

35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 301
Committee: Aseptic

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

A. Summary of Proposal

This Proposal requests a two (2) year extension of the NCIMS Aseptic Pilot Program (APP) 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 continue 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 (APC) is discontinuing their evaluation of aseptically processed and packaged Grade “A” acidified milk and/or milk products.

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

This Proposal includes a request for a two (2) year extension of the NCIMS APP to address aseptically processed and packaged Grade “A” fermented high-acid milk and/or milk products. The two (2) years will allow time to continue the study, and to develop and evaluate aseptically processed and packaged Grade “A” fermented high-acid milk and/or milk products.

The NCIMS 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.

C. Proposed Solution

Changes to be made on page(s): 130 of the (X - one of the following):

| | | | |
|-------------------------------------|-----------------|--------------------------|------------------------------|
| <input checked="" type="checkbox"/> | 2013 PMO | <input type="checkbox"/> | 2011 EML |
| <input type="checkbox"/> | 2011 MMSR | <input type="checkbox"/> | 2400 Forms |
| <input type="checkbox"/> | 2011 Procedures | <input type="checkbox"/> | 2011 Constitution and Bylaws |

MAKE THE FOLLOWING CHANGES TO THE 2013 PMO

Strike through text to be deleted and underlined text to be added.

**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. ...

| | | | |
|----------------------|---|--------------------|--|
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35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

| | |
|-------------|------------------------------------|
| Proposal #: | 302 **Constitution & Bylaws Change |
| Committee: | Constitution & Bylaws |

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

A. Summary of Proposal

This proposal formalizes the appointment of Chairs and Vice Chairs to NCIMS Committees.

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

Formalizing the position of Committee Vice Chairs and re-affirming the position of Committee Chairs at each biennial conference is a pro-active step toward assuring continuity for both short- and long-term (for example, to assure committee work continues in a timely manner and in developing future leadership, respectively).

C. Proposed Solution

Changes to be made on page(s): 77, 81 of the (X - one of the following):

- | | |
|--|--|
| <input type="checkbox"/> 2013 PMO | <input type="checkbox"/> 2011 EML |
| <input type="checkbox"/> 2013 MMSR | <input type="checkbox"/> 2400 Forms |
| <input type="checkbox"/> 2013 Procedures | <input checked="" type="checkbox"/> 2013 Constitution and Bylaws |

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

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

Subd. 1. Committee Vice Chairs shall perform the duties of the Committee Chair whenever the Committee Chair shall be absent or unable to act.

Subd. 2. Unless fulfilling the role of Committee Chair, the Committee Vice Chair shall serve as a voting member of the Committee.

Bylaws: 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 Executive Board, shall appoint a Committee Chair and Committee Vice-Chair as outlined in Article 4, Section 13. of this 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 Ad hoc Committee, the Conference Chair, with the approval of the Executive Board, shall appoint a Committee Chair and Committee Vice-Chair as outlined in Article 4, Section 13. of this Constitution.

| | | | |
|----------------------|------------------------------------|-----------------|----------------------|
| Name: | NMPF NCIMS Committee | | |
| Agency/Organization: | National Milk Producers Federation | | |
| Address: | 2101 Wilson Blvd, Suite 400 | | |
| City/State/Zip: | Arlington, VA 22201 | | |
| Telephone No.: | 703-243-6111 | E-mail Address: | bbriczinski@nmpf.org |

35th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #: 303 **Constitution & Bylaws Change
Committee: Constitution & Bylaws

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

A. Summary of Proposal

This proposal allows a vacant elected Board seat to be filled between Conferences.

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

Currently, when an elected Board seat is vacated between Conferences, it remains unfilled until the next biennial or special meeting of the Conference. Allowing elected Board seats vacated between Conferences to be filled assures representation and balance as the Board continues its inter-Conference activities.

