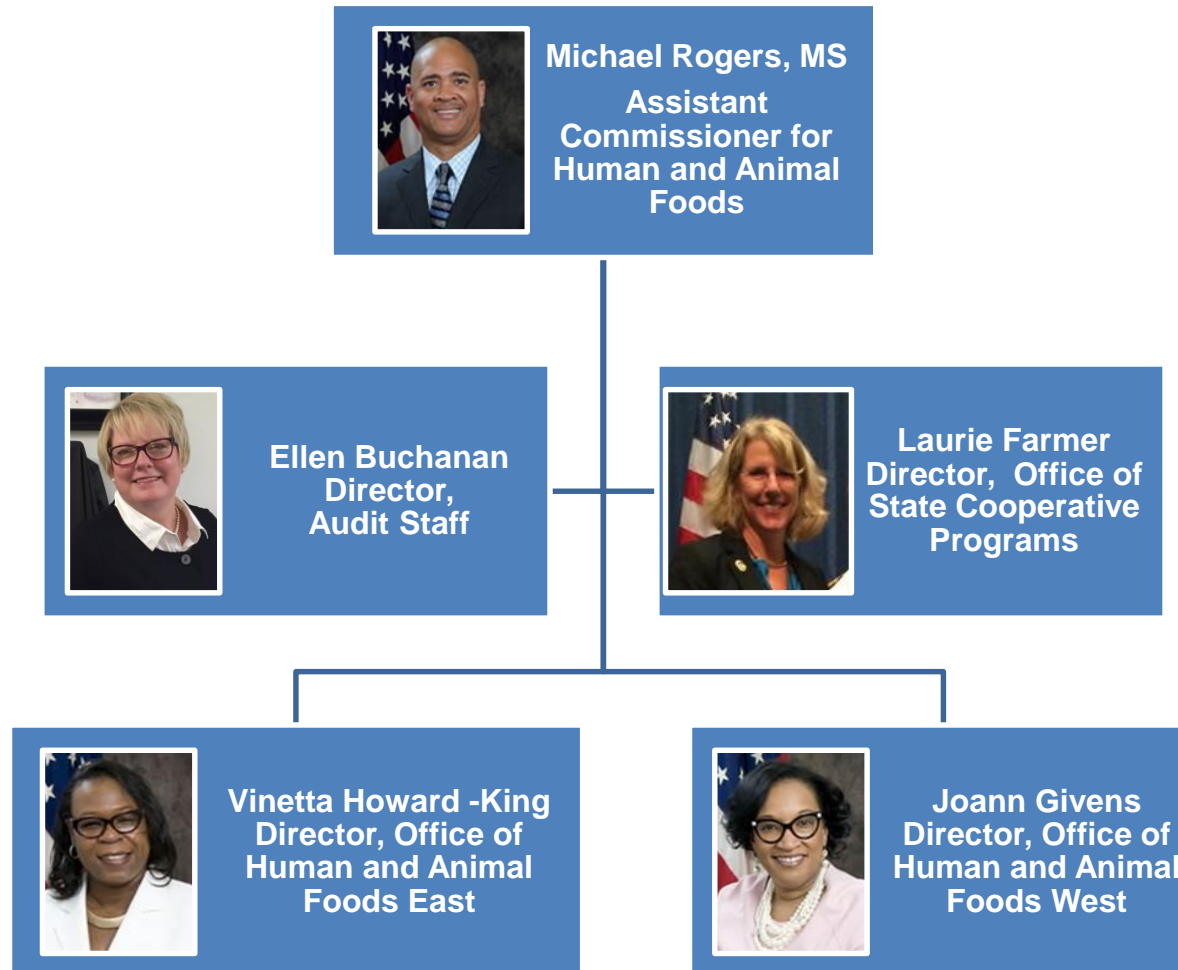


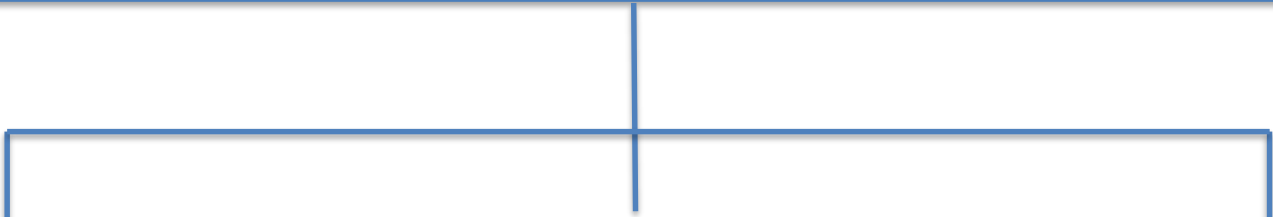
# STATE COOPERATIVE PROGRAMS REPORT

**TIM RODDY**  
**OSCP**  
**DIVISION OF MILK SAFETY**  
**DIRECTOR BRANCH #2**  
**JUNE 4, 2019**

# Office of Human and Animal Food Operations



# Office of State Cooperative Programs



Division of Retail  
Food Protection

Division of Milk  
Safety

Division of Shellfish  
Sanitation



# DMS Branches

## Branch 1 (East)

Acting Director: Robert Altobelli

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)

