

HOTLINE

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MIF TEAMWORK EXPANDS GRADE A PROCESSING OPTIONS AT 2007 NCIMS CONFERENCE

The 2007 National Conference on Interstate Milk Shipments (NCIMS) was held May 5 - 10 in Salt Lake City, UT. The Conference attendees considered 105 proposals, with state delegates passing 56. With assistance from more than 50 Milk Industry Foundation (MIF) members, IDFA successfully achieved more flexibility in the Pasteurized Milk Ordinance (PMO) for dairy processors.

Significantly, MIF's three priority proposals passed. The study committee on defining Grade "A" milk and milk products was extended for six (6) months to determine if non-standard dairy products will be regulated under the PMO. The International Certification pilot program was extended until the end of 2009 to evaluate whether independent third party certifiers can effectively inspect and rate foreign dairy farms and plants exporting Grade "A" milk products to the U.S. And, a new pilot program was established to evaluate a blended PMO and FDA Low Acid Canned Food (LACF) inspection program intended to eliminate duplicate inspections of Grade "A" aseptic plants.

Two other important MIF proposals were adopted: new technologies for treating non-dairy ingredients added after pasteurization, and separate ratings for plants that process both fluid and dry products. In addition, NCIMS delegates adopted 15 proposals that increase options for dairy processors, such as allowing the cleaning of mix-proof valves while running products, using the same receiving equipment for Grade A and non-Grade A milk, expanding the use of plant-reclaimed water and open-tower water systems for cooling milk and milk products, and allowing electronic record systems under certain guidelines. At least six other proposals, opposed by MIF, would have placed unnecessary restrictions on the dairy industry. These were defeated.

MIF is requesting anyone interested in serving on an NCIMS Committee, whether a new ad hoc committee or one of the existing NCIMS Committees to contact Cary Frye or Allen Saylor.

Changes at the NCIMS Conference affect Grade "A" milk and milk products only and serve as guidelines for state and federal programs that cover all dairy products. The final report from FDA is expected in October 2007, with implementation in October 2008. The NCIMS is the cooperative program of all fifty states, the District of Columbia, all U.S. Trust Territories, the Food and Drug Administration (FDA), the Department of Agriculture (USDA) and the dairy industry.

BACKGROUND

Of the approximately 270 attendees at the 2007 NCIMS Conference, 52 Milk Industry Foundation (MIF) members and 20 IDFA supplier members attended and provided valuable assistance to IDFA staff in the

successful outcome. IDFA staff coordinated member strategy meetings as well as state outreach and negotiations with FDA at the Conference. In addition, MIF members and the National Milk Producers Federation (NMPF) worked cooperatively to present a united industry front. These actions resulted in a successful NCIMS Conference for the processing industry, state and federal regulatory officials.

FDA is now reviewing the proposals the Conference approved. The NCIMS Executive Board is tentatively scheduled to meet with FDA on September 17 and 18, 2007 to address FDA concerns and finalize all proposals passed at the Conference. The finalized proposals will take effect in October 2008, one year after FDA publishes the Conference proceedings (IMS-a), unless other specific effective dates are established. FDA will be responsible for publishing a 2007 PMO and other Conference documents that incorporate these changes.

SUMMARY OF ACTIONS

MIF's success resulted from the significant efforts of MIF members and staff, other dairy industry partners, state regulators and FDA to work together and find common ground for solutions acceptable to all. The Conference actions will continue to provide consumers with a safe supply of milk and milk products, without imposing unnecessary or overly burdensome requirements on industry. The following list summarizes the major proposals that affect the dairy industry:

