

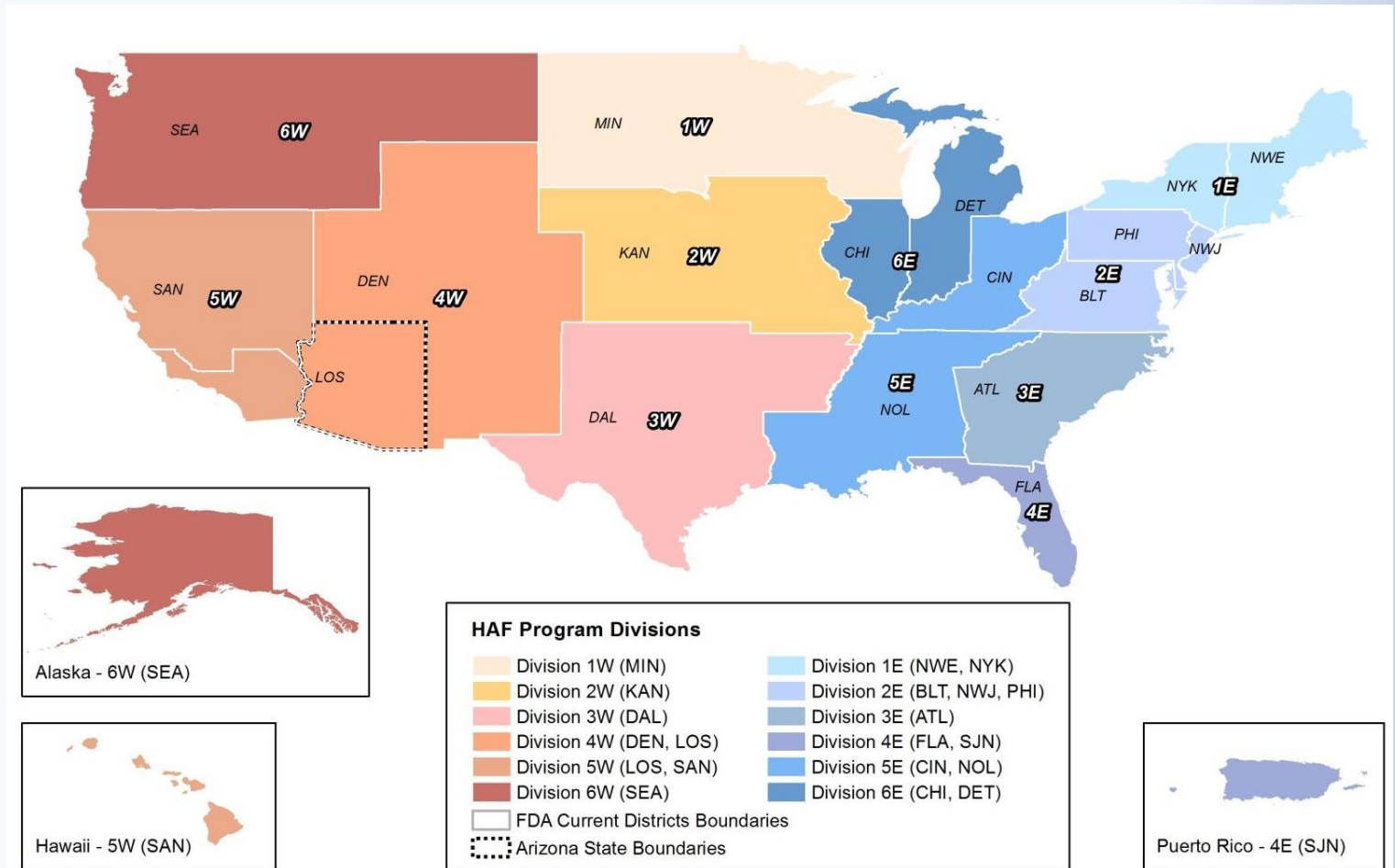
STATE COOPERATIVE PROGRAMS-DIVISION OF MILK SAFETY REPORT

**TIM RODDY
MILK SAFETY DIVISION
BRANCH #2 DIRECTOR
JULY 2023**

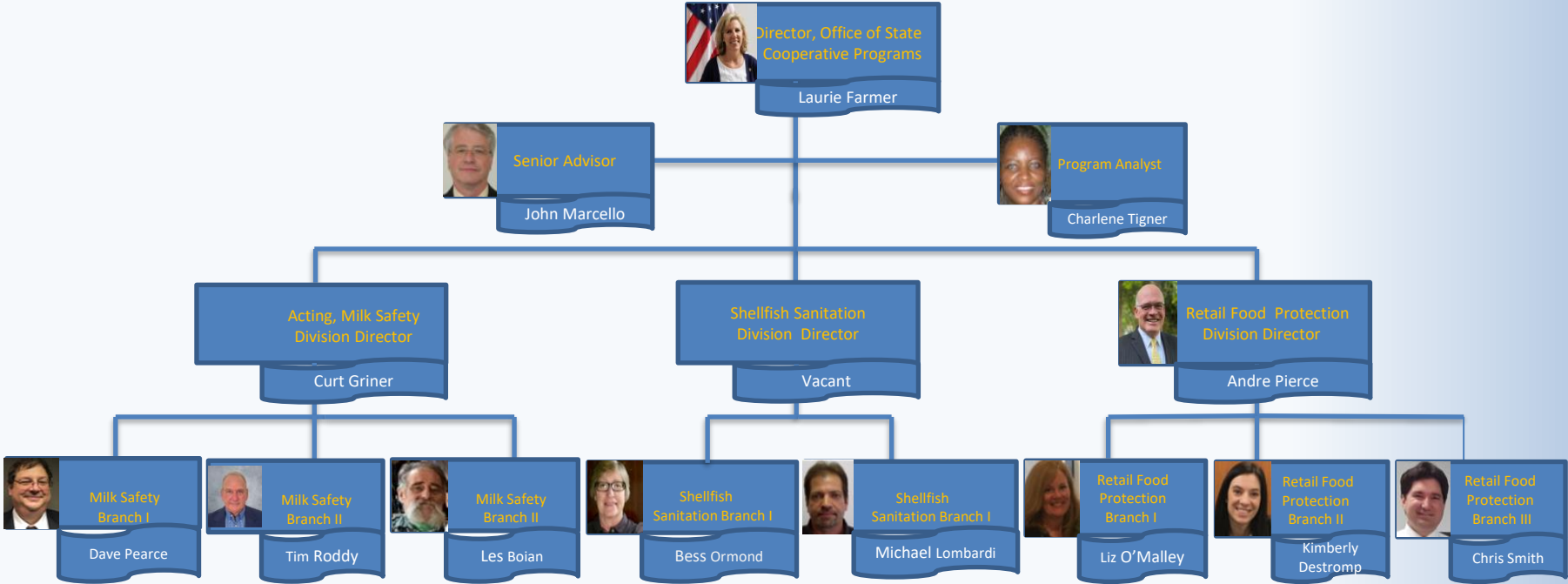
PRESENTATION OBJECTIVES

- Current - ID key organizational contacts
- Final Hiring Efforts and New Specialist Faces you may be Seeing
- Program Priorities - Results
- Training Scheduled
- FDA Funding Support
- FDA Commissioner's Proposal for a Unified Human Foods Program and New ORA Model

