

36th 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 Program Committee’s (APC) pilot program to specifically address Grade “A” fermented high-acid shelf stable milk and/or milk products. The additional two (2) years will be utilized to evaluate how the new Food Safety Modernization Act (FSMA) requirements in the PMO for regulating and rating milk plants producing Grade “A” milk and/or milk products may assist in specifically defining the regulation of the Grade “A” fermented high-acid shelf stable milk and/or milk products.

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

The current Grade “A” fermented high-acid shelf stable milk and/or milk products pilot program came about through an expansion of the original pilot program that was established by the APC for Grade “A” low-acid aseptically processed and packaged milk and/or milk products. The original low-acid pilot program provided the framework for the regulation of Grade “A” fermented high acid shelf stable milk and/or milk products processed and packaged on a Low Acid Canned Foods (LACF) filed Aseptic Processing and Packaging System (APPS).

A pilot program has been established since 2009 whereby the APC outlined a process to address Grade “A” fermented high acid shelf stable milk and/or milk products processed and packaged on an FDA filed APPS. The pilot program has operated successfully and the APC is recommending an extension to allow time to evaluate the incorporation of the new Food Safety Modernization Act (FSMA) regulations into the PMO. The two (2) years will allow time to study, develop and evaluate the FSMA regulations and the formal training program for Grade

“A” fermented high acid shelf stable milk and/or milk products under a controlled pilot program.

The APC shall be responsible for the oversight of the NCIMS Aseptic Program addressing low-acid aseptically processed and packaged Grade “A” milk and/or milk products, low-acid retort processed after packaging milk and/or milk products, as well as Grade “A” fermented high acid shelf stable milk and/or milk products in consultation with FDA, including the development of forms, documents and guidance necessary to implement, evaluate and provide training as well as study current and new technology and its application. The APC shall provide a report to the 2019 NCIMS.

**C. Proposed Solution**

Changes to be made on page(s):		131	of the (X - one of the following):
X	2015 PMO		2015 EML
	2015 MMSR		2400 Forms
	2015 Procedures		2015 Constitution and Bylaws

**MAKE THE FOLLOWING CHANGES TO THE 2015 PMO:**

~~Strikeout~~ 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 131:*

11. Aseptically processed and packaged low-acid milk and/or milk products in the definition of Milk Products of this *Ordinance* shall be considered to be Grade “A” milk and/or milk products. The sources(s) of the milk and/or milk products used to produce aseptically processed and packaged low-acid milk and/or milk products shall be IMS listed. Aseptically processed and packaged low-acid milk and/or milk products shall be labeled “Grade “A”” and meet Section 4 labeling requirements of this *Ordinance*. The milk plant or portion of the milk plant that is producing aseptically processed and packaged low-acid milk and/or milk products shall be awarded a Milk Sanitation Compliance Rating of at least ninety percent (90%) and an Enforcement Rating equal to the local supply, or equal to ninety percent (90%) or higher, or if the Enforcement Rating is below ninety percent (90%) on a rating, a re-rating shall occur within (6) months of this rating. Both the Milk Sanitation Compliance and Enforcement Ratings shall be equal to ninety percent (90%) or higher on the re-rating or the supply is

considered in violation of this Section. In the case of HACCP/Aseptic listings, an acceptable HACCP listing by a SRO is required. For milk plants that produce aseptically processed and packaged Grade “A” low-acid milk and/or milk products, prior to the milk plant participating in the NCIMS Aseptic Processing and Packaging Program or the Aseptic Pilot Program the Regulatory Agency’s and Rating Agency’s personnel shall have completed a training course that is acceptable to the NCIMS and FDA addressing the procedures for conducting regulatory inspections and ratings under the NCIMS Aseptic Processing and Packaging Program or Aseptic Pilot Program. The NCIMS Aseptic Pilot Program addressing ~~aseptically processed and packaged~~ Grade “A” fermented high-acid shelf stable milk and/or milk products regulated under 21 CFR Parts 108 and/or ~~40~~ 117 shall expire on December 31, ~~2017~~ 2019, unless extended by future conference action. ...

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36th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #:	302 *Procedures Change
Committee:	MMSR

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

**A. Summary of Proposal**

To clarify the purpose of Memorandums of Information (M-I)

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

M-I's are issued as points of information but in some instances are being enforced as if they interpret a conference document. This causes confusion in the program.

**C. Proposed Solution**

Changes to be made on page(s):		4-5	of the (X - one of the following):	
<input type="checkbox"/>	2015 PMO	<input type="checkbox"/>	2015 EML	
<input type="checkbox"/>	2015 MMSR	<input type="checkbox"/>	2400 Forms	
<input checked="" type="checkbox"/>	2015 Procedures	<input type="checkbox"/>	2015 Constitution and Bylaws	

**S. MEMORANDUM OF INFORMATION (M-I):** A memorandum issued by PHS/FDA providing the transmittal of administrative and miscellaneous information by PHS/FDA to PHS/FDA Regional staff and Regulatory/Rating Agencies. They are for information only and are not intended to interpret or clarify the intent of the Grade “A” PMO and Related Documents. Because they are for information only, they are not to be enforced. M-Is can only be used for the purpose of making Sanitation Compliance Ratings if the M-I is specifically named in a conference document which has been voted on and approved by the conference.

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# 36th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	303 *Procedures Change
Committee:	MMSR/HACCP

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

## A. Summary of Proposal

This Proposal provides clarity, consistency and uniformity to the text contained within the *Procedures* document. It requires that a BTU shall obtain a Sanitation Compliance Rating (SCR) of ninety (90) or above to be IMS listed, which will align BTU IMS listings with milk plants, receiving stations and transfer stations for consistency and uniformity purposes. It provides clarity to BTU area ratings and eliminates the term “Reinspection” for milk plants, receiving stations and transfer stations and replaces it with the term “Re-Rating” for consistency and uniformity purposes. It also clarifies languages related to milk plant, receiving station or transfer station IMS listings with an attached supply of Grade “A” raw milk and if a milk plant’s, receiving station’s, transfer station’s or a single farm’s (BTU) permit is suspended that the IMS listing shall be withdrawal.

This Proposal also requests that the Chair assign to the NCIMS MMSR Committee and HACCP Implementation Committee to work with FDA to conduct a comprehensive and thorough review of the *Procedures* and to submit a Proposal to the 2019 Conference that will provide a proposed solution that will provide editorial clarity, consistency and uniformity to text contained throughout the *Procedures*.

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

FDA Milk Safety Team (MST) conducted a thorough and comprehensive review of the *Procedures* to identify inconsistencies and lack of uniformity in text throughout the document and to provide clarity to text throughout the document where warranted related to the Items addressed in A. above. MST also reviewed the document for rating and listing practices that are no longer being utilized; or utilized by a few States; or have been modified over the course

of many years and the *Procedures* may not have been updated to reflect all of those modifications or current practices. This MST review was partially triggered by numerous questions obtained from newly FDA certified Milk Sanitation Rating Officers (SROs), newly appointed Grade “A” Milk Safety Program managers and an extremely long period of time since the last time that the MST conducted a thorough and comprehensive review of the *Procedures* related to the items addressed in A. above.

By requiring that a BTU shall obtain a Sanitation Compliance Rating (SCR) of ninety (90) or above to be IMS listed will align BTU IMS listings with milk plants, receiving stations and transfer stations for consistency and uniformity purposes. Currently, this proposed requirement that a BTU shall obtain a SCR of ninety (90) or above to obtain an IMS listing is not cited in the *Procedures* document. The practice of allowing representatives of a BTU (area or individual milk shipper) to sign a “Permission to Publish” for a rating with a SCR of less than ninety (<90) is being practiced by a few States; however, the majority of the States do not offer or allow this practice. Even if a State provides for a BTU (area or individual milk shipper) to sign a “Permission to Publish” on a rating with a SCR of less than ninety (<90) the BTU (area or individual milk shipper) still cannot ship the raw milk to an IMS listed milk plant, receiving station or transfer station. An IMS listed milk plant, receiving station or transfer station that receives raw milk from an IMS listed source with a SCR of less than ninety (<90) shall be immediately withdrawn from the *IMS List*. By making this change it brings BTUs in alignment with the IMS listing requirements for milk plants, receiving stations and transfer stations and eliminates the confusion that if a BTU is IMS listed they still cannot ship raw milk to an IMS listed milk plant, receiving station or transfer station with a SCR of less than ninety (<90).

This Proposal also eliminates the practice of when a “Reinspection” of a milk plant, receiving station or transfer station following a FDA check rating “indicates a level of sanitation compliance below that of the published rating, the Rating Agency shall submit such new rating for publication, provided that if the reinspection indicates a level of sanitation compliance equal to or better than the published rating, the PHS/FDA Regional Office or PHS/FDA MST for TPCs shall be so advised by the Rating Agency and no further action shall be necessary”. This practice is only being utilized by a few States as the majority of the States choose to get credit for the reinspection and have the reinspection with a new expiration date be listed on the *IMS List*. By eliminating this provision, it would eliminate the potential to have a reinspection conducted that would not affect the current IMS listing for a milk plant, receiving station or transfer station and a subsequent rating being required to be conducted because the current IMS listing expires in a month or two. It also will clarify and provide a consistent and uniform practice related to the provision for a “Reinspection” following a check rating for milk plants, receiving stations or transfer stations.

By eliminating the provisions for a “Reinspection” following a check rating for milk plants, receiving stations or transfer stations as cited above, for consistency and uniformity purposes the term “Reinspection” shall be replaced with the term “Re-Rating” as this is what is being utilized for BTUs (Dairy Farms (Raw Milk)). Therefore, for consistency and uniformity purposes, a “Re-Rating” applies to an IMS listed milk shipper when their current IMS listing is not being withdrawn; however because of the SCR obtained from a check rating it requires a “Re-Rating” within a specified period of time; and when an Enforcement Rating (ER) of less than ninety (<90) obtained from a rating it requires a “Re-Rating” within a specified period of



time.