C. Proposed Solution

Changes to be made on page(s): 74, 80 of the (X - one of the following):

- | | |
|-------------------------------|---|
| <u> </u> 2013 PMO | <u> </u> 2011 EML |
| <u> </u> 2013 MMSR | <u> </u> 2400 Forms |
| <u> </u> 2013 Procedures | <u> X </u> 2013 Constitution and Bylaws |

Constitution: 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 Conference Chair with the approval of the Executive 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.

Bylaws: 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 Conference Chair, with the approval of the Executive 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.

| | | |
|----------------------|---|--|
| Name: | NMPF NCIMS Committee; International Dairy Foods Association; Casey McCue; Steve Ingham | |
| Agency/Organization: | National Milk Producers Federation; International Dairy Foods Association; New York State Department of Agriculture and Markets; Wisconsin Department of Agriculture, Trade and Consumer Protection | |
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35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

| | |
|-------------|------------------------------------|
| Proposal #: | 304 **Constitution & Bylaws Change |
| Committee: | Constitution & Bylaws |

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

A. Summary of Proposal

Over the years since the 1997 Special Conference in Chicago, Bill Johnston has assisted the smooth operation of the Conference in his role as Parliamentarian. He has suggested the following changes to the BYLAWS OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS in order to clarify the role of the Parliamentarian, insure that we do not prematurely adjourn the Conference, and to explain the intersection of the Conference documents, past practices, and Roberts Rules of Order.

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

To clarify the role of the Parliamentarian, insure that we do not prematurely adjourn the Conference, and to explain the intersection of the Conference documents, past practices, and Roberts Rules of Order.

C. Proposed Solution

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

- | | |
|-----------------------|---|
| _____ 2013 PMO | _____ 2011 EML |
| _____ 2013 MMSR | _____ 2400 Forms |
| _____ 2013 Procedures | <u> X </u> 2013 Constitution and Bylaws |

BYLAWS OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS
Pages 81, 84, 85

ARTICLE II – DUTIES OF THE CHAIR

SECTION 10. The Chair may retain the services of a 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.

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 called meeting.

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, By-Laws or historic practice exist which shall take precedence.

| | | | |
|----------------------|---------------------------|-----------------|--------------------------|
| Name: | David E. Lattan | | |
| Agency/Organization: | Prairie Farms Dairy, Inc. | | |
| Address: | 1100 Broadway Street | | |
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| Telephone No.: | 618/407-2832 | E-mail Address: | dlattan@prairiefarms.com |

35th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #: 305 **Constitution & Bylaws Change

Committee: Constitution & Bylaws

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

A. Summary of Proposal

To add the Chair of the NCIMS Laboratory Committee to the NCIMS Executive Board.

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

The Executive Board is faced with many varied issues; among them are laboratory testing methods and appropriate forms for implementing new methods. The Laboratory Committee should be a resource to benefit the executive board and the conference. Having the Chair of the laboratory committee serve as a non-voting member of the board as another resource to complement the technical and scientific expertise of the board will be necessary as this program moves into the future.

C. Proposed Solution

| | | |
|--|--|------------------------------------|
| Changes to be made on page(s): | 74-75 | of the (X - one of the following): |
| <input type="checkbox"/> 2013 PMO | <input type="checkbox"/> 2011 EML | |
| <input type="checkbox"/> 2013 MMSR | <input type="checkbox"/> 2400 Forms | |
| <input type="checkbox"/> 2013 Procedures | <input checked="" type="checkbox"/> 2013 Constitution and Bylaws | |

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.

| | | | |
|----------------------|------------------------------------|-----------------|----------------------------|
| Name: | Frank Barcellos and Catherine Hall | | |
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| Telephone No.: | 503-986-4724 | E-mail Address: | fbarcellos@oda.state.or.us |

35th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #: 306 *New Procedure

Committee:

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

A. Summary of Proposal

This Proposal adds to the Table of Contents of each NCIMS document a listing of abbreviations and acronyms that are used throughout the individual PMO, MMSR, Procedures and EML documents.