- ◆ **Extend Committee work to determine if non-standard dairy products are subject to the regulations of the PMO** (Proposal 221): MIF members worked with the Grade "A" Definition Study Committee to propose a substitute solution that permitted the Committee to continue its work to define specific criteria for expanding the definition of Grade "A" dairy products. The substitute solution was passed and tasks the Committee with developing detailed recommendations to FDA and the NCIMS Executive Board within six months. FDA will then issue the Committee's recommendations in a memorandum (M-a) which requires a majority of state regulators to endorse it before it becomes final. The original proposal, opposed by MIF, would have amended the PMO to include any non-standard milk product with 4.13%, or greater non-fat milk solids content as a Grade "A" product.
- ◆ **Enact a two year pilot program to implement a new regulatory system for Grade "A" aseptic plants and milk products using both the PMO and FDA's LACF Regulations** (Proposal 303): The Grade "A" aseptic pilot program will combine aseptic requirements from the PMO and FDA's Low Acid Canned Food program to reduce duplication and conflicting regulations. The pilot will run for two years under the oversight of a new NCIMS Aseptic Pilot Program Implementation Committee and include 22 Grade "A" aseptic pilot plants, plus some international plants. Currently, all Grade "A" aseptic dairy plants receive complete inspections under both programs.
- ◆ **Extend the NCIMS International Certification Pilot Program to inspect and rate foreign firms for compliance with the PMO** (Proposal 304): The NCIMS International Certification Committee proposal adopted by the 2007 Conference extended the pilot program for foreign dairy farms and plants until late 2009. This program utilizes private, certified NCIMS inspectors and rating officers to evaluate compliance with NCIMS requirements by foreign dairy farms and plants. The pilot will document whether private certifiers can be used instead of state regulators to effectively inspect and rate dairy farms and six (6) plants against Grade "A" standards. This is intended to ensure foreign products meet the same requirements as U.S. Grade "A" products, but also will provide an expanded supply of Grade "A" ingredients.
- ◆ **Designate a Study Committee to evaluate NCIMS policy of requiring Appendix N compliance prior to the beginning of any state rating** (Proposal 123). The proposal directs a study committee (possibly the Methods of Making Sanitation Ratings Committee) to determine whether the current NCIMS policy for evaluating Appendix N compliance during state ratings should be changed to add debits and point values for non-compliance in addition to the all-or-

nothing policy now in effect. MIF will be monitoring this work very closely to ensure either the existing policy be maintained or it be replaced with a debit and point value, but not both.

- ◆ **Recognition of technologies to be used with pasteurization** (Proposal 220): This proposal, submitted by FDA and supported by MIF, recognizes filtration and bacto-fugation methods as acceptable to remove bacteria in plants conducting pasteurization. Additionally, the proposal recognizes that alternatives to pasteurization must now conform to specific provisions under the Federal Food Drug and Cosmetic Act (FFD&CA) section.
- ◆ **Permit alternatives to heat pasteurization to destroy pathogens for non-dairy ingredients added after pasteurization** (Proposal 119): This MIF proposal allows the use of non-heat based technologies accepted by FDA to be used on non-dairy ingredients that will be added after pasteurization to milk and milk products.
- ◆ **Expand in-plant use of reclaimed water and open tower water** (Proposals 125, 126): This proposal expands the options for use of plant reclaimed water from milk products, heat exchangers and compressors, as well as for the first time allowing the use of open cooling tower systems for cooling intermediate fluids used for cooling product. Specific open cooling tower configurations are required and the drawings accompanying the proposal should be referenced for details.
- ◆ **Allow higher raw milk temperatures during membrane filtration** (Proposal 120): Changes the PMO to permit raw milk to be run through reverse osmosis, ultra filtration or other types of membrane filtration systems at or below 18.3 °C (65 °F) instead of the previous 7.2 °C (45 °F) requirements. This extends the operational range of membrane systems used in Grade "A" plants.
- ◆ **Detailed guidance for the use of electronic (paperless) recording and reporting devices** (Proposal 134): This proposal provides detailed criteria to be used to evaluate electronic data collection, data storage and reporting for product storage temperatures, CIP, pasteurization and other operational information in accordance with existing PMO requirements. This will allow dairy plants to move toward paperless record systems as an acceptable substitute for paper records.
- ◆ **Allows plants to choose separate ratings and listing for fluid and dried milk products, whey, and milk products produced in the same facility** (Proposal 238): This MIF proposal permits flexibility if plants desire to have separate listings and inspections when fluid and dry milk products are produced in one facility. Therefore, if problems are found during an inspection or rating that are specific to one type of product (fluid), products (dry) under the other inspection or listing would not be affected.
- ◆ **Establishes criteria a dairy plant should submit to a state regulatory agency if requesting approval for alternatives to pasteurized water** (Proposal 116): This proposal, submitted by FDA, was significantly modified based on MIF comments to eliminate excessive and unnecessary criteria. This will provide more uniformity between states so different states will have similar information submittal requirements for dairy plants seeking approval for alternatives for pasteurized water.
- ◆ **Increasing processing equipment flexibility for values and pasteurization equipment** (Proposals 112, 113, 115, 129, 130, 132): The Conference approved a number of proposals to allow more flexibility in the types of equipment such as valves, and lines used for processing and pasteurization systems. These include permitting only one valve separation of water and raw milk and shared equipment for raw milk receiving for both Grade "A" and non-grade "A" milk. The Conference approved cleaning part of a single bodied double seat valve while running product through the same valve, and allowing the use of block and bleed valves and check valves as an

