



National Milk Producers Federation

# Regulatory Register

Special Edition

## 2019 NCIMS Edition



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## Preliminary Results of the 2019 National Conference on Interstate Milk Shipments

The National Conference on Interstate Milk Shipments (NCIMS) met in St. Louis, Missouri from April 26-May 1, 2019 to address the 74 proposals submitted to revise the Pasteurized Milk Ordinance (PMO) and its related documents. National Milk Producers Federation (NMPF) staff attended the conference to advocate positions of interest to dairy cooperatives and their producer members. Many NMPF members also attended and played key roles in the deliberations of the conference. The 2019 conference was very positive for all parties. NMPF made significant progress in achieving reasonable solutions on many key issues. State delegates, the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and dairy-industry participants all came to the conference to discuss the topics at hand and make certain the cooperative aspects of the NCIMS program remained strong and viable.

Significant proposals affecting dairy cooperatives and producers are detailed in this issue. All proposals relate to the 2017 Pasteurized Milk Ordinance (PMO), the 2017 Methods of Making Sanitation Ratings of Milk Shippers, the 2017 Evaluation of Milk Laboratories, and the 2017 Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program for Certification of Interstate Milk Shippers (Procedures) document. A total of 34 proposals were passed by the delegates either as submitted or as amended. Delegates passed an additional five proposals related to laboratory issues that will proceed through the 2400 Form process. Below is a summary of some of the significant actions that occurred at the 2019 NCIMS Conference. Complete conference actions are in the accompanying table at the end of this document.

NMPF submitted five proposals to the conference. Additional submitted proposals included significant contributions from NMPF Staff and NMPF industry members and are described in detail later in this issue. Proposals do not need to pass the conference to attain practical solutions. Success can be achieved by raising the issue to the attention of conference participants, by generating discussion, or by obtaining formal answers and gaining consensus of all stakeholders. On all accounts, positive outcomes were achieved for each NMPF-submitted proposal.

# The following summarizes the results for the NMPF proposals:

## Proposal #202

Proposal #202 sought to modify the requirements of the information required on a shipping statement for milk and milk products by eliminating the requirement for the name of the supervising regulatory agency at the point of shipment. This proposal was voted no action due to its similarity to proposal #203 which was also submitted by NMPF.

## Proposal #203

Proposal #203 sought to modify the requirements of the information required on a shipping statement for milk and milk products by eliminating the requirement for the name of the supervising regulatory agency at the point of shipment in both Section 4 Labeling and Appendix B of the PMO. This passed and eliminates unnecessary labeling requirements.

## Proposal #215

Proposal #215 added clarity to Appendix N for Farm Trace Back and Reinstatement of Producers when samples are found to be positive. It establishes that the same testing method must be used for the producer to be reinstated as was used when found to be positive. NMPF appreciated the collaborative work among the regulatory agencies, Appendix N committee and industry that went into amending this proposal. It was passed as amended.

## Proposal #217

Proposal #217 attempted to add language clarifying that the same analyst is required to complete the Appendix N testing if found to be presumptive positive. It did not pass, but NMPF appreciated the dialogue and clarification at the conference on this matter.

## Proposal #307

Proposal #307 requested a status change of the Appendix N modification committee from a study committee to a standing committee which passed solidifying the importance of antibiotic residue testing. NMPF applauds this outcome as it demonstrates our continued commitment to the prudent use of antibiotics.





## Newly Elected



**Antone Mickelson**, chair of NMPF's interstate milk shipment committee was elected as Vice Chair of the NCIMS Executive Board. Antone also serves on the Council III and the Liaison and Third Party Certification committees. Hailing from Washington, Antone is the director of farm practices for Darigold. NMPF is thrilled to have Antone nominated as vice-chair.

**Neil Bendixen** was elected to the central states region of the NCIMS Executive Board as an industry representative. Neil also serves on the Council II and is vice-chair of the Hauling Procedures committee. He works for Dairy Farmers of America as the Manager of Hauler Relations on the Mideast area council. A long-time participant in NCIMS, NMPF is excited to have Neil on the Executive Board.