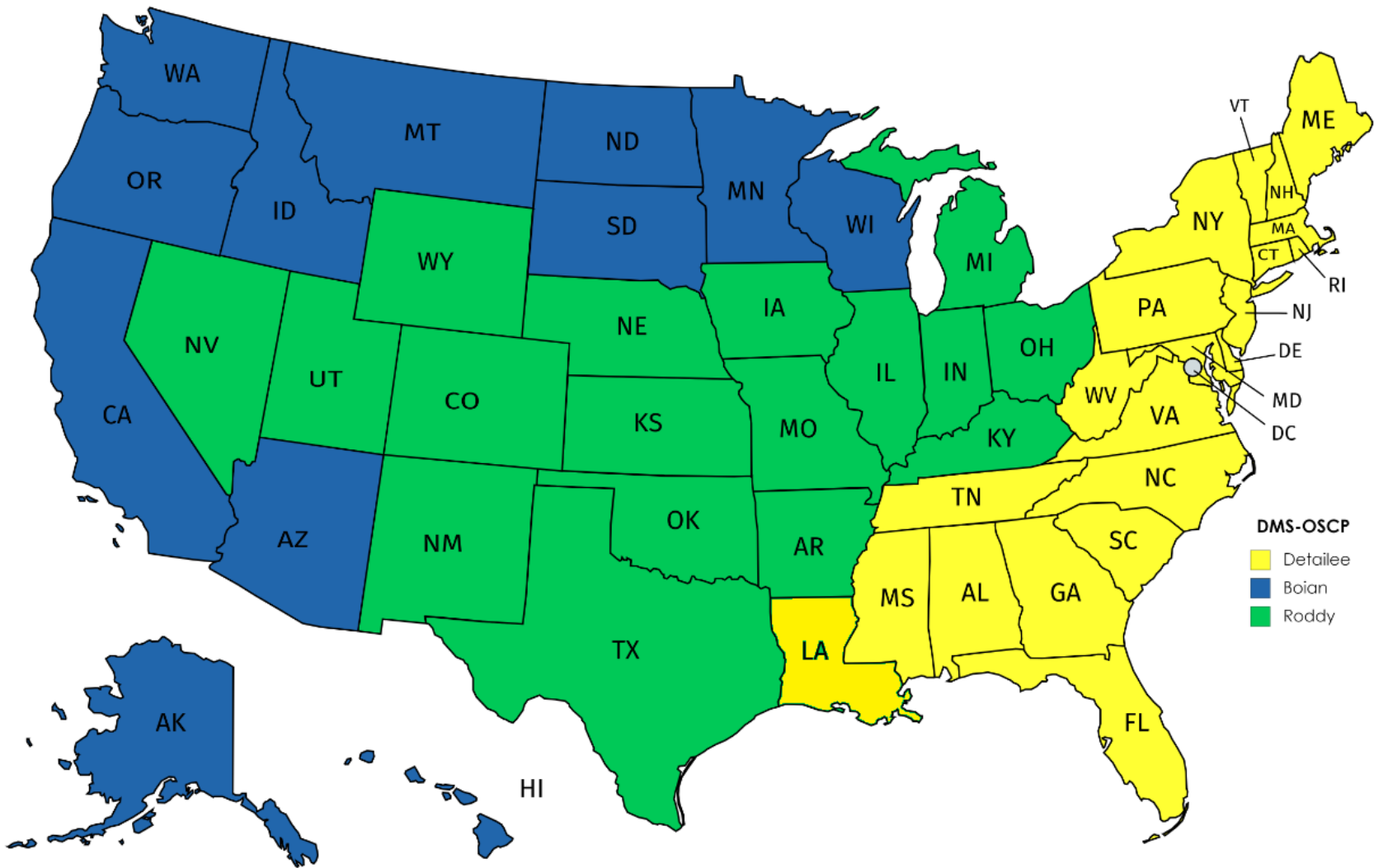
Director: Tim Roddy

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



# OSCP Milk Specialists

## State Assignments and Branches

Milk Specialist	Assigned State	Manager	NEW Branch #
Griner	AL, FL, LA, MS, SC	Detailee	1
Mitchell	MD, VA, WV	Detailee	1
Pearce	DE, PA, NJ	Detailee	1
Willis	GA, NC, PR, TN	Detailee	1
Zick	CT, MA, ME, NH, NY, RI, VT	Detailee	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



# 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
  - Plant SROs (Plant)
  - State Program Managers
  - 3<sup>rd</sup> Party SROs and Managers
  - FDA Milk Safety Team Members (ORA/CFSAN)



## FDA Group Exercises

- 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
- 38 Appendix T inspections conducted
- Action(s)
  - 2 Reinspections
  - Resulted from the absence of a Food Safety Plan or the firms lacking significant components of the Food Safety Plan.

# 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

# Dairy Inspection Pilot

- Responding to multiple stakeholder groups:
  - Coordinate an approach to non Grade “A” PC and Grade “A” check ratings
  - Maximize Federal-State resources
  - Minimize burden of inspections on IMS-listed facilities
- Goal: Integration – not duplication – of food safety inspections

# Dairy Inspection Pilot – Version 1.0

- What:
  - One combined visit from FDA
  - Simultaneous MS Check Rating with PC Inspection
  - Leverage expertise of combined visit
- When:
  - Fall 2018 (2 non-regulatory visits)

# Stakeholder Listening Session

- Washington D.C. in December 2018
- Comments from mock inspections:
  - Simultaneous inspection was a burden on facility
  - Efficiencies were not being realized
- NCIMS, States, and Industry stakeholders asked FDA to reconsider pilot structure
  - Goal: single person, single regulatory activity
