



Regulatory Register

VOLUME 13

SPECIAL ISSUE 2011

Inside this issue:

NMPF Proposals 2

Significant Proposals That Passed 3

Significant Proposals That Did Not Pass 4

Executive Board Elections 4

Final Actions by Voting Delegates on Proposals 6

Food Safety

Preliminary Results of the 2011 National Conference on Interstate Milk Shipments

The National Conference on Interstate Milk Shipments (NCIMS) met in Baltimore, Maryland from April 29 – May 4, 2011 to address the 91 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.

Overall, the 2011 Conference was very positive for all parties, and proposals were discussed

with a high degree of professionalism and cooperation. State delegates, the Food and Drug Administration (FDA), the US Department of Agriculture (USDA), and the dairy industry participants all came to the Conference to talk through the topics at hand and make certain the cooperative aspects of the NCIMS program remained strong and viable.

Proposals of significance to dairy cooperatives and producers are detailed in this issue. All proposals relate to the 2009 *Pasteurized Milk Ordinance* (PMO), the 2009 *Methods of Making Sanitation Ratings of Milk Shippers*, the 2009 *Evaluation of Milk Laboratories*, and the

2009 *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program for Certification of Interstate Milk Shippers* (Procedures) document.

A total of 41 proposals were passed by the delegates as submitted or with amendments. An additional 13 proposals were passed by the delegates to proceed through the 2400 Form process. In this issue is a summary of some of the significant actions that occurred at the 2011 NCIMS Conference. Complete Conference actions are listed in the accompanying table.

NMPF Proposals

NMPF submitted eight proposals to the 2011 Conference with mixed outcomes. The following summarizes the results for the NMPF proposals:

- **Proposal #105** for the allowance of the use of **quartermilkers** on untreated cows did not pass. The NCIMS Scientific Committee expressed concerns about the potential for microorganisms to infect other quarters in the animal. Over the next two years, NMPF will examine those concerns through the scientific literature. Based upon the scientific literature, NMPF may resubmit the proposal.
- While **Proposal #203** to allow for the use of an **electronic manifest** starting with milk pickup at the farm did not pass, resolution was found at the Conference. The NCIMS Hauling and MMSR Committees discussed the proposal, with FDA indicating that use of electronic manifests is already allowed. FDA will issue a written communication on this matter.
- **Proposal #206** to reduce the **Somatic Cell Count** threshold from the current 750,000 per mL to 400,000 per mL failed on a paper ballot (25-26). Some delegates raised concerns about impact on farms and other delegates felt this quality issue should not be addressed in the PMO.
- **Proposal #209** to remove **veal tissue residues** from the list of criteria under which additional milk residue testing could be required passed the Conference. NMPF believes that the assumed link between veal tissue residues and milk residues is, at best, tenuous.
- **Proposal #221** to establish a study committee to examine **washing of tanker trucks** which have been previously used to haul other allergenic foods did not pass. It was suggested that industry develop a study and provide the data at the next Conference.
- **Proposal #304** to allow regulatory flexibility when a **BTU scores less than a 90** did not pass. NMPF was able to present data illustrating the impact a BTU delisting had on industry, but concern was expressed in the MMSR Committee and in Council II that any deviation from the current standard would be unacceptable.
- **Proposal #307** to develop procedures to be followed for future enforcement activities that **overlap with existing NCIMS** programs did not pass. The already established NCIMS Liaison Committee can conduct such activities now. A resolution supporting this was passed at the Conference.
- **Proposal #310** to extend the **International Certification Pilot Program** to include options for domestic participation did not pass.