Also, for consistency and uniformity purposes the term “New Rating” applies for the rating conducted after an IMS listing is withdrawn following a rating or check rating.

**C. Proposed Solution**

Changes to be made on page(s):	iv, v, 2, 3, 5, 11-16, 19-22, 32-35, 38, 40-41, 43, 46-49 and 53	of the (X - one of the following):
<u>        </u> 2015 PMO	<u>        </u>	2015 EML
<u>        </u> 2015 MMSR	<u>        </u>	2400 Forms
<u>  X  </u> 2015 Procedures	<u>        </u>	2015 Constitution and Bylaws

***MAKE THE FOLLOWING CHANGES TO THE 2015 PROCEDURES:***

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

*Page iv:*

**ABBREVIATIONS AND ACRONYMS ...**

EML (*Evaluation of Milk Laboratories*)

ER (Enforcement Rating) ...

LOU (Letter of Understanding)

LPET (Laboratory Proficiency and Evaluation Team) ...

*Page v:*

RMS (Regional Milk Specialist)

RPPS (Retort Processed and Packaging System)

SCC (Somatic cell Count)

SCR (Sanitation Compliance Rating)

SMEDP (Standard Methods for the Examination of Dairy Products) ...

*Page 2:*

**SECTION III. DEFINITIONS ...**

A. **ADVERSE ACTION:** A ~~re-inspection~~, re-rating or withdrawal of the IMS ~~Listing~~ 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.

**B. AREA RATING:** An area rating, if used, shall apply to Grade “A” raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging and/or retort processed after packaging. An area rating consists of more than one (1) producer group operating under the supervision of a single Regulatory Agency and which is rated as a single entity and has attained an acceptable Sanitation Compliance Rating (SCR) and Enforcement Rating (ER) necessary for inclusion on the IMS List. An individual dairy farm shall only be included in one (1) ~~IMS Listing~~ listing. ...

**D. BULK TANK UNIT (BTU):** A dairy farm or group of dairy farms from which Grade “A” raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging and/or retort processed after packaging is collected under the routine supervision of one (1) Regulatory Agency and which is rated as a single entity and ~~given a~~ has attained an acceptable Sanitation Compliance Rating (SCR) and Enforcement Rating (ER) necessary for inclusion on the IMS List. An individual dairy farm shall only be included in one (1) ~~IMS Listing~~ listing.

Page 3:

**L. IMS LISTED MILK SHIPPER:** An interstate milk shipper (BTU, receiving station, transfer station, ~~or milk plant~~ or a milk plant, receiving station or transfer station with an attached supply of Grade “A” raw milk), which has been certified by a Rating Agency as having attained ~~the~~ an acceptable Sanitation Compliance Rating (SCR) and Enforcement Ratings Rating (ER) necessary for inclusion on the IMS List. The ratings are based on compliance with the requirements of the *Grade “A” PMO* and were made in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers (MMSR)*. For milk plants that produce aseptically processed and packaged Grade “A” low-acid milk and/or milk products and/or retort processed after packaged Grade “A” low-acid milk and/or milk products, prior to the milk plant participating in the NCIMS Aseptic Processing and Packaging Program and/or Retort Processed after Packaging Program, respectively, the Regulatory Agency’s regulatory and Rating Agency’s rating personnel shall have completed a training course that is acceptable to the NCIMS and PHS/FDA addressing the procedures for conducting regulatory inspections and ratings under the NCIMS Aseptic Processing and Packaging Program and/or Retort Processed after Packaging Program. An individual dairy farm shall only be included in one (1) IMS listing.

**M. INDIVIDUAL RATING:** An individual rating is the rating of a single producer group, dairy farm, milk plant, receiving station, and/or transfer station or a milk plant, receiving station or transfer station with an attached supply of Grade “A” raw milk under the supervision of a single Regulatory Agency and has attained an acceptable Sanitation Compliance Rating (SCR) and Enforcement Rating (ER) necessary for inclusion on the IMS List. Milk plants producing Grade “A” condensed and/or dried milk and/or milk products and/or Grade “A” condensed and/or dry whey and/or whey products may be rated separately from the same milk plant producing other Grade “A” milk and/or milk products, provided each IMS listing holds a separate permit. Milk plants that produce aseptically processed and packaged Grade “A” low-acid milk and/or milk products, and/or retort processed after packaged Grade “A” low-acid milk and/or milk products and pasteurized and/or ultra-pasteurized Grade “A” milk and/or milk products shall be rated

separately. Provided that an NCIMS HACCP ~~milk plant~~ IMS listing for milk plants that produces aseptically processed and packaged Grade “A” low-acid milk and/or milk products and/or retort processed after packaged Grade “A” low-acid milk and/or milk products shall have only an NCIMS HACCP IMS listing. An individual dairy farm shall only be included in one (1) ~~IMS Listing listing~~. ...

Page 5:

**T. MEMORANDUM OF INTERPRETATION (M-a):** A memorandum issued by PHS/FDA, following the *Procedures* document, providing clarification of the intent or meaning of wording related to the *Grade “A” PMO, 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), Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (Procedures)* and the *Evaluation of Milk Laboratories (EML)* to PHS/FDA Regional staff and Regulatory/Rating Agencies. ...

## SECTION IV. OVERSIGHT AND RESPONSIBILITIES

### A. PHS/FDA RESPONSIBILITIES ...

#### 5. Electronic Publication of Sanitation Compliance Ratings (SCRs) and Enforcement Ratings (ERs) ...

Page 11:

a. PHS/FDA shall provide an electronic publication of the *IMS List* on their web site. The electronic *IMS List* is available at ~~<http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/FederalStatePrograms/InterstateMilkShippersList/default.htm>~~ <http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2007965.htm>. The Sanitation Compliance Ratings (SCRs) of IMS listed milk shippers, the Enforcement Ratings (ERs) of Regulatory Agencies and the IMS ~~Listed~~ listed shippers' expiration rating dates contained on the electronic publication are certified by the Rating Agency to be those established by ratings conducted in accordance with 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)* by certified SROs when FORM FDA 2359i-~~Interstate Milk Shipper's Report~~ INTERSTATE MILK SHIPPER'S REPORT is signed and submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs for publication.

BTUs shall achieve a SCR of 90 percent (90%) or higher in order to be eligible for a listing on the *IMS List*.

Milk plants, receiving stations and transfer stations shall achieve a ~~Sanitation Compliance Rating~~ SCR of 90 percent (90%) or higher, except as cited in Section VIII., C.,5. for NCIMS HACCP listings, in order to be eligible for a listing on the *IMS List*. Individual

~~Sanitation Compliance Rating scores~~ SCRs for transfer and receiving stations and milk plants, receiving stations and transfer stations will not be identified on the *IMS List*.

**NOTE:** If milk plants, receiving stations or transfer stations are rated with an attached supply of Grade “A” raw milk, then both the dairy farm(s) and the individual milk plant, receiving station or transfer station, respectively shall achieve a SCR of ninety percent (90%) or higher in order to be eligible for a listing on the *IMS List*.

PHS/FDA shall update the *IMS List* not less than monthly: ...

*Page 12:*

6. Electronic Publication of Qualified Standardized ~~PHS/FDA Regional Milk Specialists RMSs State and TPC Personnel~~ and PHS/FDA Certified SROs, LEOs, SSOs and SSCs
  - a. PHS/FDA shall provide a list of PHS/FDA ~~Regional Milk Specialists RMSs~~ and SROs whose rating methods and interpretations of the ~~PHS/FDA recommended~~ Grade “A” *PMO* have been evaluated and standardized or certified, respectively, by PHS/FDA on the *IMS List*. ...
7. Interpretations and Editorial Updates
  - a. Interpretations of the ~~PHS/FDA recommended~~ Grade “A” *PMO*, ~~and related documents~~ *MMSR, Procedures and the Evaluation of Milk Laboratories (EML)* as referenced in Section VI. of these *Procedures* shall be issued to the Regulatory and Rating Agencies in accordance with the following procedure: ...

*Page 13:*

8. PHS/FDA Check Ratings of the Sanitation Compliance Status of IMS Listed ~~Interstate~~ Milk Shippers ...
  - 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~~ and withdrawals of 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.

*Page 14:*

- d. In any case a check rating cannot be conducted with a greater frequency than the official rating ~~or~~ for IMS listing. This is interpreted to mean that once a rating, re-rating or new rating has been conducted the IMS listed milk shipper can be subjected to a check rating.

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

d. In any case an audit cannot be conducted with a greater frequency than the official IMS certification listing. This is interpreted to mean that once an audit, re-audit or new audit has been conducted the IMS listed milk shipper can be subjected to a PHS/FDA audit.

