

Office of Regulatory Affairs
Office of Partnerships Update

Gerald Berg
Project Manager
OP Division of Partnership Investments and
Agreements



Eastern Milk Seminar
October 29, 2019

PRESENTATION OBJECTIVES

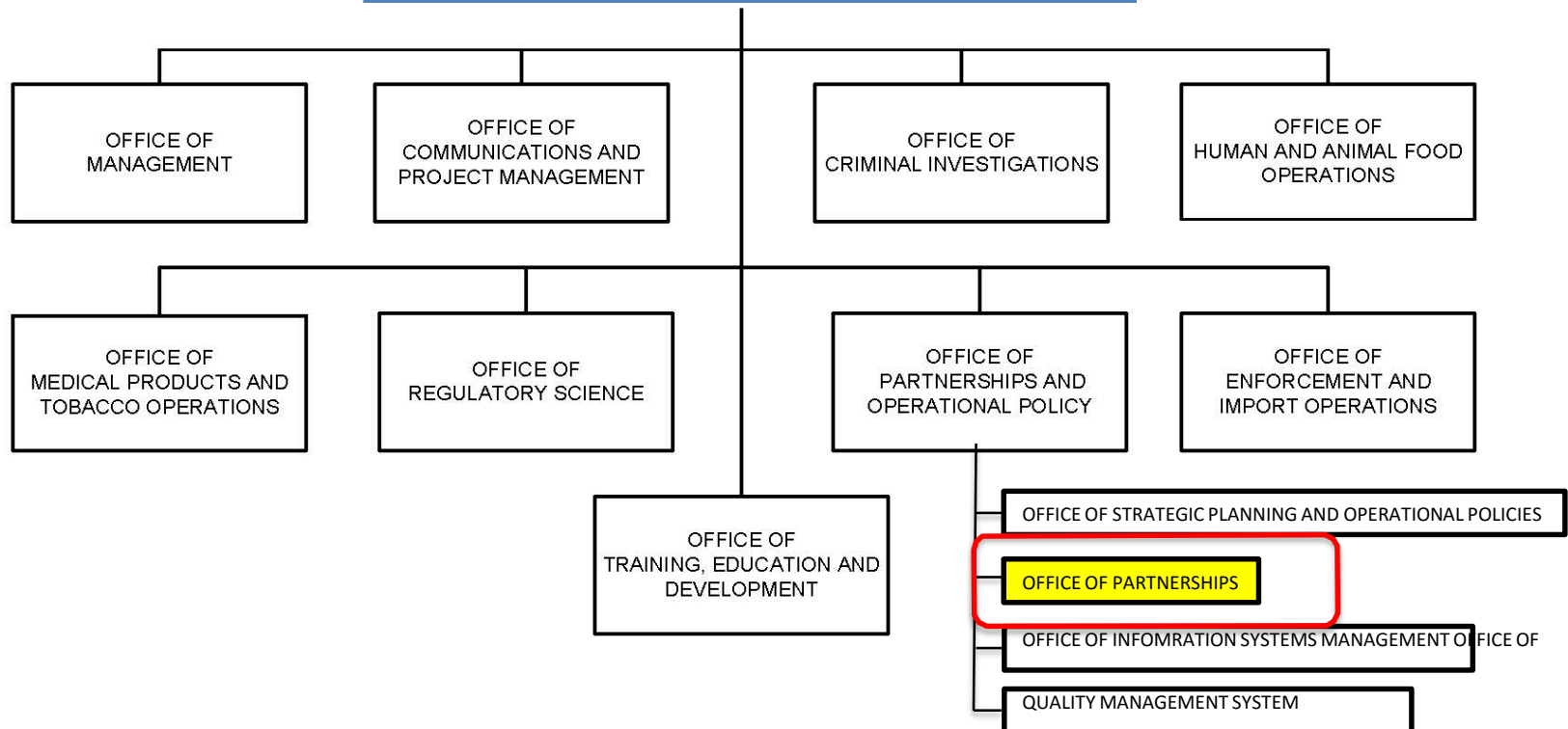
- Mission of OP
- Milk/Shellfish Cooperative Agreement



