Update to NCIMS Board: Dairy Inspection Pilot Program

Background

- Under the NCIMS state cooperative Grade "A" dairy program, FDA Milk Specialists conduct Check Ratings in IMS-listed facilities. Historically, IMS-listed facilities that also manufacture non-Grade "A" products would receive a separate inspection from an FDA CSO. Dairy industry stakeholders (industry and states) asked FDA to find a way to reduce these dual inspections.
- In November 2017, FDA announced a pilot program for inspections in IMS-listed facilities would be developed to identify and implement efficiencies in inspection activities for facilities that manufacture both Grade "A" and non-Grade "A" products while maintaining the safety of the milk supply.
- Based on stakeholder feedback and listening sessions, FDA recognized the need to develop a dairy inspection pilot program whereby a single visit from the FDA Milk Specialist fulfills both the Grade "A" and non-Grade "A" regulatory oversight including PC requirements.
- At the 2019 NCIMS Conference in April, FDA presented two general concepts to the Conference for consideration for the pilot (as part of proposal JC-1).
- All stakeholders at NCIMS (state regulators, NASDA, IDFA, NMPF) voiced unanimous support for the concepts and the NCIMS Liaison Committee was charged by the delegates to work cooperatively with FDA to develop the details of the pilot program to be implemented by FDA and the participating States.

Current Status

- The pilot offers a chance to explore options to achieve inspectional efficiencies. In recognition of the different regulatory frameworks, authorities, and resources among state programs, the pilot offers opportunities – not mandates – to States. The purpose of the pilot program is not to ultimately choose one option for use by all states. Both options will be piloted with a small group of states, and the advantages and disadvantages of each option will be evaluated. These two options were presented at the NCIMS Executive Board Meeting in October.
- **Option A: Federal-State Partnership:** Establish partnership agreements (non-contract information exchange) with individual states to co-regulate all non-Grade "A" products processed in IMS-listed facilities located in the State. During the check rating the Milk Specialist will verify the state has adequately covered the non-Grade "A" PC requirements which will then count toward the federally mandated limited scope PC inspection.

State Regulatory Agency

Grade "A" Inspection	with	Non-Grade "A" PC Inspection

Milk Specialist

Appendix T Audit	with	Non-Grade "A" Audit *(new*)*

- **Option B: Milk Specialist with Appendix T/Limited Scope PC:** All IMS-listed facilities receive an Appendix T audit by an FDA Milk Specialist (MS) on the check rating interval. For dual-grade facilities, the MS will include an inspection activity that allows FDA to count it as the federally mandated limited scope PC inspection.

Milk Specialist

Appendix T Audit	with	Activity to count as Limited Scope PC

Scope of the Pilot:

- Dual-grade IMS-listed facilities in good regulatory standing will participate in the unified inspection scheme defined by the pilot program.
- Grade "A"-only facilities receive a Check Rating/Appendix T audit by the Milk Specialist, without a separate PC inspection, and will be excluded from the pilot program.
- Certain non-Grade "A" products will be excluded from this pilot program: Infant formula (CP 7321.006), 100% juice (CP 7303.847), fish and fishery products (CP 7303.842), and domestic acidified and low-acid canned foods (CP 7303.803a) are handled via different regulatory schemes. In these situations, it is agreed that federal regulations would apply, and the FDA would have the primary responsibility.
- Except for the exclusions specified above, the pilot will include all other foods being processed at an IMS-facility.

States Selected for Pilot:

Participating State	Option
California	A
Connecticut	A
Oregon	A
Texas	A
Wisconsin	A
Ohio	B
Vermont	B
Virginia	B

Proposed Timeline

- The dairy inspection pilot will run February through December 2020. At the conclusion, FDA and the NCIMS Liaison Committee will assess the pilot outcomes and will present a report to the 2021 NCIMS Conference.

Future Reporting

- FDA and the Liaison Committee intend to update the NCIMS Executive Board at least quarterly or when there are time-sensitive items to share.