Page 15:

**B. STATE, TPC, AND SSC RESPONSIBILITIES**

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

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

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

d. ~~When a certified interstate an IMS listed milk shipper's supply, raw or pasteurized, changes status because of degrading, permit revocation, BTU or milk plant, receiving station or transfer station with an attached supply of Grade "A" raw milk has a significant change of either a decrease or an increase of twenty-five percent (25%) or higher in the number of dairy farms included in a BTU or attached supply of Grade "A" raw milk, or change in the Sanitation Compliance SCR or Enforcement Rating to less than ninety percent (90%), the shipping State or TPC shall immediately notify all known receiving States and/or TPCs and the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs the Regulatory Agency shall notify the Rating Agency and a re-rating shall be conducted within thirty (30) days of this notification.~~

**NOTE:** If a dairy farm(s) is included in an IMS listing of a milk plant, receiving station or transfer station with an attached supply of Grade "A" raw milk then the milk plant, receiving station or transfer station, respectively, shall be included in the re-rating conducted within thirty (30) days. Both the dairy farm(s) and the individual milk plant, receiving station or transfer station, respectively shall achieve a SCR of ninety percent (90%) or higher in order to be eligible for a listing on the *IMS List*.

e. ~~When a certified interstate an IMS listed milk shipper's supply, raw or pasteurized, receives an Enforcement Rating ER of less than ninety percent (90%), the State or TPC~~

~~shall immediately notify all known receiving States and/or TPCs and 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 SCR and/or Enforcement Rating ER 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 ER 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 known receiving States and/or TPCs and the appropriate PHS/FDA Office or PHS/FDA MST for TPCs.~~

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~~f. When an existing rating IMS listing is no longer valid because of a change in the SCR or ER to less than ninety percent (90%), when cited in e. above; or a listed milk plant plant's, receiving station station's, and/or transfer station's or a dairy farm's (single dairy farm BTU) permit is has been suspended or revoked, the State or TPC shall within five (5) days immediately request PHS/FDA to withdraw the milk shipper from the IMS List and notify all known receiving States and/or TPCs. ...~~

~~h. The Rating Agency shall furnish their Regulatory Agency with copies of coded memoranda, including interpretations of the PHS/FDA recommended Grade "A" PMO, MMSR, Procedures and EML and rating procedures received from PHS/FDA.~~

~~1. When a certified listed IMS listing of a manufacturer of single-service containers and/or closures for milk and/or milk products changes status is no longer valid because of permit suspension and/or revocation or the withdrawal of their certification/listing based on a change in the Sanitation Compliance Rating SCR to less than eighty percent (80%); or permit suspension and/or revocation, the shipping State, TPC or SSC, as applicable, shall immediately request PHS/FDA to withdraw the single-service containers and/or closures manufacturer 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 and SSCs.~~

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

Page 19:

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

1.) Dairy Farms (Raw Milk)

A.) Action to be Taken

The following table shall be used to determine action to be taken if the ~~Sanitation Compliance Rating~~ SCR from a check rating of a an IMS listed milk shipper's dairy ~~farms~~ farm(s) indicates the IMS listed ~~Sanitation Compliance Rating~~ SCR is not justified:

**DAIRY FARMS FARM(S) (RAW MILK)**

<u>IMS LISTED SCR RATING</u>	<u>RE-RATING SCR FROM THE CHECK RATING</u>	<u>WITHDRAW IMS LISTING ACTION REQUIRED</u>
<u>100 to 90</u>	<u>100 to 85</u>	<u>No Action</u>
<u>100 to 90</u>	<u>84 to 80</u>	<u>Re-rate Within Sixty (60) Days SCR Shall Be Ninety Percent (90%) Or Higher To Maintain IMS Listing</u>
<u>100 to 90</u>	<u>79 or Less</u>	<u>Withdraw IMS Listing</u>
<u>89 to 84</u>	<u>83 to 80</u>	<u>79 or less</u>
<u>83</u>	<u>82 to 80</u>	<u>79 or less</u>
<u>82</u>	<u>81 to 80</u>	<u>79 or less</u>
<u>81 or less</u>	<u>80</u>	<u>79 or less</u>

Page 20:

B.) Re-Rating

When check rating data indicates that the ~~Sanitation Compliance Rating~~ SCR of a an IMS listed milk shipper's dairy ~~farms~~ farm(s) requires a re-rating, PHS/FDA shall ~~formally~~ officially notify the Rating Agency that a re-rating of the dairy ~~farms~~ farm(s) shall be required within sixty (60) days.

**NOTE:** If a dairy farm(s) is included in an IMS listing of a milk plant, receiving station or transfer station with an attached supply of Grade "A" raw milk then the milk plant, receiving station or transfer station, respectively, shall be included in the re-rating conducted within sixty (60) days. Both the dairy farm(s) and the individual milk plant, receiving station or transfer station, respectively shall achieve a SCR of ninety percent (90%) or higher in order to be eligible for a listing on the IMS List.

C.) Withdrawal of ~~Listed Rating~~ IMS Listing

When check rating data indicates that the ~~Sanitation Compliance Rating~~ SCR of a an IMS listed milk shipper's dairy ~~farms~~ farm(s) requires a withdrawal of their

~~listed rating~~ IMS listing, the Rating Agency, upon written recommendation of PHS/FDA, shall immediately withdraw the ~~current listed rating~~ IMS listing of the milk shipper and notify such milk shipper, the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs, 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.

**NOTE:** If a dairy farm(s) is included in an IMS listing of a milk plant, receiving station or transfer station with an attached supply of Grade “A” raw milk then the milk plant, receiving station or transfer station, respectively, shall be included in the new rating conducted in accordance to the time period cited above. Both the dairy farm(s) and the individual milk plant, receiving station or transfer station, respectively shall achieve a SCR of ninety percent (90%) or higher in order to be eligible for a listing on the IMS List.

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

A.) Action to be Taken

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

**MILK PLANTS, RECEIVING STATIONS AND/OR TRANSFER STATIONS**

<u>IMS LISTED RATING SCR</u>	<u>REINSPECTION SCR FROM THE CHECK RATING</u>	<u>WITHDRAW IMS LISTING ACTION REQUIRED</u>
100 to 90	<u>100 to 81</u> 80	79 or less <u>No Action</u>
<u>100 to 90</u>	<u>80</u>	<u>Re-rate Within Thirty (30) Days SCR Shall Be Ninety Percent (90%) Or Higher To Maintain IMS Listing</u>
<u>100 to 90</u>	<u>79 or Less</u>	<u>Withdraw IMS Listing</u>

B.) ~~Reinspection~~ Re-Rating

When check rating data indicates that the ~~Sanitation Compliance Rating~~ SCR of the an IMS listed milk plant, receiving station and/or transfer station requires a ~~reinspection~~ re-rating, PHS/FDA shall ~~formally~~ officially notify the Rating



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

**NOTE:** If the milk plant, receiving station or transfer station is included in an IMS listing with an attached supply of Grade “A” raw milk then the dairy farm(s) shall be included in the re-rating conducted within thirty (30) days. Both the dairy farm(s) and the individual milk plant, receiving station or transfer station, respectively, shall achieve a SCR of ninety percent (90%) or higher in order to be eligible for a listing on the IMS List.

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#### C.) ~~Listed Rating~~ IMS Listing

When check rating data indicates that the ~~Sanitation Compliance Rating~~ SCR of a an IMS listed milk plant, receiving station and/or transfer station requires a withdrawal of their ~~listed rating~~ IMS listing, the Rating Agency, upon written recommendation of PHS/FDA, shall immediately withdraw the ~~current listed rating~~ IMS listing of the milk shipper and notify such milk shipper, the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs, 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 a ~~listed rating~~ an IMS listing 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.

**NOTE:** If the milk plant, receiving station or transfer station is included in an IMS listing with an attached supply of Grade “A” raw milk then the dairy farm(s) shall be included in the new rating conducted in accordance to the time period cited above. Both the dairy farm(s) and the individual milk plant, receiving station or transfer station, respectively shall achieve a SCR of ninety percent (90%) or higher in order to be eligible for a listing on the IMS List.

3.) Single-Service Containers and/or Closures 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~~ SCR from an a PHS/FDA audit of a single-service containers and/or closures for milk and/or milk products manufacturer indicates the IMS certification listing is not justified:

**SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURERS**

<u>IMS LISTED SCR CERTIFICATION</u>	<u>WITHDRAW IMS CERTIFICATION LISTING SCR FROM THE AUDIT</u>	<u>ACTION REQUIRED</u>
100 to 80	<del>79 or less</del> <u>100 to 80</u>	<u>No Action</u>
<u>100 to 80</u>	<u>79 or Less</u>	<u>Withdraw IMS Certification Listing</u>

B.) Withdrawal of IMS Certification Listing

When PHS/FDA audit data indicates that the ~~Sanitation Compliance Rating~~ SCR of a single-service containers and/or closures manufacturer requires a withdrawal of their IMS certification listing, the Rating Agency upon written recommendation of PHS/FDA, shall immediately withdraw the ~~current~~ IMS certification listing of the single-service containers and/or closures manufacturer and notify such single-service containers and/or closures manufacturer, the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs, and all known receiving States and TPCs thereof, in accordance with Section IV., B., 1.1. 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. ...

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5.) If a Rating Agency indicates that it is not in a position to make a re-rating for dairy farms; a new rating for dairy farms, milk plants, receiving stations or transfer stations; or a new certification listing for single-service containers and/or closures for milk and/or milk product manufacturers within the sixty (60) day period or a ~~reinspection~~ re-rating for milk plants, receiving stations or transfer stations within the thirty (30) days day period, PHS/FDA shall identify those States or TPCs ~~in the next listing of on~~ 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 a single dairy farm BTU; or a single-service containers and/or closures manufacturer from the *IMS List* as provided for in Section IV., B., 1.f. and B., 1.l., respectively, PHS/FDA shall, after five (5) days, provide this information to all known receiving States and/or TCPs.

## SECTION V. QUALIFICATIONS AND CERTIFICATIONS

### B. SUPERVISION REQUIREMENTS

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

**NOTE:** All Grade "A" raw, pasteurized and ultra-pasteurized milk and/or milk products required sampling and testing is to be conducted only when there are test methods available that are validated by FDA and accepted by the NCIMS. Grade "A" milk and/or milk products that do not have validated and accepted test methods are not required to be tested. (Refer to M-a-98, latest revision, for the specific Grade "A" milk and/or milk products that have FDA validated and NCIMS accepted test methods.)

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### J. AREA RATINGS

1. Area ratings shall be made at a frequency of not less than once every twenty-four (24) months.

**NOTE:** If Grade "A" raw milk from an area rating is rated with a milk plant, receiving station or transfer station as an attached supply of Grade "A" raw milk, then both the dairy farm(s) and the individual milk plant, receiving station or transfer station, respectively shall achieve a SCR of ninety percent (90%) or higher in order to be eligible for a listing on the *IMS List*.