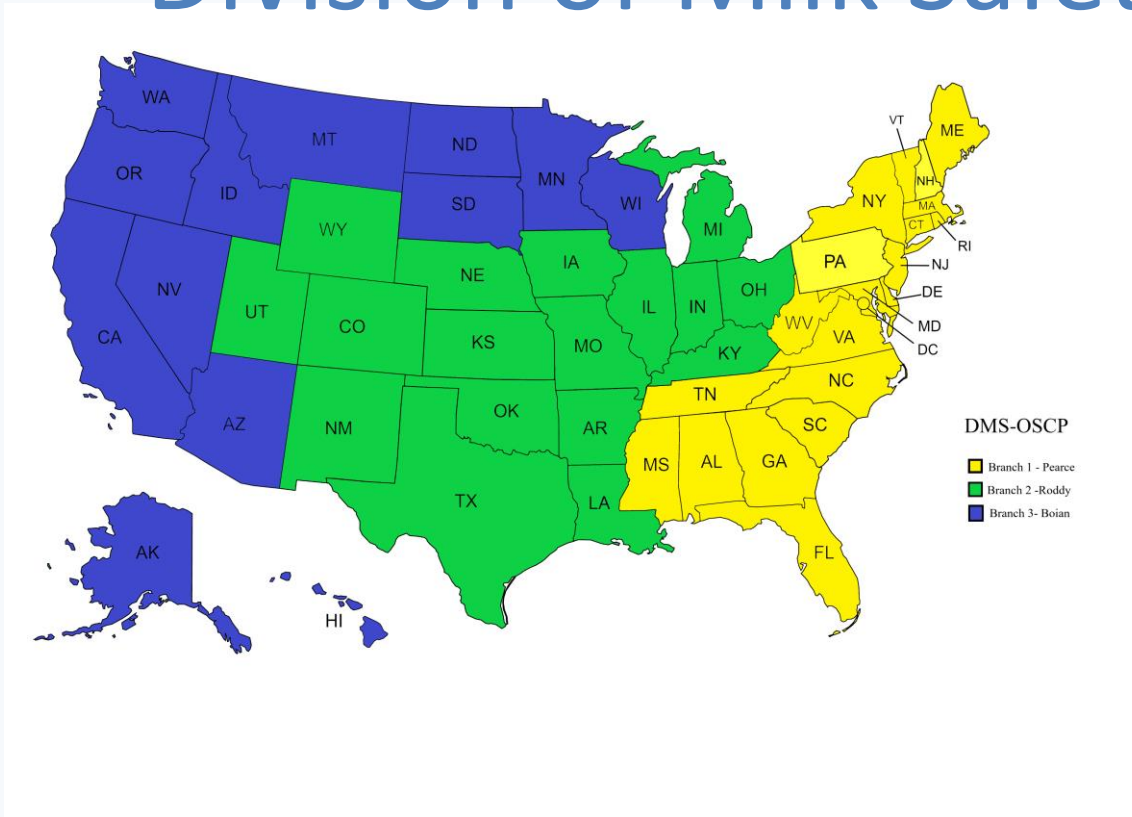
Office of Human and Animal Food Operations



Office of State Cooperative Programs



Division of Milk Safety Staff



3 Milk Safety
Branches
Nationwide

20 Milk Specialists
1 Program Support
Specialist
3 Branch Directors
0 Vacant Milk
Specialists
1 Acting Division
Director

THE NATIONAL MILK SAFETY TEAM

**FDA U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR FOOD SAFETY & APPLIED NUTRITION

Office of Food Safety

**FDA U.S. FOOD & DRUG
ADMINISTRATION**

OFFICE OF REGULATORY AFFAIRS

Office of Partnerships



**Steering Committee Serves
as Forum for FDA
Components to Deliberate
Issues Impacting FDA's Milk
Safety Program**

**FDA U.S. FOOD & DRUG
ADMINISTRATION**

OFFICE OF REGULATORY AFFAIRS

Office of State Cooperative Programs

**FDA U.S. FOOD & DRUG
ADMINISTRATION**

OFFICE OF REGULATORY AFFAIRS

Office of Training, Education and
Development

Branches

| Bran | Title | Name | States/Territories Located in Branch |
|------------------------|-----------------|----------------------|--|
| Milk Safety Branch 1 | Branch Director | David Pearce (7 MSs) | AL, CT, DE, FL, GA, MA, MD, ME, MS, NC, NH, NJ, NY, PA, PR, SC, TN, RI, VA, VT, WV |
| Milk Safety Branch II | Branch Director | Tim Roddy (7 MSs) | AR, CO, IA, IL, IN, KS, ,KY, MI, MO, NE, NM, LA, OH, OK, TX, UT, WY |
| Milk Safety Branch III | Branch Director | Les Boian (6 MSs) | AK, AZ, CA, HI, ID, MN, MT, ND, NV, OR, SD, WA, WI |

