

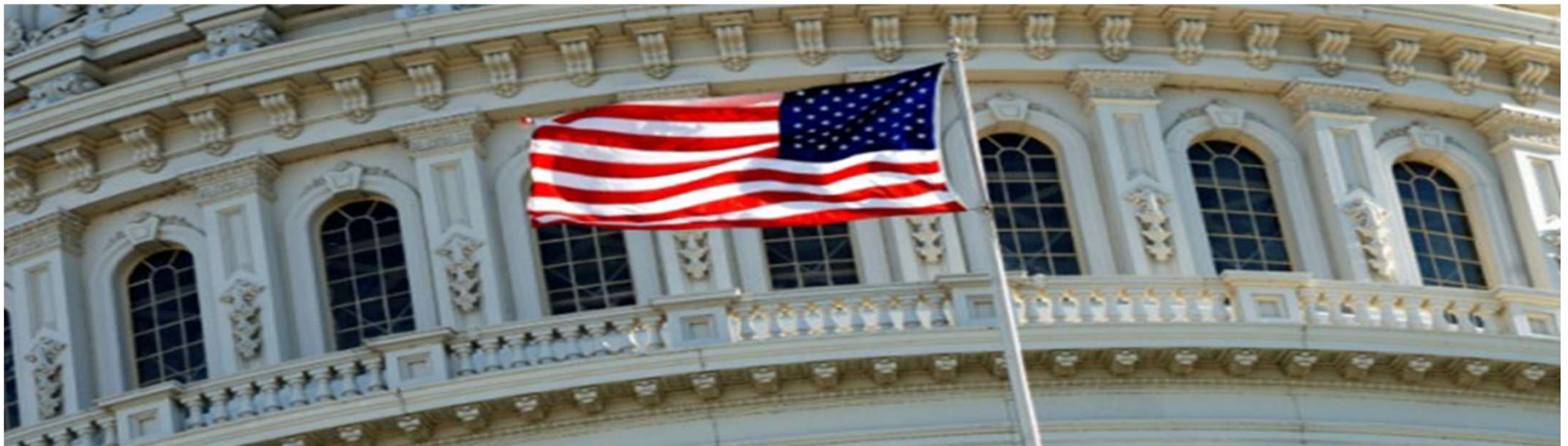
# ***FDA Office of Partnerships and Division of Standards Implementation***

## ***Updates***

### ***AFDOSS***

***Gatlinburg, TN***

***September 9, 2024***



# Speakers

- Guy Delius, MFRPS Specialist, Division of Standards Implementation (DSI)



# Objectives

- Office of Partnerships 2024
  - FDA Foods Program Reorganization
  - OP Support and Funding Initiatives
- Updates from DSI
  - DSI 2024 Outreach
  - Staffing/Management Status
  - Planning for the 2025/2026 MFRPS
  - MFRPS Funding and Reporting



# OP's Vision and Mission

## **Vision Statement:**

“A global partnership that protects the public health.”