alternative to the balance tank for HTST systems with raw milk separators. It was clarified where and when simple pressure relief valves are required for HTST, HHST and aseptic systems. FDA also provided an updated schematic diagram for the air space heater of vat pasteurizers.

- ◆ **Incorporates packaging of sour cream at temperatures above 45°F into the PMO** (Proposal 122): FDA submitted this proposal based on study data generated and submitted to them by MIF to incorporate a previously issued FDA memo (August 18, 2006) into the PMO. This permits sorbate-free cultured sour cream of all fat levels with a pH of 4.7 or below, and acidified sour cream of all fat levels with a pH of 4.6 or below to be filled above 45°F, if cooled to 45°F or less within 168 hours of filling.
- ◆ **Hygienic Sampling** (Proposals 226, 229): Allows the use of QMI aseptic samplers for milk truck samples and establishes new procedures to properly sanitize sample cocks and septums when using a single service needle.
- ◆ **Adds PMO definition for Clean-in-Place (CIP) and amends PMO definition for Colostrum** (Proposal 216 & 218). For accuracy and clarity, the definitions of "mechanically cleaned" in the PMO were changed universally to "Clean-in-place (CIP)". FDA made it clear this would not require any new recording charts, particularly on farm cleaning systems and plant COP tanks. A new definition for "Colostrum" was added to the "Undesirable milk products" section which would clearly prohibit the sale of colostrum as a Grade "A" milk product.
- ◆ **Allows exemption from the NCIMS requirements for catastrophic events such as hurricanes, if the state notifies FDA of the deviations** (Proposal 311).
- ◆ **Single Service Containers** (Proposals 142, 143): Clarified the storage requirements for single service containers and closures, and provided more flexibility for the listing for different types of materials (plastic, glass and metal) used in single service containers and closures.
- ◆ **Editorial changes to Constitution and Bylaws** (Proposals 305, 306, 307, 309, 310): One substantive change will require Council Chairs to nominate four (4) alternate Council members to take the place of any Council member that is absent during the Conference. Other proposals also modified slightly the Executive Board's authority and the timing to request changes of FDA-issued memorandum (M-a) as well as giving FDA some editorial responsibility for the changes needed to the Conference documents after each Conference. The HACCP Implementation Committee was designated a permanent standing committee.
- ◆ **Minor changes to rating and inspections were endorsed** (Proposals 240, 241, 244): These changes on the rating form 2359i will remove the requirements to list volume of milk produced for single farms, allow for prorating enforcement points for single farm Bulk Tank Units (BTU) and re-balance enforcement point values for sampling procedures.
- ◆ **Update Laboratory Procedure 2400 Forms based on FDA approval of new test methods** (Proposals 201, 202, 203, 204, 208, 213, 214): Approval of the use of Foss Bactoscan, update of laboratory procedure forms for counting and storage of 3M Petrifilm, removal of the requirements for conducting detergent residue testing for glass petri dishes and amendments to the forms for Residual Bacteria Count test.
- ◆ **Expand tests permitted for Appendix N drug residue and dairy water analysis** (Proposals 235, 230, 231): Add the Charm SL-3 Beta Lactam test for Appendix N drug residue screening and approved the use of IDEXX Colisure test for analysis of dairy water samples.