Significant Proposals That Passed

- **Proposal #101** to allow for use of **UV light** as an adjunct to pasteurization passed as amended to form a study committee. This project was initiated by the Innovation Center for U.S. Dairy.
- **Proposal #103** which was submitted by FDA to reduce the bacterial limit from 30,000 to 10,000 for Grade A **nonfat dry milk** and dry milk and milk products passed. The proposal also removed some quality tests from the list of standards for these dry products.
- **Proposal #117** to allow for the use of potassium sorbate or specific microbial inhibitors combined with filling **cottage cheese** at specified times and temperatures passed. This proposal will be effective June 15, 2011, with the issuance of FDA memorandum IMS-a-45 Supplement 2, which will amend the PMO.
- **Proposal #120** to correct PMO reference to current **TB and Brucellosis Eradication Programs** for bovines passed as amended. The amendment removed a mandate for States to implement eradication for non-bovine species (which do not have a USDA eradication program) and instead established a study committee for non-bovine species.
- **Proposal #208** approved the use of **aseptic samplers** for obtaining the universal sample from a bulk milk tank.
- **Proposal #219** approved the **Charm Beta-lactam and Flunixin Test** as a method for screening raw milk under Appendix N. The proposal approved the test, but did not change the requirements for testing raw milk under Appendix N.
- **Proposal #301** passed, which was submitted by the NCIMS **Aseptic Pilot Program** committee. This Proposal addresses the regulation of the aseptic processing and packaging system in accordance with the Low Acid Canned Foods (LACF)/Acidified Foods (AF) regulations contained in 21 CFR 108, 110, 113, and 114, while regulating the areas of the milk plant that are outside the aseptic processing and packaging system in accordance with the PMO. It provides for a separate IMS listing for Grade “A” aseptic milk and milk products.
- The **third party certification pilot program** for imported products was extended until the end of 2013 (**Proposal #309 passed**). This program will oversee third parties and allow them, with proper certification, to conduct NCIMS work for foreign dairy farms and plants. This will provide a means to ensure that any imported products meet the same regulatory requirements as U.S. dairy farms and plants. It will also enable States to detain any product that is not meeting these requirements now that an option for compliance is available. This pilot program has been operating for 6 years and has several plants participating. More facilities are needed to gather enough data to see if third party certification is appropriate under NCIMS. To assist in this, the number of facilities allowed for each third party certifier was increased from 4 to 6 (**Proposal #312 passed**).
- **Proposal #313** passed as amended, which requested the Liaison Committee to provide comments and outreach to stakeholders on the implications of the **Food Safety Modernization Act** on the IMS program.

Significant Proposals That Did Not Pass

- **Proposal #108** did not pass. This proposal would have prohibited storage of **expired drugs** on the premises of dairy farms. Expired drugs found on dairy farms would be assumed to be in use, would be considered adulterated, and would ultimately result in a 2-point debit. The use of expired drugs is already prohibited by the Food Drug & Cosmetic Act.
- **Proposal #109** and **#202** did not pass, which would have allowed **industry personnel** to collect regulatory samples of milk and water.
- **Proposal #125** did not pass. This proposal would have required that a milk plant had a person available to assist in **accessing electronic records** during FDA inspections and ratings. There was concern as to how the language would be interpreted, and industry has already accepted that providing access to records is their responsibility.
- **Proposal #201** did not pass, which would have amended **Definition X for Milk Products**. The proposal would have specified how different forms of milk-derived ingredients would be calculated (actual ingredient weight vs. reconstituted weight) when used in non-standardized milk products.
- **Proposal #305** did not pass, which would have increased the maximum **inspection frequency** for state ratings of farms, plants, receiving stations, transfer stations and single-service facilities from 24 months to 36 months.

Executive Board Elections

Elections to the Executive Board also occurred at the Conference.

John Miller, Florida Department of Agriculture & Consumer Services was elected as Chairman and Don

Breiner, Land O'Lakes was re-elected as Vice Chairman.

In addition, the new representatives on the Executive Board will consist of:

Laurie Bucher, MD
Casey McCue, NY
Terrence Philibeck, IN
Mike Wiggs, ID.

A complete list of the Executive Board is given on page 5 of this issue.

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 anticipated to occur in late September or early October 2011.

NMPF Staff would like to thank all members who attended the Conference and assisted in the deliberations of the proposals. Your assistance in advocating the

industry interests was vital to the success of the Conference.

If you have any questions about NCIMS or the disposition of any of the proposals, please contact [Jamie Jonker](#) or [Beth Briczinski](#) at the NMPF offices.

