

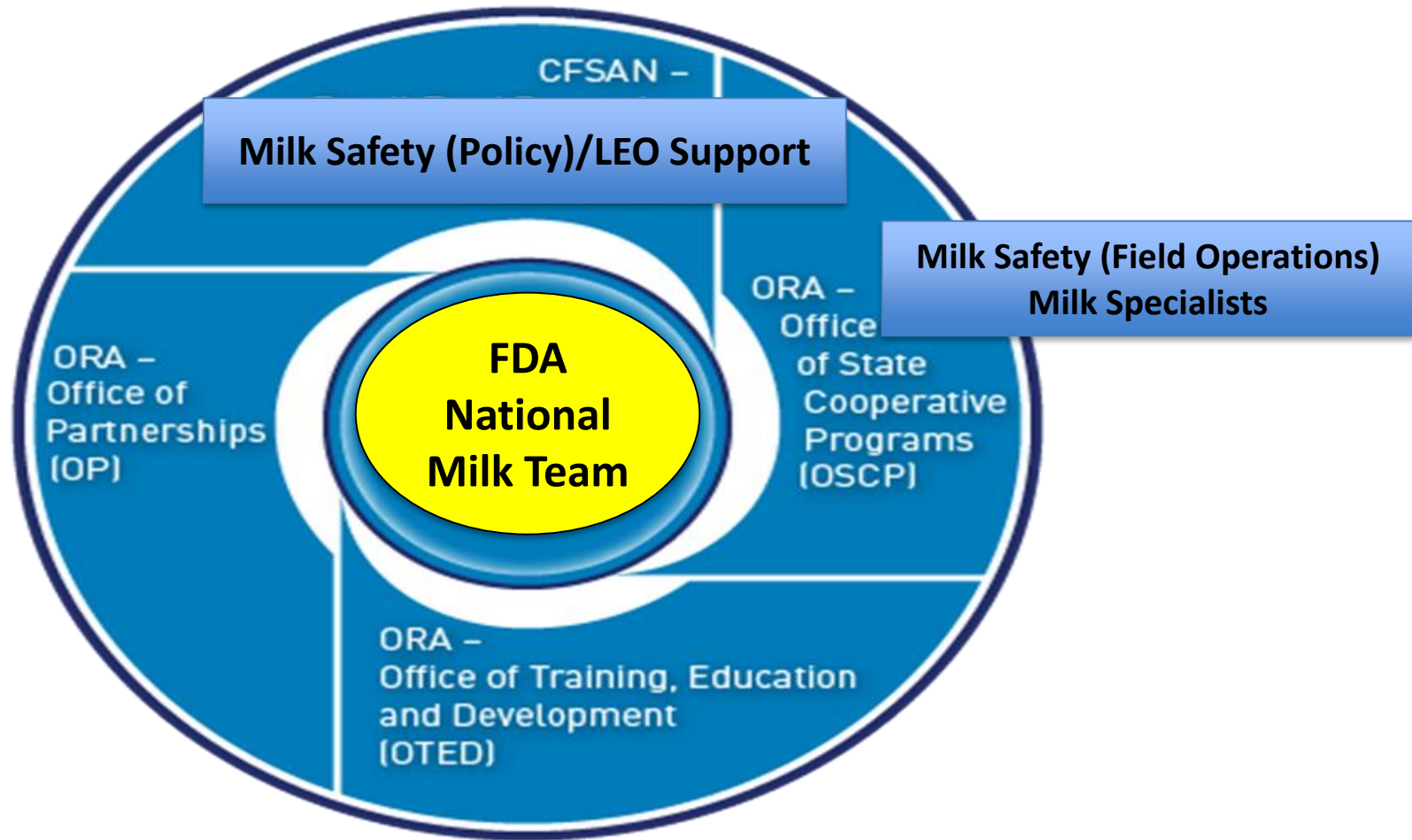
**US FOOD AND DRUG ADMINISTRATION
OFFICE OF STATE COOPERATIVE PROGRAMS
DIVISION OF MILK SAFETY**

**Eastern Milk Seminar
Madison, Wisconsin
Oct 29, 2019**



**LAURIE FARMER
DIRECTOR, OFFICE OF STATE COOPERATIVE PROGRAMS**

Partnerships Inside FDA



Office of Human and Animal Food Operations



Michael Rogers, MS
Assistant
Commissioner for
Human and Animal
Foods



Ellen Buchanan
Director,
Audit Staff



Laurie Farmer
Director, Office of
State Cooperative
Programs



Vinetta Howard -King
Director, Office of
Human and Animal
Foods East



Joann Givens
Director, Office of
Human and Animal
Foods West

Division of Milk Safety Branches

Branch 1 (East)

