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Food Safety

Preliminary Results of the 2015 National Conference on Interstate Milk Shipments

The National Conference on Interstate Milk Shipments (NCIMS) met in Portland, Oregon from April 24-29, 2015 to address the 100 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.

Although NMPF was not able to secure all desired outcomes, the 2015 Conference overall was very positive for all parties. 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 to make certain the cooperative aspects of the NCIMS program remained strong and viable.

Proposals of significance to dairy cooperatives and producers are detailed below. All proposals relate to the 2013 *Pasteurized Milk Ordinance* (PMO), the 2013 *Methods of Making Sanitation Ratings of Milk Shippers*, the 2011 *Evaluation of Milk Laboratories*, and the 2013 *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program for Certification of Interstate Milk Shippers* (Procedures) document.

A total of 44 proposals were passed by the delegates either as submitted or as amended. An additional five proposals, related to laboratory issues, were passed by the delegates to proceed through the 2400 Form process. Below is a summary of some of the significant actions that occurred at the 2015 NCIMS Conference (complete Conference actions are in the accompanying table at the end of this document).

The 2017 NCIMS Conference will be held from May 12th through May 19th, in Grand Rapids, Michigan.

NMPF-Submitted Proposals

NMPF submitted four proposals and one resolution to the 2015 Conference. Additional proposals were submitted with significant contributions by NMPF Staff and NMPF industry members, and are described in detail later in this issue.

The following summarizes the results for the NMPF proposals and resolution:

- **Proposal #218** to clarify that the drug residue test kit requirements as currently outlined in Appendix N apply only to those drug residues for which testing is required by the PMO did not pass. However, this concept was addressed through other proposals modifying Appendix N and, therefore, NMPF supported the final Conference action.

- **Proposal #302** to formalize the appointment of Chairs and Vice Chairs to NCIMS Committees passed as amended. This will assure continuity for both short- and long-term within NCIMS committees, and will help develop future leadership within the Conference.

- **Proposal #303** to allow a vacated elected Board seat to be filled between Conferences passed as amended. Prior to this proposal, vacant Executive Board seats remained unfilled until the next biennial or special meeting of the Conference. With the passage of this proposal, full representation and balance on the NCIMS Executive Board will continue between Conferences.

- **Proposal #307** to clarify that drug residue summary data shall be collected by Third Party Certifiers (TPCs) and reported to the third party database passed as amended. The *Procedures* now clarifies that TPCs will submit residue testing data to the third party database, which will report the data in aggregate form (both domestic and international). The TPCs have also agreed to submit annually a separate report to the International Certification Program Committee of their data to demonstrate the efficacy of the third party program.

- **Resolution #10**, acknowledging the significant and noteworthy efforts of the federal FDA Risk Management Team, team leader, project manager, subject matter experts, risk assessment advisors, modelers, scientific and policy experts, external peer reviewers, and expert panelists and thanking them for their contributions to the report *Multicriteria-based Ranking Model for Risk Management of Animal Drug Residues in Milk and Milk Products*, passed. This report fulfilled a 2007 request from the NCIMS Appendix N Modification Committee and is currently available online for public comment. (NMPF will be submitting comments on the report; contact Beth Briczinski.)

Significant Proposals That Passed

Proposals related to the Food Safety Modernization Act (JC-1, JC-3, JC-4, JC-5, JC-7).

NMPF staff have strongly advocated for the FDA to exempt PMO-regulated facilities from the application of the Food Safety Modernization Act (FSMA) or otherwise deem them to be in compliance. That multi-year effort culminated in a collaboration with the NCIMS Liaison Committee and the submission of individual proposals to modify the PMO to address gaps that existed between the PMO and FSMA (five proposals were submitted by the NCIMS Liaison Committee, one proposal was submitted by the NCIMS HACCP Implementation Committee).

Five of those proposals were passed as amended at the Conference:

- A proposal that states the PMO with a hazard analysis would constitute a facility's food safety plan (**Proposal JC-1**);
- Proposals that required dairy plants to have recall plans and allergen control plans (**Proposal JC-3**), an environmental monitoring program (**Proposal JC-4**), and a supplier verification program (**Proposal JC-5**); and
- A proposal to align Appendix K of the PMO with the FSMA preventive controls rule (**Proposal JC-7**).

A proposal that recognized government efforts to monitor dairy products for radiological hazards was not passed as it was deemed unnecessary (**Proposal JC-6**).

