Proposal #:	301	
Committee:	Liaison	
New Procedure		X
Procedure Change		
Const./Bylaws Ch		

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

A. Summary of Proposal

To provide a definition for "equivalence" for the USPHS/FDA responsibility to determine whether a foreign country's public health regulatory program and the government oversight of that program has an equivalent effect on the safety of the regulated milk and/or milk product.

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

The Pasteurized Milk Ordinance (PMO) rightfully provides that one way in which foreign dairy regulatory systems can be found to be in compliance with the PMO is for the foreign regulatory system to be recognized by the U.S. government as equivalent. This route to PMO participation via an equivalence determination must be maintained as it upholds U.S. WTO commitments.

In the context of international trade, the term "equivalence" has for approximately two decades been understood to mean: "the state wherein sanitary measures applied in an exporting country, though different from the measures applied in an importing country, achieve, as demonstrated by the exporting country, the importing country's appropriate level of sanitary protection" (https://www.fao.org/3/y6396e/y6396e05.htm). Despite this well-established international consensus, the PMO lacks a definition of the term.

There is currently an international effort underway in the Codex Alimentarius Commission led by New Zealand to effectively "redefine" the established understanding of "equivalence" and how it can be achieved. Current review of the proposal suggests that it would allow for equivalence recognition through a considerably less rigorous approach that differs markedly from the understanding of the term by NCIMS participants when the equivalence recognition route was added to the PMO. This new interpretation of equivalence is intended to avoid a measure-by-measure examination of the specific regulations in question in the trading partners' regulatory system and, instead, assert equivalence based on a less thorough, more subjective systems-based process.

To provide for clarity regarding this important pathway to participating in the PMO, NCIMS should include a definition of "equivalence" that reflects the long-standard measure-by-measure Codex Alimentarius Commission definition of the term and the understanding that NCIMS participants had of the term when the equivalence recognition route was added to the PMO.

C. Proposed Solution

Changes to be made on the following NCIMS Documents:

Page Number(s)	Document	Page Numbers(s)	Document
Section 1	2023 PMO		
Definitions, page	Section(s): 1		2023 EML
4	Appendix:		
	2023 MMSR		Forms Form Number:
Section III Definitions, page 3	2023 Procedures		2023 Constitution and Bylaws

Proposed Change:

(PMO Section 1 Definitions, page 4)

R. EQUIVALENCE: When specific sanitary or phytosanitary measures applied in an exporting country, though different from the individual measures applied in the United States through the Grade "A" Pasteurized Milk Ordinance and related documents, achieve, as demonstrated by the exporting country and affirmed by the U.S. Food and Drug Administration, at least the same level of sanitary or phytosanitary protection.

(Procedures Section III Definitions, page 3)

M. EQUIVALENCE: When specific sanitary or phytosanitary measures applied in an exporting country, though different from the individual measures applied in the United States through the Grade "A" Pasteurized Milk Ordinance and related documents, achieve, as

demonstrated by the exporting country and affirmed by the U.S. Food and Drug Administration, at least the same level of sanitary or phytosanitary protection.

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Proposal #:	302	
Committee:		
New Procedure		
Procedure Change		X
Const./Bylaws Change		

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

A. Summary of Proposal

This proposal allows FDA to incorporate editorial updates into NCIMS Conference Forms.

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

Per the NCIMS *Procedures*, FDA is responsible for incorporating editorial updates into NCIMS Conference documents after each NCIMS Conference, or upon request by the NCIMS Executive Board. Currently, FDA does not have the ability to incorporate editorial updates into NCIMS Conference Forms. This limits the opportunities to assure that NCIMS Forms are accurate and are drafted for maximum utility.

This proposal would allow FDA to incorporate editorial updates into NCIMS Conference Forms, as with the other NCIMS Conference documents identified in *Procedures*.

C. Proposed Solution

Changes to be made on the following NCIMS Documents:

Page Number(s)	Document	Page Numbers(s)	Document
	2023 PMO		
	Section(s):		2023 EML
	Appendix:		
			Forms
	2023 MMSR		Form Number:
			2023 Constitution and
14	2023 Procedures		Bylaws
			-

Proposed Change:

Procedures

Section IV. Oversight and Responsibilities

A. PHS/FDA Responsibilities

7. Interpretations and Editorial Updates

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

Name: Food and Drug Administration

Agency/Organization: Human Foods Program – Division of Dairy Safety

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Proposal #:	303	3
Committee:	MMSR	
New Procedure		
Procedure Change		X
Const./Bylaws Cha		

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

A. Summary of Proposal

This proposal seeks to add language to the Procedures document to capture the long-standing policy that prohibits a state rating from being conducted at the same time as a PHS/FDA check rating.

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

The purpose of an PHS/FDA check rating of a dairy farm (BTU), milk plant, transfer and/or receiving station is to ensure that the published rating of a milk shipper on the IMS List is valid and maintained during the time interval between state ratings.

