

# ORA Update

## Office of State Cooperative Programs

73<sup>rd</sup> Annual Mid-Atlantic Interstate Seafood Seminar  
and  
Gulf and South Atlantic States Shellfish Conference  
November 2023

**Michael Lombardi**  
Shellfish Sanitation Branch II  
Division of Shellfish Sanitation  
Office of State Cooperative Programs

# FDA National Shellfish Team



- CFSAN Office of Food Safety
  - Policy, priorities, SMEs, LEOs
- ORA Office of Partnerships
  - Cooperative program funding
- ORA Office of Training, Education and Development
  - Organize and facilitate training
- ORA Office of State Cooperative Programs
  - NSSP MO implementation - Field

# Proposed Unified Human Foods Program

- Proposal for re-organization into unified HFP model based on findings and recommendations from Reagan-Udall Foundation and internal review
- Transform FDA to be more efficient, nimble, and ready for the future
- Fully realize the preventive vision laid out in FSMA
- Strengthen state partnerships





# Division of Shellfish Sanitation - Staffing

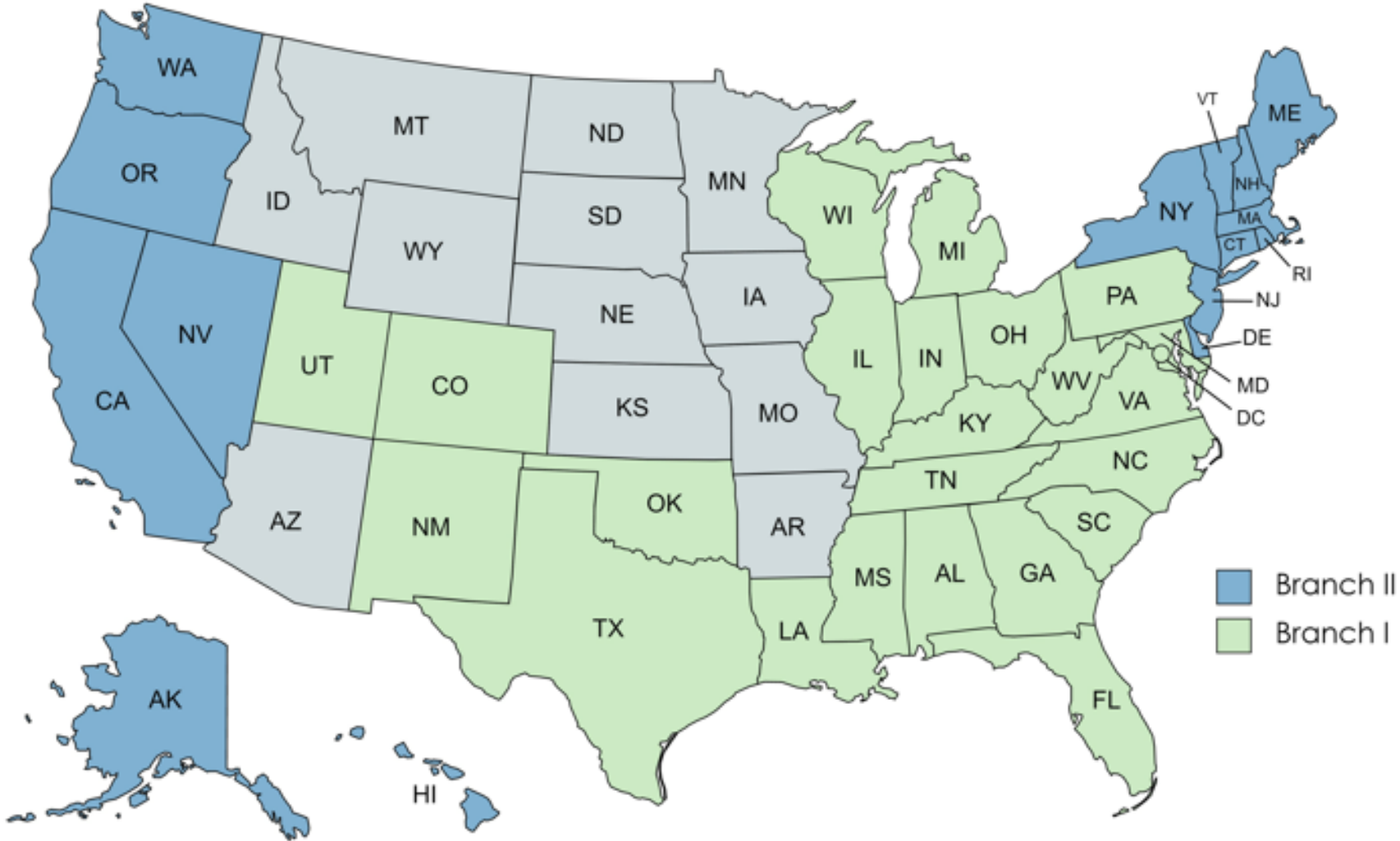
## **Branch I – Dr. Bess Ormond**

- Aaron Wozniak
- Chris Brooks
- David Wiggins
- John Veazey
- Julie Anbarchian
- Mike Pearson
- Kimberly Norgren
- Janet Talbert