Additionally, FDA stated that if the proposals were passed, an exemption would not be necessary as PMO facilities would be compliant with FSMA. FDA further stated that PMO facilities would continue to be regulated and inspected under the PMO going forward. Additional details regarding inspections and implementation will be further discussed at the 2017 NCIMS Conference.

The FDA, the States and the dairy industry are all very pleased with the outcome on these proposals and believe that the milk supply will be safer as a result of being regulated under one regulatory scheme – the PMO.

Other Significant Proposals That Passed.

- **Proposal #211** develops a pilot program to expand required testing of milk for drug residues beyond beta-lactams. The details of the pilot program (type of drug, testing parameters, implementation time, scope of testing, etc.) will be developed by the NCIMS Appendix N Committee.
- **Proposal #213** establishes the requirements for use of an "unapproved" test when one is available as well as the requirements for use of an "unapproved" test when one is not available. These protocols and responsibilities refer to testing that is done outside of what is currently required (i.e., non-beta-lactams) using test kits that have not been evaluated by FDA and accepted by the NCIMS. Such testing is often for business-to-business, contractual, or internal quality assurance reasons. NMPF staff and members successfully worked to amend the proposal to include clarifying language around the timing of enforcement activities after a positive test result is obtained.
- **Proposal #216** removes the 50% rule for the minimum sensitivity for drug residue tests. A "target testing level" will be established by FDA and used for validating test kits for drugs that have historically had "safe" levels. This proposal also removes the 50% sensitivity requirement for tetracyclines.
- **Proposal #227** changes the annual inspection frequency for milk tank trucks from at least once every twelve months to once every two years, allowing a broader timeframe to inspect milk tank trucks while still maintaining a high level of food safety.

Significant Proposals That Did Not Pass

- **Proposal #103** to lower the Somatic Cell Count limit to 400,000 cells/mL did not pass. The proposal failed on the delegate floor by a vote of 32-18. The delegates who spoke in opposition to the proposal stated that somatic cells are not a food safety issue and should not be addressed through the PMO.
- **Proposal #111** to require approved seven-day temperature recording charts for dairy farm bulk tanks and to remove the "grandfather clause" for tanks more than 15 years old did not pass. There were concerns that the proposed solution would not be workable or practical for all dairy farms, a significant number of which would have to purchase new equipment.
- **Proposal #116** to allow single-use cheese cloth/strainer bags for removal of whey during yogurt manufacture did not pass because of food safety concerns that were insufficiently addressed.
- **Proposal #137** to establish a study committee to update the list of compounds allowed for use for animal health in organic herds did not pass because of food safety concerns and regulatory compliance issues that were raised.
- **Proposal #201** and **Proposal #202** to require milk and milk products, and animal feed and forage ingredients, respectively, to be tested for glyphosate residues did not pass. There was a lack of science to suggest this was a food safety concern that would warrant testing.
- **Proposal #214** and **Proposal #215** to develop pilot programs to address "unapproved" tests for drug residues, other than beta-lactams, did not pass. **Proposal #213**, which did pass, established the requirements and protocols for using these types of tests outside of the testing that is required by the PMO.

Executive Board Elections

Elections to the Executive Board also occurred at the Conference.

Mike Wiggs (Idaho Department of Agriculture) and Dr. Stephen Beam (California Department of Food & Agriculture) were re-elected to the NCIMS Executive Board. Ken Vorgert, USDA Dairy Grading, was also re-appointed as the USDA Representative to the Board.

In addition, the newly elected representatives on the Executive Board consist of Randy Chloupek (Nebraska Department of Agriculture), Antone Mickelson (Northwest Dairy Association), and Rebecca Piston (HP Hood).

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 likely to be scheduled for September or October 2015.

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 Beth Briczinski, Clay Detlefsen, or Jamie Jonker at the NMPF offices.

NCIMS Executive Board

Dr. Stephen Beam	Chair	Sacramento, CA
David Lattan	Vice Chair	Carlinville, IL

Region I - Eastern States, Terms Expire - 2017

Casey McCue	State Enforcement	Albany, NY
Laurie Bucher	State Enf/Rating/Health	Baltimore, MD
Gary Newton	State Rating	Tallahassee, FL
Rebecca Piston	Industry	Portland, ME
John Sheehan	FDA	College Park, MD

Region II - Central States, Terms Expire - 2019

Roger Hooi	Laboratory	Dallas, TX
Steve DiVincenzo	State Enforcement	Springfield, IL
Patrick Gorden	Academia	Ames, IA
Roger Tedrick	State Enf/Rating/Health	Reynoldsburg, OH
Gene Wiseman	State Rating	Jefferson City, MO
David Lattan	Industry	Carlinville, IL
Patricia Buck	Consumer	Raleigh, NC