It has been a long-standing unwritten policy that state ratings are not conducted during official PHS/FDA check ratings. The primary reasons for this is that an PHS/FDA check rating is to verify that the last completed state rating of the BTU, milk plant, receiving station or transfer station is valid and being maintained during the interval between ratings.

If state ratings were to occur at the same time, there could also be the appearance of "teaming up" against the industry with more than one person making the official evaluation. State ratings and PHS/FDA check ratings serve two different purposes as well as scoring standards which could create some confusion. As an example, a PHS/FDA check rating could score a milk plant an 81% and be found acceptable, but if the SRO had the same score, the milk plant would be removed from the IMS List.

The objective of a state rating is to provide an assessment of the state and local sanitation activities regarding overall public health protection. The objective of a check rating is to ensure that the published state rating is valid and being maintained during the interval between state ratings. For these reasons, the practice of blending state ratings and PHS/FDA check ratings has not been permitted or acceptable.

C. Proposed Solution

Changes to be made on the following NCIMS Documents:

Page Number(s)	Document	Page Numbers(s)	Document
	2023 PMO		
	Section(s):		2023 EML
	Appendix:		
			Forms
	2023 MMSR		Form Number:
			2023 Constitution and
Page 15-16	2023 Procedures		Bylaws

Proposed Change:

2023 Procedures, Section IV., Pages 15-16:

- 8. PHS/FDA Check Ratings of the Sanitation Compliance Status of IMS Listed Milk Shippers
- a. PHS/FDA shall conduct, each year, check ratings of the Sanitation Compliance status of IMS listed milk shippers. To conduct check ratings of aseptic or retort milk plants, the PHS/FDA MS and/or PHS/FDA MMPB personnel for TPCs shall have completed a training course that is acceptable to the NCIMS and PHS/FDA MMPB addressing the procedures for conducting check ratings under the NCIMS Aseptic Processing and Packaging Program, the NCIMS Retort Processed after Packaging Program or the Fermented High-Acid, Shelf-Stable Processing and Packaging Program, respectively. Within a State or a TPC's jurisdiction, check ratings shall be conducted of a representative number of IMS listed milk shippers. The selection of IMS listed milk shippers to be check rated in a given State or a TPC's jurisdiction shall be made randomly.
- d. A check rating cannot be conducted with a greater frequency than the official <u>state</u> rating or audit for an IMS listing <u>and shall not be conducted in conjunction with an official state rating</u>.

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Proposal #:	304	l
Committee:	MMSR	
New Procedure		
Procedure Change		X
Const./Bylaws Cha		

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

A. Summary of Proposal

This proposal seeks to provide alignment and clarity in the Procedures document for when an PHS/FDA check rating occurs at a milk plant, transfer station or receiving station and the sanitation score requires a "re-inspection" to be made within 30 days of the issued report.

This proposal specifically seeks to strike the term "re-inspection" and replace the term with "re-rating" after this unique type of adverse actions. This would properly align the follow-up expectations to be consistent with how farm BTUs are currently "re-rated" following a similar outcome.

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

This proposal seeks to correct ambiguous and inconsistent language in the Procedures document surrounding the re-inspection/re-rating process following an adverse action made during an official PHS/FDA check rating of a milk plant, transfer station or receiving station.

Currently, when an PHS/FDA Milk Specialist scores a milk plant, transfer station or receiving station an exact score of 80 on the sanitation compliance rating (SCR), the Procedures documents requires a "re-inspection" to be made within 30 days. The Procedures does not specify who should perform this "re-inspection", the milk plant, the regulatory agency or the

rating agency. Due to the complexities and competencies needed when completing a rating such as the pro-ration of specific items as well as understanding weighted calculations for elements

such as processing, filling/capping and for packaging materials, the MMSR Committee is of the opinion that the term "re-inspection" is not appropriate and should correctly be changed to "rerating". By doing so, this would accurately align the Procedures document with how farm BTU check ratings scoring between 80-84 are followed-up when requested by the PHS/FDA Milk Specialist. By making this change, the "re-rating" would now be conducted by a properly trained and certified State Rating Officer who understands the complexities and nuances of the rating process which would provide the same level of consistency required for farm BTUs scoring in a similar manner.

In addition, with the SRO's submission of the new 2359i after the re-rating, the milk plant's next rating date would now be extended forward by two years from the date of the re-rating action.

The term "re-inspection" by nature, is a useful regulatory tool used by local public health agencies to gain compliance within the realm of the routine regulatory oversight and inspection structure. The check rating/ State rating process is uniquely different and moves to the hierarchal processes/procedures as dictated by the most current PMO, Methods, and Procedures documents. Therefore, the current process is at odds with the procedures in our NCIMS framework and what should be expected following this specific type of adverse action. This proposal seeks clarity and consistency with the expectations following a similar farm BTU adverse action as stated above.