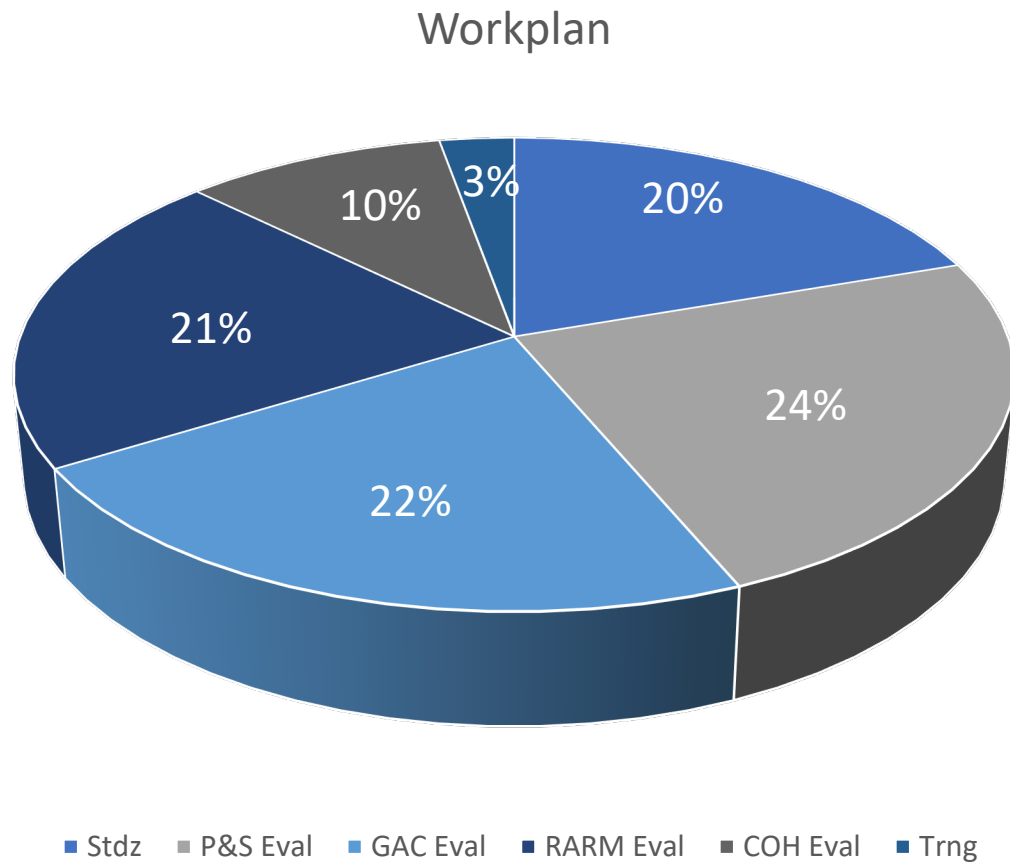
## **Branch II – Michael Lombardi**

- Amy Fitzpatrick
- David Lamoureux
- Gary Wolf
- Kristina Phelps
- Marshall Kinsey
- Tim Deatruck
- Yan Sun
- **Jacquelyn Seddon\***