Director: Vacant

States: AL, CT, DE, FL, GA, LA, MA, MD, ME, MS, NH, NJ, NY, NC, PA, PR, RI, SC, TN, VA, VT, WV

Branch 2 (Central)

Director: Tim Roddy

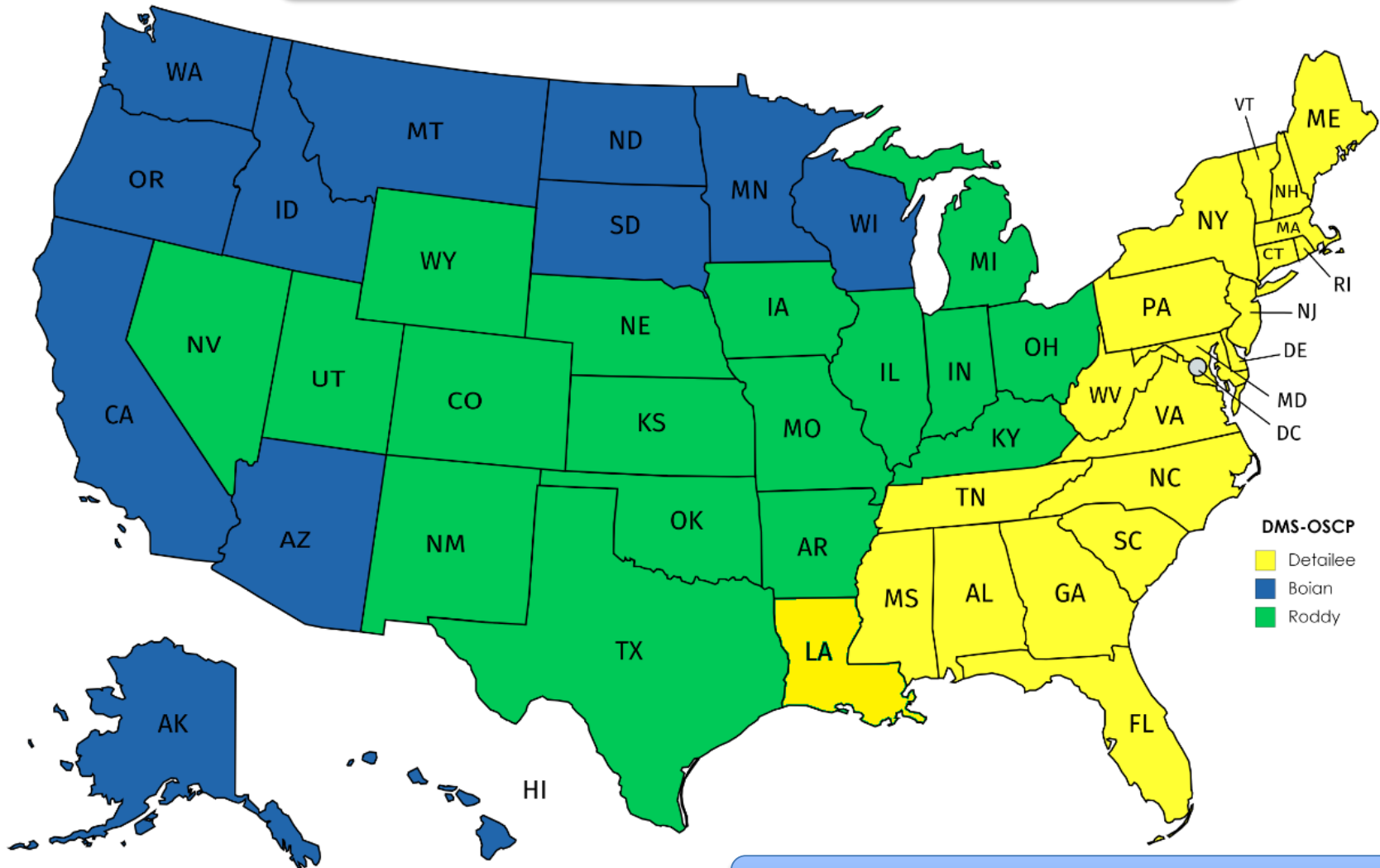
States: AR, CO, IA, IL, IN, KS, KY, MI, MO, NE, NM, NV, OH, OK, TX, UT, WY