ORA Program Aligned Organizational Model



Melinda Plaisier, MSW
Associate Commissioner for
Regulatory Affairs

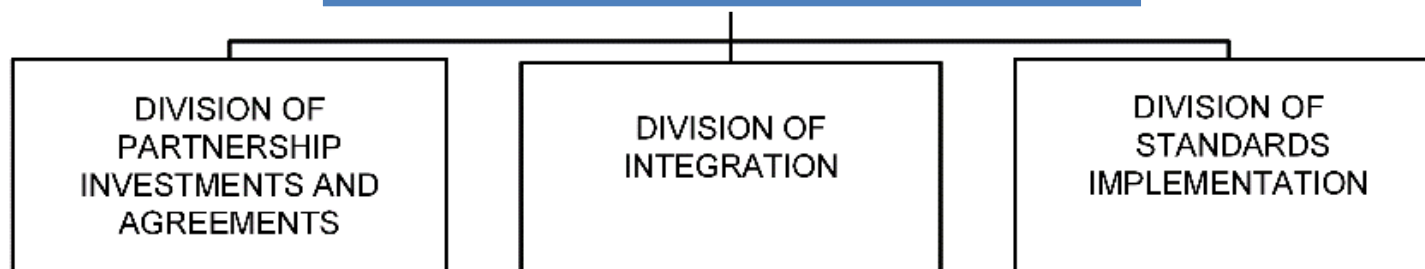


OFFICE OF PARTNERSHIPS

OFFICE OF PARTNERSHIPS AND OPERATIONAL POLICY
OFFICE OF PARTNERSHIPS



Barbara Cassens
Director , Office of Partnerships



OFFICE OF PARTNERSHIPS



Ways we accomplish our mission:

- Contracts, Grants, & Cooperative Agreements
- Federal-State Program Policy
- Coordination of State Training with ORA
- Office of Training, Education, & Development (OTED)
- Regulatory Program Standards
- Advancing National Integration
- Information Sharing
- Rapid Response Teams
- Food Protection Task Forces

OP SUPPORT FOR COOPERATIVE PROGRAMS

- Retail Food
- Shellfish Sanitation
- Grade “A” Milk
- FDA provides:
 - Guidance & Technical Assistance
 - Training & Certification
- Key players
 - OP
 - CFSAN
 - ORA Retail Food, Shellfish & Milk Specialists
 - ORA Regional Directors of State Cooperative Programs





Milk/Shellfish Cooperative Agreement

State Cooperative Program Grant in support of the Grade “A” Milk Safety Program and National Shellfish Sanitation Program, which will provided funds for state regulatory training and equipment needs in 2017/2018/2019 is being closed out.

Milk/Shellfish Cooperative Agreement

However, the NEW Cooperative Agreement went into effect September 1, 2019.

- **Covers years 2020-2024**
- **Approximately \$2.5 million per year**

Milk/Shellfish Cooperative Agreement

Priority
1

- SRO & LEO required training to maintain standardization

Priority
2

- SRO & LEO additional training

Milk/Shellfish Cooperative Agreement

- Priority
3
- Staff Training to attend FDA Courses or equivalent
- Priority
4
- Any additional state training needs



Milk/Shellfish Cooperative Agreement

2017

Milk/Shellfish Cooperative Agreement

Total \$675,000 allocated for FY2017:

- Sub-award funding allocations (Funding available for each program):
 - Grade “A” Milk (55%) \$371,250
 - Shellfish (45%) \$303,750

\$1.3 Million in applications requested

MILK

\$371,250 Total earmarked for Milk
\$300,000 earmarked for Training
\$71,250 earmarked for Equipment

\$ 846,018 Requested for Milk

SHELLFISH

\$303,750 Total earmarked for Shellfish
\$237,500 earmarked for Training
\$66,250 earmarked for Equipment

\$438,548 Requested for Shellfish

Milk/Shellfish Cooperative Agreement

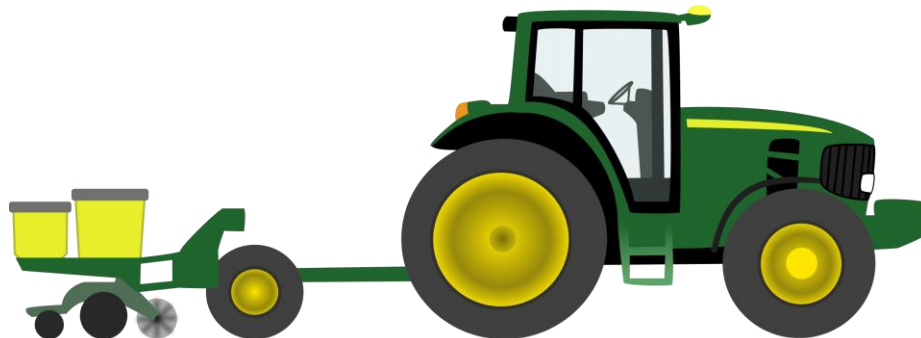
Training:

- 53 Milk Applications for Training were submitted requesting a **Total of \$727,058**
- **Total Milk Training Funded: \$367,548**
- All states were awarded funding:
 - To attend required SRO standardization training (Regional Seminars and FD577)
 - To attend required LEO standardization training (FD373)
 - To attend FD371, FD372, FD374, FD375, FD385 – these were prioritized if the states had registered candidates for the course (FD375 was at capacity)

Milk/Shellfish Cooperative Agreement

Equipment:

- 45 Milk Applications for Equipment were submitted requesting a **Total of \$118,960**
- \$71,250 earmarked for Equipment
- **Total Milk Equipment Funded: \$3702**





