timely request for a hearing, the Certification Hearing Panel shall determine whether the material submitted by the SRO, SSO, ~~or~~ LEO, or SSC raises any genuine and substantial issues of fact relevant to whether certification should be revoked.

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If the Certification Hearing Panel determines that the material submitted by the SRO, SSO, ~~or~~ LEO, or SSC does not raise any genuine and substantial issue of fact, the request for the hearing shall be denied. The Certification Hearing Panel shall notify the SRO, SSO, ~~or~~ LEO, or SSC of the decision in writing, and the revocation of the certification shall be effective immediately. If the Certification Hearing Panel determine that the material submitted by the SRO, SSO, ~~or~~ LEO, or SSC raises one (1) or more genuine and substantial issues of fact, the Certification Hearing Panel shall notify the SRO, SSO, ~~or~~ LEO, or SSC and the PHS/FDA Standard in writing that a hearing will be held.

4. Hearings

The hearing shall take place at a time, location and manner (in person or via teleconference) agreed upon by the SRO, SSO, ~~or~~ LEO, or SSC, the PHS/FDA Standard, and the Certification Hearing Panel. If an agreement cannot be reached, the hearing shall take place at a reasonable time, location, and manner as determined by the Certification Hearing Panel.

At a hearing, the PHS/FDA Standard will first give a statement of the proposed revocation, including the reasons supporting it, and may present relevant oral or written information. The SRO, SSO, ~~or~~ LEO, or SSC may then present any oral or written information relevant as to why certification should not be revoked. The hearing is informal in nature, and the rules of evidence do not apply. If either party requests that the proceeding be transcribed, the requesting party shall be responsible to cover all cost associated with the request.

The Certification Hearing Panel will have the opportunity to question the PHS/FDA Standard, the SRO, SSO, ~~or~~ LEO, or SSC, and any witnesses.

5. Decision ...

The Certification Hearing Panel shall make a written decision whether to revoke the certification of the SRO, SSO, ~~or~~ LEO, or SSC. All relevant written material presented at the hearing shall be attached to the decision. The Certification Hearing Panel may uphold or reverse the initial determination to revoke certification or may resolve the issues presented at the hearing in another manner, such as by developing an action plan with requirements for the SRO, SSO, ~~or~~ LEO, or SSC to retain certification. ...

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IJ. AREA RATINGS ...

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

3. If the Enforcement Rating is less than ninety percent (90%), the milk shipper may be listed. A re-rating of the area shall be conducted within six (6) months of the date of the rating after the Rating Agency receives written notification from an authorized representative of the Regulatory Agency indicating that the area is in substantial compliance. A re-rating of the area, which includes both a Sanitation Compliance and Enforcement Rating, shall be completed in no more than fifteen (15) days from the date of receipt of the notification.

JK. INDIVIDUAL RATINGS ...

2. If an IMS listed milk shipper receives a Sanitation Compliance Rating of less than ninety percent (90%), a re-rating shall be conducted after written notification from an authorized representative of the IMS listed milk shipper to the Rating Agency that the IMS listed milk shipper is in substantial compliance. A re-rating shall be completed in no more than fifteen (15) days, from the date of receipt of the notification, unless the Rating Agency has a reason to believe a new rating within a lesser time would result in an acceptable rating. ...

3. If an aseptic or retort milk plant has any ACLE identified by a SRO, 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 AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products), the IMS listing shall be immediately denied or withdrawn.

4. If an IMS listed milk shipper receives an Enforcement Rating of less than ninety percent (90%), the milk shipper may be IMS listed and a re-rating of both the Sanitation Compliance and Enforcement shall be completed by the Rating Agency within six (6) months of the date of the rating, after the Rating Agency receives written notification from an authorized representative of the Regulatory Agency indicating that the IMS listed milk shipper is in substantial compliance. A re-rating of the IMS listed milk shipper, which includes both a Sanitation Compliance and Enforcement Rating, shall be completed in no more than fifteen (15) days from the date of receipt of the notification. ...

Re-letter remaining capital lettered Items within this Section accordingly.

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LM. DENIAL OF RATINGS

Requests for ratings of milk shippers, which are not under supervision as described in Section V., A., shall be denied.

N. SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURER CERTIFICATIONS

1. Individual certifications conducted by Rating Agencies of manufacturers of single-service containers and/or closures for milk and/or milk products shall be made at a frequency specified in Section I of the *Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers (MMSR)*.

2. Individual certifications conducted by SSCs of foreign manufacturers of single-service containers and/or closures for milk and/or milk products shall be made at a frequency of not less than every twelve (12) months.

3. If a single-service containers and/or closures for milk and/or milk products manufacturer receives a Sanitation Compliance Rating of less than eighty percent (80%), a re-certification shall be conducted after written notification from an authorized representative of the single-service containers and/or closures for milk and/or milk products manufacturer to the Rating Agency or SSC, as applicable, that the single-service containers and/or closures for milk and/or milk products manufacturer is in substantial compliance. A re-certification shall be completed in not more than fifteen (15) days, from the date of receipt of the notification, unless the Rating Agency or SSC, as applicable, has a reason to believe a new certification within a lesser time would result in an acceptable certification/listing.

O. SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURER RE-CERTIFICATIONS

Whenever a certification results in a request for a re-certification, the effective date for the re-certification shall be determined from the date of the letter of notification by the Rating Agency or SSC, as applicable. Such letter is to be dated within five (5) working days following the date of the certification.

SECTION VI. STANDARDS ...

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E. MILK SANITATION STANDARDS

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

The current edition of Appendix J. of the *Grade "A" PMO* shall be used as the basic sanitation standards in making Sanitation Compliance Ratings/Certification Listings of single-service containers and/or closures for milk and/or milk products manufacturers.

Note: This Proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2015 National Conference on Interstate Milk Shipment following FDA's concurrence with the NCIMS Executive Board.

Proposal: 216
Document: 2013 PMO
Pages: xiv, 30 and 374

Make the following changes to the 2013 PMO:
Page xiv:

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APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

IV. ESTABLISHED TOLERANCES AND/OR SAFE TARGET TESTING LEVELS OF DRUG RESIDUES
V. APPROVED TEST METHODS

Page 30:

ADMINISTRATIVE PROCEDURES

5. Beta lactam methods which have been independently evaluated or evaluated by FDA and have been found acceptable by FDA and the NCIMS for detecting Beta lactam drug residues in raw milk, or pasteurized milk, or a particular type of pasteurized milk product at current safe target testing or tolerance levels, shall be used for each Beta lactam drug of concern. This does not apply to those milk products for which there are not any approved Beta lactam drug test kits available.

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

"Safe Target testing levels" are used by FDA as guides for prosecutorial discretion. They do not legalize residues found in milk that are below the safe level target testing levels. In short, FDA uses the "safe level target testing levels" as 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 FDA's discretion in any way; and they do not protect milk producers, or milk from court enforcement action.

"Safe level Target testing 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 level Target testing levels" do not:

1. Bind the courts, the public, including milk producers, or FDA, including individual FDA employees; and
2. Do not have the "force of law" of tolerances, or of binding rules.

Notification, changes or additions of "safe level target testing levels" shall be transmitted via Memoranda of Information (M-I's).

V. APPROVED TEST METHODS

Regulatory Agencies and industry shall use ~~tests~~ test methods from ~~the most recent revision of M-a-85, latest revision,~~ for analysis of bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for Beta lactam, following the testing procedures specified in Section III of this Appendix. AOAC First Action and AOAC Final Action methods are accepted in accordance with Section 6 of this ~~Ordinance~~ Ordinance. ~~Drug residue detection methods shall be evaluated at the safe level or tolerance.~~ Regulatory Enforcement action based on each test ~~kit~~ method may be delayed until the evaluation is completed and the method is found to be acceptable to FDA and complies with the provisions of Section 6 of this ~~Ordinance~~ Ordinance.

One (1) year after a drug test(s) test method(s) have has been evaluated by FDA and accepted by the NCIMS for a particular drug or drug family, other unevaluated drug tests test methods are not acceptable for screening milk. The acceptance of evaluated drug tests test methods does not mandate any additional screening by industry with the evaluated drug test method.

New drug test methods, which are submitted to NCIMS, from FDA, for acceptance, shall not detect drug residues at less than 50% of the tolerance level or 25% of the target testing level* for individual drugs, with the exception of the following that may be accepted for Appendix N and other drug testing:

1. Penicillin G at 2 ppb.
2. Tetracycline drug kits that detect tetracyclines at levels greater than 150 ppb for Chlortetracycline, 119 ppb for Oxytetracycline and 67 ppb for Tetracycline.

*Target testing levels are set by FDA based on available science. They are not determined by the detection limits of commercially available test methods.

Proposal: 213
Document: 2013 PMO
Pages: xiv, 28, 30 and 363-374

Make the following changes to the 2013 PMO:

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APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

V. APPROVED TEST METHODS

VI. TEST METHODS FOR NON-BETA LACTAMS RESIDUE TESTING THAT HAVE NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS

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

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Required bacterial counts, somatic cell counts and cooling temperature checks shall be performed on raw milk for pasteurization, ultra-pasteurized, aseptic processing and packaging, or retort processed after packaging. In addition, drug tests for Beta lactams 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 not be a requirement for sampling. Required bacterial counts, coliform counts, drug tests for Beta lactams, 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. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.) ...

Whenever a drug residue test is confirmed positive, an investigation shall be made to determine the cause, and the cause shall be corrected in accordance with the provisions of Appendix N of this Ordinance. ...

ADMINISTRATIVE PROCEDURES ...

LABORATORY TECHNIQUES: ...

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5. Drug Testing: Beta lactam test methods which have been independently evaluated or evaluated by FDA and have been found acceptable by FDA and the NCIMS for detecting Beta lactam drug residues in raw milk, or pasteurized milk, or a particular type of pasteurized milk product at current safe or tolerance levels, shall be used for each Beta lactam drug of concern. This does not apply to those milk products for which there are not any approved Beta lactam ~~drug test kits~~ methods available. (Refer to M-a-85, latest revision, for the approved Beta lactam drug tests test methods and M-a-98, latest revision, for the specific milk and/or milk product for which there are approved Beta lactam drug tests test methods available.) Regulatory Enforcement action shall be taken on all confirmed positive Beta lactam results. (Refer to Appendix N. of this Ordinance.) A result shall be considered confirmed positive for Beta ~~lactam lactams~~ if it has been obtained by using a test method, which has been evaluated and deemed acceptable by FDA and accepted by the NCIMS at levels established in memoranda transmitted periodically by FDA as required by Section IV of Appendix N of this Ordinance.

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APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

I. INDUSTRY RESPONSIBILITIES

MONITORING AND SURVEILLANCE:

Industry shall screen all bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers, regardless of final use, for Beta-lactams drug residues. Additionally, other drug residues shall be ~~screened~~ tested for by employing a random sampling program on bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers when the Commissioner of the FDA determines that a potential problem exists as cited in Section 6 of this *Ordinance*. The random bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers sampling and testing program shall represent and include, during any consecutive six (6) months, at least four (4) samples 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. Samples

collected under this random sampling and testing program shall be analyzed as specified by FDA. (Refer to Section 6 of this *Ordinance*.)

The bulk milk pickup tanker shall be sampled after the last producer has been picked up and before any additional commingling. These bulk milk pickup tanker samples may be collected using an approved aseptic sampler. The sample shall be representative. Bulk milk pickup tanker testing shall be completed prior to processing the milk. Bulk milk pickup tanker samples confirmed positive for drug residues using approved test methods and/or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required shall be retained as determined necessary by the Regulatory Agency. ...

NOTE: On-farm producer/processors that plan to store or ship their raw sheep milk frozen, shall sample their raw sheep milk prior to freezing. The sample shall be obtained by a bulk milk hauler/sampler permitted by the Regulatory Agency where the dairy farm is located. The raw sheep milk sample shall then be tested in a certified laboratory or screening facility. If this is the on-farm producer/processor's only raw sheep milk supply, this testing would suffice for the required Appendix N testing for all raw milk supplies that have not been transported in bulk milk pickup tankers, which are required to be completed prior to processing the milk. In the case of sheep milk dairy farms, the raw milk sample may be frozen in accordance with a sample protocol approved by the Regulatory Agency in which the dairy farm is located as specified in Appendix B. of this Ordinance and transported to a certified laboratory for testing. The test results, or raw milk samples, shall clearly distinguish the lot number of the frozen raw sheep milk and accompany the frozen raw sheep milk to the plant.

All presumptive positive test results for drug residues using approved test methods or verified screening positive test results using test methods not evaluated by FDA and accepted by the NCIMS from analysis conducted on commingled raw milk tanks, bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers; or farm raw milk tanks/silos (only milk offered for sale) or finished milk or milk product samples shall be reported to the Regulatory Agency in which the testing was conducted. Bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers samples confirmed positive for drug residues using approved test methods or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required shall be retained or disposed of as determined by the Regulatory Agency.

All presumptive positive test results using approved test methods for drug residues on finished milk and/or milk products shall be reported to the Regulatory Agency in which the testing was conducted.

Industry plant samplers shall be evaluated according to the requirements specified in Section 6. THE EXAMINATION OF MILK AND MILK PRODUCTS and at the frequency addressed in Section 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS of this *Ordinance*.

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REPORTING AND FARM TRACE BACK:

When a bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers is found to be presumptive positive for drug residues using approved test methods or verified screening positive for drug residues using test methods not evaluated by FDA and accepted by the NCIMS, the Regulatory Agency in which the testing was conducted, shall be immediately notified of the results and the ultimate disposition of the raw milk.

The producer samples from the bulk milk pickup tanker, found to be confirmed positive for drug residues using approved test methods or verified screening positive for drug residues using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required shall be individually tested to determine the farm of origin. The samples shall be tested as directed by the Regulatory Agency.

When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc., is (are) used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers, is (are) found to be confirmed positive (~~confirmed~~) for drug residues using approved test methods or verified screening positive for drug residues using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required the farm of origin of the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

Upon official notification to the Regulatory Agency and milk producer of a violative individual producer's milk, Further further farm pickups by bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers or farm use of the violative individual producer's milk shall be immediately discontinued, until such time, that subsequent tests are no longer positive for drug residues.

RECORD REQUIREMENTS:

Results of all testing may be recorded in any format acceptable to the Regulatory Agency that includes at least the following information: ...

8. Prior test documentation shall be provided for a presumptive positive load using approved test methods or a verified screening positive load using test methods not evaluated by FDA and accepted by the NCIMS. ...

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Records of all sample test results shall be maintained for a minimum of six (6) months by the industry at the location where the ~~tests~~ test methods were run, and/or another location as directed by the Regulatory Agency.

II. REGULATORY AGENCY RESPONSIBILITIES

Upon receipt of notification from industry of a bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers, which contains milk from another Regulatory Agency's jurisdiction, is found to be presumptive positive for drug residues using approved test methods or verified screening positive for drug residues using test methods not evaluated by FDA and accepted by the NCIMS, it is the responsibility of the receiving Regulatory Agency to notify the Regulatory Agency(ies) from which the milk originated.

MONITORING AND SURVEILLANCE:

Regulatory Agencies shall monitor industry surveillance activities during either routine or unannounced, on-site quarterly inspections to collect samples from bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and to review industry records of their sampling program. Samples should be collected and analyzed from at least ten percent (10%) of the bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers scheduled to arrive on the day of the inspection. The test method used shall be appropriate for the drug being analyzed and shall be capable of detecting the same drugs at the same concentrations as the test method being used by industry. Alternately, the Regulatory Agency or Laboratory Evaluation Officer (LEO) may take known samples with them on the audit visit and observe the ~~industry analyst~~ Industry Analyst (IA) test the samples. Receiving locations that choose to certify all receiving ~~analysts~~ IAs, certified under the provisions of the NCIMS Laboratory Certification Program, are exempt from the sample collection requirements of this Section. Receiving locations where all approved receiving ~~Industry Analysts~~ IAs and Industry Supervisors (ISs) successfully participate in a biennial on-site evaluation and annual spilt sample comparisons by LEOs are also exempt from the sample collection requirements of this Section. ...

To satisfy these requirements:

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- a. There ~~should~~ shall be ~~an~~ a documented agreement between the Regulatory Agency and industry that specifies how this notification is to take place. This notification shall be “timely” for example by telephone or fax, and supported in writing.
- b. The ultimate disposition should either be prearranged in ~~an~~ a documented agreement between the Regulatory Agency and the industry, or physically supervised by the Regulatory Agency. The milk should be disposed of in accordance with provisions of M-I-06-5 or an FDA and Regulatory Agency reviewed and accepted ~~Beta lactam~~ specified drug residue milk diversion protocol for use as animal feed.
- c. All screening test positive (confirmed) loads using an approved test method 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 enforcement action) shall be performed by an Official Laboratory, Officially Designated Laboratory or Certified Industry Supervisor (CIS). Positive producers shall be handled in accordance with this Appendix.
- d. All verified screening test positive loads using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required shall be broken down (producer trace back) using the same test method. Producer trace back shall be performed as cited in a prior documented agreement with the Regulatory Agency. (Refer to Section VI of this Appendix.) Verified screening positive producers shall be handled in accordance with this Appendix.
- e. When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is (are) used for a milk plant’s raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers, is (are) found to be confirmed

positive (~~confirmed~~) for drug residues using approved test methods, the farm of origin of the drug residue has consequently already been determined and further testing is not required to determine the farm of origin. Confirmation tests shall be performed by an Official Laboratory, Officially Designated Laboratory or ~~Certified Industry Supervisor CIS~~. Positive producers shall be handled in accordance with this Appendix.

f. When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is (are) used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers, is (are) found to be verified screening positive for drug residues using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required the farm of origin of the drug residue has consequently already been determined and further testing is not required to determine the farm of origin. Producer trace back shall be performed as cited in a prior documented agreement with the Regulatory Agency. (Refer to Section VI of this Appendix.) Verified screening positive producers shall be handled in accordance with this Appendix.

eg. The suspension and discontinuance of farm bulk milk tank pick up and/or the use of raw milk supplies that have not been transported in bulk milk pickup tankers is the responsibility of the industry, under the direction and supervision of the Regulatory Agency. At the discretion of the Regulatory Agency, records ~~should~~ shall be maintained by industry and/or the Regulatory Agency that:

- (1) Establish the identity of the producer for raw milk supplies that have not been transported in bulk milk pickup tankers that tested positive or the producer and the identity of the load that tested positive; and
- (2) Establish that milk is not picked up or used from the drug residue positive producer until the Regulatory Agency has fulfilled their obligations under Section II. ENFORCEMENT of this Appendix, as applicable, based on the test method utilized, and has cleared the milk for pick up and/or use.

Sufficient records ~~should~~ shall be reviewed to assure that all bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers are sampled before additional commingling at the milk receiving facility and the results were made available to the appropriate BTU(s).

The Regulatory Agency shall also perform routine sampling and testing for drug residues determined to be necessary as outlined in Section 6 of this *Ordinance*.

ENFORCEMENT:

If testing reveals milk positive for drug residues, the milk shall be disposed of in a manner that removes it from the human or animal food chain, except where acceptably reconditioned under FDA Compliance Policy Guide (CPG 7126.20). The Regulatory Agency shall determine the producer(s) responsible for the violation.

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Permit Suspension and the Prevention of the Sale of Milk: Any time milk is found to test as a confirmed positive using an approved test method, the Regulatory Agency shall immediately suspend the producer's Grade "A" permit or equally effective measures shall be taken to prevent

the sale of milk containing drug residues. Upon official notification to the Regulatory Agency and milk producer of a confirmed positive, future farm pickups by bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and/or farm use of the violative individual producer's milk are prohibited until subsequent testing reveals the milk is free of drug residue.

Prevention of the Sale of Milk: Any time milk is found to test as a verified screening positive for a drug residue using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required the Regulatory Agency shall immediately take effective measures to prevent the sale of the milk containing drug residues.

Penalties for Confirmed Positive Milk: ~~Future pickups and/or use of the violative individual producer's milk are prohibited until subsequent testing reveals the milk is free of drug residue.~~ The penalty shall be for the value of all milk on the contaminated load and/or raw milk supply that has not been transported in bulk milk pickup tankers plus any costs associated with the disposition of the contaminated load or raw milk supply that has not been transported in bulk milk pickup tankers. The Regulatory Agency may accept certification from the violative producer's milk marketing cooperative or purchaser of milk as satisfying the penalty requirements.

Reinstatement: When the permit has been suspended as required, ~~The~~ the Grade "A" producer's permit may be reinstated, or other action taken, to allow the sale of milk for human food, when a representative sample taken from the producer's milk, prior to commingling with any other milk, is no longer positive for drug residue.

Follow-Up: Whenever a drug residue test is confirmed positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS, an investigation shall be made to determine the cause. The farm inspection is completed by the Regulatory Agency or its agent to determine the cause of the residue and actions taken to prevent future violations including: ...

Permit Revocation: After a third violation for a drug residue using approved test methods in a twelve (12) month period, the Regulatory Agency shall initiate administrative procedures pursuant to the revocation of the producer's Grade "A" permit under the authority of Section 3. Permits of this *Ordinance*, due to repeated violations.

REGULATORY AGENCY RECORDS:

In regards to the industry reporting a confirmed positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers result, the Regulatory Agency's records shall indicate the following: ...

4. What screening and/or confirmatory ~~test(s)~~ test method(s) were used and who were the analyst(s)? ...

III. TESTING PROGRAM FOR DRUG RESIDUES ESTABLISHED

DEFINITIONS:

For purposes of this Appendix the following definitions are to be used:

1. **Presumptive Positive:** A presumptive positive test is a positive result from an initial testing of a bulk milk pickup tanker and/or raw milk supply that has not been transported in bulk milk pickup tankers using an M-a-85₂ (latest revision), or M-I-92-11 approved test method, which has been promptly repeated in duplicate with positive (+) and negative (-) controls that give the proper results using the same test method, on the same sample, with one (1) or both of these duplicate retests giving a positive result.
2. **Screening Test Positive (Load or Raw Milk Supply that has Not been Transported in Bulk Milk Pickup Tankers Confirmation):** A screening test positive (confirmation) result is obtained when the presumptive positive sample is tested in duplicate, using the same or equivalent (M-I-96-10, latest revision) test method as that used for the presumptive positive, with a positive (+) and negative (-) control that give the proper results, and either or both of the duplicates are positive. A screening test positive (load or farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. when used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers confirmation) is to be performed by an Official Laboratory, Officially Designated Laboratory or ~~Certified Industry Supervisor~~ CIS using the same or an equivalent test (M-I-96-10, latest revision).
3. **Producer Trace Back/Permit Suspension Action:** A producer trace back/permit suspension action test is performed after a screening test positive load (confirmation) is identified by an Official Laboratory, Officially Designated Laboratory or ~~Certified Industry Supervisor~~ CIS using the same or an equivalent (M-I-96-10, latest revision) test method as was used to obtain the screening test positive (load (confirmation)). A confirmed producer test positive result is obtained in the same manner as a ~~confirmation~~-(screening test positive (confirmation)) for a load. After an initial positive result (producer presumptive positive) is obtained on a producer sample, that sample is then tested in duplicate using the same test method as was used to obtain the producer presumptive positive result. This testing is performed with a positive (+) and negative (-) control and if either or both of the duplicates are positive and the controls give the proper results, the producer sample is confirmed as positive.

NOTE: When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is used for a milk plant's raw milk supply(ies) that has not been transported in bulk milk pickup tankers, is found to be confirmed positive (~~confirmed~~) for drug residues using approved test methods, the farm of origin for the drug residue has consequently already been determined and further testing is not required to determine the farm of origin. ...

6. **Industry Analyst (IA):** A person under the supervision of a Certified Industry Supervisor (CIS) or Industry Supervisor (IS) who is assigned to conduct screening of bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for Appendix N drug residue requirements.

7. **Industry Supervisor/Certified Industry Supervisor (IS/CIS):** An individual trained by a LEO who is responsible for the supervision and training of Industry Analysts (IAs) who test milk tank trucks and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for Appendix N drug residue requirements.

8. **Certified Industry Supervisor (CIS):** An Industry Supervisor (IS) who is evaluated and listed by a LEO as certified to conduct drug residue screening tests using approved test methods at industry drug residue screening sites for *Grade "A" PMO*, Appendix N ~~regulatory enforcement~~ actions (confirmation of bulk milk pickup tankers, farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), or other raw milk storage container(s), etc. when used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers, producer trace back and/or permit actions).

9. **Verified Screening Positive:** A verified screening positive test is a positive result from an initial testing using test methods not evaluated by FDA and accepted by the NCIMS of a bulk milk pickup tanker and/or raw milk supply that has not been transported in bulk milk pickup tankers, which has been promptly repeated in duplicate with positive (+) and negative (-) controls that give the proper results, using the same test method, on the same sample, with one (1) or both of these duplicate retests giving a positive result.

10. **Producer Trace Back With Permit Suspension Action Not Required:** A producer trace back test is performed after a verified screening positive load using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required is identified by a laboratory using the same test method as was used to obtain the verified screening positive load. A verified screening positive producer test result is obtained in the same manner as a verified screening positive for a bulk milk pickup tanker. After an initial positive result is obtained on a producer sample, that sample is then tested in duplicate using the same test method as was used to obtain the initial producer positive result. This testing is performed with positive (+) and negative (-) controls and if either or both of the duplicates are positive and the controls give the proper results, the producer sample is a verified screening positive. (Refer to Section VI of this Appendix.)

NOTE: When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is used for a milk plant's raw milk supply(ies) that has not been transported in bulk milk pickup tankers, is found to be verified screening positive for drug residues using only test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required the farm of origin for the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

CERTIFIED INDUSTRY SUPERVISORS (CISs); EVALUATION AND RECORDS:

Reference: *EML*

1. **Certified Industry Supervisors (CISs)/Industry Supervisors (ISs)/Industry Analysts (IAs):** Regulatory Agencies may choose to allow ~~Industry Supervisors ISs~~ to be certified. Under this program, these ~~Certified Industry Supervisors CISs~~ may officially confirm presumptive positive bulk milk pickup tanker loads and/or all raw milk supplies that have not been transported in bulk milk pickup tankers, and confirm producer milk for regulatory purposes (producer trace back/permit action) using approved test methods. In the implementation of Appendix N. of this *Ordinance*, the LEO shall use the appropriate Appendix N. FDA/NCIMS

2400 Form when evaluating Official Laboratories, Officially Designated Laboratories or ~~Certified Industry Supervisors CISs, Industry Supervisors ISs and Industry Analysts IAs.~~

The ~~Certified Industry Supervisor/Industry Supervisor CIS/IS~~ shall report to the LEO the results of all competency evaluations performed on ~~Industry Analysts IAs.~~ The names of all ~~Certified Industry Supervisors CISs, Industry Supervisors ISs and Industry Analysts IAs,~~ as well as their training and evaluation status, shall be maintained by the LEO and updated as replacement, additions and/or removals occur. The LEO shall verify (document) that each ~~Certified Industry Supervisor CIS~~ and/or ~~Industry Supervisor IS~~ has established a program that ensures the proficiency of the ~~Industry Analysts IAs~~ they supervise. The LEO shall also verify that each ~~Industry Supervisor IS~~ and ~~Industry Analysts 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 LEO and the FDA Laboratory Proficiency Evaluation Team (LPET) agree is appropriate.