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

To provide a quick reference to all readers for the abbreviations and acronyms that are used throughout the individual PMO, MMSR, Procedures and EML documents.

C. Proposed Solution

Changes to be made on page(s): PMO-ix & xviii; MMSR-ii & vi; Procedures-ii & iv; EML-i & iii of the (X - one of the following):

- | | |
|------------------------------|--|
| <u> X </u> 2013 PMO | <u> X </u> 2011 EML |
| <u> X </u> 2013 MMSR | <u> </u> 2400 Forms |
| <u> X </u> 2013 Procedures | <u> </u> 2013 Constitution and Bylaws |

MAKE THE FOLLOWING CHANGES TO THE 2013 PMO.

Strike through text to be deleted and underlined text to be added.

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| <u>ABBREVIATIONS AND ACRONYMS</u> | <u>xviii</u> |

...

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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 STLR (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 (Cleansed-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 (Diethylphthalate 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 Practices)
gm (Gram)
GMP (Good Manufacturing Practices)
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)
SSC (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)

MAKE THE FOLLOWING CHANGES TO THE 2013 MMSR.

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ABBREVIATIONS AND ACRONYMS vi

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Page vi:

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)

MAKE THE FOLLOWING CHANGES TO THE 2013 PROCEDURES.

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Page ii:

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PREFACE i

TABLE OF CONTENTS.....ii

ABBREVIATIONS AND ACRONYMS iv

SECTION 1 PURPOSE..... 1

...

Page iv:

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)

SSC (Somatic Cell Count)

SSO (Sampling Surveillance Officer)

TPC (Third Party Certifier)

U.S.C. (United States Code)

USDA (United States Department of Agriculture)

MAKE THE FOLLOWING CHANGES TO THE 2011 EML.

Strike through text to be deleted and underlined text to be added.

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INTRODUCTION 1

...

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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 Certification 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.

| | | | |
|----------------------|------------------------------|-----------------|---------------------------|
| Name: | CFSAN | | |
| Agency/Organization: | Food and Drug Administration | | |
| Address: | 5100 Paint Branch Parkway | | |
| City/State/Zip: | College Park, MD 20740 | | |
| Telephone No.: | (240) 402-2175 | E-mail Address: | Robert.Hennes@fda.hhs.gov |

35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

| | |
|-------------|---------------------------|
| Proposal #: | 307 *Procedures Change |
| Committee: | ICP |

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

A. Summary of Proposal

This proposal clarifies that drug residue summary data shall be collected by Third Party Certifiers (TPCs) and reported to the third party database.

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

Collection and reporting of drug residue summary data by Third Party Certifiers aligns the requirements of the voluntary International Certification Program with the domestic NCIMS program.

C. Proposed Solution

Changes to be made on page(s): 16 of the (X - one of the following):

- | | |
|------------------------------|--|
| <u> </u> 2013 PMO | <u> </u> 2011 EML |
| <u> </u> 2013 MMSR | <u> </u> 2400 Forms |
| <u> X </u> 2013 Procedures | <u> </u> 2013 Constitution and Bylaws |

6. Reports to Database

State Regulatory or Rating Agencies and TPCs shall submit drug residue summary data to a third party database, distinguishing between data collected domestically and internationally.

| | | | |
|----------------------|------------------------------------|-----------------|----------------------|
| Name: | NMPF NCIMS Committee | | |
| Agency/Organization: | National Milk Producers Federation | | |
| Address: | 2101 Wilson Blvd, Suite 400 | | |
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35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 308
*Procedures Change
Committee:

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

A. Summary of Proposal

This proposal will reduce the number of bulk milk hauler/samplers evaluated during Sampling Surveillance Officer re-certification. This will make the re-Certification process similar to the current re-delegation to state regulatory personnel process as established by the 2007 NCIMS found in the “*Procedures Governing the Cooperative State-Public Health Service / Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (2013 Revision)*” document.