NCIMS Executive Board

<i>John Miller</i>	Chair	Tallahassee, FL
<i>Don Breiner</i>	Vice Chair	Carlisle, PA

Region I – Central States, Terms Expire 2013

<i>Terry Philibeck</i>	State Rating	Indianapolis, IN
<i>Gary Cazaubon</i>	State Enforcement	Baton Rouge, LA
<i>Ron Schmidt</i>	Academia	Gainesville, FL
<i>Sue Esser</i>	State Enf./Rating/Health	Lansing, MI
<i>David Lattan</i>	Industry	Carlinville, IL
<i>Frank Barcellos</i>	Laboratory	Tulsa, OK

Region II - Western States, Terms Expire 2015

<i>Stephen Beam</i>	State Rating	Sacramento, CA
<i>Mike Wiggs</i>	State Enforcement	Boise, ID
<i>George Blush</i>	State Enf./Rating/Health	Topeka, KS
<i>Jodeen Meenderink</i>	Industry	Salt Lake City, UT
<i>Ken Vorgert</i>	USDA	Lisle, IL

Region III - Eastern States, Terms Expire - 2017

<i>Casey McCue</i>	State Rating	Albany, NY
<i>Laurie Bucher</i>	State Enforcement	Baltimore, MD
<i>John Miller</i>	State Enf./Rating/Health	Tallahassee, FL
<i>Don Breiner</i>	Industry	Carlisle, PA
<i>John Sheehan</i>	FDA	College Park, MD

Ex Officio

<i>Gary Kuhlman</i>	Council I	Springfield, IL
<i>Randy Chloupek</i>	Council II	Harvard, NE
<i>G.M. Gallaspy</i>	Council III	Montgomery, AL
<i>John Beers</i>	Past Chair	Richmond, VA
<i>Cary Frye</i>	Program Chair	Washington, DC
<i>Jamie Jonker</i>	NMPF Representative	Arlington, VA
<i>Jonathon Gardner</i>	IDFA Representative	Washington, DC
<i>Vacant</i>	Consumer Representative	
<i>Marlena Bordson</i>	Executive Secretary	Monticello, IL

The following is a list of the proposals and the final action by the voting delegates.

Proposal	Doc., Sec., Page	Summary	Final Action
101	PMO, p 28	Allow UV as an adjunct to thermal pasteurization for increase in shelf-life	Passed with Amendment
102	PMO, p 30	Update of tests required for NFDM and dry dairy products	No Action
103	PMO, p 30	Update tests required for NFDM and dry dairy products	Passed
104	PMO, p 30	Update bacterial standards for NFDM	No Action
105	PMO, p 31-32	Allow for quartermilkers	No Action
106	PMO, p 36-40	Allow direct load alternatives at the milkhouse	Passed with Amendment
107	PMO, p 46, 66	Clarify that 3A Standards and FDA Equipment Guideline should be used in evaluating dairy equipment	No Action
108	PMO, p 51	Remove and exclude expired drugs from dairy premises and clarify expired drugs are not used in treatment of animals	No Action
109	PMO, p 61	Allow regulatory milk plant water samples to be collected by industry personnel	No Action
110	PMO, p 66-68	Allow cultured product to be held in a processing tank >72 hr, increasing time after breaking	No Action
111	PMO, p 67	Ensure milk tank trucks are washed in a timely manner	No Action
112	PMO, p 72	Allows use of peracetic acid based hydrogen peroxide products to sterilize/sanitize caps and bottles	No Action
113	PMO, p 77-78	Updates PMO to 3A standards for single-bodied double seat valves	Passed with Amendment
114	PMO, p 81	Expands criteria of regenerator used for heat exchange purposes	Passed with Amendment
115	PMO, p 84	Allows circulating loop of crossflow membrane microfiltration system to be at elevated temperature during production	Passed with Amendment
116	PMO, p 102	Requires reading of airspace thermometer to be recorded on batch pasteurizer only at start of holding, if using a digital thermometer with continuous recording	Passed with Amendment
117	PMO, p 107-111	To recognize evidence that potassium sorbate or other inhibitors with filling of cottage cheese packages at 55°F enhances food safety.	Passed with Amendment
118	PMO, p 103	Exempt requirement that quarterly time accuracy for recording thermometers be duplicated on flow-rate recording charts when using magnetic flow based meters	Passed

