

**Dairy Inspection Pilot Program: Questions and Answers – Option A Procedures  
January 8, 2020**

**1. Dairy Inspection Pilot Option A (Partnership Agreement): What will happen when a Milk Specialist initially arrives at a facility for a Check Rating?**

Under Option A (Partnership Agreement), a Milk Specialist (MS) enters an IMS-listed facility with the State Partner (SP) for an NCIMS check-rating (CR). During the opening interview, the MS will explain the reason for the inspection/audit (IA), and the roles and responsibilities of FDA and the state authority.

The MS will assure that the facility representatives understand the MS will be covering all Grade “A” products under the NCIMS program CR as well as all products covered in the partnership agreement (PA; noting any product exceptions). The MS will allow time for facility representatives to ask questions, confirm that the facility representatives understand roles and responsibilities of the MS and SP, establish the facility is/is not an exempted facility, and identify all products manufactured at the facility.

The MS will list the products within the scope of the NCIMS CR and will list all the products within the scope of the IA and determine the authority of the SP. The MS will provide these product lists to the facility representatives for confirmation.

**2. Dairy Inspection Pilot Option A (Partnership Agreement): What will happen during the Inspection/Audit of the Food Safety Plan?**

The MS will initiate the IA with review of the Food Safety Plan (FSP). The MS will use the CR job aid and the GMP/Limited Scope Establishment Inspection Report Tool to evaluate all requirements of Appendix T and CFR 117 Subpart C Hazard Analysis and Risk-Based Preventive Controls.

With the SP, the MS will identify, review, and verify all parameters outlined in the FSP and regulations. Based on this review, the MS will determine compliance or the need for re-inspection.

After the FSP has been identified as in compliance, the MS will initiate the CR and the physical GMP IA using the PMO and CFR 117 Subpart B GMPs for the CR and IA criteria, respectively. If the FSP has been identified as not in compliance, the limited scope inspection will be completed on the other food products.

**3. Dairy Inspection Pilot Option A (Partnership Agreement): What will happen at the conclusion of the inspection visit?**

After the physical inspection has been completed, the MS will finalize the CR and GMP inspections and meet with the SP to discuss any non-compliance issues that were identified. This will include discussion points, corrective action possibilities, and a strategy for presenting the CR and IA findings to the facility representatives.

**4. Dairy Inspection Pilot Option A (Partnership Agreement): What will happen during the inspection visit close-out?**

During the CR/IA close-out, the MS and SP will present the findings of both the CR and IA to the facility representatives. The MS and SP will communicate potential regulatory follow-up issues for violations of the PMO and/or CFR 117 requirements that were identified through the CR and IA. The MS will allow time for the facility representatives to ask questions and to provide a response to the findings. Then the MS and SP will close the IA and exit the facility.

**5. Dairy Inspection Pilot Option A (Partnership Agreement): What regulatory follow-up, if any, will be taken by FDA?**

Following the IA, the MS will prepare a partnership agreement cover letter to the SP. This written communication to the SP will include a statement of findings for issues of noncompliance that had been previously discussed with the SP and were presented to the facility representatives during the close-out meeting.

If necessary, depending on the criticality of the noncompliance, the cover letter from the MS may request a timeline for corrective actions to be complete and the need for a written state response.

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