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

Experienced state rating officers are engaged in the evaluation of industry plant samplers and farm hauler / samplers, on a regular basis. Therefore, there is less need to evaluate the same number of bulk milk hauler/samplers, for re-certification, that are evaluated on initial certification. The process of re-delegation for sample surveillance authority to state regulatory personnel (listed in the “*Procedures*” document) already reflects this rationale, but the re-certification of Sample Surveillance Officers does not. This proposal will correct that inconsistency.

C. Proposed Solution

| | | |
|--------------------------------|------------------------------------|------------------------------------|
| Changes to be made on page(s): | 25 | of the (X - one of the following): |
| _____ 2013 PMO | _____ 2011 EML | |
| _____ 2013 MMSR | _____ 2400 Forms | |
| X _____ 2013 Procedures | _____ 2013 Constitution and Bylaws | |

MAKE THE FOLLOWING CHANGES TO THE
*“PROCEDURES GOVERNING THE COOPERATIVE STATE-PUBLIC HEALTH SERVICE /
 FOOD AND DRUG ADMINISTRATION PROGRAM OF THE NATIONAL CONFERENCE
 ON INTERSTATE MILK SHIPMENTS – 2013 REVISION”*:

(Page 25 of the 2013 *“PROCEDURES . . . “* document, Section F - Sampling Surveillance
 Personnel, number 3 & 4)

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~~ 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.

| | |
|----------------------|---|
| Brian Moyer | |
| Agency/Organization: | Wisconsin Department of Agriculture, Trade & Consumer Protection – Division of Food Safety – Milk Certification Unit |
| Address: | P. O. Box 8911 |
| City/State/Zip: | Madison, WI 53708 - 8911 |
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35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 309 *New Procedure

Committee: SSCC/MMSR

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

A. Summary of Proposal

1. To develop listing and withdrawal of listing criteria for SSCC manufacturers
2. To develop qualifications, authorization, certification/recertification procedures, etc. for consultants that currently certify or wish to certify SSCC manufacturers located outside the geographical boundaries of NCIMS Member States

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

Proposal 301: FDA requests the NCIMS Chair to assign the following charges to the identified NCIMS standing committee(s) and to report back to the 2015 NCIMS Conference

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

Proposal 305: The International Certification Pilot Program Committee (ICPPC) requests the NCIMS Chair to assign the following charge to the SSCC Committee and report back to the

2015 NCIMS Conference:

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

C. Proposed Solution

Changes to be made on page(s): PMO, Procedures and MMSR-Multiple of the (X - one of the following):

- | | | | |
|----------|-----------------|-------|------------------------------|
| <u>X</u> | 2013 PMO | _____ | 2011 EML |
| <u>X</u> | 2013 MMSR | _____ | 2400 Forms |
| <u>X</u> | 2013 Procedures | _____ | 2013 Constitution and Bylaws |

~~Strikeout~~ text to be deleted and underlined text will be added:

MAKE THE FOLLOWING CHANGES TO THE 2013 PMO:

Cover:

~~2013~~ 2015

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

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

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

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

18. HANDLING OF CONTAINERS, CLOSURES AND EQUIPMENT ...

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

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

ADMINISTRATIVE PROCEDURES ...

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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.

~~13~~14. **"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 ~~no~~ 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 (*Single-Service ~~Milk~~ Containers and/or Closures for Milk and/or Milk Products*)

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

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)*

INSPECTING AGENCY/FIRM/TPC/
CERTIFICATION AGENCY/SSC

NAME AND LOCATION OF PLANT

1. FLOORS

- Smooth; impervious; in good repair..... (a)
- Joints between walls and floors tight; impervious (b)
- Floor drains properly trapped; sloped to drain..... (c)

2. WALLS AND CEILINGS

- In fabrication areas—smooth; cleanable; light-colored (a)
- In fabrication and storage areas—good repair (b)
- Openings in walls and ceilings effectively sealed (c)

3. DOORS AND WINDOWS

- All outside openings protected against entrance of insects, rodents, dust, and airborne contamination (a)
- Outer doors tight, self-closing (b)