Failure by the ~~Industry Supervisor IS~~ or ~~Industry Analysts IA~~ to demonstrate adequate proficiency to the LEO shall lead to their removal from the LEO list of ~~Industry Supervisors ISs~~ and/or ~~Industry Analysts IAs.~~ Reinstatement 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 LEO. (Refer to the *EML*, which describes the certification requirements for ~~Certified Industry Supervisors CISs~~ and the training requirements for ~~Industry Supervisors ISs~~ and ~~Industry Analysts IAs.~~) ...

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4. Bulk Milk Pickup Tanker Unloaded Prior to Negative Test Result: If the bulk milk pickup tanker is unloaded and commingled prior to obtaining a negative test result and the screening test is presumptive positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS, the Regulatory Agency shall be immediately notified. If the bulk milk tanker sample is confirmed positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required then the commingled milk is adulterated and unacceptable for human consumption regardless of any subsequent test results from the commingled milk. The milk shall be disposed of under the supervision of the Regulatory Agency.

5. Raw Milk Supplies that have Not been Transported in Bulk Milk Pickup Tankers Processed Prior to Negative Results: If the raw milk supply that has not been transported in bulk milk pickup tankers is processed prior to obtaining a negative test result and the screening test is presumptive positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS, the Regulatory Agency shall be immediately notified. If the sample of the raw milk supply that has not been transported in bulk milk pickup tankers is confirmed positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required then the processed milk is adulterated and unacceptable for human consumption regardless of any subsequent test results from the raw milk supply and/or pasteurized milk or milk products. The processed milk shall be disposed of under the supervision of the Regulatory Agency.

BULK MILK PICKUP TANKER AND/OR ALL RAW MILK SUPPLIES THAT HAVE NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS SCREENING TEST:

...

2. **Initial Drug Testing Procedures:** The following procedures apply to testing bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for drug residues following the provisions of Appendix N. ~~Industry analysts IAs~~ IAs may screen tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and receive or reject milk. Milk plants, receiving stations, transfer stations and other screening locations may choose to participate in the ~~Industry Supervisor IS~~ IS Certification Program.

a. Industry Presumptive Positive Options Using Approved Test Methods: There are two (2) industry options for the milk represented by a presumptive positive sample using approved test methods:

(1) The Regulatory Agency involved (origin and receipt) shall be notified. The appropriate Regulatory Agency shall take control of the presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers. A written copy of the presumptive positive test results shall follow the initial Regulatory Agency notification. Testing for confirmation of that presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers shall be in an Official Laboratory, Officially Designated Laboratory or by a ~~Certified Industry Supervisor CIS~~ CIS at a location acceptable to the Regulatory Agency. Documentation of prior testing shall be provided to the analyst performing the load and/or raw milk supply that has not been transported in bulk milk pickup tankers confirmation. The presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers may be re-sampled, at the direction of the Regulatory Agency, prior to analysis with the same or equivalent test method (M-I-96-10, latest revision), as was used to obtain the presumptive positive result. This analysis shall be done in duplicate with positive (+) and negative (-) controls. If either or both of the duplicate samples are positive and the positive (+) and negative (-) controls give the correct reactions, the sample is deemed a Screening Test Positive (~~Confirmed~~ Confirmed Load and/or Raw Milk Supply that has Not been Transported in Bulk Milk Pickup Tankers Confirmation). A written copy of the test results shall be provided to the Regulatory Agency. The milk, which that sample represents, is no longer available for sale or processing into human food. ...

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NOTE: When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is used for a milk plant's raw milk supply(ies) that has not been transported in bulk milk pickup tankers, is found to be confirmed positive (~~confirmed~~) for drug residues using an approved test method, the farm of origin for the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

3. **Re-Sampling:**

a. Presumptive Results Using Approved Test Methods: Occasionally, an error in sampling or a suspicious test result is discovered after a presumptive result is initially obtained using approved test methods. When this happens, the Regulatory Agency may allow the industry to re-sample the bulk milk pickup tanker and/or raw milk supply that has not been transported in bulk milk pickup tankers. The reasons that made the re-sampling necessary shall be clearly documented in testing records and reported to the Regulatory Agency. This written record shall be provided to the Regulatory Agency and shall be maintained with the record of the testing for that load and/or raw milk supply that has not been transported in bulk milk pickup tankers.

b. Screening Test Results Using Approved Test Methods: Re-sampling or additional analysis of screening test results should be discouraged. However, the Regulatory Agency may direct re-sampling and/or analysis, when it has determined that procedures for sampling and/or analysis did not adhere to accepted NCIMS practices (*SMEDP*, FDA/NCIMS 2400 Forms, Appendix N and the applicable FDA interpretative or informational memoranda). This decision by the Regulatory Agency shall be based on objective evidence. A Regulatory Agency allowing re-sampling shall plan a timely follow-up to identify the problem and initiate corrective action to ensure the problem that led to the need for re-sampling is not repeated. If re-sampling and/or analysis is are necessary, it shall include a review of the samplers, analysts, and/or laboratories to identify the problem(s) and initiate corrective action to ensure the problem(s) is not repeated. The reasons that made the re-sampling or analysis necessary shall be clearly documented in testing records maintained by the Regulatory Agency, and shall be maintained with the record of the testing for that load and/or raw milk supply that has not been transported in bulk milk pickup tankers.

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4. **Producer Trace Back:**

a. All screening test confirmed positive (~~confirmed~~) loads using an approved test method 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 Laboratory, Officially Designated Laboratory or by a ~~Certified Industry Supervisor~~ CIS. Positive producers shall be handled in accordance with this Appendix.

NOTE: When a farm bulk milk tank(s)/silos, milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is used for a milk plant's raw milk supply(ies) that has not been transported in bulk milk pickup tankers, is found to be confirmed positive (~~confirmed~~) for drug residues using an approved test method, the farm of origin for the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

b. All verified screening positive loads using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required shall be broken down (producer trace back) using the same test method. Verification producer trace back tests shall be performed as cited in a prior documented agreement with the Regulatory Agency. (Refer to Section VI of this Appendix.) Verified screening positive producers shall be handled in

accordance with this Appendix.

NOTE: When a farm bulk milk tank(s)/silos, milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is used for a milk plant's raw milk supply(ies) that has not been transported in bulk milk pickup tankers, is found to be verified screening positive for drug residues using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required the farm of origin for the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

...

Record Requirements: Results of all testing may be recorded in any format acceptable to the Regulatory Agency that includes at least the following information: ...

4. Identity of the test method performed/lot #/any and all controls (+/-); ...
8. Prior test documentation shall be provided for a presumptive positive load when using an approved test method or a verified screening positive load when using test methods not evaluated by FDA and accepted by the NCIMS. ...

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SCREENING TESTS TEST METHODS NECESSARY TO IMPLEMENT THE PROVISIONS OF APPENDIX N FOR BULK MILK PICKUP TANKERS AND/OR ALL RAW MILK SUPPLIES THAT HAVE NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS:

1. **Performance Tests/Controls (+/-):**
 - a. Each lot of kits purchased is tested by positive (+) and negative (-) controls.
 - b. Each screening facility runs a positive (+) and negative (-) control performance test each testing day.
 - c. All NCIMS Approved Confirmation Test Methods for Bulk Milk Pickup Tanker and/or All Raw Milk Supplies that have Not been Transported in Bulk Milk Pickup Tankers Screening Tests Include the Following Format:
All presumptive positive test results 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 Laboratory, Officially Designated Laboratory or ~~Certified Industry Supervisor~~ CIS) using the same or equivalent test (M-I-96-10, latest revision). If the duplicate tests are negative, with appropriate (+/-) control results, the bulk milk pickup tanker and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers is reported as negative. If one (1) or both duplicate test(s) is positive (+), the test result is reported to the Regulatory Agency in which the testing was conducted, as a screening test positive (confirmed).
 - d. All Test Methods Used by Industry, which have Not been Evaluated by FDA and Accepted by the NCIMS for Bulk Milk Pickup Tanker and/or All Raw Milk Supplies that have Not been Transported in Bulk Milk Pickup Tankers Include the Following Format:
One (1) of the options provided for in Section VI of this Appendix shall be followed.

de. All positive (+) controls used for drug residue testing kits are labeled to indicate a specific drug and concentration level for that drug. ...

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6. Screening Test Method Sampling Requirements: ...

7. Screening Test Method Volumetric Measuring Devices: ...

V. APPROVED TEST METHODS

Regulatory Agencies and industry shall use ~~tests~~ test methods from ~~the most recent revision of M-a-85, latest revision,~~ for analysis of bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for Beta lactams residues, following the testing procedures specified in Section III of this Appendix. AOAC First Action and AOAC Final Action methods are accepted in accordance with Section 6 of this ~~Ordinance~~ Ordinance. Drug residue detection methods shall be evaluated at the safe level or tolerance. ~~Regulatory Enforcement~~ Regulatory Enforcement action based on each test ~~kit~~ method may be delayed until the evaluation is completed and the method is found to be acceptable to FDA and complies with the provisions of Section 6 of this ~~Ordinance~~ Ordinance.

One (1) year after ~~two or more drug test(s)~~ test methods have been evaluated by FDA and accepted by the NCIMS for a particular non-Beta lactam drug or drug family, other unevaluated drug tests test methods for that particular non-Beta lactam drug or drug family are not acceptable for ~~screening milk~~ determining a Screening Test Positive (Confirmation) on a milk tank truck load of milk and/or all raw milk supplies that has not been transported in bulk milk pickup tankers. The acceptance of evaluated drug tests test methods by FDA and the NCIMS for drugs other than Beta lactams does not mandate any additional screening by industry or Regulatory Agencies with the evaluated drug test method, unless it is determined by the Commissioner of FDA that a potential problem exists with other animal drug residues in the milk supply.

VI. TEST METHODS FOR NON-BETA LACTAMS RESIDUE TESTING THAT HAVE NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS

Provided, that until at least two test methods are found acceptable by FDA and the NCIMS for detecting a particular drug or drug family, other than Beta lactams, as cited in M-a-85, latest revision, and M-I-92-11 in raw milk, non-Beta lactam screening test methods, which have not been evaluated and accepted by FDA and the NCIMS, may be used for the initial screening, provided that the test method manufacturer's data indicates that testing sensitivity is at or below U.S. safe/tolerance levels.

UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS FOR INITIAL SCREENING FOLLOWED BY A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) FOR DETERMINING A SCREENING TEST POSITIVE (LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS CONFIRMATION):

Test methods not evaluated by FDA and accepted by the NCIMS may be used for screening bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for non-Beta lactam drug residues with the documented permission of the Regulatory Agency(ies). In advance of using such a test method, a prior documented agreement shall be obtained among the user of the test method, the milk supplier, and the Regulatory Agency(ies) to determine the facility and protocols to be used to confirm the presence of a non-Beta lactam drug residue with a test method evaluated by FDA and accepted by the NCIMS as cited in M-a-85, latest revision, and M-I-92-11. An M-I-96-10, latest revision, test method(s) shall be used for confirmation.

One (1) of the following two (2) options (1 or 2) shall be used for confirmation:

1. If the initial test result from a drug test method that has not been evaluated by FDA and accepted by the NCIMS is found to be positive, testing shall promptly be repeated in duplicate with positive (+) and negative (-) controls that give the proper results using the same test method on the same sample. The initial test result is verified as a screening positive when one (1) or both of these duplicate retests give a positive result. The Regulatory Agency involved (origin and receipt) shall be notified. The appropriate Regulatory Agency shall take control of the verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers. A written copy of the verified screening positive test results shall follow the initial Regulatory Agency notification. Testing for confirmation of that verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers shall utilize a test method from M-a-85, latest revision, and M-I-92-11, and shall be conducted in an Official Laboratory, Officially Designated Laboratory or by a CIS at a location acceptable to the Regulatory Agency. Documentation of all prior testing shall be provided to the analyst performing the load and/or raw milk supply that has not been transported in bulk milk pickup tanker's confirmation. The verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers may be re-sampled, at the direction of the Regulatory Agency, prior to analysis with an M-I-96-10, latest revision, test method. This analysis shall be done in duplicate with positive (+) and negative (-) controls. If either or both of the duplicate samples are positive and the positive (+) and negative (-) controls give the proper results, the sample is deemed a Screening Test Positive (Load and/or Raw Milk Supply that has Not been Transported in Bulk Milk Pickup Tanker's Confirmation). A written copy of the test results shall be provided to the Regulatory Agency. The milk, which that sample represents, is no longer available for sale or processing into human food. Producer trace back, reporting, and enforcement as defined in this Appendix shall occur.

2. If the initial test result from a drug test method that has not been evaluated by FDA and accepted by the NCIMS is found to be positive, the sample shall promptly be retested using a test method from M-a-85, latest revision, and M-I-92-11. The initial positive M-a-85 and M-I-92-11 test is found to be a presumptive positive by promptly repeating in duplicate with positive (+) and negative (-) controls that give the proper results, using the same test method, on the same sample, with one (1) or both of these duplicate retests giving a positive result. The Regulatory Agency involved (origin and receipt) shall be notified. The appropriate Regulatory Agency shall take control of the presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers. A written copy of the presumptive positive test results shall follow the initial Regulatory Agency notification. Testing for confirmation of that

presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers shall be conducted in an Official Laboratory, Officially Designated Laboratory or by a CIS at a location acceptable to the Regulatory Agency. Documentation of all prior testing shall be provided to the analyst performing the load and/or raw milk supply that has not been transported in bulk milk pickup tanker's confirmation. The presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers may be re-sampled, at the direction of the Regulatory Agency, prior to analysis with an M-I-96-10, latest revision, test method. This analysis shall be done in duplicate with positive (+) and negative (-) controls. If either or both of the duplicate samples are positive and the positive (+) and negative (-) controls give the proper results, the sample is deemed a Screening Test Positive (Load and/or Raw Milk Supply that has Not been Transported in Bulk Milk Pickup Tanker's Confirmation). A written copy of the test results shall be provided to the Regulatory Agency. The milk, which that sample represents, is no longer available for sale or processing into human food. Producer trace back, reporting, and enforcement as defined in this Appendix shall occur.

UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS FOR THE INITIAL SCREENING AND DETERMINING A VERIFIED SCREENING POSITIVE LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS WHEN A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) IS NOT AVAILABLE:

Test methods not evaluated by FDA and accepted by the NCIMS may be used for screening and verifying bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for non-Beta lactam drug residues with the documented permission of the Regulatory Agency(ies). In advance of using such a test method, a prior documented agreement shall be obtained among the user of the test method, the milk supplier, and the Regulatory Agency(ies) to determine the facility and protocols to be used to verify the presence of a non-Beta lactam drug residue.

If the initial test result from a drug test method that has not been evaluated by FDA and accepted by the NCIMS is found to be positive, the sample shall promptly be retested in a facility identified in the prior documented agreement using the same drug test method. The initial positive test is found to be a verified screening positive by promptly repeating in duplicate with positive (+) and negative (-) controls that give the proper results, using the same test, on the same sample, with one (1) or both of these duplicate retests giving a positive result. The Regulatory Agency involved (origin and receipt) shall be notified. The appropriate Regulatory Agency may take control of the verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers. A written copy of the verified screening positive test results shall follow the initial Regulatory Agency notification. The verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers shall be disposed of to remove it from the human or animal food chain. Producer trace back shall be conducted by industry using the same drug test method at the direction of the Regulatory Agency as cited in the prior documented agreement. If the initial producer test result from the drug test method is found to be positive, the sample shall promptly be retested in a facility identified in the prior documented agreement using the same drug test method. The initial positive test is found

to be a verified producer screening positive by promptly repeating in duplicate with positive (+) and negative (-) controls that give the proper results, using the same test method, on the same sample, with one (1) or both of these duplicate retests giving a positive result. The Regulatory Agency shall be notified of the producer trace-back results. The verified screening positive milk is removed from the human and/or animal food chain, which is managed between the user of the test method, the milk supplier and the dairy producer. Future pickups and/or use of the violative individual producer's milk are prohibited until subsequent testing, utilizing the same drug test method or equivalent that has not been evaluated by FDA and accepted by the NCIMS, of a representative sample taken from the producer's milk, prior to commingling with any other milk, is no longer positive for drug residue. Whenever a drug residue test is verified screening positive, an investigation may be completed by the Regulatory Agency or its agent to determine the cause of the drug residue and actions taken to prevent future violations.

NOTE: When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is used for a milk plant's raw milk supply(ies) that has not been transported in bulk milk pickup tankers, is found to be confirmed positive for drug residues using an approved test method or verified screening positive for drug residues using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required the farm of origin for the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

Note: This Proposal shall take effect one (1) year from the issuance of the IMS-a, Actions from the 2015 National Conference on Interstate Milk Shipment following FDA's concurrence with the NCIMS Executive Board.

Proposal: 207
Document: 2013 PMO
Page: 2

Make the following changes to the 2013 PMO:

Page 2:

H. CAMEL MILK: Camel milk is the normal lacteal secretion practically free of colostrum, obtained by the complete milking of one (1) or more healthy camels. Camel milk shall be produced according to the sanitary standards of this Ordinance. The word "milk" shall be interpreted to include camel milk. (Refer to the NOTE: on page 31.)

HI. CLEAN ...

Re-letter remaining DEFINITIONS accordingly.

Proposal: JC3
Document: 2013 PMO
Pages: 4, 15, 61, 81 and 89

Make the following changes to the 2013 PMO:

Page 4:

P. FOOD ALLERGENS: Are proteins in foods that are capable of inducing an allergic reaction or response in some individuals. Foods that are considered allergens are defined in Reference the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 (Public Law 108-282) and Section 201(qq) of the Federal Food Drug & Cosmetic Act (FFD&CA). Information about Food Allergens <http://www.efsa.europa.eu/en/wh-alrgy.html>. Information about Food Allergens may also be found at: <http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAllergens/default.htm>

P-1. ALLERGEN CROSS-CONTACT: Allergen cross-contact means the unintentional incorporation of a food allergen into a food. ...

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

Page 15:

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.

Milk plants shall establish and maintain a written recall plan for initiating, and effecting, the recall of adulterated milk or milk products from the market when appropriate for the protection of public health.

ADMINISTRATIVE PROCEDURES ...

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.

RECALL PLAN: A milk plant shall establish a written recall plan that shall include procedures as described in 21 CFR Part 7 (Subpart A and C).

NOTE: For additional information and guidance from FDA regarding product recalls, milk plants should also refer to the current Guidance for Industry: Product Recalls, Including Removals and Corrections at: <http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>. ...

Page 61:

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

A receiving station shall comply with Items 1p to 15p(A) and (B), inclusive, and 17p, 20p and 22p, except that the partitioning requirement of Item 5p shall not apply.

A transfer station shall comply with Items 1p, 4p, 6p, 7p, 8p, 9p, 10p, 11p, 12p, 14p, 15p(A) and (B), 17p, 20p and 22p and as climatic and operating conditions require the applicable provisions of Items 2p and 3p. Provided, that in every case, overhead protection shall be provided.

Facilities for the cleaning and sanitizing of milk tank trucks shall comply with Items 1p, 4p, 6p, 7p, 8p, 9p, 10p, 11p, 12p, 14p, 15p(A) and (B), 20p and 22p and as climatic and operating conditions require, the applicable provisions of Items 2p and 3p. Provided, that in every case, overhead protection shall be provided. ...

Page 81:

ITEM 15p. PROTECTION FROM CONTAMINATION

Milk plant operations, equipment and facilities shall be located and conducted to prevent any contamination of milk or milk products, ingredients, containers, utensils and equipment. All milk or milk products or ingredients that have been spilled, overflowed or leaked shall be discarded. The processing or handling of products other than Grade "A" milk or milk products in the milk plant shall be performed to preclude the contamination of such Grade "A" milk and milk products. The storage, handling and use of poisonous or toxic materials shall be performed to preclude the contamination of milk and milk products, or ingredients of such milk and milk products, or the product-contact surfaces of all containers, utensils and equipment. Milk plant operations that handle nondairy food allergens shall have a written food allergen control plan to protect milk and milk products from allergen cross-contact, including during storage and use, and to ensure proper declaration of allergens on product labeling.

PUBLIC HEALTH REASON

Because of the nature of milk and milk products and their susceptibility to contamination by bacteria, chemicals and other adulterants, as well as the potential for allergen cross-contact of such products in certain facilities, every effort should be made to provide adequate protection for the milk and milk products at all times. Misuse of pesticides and other harmful chemicals can provide opportunities for contamination of the milk and/or milk product or equipment with which the milk and/or milk product comes in contact; such contamination can result in adverse health consequences. Food allergens can cause mild to severe adverse reactions and sometimes may cause life threatening reactions. Thus it is important not only to declare all food allergens on milk and milk product labels, but also to prevent cross-contact of milk and milk products so they do not contain undeclared food allergens.

ADMINISTRATIVE PROCEDURES ...

15p.(C)

1. FOOD ALLERGEN CONTROL:

A milk plant operation that handles nondairy food allergens shall implement a written food allergen control plan that includes procedures, practices, and processes to control food allergens. Food allergen controls shall include those procedures, practices, and processes employed for:

1. Ensuring protection of food from allergen cross-contact, including during storage and use.
2. Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act with an undeclared food allergen.
3. Raw materials and ingredients that are food allergens, and rework that contains food allergens, must be identified and held in a manner that prevents cross-contact.

The NCIMS Liaison Committee requests an effective date for this proposal to be August 30, 2016 – or one year after the final rule is published. If the final Preventive Controls for Human Food Rule does not include mandatory provisions analogous to the allergen control plan and written recall plan in the Proposed Rule, this modification will self-terminate and will be stricken from future versions of the PMO.

***Note:** The final Preventive Controls for Human Food Rule was published September 17, 2015 and does include mandatory provisions analogous to the allergen control plan and written recall plan as cited in this Proposal. Therefore, Proposal JC3 becomes effective September 17, 2016.*

This Proposal authorizes FDA to make all appropriate changes to applicable FDA 2359 series forms.

Proposal: 203
Document: 2013 PMO
Page: 6

*Make the following changes to the 2013 PMO:
Page 6:*

V. INSPECTION/AUDIT REPORT: A hand written or electronically generated official regulatory report used for the documentation of findings observed during an inspection/audit.

~~W.~~ INTERNATIONAL CERTIFICATION PROGRAM (ICP): ...

Re-letter remaining DEFINITIONS accordingly.

Proposal: 227
Document: 2013 PMO
Pages: 21 and 144

Make the following changes to the 2013 PMO:

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

Page 21:

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~~ two (2) years plus the remaining days of the month in which the inspection is due. ...

Page 144:

VI. MILK TANK TRUCK PERMITTING AND INSPECTION ...

Milk tank trucks shall be evaluated ~~annually~~ every two (2) years plus the remaining days of the month in which the inspection is due using the requirements established in Sections 3 and 5 of this *Ordinance* using FORM FDA 2399b-MILK TANK TRUCK INSPECTION REPORT. (Refer to Appendix M.) ...

INSPECTION: Each milk tank truck shall be inspected at least once ~~each year~~ every two (2) years plus the remaining days of the month in which the inspection is due by a Regulatory Agency. (Refer to Section 5 of this *Ordinance*.) A copy of the current inspection report shall accompany the milk tank truck at all times, or the tank shall bear an affixed label, which identifies the Regulatory Agency with the month and year of inspection. The affixed label shall be located near the tank outlet valve or on the front left side of the milk tank truck bulkhead. When significant defects or violations are encountered by a Regulatory Agency, a copy of the report shall be forwarded to the permitting agency and also carried on the milk tank truck until the violations are corrected.

Milk tank truck inspections shall be conducted in a suitable location, i.e., a dairy plant, receiving or transfer station or milk tank truck cleaning facility. Inspections may not require entry of confined spaces as defined by the Occupational Safety and Health Administration (OSHA) standards. When significant cleaning, construction or repair defects are noted the milk tank truck shall be removed from service until proper confined entry safety requirements can be satisfied to determine cleaning or repairs needed. Cleaning or repairs may be verified by a qualified individual to the satisfaction of the Regulatory Agency.

Inspection reports completed by Regulatory Agencies other than the permitting agency shall be forwarded to the permitting agency for verification of ~~annual~~ inspection as required in the **PERMITTING** Section of this Appendix. The permitting agency may use these reports to satisfy permit requirements. ...

**FDA DID NOT CONCUR WITH THIS PROPOSAL AS CITED IN THEIR LETTER TO
THE NCIMS CHAIR DATED AUGUST 11, 2015**

FDA non-concurred with this Proposal strictly based on the need for granting FDA editorial license to incorporate FDA's suggested text into the related NCIMS documents. FDA believes that these proposed changes and adjustments are warranted and appropriate to maintain the consistency in the language and the conventions of the NCIMS documents. They also will eliminate conflict within the NCIMS documents. FDA also believes that these suggested wording changes do not change the intent of the Proposals as passed at the 2015 NCIMS Conference.

FDA met with the NCIMS Executive Board on October 7-8, 2015 concerning the Proposals passed during the 2015 Conference. During this NCIMS Executive Board meeting, FDA and the Executive Board reached mutual concurrence with Proposal 227 as follows:

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

Page 21:

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)~~ twenty-four (24) months. ...

Page 22:

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.

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

For the purposes of determining the inspection frequency for bulk milk hauler/samplers, industry plant samplers and dairy plant samplers, the interval shall include the designated twenty-four (24) month period plus the remaining days of the month in which the inspection is due.

For the purposes of determining the inspection frequency for milk tank trucks, the interval shall include the designated twenty-four (24) month period plus the remaining days of the month in which the inspection is due.

Page 23:

One (1) milk tank truck inspection every ~~twelve (12)~~ twenty-four (24) months; or bulk milk hauler/sampler's or industry plant sampler's pickup and sampling procedures inspection ~~each~~ every twenty-four (24) months; or one (1) 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*. For the purpose of determining the minimum audit frequency for milk plants, receiving stations and transfer stations regulated under the NCIMS voluntary HACCP Program the interval shall include the remaining days of the month in which the audit is due.