Proposal	Doc., Sec., Page	Summary	Final Action
119	PMO, p 107-110	Adds slurry temperature requirements to Item 17p (copied from Appendix H)	Passed with Amendment
120	PMO, p 117, 118, 129	Corrects text in TB and Brucellosis Eradication Programs	Passed with Amendment
121	PMO, p 174-177	Clarifies UV disinfection of water is equivalent to chemical disinfection of water for reuse purposes	Passed with Amendment
122	PMO, p 176	Allows Category II reclaimed water to be used as a non-circulated heat exchange medium	No Action
123	PMO, p 218	Allows alternate method using double-block & bleed valves to prevent continued flow to the injection point	Passed with Amendment
124	PMO, p 221-222	Clarifies requirements for use of magnetic flow meter based timing	Passed with Amendment
125	PMO, p 251	Assures a milk plant has a person to assist the regulatory/rating and FDA person with electronic records access during inspections and ratings	No Action
126	PMO, p 252	Clarifies signature requirements for storage tank temperature records with electronic records	Passed with Amendment
127	PMO, p 256	Includes new frequency drive technology in the sealing process of a pasteurization system	Passed with Amendment
128	PMO, p 258	Eliminates a 2 nd memory chip in older pasteurization system's computer/PLC technology	Passed with Amendment
129	PMO, p 267	Edit to correct a typo	Passed
130		Establish a Single Service Certification Pilot Committee	No Action
201	PMO, p 6	Amend Definition X Milk Products	No Action
202	PMO, p 3, 23, 130	Allow regulatory milk samples to be collected by industry	No Action
203	PMO, p 15, 16, 132, 133, 137, 138; MMSR,p 85	Allow use of electronic technology related to milk picked up at farms	No Action

Proposal	Doc., Sec., Page	Summary	Final Action
204	PMO, p 19 MMSR, p 76, 83	Amend permit suspension for consecutive violations of same requirement	No Action
205	PMO, p 23, 29; MMSR, p 82	Eliminate sampling and testing requirement for bulk shipped heat treated milk products	Passed with Amendment
206	PMO, p 24, 29, 30, 201	Updates SCC level	No Action
207	PMO, p 29	Updates SCC level	No Action
208	PMO, p 24, 26, 130, 132, 134	Alternative farm bulk tank sampling system to obtain the universal sample	Passed with Amendment
209	PMO, p 25	Remove veal criterion from tissue residue data	Passed
210	PMO, p 135	Allow tanker stickers on front bulkhead of milk tank trucks	Passed with Amendment
211	PMO, p 137	Requires washing of hose, pump, and parts if a milk tank truck sits idle for >4 hours	No Action
212	PMO, p 202, 210	Criteria for onsite production and sanitation use of hypochlorous acid	Passed with Amendment
213	PMO, p 46, 202, 270	Include methods for Electro-Chemical Activation for cleaning and sanitizing	No Action
214	PMO, p 46, 202,336	Corrections to sanitization sections with respect to govt agencies and CFR citations	Passed with Amendment
215	PMO, p 211	Corrections to Chemical and Bacteriological Tests	Passed with Amendment
216	MMSR, p 30, 31, 48, 51, 52, 54, 56, 76, 77, 82-84	Corrections to enforcement requirements and criteria	Passed
217	MMSR, p 39, 65	Corrections to reflect HACCP training requirements	Passed
218	MMSR, p 41, 67	Modifies Form FDA 2359n to include HACCP training requirement	Passed with Amendment

Proposal	Doc., Sec., Page	Summary	Final Action
219	2400 Forms	Accept a flunixin and beta-lactam test for Appendix N screening	Passed to 2400 Form Process
220	PMO	Assigns a committee to study using the monthly SCC in place of a single SCC for a producer each month	No Action
221		Assigns a committee to study the need for multiple washings after hauling allergenic foods	No Action
222	PMO, 2400 Forms	Assigns a committee to study SMEDP as it is referenced in the PMO	Passed
223	2400 Forms	Extends allowable time for transportation of water samples from 30 to 60 hours	No Action
224	2400 Forms	Replace Neogen BetaStar US with BetaStar Plus BetaLactam Test	Passed to 2400 Form Process
225	2400 Forms, p 15-20	Add Easygel Aerobic Plate Count Media, Pectin Gel Method, to Milk Laboratory Evaluation Form	Passed to 2400 Form Process
226	2400 Forms, p 4-5	Update Idexx SNAP 2400 series form	Passed to 2400 Form Process
227	2400 Forms, App N	Define and clarify “previously negative tested raw milk” used on Appendix N forms	Passed to 2400 Form Process
228	2400 Forms, p 1, 2	Amend forms to reflect maximum 0.5°C graduation interval for thermometers	Passed to 2400 Form Process
229	2400 Forms, Charm SL, SL6, Charm 3 SL3	Allow for unrefrigerated shipment of antibiotic test kits	Passed to 2400 Form Process
230	2400 Forms, App N GR, p 1, 2, 6	Clarify intent of requirements for Thermometers and Samples on form 2400n	Passed to 2400 Form Process
231	2400 Forms, 2400j, 1-11	Clarify Form 2400j Phosphatase Test – Fluorophos ALP Test System	Passed to 2400 Form Process
232	2400 Forms, 1	Add wording to DMSCC form for how long samples may be run after collection	Passed to 2400 Form Process
233	2400 Forms	Allow beta lactam testing of sheep milk that has been frozen and thawed	Passed to 2400 Form Process
234	2400 Forms	Update language for autoclave performance checks.	Passed to 2400 Form Process
235	EML, p 3, 22, 27, 30	Add to 2009 EML the option for the LEO to send the narrative report electronically	Passed with Amendment

