



July 21, 2022

Stephen Beam, Ph.D.
Chair, National Conference on Interstate Milk Shipments
Chief, Milk and Dairy Food Safety
California Department of Food and Agriculture
1220 N Street
Sacramento, CA 95814

Dear Chairman Beam,

FDA appreciates the extensive dialogue with, and feedback received from, the NCIMS Conference, specifically the Executive Board and the Liaison Committee, about how to best assess compliance of IMS-listed facilities with Appendix T and 21 CFR 117.

Through recent discussions and correspondence, the NCIMS Liaison Committee has asked FDA to apply a Limited Scope (LS) approach to Grade “A” facilities when assessing compliance with Appendix T of the *Pasteurized Milk Ordinance* (PMO). The NCIMS Liaison Committee has communicated their vision of the Milk Specialist performing a Limited Scope Preventive Controls (PC) inspection in conjunction with a Sanitation Compliance Check Rating. The Committee has also requested this facility-wide coverage (a single PC inspection) meet FDA’s FSMA coverage for the firm across both Grade “A” and non-Grade “A” products.

As a demonstration of our commitment toward that shared vision, FDA has agreed to a policy change to add a two-scope approach to the current Appendix T audits that are performed by Milk Specialists in IMS-listed facilities. Effective July 31, 2022, the Milk Specialist will perform a Limited Scope-activity in conjunction with a Sanitation Compliance Check Rating. This LS activity will be a broad assessment of the facility’s process, sanitation, and allergen preventive controls, as well as a CGMP inspection, with respect to the Grade “A” products manufactured in the facility.

The current Appendix T audits will be performed when implementation of a control appears to be inadequate to eliminate or reduce a significant hazard. We hope the Conference will recognize this change as a significant step toward the equity the Liaison Committee is seeking for the cooperative program relative to the assessment of PC compliance for other commodities across FDA’s foods program.

We are also looking forward to exploring in collaboration with the Liaison Committee and the Conference the impact that a Limited Scope approach will have on the dual-grade dairy inspection pilot. We stand ready to support NCIMS in developing and implementing a pilot framework that leverages our state partners and creates greater efficiencies throughout the Grade “A” program.



Please let me know if there is additional information that I can provide to the Board to add clarity to the new direction FDA will be implementing at the end of this month and how it may impact the future of the program and the dairy pilot.

Sincerely,

Beth Panko Briczinski, Ph.D.
Senior Science Advisor for Milk Safety
Center for Food Safety
and Applied Nutrition

Cc: Casey McCue, NCIMS Liaison Committee Chair