Page 144:

VI. MILK TANK TRUCK PERMITTING AND INSPECTION

Milk tank trucks shall be evaluated ~~annually~~ every twenty-four (24) months plus the remaining days of the month in which the inspection is due using the requirements established in Sections 3 and 5 of this *Ordinance* using FORM FDA 2399b-MILK TANK TRUCK INSPECTION REPORT. (Refer to Appendix M.) ...

INSPECTION: Each milk tank truck shall be inspected at least once ~~each year~~ every twenty-four (24) months plus the remaining days of the month in which the inspection is due by a Regulatory Agency. (Refer to Section 5 of this *Ordinance*.) A copy of the current inspection report shall accompany the milk tank truck at all times, or the tank shall bear an affixed label, which identifies the Regulatory Agency with the month and year of inspection. The affixed label shall be located near the tank outlet valve or on the front left side of the milk tank truck bulkhead. When significant defects or violations are encountered by a Regulatory Agency, a copy of the report shall be forwarded to the permitting agency and also carried on the milk tank truck until the violations are corrected.

Milk tank truck inspections shall be conducted in a suitable location, i.e., a dairy plant, receiving or transfer station or milk tank truck cleaning facility. Inspections may not require entry of confined spaces as defined by the Occupational Safety and Health Administration (OSHA) standards. When significant cleaning, construction or repair defects are noted the milk tank truck shall be removed from service until proper confined entry safety requirements can be satisfied to determine cleaning or repairs needed. Cleaning or repairs may be verified by a qualified individual to the satisfaction of the Regulatory Agency.

Inspection reports completed by Regulatory Agencies other than the permitting agency shall be forwarded to the permitting agency for verification of ~~annual~~ inspection as required in the

PERMITTING Section of this Appendix. The permitting agency may use these reports to satisfy permit requirements. ...

Note: This Proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2015 National Conference on Interstate Milk Shipment following FDA's concurrence with the NCIMS Executive Board.

Proposal: 208
Document: 2013 PMO
Pages: 22 and 23

Make the following changes to the 2013 PMO:

Page 22:

One (1) copy of the inspection/audit report shall be electronically generated or handed hand written to be provided to the operator, or other responsible person; or be posted in a conspicuous place on an inside wall of the establishment. Said inspection/audit report shall not be defaced and shall be made available to the Regulatory Agency upon request. An identical copy of the inspection/audit report shall be filed with the records of the Regulatory Agency.

Page 23:

ENFORCEMENT PROCEDURES ...

The penalties of suspension or revocation of permit and/or court action are provided to prevent continued violation of the provisions of this *Ordinance* but are worded to protect the dairy industry against unreasonable or arbitrary action. When a condition is found which constitutes an imminent health hazard, prompt action is necessary to protect the public health; therefore, the Regulatory Agency is authorized in Section 3, to suspend the permit immediately. However, except for such emergencies, no penalty is imposed on the milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor upon the first violation of any of the sanitation requirements listed in Section 7. A milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor found violating any requirement shall be notified in writing and given a reasonable time to correct the violation(s) before a second inspection is made, but not before three (3) days. The requirement of giving written notice shall be deemed to have been satisfied by electronically generating or the handing to the operator; or by the posting of an inspection report, as required by this Section. After receipt of a notice of violation, but before the allotted time has elapsed, the milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor shall have an opportunity to appeal the sanitarian's interpretation to the Regulatory Agency or request an extension of the time allowed for correction.

Proposal: 219
Document: 2013 PMO
Page: 28

Make the following changes to the 2013 PMO:

Page 28:

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 or by personnel approved by the Milk Laboratory Control Agency at an Official or Officially Designated Laboratory and recorded as the official results for that day, with industry consent. This is applicable for bacteria (standard plate count and coliform), somatic cell count and temperature determinations only.

**FDA DID NOT CONCUR WITH THIS PROPOSAL AS CITED IN THEIR LETTER TO
THE NCIMS CHAIR DATED AUGUST 11, 2015**

FDA non-concurred with this Proposal strictly based on the need for granting FDA editorial license to incorporate FDA's suggested text into the related NCIMS documents. FDA believes that these proposed changes and adjustments are warranted and appropriate to maintain the consistency in the language and the conventions of the NCIMS documents. They also will eliminate conflict within the NCIMS documents. FDA also believes that these suggested wording changes do not change the intent of the Proposals as passed at the 2015 NCIMS Conference.

FDA met with the NCIMS Executive Board on October 7-8, 2015 concerning the Proposals passed during the 2015 Conference. During this NCIMS Executive Board meeting, FDA and the Executive Board reached mutual concurrence with Proposal 219 as follows:

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 or by personnel approved by the Milk Laboratory Control Agency at an Official or Officially Designated Laboratory, with industry consent where applicable, and recorded as the official results for that day. This is applicable for bacteria (standard plate count and coliform), somatic cell count and temperature determinations only.

Note: This Proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2015 National Conference on Interstate Milk Shipment following FDA's concurrence with the NCIMS Executive Board.

Proposal: 224
Document: 2013 PMO
Page: 30

Make the following changes to the 2013 PMO:

Page 30:

1. Bacterial count at 32°C (~~89.6°F~~) (Standard Plate Count (SPC) or Petrifilm Aerobic Count (PAC) methods). (Refer to M-a-98, latest revision, for the specific milk and/or milk products for which these tests are approved.)
2. Alternate methods, for bacterial counts at 32°C (~~89.6°F~~), ~~including the~~ (Plate Loop Count (PLC), Spiral Plate Count (~~SPLC~~), ~~and the~~ BactoScan FC (~~BSC~~), TEMPO AC (TAC) and Peel Plate (PPAC) methods) ~~for raw milk~~. (Refer to M-a-98, latest revision, for the specific milk and/or milk products for which these tests are approved.)
3. Coliform count at 32°C (~~89.6°F~~) (Coliform Plate Count (~~CPC~~), Petrifilm Coliform Count (PCC) and/or High Sensitivity Coliform Count (HSCC), ~~TEMPO CC (TCC) and Peel Plate Total Coliform (PPEC) and/or Total Coliform High Volume Sensitivity (PPECHVS) methods) for all milk and/or milk products~~. (Refer to M-a-98, latest revision, for the specific milk and/or milk products for which these tests are approved.)
4. A viable bacterial count of nonfat dry milk shall be made in accordance with the procedures in *SMEDP* for the SPC or PAC of Dry Milk, except agar plates shall be incubated for 72 hours. ..

Proposal: 225
Document: 2013 PMO
Page: 30

Make the following changes to the 2013 PMO:

Page 30:

6. Screening and Confirmatory Methods for the Detection of Abnormal Milk: ...
 - d. Camel Milk: Any of the following confirmatory or screening test procedures shall be used: Single Strip DMSCC or ESCC. When results exceed the 750,000/mL standard set forth in this Ordinance, the count shall have been derived from, or be confirmed by, the Single Strip DMSCC using the Pyronine Y Methyl-Green Stain or the "New York modification", and conducted by analysts certified for that procedure.

Refer to the NOTE: on page 31.

Proposal: 104
Document: 2013 PMO
Page: 34

Make the following changes to the 2013 PMO:

Page 34:

Table 1 Chemical, Physical.....

GRADE "A" PASTEURIZED CONDENSED WHEY AND/OR WHEY PRODUCTS	Temperature.....	Cooled to 10°C (50°F) or less during crystallization, within 72 hours of condensing.
	Coliform Limit.....	Not to exceed 10 per gram. <u>Provided, that in the case of bulk milk transport tank shipments shall not exceed 100 per gram.</u>

Proposal: 105
Document: 2013 PMO
Page: 38

Make the following changes to the 2013 PMO:

Page 38:

ADMINISTRATIVE PROCEDURES ...

~~The method of cleaning is immaterial. Dairy operators whose barns are provided with water under pressure should scrub the floors after each milking with a stiff bristled brush. In milking barns in which water under pressure is not available, the floors floor may be brushed-dry and limed. In the latter event, care should be exercised to prevent caking of the lime. When lime or phosphate is used, it shall be spread evenly on the floor as a thin coating. If clean floors are not maintained by this method, the ~~sanitarian~~ Regulatory Agency should require cleaning with water.~~

Proposal: 112
Document: 2013 PMO
Pages: 40, 41, 43, 44, 50 and 59

Make the following changes to the 2013 PMO:

Page 40:

A transportation tank may be used for the cooling and/or storage of milk on the dairy farm. Such tank shall be provided with a suitable shelter for the receipt of milk. Such shelter shall be adjacent to, but not a part of, the milkhouse and shall comply with the requirements of the

milkhouse with respect to construction items; lighting; drainage; insect and rodent control; and general maintenance. In addition, the following minimum criteria shall be met:

1. An accurate, accessible temperature-recording device shall be installed in the milk line downstream from an effective cooling device, which cools the milk to 7°C (45°F) or less. Electronic records that comply with ~~the applicable provisions of Appendix H., IV. Temperature-Recording Devices Used in Storage Tanks and V., Criteria 4, 7, 8, 9, 11 and 12,~~ with or without hard copy, may be used in place of temperature-recording records. An indicating thermometer shall be installed as close as possible to the recording device for verification of recording temperatures. This indicating thermometer shall comply with all applicable requirements in Appendix H. This thermometer shall be used to check the temperature-recording device during the regulatory inspection and the results recorded on the recording record or into the electronic data collection, storage and reporting system.

NOTE: With the above cited Criteria within Appendix H., V., the words “dairy farm” shall be substituted for “milk plant” wherever the words “milk plant” appears. ...

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

Page 41

4. An accurate, accessible temperature-recording device shall be installed in the milk line downstream from an effective cooling device, which cools the milk to 7°C (45°F) or less. Electronic records that comply with ~~the applicable provisions of Appendix H., IV. Temperature-Recording Devices Used in Storage Tanks and V., Criteria 4, 7, 8, 9, 11 and 12,~~ with or without hard copy, may be used in place of temperature-recording records. An indicating thermometer shall be installed as close as possible to the recording device for verification of recording temperatures. This indicating thermometer shall comply with all applicable requirements in Appendix H. This thermometer shall be used to check the temperature-recording device during the regulatory inspection and the results recorded on the recording record or into the electronic data collection, storage and reporting system.

NOTE: With the above cited Criteria within Appendix H., V., the words “dairy farm” shall be substituted for “milk plant” wherever the words “milk plant” appears. ...

ADMINISTRATIVE PROCEDURES ...

Page 43:

16. A transportation tank, with or without overhead protection, may be used for cooling and/or storing milk on a dairy farm. If a suitable shelter is provided for a transportation truck, used for cooling and/or storing milk, such shelter shall be adjacent to, but not a part of, the milkhouse and shall comply with the prerequisites of the milkhouse with respect to construction items; lighting; drainage; insect and rodent control; and general maintenance. (Refer to Appendix C. for

suggested plans and information on size, construction, operation and maintenance of milkhouses.)

In addition, the following minimum criteria shall be met:

a. An accurate, accessible temperature-recording device shall be installed in the milk line downstream from an effective cooling device, which cools the milk to 7°C (45°F) or less. Electronic records that comply with ~~the applicable provisions of~~ Appendix H., IV., Temperature-Recording Devices Used in Storage Tanks and V., Criteria 4, 7, 8, 9, 11 and 12, with or without hard copy, may be used in place of temperature-recording records. An indicating thermometer shall be installed as close as possible to the recording device for verification of recording temperatures. This indicating thermometer shall comply with all applicable requirements in Appendix H. This thermometer shall be used to check the temperature-recording device during the regulatory inspection and the results recorded on the recording records or into the electronic data collection, storage and reporting system.

NOTE: With the above cited Criteria within Appendix H., V., the words “dairy farm” shall be substituted for “milk plant” wherever the words “milk plant” appears. ...

Page 44:

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

d. An accurate, accessible temperature-recording device shall be installed in the milk line downstream from an effective cooling device, which cools the milk to 7°C (45°F) or less. Electronic records that comply with ~~the applicable provisions of~~ Appendix H., IV., Temperature-Recording Devices Used in Storage Tanks and V., Criteria 4, 7, 8, 9, 11 and 12, with or without hard copy, may be used in place of temperature-recording records. An indicating thermometer shall be installed as close as possible to the recording device for verification of recording temperatures. This indicating thermometer shall comply with all applicable requirements in Appendix H. This thermometer shall be used to check the temperature-recording device during the regulatory inspection and the results recorded on the recording records or into the electronic data collection, storage and reporting system.

NOTE: With the above cited Criteria within Appendix H., V., the words “dairy farm” shall be substituted for “milk plant” wherever the words “milk plant” appears. ...

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

Page 50:

ADMINISTRATIVE PROCEDURES ...

3. There shall 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., IV. Temperature-Recording Devices Used in Storage Tanks 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. Electronic records that comply with Appendix H., IV. Temperature-Recording Devices Used in Storage Tanks and V., Criteria 4, 7, 8, 9, 11 and 12, with or without hard copy, may be used in place of temperature-recording records. 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: With the above cited Criteria within Appendix H., V., the words “dairy farm” shall be substituted for “milk plant” wherever the words “milk plant” appears. ...

ITEM 18r. RAW MILK COOLING ...

Page 59:

3. All farm bulk milk tanks manufactured after January 1, 2000 shall be equipped with an approved temperature-recording device.
 - a. The temperature-recording device shall be operated continuously and be maintained in a properly functioning manner. Circular charts shall not overlap. Electronic records that comply with ~~the applicable provisions of~~ Appendix H., IV. Temperature-Recording Devices Used in Storage Tanks and V., Criteria 4, 7, 8, 9, 11 and 12, with or without hard copy, may be used in place of temperature-recording records.

NOTE: With the above cited Criteria within Appendix H., V., the words “dairy farm” shall be substituted for “milk plant” wherever the words “milk plant” appears. ...

Proposal: 226
Document: 2013 PMO
Pages: 47, 87 and 223

Make the following changes to the 2013 PMO:

Page 47:

ITEM 8r. WATER SUPPLY

ADMINISTRATIVE PROCEDURES

7. Samples for bacteriological examination are taken upon the initial approval of the physical structure, based upon the requirements of this Ordinance; when any repair or alteration of the water supply system has been made; and at least every three (3) years. Provided, that water supplies with buried well casing seals, installed prior to the adoption of this Section, shall be tested at intervals no greater than six (6) months apart. Whenever such samples indicate either

the presence of E. coli bacteria ~~of the coliform group~~ or whenever the well casing, pump or seal need replacing or repair, the well casing and seal shall be brought above the ground surface and shall comply with all other applicable construction criteria of this Section. Provided, that when water is hauled to the dairy farm, such water shall be sampled for bacteriological examination at the point of use and submitted to a laboratory at least four (4) times in separate months during any consecutive six (6) months. Bacteriological examinations shall be conducted in a laboratory acceptable to the Regulatory Agency. To determine if water samples have been taken at the frequency established in this Section, the interval shall include the designated period plus the remaining days of the month in which the sample is due. ...

Page 87:

ITEM 15p. PROTECTION FROM CONTAMINATION

15p.(B)

(6) Protocol for the continued monitoring of criteria and procedures. Provided, that daily tests shall be conducted for one (1) week following any repairs or alteration to the system.

NOTE: Pasteurized Equivalent Water treatment systems that have undergone the “Hazard Evaluation and Safety Assessment” of subpart d. of this section prior to December 31, 2015 shall review their assessment based on the new E. coli water standards and submit any revisions or a statement that no revisions were needed to the Regulatory Agency by April 1, 2016.

Page 223:

APPENDIX G. CHEMICAL AND BACTERIOLOGICAL TESTS

I. PRIVATE INDIVIDUAL WATER SUPPLIES AND RECIRCULATED WATER -BACTERIOLOGICAL

Reference: Section 7, Items 8r, ~~18r, 7p, and 17p.~~

Application: To private individual water supplies, used by dairy farms, milk plants, receiving stations, transfer stations and milk tank truck cleaning facilities, ~~and to recirculated cooling water, used in milk plants, receiving stations and dairy farms.~~

Frequency: Water shall be tested for the presence of total coliform and E. coli initially; after repair, modification or disinfection of the private individual water supplies of dairy farms, milk plants, receiving stations, transfer stations and milk tank truck cleaning facilities, and thereafter; semiannually for all milk plants, receiving stations, transfer stations and milk tank truck cleaning facilities water supplies and at least every three (3) years on dairy farms. Recirculated cooling water in milk plants, receiving stations and on dairy farms shall be tested semiannually.

Criteria: A MPN of total coliform organisms of less than 1.1 per 100 mL, when ten (10) replicate tubes containing 10 mL, or when five (5) replicate tubes containing 20 mL are tested using the Multiple Tube Fermentation (MTF) technique, or one of the Chromogenic Substrate

multiple tube procedures; a direct count of less than 1 per 100 mL using the Membrane Filter (MF) technique; or a presence/absence (P/A) determination indicating less than 1 per 100 mL when one vessel containing 100 mL is tested using the MTF technique or one of the Chromogenic Substrate procedures. ~~The Chromogenic Substrate procedures are not acceptable for recirculated cooling water.~~ A MPN of E. coli organisms of less than 1.1 per 100 mL, when ten (10) replicate tubes containing 10 mL, or when five (5) replicate tubes containing 20 mL are tested using the Fluorogenic Substrate multiple tube procedures; a direct count of less than 1 per 100 mL using the Membrane Filter (MF) Fluorogenic Substrate technique; or a presence/absence (P/A) determination indicating less than 1 per 100 mL when one vessel containing 100 mL is tested using the Fluorogenic Substrate procedures. Any sample producing a bacteriological result of Too Numerous To Count (TNTC) or Confluent Growth (CG) by the MF technique; or turbidity in a presumptive test with no gas production and with no gas production in confirmation (optional test) by the MTF technique (both MPN and P/A format) shall be considered invalid and shall have a Heterotrophic Plate Count (HPC), from the same sample or subsequent resample, of less than 500 colony forming units (CFU) per mL in order to be deemed satisfactory. Findings by HPC shall be reported as Positive or Not-Found.

Apparatus, Methods and Procedure: Tests performed shall conform with the current edition of *SMEWW* or with FDA approved, EPA promulgated methods for the examination of water and waste water or the applicable FDA/NCIMS 2400 Forms. (Refer to M-a-98, latest revision.)

Corrective Action: When the laboratory report on the sample is positive for total coliform but negative for the presence of E. coli or indicates a Heterotrophic Plate Count of greater than 500 CFU per mL on a sample that had previously been invalidated, ~~unsatisfactory~~, the water supply in question shall be considered at risk for pathogenic contamination and shall again be physically inspected and necessary corrections made until subsequent samples are bacteriologically satisfactory. This inspection shall be completed within 30 days of the date of the positive test result. If the inspection and corrective action are complete, but the water supply in question is still testing positive for total coliform but negative for E. coli the facility shall continue to investigate and correct problems until subsequent samples are bacteriologically satisfactory. When the laboratory report on the sample is positive for both total coliform and E. coli, or the facility has failed to complete the water supply inspection within 30 day of the initial positive test result, the water supply is unsatisfactory.

II. RECLAIMED WATER AND RECIRCULATED WATER -BACTERIOLOGICAL

Reference: Section 7, Items 8r, 18r, 7p and 17p.

Application: To reclaimed water and recirculated cooling water, used in milk plants, receiving stations and dairy farms.

Frequency: Initially; after repair, modification or disinfection of the reclaimed water supplies of dairy farms, milk plants, receiving stations, transfer stations and milk tank truck cleaning facilities; reclaimed water and recirculated cooling water in milk plants, receiving stations and on dairy farms shall be tested semiannually thereafter.

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

of the Chromogenic Substrate procedures. The Chromogenic Substrate procedures are not acceptable for recirculated cooling water. Any sample producing a bacteriological result of Too Numerous To Count (TNTC) or Confluent Growth (CG) by the MF technique; or turbidity in a presumptive test with no gas production and with no gas production in confirmation (optional test) by the MTF technique (both MPN and P/A format) shall be considered invalid and shall have a Heterotrophic Plate Count (HPC) from the same sample or subsequent resample of less than 500 colony forming units (CFU) per mL in order to be deemed satisfactory. Findings by HPC shall be reported as Positive or Not-Found.

Apparatus, Methods and Procedure: Tests performed shall conform with the current edition of SMEWW or with FDA approved, EPA promulgated methods for the examination of water and waste water or the applicable FDA 2400 Series Forms.

Corrective Action: When the laboratory report on the sample is unsatisfactory, the water supply in question shall again be physically inspected and necessary corrections made until subsequent samples are bacteriologically satisfactory.

(Renumber the remaining parts of Appendix G. as needed.)

Document: FDA/NCIMS 2400 Forms

The Laboratory Committee is requested to update the FDA/NCIMS Form 2400m Dairy Waters to include the methodology for E. coli testing.

FDA DID NOT CONCUR WITH THIS PROPOSAL AS CITED IN THEIR LETTER TO THE NCIMS CHAIR DATED AUGUST 11, 2015

FDA non-concurred with this Proposal strictly based on the need for granting FDA editorial license to incorporate FDA's suggested text into the related NCIMS documents. FDA believes that these proposed changes and adjustments are warranted and appropriate to maintain the consistency in the language and the conventions of the NCIMS documents. They also will eliminate conflict within the NCIMS documents. FDA also believes that these suggested wording changes do not change the intent of the Proposals as passed at the 2015 NCIMS Conference.

FDA met with the NCIMS Executive Board on October 7-8, 2015 concerning the Proposals passed during the 2015 Conference. During this NCIMS Executive Board meeting, FDA and the Executive Board reached mutual concurrence with Proposal 226 as follows:

Page 223:

APPENDIX G. CHEMICAL AND BACTERIOLOGICAL TESTS

II. RECLAIMED WATER AND RECIRCULATED WATER -BACTERIOLOGICAL

Reference: Section 7, Items 8r, 18r, 7p and 17p.

Application: To reclaimed water and recirculated cooling water, used in milk plants, receiving stations, transfer stations and dairy farms.

Frequency: Initially; after repair, modification or disinfection of the reclaimed water and/or recirculated cooling water supplies of dairy farms, milk plants, receiving stations and transfer stations; reclaimed water and recirculated cooling water in milk plants, receiving stations, transfer stations and on dairy farms shall be tested semiannually thereafter.

Note: All other changes identified in the Proposal as passed are acceptable to FDA

Proposal: JC1
Document: 2013 PMO
Page: 61

Make the following changes to the 2013 PMO:

Page 61:

Milk plants shall comply with all Items of this Section. The Grade “A” PMO, with Appendices, and the supporting milk plant-specific procedures required herein, shall constitute a milk plant’s food safety plan as required by 21 CFR 117.126 to the extent that the procedures address all the hazards identified by the milk plant as applicable for that milk plant. A milk plant shall have a written Hazard Analysis for each kind or group of milk and/or milk product processed. 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. ...

Proposal: 114
Document: 2013 PMO
Page: 75

Make the following changes to the 2013 PMO:

Page 75:

Drying equipment, cloth-collector systems, packaging equipment and multi-use dry milk products and dry whey storage containers are cleaned at intervals and by methods recommended by the manufacturer and approved by the Regulatory Agency. Such methods may include cleaning without water (dry cleaning) by the use of vacuum cleaners, brushes, or scrapers. ~~After cleaning, such equipment is sanitized by a method approved by the Regulatory Agency.~~ Product-contact surfaces shall be subjected to an effective sanitizing treatment immediately prior to use, except where dry cleaning is permitted. Cloth collector systems and all dry product-contact surfaces downstream from the dryer shall be sanitized or purged at intervals and by methods

recommended by the manufacturer and approved by the Regulatory Agency. Storage bins used to transport dry milk or milk products shall be dry cleaned after each usage and washed and sanitized at regular intervals. ...

Proposal: 133
Document: 2013 PMO
Pages: 77, 339 and 340

Make the following changes to the 2013 PMO:

Page 77:

ITEM 12p. CLEANING AND SANITIZING OF CONTAINERS AND EQUIPMENT ...

ADMINISTRATIVE PROCEDURES ...

6. a. The residual bacteria count of multi-use containers and closures shall be conducted as outlined in Appendix J. The residual bacteria count of multi-use containers, used for packaging pasteurized milk and milk products, shall not exceed one (1) colony per milliliter (1/mL) of capacity, when the rinse test is used, or fifty (50) colonies per fifty (50) square centimeters (cm^2) (one (1) colony per square centimeter) of product-contact surface, when the swab test is used, in three (3) out of four (4) samples taken at random on a given day. Coliform organisms shall be undetectable in all multi-use containers.
- b. The residual bacteria count of single-service containers and closures, used for packaging pasteurized milk and milk products, shall not exceed fifty (50) colonies per container, or in the case of dry product packaging, shall not exceed one (1) colony per milliliter (1/mL) of capacity when the rinse test is used, except that in containers less than 100 mL the count shall not exceed ten (10) colonies or fifty (50) colonies per ~~eight (8) square inches~~ 50 cm^2 (one (1) colony per square centimeter) of product-contact surface, when the swab test is used, in three (3) out of four (4) samples taken at random on a given day. Coliform organisms shall be undetectable in all single-service containers and/or closures. ...

Page 339:

15. "**Sample Set**" shall mean:
 - a. For the rinse test, a minimum of four (4) containers shall be tested.
 - b. For the swab test, a minimum of four (4), ~~50 250 square centimeter~~ cm^2 areas of surface from separate containers shall be tested. In the case of containers or closures with a product-contact surface area smaller than ~~50 250 square centimeter~~ cm^2 , more than four (4) containers or closures to equal at least ~~50 250 square centimeter~~ cm^2 times four (4) shall be required to be swabbed.

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

2. Where a rinse test can be used, the residual microbial count shall not exceed fifty (50) per container, except that in containers less than 100 mL, the count shall not exceed ten (10), or when using the swab test, not over fifty (50) colonies ~~per 8 square inches~~ 50 cm² (1 per square centimeter) of product-contact surface in three (3) out of four (4) samples taken at random on a given day. All single-service containers and closures shall be free of coliform organisms.

Page 340:

5. A sample set from each manufacturing line, as defined in these Standards, shall consist of a minimum of four (4) containers or closures, when the rinse test is used, or a minimum of four (4) ~~50 square centimeter~~ cm² areas of surface, when the swab test is used.

Proposal: JC4
Document: 2013 PMO
Pages: 81 and 89

Make the following changes to the 2013 PMO:

Page 81:

ITEM 15p. PROTECTION FROM CONTAMINATION ...