- ◆ **Simplify test procedures for pasteurization equipment** (Proposals 138, 139, 140): Allow testing of the leak detect outlet valve on vat pasteurizers with either product or water. Also clarifies and simplifies procedures and test options to verify HTST pasteurizer operation.
- ◆ **Accept use of military time for recoding the time of sample collection and tank cleaning on wash tags** (Proposal 223).
- ◆ **Modify animal drug labeling** (Proposal 107): On-farm labeling for animal drugs will now require identification of the dispensing pharmacy and the prescribing Veterinarian, to accommodate the new ways of dispensing medicines (use of distribution pharmacies versus the more traditional method of sourcing directly from the veterinarian's office).
- ◆ **Define calibration and certification of official thermometers** (Proposals 135, 136): Permit state personnel to certify thermometers and allow test thermometers to be checked for calibration against a thermometer that is traceable to the National Institute of Standards Technology (NIST).
- ◆ **New ad hoc committee to evaluate dairy cow sharing** (Proposal 124): A new Committee will evaluate whether it is necessary to have the PMO address cow sharing where the sale is for direct consumption of un-pasteurized milk.

The major proposals that failed include:

The following proposals opposed by MIF were defeated:

- ◆ **Allowed partial pickups of farm tanks of milk** (Proposals 105 & 227).
- ◆ **Required all cleaning chemicals to have complete instructions for use, including concentrations, contact time and temperature** (Proposal 106)
- ◆ **Mandated sealing the micro-switches of all flow divert devices** (Proposal 137)
- ◆ **Required tanker seals that are at all times, visually detectable** (Proposal 228)
- ◆ **Established PMO requirements for resampling positive tankers** (Proposal 237)
- ◆ **Expanded the International Certification pilot program to US Grade A farms and plants** (Proposal 316)

Regulators were unwilling to permit industry personnel to collect official plant samples or remove enforcement debits against plant sanitation scores when state regulatory officials fail to collect required samples (Proposals 101, 108, 109, 239). State delegates voted against four proposals that would have removed unnecessary debits against the plant's sanitation score when the regulatory official failed to collect required milk plant samples. Additionally, they were unwilling to consider permitting official plant milk product or water samples to be collected by a state approved industry personnel or a third party entity such as a commercial laboratory.

A proposal to study the inspection, sampling and rating frequency failed, but minor changes on the impact of enforcement ratings on plant sanitation scores were endorsed (Proposals 313, 315): MIF and NMPF's joint proposal to lengthen the time between rating frequencies for dairy farms and plant from 24 to 36 months was modified to a study proposal, but failed. However, some relief was provided by a six month probation period if the state enforcement rating score is below 90, and the plant sanitation compliance score is above 90 points. No action will be taken against a plant in that case, but a new rating will be required within 6 months.