~~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). If an area rating receives a SCR of less than ninety percent (90%), the Rating Agency shall issue written notification to the area's milk shippers that their *IMS listing* will be withdrawn. Such written notification shall be dated within five (5) working days following the earliest rating date. A new rating of the area shall be conducted after written notification from an authorized representative of the Regulatory Agency to the Rating Agency that the area is in substantial compliance. The new rating of the area shall be initiated in not more than fifteen (15) days, from the date of receipt of the written notification from the Regulatory Agency, unless the Rating Agency has a reason to believe a new rating~~

within a lesser time would result in an acceptable rating.

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3. If an area rating receives an ~~the Enforcement Rating ER is of~~ less than ninety percent (90%), the ~~milk shipper area~~ may be IMS listed. A re-rating of the area shall be conducted by the Rating Agency within six (6) months of the earliest rating date of the this 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 SCR and Enforcement Rating ER~~, shall be ~~completed~~ initiated in ~~no~~ not more than fifteen (15) days from the date of receipt of the written notification from an authorized representative of the Regulatory Agency.

#### K. **INDIVIDUAL RATINGS**

1. Individual ratings shall be made at a frequency of not less than once every twenty-four (24) months.

**NOTE:** If Grade "A" raw milk is rated with a milk plant, receiving station or transfer station as an attached supply of Grade "A" raw milk, then both the dairy farm(s) and the individual milk plant, receiving station or transfer station, respectively shall achieve a SCR of ninety percent (90%) or higher in order to be eligible for a listing on the IMS List.

2. If an individual IMS listed milk shipper receives a ~~Sanitation Compliance Rating SCR~~ of less than ninety percent (90%), the Rating Agency shall issue written notification to the IMS listed milk shipper that their IMS listing will be withdrawn. Such written notification shall be dated within five (5) working days following the earliest rating date., ~~a re-rating~~ A new 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~~ The new rating shall be ~~completed~~ initiated in ~~no~~ not more than fifteen (15) days, from the date of receipt of the written notification from an authorized representative of the milk shipper, unless the Rating Agency has a reason to believe a new rating within a lesser time would result in an acceptable rating. ...

4. If an individual IMS listed milk shipper receives an ~~Enforcement Rating ER~~ of less than ninety percent (90%), the milk shipper may be IMS listed, ~~and a~~ A re-rating of ~~both the Sanitation Compliance and Enforcement~~ the milk shipper shall be ~~completed~~ conducted by the Rating Agency within six (6) months of the earliest rating date of the this 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 SCR and Enforcement Rating ER~~, shall be ~~completed~~ initiated in ~~no~~ not more than fifteen (15) days from the date of receipt of the written notification from an authorized representative of the Regulatory Agency.

#### L. **RE-RATINGS NEW RATINGS**

Whenever a rating results in the withdrawal of the IMS listing of a milk shipper, ~~a request for a~~

~~re-rating the effective date for the re-rating shall be determined from the date of the letter of written notification by the Rating Agency shall provide written notification to the IMS listed milk shipper of their withdrawal from the IMS List. Such letter is to written notification shall be dated within five (5) working days following the earliest rating date of the rating. If an authorized representative of the milk shipper requests in writing a new rating stating that the milk shipper is in substantial compliance, the effective date for the new rating shall be determined from the date of the written notification from the milk shipper. A new rating shall be initiated in not more than fifteen (15) days, from the date of receipt of the written notification from an authorized representative of the milk shipper, unless the Rating Agency has a reason to believe a new rating within a lesser time would result in an acceptable rating. ...~~

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**N. SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURER CERTIFICATIONS IMS CERTIFICATION LISTINGS ...**

3. If a single-service containers and/or closures for milk and/or milk products manufacturer receives a ~~Sanitation Compliance Rating~~ SCR of less than eighty percent (80%), the Rating Agency or SSC, as applicable, shall issue written notification to the IMS certified listed single-service containers and/or closures for milk and/or milk products manufacturer that their IMS certification listing will be withdrawn. Such written notification shall be dated within five (5) working days following the earliest certification date., a re-certification A new certification listing 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~~ The new certification shall be completed initiated in not more than fifteen (15) days, from the date of receipt of the written notification from an authorized representative of the single-service containers and/or closures for milk and/or milk products manufacturer, 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~~ certification listing.

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

Whenever a certification results in the withdrawal of the IMS certification listing of a single-service containers and/or closures for milk and/or milk products manufacturer, ~~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~~ the Rating Agency shall provide written notification to the single-service containers and/or closures for milk and/or milk products manufacturer of their withdrawal from the IMS List. Such letter is to written notification shall be dated within five (5) working days following the earliest certification list date of the certification. If an authorized representative of the single-service containers and/or closures for milk and/or milk products manufacturer requests in writing a new certification stating that the single-service containers and/or closures facility is in substantial compliance, the effective date for the new certification shall be determined from the date of the written notification from an authorized representative of the single-service containers and/or closures for milk and/or milk products manufacturer. A new certification shall be initiated in not more

than fifteen (15) days, from the date of receipt of the written notification from an authorized representative of the single-service containers and/or closures for milk and/or milk products manufacturer, unless the Rating Agency has a reason to believe a new certification within a lesser time would result in an acceptable IMS certification listing. ...

## **SECTION VI. STANDARDS ...**

### **A. POINTS BEYOND THE LIMITS OF ROUTINE INSPECTION**

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

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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~~ SCRs 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~~ SCRs/Certification Listings of single-service containers and/or closures for milk and/or milk products manufacturers. ...

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

### **B. HACCP DEFINITIONS:**

In addition to the definitions in Section III., the following shall apply to milk plants, receiving stations and transfer stations with NCIMS HACCP Systems regulated under Appendix K. of the *Grade "A" PMO*. ...

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**8. REGULATORY/RATING AGENCY PROGRAM EVALUATION:** Definition ~~BB~~ CC. in Section III. shall apply as written, except that for purposes of this Section the words "check ratings of IMS ~~Listed Shippers~~ listed milk shippers" shall include "PHS/FDA audits of IMS ~~Listed Shippers~~ listed milk shippers". ...

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

5. Electronic Publication of Sanitation Compliance Ratings (SCRs) and Enforcement Ratings (ERs)

Section IV., A. 5. shall apply as written, except that for purposes of this Section:

a. PHS/FDA shall provide an electronic publication of the *IMS List* on their web site. The electronic *IMS List* is available at ~~http://www.fda.gov/Food/Food-Safety/Product-SpecificInformation/MilkSafety/FederalStatePrograms/InterstateMilkShippersList/default.htm~~  
http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2007965.htm. The NCIMS HACCP IMS listings and IMS Listed listed milk shipper's expiration IMS listing dates contained in the electronic publication are certified by the Rating Agency to be those established by NCIMS HACCP IMS listing audits conducted in accordance with the *MMSR* by HACCP certified SROs when FORM FDA 2359i-~~Interstate Milk Shipper's Report~~ INTERSTATE MILK SHIPPER'S REPORT is signed and submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs for electronic publication. ....

6. Electronic Publication of Qualified Standardized PHS/FDA Regional Milk Specialists RMSs, State and TPC Personnel and PHS/FDA Certified SROs, LEOs, SSO and SSCs

Section IV., A. 6. shall apply as written, except that for purposes of this Section:

PHS/FDA shall provide a list of PHS/FDA ~~Regional Milk Specialists~~ RMSs and SROs whose NCIMS HACCP IMS listing methods and interpretations of the ~~PHS/FDA recommended~~ Grade "A" PMO have been evaluated and standardized or certified, respectively, by PHS/FDA on the *IMS List*. ...

8. PHS/FDA Audits of NCIMS HACCP IMS Listings ...

d. Except as provided for in Sections VIII., C. 8. i., VIII., D. 2., and VIII., D. 7. c.2.)A.) a PHS/FDA NCIMS HACCP audit shall not be conducted with a greater frequency than the official NCIMS HACCP IMS listing. This is interpreted to mean that once an audit, re-audit or new audit has been conducted the IMS listed milk shipper can be subjected to a PHS/FDA HACCP audit. ...

g. If a dairy ~~farms~~ farm(s) ~~are~~ is listed with a NCIMS HACCP IMS listed milk plant, receiving station or transfer station, the dairy farms farm(s) shall be check rated in conjunction with the PHS/FDA audit.

**NOTE:** If milk plants, receiving stations or transfer stations are audited with an attached supply of Grade "A" raw milk, then the dairy farm(s) shall achieve a SCR of ninety percent (90%) or higher and the individual milk plant, receiving station or transfer station, respectively shall receive an acceptable audit in order to be eligible for a listing on the

IMS List. ...

#### D. NCIMS HACCP RESPONSIBILITIES ...

##### 1. NCMS HACCP IMS Listings for Milk Plants, Receiving Stations and Transfer Stations

...

a. The Rating Agency of the shipping State or TPC shall certify the results of NCIMS HACCP IMS listing audits of each interstate milk shipper to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs, which in turn, shall transmit the NCIMS HACCP IMS listing audits to the PHS/FDA Headquarters Office for inclusion on the IMS List. (Refer to Section IV., A., 5.) The NCIMS HACCP IMS listing audit results, together with other pertinent information, shall be forwarded on an appropriate form (FORM FDA 2359i-INTERSTATE MILK SHIPPER'S REPORT).