Region III - Western States, Terms Expire - 2021

Stephen Beam	State Enf/Rating/Health	Sacramento, CA
Randall Chloupek	State Rating	Harvard, NE
Mike Wiggs	State Enforcement	Boise, ID
Antone Mickelson	Industry	Yakima, WA
Ken Vorgert	USDA	Lisle, IL

Ex Officio

Gena Reich	Council I	Olympia, WA
Thomas Angstadt	Council II	Erie, PA
Doug Cart	Council III	Rockford, IL
John Miller	Past Chair	Tallahassee, FL
Frank Barcellos	Lab Committee Chair	Salem, OR
Casey McCue	Liaison Chair	Lansing, MI
Cary Frye	Program Chair	Washington, DC
Ken Anderson	Third Party Certifier	Arlington Heights, IL
Beth Briczinski	NMPF Representative	Arlington, VA
Clay Hough	IDFA Representative	Washington, DC
Marlena Bordson	Executive Secretary	Monticello, IL

NCIMS 2015

Key: P = Passed
PA = Passed as Amended
NA = No Action
2400 = 2400 Form Process

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 September-October 2015 NCIMS Executive Board Meeting.

Proposal	Doc., Sec., Page	Summary	Final Action
JC-1	vi	Recognizes the PMO to be a facility's food safety plan as required by FSMA Preventive Controls Rule	PA
JC-2	vi	Recognizes dairy plants complying with the PMO are in compliance with FSMA with respect to micro hazards and drug residues	NA
JC-3	4, 15, 81, 89	Requires dairy plants to have recall plans and allergen control plans, to align with FSMA PC Rule	PA
JC-4	69, 70	Requires dairy plants to have an environmental monitoring program, to align with FSMA PC Rule	PA
JC-5	129, 131 (Sec 11)	Requires dairy plants to have a supplier verification program for non-dairy raw materials and ingredients, to align with FSMA PC Rule	PA
JC-6	226	Acknowledges the current programs in place in the US to monitor for radionuclides in milk	NA
JC-7	349-351	Adds requirements to Appendix K to align the PMO with the FSMA PC Rule	PA
JC-8	None	Authorizes the Board to schedule a special conference in 2016 to align the PMO with the FSMA PC Rule	NA
101	32	Would allow for the inclusion of micro-droplet formation as part of the pasteurization process	NA
102	33, 34	When the SCC exceeds 400,000, milk marketing agencies would be notified	NA
103	33, 34, 212, 380	Decreases the SCC limit to 400,000	NA
104	34	Establishes a coliform limit of 100 cfu/g for condensed whey and whey products when shipped in bulk	P
105	38	Removes the requirement that barn floors be scrubbed with a stiff brush (must be cleaned, but no method specified)	PA
106	40	Removes the requirement for a two-compartment wash vat in the milkhouse	NA
107	42	Requires seven-day temperature recording charts to record the CIP cleaning return temperature	NA
108	42	Requires dairy farms to have approved indicating thermometers to confirm minimum CIP return temperatures	NA
109	50	Exempts raw goat milk storage tanks from having to be cleaned every 72 hours, allowing for holding up to 7 days	NA
110	51, 52	The milking area and cattle housing area are not required to be completely separated	NA
111	58, 59	Requires approved seven-day temperature-recording charts for dairy farm bulk tanks, removes the "grandfather clause" for tanks >15 years old	NA
112	59	Clarifies the requirements and criteria needed for electronic records on dairy farm bulk milk storage tanks	PA
113	68	Adds requirements and responsibilities related to milk tank truck cleaning	NA