C. Proposed Solution

Changes to be made on the following NCIMS Documents:

Page Number(s)	Document	Page Numbers(s)	Document
	2023 PMO		
	Section(s):		2023 EML
	Appendix:		
		NCIMS FORM	Forms
	2023 MMSR	2359h	Form Number:
			2023 Constitution and
22-23	2023 Procedures		Bylaws

Proposed Change:

2023 Procedures, Section IV, Pages 22-23:

SECTION IV. OVERSIGHT AND RESPONSIBILITIES

B. STATE, TPC, AND SSC RESPONSIBILITIES

Page 22

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 SCR from a check rating of a milk plant, receiving station and/or transfer station indicates the IMS listing is no longer justified:

MILK PLANTS, RECEIVING STATIONS AND/OR TRANSFER STATIONS

REINSPECTION SCR FROM THE CHECK RATING	ACTION REQUIRED
100 to 81	No Action
80	Reinspect Re-rate Within Thirty (30) Day Days. SCR Shall Be Equal to or better than the published rating Ninety Percent (90%) or Higher to Maintain IMS Listing
79 or Less	Withdraw IMS Listing

B.) Reinspection Re-Rating

When check rating data indicates that the SCR of an IMS listed milk plant, receiving station or transfer station requires a reinspection re-rating, PHS/FDA shall officially notify the Rating Agency that a reinspection re-rating of the milk plant, receiving station 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 appropriate PHS/FDA MS or PHS/FDA MMPB for TPCs shall be so advised by the Rating Agency and no further action shall be necessary.

NOTE: For re-rating purposes, the preceding six (6) months of the PHS/FDA check rating or to the date of the last state rating (whichever is greater) is considered to be the elapsed period of time necessary to complete the ER.

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 Grade "A" dairy farm(s) shall be included in the reinspection re-rating conducted within thirty (30) days. Both the Grade "A" dairy farm(s) and the individual milk plant, receiving station or transfer station, respectively, shall achieve a SCR equal to or better than the published rating of 90% or higher in order to be eligible for a listing on the *IMS List*.

NCIMS FORM 2359h

FORM NCIMS 2359h (10/23) (10/25)

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Name: MMSR, Robert Wilson Chair

Agency/Organization: Oregon Department of Agriculture

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Proposal #:	305				
Committee:	SR				
New Procedure	X				
Procedure Change					
Const./Bylaws Change					

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

A. Summary of Proposal

This proposal seeks to provide guidance to state regulatory and/or rating officials for when a new (or existing non-IMS) dairy farm, milk plant, transfer station, receiving station or single-service facility requests an initial IMS listing.

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

Many states have had questions over the years as to what specific regulatory records are required or expected to be on file for a new (or existing non-IMS) dairy farm, milk plant, transfer station, receiving station, or single-service facility when an initial state rating or single-service listing audit is being requested.

It's been reported that some states require a minimum of four (4) satisfactory samples of all milk and milk products and recirculated water tests within the previous six months before initially being listed. Some states may require a recent sanitary inspection showing a "clean sheet" using NCIMS Forms 2359, 2359a or 2359c to be eligible for an initial rating. Some states may only require a satisfactory plan review and a completed pasteurization system testing before issuance of a permit and conducing the initial rating and some states may require nothing at all but a passing SCR and ER rating scores of 90% or higher.

Additionally, FDA is also conducting a critical review of M-Is containing previously issued Question and Answers and has also targeted this specific question as one needing to be captured

within the conference documents to give states the guidance they've been seeking with regards to this issue.

C. Proposed Solution

Changes to be made on the following NCIMS Documents:

Page Number(s)	Document	Page Numbers(s)	Document
	2023 PMO		
	Section(s):		2023 EML
	Appendix:		
	2023 MMSR		Forms Form Number:
26	2023 Procedures		2023 Constitution and Bylaws

Proposed Change:

2023 Procedures, Section V., Item B, Page 26:

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

A milk shipper desiring a rating of their Grade "A" milk and/or milk products for the purpose of IMS listing shall submit a request to the Rating Agency in their own State or to their TPC, respectively.

NOTE: For a new dairy farm, milk plant, transfer station, receiving station, tank truck wash facility (or existing non-IMS facility) requesting an IMS Listing, the following minimums **should** be met for the initial rating/listing to commence, unless otherwise noted:

Dairy Farm:

- An acceptable plan review of the facility, if new*
- <u>Issuance of a permit**</u>
- At least one (1) satisfactory water sample of the private water systems and recirculated cooling water from all applicable systems within the preceding three (3) years or six (6) months respectively of the initial rating. (if applicable)
- At least one (1) satisfactory sample of raw milk for pasteurization

Milk Plant, Transfer Station or Receiving Station:

- An acceptable plan review of the facility, if new*
- Issuance of a permit**

- At least one (1) satisfactory water sample of the private and recirculated cooling water from all applicable systems within the preceding three (3) years or six (6) months respectively from the initial rating. (if applicable)
- At least one (1) satisfactory sample of raw milk for pasteurization and all pasteurized milk and milk products currently being produced, if any
- At least one (1) complete test for each of the pasteurizer system(s) using NCIMS Form 2359b to include holding time determinations made within the last three (3) months of the initial listing and all required regulatory public health seals in place if applicable***
- At least one (1) satisfactory sample set of single-service containers and or closures, if applicable
- Labels reviewed and/or approved for use as applicable

Single-Service Facility:

- Acceptable plan review of the facility, if new
- <u>Issuance of a permit to operate if applicable (Only if listed for two (2) years and inspected quarterly, except for TPCs and SSCs)****</u>
- One (1) satisfactory water sample of private and recirculated cooling water from all applicable systems within the preceding three (3) years or six (6) months respectively from the initial rating. (if applicable)
- A satisfactory sample set of single-service containers, if applicable
- Letter on file for the resins used for direct or indirect food contact. 21 CFR 174-178.****
- Bacteriological test for the outer bag used to contain the finished containers or closures
- * Required by Section 12 of the PMO
- ** Required by Section 3 of the PMO
- *** Required by Section 7, Item 16p of the PMO
- **** Required by Section I of the MMSR

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

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

Name:	Name: MMSR, Robert Wilson Chair.							
Agency/Or	ganizat	tion:	Oregon Departm	ent of Agriculture				
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Proposal #:	306				
Committee:	SSCO				
New Procedure	X				
Procedure Change					
Const./Bylaws Cha					

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

A. Summary of Proposal

To allow SROs to obtain certification and recertification for single service facilities, separate from dairy plant certification. This is already in place for Single Service Consultants.

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

It can be a lengthy process for an SRO to become plant certified which can place a large burden on a rating agency that experiences personnel change over. Since single service facility surveys are distinct from dairy plant inspection in several ways, they use a different score sheet (Forms 239c and 2359e), they follow Appendix J regulations rather than Section 7 requirements in the PMO, and they may require an annual survey (stand alone facilities); it makes sense to create a new category for an SRO to be certified independent of dairy plants. While this separate certification may not be necessary in all states, it would significantly benefit those with numerous single service facilities. This certification would allow an employee to obtain SRO certification single service and begin conducting ratings while still training in dairy farms and dairy plants which can take a considerable amount of time. The number of facilities needed to recertify an SRO in single service facilities matches the requirement noted in Procedures for Single Service Consultants.

C. Proposed Solution

Changes to be made on the following NCIMS Documents:

Page Number(s)	Document	Page Numbers(s)	Document
	2023 PMO		
	Section(s):		2023 EML
	Appendix:		
	2023 MMSR		Forms Form Number:
27, 28	2023 Procedures		2023 Constitution and Bylaws

Proposed Change: 2023 Procedures (pages 27 and 28)

D. MILK SANITATION RATING PERSONNEL

SCRs and ERs shall be conducted by certified SROs and the certification/listing of U.S. manufacturers of containers and closures for milk and/or milk products shall be conducted by certified State SROs who meet the following requirements:

- 1. Have submitted to PHS/FDA a written request for certification including the following: applicant name and contact information, education, training, work experience, list of training courses attended and categories for which certification are being requested.
- 2. Have been certified by PHS/FDA as an SRO and hold a valid certificate in one (1) or any combination of the following categories:
- a. Grade "A" dairy farms;
- b. Milk plants, including HACCP, and/or aseptic processing and packaging, and/or retort processed after packaging, and/or fermented high-acid, shelf-stable processing and packaging, and/or single-service containers and closures manufacturers, if appropriate; and
- c. Transfer/receiving stations, including HACCP if appropriate.
- d. Stand-alone single-service containers and /or closures manufacturing plant.

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.

3. An 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) for which the applicant is being certified:

- a. Twenty-five (25) producer dairies. Milking time evaluations should be included.
- b. Five (5) milk plants. Milk plants of varying sizes using, vat, HTST and HHST pasteurization; aseptic processing and packaging; retort processed after packaging; and/or fermented high-acid, shelf-stable processing and packaging, if applicable, should be included in these evaluations. One (1) transfer or receiving station may also be included as one (1) of the required five (5) 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) milk plants.
- d. If HACCP certified for milk plants, receiving or transfer stations, in addition to meeting the requirements listed above for milk plants for a SRO, one (1) mock-listing audit conducted separate from an official NCIMS HACCP listing audit is required. (Refer to Section VIII., E.7. for additional NCIMS HACCP certification procedures.)
- e. One (1) single-service containers and/or closures manufacturing plant, if applicable.
- f. Five (5) single-service containers and/or closures manufacturing plant if certification is only for these types of facilities.
- f. g. Five (5) receiving and/or transfer stations if certification is only for these types of facilities.
- 8. A certified SRO shall be re-certified once each three (3) years by PHS/FDA personnel in an independent side-by-side comparison of dairy facilities using the items listed on the appropriate inspection or evaluation report form. The 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) for which the SRO is being re-certified:
- a. Ten (10) producer dairies. Milking time evaluations should be included.
- b. Three (3) milk plants. Milk plants of varying sizes using, vat, HTST and HHST pasteurization; aseptic processing and packaging; retort processed after packaging; and/or fermented high-acid, shelf-stable processing and packaging, if applicable, should be included in these evaluations.
- c. One (1) dry milk plant, if applicable. The dry milk plant may be used as one (1) of the required three (3) milk plants.
- d. If NCIMS HACCP certified for milk plants, receiving or transfer stations, in addition to meeting the requirements listed above for milk plants for a SRO, one (1) re-certification audit is required. The 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.7. for additional HACCP certification procedures.)
- e. One (1) single-service containers and/or closures manufacturing plant, if applicable.