PUBLIC HEALTH REASON

Because of the nature of milk and milk products and their susceptibility to contamination by bacteria, chemicals and other adulterants, every effort should be made to provide adequate protection for the milk and milk products at all times. Public health officials have long recognized that raw milk contains microorganisms of public health concern and it is important to understand that these microorganisms may be found in the milk plant environment if measures are not taken to minimize the risk of contamination by these microorganisms. Contamination of milk from the environment can result in milkborne illness. Misuse of pesticides and other harmful chemicals can provide opportunities for contamination of the milk and milk product or equipment with which the milk or milk product comes in contact. ...

Page 89:

15p.(C)

2. ENVIRONMENTAL MONITORING:

A milk plant shall have a written environmental monitoring program that is implemented and supported by records for milk and/or milk products exposed to the environment when the milk and/or milk products does not subsequently receive a treatment that would significantly minimize the pathogen. The environmental monitoring program shall, at a minimum:

- a. Be supported by scientific information;
- b. Include written procedures and records;

- c. Identify environmental monitoring locations and the number of sample sites to be tested during routine environmental monitoring;
- d. Identify the timing and frequency for collecting and testing samples;
- e. Identify the environmental pathogen or appropriate indicator microorganism to be tested for;
- f. Identify the test(s) conducted, including the analytical method used, and the test result;
- g. Identify the laboratory conducting the testing; and
- h. Include corrective action procedures for environmental monitoring test results.

The NCIMS Liaison Committee requests the effective date for this modification to be August 30, 2016, or one year after final rule is published. If the final Preventive Controls for Human Food Rule does not include mandatory provisions analogous to the environmental monitoring requirements in the Proposed Rule, this modification will self-terminate and will be stricken from future versions of the PMO.

***Note:** The final Preventive Controls for Human Food Rule was published September 17, 2015 and does include mandatory provisions analogous to the environmental monitoring requirements as cited in this Proposal. Therefore, Proposal JC4 becomes effective September 17, 2016.*

This Proposal authorizes FDA to make all appropriate changes to applicable FDA 2359 series forms.

Proposal: JC5
Document: 2013 PMO
Page: 89

Make the following changes to the 2013 PMO:

Page 89:

15p.(C)

3. SUPPLIER CONTROL PROGRAM:

A milk plant shall have a supplier control program for raw materials and ingredients that is implemented and supported by records to control food safety hazards.

The supplier control program shall, at a minimum;

- a. Document that all milk and/or milk product ingredients are obtained from an IMS listed source or, when an IMS source does not exist that the supplier has, at a minimum, a functional risk-based program with appropriate controls to significantly minimize hazards for all milk and/or milk product ingredients obtained from non-IMS listed sources utilized in the milk plant's Grade "A" milk and/or milk products.
- b. Document that a supplier of non-milk and/or milk product ingredients has a functional and written food safety program that includes allergen management, if utilized in the milk plant's Grade "A" milk and/or milk products.

The NCIMS Liaison Committee requests the effective date for this modification to be August 30, 2016, or one year after final rule is published. If the final Preventive Controls for Human Food Rule does not include mandatory provisions analogous to the supplier verification requirements in the Proposed Rule, this modification will self-terminate and will be stricken from future versions of the PMO.

Note: The final Preventive Controls for Human Food Rule was published September 17, 2015 and does include mandatory provisions analogous to the environmental monitoring requirements as cited in this Proposal. Therefore, Proposal JC4 becomes effective September 17, 2016.

This Proposal authorizes FDA to make all appropriate changes to applicable FDA 2359 series forms.

Proposal: 119
Document: 2013 PMO
Pages: 124 and 125

Make the following changes to the 2013 PMO:

Page 124:

SECTION 8. ANIMAL HEALTH ...

1. All milk for pasteurization, ultra-pasteurization, 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:
 - a. Areas which have Modified Accredited Advanced Tuberculosis (TB) status or higher as determined by the USDA; or
 - b. An Area which fails to maintain such status:
 - (1) Any herd shall have been accredited by USDA; or
 - (2) Shall have passed an annual tuberculosis test; or
 - (3) The Area shall have established a tuberculosis testing protocol for livestock that assures tuberculosis protection and surveillance of the dairy industry within the Area and that is approved by FDA, USDA and the Regulatory Agency.

NOTE: Under the Federal USDA Bovine Tuberculosis Eradication Program, only cattle, bison and captive cervids are covered under the USDA State tuberculosis status determination. Therefore, other hooved mammals (goats, sheep, water buffalo, etc.) are not covered within the program and shall comply with one (1) of the options cited under 3 below.

2. All milk for pasteurization, ultra-pasteurization, 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 125:

NOTE: Under the Federal USDA Bovine Brucellosis Eradication Program, only cattle and bison are covered under the USDA State brucellosis status determination. Therefore, cattle are the only dairy animal currently covered by both the Federal USDA brucellosis and tuberculosis programs. All other hooved mammals (goats, sheep, water buffalo, etc.) are not covered within the program these programs and shall comply with one (1) of the options cited under 3 below.

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

- a. Has passed an annual whole herd or flock brucellosis and/or tuberculosis test testing as recommended by the State Veterinarian or USDA Area Veterinarian in Charge (AVIC) using tests approved by USDA APHIS for the specific disease and species (blood testing for brucellosis and the caudal fold tuberculin test for tuberculosis); or
- b. Has passed an initial whole herd brucellosis and/or tuberculosis test testing, followed only by testing replacement animals or any animals entering the milking group or sold as dairy animals using tests approved by USDA APHIS for the specific disease and species (blood testing for brucellosis and the caudal fold tuberculin test for tuberculosis); or
- c. Has passed an annual random blood individual animal brucellosis and/or tuberculosis testing program, using tests approved by USDA APHIS for the specific disease and species (blood testing for brucellosis and the caudal fold tuberculin test for tuberculosis), sufficient to provide a confidence level of 99% with a P value of 0.05. Any herd or flock with one (1) or more confirmed positive animals shall go to 100% testing until the whole herd tests show no positive animals are found; or
- d. Has passed a USDA APHIS approved bulk milk test for the specific disease and species, at USDA APHIS recommended frequency, with an implementation date based on the availability of the bulk milk test once USDA APHIS has approved such a test for the specific disease and species (The brucellosis ring test is USDA APHIS approved for the bovine species and is not suitable for most non-bovine species.); or
- e. Is determined to be free of brucellosis and/or tuberculosis as provided by the development and implementation of a State administered brucellosis-free and/or tuberculosis-free herd certification program involving a documented surveillance program, which includes records supporting the tests required in this Section, and an official annual written certification from the State Veterinarian documenting their brucellosis-free and/or tuberculosis-free status. The surveillance program shall be documented and the official annual written State brucellosis-free and/or tuberculosis-free certification shall be retained on file with the State Regulatory Agency. This official annual written State brucellosis-free and/or tuberculosis-free certification shall include a current list of Grade “A” non-cattle dairy herds and/or flocks (goats, sheep, water buffalo, etc.) that are covered within the documented surveillance program and contained within the official annual written State brucellosis-free and/or tuberculosis-free certification.

(Refer to the **NOTE:** on page 31.)

Proposal: 301
Document: 2013 PMO
Page: 130

Make the following changes to the 2013 PMO:

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

ADMINISTRATIVE PROCEDURES

Page 130:

11. Aseptically processed and packaged low-acid milk and/or milk products ... 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, and/or 110, ~~and/or~~ 114 shall expire on December 31, ~~2015~~ 2017, unless extended by future conference action.

Proposal: 121
Document: 2013 PMO
Page: 164

Make the following changes to the 2013 PMO:

**APPENDIX C. DAIRY FARM CONSTRUCTION STANDARDS
AND MILK PRODUCTION ...**

V. DAIRY – CONSTRUCTION AND OPERATION ...

Page 164:

MILKING METHODS

~~Milking methods shall be geared to permit the efficient withdrawal of milk without introducing undue numbers of bacteria or causing injury to the udder.~~

~~In addition to assessing the nation's milk producers a cost, which has been estimated to approach \$500 million annually, mastitis has been found to pose serious public health hazards. The most widespread of these is a gastrointestinal disorder caused by toxins produced by certain strains of staphylococci.~~

~~It has been known for many years that a relationship exists between mastitis and milking practices. While not all the facts are known about mastitis, it is abundantly clear that its control is enhanced by use of mechanically sound milking equipment and good milking practices. The NMC has described a satisfactory milking system as one which:~~

- ~~1. Maintains a stable vacuum in the teat cup and at a level adequate for completely milking most udders in three (3) to five (5) minutes;~~

- ~~2. Does not stress the tissues of the teat by excessive stretching and ballooning;~~
- ~~3. Produces massage without harsh action; and~~
- ~~4. Is designed so that the entire system can be sanitized efficiently and satisfactorily.~~

~~The NMC considers proper milking procedure to include the following:~~

- ~~1. Before the milking unit is applied to the udder, the operator takes thirty (30) seconds to prepare the lactating animal in the recommended manner to obtain milk letdown, and the milking machine should be applied immediately thereafter;~~
- ~~2. The teat cups are attached in a manner to limit the volume of air drawn into the system;~~
- ~~3. The teat cups are positioned as low on the teats as practicable;~~
- ~~4. The operator stays near the machine and, at the end point of milk removal, the claw is briefly pulled down to open the teat cavity and remove the strippings. Stripping by machine should not extend over a period of more than fifteen to twenty (15-20) seconds. Prolonging stripping can be injurious to the udder;~~
- ~~5. Before removing the machine, the vacuum to the teat cups is broken and the cups removed in a gentle manner; and~~
- ~~6. To avoid over milking, the operator should limit the number of machines in use. Two (2) bucket-type units, two (2) movable pipeline units or three (3) fixed units, in a walk-through barn, usually represent maximum workloads with conventional milking systems. Hooded or small-mouthed pails may be used for carrying only that milk which has been drawn into them by hand milking. Their extended use as carrying pails is considered hazardous in view of their inability to be covered or otherwise protected from flies, dust, splash, etc.~~

The goal of a successful milking procedure is to ensure that most dairy animals will be milked quickly, gently and completely, under conditions that optimize udder health and result in the production of milk with a low bacteria count and somatic cell count.

3-A Accepted Practices for the Design, Fabrication, and Installation of Milking and Milk Handling Equipment, Number 606-##, provides guidance on performance and information requirements and certain dimensional requirements for satisfactory functioning of milking equipment for milking and cleaning. Methods for milking equipment testing to ensure compliance with this Accepted Practice are presented in the NMC guidelines *Procedures for Evaluating Vacuum Levels and Air Flow in Milking Systems*.

Suggested milking procedures to minimize the risk of mastitis and to enhance the quality of milk are presented in the NMC publication *Current Concepts of Bovine Mastitis* and the NMC factsheet *Recommended Milking Procedures*.

Proposal: 124
Document: 2013 PMO
Page: 244

Make the following changes to the 2013 PMO:

Page 244:

Filter Performance: Intake air filter efficiency shall be at least 98% SAE J726², June 1987³ using Air Cleaner (AC) coarse test dust. Final filter efficiency shall be at least 99% as measured by the Dioctylphthalate Fog Method (DOP) test (with a mean particle diameter of 0.3 microns).⁴ When commercially sterile air is required, the final filter efficiency shall be at least ~~99.99%~~ 99.999% as measured by the DOP test.

Proposal: 126
Document: 2013 PMO
Page: 304

Make the following changes to the 2013 PMO:

Page 304:

9.2.2 HTST - INTERWIRING OF THE DIFFERENTIAL PRESSURE CONTROLLER, WITH THE BOOSTER PUMP

Method: Determine if the booster pump stops running when the pressure differential is not properly maintained in the regenerator section(s).

Procedure:

1. Connect the pasteurized or raw regenerator section differential pressure controller sensing element to a testing tee with the other end of the testing tee capped. ...

NOTE: If there is water in the HTST pasteurization system, ensure that the recorder-controller sensing element and the pasteurized or raw regenerator section differential pressure controller sensing element ports are capped before the timing pump is turned on. ...

4. ~~Increase~~ Adjust the air supply on the testing tee to provide an adequate pressure differential to start the booster pump. The booster pump shall start running.

5. ~~Decrease~~ Adjust the air supply to the testing tee until the pasteurized milk and/or milk product differential pressure controller sensing element pressure is less than 14 kPa (2 psi) greater than the pressure on the raw milk and/or milk product side differential pressure controller sensing element. The booster pump shall stop running. Ensure that the FDD remains in the forward-flow position and the timing pump continues to operate.

Proposal: 128
Document: 2013 PMO
Pages: 311, 312, 315 and 316

Make the following changes to the 2013 PMO:

Page 311:

11.1 HTST PASTEURIZATION SYSTEMS

(Except for magnetic flow meter based timing systems.) ...

Apparatus:

1. An electrical conductivity measuring device, which is capable of detecting a change in conductivity, and is equipped with one (1) or two (2) standard electrodes; ...

Procedure: ...

Page 312:

2. If utilizing an electrical conductivity measuring device that is equipped with two (2) standard electrodes, install install one (1) electrode at the beginning of the legal holding tube and the other electrode at the end of the legal holding tube. If utilizing an electrical conductivity measuring device that is equipped with a single standard electrode, install the electrode at the end of the legal holding tube. ...

5. The accurate time measuring device shall start ~~when it detects a change in conductivity at the beginning of the legal holding tube~~ at the moment when the conductivity solution is injected. This may be accomplished by detecting a change in conductivity at the beginning of the holding tube when utilizing two (2) electrodes or by a switch placed at the beginning of the holding tube synchronized with the injection process when utilizing a single electrode placed at the end of the holding tube. ...

11.2A CONTINUOUS-FLOW PASTEURIZATION SYSTEMS UTILIZING A MAGNETIC FLOW METER BASED TIMING SYSTEM – PASTEURIZATION HOLDING TIME ...

Page 315:

Apparatus:

1. An electrical conductivity measuring device, which is capable of detecting a change in conductivity, and is equipped with one (1) or two (2) standard electrodes; ...

Procedure:

Utilize either **TEST OPTION I** or **TEST OPTION II**. ...

TEST OPTION I: ...

3. If utilizing an electrical conductivity measuring device that is equipped with two (2) standard electrodes, install install one (1) electrode at the beginning of the legal holding tube and the other electrode at the end of the legal holding tube. If utilizing an electrical conductivity measuring device that is equipped with a single standard electrode, install the electrode at the end of the legal holding tube. ...

6. The accurate time measuring device shall start ~~when it detects a change in conductivity at the beginning of the legal holding tube~~ at the moment when the conductivity solution is injected.

This may be accomplished by detecting a change in conductivity at the beginning of the holding tube when utilizing two (2) electrodes or by a switch placed at the beginning of the holding tube synchronized with the injection process when utilizing a single electrode placed at the end of the holding tube. ...

Page 316:

TEST OPTION II:

1. If utilizing an electrical conductivity measuring device that is equipped with two (2) standard electrodes, install install one (1) electrode at the beginning of the legal holding tube and the other electrode at the end of the legal holding tube. If utilizing an electrical conductivity measuring device that is equipped with a single standard electrode, install the electrode at the end of the legal holding tube. ...

4. ~~The accurate time measuring device shall start when it detects a change in conductivity at the beginning of the legal holding tube at the moment when the conductivity solution is injected.~~ This may be accomplished by detecting a change in conductivity at the beginning of the holding tube when utilizing two (2) electrodes or by a switch placed at the beginning of the holding tube synchronized with the injection process when utilizing a single electrode placed at the end of the holding tube. ...

Proposal: JC7

Document: 2013 PMO

Pages: 349, 350 and 351

Make the following changes to the 2013 PMO:

Page 349:

PREREQUISITE AND OTHER PROGRAM-PROGRAMS: HACCP is not a stand-alone program, but is part of a larger control system. PPs are the universal procedures used to control the conditions of the milk plant environment that contribute to the overall safety of the milk or milk product. They represent the sum of programs, practices and procedures that shall be applied to produce and distribute safe milk and milk products in a clean, sanitary environment. They differ from CCPs in that they are basic sanitation programs that reduce the potential occurrence of a milk or milk product safety hazard. Frequently, both HACCP Plan CCPs and PPs control measures are necessary to control a food safety hazard. ...

Page 350:

The exact set of PPs will vary since their application is milk and/or milk product and process specific. The existence and effectiveness of PPs should be assessed during the design and implementation of each HACCP Plan. PPs should be documented and regularly audited. An audit review consists of verifying that the company has a program implemented that indicates

how the company monitors and controls each of the PPs. PPs are established and managed separately from the HACCP Plan.

In addition to PPs, other programs may be necessary to assure the HACCP system is operating as intended.

1. **Required PPs:** The following required PPs shall have a brief written description or checklist that the PPs can be audited against to ensure compliance. PPs shall include procedures that can be monitored; records that specify what is monitored; and how often it will be monitored.

Each milk plant, receiving station or transfer station shall have and implement PPs that address conditions and practices before, during, and after processing. The PPs shall address:

- a. Safety of the water that comes into contact with milk and/or milk products or product-contact surfaces, including steam and ice;
- b. Condition and cleanliness of equipment product-contact surface;
- c. Prevention of cross-contamination from insanitary objects and or practices to milk and/or milk products or product-contact surfaces, packaging material and other food-contact surfaces, including utensils, gloves, outer garments, etc., and from raw product to processed product; ...
- g. Control of employee health conditions, including employee exposure to high risk situations, that could result in the microbiological contamination of milk and/or milk products, packaging materials, and product-contact surfaces; and
- h. Pest exclusion from the milk plant.
- i. An employee training program shall at a minimum address the following:
 - (1) All employees directly responsible for the unloading and storage of raw materials and ingredients, storage and loading of the Grade "A" milk and/or milk product as well as any processing, receive annual food safety training that includes food GMPs, Appendix K requirements, an overview of HACCP, and allergens.
 - (2) Reference log of all employees identified in #1 above and the date and type of training received. ...

2. **Monitoring and Correction:** The milk plant, receiving station or transfer station shall monitor the conditions and practices of all required PPs with sufficient frequency to ensure conformance with those conditions and that are appropriate both to the milk plant, receiving station or transfer station and to the safety of the milk and/or milk product being processed. Each milk plant, receiving station or transfer station shall document the correction of those conditions and practices that are not in conformance. Devices, such as indicating and recording thermometers that are used to monitor PPs shall be calibrated to assure accuracy at a frequency determined by the milk plant, receiving station, or transfer station.

Page 351:

3. **Other Programs:** Each milk plant shall have and implement other programs that are necessary to ensure the HACCP system is operating as intended. The other programs shall include:

- a. A written environmental monitoring program that is implemented and supported by records for milk and/or milk products exposed to the environment when the milk and/or milk

products does not subsequently receive a treatment that would significantly minimize the pathogen. The environmental monitoring program shall, at a minimum:

(1) Be supported by scientific information;

(2) Include written procedures and records;

(3) Identify environmental monitoring locations and the number of sample sites to be tested during routine environmental monitoring;

(4) Identify the timing and frequency for collecting and testing samples;

(5) Identify the environmental pathogen or appropriate indicator microorganism to be tested for;

(6) Identify the test(s) conducted, including the analytical method used, and the test result;

(7) Identify the laboratory conducting the testing; and

(8) Include corrective action procedures for environmental monitoring test results.

b. A supplier program that shall, at a minimum, address the following:

(1) Document that all milk and/or milk product ingredients are obtained from an IMS listed source or, when no IMS source exists, that the supplier has, at a minimum, a functional risk-based program with appropriate controls to significantly minimize hazards for all milk and/or milk product ingredients obtained from non-IMS listed sources utilized in the milk plant's Grade "A" products.

(2) Document that a supplier of non-milk and/or milk product ingredients has a functional and written food safety program that includes allergen management, if utilized in a Grade "A" product.

c. A written recall plan that, at a minimum, shall meet 21 CFR Part 7 subpart A & subpart C.

NOTE: For additional information and guidance from FDA regarding product recalls, milk plants should also refer to the current Guidance for Industry: Product Recalls, Including Removals and Corrections at:

<http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>

34. Required Records: Each milk plant, receiving station or transfer station shall maintain records that document the monitoring activities, corrections, and additional food safety programs required by this Appendix. These records are subject to the record keeping requirements of this Appendix.

HAZARD ANALYSIS: Each milk plant, receiving station or transfer station shall develop, or have developed for it, a written hazard analysis to determine whether there are milk and/or milk product hazards that are reasonably likely to occur for each type of milk and/or milk product processed or handled by the milk plant, receiving station or transfer station and to identify the control measures that the milk plant, receiving station or transfer station can apply to control those hazards.

The hazard analysis shall include hazards that can be introduced both within and outside the milk plant, receiving station or transfer station environment, including hazards that can occur during handling, transportation, processing and distribution.

A 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 possibility that, in the absence of these controls, the hazard will occur in the particular type of milk and/or milk product being processed. The hazard analysis shall be developed by an individual(s) trained in accordance with this Appendix and shall be subject to the record keeping requirements as described in this Appendix.

1. In evaluating what milk and/or milk product hazards are reasonably likely to occur, at a minimum, consideration should be given to the following: ...
2. Milk plant, receiving station or transfer station operators should evaluate product ingredients, processing procedures, packaging, storage, and intended use; facility and equipment function and design; and milk plant sanitation, including employee hygiene, to determine the potential effect of each on the safety of the finished milk and/or milk product for the intended consumer.

The NCIMS HACCP Implementation Committee requests an effective date for this proposal to be August 30, 2016 – or one year after the final rule is published.

Note: The final Preventive Controls for Human Food Rule was published September 17, 2015; therefore, Proposal JC7 becomes effective September 17, 2016.

Proposal: 229
Document: 2013 PMO
Page: 365

Make the following changes to the 2013 PMO:

APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE ...

RECORDS REQUIREMENTS: ...

Page 365:

Records of all sample results shall be maintained for a minimum of six (6) months by the industry at the location where the tests were run, and/or another location as directed by the Regulatory Agency and as agreed to by industry. For the laboratory survey, two (2) years of records shall be available at the facility at the time of the survey.

Proposal: 134
Document: 2013 PMO
Pages: 383 and 384

Make the following changes to the 2013 PMO:

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

Page 383:

GENERAL REQUIREMENTS FOR AMI COMPUTER SYSTEMS

AMIs have computer systems that are programmed for monitoring and/or controlling various sensors, instrumentation and the operational state of various devices such as pumps and valves; have data collection, storage and reporting systems; and have communication network capabilities for multiple uses and locations. While electronic and computer systems can furnish a wide range of process verification and anomaly reporting, these are criteria only for compliance with Items 1r, 13r and 14r of this Appendix.

The dairy farm shall have an identified representative(s) that has been trained by the AMI manufacturer or AMI manufacturer’s designated representative to make program changes to the AMI system.

A manufacturer’s written or electronic documentation addressing the computer system’s monitoring and controlling functions related to Items 1r, 13r, and 14r shall explain the devices controlled, the sensors or instruments monitored, and testing procedures. A document shall bear the name of the identified representative of the dairy farm and shall be available for review at the dairy farm upon request by the Regulatory Agency, Rating Agency and/or FDA.

This documentation shall address Items 1r, 13r, and 14r:

1. The software version used, the devices controlled or monitored and their locations, and the sensors or instruments monitored and their locations;
2. The testing procedures for all of the computer system’s controlled and monitoring devices;
3. The procedure for any changes or maintenance to the computers, devices, instrumentation, sensors hardware, etc.; and
4. Instructions on how to access the information available on the computer system.

NOTE: Controls for the devices are verified as directed by the Regulatory Agency.

The data supporting the electronic reports shall be stored in a database or data archival system. Written or electronic record(s) shall be maintained at the dairy farm identifying changes and verifying compliance with this Ordinance. This record shall contain the name of the identified dairy farm representative assigned to administer the computer system and these record(s) shall be available for review at the dairy farm upon request by the Regulatory Agency, Rating Agency and/or FDA.

A verification of all computer system’s controlled functions shall be conducted and documented at the commissioning of the computer system and at additional frequencies as deemed necessary by the Regulatory Agency. Computer system controlled functions should be reviewed and verified by the Regulatory Agency during routine dairy farm inspections and by the Rating Agency and FDA.

ITEM 1r. ABNORMAL MILK

AMIs shall have the capability to identify and discard milk from animals that are producing milk with abnormalities. Odor is currently evaluated on a farm bulk milk tank/silo basis and shall not be any different for a herd using AMI technology.

The dairy farm shall have a documented procedure in place describing how abnormal milk is properly detected and diverted; and that equipment used for the milking of healthy animals has not become contaminated. The procedure shall also document that a physical change to the AMI system has occurred.

A verification of all computer system’s controlled functions responsible for properly detecting and diverting abnormal milk, shall be conducted and documented at the commissioning of the computer system. This verification means the visual observation by Regulatory Agency personnel; or documentation indicating the testing that was completed by AMI manufacturer’s designated representative; or other means accepted by the Regulatory Agency. Written or electronic information for all required actions shall be maintained at the dairy farm and shall be made available upon request to the Regulatory Agency, Rating Agency and/or FDA.

Animals producing milk with abnormalities shall be diverted to a holding pen to be milked immediately prior to the milking system being cleaned and sanitized, or the animal(s) are identified through an appropriate identification system so that their milk will be automatically excluded from the milk offered for sale, provided that the parts of the milking system that came into contact with the milk with abnormalities are immediately cleaned and sanitized. ...

Page 384:

ITEM 13r. MILKING - FLANKS, UDDERS AND TEATS

AMI manufacturers shall submit data to FDA to show that the teat prepping system employed in their milking system is equivalent to Item 13r., **ADMINISTRATIVE PROCEDURES #4** of this *Ordinance*: “Teats shall be treated with a sanitizing solution just prior to the time of milking and shall be dry before milking.” Each AMI installer shall provide the dairy producer and the Regulatory Agency with a copy of this FDA acceptance, including a detailed description of the accepted equivalent procedure. Each dairy producer shall keep a copy of the accepted teat prep protocol along with the appropriate AMI manufacturer’s teat prep protocol verification procedures on file at the dairy farm.

A verification of all computer system’s controlled functions responsible for proper teat preparation shall be conducted and documented at the commissioning of the computer system. This verification means the visual observation by Regulatory Agency personnel; or documentation indicating the testing that was completed by AMI manufacturer’s designated representative; or other means accepted by the Regulatory Agency. Written or electronic information for all required actions shall be maintained at the dairy farm and shall be made available upon request to the Regulatory Agency, Rating Agency and/or FDA.

Note: Implementation date will be one (1) year from the issuance of the 2015 version of the electronic PMO.

Proposal: 307
Document: 2013 PROCEDURES
Page: 16

PROCEDURES CHANGE

Make the following changes to the 2013 PROCEDURES:

Page 16:

6. Reports to Database

State Regulatory or Rating Agencies shall submit drug residue summary data to a third party database.