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~~d. When a certified interstate an IMS listed milk shipper's supply, raw or pasteurized, changes status because of degrading, permit revocation, BTU or milk plant, receiving station or transfer station with an attached supply of Grade "A" raw milk has a significant change of either a decrease or an increase of twenty-five percent (25%) or higher in the number of dairy farms; included in a BTU or attached supply of Grade "A" raw milk, change in the Sanitation Compliance or Enforcement Rating to less than ninety percent (90%), or a change in HACCP listing status, the shipping State or TPC shall immediately notify all known receiving States and/or TPCs and the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs the Regulatory Agency shall notify the Rating Agency and a re-rating shall be conducted within thirty (30) days of this notification.~~

NOTE: If a dairy farm(s) is included in a NCIMS HACCP IMS listing of a milk plant, receiving station or transfer station with an attached supply of Grade "A" raw milk, then the milk plant, receiving station or transfer station, respectively, shall be included in the re-audit conducted within thirty (30) days. The dairy farm(s) shall achieve a SCR of ninety percent (90%) or higher and the individual milk plant, receiving station or transfer station, respectively shall receive an acceptable re-audit in order to be eligible for a listing on the IMS List.

~~f. When a NCIMS HACCP IMS listing is no longer valid because of a change in the attached supply of Grade "A" raw milk's SCR or ER to less than ninety percent (90%), when cited in IV., B. 1., e.; or a change in the NCIMS HACCP IMS listing status; or a listed milk plant plant's, receiving station station's, and/or transfer station's and/or attached supply of Grade "A" raw milk dairy farm's (single dairy farm BTU) permit is has been suspended or revoked, the State or TPC shall within five (5) days immediately request the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs to withdraw the milk shipper from the IMS List and notify all known receiving States and/or TPCs.~~

h. The Rating Agency shall furnish their Regulatory Agency with copies of coded memoranda, including interpretations of the PHS/FDA recommended Grade "A" PMO,



MMSR, Procedures and EML and NCIMS HACCP IMS listing procedures received from PHS/FDA. ...

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

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

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B.) Re-Audit

If deficiencies and/or non-conformities are significant to the point that timely correction is necessary, but do not require an immediate withdrawal of certification from the IMS List, the deficiencies and/or non-conformities shall be corrected and the correction confirmed by a re-audit conducted by an appropriate listing official a HACCP certified SRO. The period of time allowed to correct the NCIMS HACCP System deficiencies and/or non-conformities shall be specified in writing by the PHS/FDA Regional Milk Specialist RMS and/or PHS/FDA MST personnel for TPCs in writing to the State or TPC. A re-audit is not required if the deficiencies and/or non-conformities are immediately corrected, or are minor and can be corrected within a the specified time period, which will neither present a risk to the public health nor result in Grade "A" milk and/or milk product adulteration.

**NOTE:** If a dairy farm(s) is included in a NCIMS HACCP IMS listing of a milk plant, receiving station or transfer station with an attached supply of Grade "A" raw milk then the milk plant, receiving station or transfer station, respectively, shall be included in the re-audit conducted in accordance to the time period cited above. The dairy farm(s) shall achieve a SCR of ninety percent (90%) or higher and the individual milk plant, receiving station or transfer station, respectively shall receive an acceptable re-audit in order to be eligible for a listing on the IMS List.

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

If the re-audit indicates that the HACCP System deficiencies and/or non-conformities have been corrected, the Rating Agency shall ~~notify~~ submit the acceptable re-audit report with the required forms to the appropriate Regional Office of PHS/FDA or PHS/FDA MST for TPCs and further action shall not be necessary for IMS listing.

C.) Withdrawal of Certification IMS Listing ...

1.) A NCIMS HACCP IMS listing shall be requested to be withdrawn when

~~CLE's one (1) or more CLEs~~ have been noted on FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT indicating that the milk plant, receiving station or transfer station has failed to recognize or correct a deficiency(ies) and/or nonconformity(ies) indicating: ...

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iv.) Milk is received from a supply other than a ~~NCIMS~~ an IMS listed source ~~or from a listed source with a Sanitation Compliance Rating below ninety percent (90%).~~ ...

7. **OTHER NCIMS REQUIREMENTS:** Including a milk supply from a ~~an NCIMS~~ IMS listed source(s) ~~with a Sanitation Compliance Rating(s) SCR(s) of ninety percent (90%) or better~~ and a drug residue control program implemented.

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4.) When PHS/FDA audit data indicates that the milk plant, receiving station and/or transfer station or attached supply of Grade "A" raw milk, if applicable, requires a withdrawal of ~~certification~~ their IMS listing, the Rating Agency, upon written recommendation of the PHS/FDA, shall immediately withdraw the ~~current certification~~ IMS listing of the milk shipper and notify such milk shipper, the appropriate PHS/FDA Region Office or PHS/FDA MST for TPCs, and all known receiving States and/or TPCs thereof, in accordance with Section IV., B..1.d. In case of withdrawal, a new audit 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 audit listing within a lesser time period would result in an acceptable IMS 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 by PHS/FDA.

**NOTE:** If a dairy farm(s) is included in a NCIMS HACCP IMS listing of a milk plant, receiving station or transfer station with an attached supply of Grade "A" raw milk then the milk plant, receiving station or transfer station, respectively, shall be included in the new audit conducted in accordance to the time period cited above. The dairy farm(s) shall achieve a SCR of ninety percent (90%) or higher and the individual milk plant, receiving station or transfer station, respectively shall receive an acceptable audit in order to be eligible for a listing on the IMS List.

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## E. QUALIFICATIONS AND CERTIFICATIONS ...

### 3. NCIMS HACCP IMS Listing

a. An acceptable NCIMS HACCP IMS listing shall be substituted for an acceptable ~~Sanitation Compliance SCR and Enforcement Rating ER~~ for a milk plant, receiving station or transfer station participating in the NCIMS voluntary HACCP Program. FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT and FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT shall be completed as a part of all milk plant, receiving station or transfer station NCIMS HACCP listing audits, re-audits and new audits. Provided that for NCIMS HACCP IMS listed milk plants producing aseptically processed and packaged Grade “A” low-acid milk and/or milk products and/or retort processed after packaging Grade “A” low-acid milk and/or milk products, FORM FDA 2359p-NCIMS ~~Aseptic~~ 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) shall be completed as a part of all HACCP aseptic and/or HACCP retort IMS listing audits.

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

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

~~a.~~ Individual milk plants, receiving stations or transfer stations participating in the NCIMS voluntary HACCP listing process Program shall be audited for an IMS listing at a frequency of not less than once every twenty-four (24) months.

~~b.~~ ~~If an audit for a NCIMS HACCP listing is unsatisfactory, another audit shall be conducted after written notification from an authorized representative of the IMS Listed shipper to the Rating Agency that the IMS Listed shipper is in substantial compliance. The audit shall be completed in not more than fifteen (15) days from the date of receipt of the notification, unless the Rating Agency has a reason to believe a new listing within a lesser time would result in an acceptable listing.~~

10. ~~Re Audits~~ New Audits

Whenever a NCIMS HACCP IMS listing audit results in the withdrawal of the NCIMS HACCP IMS listing of a milk shipper, ~~a request for a re-audit, the effective date for the re-audit shall be determined from the date of the letter of notification by the Rating Agency shall provide written notification to the NCIMS HACCP IMS listed milk shipper of their withdrawal from the IMS List.~~ Such letter is to written notification shall be dated within five (5) working days following the earliest listing date of the IMS listing audit. If an authorized representative of the milk shipper requests in writing a new audit stating that the milk shipper is in substantial compliance, the effective date for the new audit shall be determined from the date of the written notification from the milk shipper. A new audit

shall be initiated in not more than fifteen (15) days, from the date of receipt of the written notification from an authorized representative of the milk shipper, unless the Rating Agency has a reason to believe a new audit within a lesser time would result in an acceptable NCIMS HACCP IMS listing. ...

FDA requests the Chair to assign to the NCIMS MMSR Committee and HACCP Implementation Committee to work with FDA the task of conducting a comprehensive and thorough review of the *Procedures* and to submit a Proposal to the 2019 Conference that will provide a proposed solution that will provide clarity, consistency and uniformity to text contained throughout the *Procedures*.

*Grant FDA editorial license to work with the NCIMS Documents Review Committee to make editorial corrections that are identified in this Proposal, which may have been missed, wherever appropriate throughout the document to produce a more consistent and uniformly worded Procedures.*

**Note:** *This Proposal shall take immediate effect upon the issuance of the IMS-a Actions from the 2019 National Conference on Interstate Milk Shipments following FDA's concurrence with the NCIMS Executive Board.*

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36th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #:	304 *Procedures Change
Committee:	Appendix N/ Other Species

	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 reported to the third party database, distinguishing between bovine and non-bovine species milk.

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

Collection and reporting of drug residue summary data, separating data obtained from bovine milk from that obtained from other species, improves the accuracy of the data and annual reports that are published.

According to the FY 2015 Annual Report from the National Milk Drug Residue Data Base, a “validated test” is defined as “a test used for the screening of raw milk for drug residue, which has been evaluated by FDA in accordance with the standards established for the evaluation of these types of tests and found acceptable by the NCIMS in accordance with Appendix N of the PMO.”

In the report, Table 3 “Tests Conducted” is followed by two tables that show the data broken down into “Validated Tests Conducted” (Table 3A) and “Non-Validated Tests Conducted” (Table 3B). Similarly, details are provided in Table 4 (Tests Conducted by Industry and

Regulatory Agencies), Table 5 (Number of Tests Conducted by Family/Drug), and Table 6 (Number of Tests by Method by Family/Drug), each followed with additional tables with data for “Validated” and “Non-Validated” tests.

However, per M-a-85, milk drug residue screening tests are accepted only for certain species of milk (e.g., raw commingled cow, goat, sheep, water buffalo, camel). Without an indication of the species of milk on which the drug residue testing was performed, it is not possible to indicate whether a test is “validated” or “non-validated”.

