

November 29, 2022

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

Dear Dr. Beam,

FDA greatly appreciates the ongoing extensive and constructive dialogue with the NCIMS Executive Board and the Liaison Committee about how to assess compliance of IMS-listed facilities with both Appendix T of the *Pasteurized Milk Ordinance* (PMO) and the Preventive Controls for Human Foods Rule. Since 2019, FDA and NCIMS have been collaborating on how to best coordinate an approach to non-Grade "A" Preventive Controls inspections and Grade "A" check ratings to maximize Federal-State resources and minimize the burden of inspections in IMS-listed facilities.

Earlier this year, in response to discussions with the NCIMS Liaison Committee, FDA applied a Limited Scope (LS) Preventive Controls (PC) inspection approach to Grade "A" facilities when assessing compliance with Appendix T, implementing 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 Specialists have been performing a LS-activity for Grade "A" products in conjunction with a Sanitation Compliance Check Rating.

The next step in NCIMS and FDA's shared vision to establish a regulatory framework to identify efficiencies in inspection activities for facilities that manufacture both Grade "A" and non-Grade "A" products is for the Milk Specialists to provide Food Safety Modernization Act (FSMA) coverage for other food products manufactured at Grade "A" firms. We are pleased to share that, effective November 7, 2022, FDA successfully initiated a national rollout for coverage of the Grade "A" Safety and the Preventive Controls and Sanitary Human Foods Operations Compliance Programs for all IMS-listed firms, to be done concurrently by the Milk Specialist during check ratings. The Milk Specialists are assessing conformity of these compliance programs using a broad-based LS PC approach in IMS-listed facilities that are single- or dual-grade.

All these efforts are the result of continued discussion and interaction with the NCIMS Liaison Committee and Executive Board over the past 3 years. This new facility-wide inspectional model will continue to be evaluated and refined in collaboration with NCIMS as part of our commitment to the pilot program established in 2019 under proposal JC-1.

Thank you for your unwavering commitment to work with FDA in a true spirit of cooperation and collaboration that is the hallmark of NCIMS. Please let us know if there is additional information that we can provide to the Conference.

Sincerely,

Michael C. Rogers, MS Assistant Commissioner for Human and Animal Food Operations Office of Regulatory Affairs

Mark A. Moorman, PhD Director, Office of Food Safety Center for Food Safety and Applied Nutrition

Cc:

Laurie Farmer, FDA-ORA Beth Briczinski, FDA-CFSAN Casey McCue, NCIMS Liaison Committee Chair