4. LIGHTING AND VENTILATION

- Adequate light in all rooms..... (a)
- Ventilation sufficient (b)
- Pressure ventilation systems properly filtered (c)

5. SEPARATE ROOMS

- Fabrication areas separate from non-fabrication areas when required..... (a)
- Regrinding plastic and paper trim shredding, packaging and baling conducted in separate room(s) from fabrication areas or as Appendix J permits (b)

6. TOILET FACILITIES-SEWAGE DISPOSAL

- Disposal of sewage; other waste; in public sewage system or in compliance with Local and State Regulations (a)
- All plumbing complies with Local and State plumbing Regulations (b)
- Solid, tight-fitting, self-closing doors (c)
- Toilet rooms and fixtures clean; in good repair (d)
- Adequate light and ventilation; ducts vented to the outside..... (e)
- Proper handwashing facilities (f)
- Open windows effectively screened (g)
- Employee handwashing signs posted (h)
- Eating/food storage prohibited (i)

7. WATER SUPPLY

- Safe; complies with bacteriological and construction requirements (a)
- No direct or indirect connection between safe and unsafe water (b)
- Sampled and examined as required (c)
- Recirculated cooling water used in water baths complies with bacteriological standards, tested semi-annually..... (d)
- Testing records maintained as required (e)

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)
- Handwashing facilities clean (b)

9. PLANT CLEANLINESS

- Floors, walls, ceilings, overhead beams, fixtures, pipes and ducts clean in rooms as required..... (a)
- Plant free of evidence of insects, rodents and birds (b)
- Machines and appurtenances clean (c)

10. LOCKERS AND LUNCHROOMS

- Separate from plant operation; self-closing doors (a)
- Eating/storage of food prohibited in fabrication and storage areas (b)
- Locker and lunchrooms clean..... (c)
- Cleanable trash containers provided; properly labeled, covered..... (d)
- Handwashing facilities convenient..... (e)
- Employee handwashing signs posted (f)

11. DISPOSAL OF WASTES

- Stored in covered, impervious, leak-proof containers; does not apply to production scrap (a)
- Waste containers properly identified (b)
- Storage of garbage/rubbish meets requirements..... (c)

12. PERSONNEL - PRACTICES

- Hands washed as required (a)
- Clean outer garments; hair restraints (b)
- 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)
- Tobacco use in authorized areas only..... (d)
- Insecured jewelry not permitted in fabrication areas..... (e)

13. PROTECTION FROM CONTAMINATION

- Product contact surfaces protected; all materials in process properly protected (a)
- Air under pressure directed at materials or product contact surfaces in compliance (b)
- Air directed at materials or product contact surfaces by fans or blowers in compliance (c)
- Pesticides approved; EPA registered..... (d)
- Pesticides used in accordance with directions; precludes contamination of containers/closures (e)
- Single-service articles in process protected from contamination..... (f)
- Equipment cleaned after use of non-food-grade materials..... (g)
- Cross contamination with non-food-grade material prevented (h)
- No overcrowding of equipment and operations (i)
- Toxic chemicals separated from raw materials and finished products..... (j)
- Food containers manufactured by facility not used for storage of miscellaneous items or chemicals (k)

14. STORAGE OF MATERIALS AND FINISHED PRODUCT

- Away from any wall; soiled outer turns or edges discarded..... (a)
- Stored in clean, dry place, protected from splash, insects, and dust..... (b)
- Containers and closures stored in original cartons and sealed until used; partially used cartons resealed during storage (c)
- Containers for storage of resin, raw and reuse materials are covered, clean, impervious and properly identified..... (d)
- In-process storage bins that touch the product contact surface constructed of cleanable, nonabsorbent material; clean..... (e)

15. FABRICATING EQUIPMENT

- Contact surfaces clean; milk plant equipment utilized for performing containers clean and sanitized prior to operation (a)