<b>C. Proposed Solution</b>			
Changes to be made on page(s):		18	of the (X - one of the following):
<input type="checkbox"/>	2015 PMO	<input type="checkbox"/>	2015 EML
<input type="checkbox"/>	2015 MMSR	<input type="checkbox"/>	2400 Forms
<input checked="" type="checkbox"/>	2015 Procedures	<input type="checkbox"/>	2015 Constitution and Bylaws

**PROCEDURES (page 18):**

6. Reports to Database

Regulatory or Rating Agencies shall submit drug residue summary data to a third party database, distinguishing between data collected from bovine milk and from milk of other species by submitting two separate forms, one for bovine data and one for data from non-bovine species.

**OTHER:**

This proposal would require a change in the Instructions for Submitting Data For The National Milk Drug Residue Database Program and the National Milk Drug Residue Data Base Reporting Form. The top portion of the Database Reporting Form would need to include a field to indicate whether the milk was from bovine, or from non-bovine species. (For reference, the current reporting form is attached on the next page of this proposal.)

~~May 23, 1995~~ November 30, 2003

**NATIONAL MILK DRUG RESIDUE DATA BASE REPORTING FORM**

1. State: \_\_\_\_\_ 2. Grade A: \_\_\_\_\_ (Yes/No) 3. Analyzed By: \_\_\_\_\_

4. Source of Samples: \_\_\_\_\_ 5. Reporting Period: \_\_\_\_\_

6. Total Samples Analyzed: \_\_\_\_\_

7. Number of Positive Loads or Lots: \_\_\_\_\_

8. Pounds of Positive Milk (000's) \_\_\_\_\_

9. Disposition in Compliance with PMO/State Regulations: (Yes/No) \_\_\_\_\_

10. Contact Person and Organization: \_\_\_\_\_

11. Telephone Number : \_\_\_\_\_

12. Remarks: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

TESTS		
Test Code	Number of Tests	Number Positive
<b>TOTALS</b>		

Test Code Enter the Test Code. Note. If you enter a test code, you must enter data for the number of tests and the number positive.

Number of Tests Enter the number of tests.

Number of Positive Enter the number of tests which were positive.

Name: NMPF NCIMS Committee

Agency/Organization: National Milk Producers Federation

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36th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #:	305 *Procedures Change
Committee:	ICP/Appendix N

	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 for State Regulatory or Rating Agencies.

**C. Proposed Solution**

Changes to be made on page(s):		18	of the (X - one of the following):	
<input type="checkbox"/>	2015 PMO	<input type="checkbox"/>	2015 EML	
<input type="checkbox"/>	2015 MMSR	<input type="checkbox"/>	2400 Forms	
<input checked="" type="checkbox"/>	2015 Procedures	<input type="checkbox"/>	2015 Constitution and Bylaws	

*Procedures, Page 18:*

6. Reports to Database

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

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# 36th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #: 306 \*Procedures Change  
Committee:

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

## A. Summary of Proposal

This Proposal makes editorial corrections to SRO and LEO certification and related procedures as cited in the *Procedures* document. It clarifies that FDA may certify Sampling Surveillance Officers (SSOs) for the following categories: bulk milk hauler/samplers and plant samplers (dairy plant samplers and industry plant samplers); bulk milk hauler/samplers; or plant samplers (dairy plant samplers and industry plant samplers). It also clarifies that a certified SSO for a specified category may delegate to designated Sampling Surveillance Officers (dSSOs) for the same specified category.

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

To clarify in the *Procedures* that SSO certification and dSSO delegation for sampling surveillance activities may be for the following categories: bulk milk hauler/samplers and plant samplers (dairy plant samplers and industry plant samplers); bulk milk hauler/samplers; or plant samplers (dairy plant samplers and industry plant samplers) and to clarify the procedures for conducting such FDA SSO certifications and SSO delegations. To provide clarification to SRO certification and related procedures. Also, to provide editorial updates to the hearing procedure for revoking the certification of a SRO, SSO, LEO, or SSC.

**C. Proposed Solution**

Changes to be made on page(s):	23-28 and 31	of the (X - one of the following):
<u>        </u>	2015 PMO	<u>        </u> 2015 EML
<u>        </u>	2015 MMSR	<u>        </u> 2400 Forms
<u>  X  </u>	2015 Procedures	<u>        </u> 2015 Constitution and Bylaws

***MAKE THE FOLLOWING CHANGES TO THE 2015 PROCEDURES:***

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

**SECTION V. QUALIFICATION AND CERTIFICATIONS ...**

*Page 23:*

**D. MILK SANITATION RATING PERSONNEL ...**

2. Have been certified by PHS/FDA as a SRO and hold a valid certificate of qualification in one (1) or any combination of the following categories:
  - a. Dairy farms;
  - b. ~~milk pasteurization~~ Milk plants, including HACCP and/or aseptic processing and packaging, and/or retort processed after packaging, and/or single-service container and closure manufacturers, if appropriate; ~~dairy farms~~ and
  - c. ~~transfer~~ Transfer/receiving stations, including HACCP if appropriate.

The PHS/FDA shall issue a certificate, valid for three (3) years, to each individual who meets the criteria listed below, as applicable. Certification of a SRO shall qualify that SRO to perform ratings or HACCP listings, if applicable, upon the request of that State's or TPC's Regulatory/Rating Agency as long as the SRO's certification is valid. ...

*Page 24:*

3. A SRO applicant for initial certification shall be evaluated by PHS/FDA personnel in an independent side-by-side comparison of dairy facilities using the items listed on the appropriate inspection or evaluation report form. The applicant and PHS/FDA personnel shall be in agreement at least eighty percent (80%) of the time on each listed item. Comparison evaluations shall be performed on at least the following number of dairy facilities, applicable to the category(ies) that the applicant is being certified for:
  - a. Twenty-five (25) producer dairies. Milking time evaluations should be included.

- b. Five (5) ~~pasteurization~~ milk plants. Milk plants of varying sizes using, vat, HTST and HHST pasteurization; ultra-pasteurization; aseptic processing and packaging; and/or retort processed after packaging, if applicable, should be included in these evaluations. One (1) transfer or receiving station may also be included as one (1) of the required five (5) ~~pasteurization~~ milk plants.
- c. One (1) dry milk plant, if applicable. The dry milk plant may be used as one (1) of the required five (5) ~~pasteurization~~ milk plants.
- d. If HACCP certified for milk plants, receiving or transfer stations, in addition to meeting the requirements listed above for ~~pasteurization~~ milk plants for a SRO, one (1) mock-listing audit conducted separate from an official HACCP listing audit is required. (Refer to Section VIII., E.6. for additional HACCP certification procedures.)
- e. One (1) single-service ~~container~~ containers and ~~closure~~ closures manufacturing plant, if applicable.
- f. Five (5) receiving and/or transfer stations if certification is only for these types of facilities. ...

5. Applicants shall also have attended a course on “Milk Pasteurization Controls and Tests” and demonstrate proficiency in applying pasteurization equipment tests in at least one (1) ~~pasteurization~~ milk plant, including demonstrating knowledge of milk and/or milk product flow through individual pasteurization systems. ...

*Page 25:*

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

- a. Ten (10) producer dairies. Milking time evaluations should be included.
- b. Three (3) ~~pasteurization~~ milk plants. Milk plants of varying sizes using, vat, HTST and HHST pasteurization; ultra-pasteurization; aseptic processing and packaging; and/or retort processed after packaging, if applicable, should be included in these evaluations.
- c. One (1) dry milk plant, if applicable. The dry milk plant may be used as one (1) of the required three (3) ~~pasteurization~~ milk plants.
- d. If HACCP certified for milk plants, receiving or transfer stations, in addition to meeting the requirements listed above for ~~pasteurization~~ milk plants for a SRO, one (1)

~~re-certification~~ recertification audit is required. The ~~re-certification~~ recertification audit can be done independent as a mock-listing audit or as part of an official HACCP listing audit, at the discretion of the PHS/FDA personnel and SRO. (Refer to Section VIII., E.6. for additional HACCP certification procedures.)

e. One (1) single-service ~~container~~ containers and ~~closure~~ closures manufacturing plant, if applicable.

f. Three (3) receiving and/or transfer stations if certification is only for these types of facilities.

9. The requirements listed in 8. above will be dependent on a SROs range of responsibilities and the category(ies) in which they are being ~~certified~~ recertified. ...

10. To be ~~re-certified~~ recertified, a certified SRO shall have during the three (3) year period attended at least one (1) PHS/FDA Regional Milk Seminar, attended at least one (1) training course, which includes the auditing of milk plant NCIMS HACCP Systems and NCIMS HACCP IMS listing, if applicable, and attended at least one (1) PHS/FDA training course on “Special Problems in Milk Protection” or other training judged by PHS/FDA to be equivalent and appropriate.

11. Should PHS/FDA determine that a certified SRO has failed to demonstrate proficiency in the ~~above~~ applicable ~~re-certification~~ recertification procedures cited in 8. above; PHS/FDA ~~may~~ shall require the certified SRO to perform the applicable initial certification procedures cited in 3. above.

Page 26:

## F. SAMPLING SURVEILLANCE PERSONNEL

Evaluation of sampling practices shall be made by certified sampling surveillance personnel who meet the following requirements:

1. 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 delegated Sampling Surveillance Regulatory Agency Official (dSSO).

~~2~~2. Have submitted to PHS/FDA a written request for certification including the following: applicant name and contact information, education, training, work experience, ~~and~~ a list of training courses attended and the category for which certification is being requested.

~~3~~3. Have been certified by PHS/FDA as a SSO and hold a valid certificate of qualification in one (1) of the following categories:

a. Bulk milk hauler/samplers and plant samplers (dairy plant samplers and industry plant samplers);

b. Bulk milk hauler/samplers; or

c. Plant samplers (dairy plant samplers and industry plant samplers).

The PHS/FDA shall issue a certificate, valid for three (3) years, to each individual who meets the criteria listed in 34. and 46. below, as applicable.

