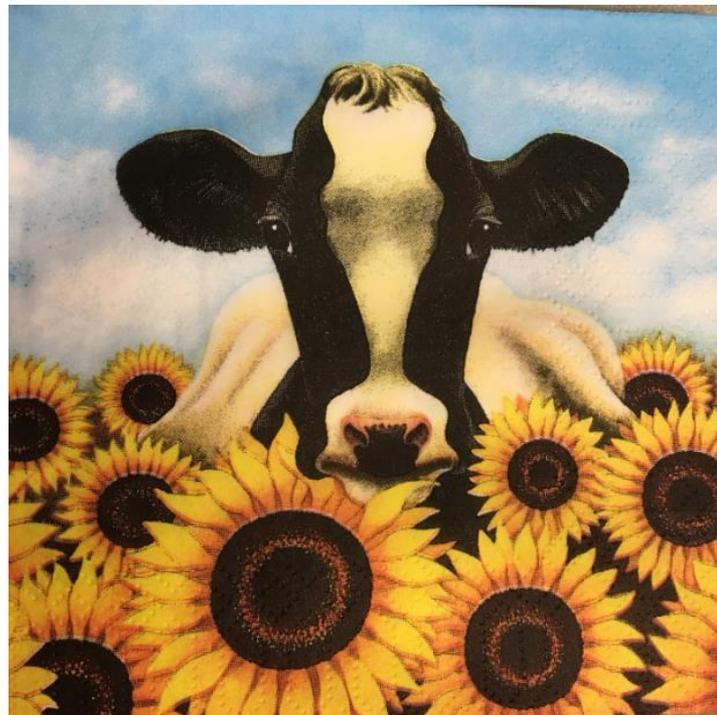


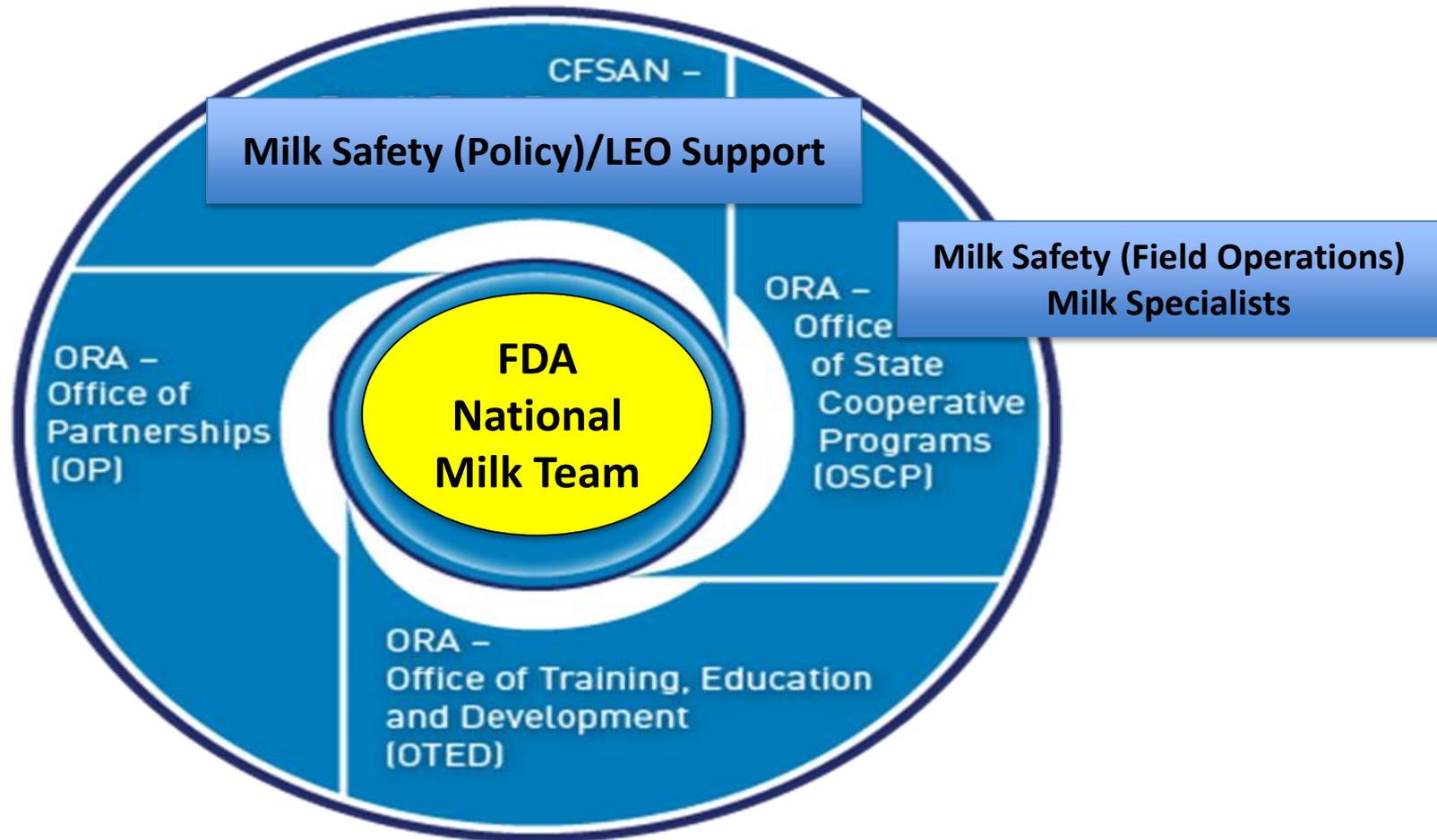
**US FOOD AND DRUG ADMINISTRATION  
OFFICE OF STATE COOPERATIVE PROGRAMS  
DIVISION OF MILK SAFETY**