f. Two (2) single-service containers and/or closures manufacturing plant if certification is only for these types of facilities.

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

**********	1				**			
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Proposal #:	307		
Committee: MMSR			
New Procedure			
Procedure Change	X		
Const./Bylaws Cha			

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

A. Summary of Proposal

Proposal #208 as passed by the conference delegates at the 2023 NCIMS Conference failed to also update the Procedures document to allow for individuals to be certified for this new option for delegation. This proposal seeks to include the necessary changes from the 2023 conference into the Procedures document.

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

This proposal seeks alignment with the PMO and the Procedures document which incorporated the delegation for the evaluations of Industry Plant Samplers to the industry. Currently, the Procedures document lists three (3) specific categories whereby an individual can be certified by a certified Sample Surveillance Officer (SSO). The Procedures states an individual can be delegated by an SSO to conduct;

- a) Bulk milk hauler/samplers and plant samplers (dairy plant samplers and industry plant samplers);
- b) Bulk milk haulers/samplers; or
- c) Plant Samplers (dairy plant samples and industry plant sampler)

This proposal correctly adds the updated language from the 2023 PMO to letter "b" above in the Procedures which extends the delegation of industry plant samplers to qualified industry personnel.

C. Proposed Solution

Changes to be made on the following NCIMS Documents:

Page Number(s)	Document	Page Numbers(s)	Document
	2023 PMO		
	Section(s):		2023 EML
	Appendix:		
	2023 MMSR		Forms Form Number:
31	2023 Procedures		2023 Constitution and Bylaws

Proposed Change:

2023 Procedures, Section V., Page 3:

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

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:

- a. Bulk milk hauler/samplers and plant samplers (dairy plant samplers and industry plant samplers);
- b. Bulk milk hauler/samplers; and/or industry plant samplers; or
- c. Plant samplers (dairy plant samplers and industry plant samplers).

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

Name:	e: MMSR, Robert Wilson Chair.							
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Proposal #: 308			
Committee:	Const./ Bylaws		
New Procedure			
Procedure Change	X		
Const./Bylaws Cha	X		

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

A. Summary of Proposal

This proposal would replace the language "U.S. Trust Territories" with "U.S. Territories" in the 2023 Procedures Governing the Cooperative State-Public Health Service / Food and Drug Administration Program of the National Conference on Interstate Milk Shipments, including the Constitution and Bylaws of the National Conference on Interstate Milk Shipments.

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

This proposal would update the language used in the Procedures Governing the Cooperative State-Public Health Service / Food and Drug Administration Program of the National Conference on Interstate Milk Shipments, including the Constitution and Bylaws of the National Conference on Interstate Milk Shipments, recognizing that all 11 U. S. Trust Territories became independent sovereign nations or joined neighboring independent countries by 1993.

C. Proposed Solution

Changes to be made on the following NCIMS Documents:

Page Number(s)	Document	Page Numbers(s)	Document
	2023 PMO		2023 EML
	2023 MMSR		Forms
			Form Number
61	2023 Procedures	94, 96, 102, 106	2023 Constitution and
			Bylaws

Proposed Change:

PROCEDURES GOVERNING THE COOPERATIVE STATEPUBLIC HEALTH SERVICE/FOOD AND DRUG ADMINISTRATION PROGRAM OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

SECTION IX. PROCEDURES GOVERNING THE NCIMS VOLUNTARY INTERNATIONAL CERTIFICATION PROGRAM

A. PURPOSE AND SCOPE

The policies and procedures contained in this Section apply only to TPCs and MCs that are authorized by a signed and dated LOU with the NCIMS as participants in the NCIMS voluntary ICP. This Section does not apply to NCIMS Member State and U.S. territory Regulatory/Rating Agency Grade "A" Milk Safety Programs that operate under the requirements of the NCIMS, nor does it apply to dairy facilities located within the geographic boundaries of those NCIMS Member States and trust territories Territories. The NCIMS voluntary ICP does not establish requirements for regulatory programs operated by any governmental agency within or outside of the United States. (p.61)