Branch 3 (West)

Director: Les Boian

States: AK, AZ, CA, HI, ID, MN, MT, ND, OR, SD, WA, WI

FDA/OSCP/Milk Division Branches



**2017: 5 Regions to 1 Centralized HQ Field Office
NATIONAL PROGRAM**

OSCP Milk Specialists

State Assignments and Branches

Milk Specialist	Assigned State	Manager	NEW Branch #
Griner	AL, FL, LA, MS, SC	Vacant	1
Mitchell	MD, VA, WV	Vacant	1
Pearce	DE, PA, NJ	Vacant	1
Willis	GA, NC, PR, TN	Vacant	1
Zick	CT, MA, ME, NH, NY, RI, VT	Vacant	1
Himebaugh	NM, UT, NV, WY, CO, TX	Roddy	2
Klug	IA, MO, NE, AR, OK, KS	Roddy	2
Oliver	IL, IN	Roddy	2
Pitts	OH, KY, MI	Roddy	2
Goldsmith	MN, ND, SD	Boian	3
Miller	CA, AZ, HI	Boian	3
Navarrete	OR, WA, AK, ID, MT	Boian	3
Torgerson	WI	Boian	3

Milk Specialists Hiring



Expect Two Rounds of Hiring:

Round 1: Project Selections made by Mid-November

Round 2: Expect to Hire all Milk Specialist Openings

Milk Specialists Changes

- Branch I (Eastern)
 - 2-3 New Hires
- Branch II (Central)
 - 2-3 New Hires
- Branch III (Western)
 - 2-3 New Hires
 - Lezette Earhart retired in March 2019



Grade "A" CHECK RATINGS FY 2019 (11-12 Working Milk Specialists)

<u>BRANCH</u>	<u>BTU's</u>	<u>PLANTS</u>	<u>RS/TS</u>	<u>TOTAL</u>	<u>Single Service</u>
I-(East)	30	32	1	63	20
II- (Central)	49	38	6	93	14
III (West)	40	40	3	83	9
TOTALS	119	110	10	239	43

FDA - Priority List:

- **1) Standardizations for SROs and SSOs**
 - Timelines of (re)Certifications
 - FDA Staffing Issues
 - Milk Specialists Sharing the Priority Workload



Continue....FDA Priorities



- **2) Training**
 - OTED courses
 - Course in a Box



This was elevated due the recognition of the significant turnover in staffing with our state partners and the new instructional demands on the program.

Continue....**FDA Priorities**

- **3) State Program Evaluations- Completed**

This has been elevated due to the discussion with the states at NCIMS on the importance of SPEs. FDA has heard the concerns and we have moved the SPE work to this priority to ensure we meet that request.

Continue....**FDA Priorities**

- **4) Checkratings** for workplan numbers
 - Focus on plant CRs to meet the 3-year cycle for PC inspections.
 - This will be in place when FDA Milk Specialists are on-board and trained.

FDA Group Exercises Calibration & Training



- Group exercise in Omaha, Nebraska at Prairie Farms and LaLa-U.S. firms the week of October 22, 2018



- Group exercise in Dallas, Texas at Dean Foods and Kroger firms the week of April 1, 2019

Special “Thank You” to the States and companies that participated in the exercises!

Appendix T Inspections

- Start Date: December 1, 2018
- 71 Appendix T inspections conducted (Current)
- Action(s)
 - 4 Reinspections
 - Resulted from the absence of a Food Safety Plan or the firms lacking significant components of the Food Safety Plan.

Top 5 Issues

1. Recall plans

Incomplete,

2. Hazard Analysis

Incomplete, missing, not all hazards identified, only one HA for entire plant with multiple different processes.

3. Plants using modified HACCP and SQF plans

Modeled to meet 3rd party audits.