# Branch Coverage of NSSP

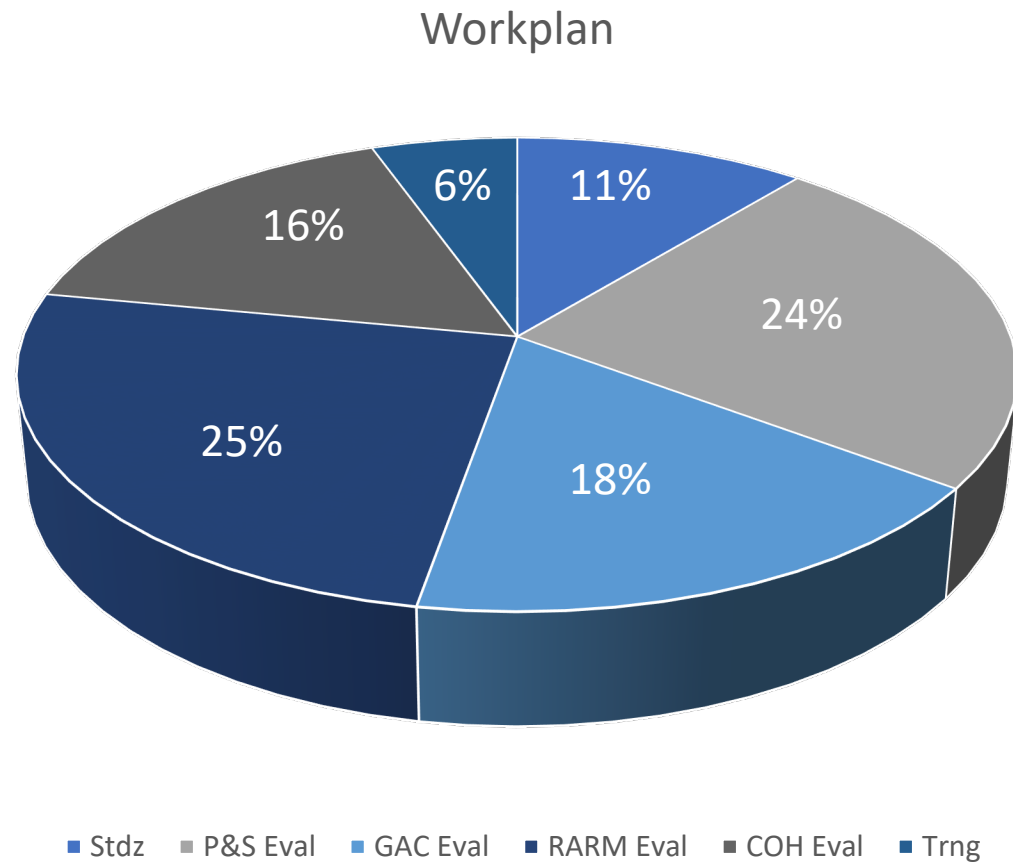


# FY2023 Workplan Accomplished



- 14 SSO standardization officer (SSO) audit certifications
- 17 plant processing and shipping program element evaluations
- 16 growing area component program element evaluations
- 15 risk assessment and risk management element evaluations
- 7 control of harvest program element evaluations
- 2 national training courses

