



April 4, 2022

Mr. Casey M. McCue
Chair, NCIMS Liaison Committee
Director, Division of Milk Control and Dairy Services
New York State Department of Agriculture and Markets
10B Airline Drive
Albany, NY 12235-0001

Dear Mr. McCue,

Thank you and the Liaison Committee for your March 16, 2022 letter, which clearly articulated your perspectives on the incorporation of Limited Scope Preventive Controls (PC) inspections to the Grade “A” Program and to the Dual-Grade Dairy Inspection Pilot.

FDA values our relationship with the National Conference on Interstate Milk Shipments (NCIMS) and is firmly committed to collaborating with the NCIMS Liaison Committee to advance effective approaches for maximizing state and federal resources and implementing strategies to bring greater efficiencies to regulatory oversight in dual-grade dairy facilities. The dual-grade dairy inspection pilot is a notable example from the long history of FDA working collaboratively with the Conference to strengthen the Grade “A” program in response to changes in the regulatory environment and stakeholder perspectives, while assuring protection of public health.

The NCIMS Liaison Committee has asked FDA to consider allowing the use of Limited Scope PC inspections for the dairy industry under the NCIMS Joint Council (JC-1 Proposal) Dual-Grade Dairy Inspection Pilot and also to consider applying a Limited Scope approach to Grade “A” facilities when assessing compliance with Appendix T of the *Pasteurized Milk Ordinance* (PMO). As you noted, with the incorporation of Appendix T into the PMO, FDA determined that facilities in compliance with the PMO are fully compliant with 21 CFR 117. The rationale for the Committee’s request is a new understanding among committee members of how FDA currently applies Limited Scope PC inspections in other (non-IMS listed) food facilities.

Regarding the request from the NCIMS Liaison Committee – to apply a Limited Scope PC inspection approach to IMS-listed facilities that are single- or dual-grade when assessing compliance with Appendix T of the PMO – FDA is in agreement. The development of the Appendix T training course, FD 378 (Preventive Controls for Grade “A” Dairy Regulators), and implementation of the current format of the Appendix T audit occurred separately from FDA’s decision to prioritize food facilities for receiving Full Scope or Limited Scope PC inspections. Incorporating a 2-scope inspection approach when evaluating compliance with Appendix T will align with the risk-based approach FDA is taking with other (non-IMS listed) food facilities whereby Full Scope PC inspections are performed at prioritized facilities.

We will be seeking NCIMS’ feedback in the near future as we work to revise the Appendix T audit and training materials to include a two-scope inspection scheme. While we do not anticipate making changes to the requirements found in Appendix T of the PMO, we would like to collaborate with the Conference on communicating with stakeholders about the changes to FDA’s approach to assess compliance with Appendix T.

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The other request from the NCIMS Liaison Committee is to allow the use of Limited Scope PC inspections for the dairy industry under the dual-grade dairy inspection pilot program. As referenced by former FDA Commissioner Dr. Gottlieb in 2017, FDA recognizes the importance of the dairy inspection pilot in continuing to assure the safety of the milk supply while seeking to “maximize state and federal resources and create greater efficiency through [our] obligations under the FDA Food Safety Modernization Act”. The ask of the NCIMS Liaison Committee to add a Limited Scope PC approach to the dairy inspection pilot would be reflective of the application of a two-scope inspection approach to the Grade “A” program and of a risk-based, prioritized approach to the use of state/federal inspectional resources.

FDA further recognizes that, with the NCIMS delegates passing of the Joint Council-1 proposal at the 2019 Conference, ultimately, it is the NCIMS Liaison Committee that has been charged to develop the dual-grade dairy inspection pilot, with the collaboration of FDA. FDA will support the direction of the NCIMS Liaison Committee about the implications of Limited Scope relative to the dual-grade dairy inspection pilot, including revising current options or incorporating additions of new options to pilot. As the NCIMS Liaison Committee noted, discussions over the past two years have allowed us to explore and learn about the impact of Appendix T requirements on the framework of the Grade “A” program. We have an opportunity to together further our learning about Limited Scope inspections in Grade “A” facilities.

In closing, I want to again thank the NCIMS Liaison Committee for your steadfast commitment to our shared goal of assuring the safety of the milk supply and the continued success of the Grade “A” program. FDA affirms our desire to work with the Committee to develop and implement the pilot in the true spirit of cooperation and collaboration that is a hallmark of the NCIMS Conference. We stand ready to support the Committee in your efforts and look forward to continuing our dialogue about a two-scope inspection approach and how it may impact the program, as well as the dairy pilot.

Sincerely,

Beth Panko Briczinski, Ph.D.
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Cc: Dr. Steve Beam, NCIMS Conference Chair
Dustin Cox, NCIMS Liaison Committee Co-chair