New Milk
Specialist
Branch II -
Lyndsey
Giles-Austin



New Milk
Specialist Branch
III - Michele
Orner



DMS Priorities Coming out of the Pandemic for State Rating Officer Certifications

- FDA criteria for planning future standardization of State officials:
- High priority (HP) is urgent need for a replacement SRO, and re-certification of past due SROs.

Priority (P) are SROs past due or coming due in 2022.

Current (C) are SROs that will be coming due in 2023 and later.

Totals:

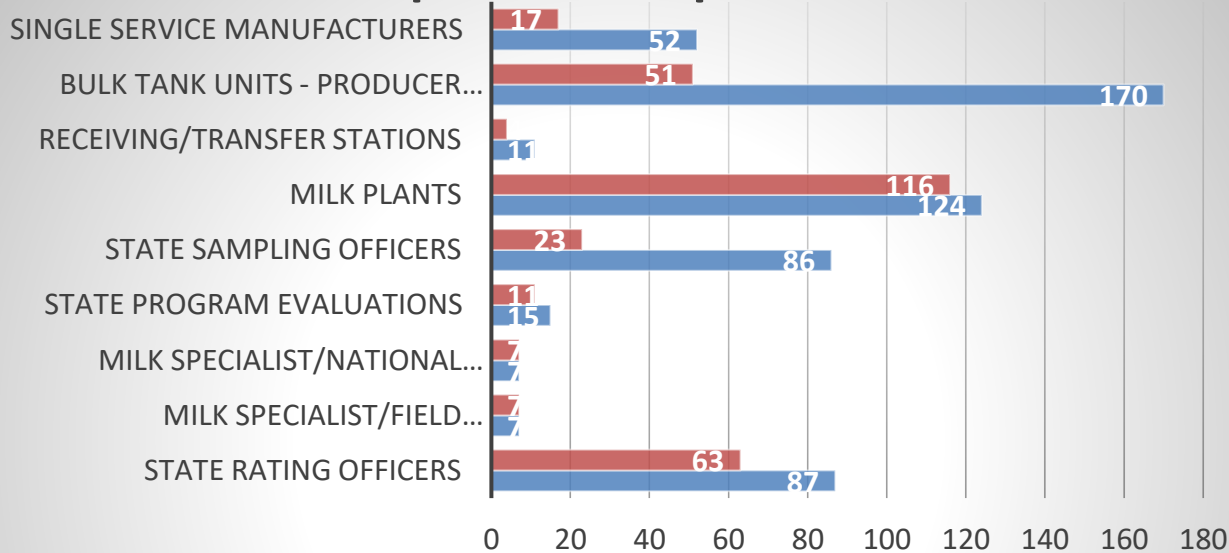
- Current Number of State Rating Officers (SROs): 132
- High Priority: 45
- Priority: 34
- Current: 53

OSCP
Division of Milk Safety

- Top priorities:
- Standardization of State Rating Officers(SRO)
 - Field Standardization of Milk Specialists (MS)
 - National Standardization of Milk Specialists (MS)
 - State Program Evaluations (SPE)



FY22 Workplan Accomplishments Final



| | State Rating Officers | Milk Specialist/Field Standardization | Milk Specialist/National Standardization | State Program Evaluations | State Sampling Officers | Milk Plants | Receiving/Transfer Stations | Bulk Tank Units - Producer Groups | Single Service Manufacturers |
|--------------|-----------------------|---------------------------------------|--|---------------------------|-------------------------|-------------|-----------------------------|-----------------------------------|------------------------------|
| Planned | 63 | 7 | 7 | 11 | 23 | 116 | 4 | 51 | 17 |
| Accomplished | 87 | 7 | 7 | 15 | 86 | 124 | 11 | 170 | 52 |

Planned Accomplished



Huge Thank You From DMS and CFSAN

- DMS had Seven (7) New Hire MSs Field and Nationally Standardized In Basically a Twelve-Month Span.
- That is a Substantial Commitment in Time and Resources from our State Partners.