# FY2024 Workplan Projection

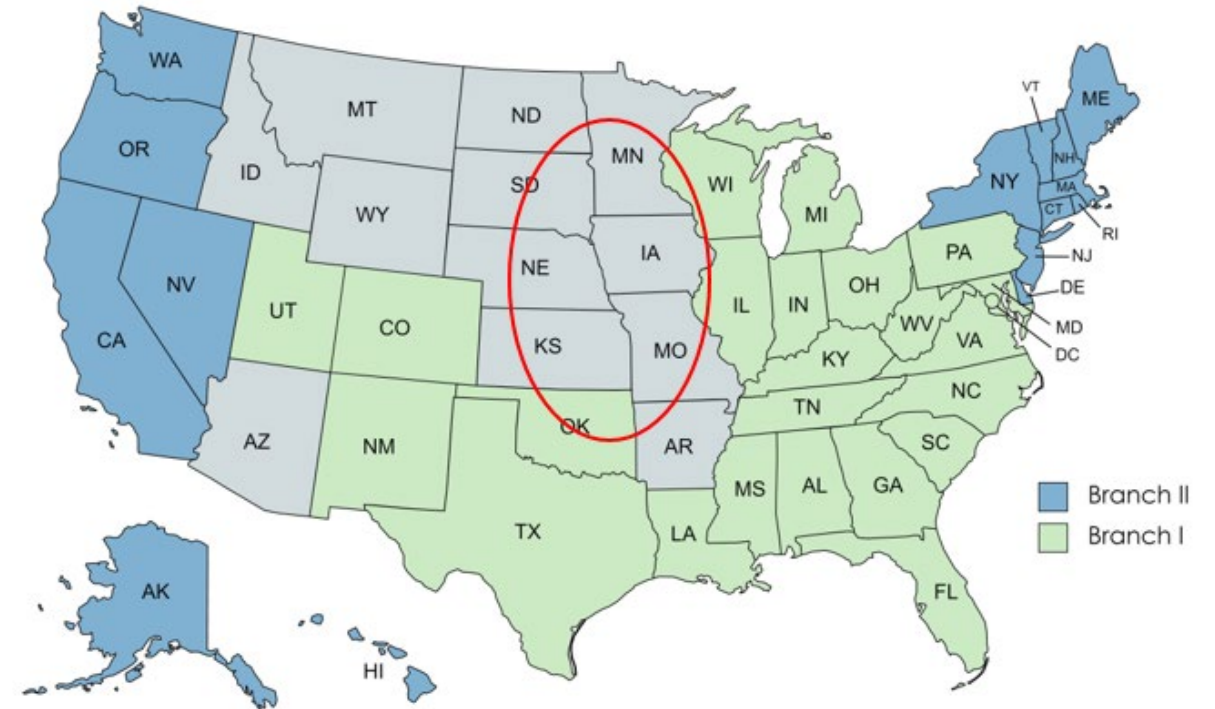


- 10 SSO standardization officer (SSO) audit certifications
- 22 plant processing and shipping program element evaluations
- 16 growing area component program element evaluations
- 23 risk assessment and risk management element evaluations
- 15 control of harvest program element evaluations
- 5 national training courses



# Outreach: Non-Participating States

- Met with IA, KS, MN, MO, NE
- Overview of NSSP
- Importance of membership
- Identify challenges by program
- Develop tools to assist adoption
- Efforts ongoing





# Outreach: Retail Food Seminars

- Started in Ashville, NC
- Overview of NSSP
- Illness investigation refresher
- Review of tagging and label requirements
- Strengthen program at retail
- Efforts ongoing



# Shellfish Illness Outbreak Investigation SOP



- New SOP outlining internal FDA procedures for illness response
- Roles, info sharing, investigations, advisories, after action reviews
- Developing shared tools
- Common expectations
- Efficient and effective response
- Consistency and transparency

# Training and Technical Assistance Requests

- Monitor, track and report
- Ensures timely routing and completion of state requests
- Training and specialized courses
- Combined with GARB/VARB
- Technical assistance (MO, PEER)
- 2023 – 11 states
- PEER, email, or just call!





# New Training Course Offerings

## **FD245W-200: Wet Storage and Depuration**

- Identified as a training need
- Interactive and comprehensive
- 16 lessons
- Online asynchronous course
- Used in conjunction with FD245
- Module to be added to FD245

## **FD248: Shellfish Risk Assessment and Risk Management**

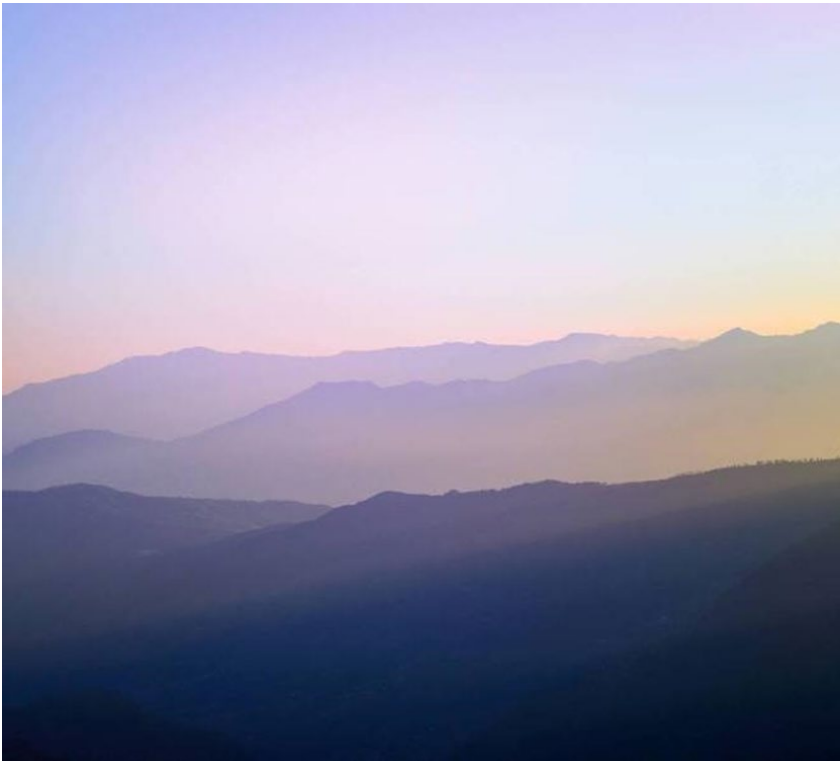
- Priority need based on gaps
- Covers requirements of MO Ch II
- Illness investigation and response
- Notification through closure
- First offering June 3 – 7, 2024
- In-person ILT or virtual ILT – TBD