34. Initial Certification: 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/or plant samplers, applicable to the category that the applicant is being certified for, at dairy facilities:

- a. Five (5) bulk milk hauler/samplers during a routine milk pick-up at a producer dairy, if applicable.
- b. One (1) dairy plant sampler that collects raw and finished milk and milk product samples and single-service containers/closures at one (1) ~~pasteurization~~ milk plant, if applicable.
- c. One (1) industry plant sampler that collects a raw milk sample from a milk tank truck at one (1) ~~pasteurization~~ milk 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 delegated Sampling Surveillance Regulatory Agency Official (dSSO).~~

5. The requirements listed in 4. above will be dependent upon the applicant's range of responsibilities and the category in which the applicant is being certified.

46. Recertification: A certified SSO shall continue to 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. The SSO shall be ~~re-certified~~ recertified once each three (3) years by PHS/FDA personnel in an independent side-by-side comparison of sampling procedure observations using the items listed on the appropriate inspection or evaluation report form. The ~~applicant~~ SSO 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/or plant samplers, applicable to the category that the SSO is being recertified for, at dairy facilities:

- a. Three (3) bulk milk hauler/samplers during a routine milk pick-up at a producer dairy, if applicable.
- b. One (1) dairy plant sampler that collects raw and finished milk and milk product samples and single-service containers/closures at one (1) ~~pasteurization~~ milk plant, if applicable.

c. One (1) industry plant sampler that collects a raw milk sample from a milk tank truck at one (1) ~~pasteurization~~ milk 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.~~

7. The requirements listed in 6. above will be dependent upon the SSO's range of responsibilities and the category in which the SSO is being ~~re-certified~~ recertified for.

8. Should PHS/FDA determine that the certified SSO has failed to demonstrate proficiency in the recertification procedures cited in 6. above; PHS/FDA shall require the certified SSO to perform the initial certification procedures cited in 4. above.

Page 27:

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

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

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

When the delegation of sampling surveillance responsibilities is necessary, the SSO certified by PHS/FDA, shall initially certify responsible individuals in one (1) of the following categories following the same procedures that govern initial SSO certification ~~listed in a. below.:~~

a. Bulk milk hauler/samplers and plant samplers (dairy plant samplers and industry plant samplers);

b. Bulk milk hauler/samplers; or

c. Plant samplers (dairy plant samplers and industry plant samplers).

~~Individuals~~ dSSOs shall be ~~re-certified~~ recertified every three (3) years in accordance with the procedures listed in c. below. Reports of all joint evaluations shall be submitted to PHS/FDA.

a. Initial Certification: The applicant for the delegation of sampling surveillance responsibilities shall be evaluated by a PHS/FDA certified SSO in an independent side-by-side comparison of sampling procedure observations using the items listed on the appropriate inspection or evaluation report form. The applicant and SSO shall be in agreement at least eighty percent (80%) of the time on each listed item. Comparison



evaluations shall be performed on at least the following number of bulk milk hauler/samplers and/or plant samplers, applicable to the category the applicant is being certified for, at dairy facilities:

1.) Five (5) bulk milk hauler/samplers during a routine milk pick-up at a producer dairy, if applicable.

2.) One (1) dairy plant sampler that collects raw and finished milk and milk product samples and single-service containers/closures at one (1) ~~pasteurization~~ milk plant, if applicable.

3.) One (1) industry plant sampler that collects a raw milk sample from a milk tank truck at one (1) ~~pasteurization~~ milk plant, if applicable.

b. The requirements listed under Initial Certification above will be dependent on the applicant's range of responsibilities and the ~~category(ies)~~ category in which ~~they are~~ the applicant is being certified.

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

1.) Two (2) bulk milk hauler/samplers during a routine milk pick-up at a producer dairy, if applicable.

*Page 28:*

2.) One (1) dairy plant sampler that collects raw and finished milk and milk product samples and single-service containers/closures at one (1) ~~pasteurization~~ milk plant, if applicable.

3.) One (1) industry plant sampler that collects a raw milk sample from a milk tank truck at one (1) ~~pasteurization~~ milk plant, if applicable.

d. The requirements listed under recertification above will be dependent on the applicant's dSSO's range of responsibilities and the ~~category(ies)~~ category in which ~~they are~~ the dSSO is being ~~certified~~ recertified.

e. Should the SSO determine that the dSSO has failed to demonstrate proficiency in the recertification procedures cited under Recertification above; the SSO shall require the sSSO to perform the initial certification procedures cited under Initial Certification above.

## **G. MILK LABORATORY EVALUATION PERSONNEL ...**

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

1. Have been certified and approved by PHS/FDA as a LEO per the requirements and criteria listed in the most recent edition of the *EML*. (Refer to Section 3 4 of the *EML*.) ...

*Page 31:*

## **I. THE HEARING PROCEDURE FOR REVOKING THE CERTIFICATION OF A SRO, SSO, LEO, OR SSC**

### **1. Certification Hearing Panel Members**

Representatives from the following organizations will comprise the Certification Hearing Panel:

- a. The Regional Food and Drug Director or designee.
  - b. The Director of the ~~Division of Federal State Relations~~ Office of Partnerships or designee.
  - c. The Director of the Division of ~~Plant and Dairy, Egg and Meat Products Food Safety~~ Food Safety or designee.
2. Notification of Intent to Revoke PHS/FDA Certification and an Opportunity for a Hearing

If the PHS/FDA Standard (Regional Milk Specialist, or PHS/FDA MST personnel, or member of LPET, respectively) makes an initial determination to revoke certification, PHS/FDA shall notify the SRO, SSO, 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, 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, Egg and Meat Products Food Safety~~ within fifteen (15) days of the date the SRO, SSO, 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. ...

*Note: This Proposal shall take immediate effect upon the issuance of the IMS-a Actions from the 2019 National Conference on Interstate Milk Shipments following FDA's concurrence with the NCIMS Executive Board.*

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36th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 307 \*Procedures  
Change  
Committee: Liaison

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

**A. Summary of Proposal**

Given the importance of transparency in matters of public health and food safety, this proposal calls for, on the part of FDA, greater information sharing with and oversight by the NCIMS Executive Board regarding evaluations and ultimate determinations of milk safety program equivalence in other countries.

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

For decades, NCIMS members, together with FDA, have invested in building a robust Grade “A” Milk Safety program that has fostered extraordinarily strong food safety results for milk produced under this system. U.S. companies and farmers have significantly invested in ensuring compliance with the PMO’s exacting standards to safeguard this earned U.S. public trust in a safe and high-quality milk supply.

As the degree of foreign participation in this program potentially expands and FDA determines whether the officials and industries in other countries can consistently achieve the same results, it is critical to ensure that the potential public health ramifications of these decisions are fully understood by NCIMS members charged with directly overseeing and responding to food safety issues in their respective states.

FDA is conducting equivalence evaluations in multiple foreign countries, none of which have extensively utilized the third-party certifier program that is already in place. These countries

include Canada, New Zealand and multiple European Union members. In addition, Mexico has expressed interest in a Grade “A” PMO equivalence evaluation.

To date, very little information has been shared on the specific findings and process FDA is following to conduct the evaluations despite their clear relevance to the interests of NCIMS members. An agreed-upon process with mandatory sharing of information and transparent decision-making are needed to ensure a continued collaborative partnership between FDA and NCIMS on these issues of critical importance to the integrity of the U.S. Grade “A” Milk Safety Program.

**C. Proposed Solution**

Changes to be made on page(s):	35	of the (X - one of the following):
<input type="checkbox"/> 2015 PMO	<input type="checkbox"/>	2015 EML
<input type="checkbox"/> 2015 MMSR	<input type="checkbox"/>	2400 Forms
<input checked="" type="checkbox"/> 2015 Procedures	<input type="checkbox"/>	2015 Constitution and Bylaws

*Page 35:*

**SECTION D – PROCEDURES PURPOSE IN EACH PARTICIPATING NON-U.S. COUNTRY OR POLITICAL SUBDIVISION**

For the purpose of these *Procedures* and NCIMS in total, each participating non-U.S. country or political subdivision thereof shall be considered as a State with all the rights, duties, responsibilities, and privileges of a State, providing the governing regulatory body of such non-U.S. country or political subdivision thereof shall meet the requirements of Part A. of this Section by establishing a MOU with PHS/FDA, which provides an acceptable basis for NCIMS to verify equivalence in the State or Local area concerned.

The determination that a foreign country’s public health regulatory program, ~~and~~ the government oversight of that program and its execution in practice by the foreign country’s industry has an equivalent effect on the safety of the regulated milk or milk product is the responsibility of PHS/FDA. PHS/FDA shall regularly inform and confer with NCIMS to answer questions and sufficiently address NCIMS member concerns prior to finalizing a determination of equivalence. This engagement shall include annual reporting on the status of PHS/FDA’s work, an annual opportunity for receiving and answering questions and addressing concerns of NCIMS members and issuing a notice to the NCIMS Executive Board at least one year prior to the intent to issue an approval of equivalence determination at the subsequent NCIMS meeting.

PHS/FDA shall publish for public review and comment such proposed equivalence

determinations through the *Federal Register* and provide a comment period of 180 days.

The foreign government shall provide ~~adequate assurance~~ **strong and demonstrable evidence** that the level of public health protection provided by the NCIMS program is met **by their program**. **Where a foreign entity provides for the free flow of products, including milk, between countries or provinces, the foreign entity being considered for equivalence must demonstrate how it will segregate products and facilities intended for shipment to the U.S. If such a segregation cannot be clearly proven, PHS/FDA should grant equivalence only when the entire region in which products circulate freely has been evaluated and their milk regulatory program(s) determined to be equivalent.** When PHS/FDA determines that a foreign country's milk regulatory program, government oversight of that program, and its execution in practice by the foreign country's industry are ~~is~~ equivalent, PMO defined milk and milk products from that country are accepted in the IMS program after their incorporation into the program by NCIMS at the next NCIMS meeting, provided that the procedures for notification and information sharing with the NCIMS Board have been met.