## Full Board

Dr. Stephen Beam, Chair, Sacramento, CA  
Antone Mickelson, Vice Chair, Yakima, WA

### Region I - Eastern States (terms expire in 2023)

Casey McCue, State Enforcement, Albany, NY  
Rebecca Piston, Industry, Portland, ME  
Ellen Fitzgibbons, State Enf/Rating/Health, Jamaica Plain, MA  
James Williamson, State Rating, Columbia, SC  
John Sheehan, FDA, College Park, MD

### Region II- Central States (term expires in 2025)

Roger Hooi, Laboratory, Dallas, TX  
Neil Bendixen, Industry, Springfield, MO  
Stephen DiVencenzo, State Enf, Springfield, IL  
Dr. Patrick Gorden, Academia, Ames, IA  
Roger Tedrick, State Enforcement/Rating, Reynoldsburg, OH  
Gene Wiseman, State Rating, Jefferson City, MO

### Region III - Western States (terms expire in 2021)

Stephen Beam, State Enf/Rating/Health, Sacramento, CA  
Randall Chloupek, State Rating, Harvard, NE  
Clint George, State Enforcement, Dallas, TX  
Antone Mickelson, Industry, Yakima, WA  
William Francis, USDA, Washington, DC

### Ex Officio

Thomas Benthien, Council I, Rockford, IL  
Thomas Angstadt, Council II, Erie, PA  
Casey McCue, Council III and Liaison Chair, Albany, NY  
John Miller, Past Chair, Tallahassee, FL  
Frank Barcellos, Lab Committee Chair, Salem, OR  
Cary Frye, Program Chair, Washington, DC  
Ken Anderson, Third Party Certifier, Arlington Heights, IL  
VACANT Consumer  
Clay Detlefsen, NMPF Representative, Arlington, VA  
John Allan, IDFA Representative, Washington, DC  
Marlena Bordson, Executive Secretary, Monticello, IL

## Other Information

The changes to conference documents will become effective within 1 year of publication of the PMO in electronic form. This will occur after the meeting between the NCIMS Executive Board and FDA to discuss the proposals with which FDA does and does not concur. This meeting is scheduled for October 2019.

NMPF would like to thank all members who attended the conference and assisted in the deliberations of the proposals. Your assistance in advocating for the industry's interests was vital to the success of NCIMS.

If you have any questions about NCIMS or the disposition of any of the proposals, please contact [Clay Detlefsen](#), [Jamie Jonker](#) or [Miquela Hanselman](#) at NMPF.

2021 NCIMS Conference date and location is TBD.



# NCIMS 2019 Preliminary Results

<b>Key</b> P=Passed PA= Passed as Amended NA= No Action 2400= 2400 Forms
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The following is a list of the proposals and the final action by the NCIMS voting delegates.

\*\*Outcomes represent NMPF staff record and are subject to change based on official NCIMS

Meeting Transcript and October 2017 NCIMS Executive Board Meeting.\*\*

Proposal	Doc., Sec., Page	Summary	Final Action
JC-1	PMO-21, 33; Procedures: 26; MMSR: 13-14	This proposal calls for FDA to recognize and utilize the NCIMS PMO Appendix T process as meeting the requirements of the FSMA in the review of a milk processing facility producing both Grade A and Non-Grade A Dairy Products. It was amended to be assigned to a committee to work cooperatively with the FDA to develop a pilot program which finds efficiencies in inspection activities for facilities which manufacture both Grade "A" and non-Grade "A" products.	PA
JC-2	PMO, MMSR, Procedures, EML	This proposal contains modifications to the PMO, Methods, Procedures and Bylaws documents that address the regulation and rating of milk plants producing Grade "A" fermented high acid shelf stable milk and/or milk products.	PA
101	39 (PMO)	This proposal provides protection for the milker and milking equipment from urine and feces from the cow while milking.	NA
102	PMO: 41, 42, 44, 45	This proposal will require the installation of an indicating thermometer in milk tank trucks used for direct loading of milk. It is the goal of the proposal that all existing milk tank trucks used for direct loading of milk that are structurally modified or new milk tank trucks used for direct loading of milk manufactured after January 1, 2020 shall be equipped with an approved temperature indicating device.	NA
103	PMO: 58	Reflect a better understanding of work and milking activities at the milk barn by removing milk barn and stable from required hand wash facilities. Eliminate statements that are not enforced.	NA
104	PMO: 58	To correct language inferring personnel are doing activities they don't do while keeping the intent of clean outer garments in place.	NA
105	PMO: 68	To align the requirements for safe water supply as identified in item 7p. Water Supply, Administrative Procedures, point 3 of the PMO with the guidance outlined in M-I-18-3, question 50, a-c, to ensure manufacturers are installing the right equipment at the right points of possible pollution.	NA
106	PMO: 74 item 12p, p. 1, letter I	The purpose of this proposal is to provide clarification on the emptying and cleaning of storage tanks as identified by item 12p within the PMO.	PA
107	PMO: 95 and 290	This proposal contains modifications to the PMO to provide clarification to industry and regulatory on the operation and testing of temperature-recording devices for batch pasteurization processes utilizing temperatures greater than 71°C (160°F) as specified in Appendix H, section IV of the PMO.	NA
108	PMO: 102	This proposal adds language to Item 16p.(B)2.f.(2)ii. and Appendix H that will allow use of the partial homogenization for producing the milk and/or milk products.	PA