CONSTITUTION OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

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

SECTION 1. The voting delegates, of the Conference, are representatives of the State Rating Agencies, State Regulatory Agencies, and like representatives from the District of Columbia, participating U.S. Trust Territories, and each participating non-U.S. country or political subdivisions thereof, as identified in Article VII, Section 4., Subdivision 3. of the Bylaws. (p.94)

SECTION 5. The membership of the Board shall be selected as follows: Subd. 4. Other Membership

In the case of participating U.S. Trust Territories, non-U.S. countries or political subdivision thereof, each U.S. Trust Territory, non-U.S. country or subdivision thereof shall be assigned to Group I, Group II, or Group III by the Board. (p.96)

BYLAWS OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

ARTICLE IV ----- DUTIES OF THE EXECUTIVE SECRETARY

SECTION 3. At least sixty (60) days prior to a biennial meeting, or as soon as possible for a special meeting of the Conference, the Executive Secretary shall notify the office or offices of the Rating and/or Regulatory Agency or Agencies in each participating State and Third Party Certifier, or a like representative from the District of Columbia, participating U.S. Trust Territories and each participating non-U.S. country or political subdivision thereof, of the time and place of the next Conference, and the issues which are to be voted on in the General Assembly of the Conference under the heading of unfinished business. (p.102)

ARTICLE VII ----- RULES OF THE CONFERENCE

SECTION 4. Rules of the delegate business meeting.

Subd. 3. Only a registrant at the Conference, who is a representative of a participating State Rating Agency or a State Regulatory Agency responsible for the enforcement of sanitation laws for Grade "A" milk and milk products, Grade "A" condensed and dry milk products and Grade "A" whey and whey products, or a like representative from the District of Columbia, or a participating U.S. Trust Territory, or a participating non-U.S. country or political subdivision thereof, is entitled to be a voting delegate. When any State is represented by both Rating and Regulatory Agencies, the vote may be cast together as one (1) vote or separately as one-half (1/2) vote each, provided that any State represented by both Rating and Regulatory delegates certified in compliance with the provisions of Subdivision 4. of this Section may during any delegate business meeting, reassign its one-half (1/2) vote privilege to the other duly certified State delegate by giving written notice of such action to the Chair. When any State is represented by only one (1) Agency, the voting delegate at the Conference may cast a full vote for that State. Each voting delegate at the Conference may cast a vote only for the voting delegate's own State. Delegates and/or alternates will not be allowed to vote at

the Conference from a State, which fails to honor the reciprocity provisions set forth in Section VI., paragraphs A. and B. of the Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments.

Subd. 4. Ninety (90) days prior to the biennial meeting of the Conference, or as soon as possible for a special meeting of the Conference, the Executive Secretary shall send to the office, or offices, of the State Rating or State Regulatory Agency or Agencies in each

participating State, the District of Columbia, participating U.S. Trust Territories and each participating non-U.S. country or political subdivision thereof, notice of the forthcoming

meeting. Each notice shall include a copy of Article VII, Section 4., Subdivisions 3. and 4. of the Bylaws that outlines the designation of voting delegates and their privileges. (p.106)

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Agency/Organization: NCIMS Constitution and Bylaws Committee									
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Proposal #:	309		
Committee:	MMSR		
New Procedure		X	
Procedure Change			
Const./Bylaws Cha	ange		

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

A. Summary of Proposal

The purpose of this proposal is to bring clarity and uniformity to when a new state rating should be conducted of a BTU due to a significant change in number of farms/producers within the unit.

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

State rating agencies have asked for an official interpretation of what constitutes a "significant" change in the number of dairy farms within a BTU which would trigger a rerating to be made. It was FDA's opinion in question #31 within M-I-00-8 that suggested a significant change would be 25% or more of the farms being added or subtracted from a BTU. M-I-00-08, Question #31 stated "What does it mean when a re-rating of an IMS listed BTU is due from a change in status because of a significant change in number of producers?" The answer given by FDA was "FDA considers that a significant change has occurred when a 25% or higher (increase or decrease) in the total number of producers within a BTU as occurred."

The only other reference states could use to support a new rating for this situation was the language in the Procedures that referenced a "significant change" in the number of producers. This specific text was removed in 2023 as part of the passage of proposal #305 as the delegates agreed it was unnecessary to notify all known receiving states when the number of farms within a BTU had changed.

The referenced answer within M-I-00-8 has now sunset, leaving no clarity to a change in number of producers within a BTU that would trigger a new rating to be made. To bring consistency to this issue we are proposing the additional language to the text and would suggest a change of 40% or more of the farms within a BTU would necessitate a new rating be conducted.