Proposal: 308
Document: 2013 PROCEDURES
Page: 25

PROCEDURES CHANGE

Make the following changes to the 2013 PROCEDURES:

Page 25:

3. A SSO applicant for initial 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:

- a. Five (5) bulk milk hauler/samplers during a routine milk pick-up at a producer dairy.
- b. One (1) plant sampler that collects raw and finished product samples and single service containers/closures at one (1) pasteurization plant, if applicable.
- c. One (1) industry plant sampler that collects a raw milk sample from a milk tank truck at one (1) pasteurization plant, if applicable.
- d. Hold a valid certificate of qualification as a SRO, LEO, or in the case of a State or TPC Regulatory Supervisor, hold a valid certificate as a ~~SSO~~ delegated Sampling Surveillance Regulatory Agency Official (dSSO).

4. A certified SSO shall be re-certified once each three (3) years by PHS/FDA personnel in an independent side-by-side comparison of the 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.~~ on at least the following number of milk hauler/samplers and plant samplers at dairy facilities:

- a. Three (3) bulk milk hauler/samplers during a routine milk pick-up at a producer dairy.
- b. One (1) plant sampler that collects raw and finished product samples and single service containers/closures at one (1) pasteurization plant, if applicable.
- c. One (1) industry sampler that collects a raw milk sample from a milk tank truck at one (1) pasteurization plant, if applicable.
- d. Hold a valid certificate of qualification as a SRO, LEO, or, in the case of a State or TPC Regulatory Supervisor, hold a valid certificate as a SSO.

Proposal: 305
Document: 2013 CONSTITUTION
Page: 74

Make the following changes to the 2013 CONSTITUTION OF THE NCIMS:

Page 74:

**ARTICLE IV -- VOTING DELEGATES, EXECUTIVE BOARD, OFFICERS,
EXECUTIVE SECRETARY, COMMITTEES, COUNCILS, AND
PROGRAM CHAIR**

SECTION 4. The Board shall be composed up to ~~twenty-six (26)~~ twenty-seven (27) 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, Chair of the

NCIMS Laboratory 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, Chair of the NCIMS Laboratory 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.

Proposal: 303
Document: 2013 CONSTITUTION AND BYLAWS
Pages: 74 and 80

Make the following changes to the 2013 CONSTITUTION OF THE NCIMS:

Page 74:

**ARTICLE IV -- VOTING DELEGATES, EXECUTIVE BOARD, OFFICERS,
EXECUTIVE SECRETARY, COMMITTEES, COUNCILS, AND
PROGRAM CHAIR**

SECTION 4. The Board shall be composed up to 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) or, in the case of a vacancy between Conferences, as appointed by the Chair and confirmed by the Board; 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.

Make the following changes to the 2013 BYLAWS OF THE NCIMS:

Page 80:

ARTICLE I ---- DUTIES OF THE BOARD

SECTION 8. An elected Board membership vacancy occurring between Conferences shall ~~remain vacant until the next Conference. The~~ be filled by the Chair and confirmed by the Board, to serve until the next biennial or special meeting of the Conference. The vacancy shall be filled by a qualified registrant from the most recent biennial or special meeting of the Conference. At the next biennial or special meeting of the Conference, the vacancy shall be filled for the balance of the term by a qualified registrant who is nominated by the Nominating Committee or from the floor in General Assembly and is elected by the voting delegates.

Proposal: 302

Document: 2013 CONSTITUTION AND BYLAWS

Pages: 77 and 81

Make the following changes to the 2013 CONSTITUTION OF THE NCIMS:

Page 77:

ARTICLE IV -- VOTING DELEGATES, EXECUTIVE BOARD, OFFICERS, EXECUTIVE SECRETARY, COMMITTEES, COUNCILS, AND PROGRAM CHAIR ...

SECTION 13. Each Standing, Study and Ad hoc Committee shall have a Committee Chair and Committee Vice Chair who are appointed by the Conference Chair and confirmed by the Board after each biennial meeting of the Conference.

Subd. 1. If the Committee Chair represents a Rating and/or Regulatory Agency, the Committee Vice Chair may represent industry. If the Committee Chair represents industry, the Committee Vice Chair may represent a Rating and/or Regulatory Agency.

Subd. 2. Committee Vice Chairs shall perform the duties of the Committee Chair whenever the Committee Chair is unable to attend.

Subd. 3. Unless fulfilling the role of Committee Chair, the Committee Vice Chair shall serve as a voting member of the Committee.

Make the following changes to the 2013 BYLAWS OF THE NCIMS:

Page 81:

ARTICLE II – DUTIES OF THE CHAIR

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, Other Species and International Certification Program Committees, and Councils as is necessary to carry out the mission of the Conference. From among the members of each Standing Committee, the Conference Chair, with the approval of the Board, shall appoint a Committee Chair and Committee Vice-Chair as outlined in Article IV, Section 13, of the Constitution.

SECTION 4. The Chair shall appoint Study and Ad hoc Committees as directed by the voting delegates or the Board. From among the members of each Study and Ad hoc Committee, the Conference Chair, with the approval of the Board, shall appoint a Committee Chair and Committee Vice-Chair as outlined in Article IV, Section 13. of the Constitution.

Proposal: 304

Document: 2013 BYLAWS

Pages: 81, 84 and 85

Make the following changes to the 2013 BYLAWS OF THE NCIMS:

ARTICLE II ----- DUTIES OF THE CHAIR ...

Page 81:

SECTION 10. The Chair may retain the services of a ~~parliamentarian~~ Parliamentarian to rule on Parliamentary Procedures at Board meetings, Council meetings and during the delegate business meetings of the Conference, employing Roberts Rules of Order Modern Edition. ...

Page 84:

ARTICLE VII ----- RULES OF THE CONFERENCE

SECTION 1. All Conferences shall be at least two (2) days' duration- and shall not adjourn until all business matters have been dispensed with. Each day's session shall be recessed until a specified time the following day, whereas the end of business at the conclusion of the Conference shall be adjourned until the next biennial or special meeting of the Conference.

Page 85:

SECTION 4. Rules of the delegate business meeting

Subd. 1. Roberts Rules of Order Modern Edition shall prevail, unless ~~specific rules are established.~~ provisions of the Constitution, Bylaws or historic practice exist which shall take precedence. ...

Proposal: 231
Document: 2011 EML (Entire Document)
Pages: Entire Document

Evaluation of Milk Laboratories ~~2011~~ 2015 Revision

U.S. Department of Health and Human Services
Public Health Service
Food and Drug Administration
and the
National Conference on Interstate Milk Shipments

PREFACE

In 1941 the United States Public Health Service began evaluations of the facilities, procedures and techniques of analysts in state and local milk laboratories doing official analysis. In 1977, the Food and Drug Administration (FDA) and 46 States had programs for measuring analyst performance in official and officially designated milk laboratories, by on-site ~~evaluations~~ surveys of techniques and proficiency testing. Today all 50 States, Puerto Rico and the Virgin Islands participate in the National Conference on Interstate Milk Shipments (NCIMS) Milk Laboratory Program. These evaluations have resulted in greater uniformity, accuracy and precision of microbiological and chemical analysis.

The material in this publication provides the procedures for the evaluation of milk laboratories required to meet the sanitation standards of the current in use edition of the Grade 'A' 'A' Pasteurized Milk Ordinance (PMO).

The information in this booklet was revised by the ~~Food and Drug Administration~~ FDA Laboratory Proficiency Evaluation Team (~~FDA~~/LPET) in conjunction with the NCIMS and its Laboratory Committee. The basic responsibility for preparation of this revision was assumed by the ~~Food and Drug Administration~~ FDA, Center for Food Safety and Applied Nutrition, Office of Food Safety, Division of Food Processing Science and Technology, Laboratory Proficiency and Evaluation Team, ~~HFH-450~~ HFS-450, 6502 South Archer Road, Bedford Park, IL 60501, USA (Telephone (708) ~~728-4114~~ 924-0614; Fax (708) ~~728-4179~~ 924-0690), hereafter referred to as the FDA/LPET.

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EVALUATION OF MILK LABORATORIES

2014~~5~~ Revision

INTRODUCTION

Official accreditation of milk laboratories and Certified Industry Supervisors (CIS) facilities requires that FDA/LPET or the appropriate ~~Federal or State~~ Milk Laboratory Control Agency conduct an on-site survey to determine satisfactory performance of analysis in milk laboratories and performance of analysis by CIS in facilities where the examinations, required by the *Grade 'A' "A" Pasteurized Milk Ordinance* (PMO), are performed. In addition, satisfactory performance in the analysis of annual proficiency test samples must be demonstrated. An accredited milk laboratory ~~may~~ shall 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) and Industry Analysts (IAs) requires verification of proficiency in performing drug residue analysis at least biennially, through laboratory evaluations and/or ~~on-site~~ performance evaluations and/or by analysis of split samples or by other means as noted in SECTION ~~1~~ below 2.

~~The State~~ Laboratory Evaluation Officer (State-LEOs) ~~certified by the FDA/LPET~~ will shall use the appropriate FDA/NCIMS 2400 Series Forms when evaluating official laboratories, officially designated laboratories, CISs, ISs and IAs. ~~The Federal~~ FDA/LPET laboratory evaluation officer (~~Federal~~ FDA/LPET LEOs) will shall use the appropriate FDA/NCIMS 2400 Series Forms when evaluating State Central Milk Laboratories and ~~State~~ LEOs. Appropriate 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)~~ FDA/LPET and the NCIMS Executive Board, and are effective ninety (90) days after Executive Board approval. Approved forms shall be issued within ninety (90) days of NCIMS Executive Board approval. If the FDA/LPET 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 ninety (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).~~

~~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 functions:

1. FDA accreditation of state central milk laboratories and certification of analysts is based on:
 - a. Satisfactory triennial on-site evaluations surveys of laboratory facilities, equipment, records, and analyst performance of techniques, and
 - b. Satisfactory annual proficiency testing (the examination of split milk samples) to continuously appraise analyst performance.
2. FDA/LPET certification of ~~State~~ LEOs who:
 - a. Accredit local laboratories and certify analysts and CIS based on:
 1. Satisfactory biennial on-site evaluations surveys of laboratory facilities, equipment, records and analyses and
 2. Satisfactory annual proficiency testing which meets established national standards.
 - b. Approve ISs and IAs (who only screen for drugs) based on:
 1. 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 IAs they supervise and
 2. 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 an LEO as certified to conduct drug residue screening tests at industry drug residue screening sites for Grade “A” PMO, and Appendix N regulatory actions (confirmation of 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 FDA/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 who has a valid certificate of qualification.
4. **FOOD AND DRUG ADMINISTRATION/LABORATORY PROFICIENCY EVALUATION TEAM LABORATORY EVALUATION OFFICER (FDA/LPET):** An 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 a CIS or IS who is assigned to conduct screening of milk tank trucks for *Grade “A” PMO*, Appendix N drug residue requirements.
6. **INDUSTRY SUPERVISOR (IS):** An individual trained by an LEO who is responsible for the supervision and training of IAs who screen milk tank trucks for *Grade “A” PMO*, Appendix N drug residue requirements.
7. **INTERNATIONAL CERTIFICATION PROGRAM (ICP):** The NCIMS voluntary program designed to utilize Third Party Certifiers (TCPs) authorized by the NCIMS Executive Board in applying the requirements of the NCIMS Grade “A” Milk Safety Programs 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 governmental or other Regulatory Agency body which has adopted an ordinance, rule or regulation in substantial compliance with the current edition of the *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 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 in this *EML*.
9. **OFFICIAL LABORATORY:** 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:** 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 ultra-pasteurization, aseptic processing and packaging or retort processed after packaging and commingled milk tank truck samples of raw milk for drug residues.
11. **RATING AGENCY:** 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 are 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 in the *IMS List*. The certifications are based on compliance with the requirements of the *Grade “A” PMO* and are conducted in accordance with the procedures set forth in the *MMSR*. The definition of a Rating Agency also includes a 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:** 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 “Regulatory Agency”, whenever it appears in the *EML* shall also mean the appropriated 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, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging, pasteurized milk and milk products, and dairy waters, as necessary.

14. **THIRD PARTY CERTIFIER (TPC):** Non-governmental individual(s) or organization authorized under the NCIMS voluntary 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 ICP. The 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 ICP, a valid Letter of Understanding (LOU) shall be signed between the NCIMS Executive Board and the TPC.

SECTION 1 2: LABORATORY EVALUATION PROGRAMS

An evaluation of a milk laboratory ~~must~~ shall include an on-site ~~visit to~~ survey of 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/NCIMS 2400 ~~Series~~ Forms). The ~~Federal~~ FDA/LPET or ~~State~~ LEO shall determine if the laboratory facilities, equipment, records and techniques of analysts are in compliance with the FDA/NCIMS 2400 ~~Series~~ Forms.

A copy of the “Grade ‘A’ Milk Laboratory Evaluation Request and Agreement Form” (see page 24) ~~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~~ FDA/LPET or ~~State~~ LEO.

A set of completed evaluation forms may accompany the narrative report ~~which~~ that describes the degree of suitability of the laboratory facilities, equipment, records, the analysts’ ~~procedures~~ technique, 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/NCIMS 2400 ~~Series~~ Forms.

~~Survey-r~~ Reports of on-site evaluations surveys of Official Milk Laboratories and CISs facilities 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 facility, 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 facilities ~~must~~ shall include the narrative report and may include

copies of the completed FDA/NCIMS 2400 Series Forms. Reports to the appropriate FDA Regional Office and FDA/LPET shall be sent electronically and shall include the narrative report only. ~~and appropriate,~~ Reports to the FDA/LPET shall be sent electronically and shall include the narrative report and completed FDA summary template only (see pages 47 – 48).

~~Survey-r~~ Reports of on-site evaluations surveys of screening sites shall be sent to the facility within sixty (60) days of the initial, biennial anniversary, or supplemental date of the laboratory ~~evaluation~~ survey.

CERTIFICATION/APPROVAL OF MILK LABORATORY ANALYSTS

Certification of milk laboratory analysts by the ~~Federal~~ FDA/LPET or ~~State~~ LEO shall be based on the following criteria:

1. Evaluations of State Central Milk Laboratories ~~evaluations~~ shall be scheduled and performed by their triennial expiration date. State central milk laboratories shall submit requests, in writing, for on-site ~~evaluation~~ survey 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~~ survey 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 thirty (30) days of the receipt of the request for an evaluation.
3. The laboratory facilities, equipment and records shall meet the requirements stated on the FDA/NCIMS 2400 Series Forms, as determined by an on-site ~~evaluation~~ survey.
4. Analyst performance is in compliance during an on-site evaluation, with procedures required by the FDA/NCIMS 2400 Series Forms and the Grade "A" PMO.
5. Analysts meet the performance levels of the proficiency testing program (SECTION 2 3). The ~~State~~ LEO may issue a certificate of approval to each laboratory analyst who meets the stated criteria in numbers 3 and 4 above. The certificate, if issued, shall indicate the specific laboratory procedure(s) for which he or she is certified or approved.
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 2 3).

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 certified or 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~~ an 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 certification or approval to conduct official examinations shall be withdrawn.

When a new analyst is assigned to an accredited laboratory between on-site ~~evaluations~~ surveys, conditional certification or approval status ~~will~~ shall be provided to the new analyst upon satisfactory completion of criteria 4 or 5 above. Full certification will follow after acceptable completion of both criteria 4 and 5. Conditionally certified or approved analysts failing to meet the established applicable criteria of laboratory performance during an on-site laboratory ~~evaluation~~ survey ~~will~~ shall have their conditionally certified or approved status revoked.

The Certified analysts and 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 samples ~~evaluation~~ or failure to meet established satisfactory performance criteria ~~will~~ shall result in the certified analyst(s) or CIS(s) or certified analyst(s) having their certification status downgraded from full to provisional. Failure of a provisionally certified analyst or CIS 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 or more tests cannot examine official samples using a test for which their certification was withdrawn. Recertification procedures are shown in “SECTION ~~2~~ 3: PROFICIENCY TESTING PROGRAMS”.

Copies of notices of changes of certification or revocation of certification shall be sent to the laboratory or facility involved, the milk Regulatory Agency, the ~~state milk sanitation~~ Rating Agency, the appropriate FDA Regional Office and the FDA/LPET. For FDA/LPET notification, changes in certification shall be indicated on the ~~appropriate~~, completed FDA summary template and shall be submitted electronically.

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~~ the FDA/LPET or ~~State~~ 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/NCIMS 2400 Series Forms and for CISs, appropriate Appendix N 2400 ~~Series~~ Forms, as determined by an on-site ~~evaluation~~ survey.
2. All official examinations required by the Grade “A” PMO ~~must~~ shall only be performed by certified analysts or 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 2 3).

~~The State~~ An LEO may issue a certificate of accreditation or approval to each official, commercial, and industry laboratory meeting criteria 1 and 2 above. The certificate shall be valid for two (2) years unless revoked.

When an accredited laboratory changes location or undergoes substantial remodeling, ~~an evaluation survey~~ of the new laboratory or screening facility is required within 3 months ninety (90) days. ~~No evaluation~~ A survey of personnel or procedures is not required at this time.

For initial accreditation, milk laboratories shall have a minimum of fifteen (15) days of required records available at the time of the on-site ~~evaluation survey~~. The laboratory has records to show that all necessary quality control requirements have been performed and are satisfactory, and that there are fifteen (15) days of records to ~~demonstrate~~ demonstrating that critical equipment is functional.

When a certified analyst or CIS leaves an accredited laboratory, the laboratory/facility manager ~~must~~ shall notify the ~~Federal FDA/LPET or State~~ 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/facility's accreditation. For example, a laboratory having only one certified analyst or CIS will ~~will~~ shall lose accreditation. Official examinations cannot be conducted at non-accredited laboratories/facilities. When a laboratory or CIS facility loses its accreditation because of lack of certified analysts or CISs, or for some other reason, the ~~Federal FDA/LPET or State~~ LEO shall immediately notify the milk laboratory involved, the state Milk regulatory Control Agency, the respective state milk sanitation Regulatory/Rating Agency, any out-of-state milk other Regulatory/Rating Agencies 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.

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 respective state milk sanitation Regulatory/Rating Agency, any out-of-state milk other Regulatory/Rating Agencies 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. For FDA/LPET notification, changes in accreditation shall be indicated on the ~~appropriate,~~ completed FDA summary template and shall be submitted electronically.

State Central Milk Laboratories requesting withdrawal of accreditation shall notify the FDA/LPET in writing and shall notify the appropriate FDA Regional Office in writing within five (5) working days of FDA/LPET's receipt of the written request.

Additionally, the laboratory/CIS facility shall notify its customers in writing, that it has withdrawn or ~~been decertified~~ has had its accreditation withdrawn 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~~ Withdrawal of accreditation ~~will~~ shall remain in effect until measures are taken by the laboratory/CIS facility to attain compliance and another on-site survey is completed successfully.

APPROVAL OF INDUSTRY ANALYSTS/INDUSTRY SUPERVISORS

Approval of Industry Supervisors (ISs) and Industry Analysts (IAs) by ~~the State~~ LEOs shall be based on meeting all of the following requirements:

1. The laboratory facilities, equipment, procedures and records meet the requirements stated on the approved FDA/NCIMS 2400 Series Forms associated with the Grade "A" PMO, Appendix N program.
2. All screening tests required by the Grade "A" PMO, Appendix N ~~must~~ shall only be performed by approved ISs, IAs or by a certified entity.
3. Analyst performance is in compliance with procedures required by the approved FDA/NCIMS 2400 Series Forms associated with the Grade "A" PMO, Appendix N program.
4. The analyst meets the performance levels of the proficiency testing program (the examination of milk split samples).
5. Approval of ISs and IAs require verification of proficiency in performing drug residue analyses at least biennially, through an on-site survey performance evaluation and/or analysis of split samples, or by other means of determining another proficiency determination that the ~~State~~ LEO and the FDA/LPET agree is appropriate. (Grade "A" PMO, Appendix N)
6. The IS has attended and received training by ~~the State~~ an LEO. This training ~~must~~ shall be documented.

The IS shall report to the ~~State~~ LEO the result of all competency evaluations performed by IAs. The name of each IS and IA (as well as their training and ~~evaluation~~ approval 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 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 survey ~~performance evaluation~~ or by

~~another other means of determining proficiency determination~~ that the State LEO and the FDA/LPET agree is appropriate.

When a new analyst is assigned to an approved laboratory, conditional approval status ~~will~~ shall be provided to the new analyst upon satisfactory demonstration of competency to the IS. Full approval status ~~will~~ shall follow after verification of proficiency (see criteria #5, above). Conditionally approved analysts failing to meet the established applicable criteria of laboratory performance during an on-site ~~survey laboratory evaluation~~ or analysis of split samples ~~will~~ shall have their conditionally approved status revoked.

Fully approved analysts failing to meet the established applicable criteria of laboratory performance during an on-site ~~survey laboratory evaluation~~ or analysis of split samples ~~will~~ shall have their fully approved status downgraded to “provisional”. Provisionally approved analysts failing to meet the established applicable criteria of laboratory performance during an on-site ~~survey laboratory evaluation~~ or analysis of split samples ~~will~~ shall have their provisionally approved status revoked.

Failure by the ISs or the IAs to demonstrate adequate proficiency to the State LEO shall lead to their removal from the State LEO List of Approved ISs/IAs. Reinstatement of their testing status shall only be possible by completing retraining and/or successfully analyzing split samples and/or passing an on-site ~~survey evaluation~~ or otherwise demonstrating proficiency to the State LEO. Analysts not on the State LEO List of Approved ISs/IAs are not approved to test raw, commingled, bulk milk in the Grade “A” PMO, Appendix N program.

When a screening facility loses its approval because of the lack of approved ISs or IAs, or for some other reason, the State LEO shall immediately notify the screening facility involved, the ~~respective state milk sanitation~~ Regulatory/Rating Agency, any ~~out-of-state milk other~~ Regulatory/Rating Agencies 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.

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 Control Agency, the ~~respective state milk sanitation~~ Regulatory/Rating Agency, any ~~out-of-state milk other~~ Regulatory/Rating Agencies 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 remain in effect until measures are taken by the screening facility to attain compliance and another on-site 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/NCIMS 2400 Series Form) for training and ongoing oversight of the BIO(s).
3. Refer to the Foss BactoScan FC BIO Companion Protocol approved training procedures at the end of the BactoScan FDA 2400 series form.
4. The BIO(s) meets the performance levels of the proficiency testing program (the examination of milk split samples)
5. Records are to be maintained for BIO(s) oversight.

NOTE: A BIO can analyze samples for regulatory compliance.

SECTION 2 3: PROFICIENCY TESTING PROGRAMS

SPLIT SAMPLES - MICROBIOLOGY

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)~~ Milk Laboratory Control Agency ~~central~~ accredited Central Milk Laboratory. State 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 CISs. State 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~~ laboratory evaluation and/or analysis of split samples annual performance evaluation, or ~~another~~ by other means of determining proficiency determination that the State LEO and the FDA/LPET agree is appropriate.

State 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 that~~ can meet the criteria for certification of analysts and accreditation of laboratories. In cases where a minimum number of analysts (≥ 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:

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 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 31.
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 31.
3. When an analyst examines only pasteurized milk and milk products, a minimum of sixteen (16) 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 31.
4. When a CIS examines commingled raw bulk milk tanker milk or its equivalent for Grade "A" PMO, 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~~ is reduced one (1) level of certification. If this occurs twice consecutively, the CIS is ~~no longer~~ not certified ~~or approved~~ (rules for recertification of analysts and accreditation of laboratories apply).
5. When an IS or an IA examines commingled raw bulk milk tanker milk or its equivalent for Grade "A" PMO, 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 level of approval. If this occurs twice consecutively, the IS or IA is ~~no longer~~ not approved. Reinstatement of their testing status shall only be possible by completing retraining and/or successfully analyzing split samples and/or passing an on-site evaluation survey 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.

7. An acceptable annual proficiency testing program for the BactoScan FC (all NCIMS approved models), shall meet the following applicable criteria.
 - (a) The BactoScan FC (all NCIMS approved models) shall be used to examine a minimum of fourteen (14) samples and be operated by a certified analyst or an approved BIO using the procedures approved to operate the BactoScan FC and for which the analyst or BIO has been certified/approved, respectively.
 - (b) Split samples (minimum of fourteen (14)) shall be made up using BactoScan FC Blank solution and BactoScan FC Bacteria Control Samples.
 - (c) Value ranges (count ranges) and dilutions shall be made to achieve the levels as set by the FDA. Recommended duplicates of samples are shown in Table 1, page ~~27~~ 31.

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), and Electronic Phosphatase Count and Vitamin A and D₃ result of each certified analyst shall fall within the limits shown in Table 2, page ~~27~~ 32. The vitamin A and D₃ results of each analyst shall be calculated by z-scores, which are based on ISO Standards, and are calculated for individual set of split samples.

The steps for statistical analysis of split sample results are as follows:

1. A minimum of ten (10) results per sample per test is required for statistical analysis.
2. ~~Calculate~~ Determine the logarithmic ~~mean~~ of each test sample 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, and Electronic Phosphatase Count and Vitamin A and D₃ results of each test sample; using a table of common logarithms; and list the logarithms of all analyst counts for a given sample. Calculate the mean of the logarithms for ~~the~~ each sample.~~
3. Determine for each sample for each test whether there are results outside of the Rejection Limit (L_1). Rejection results are identified by applying to each analyst's result the limit (sample mean $\pm L_1$). Results falling outside the limit are classified as outliers and are unacceptable. Note, by sample and test, the analysts who have results outside of the limits.
4. Determine for each sample for each test whether there are analyst results outside of the Rejection Limit (L_2). Remove unacceptable analyst result and re-compute the mean of each

sample if results have been rejected in accordance with 3 above. If there are none, use the same means calculated in 2 or 3 above. Rejection results are identified by applying to each analyst's result the limit (sample mean \pm L₂). Results falling outside the limit are classified as "out of limits" and are unacceptable. Note, by sample and test, the analysts who have results outside of these limits.