- Makeshift devices not used; fasteners, guides, hangers, supports and baffles properly constructed; good repair..... (b)
- Take-off tables and other container contact surfaces properly constructed; clean; in good repair..... (c)
- Grinders, shredders and similar equipment properly installed; protected from contamination (d)
- Resin storage silos, other containers, constructed to protect resin from contamination; air vents filtered; air tubes good repair and properly protected..... (e)

16. MATERIALS FOR CONSTRUCTION OF CONTAINERS AND/OR CLOSURES

- Materials from approved source..... (a)
- Food-grade lubricants used on contact surfaces; stored to prevent cross contamination; storage clean and ventilated..... (b)
- Containers, closures or materials on floor not used (c)

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)
- Unused materials covered, labeled and properly stored (b)
- Nontoxic; imparts no flavor or odor; non-contaminating; complies with 21 CFR Parts 475-174-178 (c)
- Transfer containers clean; covered, properly identified (d)
- Waxing, when used, performed as required; wax kept at proper temperature..... (e)

18. HANDLING OF CONTAINERS, CLOSURES AND EQUIPMENT

- Handling of container and closure surfaces minimized (a)
- Hands sanitized frequently or clean, single-use gloves worn; sanitizing dispensers convenient (b)

19. WRAPPING AND SHIPPING

- Single-service articles properly containerized prior to shipping..... (a)
- Packaged contents protected from contamination (b)
- Transportation vehicles clean; in good repair; not used for unapproved uses (c)
- Paperboard containers, wrappers and dividers not reused (d)
- Packaging materials in compliance..... (e)

20. IDENTIFICATION AND RECORDS

- Plant identification on outer wrapping as required..... (a)
- Glass containers properly labeled..... (b)
- Required bacteriological tests on file; maintained as required; and in compliance (c)
- Required bacteriological and chemical test records for all component parts used in final assembled product on file..... (d)
- Information on file from suppliers of raw materials, waxes, adhesives, sealants, coatings and inks indicating compliance..... (e)
- Information on file from suppliers of packaging materials indicating compliance (f)

21. SURROUNDINGS

- Surroundings neat and clean and free of breeding areas, conditions attracting or harboring flies, insects or rodents (a)
- Driveways graded; no standing water (b)

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

DATE

SANITARIAN/CONSULTANT/SRO/SSC/RMS

NOTE: This Form has been developed for use with Appendix J of the *Grade "A" Pasteurized Milk Ordinance*.

FORM FDA 2359c (10/44-15)

PREVIOUS EDITION IS OBSOLETE

MAKE THE FOLLOWING CHANGES TO THE 2013 MMSR:

Strikeout text to be deleted and underlined text will be added:

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

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2. SUMMARY OF CERTIFICATION RESULTS

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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*)"

1. PURPOSE

2. PREPARATION OF THE "REPORT OF CERTIFICATION"

G.J. 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 PRODUCTS MANUFACTURERS CERTIFICATION/LISTING FORMS.....

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

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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 ...

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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:

~~23~~24. **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.

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

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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.

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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*)

Page 50:

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 ...

Page 51:

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:

| | |
|----------------------|---|
| 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)

| | |
|----------------------|---|
| 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 (10/4/15)

MAKE THE FOLLOWING CHANGES TO THE 2013 PROCEDURES:

~~Strikeout~~ text to be deleted and underlined text will be added:

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~~ 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.

Page 14:

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.

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.l.~~ 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) ...

Page 18:

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 IMS LISTING |
|----------------------|---------------------|--|
| 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 RATING 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, (2013 PMO Text)]~~ 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 action₂ 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.k₁., respectively, PHS/FDA shall, after five (5) days, provide this information to all receiving States and/or TCPs.

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 TPC₂ 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*.

Page 22:

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.

Page 24:

E. DRUG RESIDUE COMPLIANCE

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

Page 27:

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.

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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.

J. 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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L. 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.

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|----------------------|--|-----------------|--|
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