C. Proposed Solution

Changes to be made on the following NCIMS Documents:

Page Number(s)	Document	Page Numbers(s)	Document
	2023 PMO Section(s): Appendix:		2023 EML
10	2023 MMSR		Forms Form Number:
18	2023 Procedures		2023 Constitution and Bylaws

Proposed Change:

MMSR – Section B., page 10:

b. Random Selection of Dairy Farms to be Rated

The individual dairy farms included in the rating or PHS/FDA check rating shall be representative to reflect conditions throughout the BTU or attached supply of Grade "A" raw milk. It is important that the selection method excludes elements of pre-selection and prenotification and provides a truly random sample. The selection of dairy farms for a rating should be made from a current listing of dairy farms making up the BTU or attached supply of Grade "A" raw milk and may be compared to a list for the previous sixty (60) days to determine if an appreciable shifting of dairy farms has taken place. An appreciable shift

in dairy farms of a BTU containing at least five (5) farms or more, is defined as at least a 40% or more change in the number of new producers or exchange of existing producers from the previous rating.

Example: A farm BTU comprised of twenty (20) farms adds an additional eight (8) farms, (change of 40%), would require a new rating be conducted. Or if a BTU comprised of twenty (20) farms and then lost eight (8) farms but added eight (8) other farms that were not already in the BTU, a new rating would be required.

Random selections, once made, should be deviated from only in cases of emergencies. Replacements, where necessary, should also be selected at random. Whenever possible, random selection or announcements of such selections for only one (1) day's work at a time should be made.

Procedures, Section IV., page 18:

- h. The Rating Agency shall keep current the ratings of all IMS listed milk shippers within its State or a TPC's jurisdiction.
- i. Whenever an appreciable shift in dairy farms of a BTU containing five (5) farms or more occurs, a re-rating of the BTU shall be made. An appreciable shift in dairy farms constitutes a 40% or more increase in the number of new producers or exchange of existing producers from the previous rating.
- j ÷. The State Rating Agency shall certify U.S. manufacturers of single-service containers and/or closures for milk and/or milk products based on compliance with Appendix J. of the *Grade "A" PMO* and in accordance with the *MMSR* for inclusion on the *IMS List*.

When an IMS listing of a manufacturer of single-service containers and/or closures for milk and/or milk products is no longer valid because of a change in the SCR to less than eighty percent (80%); or permit revocation, the shipping State, TPC or SSC, as applicable, shall immediately (within five (5) days) 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.

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Proposal #:	310	
Committee:	laws	
New Procedure		
Procedure Change		
Const./Bylaws Cha	X	

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

A. Summary of Proposal

This proposal will change the Constitution and By-Laws to more accurately reflect the current requirements for small non-profit organizations and the current duties and responsibilities of the Executive Secretary. It will also remove the requirement that the Executive Secretary be Bonded and allow for flexibility in the format used to tally votes in Board meetings and in General Assembly.

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

Financial records and tax reporting requirements for non-profit organizations are complex and require the assistance of a Certified Public Accountant. The requirements and cost of a full financial audit are expensive and disproportionate to the amount of assets held by a small non-profit organization. It is recommended that a financial review would be more appropriate for the NCIMS organization.

The Executive Board and its members, including the Executive Secretary, are covered by a Directors and Officers Liability insurance policy that is reviewed and renewed annually. This policy would include coverage for the Executive Secretary, who is an at-large member of the Executive Board. Historically the Executive Secretary has not held a Surety Bond as

insurance firms were not able to provide this service.

C. Proposed Solution

Changes to be made on the following NCIMS Documents:

Page Number(s)	Document	Page Numbers(s)	Document
	2023 PMO		
	Section(s):		2023 EML
	Appendix:		
			Forms
	2023 MMSR		Form Number:
		06 100 100	2022 G
	2022 D	96, 100, 102	2023 Constitution and
	2023 Procedures		Bylaws

Proposed Change:

CONSTITUTION OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

ARTICLE IV ----- VOTING DELEGATES, EXECUTIVE BOARD, OFFICERS, EXECUTIVE SECRETARY, COMMITTEES, COUNCILS, AND PROGRAM CHAIR page 96

SECTION 6. The Board shall elect a Chair and a Vice Chair from its membership after each biennial meeting of the Conference and they may retain their position at the pleasure of the Board as long as they are officially members of the Board. If the Chair cannot perform the duties, the Board shall again elect a Chair. The Board shall retain the services of an Executive Secretary. The Executive Secretary shall be bonded, shall not have a vote on the Board and in biennial or special meetings of the Conference; but shall perform all duties required in Article IV of the Bylaws. The Board shall retain the services of a Certified Public Account to prepare quarterly financial reports and tax filing documents. The compensation of the Executive Secretary shall be set by the Board.

BYLAWS OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

ARTICLE I ----- DUTIES OF THE BOARD page 100

SECTION 9. The Board shall direct the Executive Secretary to collect registration and affiliation fees as necessary to defray the costs of the operation of the Conference. The Board shall cause an annual audit to be made of the Executive Secretary's records, which are a part of the Board's records. At the Board's request, a review shall be made of the Executive Secretary's records and the tax accounting firm's financial reports, provided by an independent accounting firm, which are part of the Board's records.