109	PMO: 108	To allow milk pasteurization plants to list either their name and location or their milk plant code on their milk pasteurization charts.	P
110	PMO: 109, Item 16p, number 2, letter C	The purpose of this proposal is to revise the requirement on the frequency of training on the milk plant emergency sealer program as stated in item 16p of the PMO to every two years and to allow for additional milk plant personal to be properly trained in equipment sealing.	NA
111	PMO: 112-115	The PMO should allow for an exception to the pH of yogurt needing to be 4.8 or less at filling for cup set yogurt. Cup set yogurt should have the requirements of reaching a pH of 4.6 within 24 hours and cooled to 7°C or less within seventy-two (72) hours.	PA
112	PMO: 119	To allow for the transportation of yogurt in a sealed container from one plant to another for addition of flavoring and packaging as is allowed for cottage cheese. This proposal was assigned to a standing committee with input from affected stakeholders to review the NCIMS role in regulating the repackaging of cultured milk and/or milk products.	PA
113	PMO: 182,183, 282	Add a "flow control system" as an alternative to a "flow control valve" in Appendix D and Appendix H for controlling performance in UV light systems used to treat water. Remove reference to "design flow".	P
114	PMO: 181-186 in appendix D; 282-283 in appendix H	This proposal was amended to be assigned to an NCIMS standing committee to address the issues identified in this proposal and proposals 115 and 116 involving UV disinfection and other technologies to product disinfected and or/ pasteurized equivalent water as prescribed in Section VII, Appendix D and Appendix H.	PA
115	PMO: 14, 182, Appendix D, 282-283, Appendix H	Add a certificate to accompany all new UV light systems installed in dairy plants intended for general treatment of potable water or to achieve an equivalency in pasteurized water and be available upon request to dairy plant inspectors as a tool to increase confidence in the safety of water used in dairy plants.	NA
116	PMO: 282-283	The purpose of this proposal is to include membrane microfiltration technology in Appendix H, section IX as an acceptable method to produce Pasteurized Equivalent Water (PEW).	NA
117	Various	The proposal outlines clarifications and editorial changes made to Item 16p and Appendix H of the PMO.	P
118	Various	The technical engineering review committee determined that AMI technology shouldn't be regulated any differently than other dairy farm technology.	P
119	PMO: 278	This proposal would allow a flow diversion system with a long successful history in the LACF program to be used on HHST systems to produce Grade A milk products in a non-aseptic setting.	NA
120	PMO: 301	This proposal adds language that will limit PMO Appendix I Tests 9.2.1 and 9.2.3 (of Test 9.2) to plate type and double tube/triple tube type HHST and HTST pasteurization systems, to clarify that test 9.2.1 and 9.2.3. do not apply to spiral tubular regenerators such as those in Spyrotherm and Unitherm HHST pasteurization systems.	P
121	PMO: 339	To provide an exception for the presence/consumption of water (in an acceptable, hygienic format) by employees working in fabrication and storage areas.	NA
122	PMO: 78, 337	This proposal clarifies that to comply with the bacteria standard noted in Item 12p and Appendix J, a sample set shall not have two (2) or more out of four (4) samples exceeding the bacterial standard.	P