- FDA committed to explore new possibilities

# Dairy Inspection Pilot – Version 2.0

- An IMS-listed plant that solely manufactures Grade “A” dairy products and complies with the revised PMO would also comply with the PC rule (Appendix T audit only).
- FDA will pilot two approaches for dual-grade facilities:
  - Federal-State Partnership
  - Appendix T/Limited Scope PC Combination

# 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 (*new\**)



# Appendix T/Limited Scope PC Combination

## Milk Specialist

Appendix T  
Audit      with      Activity to count as  
Limited Scope PC



At the 2019 NCIMS Conference,  
Proposal JC-1 was unanimously passed  
by the Delegates.

- The NCIMS Liaison Committee was charged to work cooperatively with FDA to develop the pilot program which will be implemented by FDA and the participating States.
- The Committee will determine the eligibility criteria for pilot consideration, the types of non-Grade “A” products manufactured in dual-grade facilities that will be covered, the resource needs and potential hurdles likely to be encountered, and the metrics for evaluating success.

# FDA Fully Supported JC-1

- Recognized that it demonstrated FDA's strong commitment to develop the dairy pilot program.
- This option assures varied expertise and perspectives are considered.
- A complete report of the Pilot program will be shared with the 2021 NCIMS Conference.

# 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.

## Proposals of Interest – 2019 NCIMS

- 112 – Yogurt Repacking – Study Committee
- 118 - Robot Proposal – Update for PMO
- 210 - Automatic Sampling System for Tankers
- 303 - Q&A Review Process to go through the Document Review Committee
- 304 - Performance Based Extension of SPEs
- JC-2 - Put Fermented High Acid Foods in the PMO

# Questions