# Thank You



# *Milk Shellfish Cooperative Agreement*



- **Purpose - Training and Equipment**
- **Award duration (2020-2024)**
- **Projected award amount: \$3 million per year**
- **2024 Grant Guidance is posted at:**  
<http://afdo.org/msgiants>
- **Training portal deadline: Nov. 10, 2023**



# *CY 2023 Training Awards*

## **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 Portal Openings:
  - FD242: \$41,645
  - ISSC: \$92,150

**Total: \$645,117**



# *CY 2023 Equipment Funding*

## **Equipment:**

- **Currently have  
~\$1,414,293 being  
requested in  
combined programs**

## **Currently funded CY23:**

- **~\$393,342**



# NOW

<b>2023-2024 MS CA Budget</b>	
<b>Current Balance Estimate=</b>	<b>\$ 1,631,000.00</b>
<b>2024 NOA=</b>	<b>\$ 2,400,000.00</b>
<b>Subtotal=</b>	<b>\$ 4,031,000.00</b>
<b>AFDO Costs=</b>	<b>\$ 450,000.00</b>
<b>Total Funds Available=</b>	<b>\$ 3,581,000.00</b>
<b>Hold for 2024 Training=</b>	<b>\$ 3,000,000.00</b>
<b>Amount Available for 2023 Equipment=</b>	<b>\$ 581,000.00</b>
<b>Amount Awarded for Milk 2023 Equipment=</b>	<b>\$ 239,119.15</b>
<b>Amount Awarded for Shellfish 2023 Equipment=</b>	<b>\$ 157,548.97</b>
	<b>\$ 396,668.12</b>
<b>Remaining Funds available=</b>	<b>\$ 3,184,331.88</b>
<b>Amount Awarded for 2024 Training=</b>	
<b>Amount Awarded for Second 2023 Equipment=</b>	
<b>Amount Available for 2024 Equipment=</b>	



# ***2024 Training Awards Schedule\****

- **Portal Dates: October 2 – November 10**
- **AFDO review: November 13 – 17**
- **FDA review: November 20 – December 1**
- **JAG review: December 7 at 2:00 pm**
- **Award notices issue: December 8, 2023**
- **Project period: January 1 – December 31, 2024**

# *What's Next?*

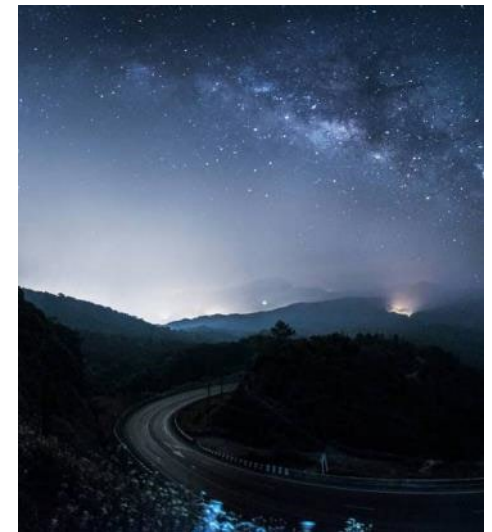
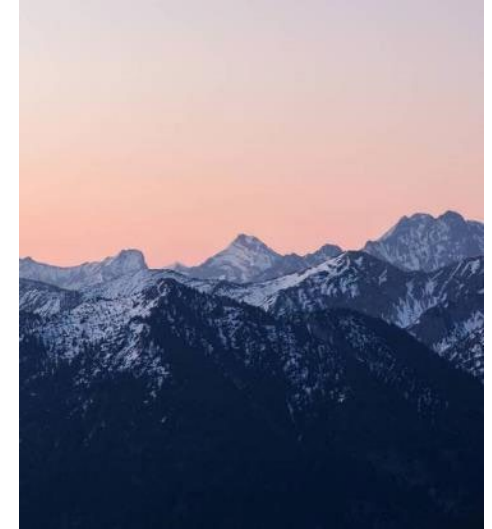
- **Funding Opportunity Announcement for next cycle**
- **Three-year cooperative agreement  
(CY2025 – CY2027)**
- **\$\$\$ unknown**



# ***STANDARDS***

## ***VNSRPS***

- ❖ Plant and Shipping***
- ❖ Growing Area***
- ❖ Control of Harvest***
- ❖ Others***



# QUESTIONS

