

NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

“Assuring the Safest Possible Milk Supply for All the People”

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Dear Dr. Briczinski:

The National Conference on Interstate Milk Shipments (NCIMS) Liaison Committee (NCIMS-LC) requests the United States Public Health Service, Food and Drug Administration (FDA) to consider allowing the use of Limited Scope Inspections (LSI) for the dairy industry under the NCIMS Joint Council-1 (JC-1 Proposal) Dual-Grade Dairy Inspection Pilot noted below and also apply the LSI approach to the Grade A facilities when assessing compliance with Appendix T of the Pasteurized Milk Ordinance (PMO), which is fully equivalent to 21 CFR 117.

The NCIMS is a cooperative state-federal program for the certification of Interstate Milk Shippers that includes the FDA, all fifty (50) states, the District of Columbia and U.S. Trust Territories. The Official goal of NCIMS is to “*Assure the safest possible milk supply for all the people.*” This important public health mission is accomplished by the national uniform enforcement of the food safety standards and requirements of the *Grade “A” Pasteurized Milk Ordinance* published biennially by FDA and implemented through an active 1977 Memorandum of Understanding (MOU) between FDA and NCIMS. The NCIMS at its biennial conferences, held since 1950, recommends changes and modifications to the PMO, and other related technical documents, and thereby ensures that the PMO represents the most current science-based knowledge and experience concerning the safe production and processing of Grade “A” milk and Milk products.

Going back to the 2015 NCIMS conference, there were strategic and progressive moves made to align the PMO with the then draft requirements of the Food Safety Modernization Act (FSMA) 21 CFR 117 Preventive Controls for Human Foods (PCHF). This alignment was embraced by members of state and federal regulatory agencies, the entire dairy industry and academia to demonstrate NCIMS’s dedication to food safety and the confidence in the collective dairy industry at being able to meet those sweeping new requirements. It was reverberated over and over that the language in FSMA’s Preamble from Congress noted the PMO as a model document for FSMA authors to reference when drafting the FSMA requirements.

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At the 2017 biennial conference, the NCIMS further enhanced the language in the PMO and solidified the FSMA alignment via Appendix T and as a result, through extensive collaboration and input, the **PMO was deemed by FDA to be equivalent to 21 CFR 117 PCHF**. From the early onset of the FSMA/Grade A discussions there was a constant concern surrounding the Non-Grade A products being manufactured in Grade A facilities and the interplay between the two grades of processing with respect to overall PCHF rule compliance in dual-grade (both Grade A and Non-Grade A) facilities. Through many discussions with different groups within FDA dating back to a 2016 in-person meeting in College Park to outline these concerns, the dual-grade scenario in the dairy industry has proven a challenge to address.

In response to the 2017 NCIMS conference discussions and action, FDA released a press release stating the following:

“When it comes to the FDA’s milk inspection protocols, the agency is seeking additional ways to maximize state and federal resources and create greater efficiency through its obligations under the FDA Food Safety Modernization Act.”

“We believe there’s more opportunity for FDA and state regulators to better coordinate oversight efforts of the dairy industry, making the process more efficient while maintaining the high safety of the U.S. milk supply.”

Dr. Scott Gottlieb, FDA Commissioner, November 1, 2017

At the 2019 NCIMS Conference, the NCIMS-LC attempted to address this longstanding issue via a proposal. The issue had a constant drum beat of consensus on several key items/concepts:

- The PMO’s alignment with the PCHF rule was monumental and should be given recognition and credit within the FSMA regulatory structure.
- It was noted this alignment with the PMO, as a NCIMS initiative, demonstrates to FDA that the NCIMS was a dedicated and committed partner in this new food safety structure, while also recognizing that in doing so it created a dual dairy inspection structure under FDA’s FSMA requirements.
- The inspections and work completed by states in this heavily regulated industry, with inspection frequencies that surpass most commodities, should be reflected in the risk-based decisions the agency makes in using inspectional resources to assess FSMA-PCHF requirements.
- In a large percentage of dual-grade facilities, the same processing lines, equipment, and records are already being reviewed and inspected by both states and FDA staff.
- To recognize and utilize FDA Milk Specialists (FDA-MS) as experts in evaluating dairy facilities for both Grade A and Non- Grade A functions. The original discussions noted that an FDA-MS would complete the Grade A work and then a separate inspection by a district

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- FDA- Consumer Surveillance Officers (FDA-CSO) would need to complete the Non-Grade A evaluation leading to a second inspection in the dairy industry under FDA's single FSMA umbrella.
- Collectively the NCIMS-LC felt strongly the time had come to address this issue and the potential efficiencies or inefficiencies needed to be outlined to seek a positive change to what appeared to be a negative impact on the dairy industry under the overarching FSMA requirements due simply to the dairy industry's Grade A and Non-Grade A structure.

As you are aware, the National Conference on Interstate Milk Shipments NCIMS-LC was charged under the 2019 conference Proposal JC-1 to:

The assigned committee is charged to work cooperatively with FDA to develop a pilot program which will establish a regulatory framework to find efficiencies in inspection activities for facilities that manufacture both Grade "A" and non-Grade "A" products and be implemented by FDA and the participating States.