The Conference selected the following individuals to serve on the NCIMS Executive Board:

NCIMS Executive Board Officers

John Beers	Chairman
Don Breiner	Vice Chairman
Marlena Bordson	Past Chair
Leon Townsend	Executive Secretary and Treasurer

Region I - Eastern States (Terms Expire 2011)

Don Breiner	Land O'Lakes
Byron Moyer	Vermont Department of Agriculture
John Beers	Virginia Department of Agriculture
Will Francis	New York Department of Agriculture & Markets
John Miller	Florida Department of Agriculture
Bob Childers	FDA, Dairy and Egg Branch

Region II - Central States (Terms Expire 2013)

Lewis Jones (newly elected)	Ohio Department of Agriculture
Ronald Schmidt (newly elected)	University of Florida
Dave Lattan (newly elected)	Prairie Farms Dairy, Inc.
Frank Barcellos (re-elected)	Oklahoma Department of Agriculture
Susan Esser (re-elected)	Michigan Department of Agriculture
Gary Cazaubon (newly elected)	Louisiana Department of Health

Region III - Western States (Terms Expire 2009)

Dan Borer (newly elected)	Nebraska Department of Agriculture
Jodeen Meenderink	Dean Foods, Southwestern Region
Kyle Stephens	Utah Department of Agriculture
Darwin Kurtenbach	South Dakota Department of Agriculture
Ken Vorgert	USDA, Agriculture Marketing Service

Ex Officio Board Members

C. Thomas Leitzke	Wisconsin Department of Agriculture - Council I Chair
Roger Hooi	Dean Foods - Council II Chair
Dave Lattan	Prairie Farms Dairy, Inc - Council III Chair
Cary Frye	International Dairy Foods Association and Program Chair
Rob Byrne	National Milk Producers Federation
Vacant	Consumer Representative

IDFA would like to thank all of our member companies who participated in its preparatory meetings and conference calls, as well as Council Representatives and Leaders who helped make the 2007 NCIMS Conference a great success for processors and the entire dairy industry.

If you have any questions about the above issues, please contact Allen Saylor (202-220-3544), Cary Frye (202-220-3543) or Clay Hough (202-220-3516). A list of the final actions and amendments for the proposals and resolutions are posted on IDFA's web site at www.idfa.org. This information can be found in the "members only" section by clicking on "Regulatory Affairs" and then "NCIMS".

Summary of Actions from 2007 NCIMS Conference

Proposal Number	Action Taken	Proposal Number	Action Taken	Proposal Number	Action Taken	Proposal Number	Action Taken
101	NA	131	NA	217	Passed*	301	NA
102	NA	132	Passed*	218	Passed*	302	NA
103	NA	133	NA	219	NA	303	Passed*
104	NA	134	Passed*	220	Passed*	304	Passed*
105	NA	135	Passed*	221	Passed*	305	Passed
106	NA	136	Passed	222	NA	306	Passed
107	Passed	137	NA	223	Passed*	307	Passed*
108	NA	138	Passed	224	NA	308	Passed*
109	NA	139	Passed*	225	NA	309	Passed
110	NA	140	Passed	226	Passed*	310	Passed*
111	NA	141	NA	227	NA	311	Passed
112	Passed*	142	Passed	228	NA	312	NA
113	Passed*	143	Passed*	229	Passed*	313	NA
114	NA			230	Passed	314	Passed
115	Passed*	201	Passed*	231	Passed*	315	Passed
116	Passed*	202	Passed*	232	NA	316	NA
117	NA	203	Passed	233	NA		
118	NA	204	Passed	234	NA		
119	Passed*	205	NA	235	Passed*		
120	Passed*	206	NA	236	NA		
121	NA	207	NA	237	NA		
122	Passed	208	Passed	238	Passed*		
123	Passed*	209	NA	239	NA		
124	Passed*	210	NA	240	Passed*		
125	Passed*	211	NA	241	Passed*		
126	Passed*	212	NA	242	NA		
127	NA	213	Passed	243	NA		
128	NA	214	Passed*	244	Passed*		
129	Passed*	215	NA	245	NA		
130	Passed	216	Passed*	246	NA		

NA = No Action

Passed = Passed as submitted

Passed* = Passed as amended