OSCPion of Milk Specialists (MS)
 -National Standardization of Milk Specialists (MS)
 priorities:

OSCP
 Division of Milk Safety

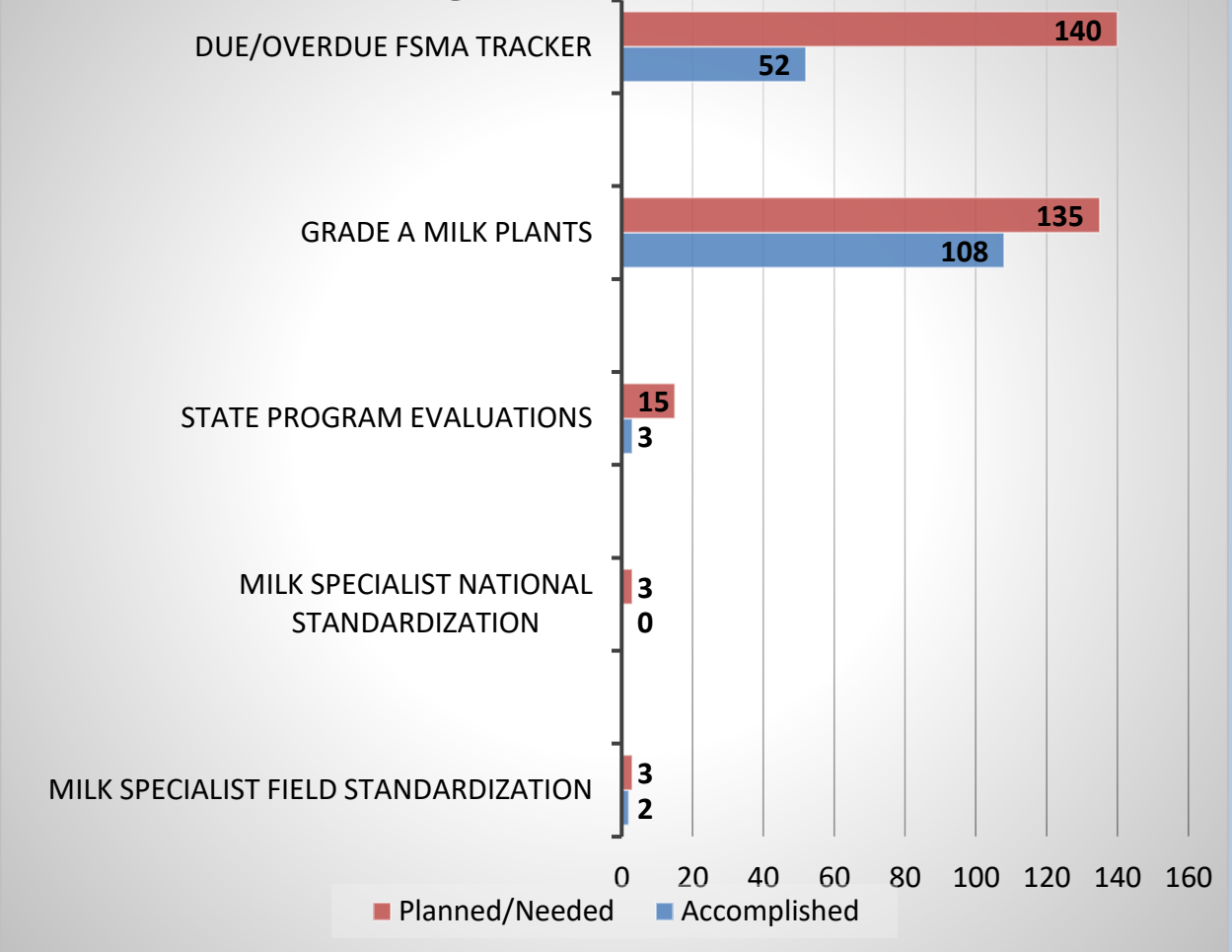
FY23 DMS Priorities Percentages

- MS Field Standardization– 67%
- MS National Standardization– 0%
- State Program Evaluations – 20%
- Plant CRS– 80%
- Due FSMA Tracker – 37%