123	PMO: 342	To allow for reusable slip sheets and packaging material of single service containers and closures provided that it is properly constructed, cleaned and sanitized.	NA
201	PMO: 6	Add definitions to the PMO for HHST and HTST.	NA
202	PMO: 19	To modify the requirements of the information required on a shipping statement for milk and milk products by eliminating the requirement for the need for the "Name of the supervising Regulatory Agency at the point of shipment."	NA
203	PMO: 19, 147	Eliminates the requirement for the need for the "Name of the supervising Regulatory Agency at the point of shipment."	P
204	PMO: 20	This proposal is to allow dairy plants (packaging dry milk products) the option to apply the "Grade A" designation to bags of powder either before or after filling. This proposal would require those plants (that want to apply the label after filling) to apply the label immediately, and in the same room where the container was filled.	NA
205	PMO: 27, 29	The 2017 Procedures Manual requires Sampling Surveillance Personnel to be recertified once every three years. This proposal would allow for recertification period to include the remaining days of the month similar to what is allowed in the "Industry Plant Sampler" and "Dairy Plant Sampler" definitions found in the 2017 PMO.	P
206	PMO: 30	To clarify primacy of the FDA/NCIMS 2400 forms over <i>SMEDP</i> and <i>OMA</i> in the PMO.	PA
207	PMO: 30	Ensure the milk tests listed under Section 6 of the PMO are kept current by referring to the latest version of M-A-98.	PA
208	PMO: 30, 74, 76, 107, 116, 213	This proposal eliminates the requirement that vitamin volume control records, cleaning charts/records, pasteurization charts, temperature records/charts for refrigerated rooms and pH recording charts be reviewed, dated, signed or initialed by or under the oversight of a Preventive Control Qualified Individual (PCQI) at facilities that are exempt from some or all of 21 CFR part 117 preventive controls regulations.	PA
209	PMO: 140	To align the requirement for verifying the accuracy of farm bulk milk tanks to six (6) months in Item 18r with Appendix B item 3.c. in the 2017 PMO.	NA
210	PMO: Appendix B, pg 143-144	This proposal is to allow for the use of the Piper DynaStream, an automated truck-mounted metering and sampling system, for the acquisition of representative samples of milk as described in the PMO.	PA
211	PMO: 138-148	This proposal includes new procedures for the sampling required by aseptic in-line sampling systems, petcocks and in-line sample points.	PA
212	FDA Form 2399a	FDA Form 2399a will need to be revised to reflect changes to Appendix B of the 2017 PMO.	PA
213	PMO: 30, 74-75, 76, 107, 116, 213	To clarify that the PCQI reference is only applicable in these sections if it is required in the firm's food safety plan.	NA
214	PMO: 359, 384	Proposal is to make changes to the current PMO, appendix N, that takes into account the burden placed by appendix on the Very Small Business.	NA

215	PMO: 360	To add clarity to Appendix N for Farm Trace back and Reinstatement of Producers found to be positive and shipments discontinued for the period until found to be no longer positive for drug residues.	PA
216	PMO: 362, 363	This proposal eliminates the Appendix N reference to M-I-06-5 for the disposal of adulterated milk and updates the referenced FDA Compliance Policy Guide to the current CPG.	PA
217	PMO: 364-365	To add language to clarify the same analyst is required to complete the Appendix N testing if found to be presumptive positive.	NA
218	PMO: 32, MMSR: 8, 15, 22, 32, 99, 102, 107, 108	To clarify and make consistent the language and intent of the PMO in regards to record keeping methods and format.	NA
219	PMO: 14, 223; MMSR: 6	To allow the Regulatory Agency to designate the Government Water Control Authority Agency to perform the inspections of water systems after corrective actions have been taken and to define Government Water Control Agency.	NA
220 MMSR	MMSR: 49, 78	To require that all BTUs be labeled as such when entered in the 2359i form and in doing so require that the naming conventions for IMS list submissions of a designation BTU follow the example on pages 78 of 2017 Revision of Methods.	NA
221	PMO: 359-364, MMSR: 7	To clarify that when a producer's milk is found to be confirmed positive for drug residues using an approved test method that all subsequent reinstatement work is done using the same or equivalent test method as was used when the producer was initially found to be violative.	NA
222	MMSR: 117	To change the five (5) point violation of a water line which by-passes a pre-cooler from five (5) points to two (2) points.	NA
223	EML	Grant LPET the option to extend certification from 3 to 6 years for LEOs in good standing. Allow on-site surveys to be done up to 60 days early yet maintain the previous date for determining the new biennial or triennial expiration dates.	PA
224	2400 Forms	Hygiena LLC require to have validated through NCIMS a new electronic measurement assay for Alkaline Phosphatase in milk. The assay is branded ZymoSnap and uses bioluminescence as the measured in the system.	NA
225	2400 Forms	To propose a test for the simultaneous qualitative detection of 34 drug residues in milk by Infiniplex – Evidence Investigator.	NA
226	2400 Forms	To propose a test for the simultaneous qualitative detection of 34 drug residues in milk by Infiniplex – MultiStat.	NA
227	2400 Forms	To propose a test for the quantitative simultaneous detection of 15 sulphonamides in milk.	NA
228	PMO, 2400 Forms	Proposing to have Colitag, a Presence/Absence Chromogenic Substrate (ONPG-MUG), included as an approved test method for Coliforms in Potable Water.	2400- PA
229	PMO, 2400 Forms	Proposing to have Colitag, an MPN Chromogenic Substrate (ONPG-MUG), included as an approved test method for Coliforms in Potable Water.	2400- PA