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

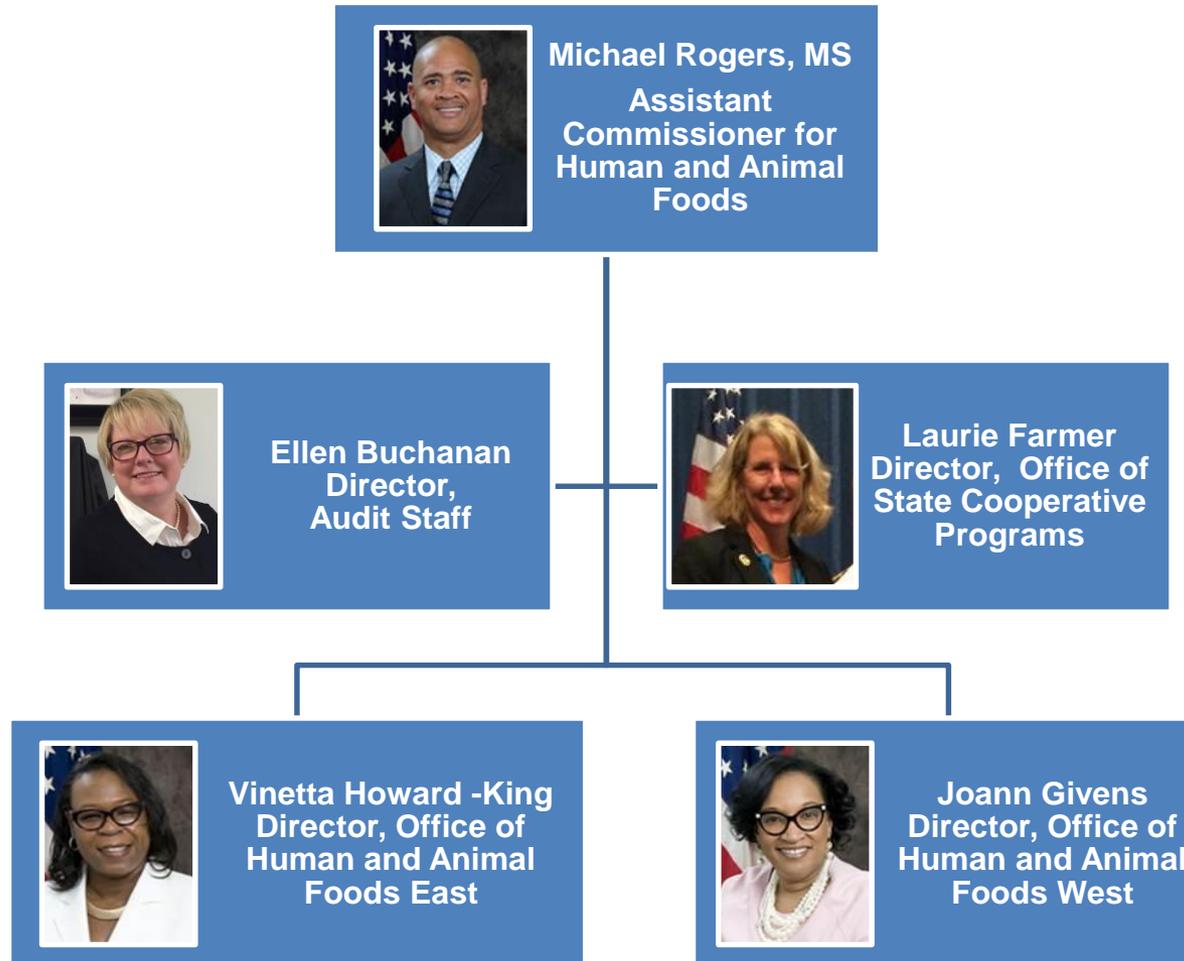


**LAURIE FARMER  
DIRECTOR, OFFICE OF STATE COOPERATIVE PROGRAMS**

# Partnerships Inside FDA



# Office of Human and Animal Food Operations





# 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**

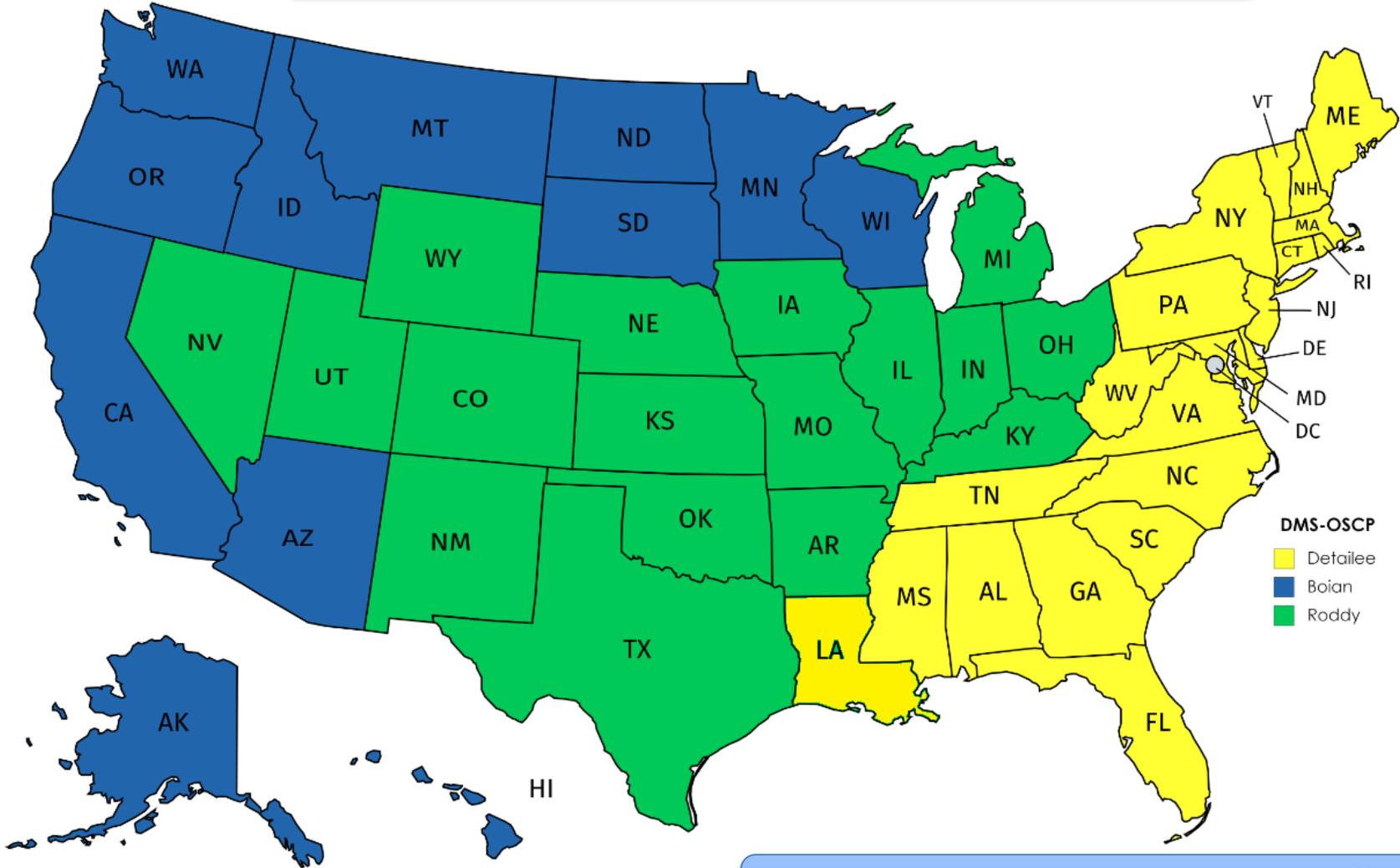
States: AR, CO, IA, IL, IN, KS, KY, MI, MO, NE, NM, NV, OH, OK, TX, UT, WY

## 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
<b>TOTALS</b>	<b>119</b>	<b>110</b>	<b>10</b>	<b>239</b>	<b>43</b>

# 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 3<sup>rd</sup> party audits.

## **4. Lack of Corrective Actions.**

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

# FY2020 Dairy Seminars



## Eastern Seminar

October 27<sup>th</sup> - 30<sup>th</sup>, 2019

in Madison, Wisconsin

## Western Seminar

May 3<sup>rd</sup> - 6<sup>th</sup>, 2020

in San Antonio, Texas



# Training

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

[Jasjeet.Sekhon@fda.hhs.gov](mailto: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
  - 3<sup>rd</sup> 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

Tasks	2019			2020						2021			
	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June	...	Mar	Apr	May
Finalize selection criteria for States	■												
Refine SOP for Non-Grade “A” audit by MS (Option A)	■												
Draft partnership agreements (Option A)		■											
Selection of states for participation in pilot		■											
Refine logistics and protocols for Options A/B		■											
Develop information sharing protocols for Options A/B		■											
Review pilot responsibilities with participating states			■										
Review pilot responsibilities with Milk Specialists (Team mtg Feb 7)				■		◆							
Formal Pilot Program Launch (February 10, 2020)					◆								
Review of Pilot Program progress/outcomes					■								
Presentation to NCIMS Conference, next steps for national program													◆



# 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)