5. Using Table 3, page ~~26~~ 32, list all analysts who have more than the maximum number of sample results per test classified as unacceptable by either the L₁ or L₂ or both limits.
6. Analysts certified for vitamin analysis shall meet the acceptance ~~limits (L₁ and L₂) and performance levels shown in Tables 2 and 3, page 28~~ criteria using z-scores.
7. An acceptable annual proficiency testing program for the ~~BactoScan FC Count~~ BSC (all NCIMS approved models), shall meet the following applicable criteria.
 - (a) ~~BactoScan FC Count~~ BSC (all NCIMS approved models) shall be used to examine a minimum of fourteen (14) samples and be operated by a certified analyst or an approved BIO using the procedures approved to operate the BactoScan FC Count and for which the analyst or BIO has been certified/approved, respectively.
 - (b) Split samples (minimum of fourteen (14)) shall be made up using BactoScan FC Blank solution and ~~BactoScan FC Count~~ BSC Bacteria Control Samples.
 - (c) Value ranges (count ranges) and dilutions shall be made to achieve the levels as set by the FDA. Recommended duplicates of samples are shown in Table 1 page ~~27~~ 31.
8. The annual proficiency testing (PT) program for vitamins A and D₃ shall be based on z-scores following ISO Standards. Data shall be converted to log base 10 values and a consensus mean determined. Based on the data for each PT, standard deviations shall be determined. Acceptable results shall be within plus or minus two (2) standard deviations.

ANALYST PERFORMANCE LEVEL

Analysts certified to perform the examinations required by the "~~Grade 'A' PMO~~" Grade "A" PMO 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, and 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~~ 32.
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 drug other than beta-lactam, samples ~~must~~ shall be spiked in duplicate. See Table 3, page 28 32.

3. Analysts certified to perform phosphatase tests shall detect samples that contain residual phosphatase detectable by appropriate official test methods. Analysts certified for Electronic Phosphatase Count methods shall detect samples that contain between 100 and 2,500 mU (the majority of values at the action level of 350 mU) within the specified limits in Table 2, page 28 32.
4. Analysts certified for the coliform procedure shall qualitatively detect and verify coliform organisms in samples containing at least five (5) but not greater than ten (10) coliform organisms per milliliter or gram of product. See Table 3, page 28 32.
5. ~~Certified Industry Supervisors~~ CISs certified to perform Grade "A" PMO, 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 32.
6. Analysts certified to perform vitamins A and D₃ tests shall detect samples that contain vitamins A and D₃ and shall meet the acceptance limits and performance levels for the calculated z-scores, which are based on ISO Standards. Acceptable results shall be within plus or minus two (2) standard deviations.

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 Control Agency before requesting recertification. Recertification after training shall be based on the analyst meeting the certification criteria described in SECTION 4 2: LABORATORY EVALUATION PROGRAMS. A formerly certified analyst who has lost certification may only become ~~conditionally approved~~ certified 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~~ the analyst can only become conditionally certified by passing the next set of milk split samples. If the analyst failed an on-site ~~evaluation survey~~ that leads to his/her loss of certification then ~~he/she~~ the analyst must 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.

Copies of the proficiency testing report, including tabulation of analyst results, shall be sent within four (4) months of the split sample examination date to the participating laboratory, the appropriate FDA Regional Office, and the FDA/LPET.

SPLIT SAMPLES – CHEMISTRY

VITAMINS

The Grade “A” PMO Vitamin Proficiency Test PT 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” PMO Vitamin Proficiency Test PT Program involves the analysis of ~~sets of four~~ six (6) to eight (8) samples sent to participating laboratories every ~~four (4)~~ six (6) months, i.e., ~~three~~ two (2) times a year with a ~~total~~ minimum 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~~) which are evaluated using z-scores that are based on ISO Standards and calculated for each set of split samples. 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 more than 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)~~ both 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 12~~) are missed. Failure without cause to analyze all ~~twelve (12)~~ samples during the course of the year ~~will~~ shall result in the downgrading 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 12~~) then that analyst ~~will~~ shall be downgraded to provisional certification. Full certification ~~will~~ shall be regained if that analyst misses no more than one 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~~ set of samples analyzed after receiving the respective status ~~will~~ shall have certification/~~approval~~ removed.

Once certification/~~approval~~ is removed an analyst may only regain conditional certification by satisfactory performance on the next ~~eight~~ set of 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 subject to meeting all 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~~ not 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.

An acceptable annual ~~proficiency testing~~ PT program shall consist of the analyst examining pasteurized milk and milk products for Vitamins A and D₃, a minimum of ~~four (4)~~ six (6) samples ~~three (3)~~ two (2) times a year for a total of twelve (12) samples annually using the methods developed by the FDA, or methods that give statistically equivalent results to the FDA methods, 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~~ 32.

WATER MICROBIOLOGY

Laboratories using Environmental Protection Agency (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 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 this split sample program is voluntary.

Each accredited 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~~ should participate annually in a microbiological proficiency testing program for each water analysis methodology for which the laboratory is ~~certified~~ accredited. The ~~proficiency testing~~ PT samples are to be provided by ~~State~~ Milk Laboratory Control Agencies ~~programs~~ or through private providers.

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

1. When a laboratory examines dairy water for the presence of coliforms, a minimum of eight (8) samples shall be examined by the laboratory using those procedures for which the laboratory has been approved unless excused for due cause. The laboratory tests, categories, types and recommended duplicates are shown in Table 1, page ~~27~~ 31.

SPLIT SAMPLE ANALYSIS

The multiple tube fermentation (Lauryl Tryptose Broth or Chromogenic substrate), membrane filtration and heterotrophic plate count result of each laboratory shall fall within the limits shown in Table 2, page ~~28~~ 32.

The steps for statistical analysis of split sample results are as follows:

1. A minimum of ten (10) results per sample per test is required for statistical analysis.

2. ~~Calculate~~ Determine the logarithmic ~~mean~~ for the multiple tube fermentation, membrane filtration and heterotrophic plate count for each test sample; using a table of common logarithms, list the logarithms of all counts for a given sample. Calculate the mean of the logarithms for the sample.
3. Determine for each sample for each test whether there are results outside of the Rejection Limit (L_1). Rejection results are identified by applying to each laboratory's result the limit (sample mean $\pm L_1$). Results falling outside the limit are classified as outliers and are unacceptable. (Note by sample and test, the laboratories that have results outside of the limits.)
4. Determine for each sample for each test whether there are laboratory results outside of the Rejection Limit (L_2). Remove unacceptable laboratory results and re-compute the mean of each sample if results have been rejected in accordance with 3 above. If there are none, use the same means calculated in 2 or 3 above. Rejection results are identified by applying to each laboratory's result the limit (sample mean $\pm L_2$). Results falling outside the limit are classified as "out of limits" and are unacceptable. (Note by sample and test, the laboratories that have results outside of these limits.)
5. Using Table 3, page ~~26~~ 32, list all laboratories that have more than the maximum number of sample results per test classified as unacceptable by either the L_1 or L_2 or both limits.
6. Laboratories accredited for dairy water analysis shall meet the acceptance limits (L_1 and L_2) and performance levels shown in Tables 2 and 3, page ~~28~~ 32.

LABORATORY PERFORMANCE LEVEL

Laboratories accredited to perform the examinations of dairy water for coliforms required by the PMO shall meet the following performance levels on an annual basis.

1. Laboratories accredited to perform the multiple tube fermentation, membrane filtration, heterotrophic plate count and chromogenic substrate analysis shall meet the acceptance limits and performance levels shown in Tables 2 and 3, page ~~28~~ 32.
2. Laboratories accredited for presence-absence procedures shall qualitatively detect and verify coliform organisms in samples containing coliform organisms.

Fully accredited laboratories not meeting the described performance levels shall be provisionally accredited for the test procedure(s) in which ~~they~~ it 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 its accreditation ~~must~~ shall participate in a training program acceptable to the Milk Laboratory certifying authority Control Agency before requesting reaccreditation.

Reaccreditation after training shall be based on the laboratory meeting the accreditation criteria described in SECTION 4: LABORATORY EVALUATION PROGRAMS.

Copies of the ~~proficiency testing~~ PT 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.

SECTION 3 4: CERTIFICATION OF MILK LABORATORY CONTROL AGENCY LABORATORY EVALUATION OFFICERS

Initial certification of an 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 Milk Laboratory Control Agency and demonstrate competence in evaluating milk testing laboratories and analysts' performance of milk laboratory test methods and/or Grade "A" PMO, Appendix N procedures as stated on the FDA/NCIMS 2400 Series Forms when accompanied by a representative of the FDA/LPET on an the initial check laboratory on-site survey(s). The ~~Federal LEO~~ FDA/LPET shall accompany the ~~State~~ LEO to not more than two (2) laboratories/facilities during an the initial check survey(s) for initial certification purposes. Initial check on-site survey(s) (for certification) should not be conducted at sites that have been evaluated within the past ninety (90) days. The individual check surveys of an initial LEO evaluation must be official, but may be conducted as (1) biennial (all inclusive) or (2) supplemental (where the number of participating analysts may be reduced and the time span of records may be reduce, but all applicable record types must be reviewed) to facilitate the timely survey of the laboratory or Appendix N facility.
2. The individual ~~must~~ shall submit an acceptable written report(s) of the milk laboratory initial check on-site survey(s) to the FDA/LPET within sixty (60) days of the evaluation. Reports to the appropriate FDA Regional Office and FDA/LPET shall be sent electronically and shall include the narrative report only. ~~and appropriate,~~ Reports to the FDA/LPET shall be sent electronically and shall include the narrative report and completed FDA summary template only (see pages 47 – 48).
3. The individual ~~must~~ shall attend the Milk Laboratory Evaluation Officers Workshop (FDA Course #373) conducted by the FDA/LPET ~~in conjunction with the Food and Drug Administration, State Training Team.~~ If the individual does not have experience in the examination of dairy products, ~~they~~ the individual must shall attend Course FDA Course #374 "Laboratory Examination of Dairy Products" conducted by the FDA/LPET prior to or within the year of attending the Milk Laboratory Evaluation Officers Workshop.

NOTE: It is recommended that the individual attend the Milk Laboratory Evaluation Officers Workshop prior to step 1 above.

Laboratory evaluations conducted by conditionally ~~approved~~ certified ~~State~~ LEOs ~~will~~ shall be considered official.

Conditional certification of a ~~State~~ new LEO can occur following the initial check on-site survey(s) described in items 1 and 2 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 Workshop, unless excused with cause by the FDA/LPET, will require that the ~~State~~ LEO must restart the process. The ~~State~~ LEO candidate would then be required to participate in another check on-site survey(s) with a representative of the FDA/LPET, and then attend the next scheduled Milk Laboratory Evaluation Officers Workshop.

Recertification of ~~the State~~ an LEO will 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 or Milk Laboratory Control Agency and demonstrate continued competence in evaluating milk testing laboratories and analysts' performance of milk laboratory test methods and/or Grade "A" PMO, Appendix N procedures as stated on the FDA/NCIMS 2400 Series Forms when accompanied by a representative of the FDA/LPET on a check laboratory on-site survey(s). The ~~Federal LEO~~ FDA/LPET shall accompany the ~~State~~ LEO to not more than two (2) laboratories/facilities during a check on-site survey(s) for recertification purposes. The individual check surveys of a continuing LEO evaluation may be conducted as (1) biennial (all inclusive), (2) supplemental (where the number of participating analysts may be reduced and the time span of records may be reduce, but all applicable record types must be reviewed) to facilitate the timely survey of the laboratory or Appendix N facility, or (3) unofficial (where the same criteria for a biennial or supplemental may apply) to facilitate a timely survey and/or avoid assessment of a fee to the laboratory or Appendix N facility.
2. The individual ~~must~~ shall submit an acceptable written report(s) of the milk laboratory check on-site survey(s) to the FDA/LPET within sixty (60) days of the ~~evaluation~~ survey(s). Reports to the appropriate FDA Regional Office ~~and~~ FDA/LPET shall be sent electronically and shall include the narrative report only. ~~and appropriate,~~ Reports to the FDA/LPET shall be sent electronically and shall include the narrative report and completed FDA summary template only (see pages 47 – 48).
3. The individual ~~must~~ shall have all laboratory evaluations, proficiency test examinations, and reports current (in particular biennial on-site 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~~ Regulatory 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 an FDA Regional Milk Seminar, then ~~State~~ LEOs in that region are obligated to attend. If another region holds their milk seminar in the same year the ~~State~~ LEO may opt to attend that regional milk seminar in lieu of attending the seminar held in their region and still meet the requirement.

Once an individual has become a ~~State~~ an LEO and is therefore considered fully certified, if ~~he/she~~ the individual fails to submit acceptable written reports of milk laboratory evaluations on-site surveys 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 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 have to~~ shall 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~~ certified ~~State~~ LEOs ~~will~~ shall be considered official.

Should a provisionally certified ~~State~~ LEO meet the criteria specified by their action plan and EML, SECTION ~~3~~ 4, their certification status will shall be returned to full certification once they have successfully undergone their next check ~~evaluation~~ on-site survey(s) with the FDA/LPET.

Should a provisionally certified ~~State~~ LEO fail to meet the criteria specified in EML, SECTION ~~3~~ 4 and/or follow the action plan, then their certification ~~would~~ shall be revoked.

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.

SECTION 4 5: EQUIPMENT AND APPARATUS OF AID TO MILK LABORATORY EVALUATION OFFICERS

While conducting laboratory evaluations on-site surveys, the ~~Federal~~ FDA/LPET or ~~State~~ LEO may find it extremely useful to have in ~~his/her~~ their 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.

1. Brom thymol blue solution.
2. Chlorine test kit (chloramine or free chlorine).
3. Conductivity meter.

4. Anemometer.
5. Level (or cross test level).
6. Light meter (in foot-candles).
7. Maximum registering thermometer (MRT) for autoclaves.
8. Reference books (e.g., AOAC Official Methods of Analysis, Standard Methods for the Examination of Water and Wastewater).
9. Ruler, pocket - metric.
10. Special measuring flask (calibrated at 97-99-101-ml).
11. Taper gauge or drill bits for PLC loops.
12. Thermometer(s).
13. Weights - accurate (S/S1 or ASTM 1, 2 or 3).

SECTION 5 6: GUIDELINES FOR CONDUCTING LABORATORY EVALUATIONS

The evaluations of laboratories by a ~~Federal~~ FDA/LPET or ~~State~~ 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~~ FDA/LPET or ~~State~~ LEO. The application ~~will~~ shall include the statement:

“I AGREE TO THE PROVISIONS OF THE NCIMS AND THE PROCEDURES FOR THE EVALUATION OF MILK LABORATORIES.”

In preparation for an on-site survey ~~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 on-site survey, laboratory officials should be told that all tests ~~must~~ shall be set up and that during the evaluation on-site survey the work of all analysts, who may perform any official methods ~~must~~ shall be observed. If laboratory evaluations on-site surveys 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~~ FDA/LPET or ~~State~~ LEO to permit observations of counting procedures.

On the designated ~~laboratory evaluation~~ day of the on-site survey, delay arrival at the laboratory/facility until 10 - 15 minutes after the opening of the laboratory, to allow all personnel to start their day's activities normally. A visit to the laboratory director and/or supervisor's office should be made prior to entering the laboratory. At this time the purpose of the evaluation on-site survey should be reviewed, and arrangements made to discuss the completed laboratory evaluation on-site survey informally with the laboratory director and/or supervisors on completion of the evaluation on-site survey. Assure that the “~~Grade ‘A’~~ Grade “A” PMO Milk

Laboratory Evaluation Request and Agreement Form” has been signed by a representative of the facility.

After entering the laboratory, the ~~Federal~~ FDA/LPET or ~~State~~ LEO should note the names of all analysts in laboratory as/or after they are introduced and record the procedures performed by each analyst.

Before beginning the survey, the ~~Federal~~ FDA/LPET or ~~State~~ LEO should discuss the “ground rules” for the survey. Rules should be established for ~~procedural evaluations~~ the observation of the analysts’ technique (e.g. whether an analysts can restart a procedure if ~~the~~ analysts notices that ~~he/she~~ they have ~~make~~ made an error, how many times may ~~an~~ analysts restart, etc.).

During an ~~evaluation~~ on-site survey of a large laboratory, various analysts may be performing different examinations, which may make a comprehensive ~~evaluation~~ survey 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 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 be used at separate times, it is advisable to note observed items of the various procedures on the ~~left-hand~~ margins of the evaluation FDA/NCIMS 2400 Series Forms. By frequent referral to the noted items, the ~~Federal~~ FDA/LPET or ~~State~~ 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.

While observations of procedures are being made and the evaluation forms completed, certain precautions should be taken by the ~~Federal~~ FDA/LPET or ~~State~~ LEO:

1. Do not ask leading questions, e.g., do not ask analysts if plating media and dilution blanks are autoclaved at 120±1C for 15 minutes; simply ask how media and water blanks are autoclaved;
2. Try to keep the ~~evaluation~~ on-site survey on an informal basis and to minimize nervousness on the part of analysts, e.g., do not over emphasize the evaluation of procedures by unusually close physical observation; and
3. Stay alert during the observation of procedures so as to avoid necessary requests to repeat a technique overlooked during a procedure.

During the laboratory ~~evaluation~~ on-site survey it is probable that some items pertinent to receiving samples ~~will~~ may not be observed. However, the ~~Federal~~ FDA/LPET or ~~State~~ LEO should determine from consultation with the laboratory supervisor the procedures used in receiving samples from the sample collectors:

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

2. Are the samples suitably identified as to date, temperature and time of pickup, identification of sampler (e.g. name or initials) and sample identification or this information is readily available?
3. Is an extra sample or pilot container of appropriate size provided as a temperature control (TC)?
4. Are the raw milk sample containers no more than three-quarters (3/4) full?
5. Are samples ever rejected because they are outside of the acceptable temperature range at the time of pick-up from a sample storage depot or arrival at the laboratory, are samples ever rejected because they are too full or not properly identified?
6. How many hours pass (from initial time of collection of samples) before samples are plated?

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 results, remedial action suggested and reasons justifying the change. All interested personnel should have an opportunity to look over the completed ~~evaluation form~~ FDA/NCIMS 2400 Series Forms and each major deviation should be discussed by the officer with interested staff. At that time comments should be invited from the staff concerning the evaluation. The ~~Federal~~ FDA/LPET or ~~State~~ LEO should make suggestions concerning any needed improvement of laboratory techniques. Following the discussion of procedures and competence of analysts, past split sample results of the laboratory should be discussed, suggestions made for improvement, and/or commendations made for superior performance.

In addition to a regularly scheduled visit, some ~~Federal~~ FDA/LPET or ~~State~~ LEOs may find that an occasional unannounced visit to an accredited laboratory provides them with supporting information concerning laboratory practices. Information generated on all on-site surveys (unannounced, scheduled, and check on-site surveys) ~~must~~ shall be evaluated by the ~~Federal~~ FDA/LPET or ~~State~~ LEO and used to determine compliance with the NCIMS Milk Laboratory Program.

If at any time during an on-site survey there is interference with or willful refusal to permit the survey, the ~~Federal~~ FDA/LPET or ~~State~~ LEO ~~will~~ shall serve notice that the laboratory ~~will~~ shall not be ~~certified~~ accredited or ~~will~~ shall ~~be decertified~~ have its accreditation withdrawn until such time as the laboratory agrees to abide by the voluntary ~~certification~~ accreditation program. The laboratory may make reapplication by completing the application form and stipulating that future interference or refusals ~~will~~ shall result in ~~non-certification~~ non-accreditation or ~~decertification~~ removal of accreditation for thirty (30) days. Or, if at any time before or during any on-site survey the ~~Federal~~ FDA/LPET or ~~State~~ LEO feels their safety is in jeopardy or determines extensive non-compliance, they may terminate the survey. The ~~Federal~~ FDA/LPET or ~~State~~ LEO ~~must~~ shall indicate to the laboratory management the reason why the survey was terminated and ~~must~~ shall indicate what steps must be taken before a resurvey ~~will~~ shall be scheduled. The laboratory may make reapplication 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.

SECTION 6 7: LABORATORY EVALUATION REPORTS

EVALUATION FORMS

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. Forms pertaining to procedures not used should not be returned with the report.

Copies of the completed evaluation survey forms may be prepared for the laboratory evaluated. The ~~Federal~~ FDA/LPET or ~~State~~ LEO ~~must shall~~ maintain a complete copy of the survey on-site report, including forms. The laboratory/facility and ~~Federal~~ FDA/LPET or ~~State~~ LEO ~~must shall~~ maintain, at minimum, copies of the last two (2) biennial/triennial surveys, subject to verification by the ~~State~~ LEO and the FDA/LPET. In marking the official copies of the completed survey evaluation forms, leave items in compliance blank. When ~~typing~~ preparing copies for transmittal to others, do not include check marks in the margins ~~which that~~ were made at the time of the actual on-site survey for the convenience of the evaluating ~~official~~ FDA/LPET or LEO.

NARRATIVE REPORT

The set of completed survey evaluation forms for the laboratory may accompany the narrative report, which states the conclusions of the ~~Federal~~ FDA/LPET or ~~State~~ LEO as to whether or not the laboratory is doing acceptable work. If the completed evaluation forms do not accompany the narrative report, the report ~~must shall~~ be sufficiently detailed to allow readers to determine what is being cited without having to refer to the FDA/NCIMS 2400 Series Forms. Each form used shall have the revision date noted in the report. Additional narrative reports, without FDA/NCIMS 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 on-site survey, ~~who made~~ name of the LEO that conducted 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~~ necessary changes to the IMS List.

Formats suitable for narrative reports appear on pages ~~29—36~~ 33 - 46.

If choosing the option to send the narrative only via electronic submission, it ~~will~~ shall be necessary to summarize what each item is. Grouped under the title of each method observed (e.g., Standard Plate Count), list each major and/or minor deviation or omission numbered

identically with the item number on the evaluation form and the corrective action necessary for compliance with standard procedures or good laboratory practices.

A paragraph headed "Remarks" or "Recommendations" may be included if the ~~officer~~ FDA/LPET 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.

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").

Demonstrated proficiency or outstanding ability of individuals for one or more procedures which deserve special commendation may be given after the side heading "Commendations". If no commendation is warranted, delete this side heading from the narrative report. Such commendations should be used for outstanding performance.

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~~ Milk Laboratory Control Agency for use in rating milk for interstate shipment, where this is the purpose of the evaluation.

CONCLUSIONS

1. This laboratory is accredited/approved as the procedures, records, facilities and equipment in use at the time of the survey were in compliance with the requirements of the *Grade "A" PMO*.

Explanation: Unqualified acceptance of the laboratory.

2. Although the procedures, records, facilities and/or equipment in use at the time of the ~~evaluation~~ on-site survey were in substantial compliance with the requirements of the *Grade "A" PMO* the analyst/facility/equipment/records deviations noted must 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 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~~ FDA/LPET or ~~State~~ 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~~ on-site survey did not substantially comply with the requirements of the *Grade "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 or LEO during this period. A new survey ~~will~~ shall be scheduled upon receipt of the letter to assure full compliance.

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 FDA/LPET or LEO, a period of no 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/facility.

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" 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~~ FDA/LPET or ~~State~~ 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~~ survey.

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~~ is one (1) FDA summary templates: ~~one~~ for full service laboratories and ~~one for~~ Grade "A" PMO, Appendix N screening ~~Only~~ facilities (CISs and ISs). The information captured on the FDA summary template must match the information provided in the narrative report (i.e., IMS number, facility identification, accreditation and certification status, dates, procedures, conclusion, etc.). The information captured may also lend itself to analyst/laboratory tracking and filing by the ~~State~~ LEO.

The appropriate FDA summary template form ~~must~~ shall also be used for the notification of changes in accreditation and certification status, and ~~must~~ shall be submitted by email to the FDA/LPET.

Directions for completing the FDA summary template, authored by FDA/LPET, ~~will~~ shall be updated with each revision of the FDA summary template, as necessary, and provided to the LEOs by email.

An example of a completed FDA summary template for each application appears on pages ~~37-40~~ 47 - 48.

REFERENCES

1. Copies of the FDA/NCIMS 2400 Series Forms can be obtained from ~~Federal~~ FDA/LPET or State LEOs.

A list of ~~Federal~~ FDA/LPET or State LEOs can be found at the website:
~~<http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/FederalStatePrograms/InterstateMilkShippersList/default.htm>~~

<http://www.fda.gov/food/guidanceregulation/federalstatefoodprograms/ucm2007965.htm>

Once at that website:

For 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~~ the 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 LEOs.

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 TCP LEOs.

TABLE 1: SPLIT SAMPLE COMPOSITION

<u>PRODUCTS</u>	<u>NUMBER OF SAMPLES</u>	<u>DUPLICATES</u>	<u>ANALYSIS</u>	<u>NUMBER OF PRODUCT SAMPLES ANALYZED</u>
HVD, or 2%, or Skim	3	1	Plate Count /Coliforms	3
			Phosphatase	1
			Vitamins	3 1-8
Cream, heavy	2	1	Plate Count /Coliforms	2
			Phosphatase	2
			Vitamins	2 1-8
Cream, light	2 ^a	0 or 1	Plate Count /Coliforms	1
			Phosphatase	2 ^b
			Vitamins	1 1-8
Chocolate	2	1	Plate Count /Coliforms	2
			Phosphatase	1
			Vitamins	2 1-8
Raw	6	3	Plate Count	6
Raw	8	4	Inhibitors	8
			Somatic Cells	8
			Added Water ^c	8
Dairy Water	8	4	Coliforms	8
			Heterotrophic Plate Count	8
Milk Totals	23 ^a	10 or 11	Plate Count	14
			Coliforms	8
			Phosphatase	6
			Vitamins	8 12-16
			Inhibitors	8
			Somatic Cells	8
Dairy Water Total	8	4	Coliforms	8
			Heterotrophic Plate Count	8

a - One of these samples serves as the temperature control (TC).

b - These two (2) samples are tested for both residual and reactivated phosphatase

c - This analysis is optional.

TABLE 2: STATISTICAL LIMITS

<u>TEST</u>	<u>REJECTION LIMIT 1</u> <u>(L₁)*</u>	<u>REJECTION LIMIT 2</u> <u>(L₂)*</u>
Plate Counts	0.268	0.179
Direct Somatic Cell Count	0.300	0.200
Electronic Somatic Cell Count	0.212	0.143
Vitamins	0.300 **	0.200 **
Electronic Phosphatase Count	0.300	0.200
Dairy water MPN	0.949	0.632
Heterotrophic Plate Count	0.300	0.200

* To be used with logarithmic mean.

** Limits for vitamin test results shall be based on z-scores. Acceptable results shall be within plus or minus two (2) standard deviations.