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Proposal	Doc., Sec., Page	Summary	Final Action
114	75	Clarifies that sanitizing drying and dry product equipment is necessary only after wet cleaning	PA
115	75	Clarifies that sanitizing drying and dry product equipment is necessary only after either wet or dry cleaning	NA
116	83	Allows single-use cheese cloth/strainer bags for removal of whey during yogurt manufacture	NA
117	93	Exempts pasteurized cream from re-pasteurization when being transported to another facility for butter manufacture	NA
118	119, 136	Permits the transfer of yogurt to another plant for packaging without requiring additional pasteurization	NA
119	124, 125	Addresses the brucellosis and TB in small ruminants	P
120	124-127	Updates brucellosis and TB language	NA
121	164, 165	Revises language for “Milking Methods”	PA
122	235	Clarifies the PMO does not allow any flow promoting devices on a continuous flow pasteurization system which utilizes a magnetic flow meter based timing system	NA
123	235	Clarifies the PMO does allow any flow promoting devices on a continuous flow pasteurization system which utilizes a magnetic flow meter based timing system	NA
124	244-259	Clarifies the PMO App H, Section II, Air Under Pressure – Milk Product-Contact Surfaces, final filter efficiency. Updates PMO’s “commercially sterile air” filter efficiency criteria, consistent with 3-A	PA
125	278, 298	Add test procedures for Steam-Block Type Flow Diversion Devices (SB-FDD) to Appendix I	NA
126	304	Add additional instruction options to perform HTST test 9.2.2, allows for usage of the raw regenerator section differential pressure controller sensing element	PA
127	312, 315, 316	Adds an additional method for testing pasteurization holding times using a salt timing system with manual switch	NA
128	312, 315, 316	Adds an additional method for testing pasteurization holding times using a salt timing system with manual switch	PA
129	312	Clarifies that timing pumps controlled by variable frequency drives would not be required to have milk-to-water (adjusted pasteurization holding time) tests done on the quarterly pasteurization tests	NA
130	312	Clarifies that timing pumps controlled by variable frequency drives would be required to have milk-to-water (adjusted pasteurization holding time) tests done on the quarterly pasteurization tests	NA
131	335	Clarifies within Appendix I – Test 15, further defining which control devices require testing for Electromagnetic Interference	NA
132	323 (in 2011 PMO)	Permit use of production scrap as regrind material for SSCC	NA
133	339, 340	Changes container sampling area to be in alignment between Appendix J and 2400 forms	PA
134	383-384	Addresses concerns and provides guidance for written procedures for milk with abnormalities, computer system(s) verification, and general computer requirements for Automatic Milking Installations (AMIs)	PA
135	383	Clarifies the requirements for an Automatic Milking Installation (AMI) with regard to abnormal milk sensing	NA

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Proposal	Doc., Sec., Page	Summary	Final Action
136	385	Changes cooling requirements for Automatic Milking Installation	NA
137		Study committee: Update list of compounds allowed for use for animal health in organic herds	NA
201	1, 33, 225-225	Requires milk and milk products to be tested for glyphosate residues	NA
202	1, 36	Requires animal feed and forage ingredients to be tested for glyphosate residues	NA
203	6	Adds the definition for "inspection/audit report"	PA
204	6, 27, 138	Allows States the option of having dairy plants collect finished product samples for regulatory purposes	NA
205	7, 9, 135, 136	Removes the option for States to not regulate intrastate sale of cottage cheese and dry curd cottage cheese under the PMO	NA
206	11	Allows for products rinsed from storage and transport vessels to be reclaimed	NA
207	14	Defines camel milk	PA
208	22	Allows for the use of electronically generated inspection/audit reports (keeps the option for use of hand written)	PA
209	23	Allows the Regulatory Agency discretion in the enforcement procedures which currently require automatic permit suspension if the same non-critical requirement is found on two successive inspections	NA
210	xiv, 26-30, 363-374	Changes required testing for drug residues (beyond beta-lactams), proposing a new testing scheme employing a random sampling program	NA
211		Pilot Program: to expand required testing of milk for drug residues beyond beta-lactams	PA
212	30, 363, 374	Requires all milk to be tested for sulfa drug residues	NA
213	xiv, 28-30, 363-374	Establishes requirements for use of an "unapproved" test when one is available; Establishes requirements for use of an "unapproved" test when one is not available	PA
214		Pilot Program: to address "unapproved' tests for drug residues (beyond beta-lactams) when an approved test is available	NA
215		Pilot Program: to address "unapproved" tests for drug residues (beyond beta-lactams) when an approved test does not exist	NA
216		Deletes "safe" from the 50% rule, for the minimum sensitivity for drug residue tests. Deletes the 50% sensitivity requirement for tetracycline testing	PA
217	xiv, 26-30, 363-374	Combines Proposals #210, #213, #216	NA
218	374	Clarifies that the drug residue test kit requirements as currently outlined in Appendix N apply only to those drug residues for which testing is required by the PMO	NA
219	28	Allows personnel in an Official, Commercial or Industry Laboratory approved by the Milk Laboratory Control Agency to do the averaging of sample results	PA
220	28	Allows sheep milk producers to not carry their SCC forward during periods of the year when not milking	NA