In developing the details of the inspectional model(s) to pilot, the assigned committee will, at least, consider: the regulatory authorities of state regulatory agencies, the eligibility criteria for pilot consideration, the types of non-Grade "A" products manufactured in dual-grade facilities, the resource needs, and potential hurdles likely to be encountered, and the metrics for evaluating success.

When implemented, the pilot program will meet the Agency's commitment to the NCIMS of identifying additional ways to maximize state and federal resources and to create greater efficiencies through its obligations under the FDA Food Safety Modernization Act while maintaining the high safety of the U.S. milk supply.

FDA shall inform and confer with the assigned committee to answer questions and address concerns to provide clarity and transparency at a frequency determined by the NCIMS Executive Board. A complete report of the pilot program will be shared at the 2021 Conference.

In recognition that FDA is strongly committed to developing and implementing the dairy inspection pilot program and stands ready to work in a collaborative spirit on the framework for this pilot program immediately with the assigned committee, the Liaison Committee requests an effective date of the receipt and acceptance of FDA concurrence at the next NCIMS Executive Board meeting after the Conference.

Since the 2019 conference the NCIMS-LC and FDA have engaged to develop an inspection scheme under FSMA-PCHF to leverage both the Milk Specialists and the states' strengths in search of efficiencies and best use of resources to create a minimal impact on the dairy industry in dual-grade facilities, noting there is no other commodity the working group is aware of, that carves out a different inspection scheme based upon grades within a commodity (Grade A versus Non-Grade A). We deeply appreciate the countless hours of discussion and collaboration as we navigated through our findings and worked to address the agency's policies under FSMA.

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On multiple occasions the group had begun building out details of the pilot through our understanding of FSMA via the Appendix T audit (based on a Full Scope Inspection model), only to learn the pilot was overbuilt due to changes in FSMA-PCHF implementation policy and procedures, some examples of that are:

- **Pilot Metrics-** As per JC-1, success needed to be measured and efficiencies in resources noted, so there were hours of discussions conceptualizing ways to do this, from inclusions into the existing State Program Evaluations, to a new audit function under this pilot/program, potentially creating an additional layer of oversight. This all changed with the later understanding of the training requirements, which were far less burdensome than originally thought (see below).
- **Training-** Discussions entertained the weeklong FD-378 Appendix T training as well as a belief staff needed FD-190 and potentially FD-254 for competency, only to find out the perceived investment in training was far too excessive and states only needed PCQI and FD-8000R, a webinar, to meet the Limited Scope Inspection training requirements.
- **Inspectional Approach-** The most recent and impactful discovery was the use of Limited Scope Inspections (LSI) across all of the other commodities to include its application to the Non-Grade A side of the dairy industry. This game changing regulatory scheme took the previous trajectory of the pilot and inverted it. At the same time, the NCIMS-LC was revisiting the goals and objectives of the pilot and the commitment to leveraging all resources both federal and state. This impact on the dairy industry in comparison to the other commodities, was coupled with the industry's regulatory scheme involving a far higher inspection frequency via the Pasteurized Milk Ordinance (every 90 days) and the work being done by states in most cases at the Non-Grade A facilities used the same or similar inspection frequency. These collective findings warranted a step back to fully consider and evaluate all the work being conducted in the dairy industry under FSMA-PCHF.

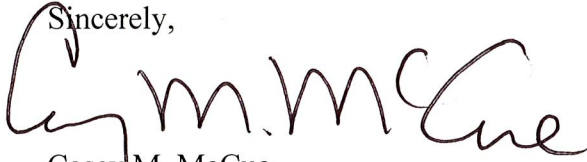
As a result of that evaluation and the recognition of the PMO's Appendix T, which is equivalent to 21 CFR 117, and the application of LSI's across the other commodities as per FDA's Compliance Program Guidance Manual Program 7303.040 and as noted on pages 23/24 outlining the LSI process, the NCIMS-LC respectfully requests the Food and Drug Administration allow the utilization of a Limited Scope Inspection scheme to be applied across the entire Cooperative Program and also be the focus of this dual-grade pilot. This change in direction across the entire dairy industry will give the cooperative program the equity noted in the other commodities and meet both the agency's and the pilot's goals and objectives. The request would require a shift in the full scope audit approach of Appendix T of the Pasteurized Milk Ordinance and pivot to the agency's already existing use of Limited Scope Inspections. Again, recognizing the prescriptive nature of the Grade A system and the NCIMS's ongoing commitment to public health and food safety, while acknowledging the often similar regulatory approach by the states to non-Grade A facilities and the dairy industry's track record. **The NCIMS-LC feels strongly this request does not diminish the overall goal of the pilot program nor the focus of the regulatory oversight of the dairy industry.**

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The NCIMS-LC stands at the ready to engage into further details of this request and look forward to the continued collaboration, support and forward-thinking as we work cooperatively to make the dairy industry the safest possible, while meeting the requirements of the Food Safety Modernization Act as implemented by your agency.

Sincerely,



Casey M. McCue
Director, Division of Milk Control and Dairy Services
New York State Department of Agriculture and Markets

CMM/amf

cc: Mark A. Moorman, Ph.D., Director of Food Safety and Applied Nutrition, U.S. Food and Drug Administration

Laurie Farmer, Office of State Cooperative Programs Director

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