TABLE 3: MAXIMUM NUMBER OF UNACCEPTABLE RESULTS

<u>NUMBER OF RESULTS PER TEST</u> <u>(N)</u>	<u>MAXIMUM NUMBER OF</u> <u>UNACCEPTABLE RESULTS PER</u> <u>TEST FOR APPROVAL</u>
5 – 10	1
11 – 20	2
21 – 30	3

EXAMPLE NARRATIVE REPORT #1

Report of a Biennial Evaluation of

{Laboratory Name}

{Address of Physical Location}

{City, State & Zip Code}

IMS LAB # {SSXXX}

On

{Date of Survey (Month Day(s), Year)}

By

{Name of LEO}

Laboratory Evaluation Officer

State Department of {Health or Agriculture}

{Physical / Mailing Address}

{City, State & Zip Code}

Date of Last Evaluation: {Month Day(s), Year}

Prior Procedures (IMS Code): 5, 9C13, 9C14, 9D3, 12, 20, 22, 24, 28

Prior Laboratory Status: Fully Accredited

Evaluated Procedures: 5, 9C13, 9D3, 12, 16, 20, 22, 24, 28

Present Laboratory Status: Fully Accredited, pending receipt of a satisfactory written response to cited deviations on or before {Month Day(s), Year - specified date usually sixty (60) days from expected receipt of the narrative report}.

Changes to IMS List: Drop procedure 9C14, add procedure 16, New expiration date.

A copy of the Grade "A" Milk Laboratory Evaluation Request and Agreement Form is signed and on file.

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade "A" Pasteurized Milk Ordinance. If FDA/NCIMS 2400 Forms accompany the narrative report, deviated items are marked with an "X"; undetermined items because of local conditions at the time of the evaluation are marked "U"; on the accompanying evaluation forms, laboratory procedures and/or equipment not used are marked "O"; optional procedural techniques and/or equipment not applicable to designated laboratory procedures are marked "NA"; repeat deviations from the previous on-site survey are marked with an asterisk "*"; and supplementary information or suggested good laboratory practices not specifically listed in the FDA/NCIMS 2400 Forms or considered stand-alone deviations but are intended to improve laboratory function are designated by "Note" and do not require a written response.

DEVIATIONS AND CORRECTIVE ACTIONS:

Item Method

{Cite procedure title and revision date for each FDA/NCIMS 2400 Form used to conduct the survey followed by any applicable deviations, notes or relevant remarks/comments}

{Item} {First statement should be a concise descriptive representation of the observed issue with specific example(s) of occurrence(s) in one or two sentences} {Second statement should specifically describe what, how and/or when the lab is to remedy the issue} {The third statement should specifically describe what is to be submitted by the lab along with the written response (copies of new or revised records, service manifest, new purchase shipping manifest, certificate of authenticity, etc.) to the LEO as verification that appropriate corrective action was taken, when applicable}.

Cultural Procedures – General Requirements (rev. 2/10 mm/vv)

- 2e During the review of the autoclave records it was observed that there were several data points written over. Analysts are to use proper protocol for correcting mistakes: cross out the error with a single line, initial and write the correct information next to it. The date discovered/corrected should also be documented as a good laboratory practice. Lab is to send copies of the autoclave records from the time of the survey that demonstrates proper corrective action being taken.
- 3a Note: The graduations on the lower end of the NIST thermometer are so worn that it is difficult to read. If the graduations cannot be restored, it is suggested that a new thermometer be purchased. Optionally, the lab may use the new electronic/digital NIST traceable temperature measuring device (with access to certificate of accuracy and annual ice point check records) that is available for use in the rest of the laboratory.
- 3c3 Although the accuracy check was documented, no tag was found on the freezer thermometer. Tag the thermometer with the following information: identification or serial number (SN) / location, date of check, temperature checked and the correction factor. Send a copy of the new tag.
- 5b Over the past four months at least 50% of the days observed in the temperature monitoring records showed that the freezer was consistently greater than the acceptable temperature range with no corrective action documented. This is a serious violation and no reagents or controls may be kept in this freezer until it is proven that the freezer holds the temperature within the acceptable temperature range (<-15.0 °C). If this freezer cannot maintain the proper temperature, then a new freezer will need to be purchased. Send copies of the repaired or new freezer temperature monitoring records for the next 4 months from the date of the survey.

13i There were no accuracy-checked thermometers for the spore incubation units used for the autoclave performance check. There must be a way to check the appropriate temperature range for the test. Lab must obtain/purchase thermometers dedicated for these units. Send a copy of the shipping manifest (if newly purchased), the accuracy check records and the temperature monitoring records for the following two months.

Petrifilm Aerobic and Coliform Counts (5 & 20, rev. 4/13 mm/yy)

No deviations were observed.

Comment: The analysts showed marked improvement over the last biennial on-site survey.

Pasteurized Milk Containers (22, rev. 4/13 mm/yy)

10b2 One analyst held the bottle against the container while adding the rinse solution. Use aseptic technique while adding the rinse solution to the container, and do not touch the bottle while pouring the rinse solution to the container.

Appendix N – General Requirements (rev. 2/10 mm/yy)

1-8 See Cultural Procedures, items 1-32 (as applicable).

9 See Cultural Procedures, item 33 (as applicable).

10a Note: Suitability on new purchased lot of test kits should be conducted in a timely manner that allows enough time to replace the new lot of test kits upon failure and prior to running out of previous lot in use.

12 The lab records showed that a new bulk milk tanker sample was collected without a documented explanation to perform confirmation testing of a presumptive positive load. A resample may only be collected at the discretion of the State regulatory agency and with appropriate justification and documentation.

14 See Cultural Procedures, item 34 (as applicable).

15 See Cultural Procedures, items 35 (as applicable).

Delvotest P 5 Pack (9D3, rev. 12/11 mm/yy)

No deviations were observed.

Charm SL Beta-Lactam Test (IMS# 9C13 rev. 12/11 mm/yy)

4c1 Commingled raw milk was being collected from a raw milk silo for preparation of the Negative and subsequent Positive Controls without prior testing for the presence of drug residues. Silo milk must be shown to test negative using the test kit of use prior to preparing the controls for use or storage (previously tested negative). Send copy of records demonstrating that previously tested negative raw milk is used to prepare the Negative and Positive Controls.

Direct Microscopic Somatic Cell Count (12, rev. 2/10 mm/yy)

21e When preparing the milk smears, one analyst held the metal (positive displacement) syringe above the slide and dripped the milk sample test portion. Holding the syringe almost vertically and the syringe tip contacting the slide near the center of the delineated area for the milk smear gently depress the plunger to slowly expel the milk. Maintaining the plunger fully depressed, remove the tip from the milk and touch off to a dry spot.

Electronic Somatic Cell Count – Bentley 150 (16, rev. 03/11 mm/yy)

No deviations were observed.

Dairy Waters using Multiple Tube Fermentation (MTF) Technique by Most Probable Number (MPN), Heterotrophic Plate Count (HPC) and Idexx Colilert-24 by Presence-Absence (24, rev. 1/09 mm/yy)

No deviations were observed.

Alkaline Phosphatase Test – Advanced Instruments Fluorophos (28, rev. 6/05 mm/yy)

15g2b The A/D value for substrate/buffer stability as part of the Daily Performance Check was missing on several days of official sample testing records reviewed during the survey period. While this may be from having to reconstitute a new bottle of substrate because the A/D value was greater than 1200, the corrective action must be documented with both the old and new values recorded.

{Laboratory Name}

{City, State & Evaluation Date} Page # of 5

PERSONNEL & PROCEDURES CERTIFIED:

Analyst	Procedures (IMS Codes)									ON-SITE Last 2	SPLITS Last 2
	5	9C13	9D3	12	16	20	22	24	28		
Analyst 1	F	F	F	F	F	F	F	F	F	m/yy, m/yy	m/yy, m/yy
Analyst 2	F	F	F	F	F	F	F	F	F	m/yy, m/yy	m/yy, m/yy
Analyst 3	F	F	F			F	F	F	F	m/yy, m/yy	m/yy, m/yy
Analyst 4	F	F	F			F	F	F	F	m/yy	m/yy
Analyst 5*	F	F	F	F	F	F	F	F	F	m/yy, m/yy	m/yy, m/yy

F = Fully Certified

P = Provisionally Certified

C = Conditionally Certified

N = Not Certified

* = Analyst excused – on medical leave.

To maintain certification, analysts shall successfully participate in the Annual Proficiency Testing Program for all procedures for which certification has been granted.

CONCLUSION:

Although the procedures, records and/or equipment in use at the time of the evaluation were in substantial compliance with the requirements of the *Grade "A" Pasteurized Milk Ordinance*, the analyst/facility deviations noted shall be corrected. This laboratory is accredited, pending correction of the deviations and receipt of a letter detailing the corrections made. Upon receipt of a satisfactory written response and other appropriate documentation detailing the corrective actions taken on or before {Month Day(s), Year - specified date usually sixty (60) days from expected receipt of the narrative report}, full accreditation status shall be granted.

EXAMPLE NARRATIVE REPORT #2

Report of a Supplemental {used for interim accreditation of *new analyst(s), new procedure(s), check surveys or walk-through*} Evaluation of

{Laboratory Name}
{Address of Physical Location}
{City, State & Zip Code}

IMS LAB # {SSXXX}

On

{Date of Survey (Month Day(s), Year)}

By

{Name of LEO}
Laboratory Evaluation Officer
State Department of {Health or Agriculture}
{Physical / Mailing Address}
{City, State & Zip Code}

Date of Last Evaluation: {Month Day(s), Year}

Prior Procedures (IMS Code): 5, 9C13, 9C14, 9D3, 12, 20, 22, 24, 28

Prior Laboratory Status: Fully Accredited

Evaluated Procedure: 12 and 16

Participating Analysts: Analyst 3 and Analyst 4

Present Laboratory Status: Fully Accredited, pending receipt of a satisfactory written response to the cited deviations on or before {Month Day(s), Year - specified date usually sixty (60) days from expected receipt of the narrative report}.

Changes to IMS List: None.

A copy of the Grade "A" Milk Laboratory Evaluation Request and Agreement Form is signed and on file.

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the *Grade "A" Pasteurized Milk Ordinance*. If FDA/NCIMS 2400 Forms accompany the narrative report, deviated items are marked with an "X"; undetermined items because of local conditions at the time of the evaluation are marked "U"; on the accompanying evaluation forms, laboratory procedures and/or equipment not used are marked "O"; optional procedural techniques and/or equipment not applicable to designated laboratory procedures are marked "NA"; repeat deviations from the previous on-site survey are marked with an asterisk "*"; and supplementary information or suggested good laboratory practices not specifically listed in the FDA/NCIMS 2400 Forms or considered stand-alone deviations but are intended to improve laboratory function are designated by "Note" and do not require a written response.

DEVIATIONS AND CORRECTIVE ACTIONS:

Item Method

Cultural Procedures – General Requirements (rev. 2/10 mm/yy)

3 The thermometer used in the water bath dedicated for the Electronic Somatic Cell Count procedure was not labeled. Records for this thermometer's accuracy check were current. The thermometer label was replaced during the survey. No further corrective action is required.

20 See ESCC item 4a below.

Direct Microscopic Somatic Cell Count (12, rev. 2/10 mm/yy)

25i Monthly comparison counts were not being evaluated properly. When 3 or more analysts are participating, the RpSm method of evaluation must be used (see PAC item 17a1). Submit copies of the monthly comparison counts from the date of this on-site survey showing the use of the RpSm method of evaluation.

No technique deviations were observed.

Electronic Somatic Cell Count – Bentley 150 (16, rev. 03/11 mm/yy)

4a The water in the ESCC water bath was not circulating. Lab must repair or replace the circulating water pump before the water bath can be used to warm the ESCC samples immediately prior to analysis. Submit itemized service receipt or shipping manifest along with written response.

No technique deviations were observed.

{Laboratory Name}

{City, State & Evaluation Date} Page # of 5

PERSONNEL & PROCEDURES CERTIFIED:

Analyst	Procedures (IMS Codes)									ON-SITE Last 2	SPLITS Last 2
	5	9C13	9D3	12	16	20	22	24	28		
Analyst 1	F	F	F	F	F	F	F	F	F	m/yy, m/yy	m/yy, m/yy
Analyst 2	F	F	F	F	F	F	F	F	F	m/yy, m/yy	m/yy, m/yy
Analyst 3	F	F	F	C	C*	F	F	F	F	m/yy, m/yy	m/yy, m/yy
Analyst 4	F	F	F	C	C*	F	F	F	F	m/yy	m/yy
Analyst 5	F	F	F	F	F	F	F	F	F	m/yy, m/yy	m/yy, m/yy

F = Fully Certified

P = Provisionally Certified

C = Conditionally Certified

N = Not Certified

E = Analyst excused – on medical leave.

* Conditional certification status was granted at the end of the on-site survey because the comparison study was submitted on {Month Day, Year} and found to be satisfactory as of {Month Day, Year}, and are on file.

To maintain certification, analysts shall successfully participate in the Annual Proficiency Testing Program for all procedures for which certification has been granted.

CONCLUSION:

Although the procedures, records and/or equipment in use at the time of the evaluation were in substantial compliance with the requirements of the *Grade "A" Pasteurized Milk Ordinance*, the analyst/facility deviations noted shall be corrected. This laboratory is accredited, pending correction of the deviations and receipt of a letter detailing the corrections made. Upon receipt of a satisfactory written response and other appropriate documentation detailing the corrective actions taken on or before {Month Day(s), Year - specified date usually sixty (60) days from expected receipt of the narrative report}, full accreditation status shall be granted.

EXAMPLE NARRATIVE REPORT #3

Report of a Supplemental Evaluation of
an Appendix N Bulk Milk Tanker Screening CIS Facility at
{Laboratory Name}

{Address of Physical Location}
{City, State & Zip Code}

IMS LAB # {SS6xx}

On

{Date of Survey (Month Day(s), Year)}

By

{Name of LEO} Laboratory Evaluation Officer
State Department of {Health or Agriculture}
{Physical / Mailing Address}
{City, State & Zip Code}

Date of Last Evaluation: {Month Day(s), Year}

Prior Procedures (IMS Code): 9C14

Prior Laboratory Status: Fully Accredited

Evaluated Procedures: 9C15

Participating Analysts: Analyst 1 and Analyst 2

Present Laboratory Status: Fully Accredited, pending receipt of a satisfactory written response to the cited deviations on or before {Month Day(s), Year - specified date usually sixty (60) days from expected receipt of the narrative report}.

Changes to IMS List: Drop procedure 9C14 and add procedure 9C15.

A copy of the Grade "A" Milk Laboratory Evaluation Request and Agreement Form is signed and on file.

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the *Grade "A" Pasteurized Milk Ordinance*. If FDA/NCIMS 2400 Forms accompany the narrative report, deviated items are marked with an "X"; undetermined items because of local conditions at the time of the evaluation are marked "U"; on the accompanying evaluation forms. laboratory procedures and/or equipment not used are marked "O"; optional procedural techniques and/or equipment not applicable to designated laboratory procedures are marked "NA"; repeat deviations from the previous on-site survey are marked with an asterisk "*"; and supplementary information or suggested good laboratory practices not specifically listed in the FDA/NCIMS 2400 Forms or considered stand-alone deviations but are intended to improve laboratory function are designated by "Note" and do not require a written response.

DEVIATIONS AND CORRECTIVE ACTIONS:

Item Method

Appendix N – General Requirements (rev. 2/10 mm/yy)

1c During survey of analyst technique, the previously dedicated wall light was not used. The lighting measured 14-24 foot candles in the testing area, which was below the requirement of > 50 foot-candles at the working surface. The testing area had 83-105 foot candles when the wall light was utilized. Whenever testing is being conducted the wall light must be utilized.

3c3a The tags for those temperature measuring devices in the media preparation area did not include correction factors. These tags are to include the correction factor determine at the temperature of use. Send copies of the revised tags.

Charm 3 SL3 Beta-Lactam Test (9C15, rev. 11/12 mm/yy)

5b1 Two analysts shook samples 25 times, but always took greater than 7 sec. Analysts are to shake raw milk samples 25 times in 7 sec with 1 ft. movement.

{Laboratory Name}

{City, State & Evaluation Date} Page # of 5

PERSONNEL & PROCEDURES CERTIFIED:

<u>Analyst</u>	<u>Procedures (IMS Codes)</u>								<u>ON-SITE</u>	<u>SPLITS</u>
	<u>9C¹⁴</u>	<u>9C¹⁵</u>							<u>Last 2</u>	<u>Last 2</u>
<u>Analyst 1 CIS</u>	<u>N¹</u>	<u>C</u>							<u>m/yy, m/yy</u>	<u>m/yy, m/yy</u>
<u>Analyst 2 CIS</u>	<u>N¹</u>	<u>C</u>							<u>m/yy, m/yy</u>	<u>m/yy, m/yy</u>
<u>Analyst 3 IA</u>	<u>NA²</u>								<u>m/yy, m/yy</u>	<u>m/yy, m/yy</u>
<u>Analyst 4 IA</u>	<u>NA²</u>								<u>m/yy, m/yy</u>	<u>m/yy, m/yy</u>

F = Fully Certified

FA = Fully Approved

P = Provisionally Certified

PA = Provisionally Approved

C = Conditionally Certified

CA = Conditionally Approved

N = Not Certified

NA = Not Approved

1 Laboratory accreditation, and as a consequence analyst certification has been removed due to voluntary withdraw during this on-site survey for the indicated procedure.

2 Approval status was removed due to analyst no longer employed.

To maintain approve status, analysts shall successfully participate in annual milk split sample performance evaluation provided by the Industry Supervisor or a State Laboratory Evaluation Officer for all procedures for which approval has been granted.

CONCLUSION:

Although the procedures, records and/or equipment in use at the time of the evaluation were in substantial compliance with the requirements of the *Grade "A" Pasteurized Milk Ordinance*, the analyst/facility deviations noted shall be corrected. This laboratory is approved, pending correction of the deviations and receipt of a letter detailing the corrections made. Upon receipt of a satisfactory written response and other appropriate documentation detailing the corrective actions taken on or before {*Month Day(s), Year - specified date usually sixty (60) days from expected receipt of the narrative report*}, fully accreditation status shall be granted.

EXAMPLE NARRATIVE REPORT #4

Report of a Biennial Evaluation of
an Appendix N Bulk Milk Tanker Screening Only Facility at

{Laboratory Name}
{Address of Physical Location}
{City, State & Zip Code}

IMS LAB # {SS999-yyyy}

On

{Date of Survey (Month Day(s), Year)}

By

{Name of LEO}
Laboratory Evaluation Officer
State Department of {Health or Agriculture}
{Physical / Mailing Address}
{City, State & Zip Code}

Date of Last Evaluation: {Month Day(s), Year}

Prior Procedures (IMS Code): 9I1

Prior Laboratory Status: Fully Approved

Evaluated Procedures: 9I1

Present Laboratory Status: Fully Approved, pending receipt of a satisfactory written response to the cited deviations on or before {Month Day(s), Year - specified date usually sixty (60) days from expected receipt of the narrative report}.

A copy of the Grade "A" Milk Laboratory Evaluation Request and Agreement Form is signed and on file.

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade "A" Pasteurized Milk Ordinance. If FDA/NCIMS 2400 Forms accompany the narrative report, deviated items are marked with an "X"; undetermined items because of local conditions at the time of the evaluation are marked "U"; on the accompanying evaluation forms. laboratory procedures and/or equipment not used are marked "O"; optional procedural techniques and/or equipment not applicable to designated laboratory procedures are marked "NA"; repeat deviations from the previous on-site survey are marked with an asterisk "*"; and supplementary information or suggested good laboratory practices not specifically listed in the FDA/NCIMS 2400 Forms or considered stand-alone deviations but are intended to improve laboratory function are designated by "Note" and do not require a written response.

DEVIATIONS AND CORRECTIVE ACTIONS:

Item Method

Appendix N – General Requirements (rev. 2/10 mm/yy)

- 1c Note: During the survey of analyst technique, the lighting in the immediate testing area measured 20-25 foot candles. Additional lighting should be added to the testing area, increasing the lighting to be >50 foot-candles. Whenever testing is being conducted the additional lighting should be utilized.
- 3 Digital thermometer placed in well of heat block fit loosely. Probe/sensor of digital/electronic temperature measuring device must have proper diameter to fit snugly into heat block or it must be placed in tube with water and placed in test well.

Idexx New Snap Beta-Lactam Test (9I1, rev. 7/12 mm/yy)

- 6c The sample and control tubes were not labeled during observation of the analysts' testing technique. All tubes and devices must be properly labeled for testing regardless of how many samples are being tested.

{Laboratory Name}

{City, State & Evaluation Date} Page # of 5

PERSONNEL & PROCEDURES APPROVED:

<u>Analyst</u>	<u>Procedures (IMS Codes)</u>								<u>ON-SITE</u>	<u>SPLITS</u>
	<u>9I</u>								<u>Last 2</u>	<u>Last 2</u>
<u>Analyst 1</u>	<u>FA</u>								<u>m/yy, m/yy</u>	<u>m/yy, m/yy</u>
<u>Analyst 2</u>	<u>FA</u>								<u>m/yy, m/yy</u>	<u>m/yy, m/yy</u>
<u>Analyst 3</u>	<u>FA</u>								<u>m/yy, m/yy</u>	<u>m/yy, m/yy</u>
<u>Analyst 4</u>	<u>FA</u>								<u>m/yy, m/yy</u>	<u>m/yy, m/yy</u>

FA = Fully Approved

PA = Provisionally Approved

CA = Conditionally Approved

NA = Not Approved

To maintain approve status, analysts shall successfully participate in annual milk split sample performance evaluation provided by the Industry Supervisor or a State Laboratory Evaluation Officer for all procedures for which approval has been granted.

CONCLUSION:

Although the procedures, records and/or equipment in use at the time of the evaluation were in substantial compliance with the requirements of the Grade "A" Pasteurized Milk Ordinance, the analyst/facility deviations noted shall be corrected. This laboratory is approved, pending correction of the deviations and receipt of a letter detailing the corrections made. Upon receipt of a satisfactory written response and other appropriate documentation detailing the corrective actions taken on or before {Month Day(s), Year - specified date usually sixty (60) days from expected receipt of the narrative report}, fully approved status shall be granted.

FDA SUMMARY TEMPLATE

LPET Summary Template v2015x
 Accredited Lab Reports- Foreign
[CAUTION: On cells with dropdowns, please do not use 'Cut-N-Paste']

Report Type

Lab Type
 Evaluation Date
 Month Year

Lab ID (Not Fillable)
 Facility Code
 Lab#
 Expiration Date
 Month Year

Lab Status
 FCN (Not Fillable)

LEO Initials
 Current Split Sample
 Month Year

Lab Name
 Previous Split Sample
 Month Year

Address-1 / Postal Box #

Address-2

City / Town

Subdivision (Prov., State, Outlying areas)
 or **State**
 ZIP/Postal Code

Country

Certified Laboratory Procedures
(Please fill in by row, L-R)

Plate Counts	<input type="text" value="02"/>	<input type="text"/>				
Drug Residues	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Drug Residues	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Somatic Cell Counts	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
PMC, Dairy Waters, Alkaline Phosphatase, etc	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Lab Codes for Other1, Other2, Other3	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Click Below for Description of Procedures (Not Fillable)

LPET Summary Template v2015x

LEOReports Template v2015x.xlsm

Date Printed: 4/21/2015

Fig. 1: Summary sheet, FDA/LPET Summary Template v2015x.xls

Lab ID: DE-01-F-M0012

F - Vitamin - Supplemental
Certified Laboratory Procedures

Personnel (Last Name, First Name)		Position	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	Count	
1	xxx	CA	02																		1	
2																						
3																						
4																						
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LPET Summary Template v2015x

Procedures Sheet

LEORepos Template v2015x.xsm

Date Printed: 4/21/2015

Fig. 2: Procedures sheet, FDA/LPET Summary Template

Proposal: 232
Document: 2011 EML
Page: 3

Make the following changes to the 2011 EML:

Page 3:

CERTIFICATION/APPROVAL OF MILK LABORATORY ANALYSTS

Certification of milk laboratory analysts by the federal or State LEO shall be based on the following criteria:

1. State central milk laboratories' evaluation 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 LEO shall schedule a mutually agreeable date within 30 days of the request for evaluation. If the FDA/LPET LEO is unable to travel to the state central milk laboratory requesting the analyst evaluation within 90 days, the state central laboratory may request that FDA/LPET allow an LEO from that state to perform the evaluation and based on this evaluation grant conditional certification of the analyst. If the requesting LEO is directly affiliated with the laboratory (as determined by FDA/LPET) another state's LEO may be used for the evaluation and conditional certification of the analyst. Full certification of state central milk laboratories analyst(s) shall remain with the FDA/LPET LEO as described below. ...

Proposal: 221
Document: 2011 EML
Pages: 10 and 11

See wording in Solution to Proposal 224.

Make the following changes to the 2011 EML:

Section 2: **Proficiency Testing Programs**, page 10, Split Sample Analysis: add *TEMPO AC method* to the list of methods listed in the introductory paragraph.

Section 2: **Proficiency Testing Programs**, page 10, Split Sample Analysis, Item 2: Amend to read: Calculate the logarithmic mean for the Standard Plate Count, Plate Loop Count, BactoScan FC Count (BSC), *TEMPO AC method*, Direct Microscopic Somatic Cell Count, Electronic Somatic Cell Count, Electronic Phosphatase Count and Vitamin A and D³ results of each test sample;

Section 2: **Proficiency Testing Programs**, page 11, Analyst Performance Level, Item 1: add *TEMPO AC method* to the list of methods listed.

A draft 2400 form will also be submitted to the NCIMS Laboratory Committee

Proposal: 233
Document: 2011 EML
Pages: 10 and 11

Make the following changes to the 2011 EML:

Page 10:

SPLIT SAMPLE ANALYSIS

The Standard Plate Count (SPC), Petrifilm Aerobic Count (PAC), PeelPlate-AC (PPAC), 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:

1. A minimum of ten (10) results per sample per test is required for statistical analysis.
2. Calculate the logarithmic mean for the Standard Plate Count, Petrifilm Aerobic Count, Peel Plate-AC aerobic count, Plate Loop Count, BactoScan FC Count (BSC), Spiral Plate Count Method (SPLC), Direct Microscopic Somatic Cell Count, Electronic Somatic Cell Count, Electronic Phosphatase ...

Page 11:

ANALYST PERFORMANCE LEVEL

Analysts certified to perform the examinations required by the “Grade ‘A’ PMO” shall meet the following performance levels on an annual basis.

1. Analysts certified to perform the Standard Plate Count, Petrifilm Aerobic Count, PeelPlate-AC aerobic count, Plate Loop Count, BactoScan FC, Spiral Plate Count Method, Direct Microscopic Somatic Cell Count, Electronic Somatic Cell Count, 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. ...
-

Proposal: 222
Document: FDA/NCIMS 2400 Forms

See wording in Solution to Proposal 224.