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Proposal	Doc., Sec., Page	Summary	Final Action
221	PMO p 29, EML	TEMPO® AC is proposed as an alternative method to the SPC	PA
222	PMO p 29	TEMPO® AC is proposed as an alternative method to the SPC	PA
223	30, 34	Raises the SCC limit for sheep milk from the current 750,000/mL to 1,000,000/mL	NA
224	30	Revises wording for Lab Techniques to allow new simplified methods for bacterial detection (instead of brand name products)	PA
225	30	Include SCC method and SCC standard for use with camel milk	P
226	PMO, 2400 Forms	Change PMO bacteriological water standards to address EPA elimination of the Maximum Contaminate Level for Total Coliform and implementation of an E. coli MCL	PA
227	135, 136	Changes the annual tank inspection to a 3 year inspection	PA
228	PMO p 223, MMSR p 87, 95	Limits the number of consecutive bacteriologically unsatisfactory water sample test results to 3 before a farm and/or plant would lose their Grade A permit	NA
229	365	Requires records of all sample results to be maintained for a minimum of two years by the industry	PA
230	MMSR p 14	Clarifies that when a Grade A milk plant is de-listed for inadequate sampling, only one re-sample of each debited product would be needed prior to the re-survey	NA
231	EML	Revises EML	P
232	EML p 3	Allows FDA certified State LEOs to evaluate and conditionally certify new analysts at the state central milk laboratories	PA
233	EML p 10, 11	Adds PeelPlate methods to the EML as techniques for evaluating aerobic bacteria and coliform counts	P
234	EML p 16, 17	LEOs be allowed to be certified for a period of 5 years instead of the present 3 years; Changes the on-site check evaluation to a mock survey situation	NA
235	2400 Forms	Omit the requirement for DMSCC certification as a co-requisite for ESCC certification in laboratories that purchase certified somatic cell standards for instrument calibration and verification	2400
236	2400 Forms	Increase the required autoclave temperature for media sterilization by moist heat by 1°C from 120±1°C to 121±1°C	NA
237	2400 Forms	Update 2400 Pasteurized Milk Containers, Closures and Packaging Form with new PeelPlate methods	2400
238	2400 Forms	Update 2400 Form for Cultural Procedures General Requirements with new PeelPlate methods	2400
239	2400 Forms	Approve a new 2400 Form for PeelPlate and update M-a-98-10 (method/matrix)	P
240	2400 Forms	Expands training requirements and documentation for performance testing under Appendix N general Requirements section 10	NA
241	2400 Forms	Allows the use of an alternative pre-incubation step to the Colilert-18 method	2400

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Proposal	Doc., Sec., Page	Summary	Final Action
242	2400 Forms	Clarifies procedure for accuracy check of dairy pipettors in regards to matrix used	NA
243	2400 Forms	States the sample temperature and time requirements for raw milk in the Appendix N testing program, as well as wording to reflect single producer/ farm bulk tank sampling and testing	NA
244	2400 Forms	Omit the requirement for DMSCC certification as a co-requisite for ESCC certification in laboratories that purchase certified somatic cell standards for instrument calibration and verification	NA
245	2400 Forms	Gives the option of standardization temperatures on the immersion oil on the DMSCC Form	2400
246 (#231-2013)	2400 Forms	Extends the allowable time for the transportation of water samples from 30 hours to 48 hours for water samples	P
301	130	Requests a two year extension of the NCIMS Aseptic Pilot Program (APP) to specifically address aseptically processed and packaged Grade “A” fermented high-acid milk and/or milk products	P
302	Const/Bylaws p 77, 81	Formalizes the appointment of Chairs and Vice Chairs to NCIMS Committees	PA
303	Const/Bylaws p 74, 80	Allows a vacant elected Board seat to be filled between Conferences	PA
304	Const/Bylaws p 81, 84, 85	Clarifies the role of the Parliamentarian, insures that we do not prematurely adjourn the Conference, and explains the intersection of the Conference documents, past practices, and Roberts Rules of Order	PA
305	Const/Bylaws p 74-75	Adds the chair of the NCIMS Lab Committee to the NCIMS Executive Board	P
306	PMO, MMSR, Proc, EML	Adds list of acronyms and abbreviations to TOC of Conference documents	P
307	Proc p 16	Clarifies that drug residue summary data shall be collected by Third Party Certifiers and reported to the third party database	PA
308	Proc p 25	Reduces the number of bulk milk hauler/samplers evaluated during Sampling Surveillance Officer re-certification	PA
309	PMO, Proc, MMSR	Develops listing and withdrawal of listing criteria for SSCC manufacturers; Develops qualifications, authorization, certification/recertification procedures, etc. for consultants that currently certify or wish to certify SSCC manufacturers located outside the geographical boundaries of NCIMS Member States	P