4. Lack of Corrective Actions.

5. Food Safety Plan not signed by most responsible individual.

FY2020 Dairy Seminars



Eastern Seminar

October 27th - 30th, 2019
in Madison, Wisconsin

Western Seminar

May 3rd - 6th, 2020
in San Antonio, Texas

Training

FDA's Office of Training Education and Development (OTED)

Jasjeet.Sekhon@fda.hhs.gov

FDA OTED Courses for FY2020



Milk Courses		Location	Approximate Timeframe
FD371	Milk Pasteurization Controls and Tests	Nashville, TN	5/11/2020
FD371	Milk Pasteurization Controls and Tests	Oklahoma City, OK	3/23/2020
FD372	Milk Plant Sanitation and Inspection	Denver, CO	6/15/2020
FD372	Milk Plant Sanitation and Inspection	Buffalo, NY	8/10/2020
FD373	State Milk Laboratory Evaluation Officer (LEO)	Long Beach, CA	4/20/2020
FD374	Laboratory Examination of Dairy Products	Boise, ID	3/9/2020
FD375	Dairy Farm Sanitation and Inspection	Palm Beach, FL	2/10/2020
FD375	Dairy Farm Sanitation and Inspection	Springfield, MO	7/13/2020
FD378	Preventive Controls for Grade "A" Dairy Regulators	Seattle, WA	7/27/2020
FD577	Special Problems in Milk Protection	Austin, TX	2/24/2020

Appendix T Training 2018

- Appendix T is accepted by FDA as equivalent to Title 21 CFR Part 117 for Grade “A” firms
- PMO-PC Cadre Assembled
- FD378 – Preventive Controls for Grade “A” Milk Plant Regulators
- Successful completion of this course meets FDA criteria for the Grade “A” PMO Preventive Controls Training for Regulatory Agencies.

PC-PMO Regulatory Training

- FDA budgeted \$250,000 to fund states' travel
- Five classes conducted: Dallas, Chicago, Newport Beach, Washington D.C., and Denver
- 166 Total participants
 - SROs (Plant)
 - State Program Managers
 - 3rd Party SROs and Managers
 - FDA Milk Safety Team Members (ORA/CFSAN)



Dairy Pilot: Dual Grade Facility





FDA Dairy Inspection Pilot

“When it comes to the FDA’s milk inspection protocols, the agency is seeking additional ways to maximize state and federal resources and create greater efficiency through its obligations under the FDA Food Safety Modernization Act.”

“We believe there’s more opportunity for FDA and state regulators to better coordinate oversight efforts of the dairy industry, making the process more efficient while maintaining the high safety of the U.S. milk supply.”

Dr. Scott Gottlieb, FDA Commissioner, November 1, 2017

Background

- The overall objective of the pilot program is to 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.
- The pilot will identify *“ways to maximize state and federal resources and create greater efficiency through (FDA’s) obligations under the FDA Food Safety Modernization Act.”* (Dr. Gottlieb, 11/1/2017).
- The ideal outcome would achieve efficiency gains in use of inspectional resources while assuring protection of public health.
- Minimize burden of inspections on IMS-listed facilities
- Goal: Integration – not duplication – of food safety inspections

Dual Grade Facility Pilot

- NCIMS 2015/2017: Establish Appendix T
- Pilot version 1.0
- December Stakeholder Meeting
- Federal Furlough → Assessment of Stakeholder Meeting
- NCIMS
 - JC-1
 - FDA work with Liaison Committee

Dairy Inspection Pilot – Version 2.0

FDA Partnership with Liaison Committee

- FDA will pilot two approaches for dual-grade facilities:
 - Federal-State Partnership
 - Appendix T/Limited Scope PC Combination

Option A: Federal-State Partnership

State Regulatory Agency

Grade “A”
Inspection with Non-Grade “A”
PC Inspection

Milk Specialist

Appendix T
Audit with Non-Grade “A”
Audit

Option B: Appendix T/Limited Scope PC Combination

Milk Specialist

Appendix T
Audit

with

Activity to count as
Limited Scope PC

Scope of Pilot Program

- Grade “A” Facilities
 - On the IMS List
 - In “good regulatory standing”
- Excluded from the Pilot: Grade “A”-only facilities.
 - These facilities receive a Check Rating/Appendix T audit by the MS, without a separate PC inspection.

