2019 National Conference of Interstate Milk Shippers

Washington Association of Food Protection
September 2019

Background on the NCIMS

- The U.S. Public Health Service (USPHS) and FDA developed a model regulation known today as the *Grade "A" Pasteurized Milk Ordinance* (PMO).
  - Incorporates the provisions governing the processing, packaging and sale of Grade "A" milk and milk products including yogurt, fermented milk products, whey, whey products and condensed and dry milk products.
- The PMO serves as the standard in the voluntary Cooperative State-USPHS Program for the Conference of Interstate Milk Shippers
  - Program participants include all 50 states, the District of Columbia and U.S, Territories
- The NCIMS in accordance with "Memorandum of Understanding" with the FDA, recommends changes and modifications to the Grade "A" PMO at its biennial conference

Background on the NCIMS

- Conference participants represent a wide cross-section of the dairy industry:
  - Dairy farmers
  - Processors
  - Regulatory (FDA, USDA, States)
  - Academia

2019 NCIMS OVERVIEW

- There were more than 400 registrants for the 2019 conference
- There were 75 proposals submitted for consideration
- State delegates passed 39 of the submitted proposal
- There were numerous scheduled meetings, as well as informal, ad hoc meeting with state delegates and FDA staff
- FDA is now reviewing the proposals approved at the Conference
  - NCIMS Board will meet with FDA in October 2019 to finalize all proposals passed at the Conference
  - FDA will publish the 2019 version of the PMO along with other Conference documents with these changes in early 2020
  - The finalized proposals will take effect in October 2020, one year after FDA publishes the Conference proceedings (IMS-a-50), unless other effective dates for individual proposals have been established

Summary of Passed Actions

- **State Roles in Appendix T Inspections – Proposal Joint Council JC-1**
  - Allows State Rating Agencies, upon agreement with FDA, to conduct inspections of Grade "A" milk plants and milk and milk products for compliance with Appendix T of the PMO, which incorporates the FDA Preventative Controls for Human Food (PCHF) rule requirements
  - The Liaison Committee, which drafted the proposal, was also tasked to work with FDA to develop a revised pilot program, which will establish a regulatory framework to find efficiencies in conducting Appendix T and PCHF inspection activities for facilities that manufacture both Grade "A" and non-Grade "A" products, respectively, and will be implemented by FDA and the participating states.
    - A complete report of the pilot program will be shared at the 2021 Conference

Summary of Passed Actions

- **Repackaging Grade "A" Products Outside of Grade "A" Plants – Proposal 112**
  - There was a vigorous debate between state regulatory agency Delegates and industry whether yogurt parfaits should be considered Grade "A" milk products and thus be required to be regulated under the PMO
    - Typically produced in commissaries or other non-Grade "A" food production facilities for sale as foodservice items for quick consumption, unlike longer shelf-life Grade "A" yogurts sold at retail
  - Wide diversity between states in how they view these products
  - All stakeholder agreed this needs to be addressed
  - Proposal was revised directing the NCIMS to form a study committee to review the NCIMS role in regulating the repackaging of not only yogurt, but also sour cream, acidified sour cream and other cultured milk and/or milk products
  - The committee will report its findings at the 2021 NCIMS Conference

Summary of Passed Actions

- **Use of UV Light Systems for Pasteurized Equivalent Water Production – Proposal 114 & 115**
  - Two proposals that were submitted by Trojan Technologies, a UV treatment technology provider, were considered that sought several changes to the PMO regarding standardization and criteria for such systems
  - The NCIMS will establish a committee to study the safety of water used in the dairy industry, including technologies to produce disinfected and/or pasteurized equivalent water and discuss how the PMO should be used to regulate these systems
  - The committee will report its findings at the 2021 Conference

Summary of Passed Actions

- **Use of Automated Truck-Mounted Meter and Samplers – Proposal 210**
  - Several committees debated a proposal by Piper Systems to authorize the use of an automated, truck-mounted, bulk milk tank aseptic sampler
    - May be used for the taking of official milk samples from single and multiple farm pickups
  - This technology is used widely in Australia, New Zealand and Europe
  - Delegates ultimately approved the use of the technology provided users:
    1. Receive a description of the minimum protocols for a standard operating procedure
    2. Have a mandatory consultation with state regulatory agencies
    3. Give regulatory agencies a list of bulk milk haulers and samplers trained to maintain and operate the sampler as well as collect, identify, handle and store the milk samples

Summary of Passed Actions

- **Appendix N Test Methods and Positive Producer Drug Residue Confirmation – 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.
  - In addition, revised the reporting requirements for confirmed positives to require regulatory agencies to indicate a record of negative test results, using the same or equivalent latest reviewed test method (M-I-96-10) as used when the producer was found to be in violation, from a prior subsequent pickup

Additional Passed Proposals

- **Storage Tank Emptying – Proposal 106**
  - Clarifies timeframe for compliance with this provision; the 72-hour time period starts when milk first enters a cleaned and sanitized storage tank
- **Pasteurization of Partially Homogenized Milk – Proposal 108)**
  - Adds requirements to pasteurizer when milk is partially homogenized
- **Milk Pasteurization Chart Records – Proposal 109**
  - Allows plants to list either their name and location or plant code number on milk pasteurization chart records
- **Cup Set Yogurt – Cooling Requirements Clarified – Proposal 111**
  - Provided that yogurt cultured in the cup must reach a pH of 4.6 within 24 hours of being moved out of the culturing room and cooled to 45^0F or less within 96 hours