A draft 2400 form will also be submitted to the NCIMS Laboratory Committee.

Proposal: 235

Document: FDA/NCIMS 2400 Forms

Make the following changes to the FDA/NCIMS 2400 Form:

2. Comparative Test with DMSCC (co-requisite for certification, unless certified somatic cell standards are being purchased)

- a. Analyst(s) certified for DMSCC
 - b. Each analyst seeking certification for the ESCC test shall perform the comparative test
 1. Test 4 samples (100K-200K, 300K-500K, 600K-800K and 900K-1.2M) in triplicate for both DMSCC (three separate smears each) and ESCC
 2. Results must be evaluated by State/Federal LEO and shown to be acceptable prior to official use of test in laboratory
 3. Copy of comparison and results in QC record (or easily accessible on file in the laboratory); kept for as long as analyst is certified
-

Proposal: 237

Document: FDA/NCIMS 2400 Forms

Make the following changes to the FDA/NCIMS 2400 Form:

PASTEURIZED MILK CONTAINERS, CLOSURES, AND PACKAGING

[Unless otherwise stated all tolerances are $\pm 5\%$]

IMS #22 ...

MATERIALS

5. Rinse Solutions

- a. Buffered Rinse Solution or Nutrient broth (see CP items 27.i-j) for Standard Plate Count (SPC) and Coliform Plate Count (CPC) agar based media
- b. Nutrient broth (see CP item 27.j) for 3M™ Petrifilm™ Aerobic Count (PAC), Coliform Count (PCC) and High Sensitivity Coliform Count (HSCC) plates, Charm™ PeelPlate™ Aerobic Count (PP-AC), PeelPlate Coliform Count (PP-EC) and PeelPlate High Sensitivity Coliform Count (PP-EC-HVS) ...

PROCEDURE

- 8. **Identify Plates (SPC item 5 or Petrifilm item 6 or PeelPlate item 5)**
- 9. **Controls (See SPC item 6 or Petrifilm item 7 or PeelPlate item 6), in addition;**
 - a. Transfer 1 mL of rinse solution to SPC or PAC or PP-AC plate for sterility control ...
- 12. **Sample Measurements**
 - a. As described in SPC items 9 & 10 or Petrifilm items 10 & 11, or PeelPlate items 9 & 10 except:
 - 1. For Residual Bacterial Count (RBC), pipet 2 mL portion in a single SPC plate or pipet two 1 mL portions on 2 PAC or PP-AC plates
 - 2. For Residual Coliform Count (RCC), pipet 10 mL of remaining rinse solution among 3 CPC plates, or pipet ten 1 mL portions of remaining rinse solution on 10 PCC or PP-EC plates or two 5 mL portions on 2 HSCC or PP-EC-HVS plates ...
- 14. **Incubating Plates (See SPC item 14 or Petrifilm item 13 or PeelPlate item 12)...**
- 16. **Counting and Recording Colonies**
(See SPC items 15-17 or Petrifilm items 14-16 or PeelPlate items 13-15) ...

PROCEDURE

- 24. **Identify Plates (See SPC item 5 or Petrifilm item 6 or PeelPlate item 5)**
- 25. **Controls (See SPC item 6 or Petrifilm item 7 or PeelPlate item 6), in addition;**
 - a. Pipet 1 mL of rinse solution to SPC or PAC or PP-AC plate for sterility control ...
- 27. **Sample Measurement ...**
 - b. As described in Petrifilm items 10 & 11 or PeelPlate items 9 & 10; ...
 - c. For RBC, pipet 1 mL portion to a single SPC or PAC or PP-AC plate
 - d. For RCC, pipet 3 mL to a single CPC plate or three 1 mL portions on three PCC or PP-EC plates ...
- 29. **Incubation (See SPC item 14 or Petrifilm item 13 or PeelPlate item 12) ...**
- 31. **Counting and Recording Colonies**
See SPC items 15-17 or Petrifilm items 14-16 or PeelPlate item 13-15)

Proposal: 238
Document: FDA/NCIMS 2400 Forms
Pages: 11, 17 and 18

Make the following changes to the FDA/NCIMS 2400 Form:

CULTURAL PROCEDURES-GR

Page 11:

24. Microbiologically Suitable (MS) Water ...

- c. Monthly testing criteria
 - 1. Standard plate count or Petrifilm Aerobic Count or PeelPlate Aerobic Count < 1,000 colonies/mL (< 10,000 colonies/mL if stored)

Page 17:

27. Media

[Follow manufacturer's instructions unless otherwise stated] ...

- s. PeelPlate Aerobic Count (PPAC) Plate
 - 1. Lot #: _____ Exp. Date: _____
- t. PeelPlate Coliform Count (PPEC) Plate
 - 1. Lot #: _____ Exp. Date: _____
- u. PeelPlate Coliform Count High Volume (PPEC-HVS) Plate
 - 1. Lot #: _____ Exp. Date: _____

Page 18:

29. Prepared Media Storage ...

- h. PeelPlate storage
 - 1. Refrigerate unopened packages of PeelPlate plates at or below 8°C; if frozen allow 30 min room temperature thaw time before opening packages
 - 2. Use before expiration date on package
 - 3. After opening, return unused plates to the foil pouch with desiccant indicator, Zip-seal open end shut
 - 4. Store opened (re-sealed) packages refrigerated at or below 8°C
 - 5. Check desiccant indicator of PeelPlate plates before use.
Do not use if desiccant has turned white or pink. Do not use if plates are discolored, pink, yellow or brown. Use within product expiration date

Proposal: 239

Document: FDA/NCIMS 2400 Forms

Approve a 2400 form (below) that has been supplied to laboratory committee for amendment and adoption.

Amend M-a-98-10 (or last revision) by adding the PeelPlate methods for dairy matrices and with dairy products as appropriate with FDA-LPET and AOAC-RI submitted matrix data.

STANDARD PLATE AND COLIFORM COUNT
PEEL-PLATE™ AEROBIC, COLIFORM AND HIGH SENSITIVITY COLIFORM
METHODS
IMS #??

[Unless otherwise stated all tolerances are $\pm 5\%$]

SAMPLES

1. **Laboratory Sample Requirements (see CP items 33 & 34)**
[For inhibitor testing requirements, refer to Section 6 of the PMO]

MATERIALS AND APPARATUS

2. **Peel Plate Aerobic Count (PP-AC), Peel Plate Total Coliform (PP-EC, E.coli+Coliform) and Peel Plate Total Coliform High Volume Sensitivity (PP-EC-HVS,)**

PROCEDURE

3. **Work Area**
 - a. Level plating bench not in direct sunlight
 - b. Sanitize immediately before start of plating
4. **Selecting Dilutions**
 - a. Aerobic Count, PP-AC
 1. Plate two decimal dilutions per sample
 2. Select dilutions that would be expected to yield one plate with 25-250 colonies
 - a. Raw milk is normally diluted to 1:100 and 1:1000
 - b. Finished products are normally diluted to 1:10 and 1:100
 3. PP-AC not performed on cultured or acidified products
 - b. Total Coliform, PP-EC
 1. For pasteurized fluid milk samples (except chocolate), 1 mL direct and/or decimal dilutions, as appropriate
 2. For chocolate milk samples, distribute 2 mL of a 1:2 dilution among two (2) Peel Plate EC tests, 1 mL per plate
 3. For samples other than milk (item 12) distribute 10 mL of a 1:10 dilution among ten (10) Peel Plate EC tests, 1 mL per plate or use Peel Plate EC-HVS plates (see 4c below)
 4. For PP-EC performed on cultured product containing active Lactic Acid Bacteria (LAB), e.g. yogurt and cottage cheese, homogenize 1:10 dilution and centrifuge 1200g for 1 minute to settle solids. Distribute supernatant among ten (10) Peel Plate EC tests, 1 mL per plate or use Peel Plate EC-HVS plates (see 4c below)
 - c. High Volume Sensitivity Coliform, Peel Plate EC-HVS

1. At least a 1:10 minimum dilution required for: evaporated milk, sour cream, and sour cream based dips and eggnog (flavored milk optional)
 2. For cultured product containing active LAB, e.g. yogurt and cottage cheese, homogenize 1:10 dilution and centrifuge 1200g for 1 minute to settle solids.
 3. Test 10 mL of 1:10 dilution (5 mL on 2 plates)
- d. For acidified products, it is not necessary to adjust pH because of buffering capacity in the Peel Plate test. The pH range of the rehydrated test may be checked with different acidified products using pH paper:
1. Peel Plate EC – pH range 6.6 to 7.2
 2. Peel Plate HVS – pH range 6.5 to 7.5
 3. Refer to manufacturer’s instructions for list of low pH products that may require adjustment before plating

5. Identifying Peel Plate Tests

- a. Select number of samples in any series so that all will be plated within 20 min (pref ≤ 10) after diluting first sample
- b. Label each plate with sample or control identification and dilution
- c. Arrange plates in order before preparation of dilutions

CONTROLS

6. Controls (AM and PM)

- a. Check sterility of dilution blanks, Peel Plate-AC plates, and pipets/tips used for each group of samples
- b. Expose a rehydrated Peel Plate plate to air during plating for 15 min
 1. The air control plate must be the first plate set up immediately before samples are shaken and must be located such that it is in the area of the plating activity (not off to the side)
 - a. Inoculate the center of the PP-AC with 1 mL dilution buffer as described in items 9.i.1 or 10.i
 - b. Pull adhesive film off and save to side. Leave plate open, completely exposing rehydrated surface for 15 min; timer used
 - c. After 15 min, replace adhesive film back down as described in 9.i.2 and incubate as described in item 10.i.2
 2. After incubation, air plate(s) shall contain <10 colonies
 3. Take and record corrective actions for air control plate(s) with >10 colonies
 - a. Maintain records
 - b. Include information on bench sheet, work sheet or report sheet(s)

DILUTING SAMPLES

7. Sample Agitation

- a. When appropriate, wipe top of unopened containers with sterile, ethyl

- alcohol-saturated cloth
- b. Before removal of any portion or sub-samples, thoroughly mix contents of each container _____
 1. Mix raw sample(s) by shaking 25 times in 7 sec with a 1 ft movement (containers approx $\frac{3}{4}$ full)
 2. Mix retail milk samples by inverting containers top to bottom, then bottom to top (a complete half circle or 180 degrees) without pausing, 25 times
- c. Remove test portion within 3 min of sample agitation

8. Dilution Agitation

- a. Before removal of any portion, shake each dilution bottle 25 times in 7 sec with a 1 ft movement
- b. Remove test portion within 3 min of dilution agitation
- c. Mechanical shakers may be used only if a laboratory provides validation data on a specific unit. Data must pass validation criteria

PLATING

9. Sample and Dilution Measurement, Pipets

- a. Use separate sterile pipets for the initial transfers from each container, adjust pipets in pipet container without touching the pipets
- b. Do not drag pipet tip over exposed exterior of pipets in pipet container
- c. Do not drag pipet across lip or neck of sample container or dilution blank
- d. Insert pipet not more than 2.5 cm (1") below sample surface or dilution surface (avoid foam and bubbles)
- e. Using pipet aid, draw test portion above pipet graduation mark and remove pipet from liquid (mouth pipetting not permitted)
- f. Adjust test volume to mark with lower side of pipet:
 1. In contact with inside of sample container (above the sample surface)
 2. Or, in contact with inside of dilution blank neck or area above buffer on straight-walled container
 3. Ensure excess liquid does not adhere when pipet is removed from the sample container or dilution blank
- g. For dilutions, dispense test portion to dilution blank (with lower side of pipet in contact with neck of dilution blank, or area above buffer on straight-walled containers) with column drain of 2-4 sec
- h. Keeping plate flat on bench, peel back the top adhesive film (Peel Plate EC) or lift plate top (Peel Plate EC-HVS) to fully expose the test plate
- i. Deposit 1 mL (PP-AC/PP-EC), or 5 mL (Peel Plate EC-HVS) of sample or dilution keeping plate flat and pipet nearly vertical and in center of plate
 1. Release sample or dilution portion just above the center of the plate base with tip slightly above but not in contact with plate base plate with a column drain of 2-4 sec
 - a. Using pipet aid, blow out last drop of undiluted sample, away from main part of sample on plate

- b. Gently touch off pipet to dry area
- 2. PP-AC/PP-EC- Replace the adhesive film onto base preventing wrinkles. Apply pressure around perimeter to seal
- 3. Peel Plate HVS – Gently rotate plate to expose dry area to sample. Replace the lid.
- j. Leave plates undisturbed for gel solidification:
 - 1. 10 seconds for PP-AC/PP-EC
 - 2. 1 min for PP-EC-HVS
- k. Discard pipets into disinfectant OR dispose into biohazard bags or containers to be sterilized, (using this method of disposal does not require placing into disinfectant first)

10. Sample & Dilution Measurements, Pipettors [for electronic pipettors, follow manufacturer instructions] Mechanical ____ Electronic ____

- a. Each day before use, vigorously depress plunger 10x to redistribute lubrication and assure smooth operation (mechanical pipettors)
- b. Before each use examine pipettor to assure that no liquid is expelled from the pipettor nose-cone (contaminated), if fouling is detected do not use until cleaned as per manufacturer recommendation
- c. Use separate sterile tip for the initial transfers from each container
- d. Depress plunger to first stop (mechanical pipettors)
- e. Do not drag tip/barrel across lip or neck of sample container or dilution blank, and do not allow pipettor barrel within sample container
- f. Insert tip approximately 0.5-1.0 mm below sample or dilution surface (avoid foam and bubbles)
- g. With plate flat and pipettor vertical, slowly and completely release plunger on mechanical pipettor; do not lay pipettor down once sample is drawn up, use vertical rack or charging stand if necessary
- h. Touch off lower side of tip:
 - 1. To inside of sample container above the sample surface, excess liquid not adhering to tip
 - 2. Or to the inside of dilution blank neck or area above buffer on straight-walled containers, excess liquid not adhering to tip
 - a. For dilutions, hold pipettor nearly vertical with lower side of tip touching neck of dilution blank (or area above buffer on straight-walled containers), dispense test portion to blank by slowly depressing plunger to stop (mechanical pipettor)
 - 3. For two (2) stop pipettors, depress plunger to second stop with tip remaining in contact with dilution blank
- i. Lift the top adhesive film, fully exposing medium circle and keep plate flat. Deposit 1 mL (PP-AC/PP-EC), or 5 mL (PP-EC-HVS) of sample or dilution keeping pipettor nearly vertical
 - 1. Release sample or dilution portion within 2-4 seconds onto the center or just above the center of the plate with tip slightly above but not in
 - a. If pipettor has two (2) stops, depress plunger to second stop
 - b. Do not touch off pipettor tip(s) on plates

- c. Optionally, deposit samples with pipettor capable of making a 1:10 dilution in the tip
 - 2. PP-AC/PP-EC – Replace the adhesive film onto base preventing wrinkles. Apply pressure around perimeter to seal
 - 3. PP-EC-HVS – Gently rotate plate to expose dry area to sample. Replace the lid
- j. Allow sample to wick into test material
 - 1. 10 seconds for PP-AC/PP-EC
 - 2. 1 minute for PP-EC-HVS
- k. Discard tips into disinfectant OR dispose into biohazard bags or containers to be sterilized (using this method of disposal does not require placing into disinfectant first)

11. Samples other than milk

- a. Weigh 11g aseptically into a 99mL dilution blank heated to 40-45°C

INCUBATION

12. Incubating Peel Plate Plates (see CP item 15)

- a. Stack plates in horizontal position, clear side up
 - 1. PP-AC/PP-EC – no more than 20 high
 - 2. PP-EC-HVS – no more than 10 high
- b. Incubate within 10 min
 - 1. PP-AC/PP-EC and PP-EC-HVS - 24±2 hours at 32±1°C

COUNTING COLONIES

13. Counting Aids (see CP item 17)

- a. Count colonies with aid of magnification under uniform and properly controlled artificial illumination
- b. Hand tally (see CP item 17)

14. Counting, Recording and Computing Aerobic Count, PP-AC

- a. After incubation count all colonies on selected plates
- b. Where impossible to count at once, store plates at 0.0-4.4°C for not longer than 24 hours (avoid as a routine practice)
- c. Record results of sterility and control tests
- d. Record dilutions used and number of colonies on each plate counted
- e. When possible, select spreader colony free plates with 25-250 colonies and count all red colonies
 - 1. Use higher magnification if necessary to distinguish colonies from foreign matter
 - 2. Examine edge of plates for colonies
 - 3. Count all colonies stained various shades of red, even those outside the circular indentation left by the spreader
- f. If consecutive plates yield 25-250 colonies, count all colonies on plates

- from both dilutions
- g. Spreader colonies or plates with gel liquefaction
 1. Count colonies on representative portion only when colonies are well distributed and area covered, repressed or liquefied colonies do not exceed 25% of plate
 2. Do not count if repressed growth area or gel liquefaction >25% of plate area
 3. When spreader colonies must be counted, count each as a single colony
 4. Count chains/spreader colonies from separate sources as separate colonies
 5. If 5% of plates are more than 25% liquefied or covered by spreader colonies, take immediate steps to eliminate and resolve problem
 - h. If there is no plate yielding 25-250 colonies, use plate having nearest to 250 colonies
 - i. If plates from all dilutions exceed 250 colonies, estimate
 - j. If plates from all dilutions yield < 25 colonies each, record actual number in lowest dilution
 - k. If all plates from a sample show no colonies, record count as 0
 - l. Multiply number of colonies (or estimated number if necessary) by the reciprocal of the dilution
 1. If consecutive dilutions yield 25-250 colonies, compute count using formula below

$$N = \Sigma C / [(1 \times n_1) + (0.1 \times n_2)]d$$

Where, N = number of colonies per milliliter or gram

ΣC = sum of all colonies on all plates counted

n1 = number of plates in lower dilution counted

n2 = number of plates in next highest dilution counted

d = dilution from which the first counts were obtained

Example: 1:100 = 244 colonies 1:1,000 = 28 colonies

$$N = (244 + 28) / [(1 \times 1) + (0.1 \times 1)]0.01$$

$$= 272 / [1.1]0.01$$

$$= 272 / 0.011$$

$$= 24,727 [25,000 \text{ (reported)}]$$

Note: In the NCIMS Program the denominator will always be 0.11 for 1:10 dilutions and 0.011 for 1:100 dilutions

15. Counting, Recording and Computing Total Coliform, PP-EC and PP-EC-HVS

- a. After incubation count all colonies on selected plates
- b. Where impossible to count at once, store plates at 0.0-4.4°C for not longer than 24 hours (avoid as a routine practice)
- c. Count all colonies regardless of color or size. Red colonies are coliform producing galactosidase while blue/purple and black colonies are coliform producing the

- enzymes galactosidase and glucuronidase. (No further confirmation is required)
- d. If no colonies appear on plate(s), record count as 0
 - e. If there are 1-154 colonies on a plate, record number counted
 - f. If >154 colonies develop on highest dilution plate, record number as >150
 - g. When multiple plates of a dilution are used (items 4.a.2 and 4.a.3), sum counts of the plates
 - h. Multiply number of colonies (or estimated number if necessary) by the reciprocal of the dilution

15. Identifying Counting Errors

- a. Perform monthly counting for PP-AC
 1. With 3 or more analysts, use the RpSm method (see current SMEDP); maintain records
 2. With two analysts, comparative counts agree within <10%; maintain records
 3. If only one analyst, replicate counts agree within 8% of one another; maintain records

REPORTING

16. Reporting (see CP item 34.b.2.d)

[When samples are demonstrated to contain inhibitors, no bacteria counts are reported; report as positive for inhibitors or growth inhibitors (GI)]

- a. Aerobic Count, PP-AC
 1. Report computed count as Peel Plate Aerobic Count/mL or /g (PP-AC/mL or PP-AC/g) when taken from plate(s) in the 25-250 range
 2. Report PP-AC plate counts of 0 to 24 as < 25 times the reciprocal of the dilution and report as Estimated PP-AC (EPP-AC)
 3. When colonies on PP-AC plates exceed 100/sq cm, compute count by multiplying 100 x dilution factor x 20 sq cm and report as > computed count Estimated (EPP-AC)
 4. If computed counts from PAC plates >250, report as Estimated PP-AC (EPP-AC)
 5. If for any reason, an entire plate is not counted, the computed count is reported as Estimated (EPP-AC) _____
- b. Total Coliform, PP-EC
 1. Report count as Peel Plate Coliform/mL or /g (PP-EC/mL or PP-EC/g) when taken from plate(s) in the 1-154 range
 - a. For chocolate milk run 1:2 dilutions in duplicate and sum results to get a sensitivity of 1 coliform/mL as required by the PMO (PP-EC/mL)
 2. If no colonies appear on coliform plates, report as < 1 times the reciprocal of the dilution and report as Estimated (EPP-EC)
 3. Counts from coliform plates > 154 are reported as > 150 Estimated Peel Plate Coliform Count (EPP-EC)
- c. High Sensitivity Total Coliform, PP-EC-HVS

1. Run 1:10 dilutions in duplicate to get a sensitivity of 1 coliform/mL or g as required by the PMO (PP-EC-HVS)
 2. If for any reason, an entire plate is not counted, the computed count is reported as Estimated (EPP-EC-HVS)
 - d. Report only first two left-hand digits
 1. If the third digit is 5 round the second number using the following rules
 - a. When the second digit is odd round up (odd up, 135 to 140)
 - b. When the second digit is even round down (even down, 125 to 120)
 - e. If all plates from a sample have excessive spreader colony growth or liquefiers, report as spreaders (SPR) or liquefiers (LIQ)
 - f. If a laboratory accident renders a plate uncountable, report as laboratory accident (LA)
-

Proposal: 241

Document: FDA/NCIMS 2400 Forms

Page: 7

Make the following changes to the FDA/NCIMS 2400 Form:

DAIRY WATER

Page 7:

24. Materials ...

f. Water bath, circulating, maintains 44.5±0.5°C; records maintained during periods of use (optional for Colilert-18)

25. Procedure ...

d. For Colilert-18, thermally equilibrate test solution for 20 min in a 35±0.5°C circulating water bath or alternatively 7-10 minutes (not to exceed 10 minutes) in a 44.5±0.2°C circulating water bath, and then continue incubation in 35±0.5°C water bath or dry incubator for a total of 18 hours (minimum), not to exceed 22 hours

Proposal: 245

Document: FDA/NCIMS 2400 Forms

Make the following changes to the FDA/NCIMS 2400 Form:

DMSCC

Item 13.a

- a. Refractive index 1.51-1.52 at 20°C.
-

Proposal: 246

Document: FDA/NCIMS 2400 Forms

Make the following changes to the FDA/NCIMS 2400 Form:

DAIRY WATERS

1. Laboratory Requirements

- e. Transit time does not exceed ~~30~~ 48 hours
f. Samples examined within ~~30~~ 48 hours of collection or within 2 hours of receipt (item 1d)

FDA DID NOT CONCUR WITH THIS PROPOSAL AS CITED IN THEIR LETTER TO THE NCIMS CHAIR DATED AUGUST 11, 2015

FDA maintains that there was not appropriate science provided by the author of this Proposal and reviewed by the Scientific Advisory Committee to justify this change.

During the October 7-8, 2015 NCIMS Executive Board meeting, FDA and the Executive Board did not reach mutual concurrence with Proposal 246; therefore, Proposal 246 in accordance with Section IX-Application of Conference Agreements, A-Implementation of Changes, 4. of the *Procedures* will be referred to the next Conference for discussion.

Proposal: 211

Document: No Document Referenced

The Appendix N Modification Committee requests the Chair to assign this proposal to an NCIMS standing committee, special committee, or ad hoc committee as approved by the NCIMS Executive Board.

The Appendix N Modification Committee is charged to develop a pilot program, establishing a regulatory framework by which testing raw milk for veterinary drugs would be *required for drugs other than beta-lactams*. The pilot program, when finalized, would include, but is not limited to, consideration of the following criteria:

1. **Veterinary drugs required to be tested:** The Appendix N Modification Committee shall define the drugs other than beta-lactams for which raw milk is required to be tested. This will be based on FDA's recommendation from the output of the risk ranking model, among the top 20 drugs of the 54 drugs analyzed were from the following families of drugs: Beta-lactams, Amphenicols (florfenicol), NSAIDs (flunixin), Sulfonamides, Macrolides, Tetracyclines, Aminoglycosides, and Avermectins.
2. **Testing methodology required to be used:** Methods evaluated by FDA and accepted by

NCIMS shall be used for consistency and reliability. 2400 Forms shall be developed by the Laboratory Committee. Official Laboratories, Officially Designated Laboratories, and Certified Industry Supervisors shall be certified in appropriate testing methods.

3. **Availability of suitable test methods:** The pilot shall account for method availability, accessibility, logistical feasibility (including practicality and timeliness of results) and cost.

4. **Number of samples to be collected and assayed:** The pilot shall determine the number of samples to test based on a statistical analysis. Sampling shall be no less than 1 in 15 bulk milk tankers and/or all raw milk supplies that have not been transported in bulk milk tankers, except for sulfonamides at no less than 1 in 7.

5. **Reduction of required Beta-Lactam testing:** The pilot shall consider the potential for reducing beta-lactam testing of incoming raw milk in a manner consistent with FDA's recommendations.

6. **National Milk Drug Residue Database:** Results of testing for veterinary drugs other than beta-lactams shall be reported to the National Milk Drug Residue Database. The pilot shall require for timely reporting of results to the NCIMS Executive Board. This requirement will have to determine resources needed, how data shall be collected, and reported.

7. **Report of challenges of program implementation:** The committee shall review the framework of the pilot program for hurdles likely to be encountered by stakeholders in implementing this new program and report back to the 2017 Conference with potential solutions to address these challenges.

8. A complete report of the pilot program, including all test results and recommendations for a future testing framework, will be shared at the 2017 Conference. Based on this report, a proposal may be submitted to formalize the requirements of the program into the PMO as a required program (potentially, but not limited to in Appendix N, in a subpart to Appendix N, or as a separate appendix in the PMO).

The Appendix N Modification Committee stands ready to begin work on the framework for this pilot program immediately and requests an effective date of the receipt and acceptance of FDA concurrence at the next NCIMS Executive Board meeting after the Conference.

All Proposals that make changes to the NCIMS documents will be incorporated into the next edition of the affected document as they are updated. Copies of this memorandum are enclosed for distribution to Regional Milk Specialists, Milk Regulatory Agencies, Laboratory Evaluation Officers, and Milk Rating Officers. This memorandum should be widely distributed to representatives of the milk industry and other interested parties, and will be available on the FDA Web Site at www.fda.gov at a later date.

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



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CAPT, US Public Health Service
Milk and Milk Products Branch