Scope of Pilot Program

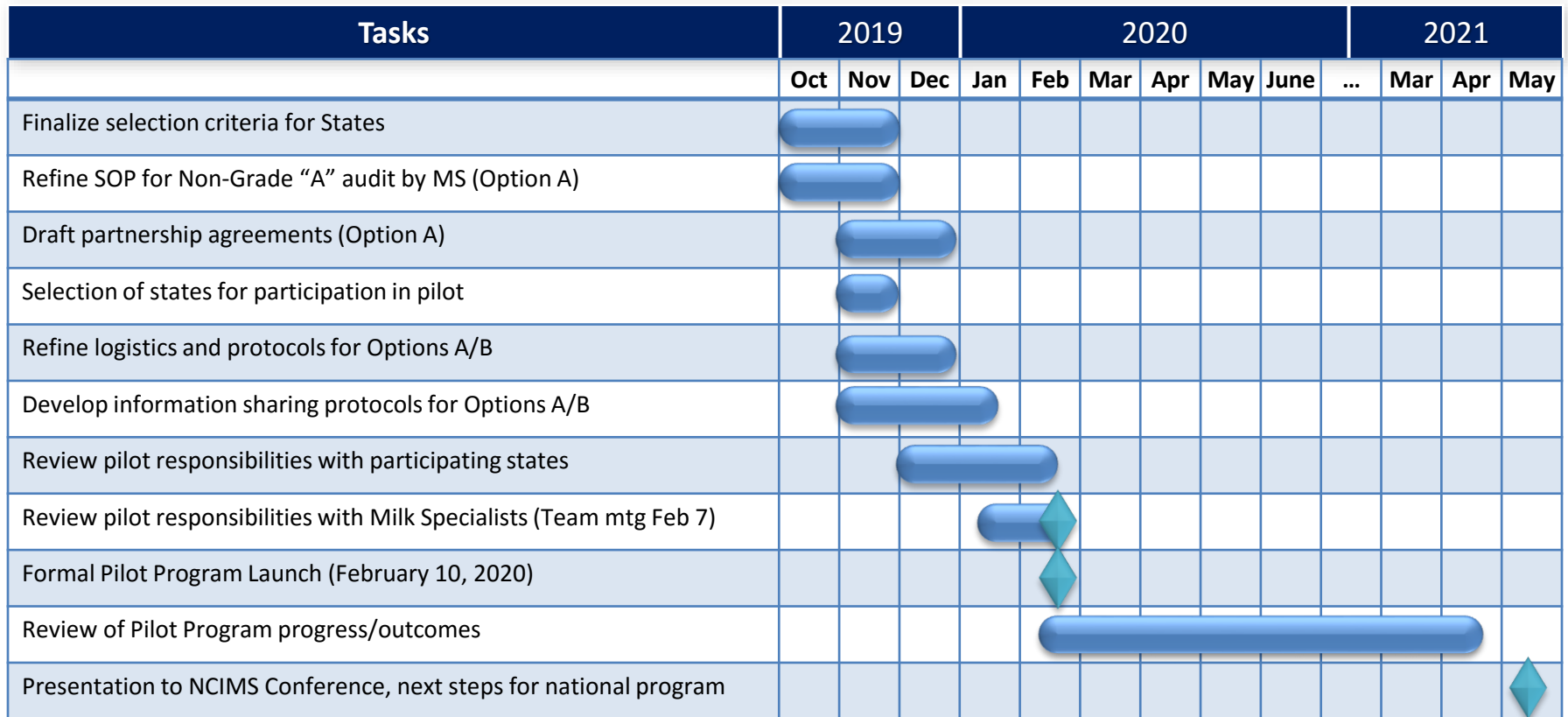
- Products excluded from the Pilot:
 - Infant formula
 - 100% juice
 - Non-dairy foods that are under a current FDA-filed aseptic process
 - Raw milk

State Selection Criteria for the Dual Grade Pilot

- (For Option A) States must have adopted Title 21 CFR 117 or the PMO (or equivalent) for non-Grade “A” products into their regulations for the inspection to count toward the federally mandated FSMA coverage.
 - At least one state that has adopted 21 CFR 117; and one state that has a different means of assuring the state has the regulatory authority to cover non-Grade “A” products.
- (For Option A) At least one state that previously had a partnership agreement (former Pac-SW region).
- (For Option A) At least one state that has the same agency covering Grade “A” and non-Grade “A” products.
- (For Option A) At least one state that has different agencies covering Grade “A” and non-Grade “A” products.

Dairy Inspection Pilot Program

DRAFT – FOR DISCUSSION PURPOSES ONLY



FDA Messages and Takeaways

- FDA recognizes the value and quality of work that the NCIMS program provides the FDA Milk Safety Program
- FDA will continue to support the NCIMS MOU and the integration of food safety through our Cooperative Programs

Next Steps

- FDA looks forward to the development and implementation of the new version of the Dairy Inspection Pilot with the NCIMS Liaison Committee.
- FDA will commit to open and transparent dialogue on the pilot with all stakeholders.

Questions



Steve Beam, NCIMS Chair (CA); Beth Briczinski, FDA; Laurie Farmer, FDA; Mark Moorman, FDA Board Rep; Casey McCue, NCIMS Liaison Cmty Chair (NY)