230	2400 Forms 24001: 2	Include two additional controls to the disintegration procedure, and remove a control that should not be listed.	2400- P
231	2400 Forms 2400a: 1	Include microwaving as an acceptable method for the remelting of plating agars.	NA
232	2400 Forms: 8	Change FORM FDA/NCIMS 2400 Cultural Procedures – General Requirements to clarify sterilization of media by moist heat (autoclave).	NA
233	2400 Forms: 8	Change FORM FDA/NCIMS 2400 Cultural Procedures – General Requirements to clarify sterilization of media by moist heat (autoclave).	NA
234	2400 Forms: 5	Change FORM FDA/NCIMS 2400 Cultural Procedures – General Requirements to remove the requirement that Temperature Monitoring Systems described in section 3e that meet prerequisites of section 3c are compared weekly to an accurate thermometer.	2400- P
235	2400 Forms: 13	Change FORM FDA/NCIMS 2400 Cultural Procedures – General Requirements to remove the requirement that laboratories check volume, pH and toxicity of purchased dilution water blanks if the manufacturer provides a technically valid certificate of analysis of these parameters and the lot has passed requirements outlined in section 25.	NA
236	2400 Forms: 18	Change FORM FDA/NCIMS 2400 Cultural Procedures – General Requirements to clarify “room temperature”.	NA
237	2400 Forms	To remove the 2400 forms circulation requirement in water baths, in order to allow for the use of thermal metallic beads.	NA
238	2400 Forms	Remove equipment listed in the FDA/NCIMS 2400 forms that is no longer approved for use.	2400- PA
239	2400 Forms: J-2, J-3	Update Charm FAP and Paslite Phosphatase 2400 forms with next generation novaLUM II X instrumentation.	2400- PA
240	2400 Forms: N-1	Approve the Charm beta-lactam 30 second test (BL30SEC) and incorporate into the SL/SL3 2400 form.	2400- P
241	2400 Forms: A-6 and Cultural Procedures GR	Update Peel Plate 2400 form with room temperature stability and prepared cultured dairy plates.	2400- P
242	2400 Forms: GR 10,13	This proposal would add bulk milk tanker sampling requirement information into the FORM FDA/NCIMS 2400n Appendix N – General Requirements rev. 10/13. The additional information would include: 1) Acceptable temperature requirements for receiving raw milk in bulk milk tanker trucks; 2) Acceptable volume limits in a sample container; 3) Proper identification of bulk milk tanker truck samples.	NA
301	PMO: 346 347, 250; FORM FDA 2359m	To reconcile APPENDIX K. HACCP PROGRAM language with the APPENDIX T. PREVENTIVE CONTROLS FOR HUMAN FOOD REQUIREMENTS FOR GRADE “A” MILK AND MILK PRODUCTS language.	PA
302	PMO: 397-400	Clarity in the requirements of Appendix T and improved alignment with FSMA.	NA
303	Procedures: 4-5	To clarify the issuance process for Memorandums of Information (M-I) to be reviewed by the NCIMS document review committee.	PA

304	Procedures: v, 10, 38, 65, 74; Bylaws: 84	This proposal would allow States and TPCs the option of having their State Program Evaluations (SPEs) conducted once every five (5) years instead of every three (3) years dependent on if The State or TPC had two (2) consecutive triennial written Regulatory/Rating Agency Program Evaluations conducted and completed within the established 3-year time frames, and both of these SPEs are classified as being "in compliance" with the requirements of the Grade "A" PMO and the NCIMS Procedures document.	PA
305	Procedures: 15	This proposal eliminates the requirement that shipping states and TPCs must immediately notify all known receiving States when there is a significant change in the number of dairy farms within certified interstate milk shippers supply (BTU).	P
306	EML: 22, Procedures: 29	Clearly define attendance at the FDA Regional Milk Seminar for Laboratory Evaluation Officers.	PA
307	Procedures: 85	The Appendix N Modification Committee will become a standing committee.	P
308	PMO; Procedures	The utilization of the training from the PHS/FDA Milk Specialists on Appendix T coupled with the abbreviated training course approved by the HACCP Implementation Committee constitutes sufficient and adequate training for original certification of the SRO. The abbreviated training course approved by the HACCP Implementation Committee meets the training requirements for recertification of the SRO.	PA