Additional Passed Proposals

- **UV Water Treatment System Dosing Controls – Proposal 113**
  - Added wording to explicitly permit UV light dose control utilizing an "automated flow control system" as an option instead of only flow valves for UV water treatment equipment
- **Updates to Pasteurization, Aseptic Processing and Packaging and Retort Process Requirements – Proposal 117**
  - Updates Section 16p and Appendix H of the PMO for clarity and accuracy
- **Automated Milking Installation – Proposal 118**
  - Removes restrictive and redundant language about Automated Milking Installation (AMI) technology in Appendix Q for the PMO
- **Pasteurizer Tests – Proposal 120**
  - Specifies pasteurizer tests needed for plate-type or double/triple tube-type heat exchangers

Additional Passed Proposals

- **Single-Service Container & Closures – Proposal 122**
  - Clarifies that compliance for single-service containers and closures shall be determined as not having 2 or more out of 4 samples exceeding the bacterial standards
- **Shipping Statement Information – Proposal 203**
  - Reduces unnecessary paperwork by eliminating the requirement to identify the name of the supervising regulatory agency at the point of shipment on the shipping statement.
- **Recertification of Sampling Surveillance Personnel – Proposal 205**
  - Modifies the time SSOs shall be recertified to once every 3 years to include the remaining days of the month in which the certification expires
- **Primacy of the FDA/NCIMS 2400 Forms Over SMEDP/OMA in the PMO – Proposal 206**
  - Clarifies that all sampling procedures and required laboratory examinations shall be in substantial compliance with the FDA/NCIMS 2400 forms. SMEDP/OMA may also be referenced, but only when 2400 forms are unclear

Additional Passed Proposals

- **Maintaining Current List of Approved Milk Tests – Proposal 207**
  - Ensures that the list of approved laboratory tests for milk and milk products is current by referencing the latest version of M-a-98
- **Safety Plan Exemptions for Very Small Businesses – Proposal 208**
  - States that very small businesses exempt from some or all of 21 CFR 117 preventative control requirements would no longer need certain records reviewed and signed by preventative controls qualified individuals. Removes specifications for temperature measuring and recording devices for the cooling of milk and milk products
- **Disposal of Antibiotic Adulterated Milk – Proposal 216**
  - Eliminates the Appendix N reference to M-I-06-5 for the disposal of adulterated milk and updates the referenced FDA Compliance Policy Guide.

Additional Passed Proposals

- **Hauling Procedures Committee Review of Appendix B & FDA Form 2399a – Proposals 211 and 212**
  - After careful review, several new procedures were approved for inline sampling systems, petcocks and inline sample points in Appendix B. The Hauling Committee will conduct a comprehensive review of FDA's Bulk Milk Hauler/Sampler Reevaluation Report Form 2399a to reflect the changes made to Appendix B and report back to the 2021 Conference
- **Procedures for Laboratory Evaluation Programs – Proposal 223**
  - To provide additional flexibility, LEOs may conduct on-site certification/surveys of central and other milk laboratories up to 60 days early. LEO attendance at FDA Milk Seminars is now mandatory. Throughout the lab evaluation programs section, editorial changes replace FDA Regional Offices with milk specialists responsible for the state in which the laboratory/facility resides

Additional Passed Proposals

- **HACCP Program Updates to Align with Appendix T – Proposal 301**
  - The HACCP Implementation Committee was tasked with making editorial adjustments to the PMO Appendix K HACCP Program identified by FDA and its committee to be more consistent with Appendix T Preventative Control for Human Food requirements for Grade "A" Milk and Milk Products
- **Procedures for Issuing Memorandums of Interpretation (M-I's) – Proposal 303**
  - Adds new requirements to the procedures for issuing M-I's related to questions and answers received from the field (milk seminars, FDA training and workshops) to specify the roles and timing for FDA and NCIMS Document Review Committee to resolve issues and requires that unresolved issues shall be removed from the draft M-I

Additional Passed Proposals

- **State Program Evaluation Changes – Proposals 304, 305**
  - Provides an option for State Program Evaluations to be conducted once every 5 years instead of every 3 years when two previous 3-year evaluations are in compliance. Eliminates the need for a shipping state to notify all receiving states when there is a change in the number of dairy farms within a certified interstate milk shipper's supply (BTU)
- **Milk Evaluation Personnel Training – Proposal 306**
  - Specifies the required training for Milk Laboratory Evaluation Personnel within 3-year time period, including FDA milk seminars and Milk Laboratory Evaluation Officers' workshops or other training courses judged equivalent
- **Appendix N Modification Study Committee Status – Proposal 307**
  - Changes the status of the Appendix N Drug Residue Committee to a permanent standing committee

Additional Passed Proposals

- **Training for HACCP Program – Proposal 308**
  - Recognizes utilization of the training from the PHS/FDA Milk Specialists on Appendix T coupled with the abbreviated training course approved by the HACCP Implementation
- **Requirements for Fermented High-Acid, Shelf-Stable Product Processing and Packaging – Proposal JC-2**
  - The Aseptic Program Committee developed 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 milk products

2400 Form Approved Changes

- **Proposals 228 and 229**
  - As listed in M-a-98 Table 4, modified Colitag will be included in the 2400m Dairy Waters form
- **Proposal 230**
  - Adds requirements to check for sterility of forceps and pipets under number 14 Controls for each group of samples
- **Proposal 234**
  - Made changes to the Temporary Monitoring System requirements
- **Proposal 238**
  - Removes equipment that is no longer approved for use

2400 Form Approved Changes

- **Proposal 239**
  - Updates Charm FAP and Paslite Phosphatase forms with NovaLUM II X instrumentation
- **Proposal 240**
  - Approves Charm beta-lactam 30-sec. test and incorporates into the SL/SL3 2400 form
- **Proposal 241**
  - Updates Peel Plate 2400 form