(MS)
 -Complete Coverage of Manufacturing



Tracking FY23 DMS Priorities



State Program Evaluations

- FY21 - 15 SPEs
- FY22 - 7 SPEs additionally projected for an FY total of 22.
- **FY23 - 15 SPEs and All States on Agreed To Timelines**

OTED and DMS Sponsored Training



- Independent Course Delivery (ICD) and Train-the-Trainer (TTT) programs
- OPTIONS: OTED Plan for Expanding Course Options Still have the States as Traditional Hosts (Replace Course in the Box)
- Training Needs Survey (MSs Will be Requesting Numbers)
- Tentatively Will have Five Courses Scheduled for FY2024. (2- Farm, 1-Plant, 1-HTST, and 1-PC Courses Planned)

FY2023 Training - OTED

| Course ID | Course Name | Locations | Course Dates |
|-----------|---|----------------|-------------------------------------|
| FD375 | Dairy Farm Sanitation & Inspections | Tulsa, OK | August 22-25, 2023 |
| FD371 | Milk Pasteurization Controls & Tests | Virtual (2) | April 17-20, 2023 June 5-8, 2023 |
| FD373 | State Milk Laboratory Evaluation Officer Workshop (LEO) | Virtual | TBD |
| FD577 | Special Problems Course | Alameda, CA | 12/6/2022 |
| FD374 | Laboratory Examinations of Dairy Products | At Site | TBD |
| FD372 | Milk Plant Sanitation and Inspection | Virtual | May 1-4, 2023 |

FY2023 Training – State Hosted

| Course ID | Course Name | Locations | Course Dates |
|---------------------|--------------------------------------|------------------|-----------------------|
| State Hosted | Milk Plant Sanitation | Boise, ID | August 8-11, 2023 |
| State Hosted | Milk Pasteurization Controls & Tests | Valley Forge, PA | August 28-30, 2023 |
| State Hosted | Milk Pasteurization Controls & Tests | Arlington, Texas | September 18-22, 2023 |
| State Hosted | Special Problems | Athens, GA | May 15-19, 2023 |
| State Hosted | Special Problems | New York | May 30-June 2, 2023 |

Tentative 2024 Training

| Course ID | Course Name | Locations | Course Dates |
|--------------|---|--------------------|--------------|
| FD375 (2) | Dairy Farm Sanitation & Inspections | At Site | TBD |
| FD371 | Milk Pasteurization Controls & Tests | At Site | TBD |
| FD373 | State Milk Laboratory Evaluation Officer Workshop (LEO) | At Site | TBD |
| FD378 | PC for Grade A Dairy Plant Reg Course | At Site or Virtual | TBD |
| FD374 | Laboratory Examinations of Dairy Products | At Site | TBD |
| FD372 | Milk Plant Sanitation and Inspection | At Site | TBD |

Milk Seminars

- One Seminar per Year
- East/West Concept
- East – Fall after NCIMS Conference
- West – Spring of the Even Numbered Years
- Continue to Provide Funding Option Through Cooperative Agreement





Future Milk Seminars

2023 EASTERN MILK SEMINAR

October 24-26, 2023

Holiday Inn Express in Nashville, TN



Future Milk Seminars

2024 WESTERN MILK SEMINAR

April 22-25, 2024

Marriot in Denver, CO



NCIMS
National Conference on
Interstate Milk Shipments



Milk / Shellfish Cooperative Agreement CY 2020-2024 Sub-awards

Cooperative Agreement: Summary of Key Details

5 Years of Funding – CY 2020 thru CY 2024

- \$2.8 million for Year 1;
- \$3 million per year projected for remaining years

75% of funds must go to State, Tribal, Territorial, DC jurisdictions -

- \$2.1 million for Year 1;
- \$2.25 million for years 2-5
 - The budget for each year includes \$25,000 sub-awards for ISSC and NCIMS