*Note: This Proposal shall take immediate effect upon the issuance of the IMS-a Actions from the 2017 National Conference on Interstate Milk Shipments following FDA's concurrence with the NCIMS Executive Board.*

Name:	NMPF NCIMS Committee		
Agency/Organization:	National Milk Producers Federation		
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City/State/Zip:	Arlington, VA 22201		
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36th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #:	308 *New Procedure
Committee:	ICP/Appendix N

	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 annually to the International Certification Program (ICP) Committee and NCIMS Executive Board.

**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 provides transparency to and demonstration of integrity of the voluntary International Certification Program (ICP).

**C. Proposed Solution**

Changes to be made on page(s):		61	of the (X - one of the following):	
<input type="checkbox"/>	2015 PMO	<input type="checkbox"/>	2015 EML	
<input type="checkbox"/>	2015 MMSR	<input type="checkbox"/>	2400 Forms	
<input checked="" type="checkbox"/>	2015 Procedures	<input type="checkbox"/>	2015 Constitution and Bylaws	

**C. THIRD PARTY CERTIFIER (TPC) RESPONSIBILITIES**

...

*Page 61:*

4. Performance of Duties and Responsibilities

...

e. TPCs shall submit a drug residue summary data report annually to the ICP committee and NCIMS Executive Board.

Name:	NMPF NCIMS Committee		
Agency/Organization:	National Milk Producers Federation		
Address:	2107 Wilson Blvd, Suite 600		
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Telephone No.:	703-243-6111	E-mail Address:	jjonker@nmpf.org

36th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #:	309 **Constitution & Bylaws Change
Committee:	Constitution & Bylaws

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

**A. Summary of Proposal**

This proposal would limit members of NCIMS Councils to serving through five (5) consecutive biennial meetings of the Conference.

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

Limiting membership on Councils to a defined term will encourage increased rates of turnover, increase the number of participants on Councils, and develop future leadership within the Conference.

<b>C. Proposed Solution</b>
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Changes to be made on page(s):	77 - 78, 85	of the (X - one of the following):
2015 PMO		2015 EML
2015 MMSR		2400 Forms
2015 Procedures	X	2015 Constitution and Bylaws

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

*Page 77:*

SECTION 10. Each Council shall have a voting membership of twenty (20) members to be appointed by the Chair with the approval of the Board.

Subd. 1. Each Council shall have ten (10) representatives from Rating and/or Regulatory Agencies and ten (10) representatives from industry.

Subd. 2. Industry Council members shall be equally divided between producer and processor representatives.

Subd. 3. Each Council member shall be eligible to serve on a specific Council through no more than five (5) consecutive biennial meetings of the Conference.

SECTION 11. Each Council shall have a Council Chair and a Vice Chair who are appointed by the Chair and confirmed by the Board. The Council Chairs

*Page 78:*

and Vice Chairs shall serve on the Councils as non-voting members. After each biennial meeting of the Conference, each Council Chair shall select twenty (20) Council members from qualified Conference registrants and offer their names for Chair appointment and Board confirmation. Careful attention must be given by the Council Chair in the selection of Council members to achieve the discipline balance required in Article IV, Section 10. of this *Constitution*.

Subd. 1. Council Chairs and Vice Chairs shall after appointment serve through two (2) consecutive biennial meetings of the Conference. Council Chairs and Vice Chairs may exceed the limit of five (5) consecutive biennial meetings cited in Article IV, Section 10 of this Constitution only to fulfill their terms as Chair and/or Vice Chair.

Subd. 2. If the Council Chair represents a Rating and/or Regulatory Agency, the Vice Chair shall represent industry. If the Council Chair represents industry, the Vice Chair shall represent

a Rating and/or Regulatory Agency.

Subd. 3. At the end of the Council Chair's term of office, the Vice Chair will become Council Chair and a new Vice Chair will be appointed from that Council and represent the same segment of the Conference as the out going Council Chair.

**BYLAWS: ARTICLE VI ----- DUTIES AND RESPONSIBILITIES OF COUNCILS**

*Page 85:*

SECTION 5. The Chair of each Council shall appoint a minimum of four (4), but no more than eight (8), alternate Council members representing a one (1) or two (2) dairy processor processors, a one (1) or two (2) dairy producer producers, a one (1) or two (2) Regulatory Agency Agencies and a one (1) or two (2) Rating Agency Agencies for review and approval by the NCIMS Executive Board prior to each Conference. Alternate Council members shall be seated to cast votes during periods of temporary absence of Council members and shall be designated to replace Council members for the entire Conference if they cannot attend. Alternates must be affiliated with the current Conference and meet the same eligibility requirements to serve on a Council as the member for whom they will temporarily replace. Alternates shall be required to be in attendance at the Conference and be present at each Council meeting, even if not called upon by the Council Chair to temporarily replace an existing Council member. Alternates are only eligible to replace existing Council members from the same stakeholder group and shall be seated for the entire Conference as a temporary replacement for the original Council member. Council Chairs are encouraged to consider Council alternates when recommending permanent Council replacements to the Board for approval.

*Note: For purposes of calculating serving on Council through no more than five (5) consecutive biennial meetings, the 2017 Conference will count as the first of the five (5) meetings.*

Name:	NCIMS Continuity Task Force, Beth Briczinski, chair		
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Address:	2107 Wilson Blvd, Suite 600		
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# 36th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #: 310

Committee:

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

## A. Summary of Proposal

This proposal requests the Board’s assistance and guidance on the requirements of alternative milk treatment methods. The Board’s assistance would insure that adequate data is collected on the efficacy of alternative milk processing methods for approval at a future NCIMS conference. Initial guidance is requested for high pressure processing. Processing parameters need to be validated through microbial challenge studies and the quality and wholesomeness of the milk confirmed through new tests.

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

Alternative processing methods that retain the same safety as conventional thermal treatment may be a way to reduce the consumption of raw milk by the public and reduce foodborne illness outbreaks related to dairy products. As noted in the PMO 2015, the USPHS/FDA’s culminated studies report that the risk of being infected by a disease from raw is approximately 50 times greater than then from milk that has been pasteurized (91). Despite the research finding presented to the public by the USPHS, FDA, and CDC, a substantial number of consumers still seek to drink raw milk. In states where selling raw milk is not legal, enterprising consumers still find ways to by-pass interstate regulation that prevents the selling of raw milk. As a result, public health outbreaks reported by the CDC related to raw milk consumption continue to grow year after year. Due to USPHS/FDA’s limited jurisdiction in the enforcement of intrastate milk sanitation standards, the options to prevent the increasing outbreaks due to raw milk consumption is limited (vii).

Part of the attractiveness of drinking raw milk and giving it to their children comes from

consumers who are concerned about the effect of heat treatment of pasteurized milk on the quality and heat denaturation of naturally occurring bioactive components of milk. Educational efforts to correct the misunderstanding of thermal processing effects on milk has had only limited success as evident by the increasing number of consumers who decide to drink raw milk. However, the “average” consumer who drinks raw milk may be accepting of alternative nonthermal treatment of fluid milk. High pressure processing (HPP) is an alternative nonthermal treatment accepted by consumers for other food products. Moreover, HPP maintains the same safety as conventional processing, but a challenge study using HPP for milk has yet to be successfully accepted by the FDA.

**C. Proposed Solution**

Changes to be made on page(s):		_____ of the (X - one of the following):	
_____ 2015 PMO	_____	_____ 2015 EML	
_____ 2015 MMSR	_____	_____ 2400 Forms	
_____ 2015 Procedures	_____	_____ 2015 Constitution and Bylaws	

We ask the Chair to assign this proposal to an NCISM standing committee, special committee, or ad hoc committee as approved by the NCIMS Executive Board.

Dr. Philip Crandall’s lab of the University of Arkansas is investigating the use of nonthermal technology as an equivalent process to heat pasteurization. Our desire is to put a Task Force together with thermal processing experts representing NCIMS to develop and execute a challenge study that would collect the necessary data for an FDA petition for regulatory acceptance of nonthermal high pressure processing of milk. Moreover, we would like their input on developing testing procedures for a confirmation tests that will need to verify proper treatment of milk based on pressure treatment in lieu of heat treatment. We have spoken with manufactures of HPP equipment and other universities who are interested in helping us conduct a challenge study as well. HPP milk must be validated to show the same safety as current thermal pasteurization standards. Furthermore, cleaning methods will need to be created to ensure proper sanitation of HPP equipment and product containers. Finally, since HPP milk would be processed in-container, there is also a reduced risk due to post-pasteurization contamination.

The central aim of this study is to reduce the risk of drinking raw milk that has not been heat pasteurized.

Expected outcomes:

1. Developed and execute microbiological challenge studies for USPHS/FDA review and be submitted to the NCIMS at another meeting.
2. Development of confirmation test to be amended to Appendix G and added to 2400



Form.

3. Development of validated processing parameters using nonthermal milk treatment of HPP to be submitted for approval for Appendix H.
4. Development of cleaning and sanitation procedures for HPP technology to be submitted for approval for Appendix F.
5. Defining approved standard for packaging of HPP fluid milk to be submitted for approval for appendix J.
6. Submission for a standard of identity to FDA and then to submitted for approval for Appendix L
7. Creation of a new appendix T for HPP operation
8. Future work with NCIMS on amending the definition of pasteurization in the PMO to reflect the recommended National Advisory Committee on Microbiological Criteria for Foods' (NACMCF) definition of pasteurization which is:

“Any process, treatment, or combination thereof, that is applied to food to reduce the most resistant microorganism(s) of public health significance to a level that is not likely to present a public health risk under normal conditions of distribution and storage”

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