Milk/Shellfish Cooperative Agreement

2018

Milk/Shellfish Cooperative Agreement

-
- 50 Milk Applications for Training were submitted requesting a **Total of \$578,175**
 - **Total Milk Training Funded: \$462,009**
 - Awarded funding:
 - All Priority 1 request were funded after a few minor adjustments (Western Seminar and 2-FD577, FD373) (indirect cost were removed)
 - Primarily all of Priority 2 and Priority 3 training needs were funded
 - Priority 4 request to host a FD371 Course-in-Box was funded to provided additional training and fulfill the training needs

Milk/Shellfish Cooperative Agreement

Equipment:

- 30 Milk Applications for Equipment were submitted requesting a **Total of \$71,418**
- \$0 earmarked for Equipment
- **Total Milk Equipment Funded: \$0**



Milk/Shellfish Cooperative Agreement

HOWEVER



Milk/Shellfish Cooperative Agreement



\$194,000

From year 1 was returned



Milk/Shellfish Cooperative Agreement

\$113,770

From Milk



Milk/Shellfish Cooperative Agreement

Year 2 Equipment Requests	Amount Requested	Amount Funded
Milk	\$71,418.13	\$68,718.65
Shellfish	\$88,526.94	\$88,526.94
Total	\$159,945.07	\$157,245.59



Milk/Shellfish Cooperative Agreement

2019

Milk/Shellfish Cooperative Agreement

- **\$997,676+ to be awarded for 2019 M/S Training**
 - **\$546,523 for Milk recommended**
 - **\$820,763 for Milk requested**
- **2019 Annual Training Needs Grants (\$500 up to an average of \$2,000 per person/per course)**
 - **\$654,383 for Milk funded (67.2%)**

Milk/Shellfish Cooperative Agreement

- **Based on returned fund balance**
- **(Year 1 + 2 Carryover)**
- **Anticipated total balance: \$200,000 to \$300,000**
- **Goal: Maximize awards to State Programs**
- **State labs were also able to apply**
- **Requested: \$192,736 (Milk only)**
- **Awarded: \$190,020 (Milk only)**



Milk/Shellfish Cooperative Agreement

2020



Milk/Shellfish Cooperative Agreement

- **Year 2020: anticipate \$2.3 million to be used for training and equipment needs**
- **To be shared with the National Shellfish Sanitation Program**
- **If your state has limitations please let us know**

Milk/Shellfish Cooperative Agreement

Needs assessment:

Assess your training needs for the **ENTIRE** year:

- All required SRO & LEO training for maintenance of standardizations
- Personnel training

Assess your equipment needs:

- Equipment needed for the performance of regulatory duties
- <http://afdo.org/msgrants>

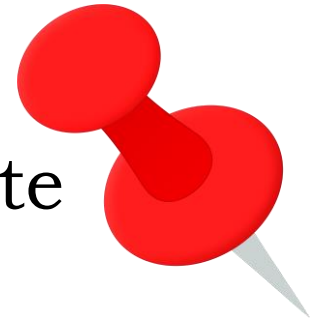


Milk/Shellfish Cooperative Agreement



Items to consider

- Work with your specialist
- Inform AFDO asap for any returns
- Indirect Costs
- Not available for NCIMS
- Reimbursement is only to the state



Milk/Shellfish Cooperative Agreement

- **Budget requesting:**

- **Prepare in advance a budget spreadsheet with expenses for airfare, hotels, meals, parking, taxis, etc....for EACH TRAVELER**
- **Maintain receipts for reimbursement from the grant.**





Milk/Shellfish Cooperative Agreement



- **Justifications:**

- **Provide a justification for each traveler or travel request**

- **Example:**

- **Travel for John Doe required as maintenance of SRO Standardization**
- **Travel for Jane Doe required as maintenance of LEO standardization**
- **Travel for Jane Doe being requested as training to advance her knowledge in the Sanitation requirements for the inspection of Dairy farms.**

Milk/Shellfish Cooperative Agreement



- **Provide a justification for each piece of equipment being requested**
 - **Example:**
 - **Sample dippers are required as part of the regulatory staff standard equipment to collect regulatory samples monthly/routinely**
 - **Lumenite/Salt test meters are an integral part of the testing and calibration of HTST systems and are required to be tested by regulatory staff every 3 months.**



Milk/Shellfish Cooperative Agreement

AFDO contact:

MSGRANTS@AFDO.ORG

<http://afdo.org/msgrants>

Feedback



- **OP welcomes your feedback on this presentation and any services provided by OP**
- **Any feedback provided to this address will be reviewed by the Director of Office of Partnerships**
- **OP.Feedback@fda.hhs.gov**



Contact Information

Belinda Clifton
FDA Office of Partnerships
(206) 713-6172 (cell)

Email:

Belinda.Clifton@fda.hhs.gov

OP Website:

www.fda.gov/regulatorypartners