SECTION 11. The Board shall authorize the form used to tally votes in Board meetings and in General Assembly

ARTICLE IV ----- DUTIES OF THE EXECUTIVE SECRETARY page 102

SECTION 2. The Executive Secretary shall tally and record all voting of the Board and each delegate business meeting on forms authorized by the Board.

SECTION 4. The Executive Secretary shall collect registration and affiliation fees and shall pay all bills as directed by the Board. The Executive Secretary shall obtain <u>a copy of the bill or</u> a receipt for all disbursements and shall make all <u>such bills or</u> receipts a part of the Board records.

SECTION 8. The Executive Secretary shall manage and update the NCIMS website, including posting NCIMS 2400 Laboratory Forms, Inspections Forms and Non-IMS listed Approved Milk Tank Truck Washing Facilities, information about current programs and activities.

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Proposal #: 31		
Committee:	ylaws	
New Procedure		
Procedure Change		
Const./Bylaws Cha	X	

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

A. Summary of Proposal

Create a "Farm Practices" or "Milk Production Practices" Committee to provide a forum to discuss proposals that directly relate to on-farm regulation.

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

Multiple areas of the PMO deal specifically address farms and production practices. The farm environment presents unique challenges to regulation not seen in other areas of the dairy industry. In recent years a number of proposals to the NCIMS have suggested changes to onfarm regulations. Those proposals were not assigned to a Committee and did not get adequate consideration in Council because they did not come with a Committee recommendation.

The proposed "Farm Practices" or "Milk Production Practices" Committee would discuss proposals relating to Section 7, Items 1r-19r, the areas of the following Appendices that pertain to farms: Appendix A, Appendix C, Appendix D, Appendix E, and Appendix H, and other areas relevant to milk production and farms.

C. Proposed Solution

Changes to be made on the following NCIMS Documents:

Page Number(s)	Document	Page Numbers(s)	Document
	2023 PMO		
	Section(s):		2023 EML
	Appendix:		
	2023 MMSR		Forms Form Number:
	2023 Procedures	X	2023 Constitution and Bylaws

Proposed Change:

Upon ratification, the NCIMS chair is to appoint a "Farm Practices" or "Milk Production Practices" committee.

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Proposal #:	312	
Committee:	Liaison	
New Procedure		
Procedure Change		
Const./Bylaws Cha		

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

A. Summary of Proposal

This proposal establishes a study committee to clarify situations when NCIMS may need to rapidly respond to a potential public health emergency.

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

Through the federal government's response to Highly Pathogenic Avian Influenza (HPAI or H5N1) in dairy cattle event, a need to strengthen the ability of the NCIMS to rapidly respond to *prevent* a potential public health emergency was identified.

Changing NCIMS's posture from reactionary to preventative will strengthen overall coordinated response efforts and, ultimately, assure a dairy food supply that protects consumers of U.S. dairy products.

C. Proposed Solution

Changes to be made on the following NCIMS Documents:

Page Number(s)	Document	Page Numbers(s)	Document
	2023 PMO Section(s): Appendix:		2023 EML
	2023 MMSR		Forms Form Number:
	2023 Procedures	2023 Constitution and Bylaws	

Proposed Change:

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

The assigned study committee would conduct a thorough review (debrief) of the response of NCIMS stakeholders (i.e., federal, state, industry) to the Highly Pathogenic Avian Influenza (HPAI or H5N1) dairy cattle health outbreak. The review shall include, at least, discussion of strengths of the NCIMS cooperative program and areas for potential enhancement to future public health emergencies.

Based on the study committee's review, a list of recommendations will be developed and may include:

- Clarifying the responsibilities (Section IV of *Procedures*) of PHS/FDA, States, TPCs, and SSCs when there is a need to respond rapidly to a public health emergency, or when there is a need to respond rapidly to prevent a potential public health emergency.
- Defining "public health emergency" (see the "NOTE" on page 14 of *Procedures*), the conditions under which PHS/FDA may exercise its authority to protect public health under the provisions of the FFD&CA and the Public Health Service Act.
- Defining conditions (outside of a 'public health emergency'), when PHS/FDA may issue an M-a to prevent a potential public health emergency outside of the "Procedure for Issuing Interpretations" (see *Procedures*, page 13-14). This shall include appropriate guardrails to allow for input and/or approval from the NCIMS Executive Board.
- In addition to defining the scope (i.e., defining 'public health emergency'), the recommendations will also include a timeframe for operating under these conditions (i.e., when will amended requirements be effective through).

The study committee shall report their findings to the NCIMS Executive Board and may include a report to the next meeting of and/or proposals to the next NCIMS Conference.

Name: Food and Drug Administration

Agency/Organization: Human Foods Program – Division of Dairy Safety

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