Proposal	Doc., Sec., Page	Summary	Final Action
236	EML, p 3, 5, 6, 7, 16, 22, 24, 33-xx	Add requirement for a summary template to be submitted with the lab narrative report	Passed with Amendment
237	EML, p 28-32	Update examples and clarify "NOTE"	Passed
238	EML, p 3	Allow State LEO the same time as federal LEO for supplemental surveys	Passed with Amendment
239	EML, p 23	Edit to text	No Action
240	EML, p 1	Addition regarding issuance of 2400 Series Forms	No Action
241	EML, p 3, 4, 16, 18	Remove non-applicable references to SMEDP	Passed
242	EML, p 1, 2, 5, 16-22	Update with addition of Federal LEOs to reflect the cooperative program	Passed with Amendment
243	EML	Specify NCIMS Lab Cmte will issue a draft of 2400 series forms 90 days after NCIMS Board approval if FDA is unable to issue within this time frame	Passed with Amendment
244	EML, p 3	Allow State LEO to input info for IMS List online	No Action
245		Allow State LEO to follow same input process to IMS list that SROs currently do	No Action
246	EML, p 16	Include pre-req for FD373 State LEO workshop	Passed
247	EML, p 24	Remove website listed as a source for 2400 series forms	Passed
248	2400 Forms	Change the ranges for the standards for calibrating/ validating the instruments used to measure somatic cells in milk. These changes would apply to standards used on all approved electronic cell counters.	Passed to 2400 Form Process
301	PMO, MMSR, Procedures	Incorporates findings of Aseptic Pilot Program Committee for Grade A low acid aseptic milk/milk products. Also requests 2-year extension of Aseptic Pilot Program.	Passed
302	Procedures, p 20, 21 PMO, p 71, 314, 315	To remove the requirement for the sampling and testing of single service containers; To update 2400 series forms to reflect testing of reusable glass containers	No Action
303	Procedures, p 7, 27	Update procedures document to same as EML	Passed with Amendment

Proposal	Doc., Sec., Page	Summary	Final Action
304	Procedures, p 11, 24, 33-34, 38; MMSR, p 11, 13, 18, 19, 23-25 Forms 2359o	Regulatory discretion on BTU delisting when score on rating is <90	No Action
305	Procedures, p 24, 44	Increase maximum inspection frequency for State Ratings of farms, plants, RS/TS, and SSF from 24 to 36 months	No Action
306	MMSR, Procedures	To modify the current State Enforcement Rating for NCIMS Grade A Plants to be uniform throughout the Grade A program.	No Action
307		To develop processes to be followed for future enforcement activities that overlap with existing NCIMS programs	No Action
308	PMO, p 121-122	For the NCIMS Aseptic Pilot Program Implementation Committee to develop, implement, oversee, and evaluate an NCIMS Retort Pilot Program	Passed
309	PMO, p 122	Extends ICPP until December 31, 2013	Passed
310	PMO, p 122	Extends ICPP to include options for domestic participation	No Action
311		Expand ICPP to 5 TPCs	No Action
312		Expand ICPP to allow each TPC to certify up to 6 plants	Passed with Amendment
313	PMO	To establish an ad hoc committee to align the PMO with the FSMA	Passed with Amendment

Outcomes represent NMPF staff record and subject to change based on official NCIMS meeting Transcript and September 2011 NCIMS Executive Board Meeting.