CY 2023

Milk Awarded Funding

- ❖ Training - \$1,277,275
- ❖ Special training:
 - NCIMS: \$203,943
 - State Hosted & FD375: \$124,685
 - FD577: \$7,558
- ❖ Milk Sampling Assignment:
 - CFSAN \$23,165

Total: \$1,613,461

Shellfish Awarded Funding

- ❖ Training - \$511,322
- ❖ Special Training:
 - FD242: \$41,645
 - ISSC: \$92,150

Total: \$645,117

CY 2023

Equipment:

- Available funding for equipment
- ~\$1,186,000
- Currently have ~\$1,000,000 being requested in combined programs



Possible Rollover to FY24:

- ~\$200,000

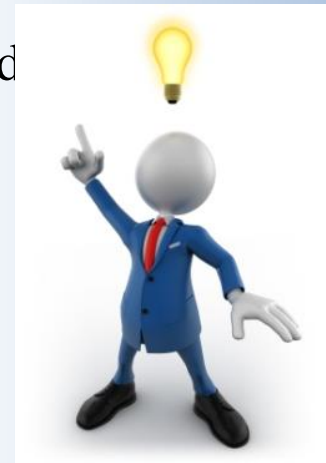
Ideas to move forward

Pros?

- \$25,000 for equipment, possibly increase this amount for a special expenditure
- Limit to 5 states per year
- Course in a box request
- Milk related State staff meetings
- University courses

Cons?

- Must be topic/program specific and not general use
- Creates competition
- Adds to MS work sched



Any other key considerations?

What's Next?

- Funding Opportunity Announcement is being developed for the next cycle
- Will be a 3-year cooperative agreement FY2025 – FY2027
- \$\$\$ unknown



Contact Information

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www.fda.gov/regulatorypartners



Dr. Califf's Public Statement

“With a human food landscape that is rapidly evolving as consumer preferences, products, and manufacturing processes grow increasingly complex and public health needs increase, the FDA must build a stronger Human Foods Program and Office of Regulatory Affairs. Earlier this year the FDA announced steps to modernize and streamline our food program, including field operations, to address these mounting challenges,” said FDA Commissioner Robert M. Califf, M.D. **“Listening closely to feedback provided by employees and stakeholders, our thinking has significantly broadened. We know that in front of us is a once-in-a-generation opportunity to unify our field work with the priorities of program offices and Centers.**

Proposed Organization Chart for Human Foods Program

Department of Health and Human Services
Food and Drug Administration
Human Foods Program

Commissioner of Food and Drugs

Office of Quality Assessment

Deputy Commissioner for Human Foods

Office of Executive Programs & Strategic Planning

Nutrition Center of Excellence*

Office of Microbiological Food Safety

Office of Food Chemical Safety, Dietary Supplements & Innovation

Office of Resource Management

Office of Risk Prioritization & Surveillance Strategy

Office of Communications, Education & Engagement

Office of Compliance & Enforcement

Office of Integrated Food Safety System Partnerships**

Office of Policy & International Engagement

Office of Laboratory Operations & Applied Science***

Office of Preparedness & Response

*Includes Office of Critical Foods

**OFSSP will work in close coordination with the Center for Veterinary Medicine

***OLAS will work in close coordination with the Office of the Chief Scientist and Center for Veterinary Medicine

June 27, 2023, Press Release

- <https://www.fda.gov/news-events/press-announcements/fda-provides-update-proposal-unified-human-foods-program-including-new-model-office-regulatory>

DMS Contacts

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- <https://www.fda.gov/food/federalstate-food-programs/milk-safety-programs-contacts-fda-personnel>

Questions