## **Mission Statement:**

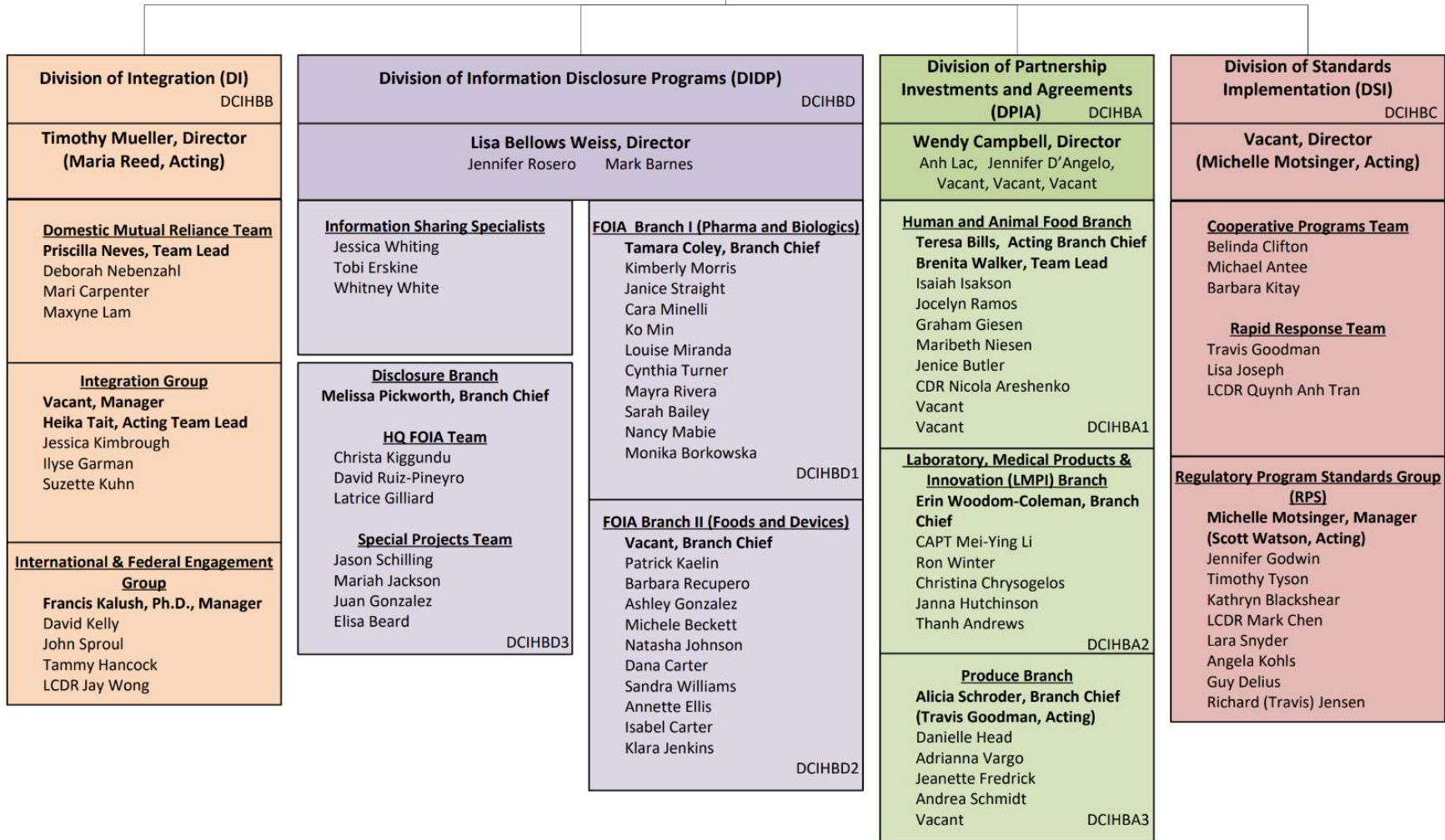
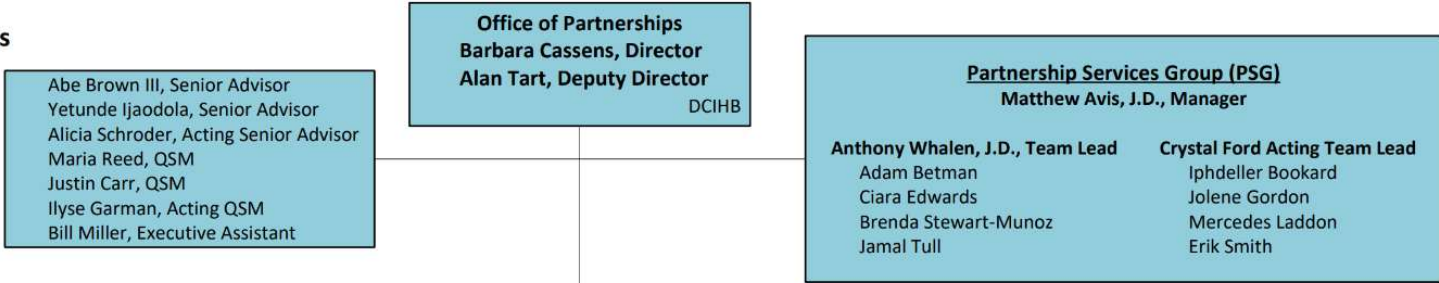
“We make partnerships happen through fostering funding opportunities and promoting domestic and international mutual reliance and systems recognition.”

# Staffing Updates – OP Org Chart



**Office of Partnerships**  
 Organization Chart  
 March 2024

FTE Ceiling: 116

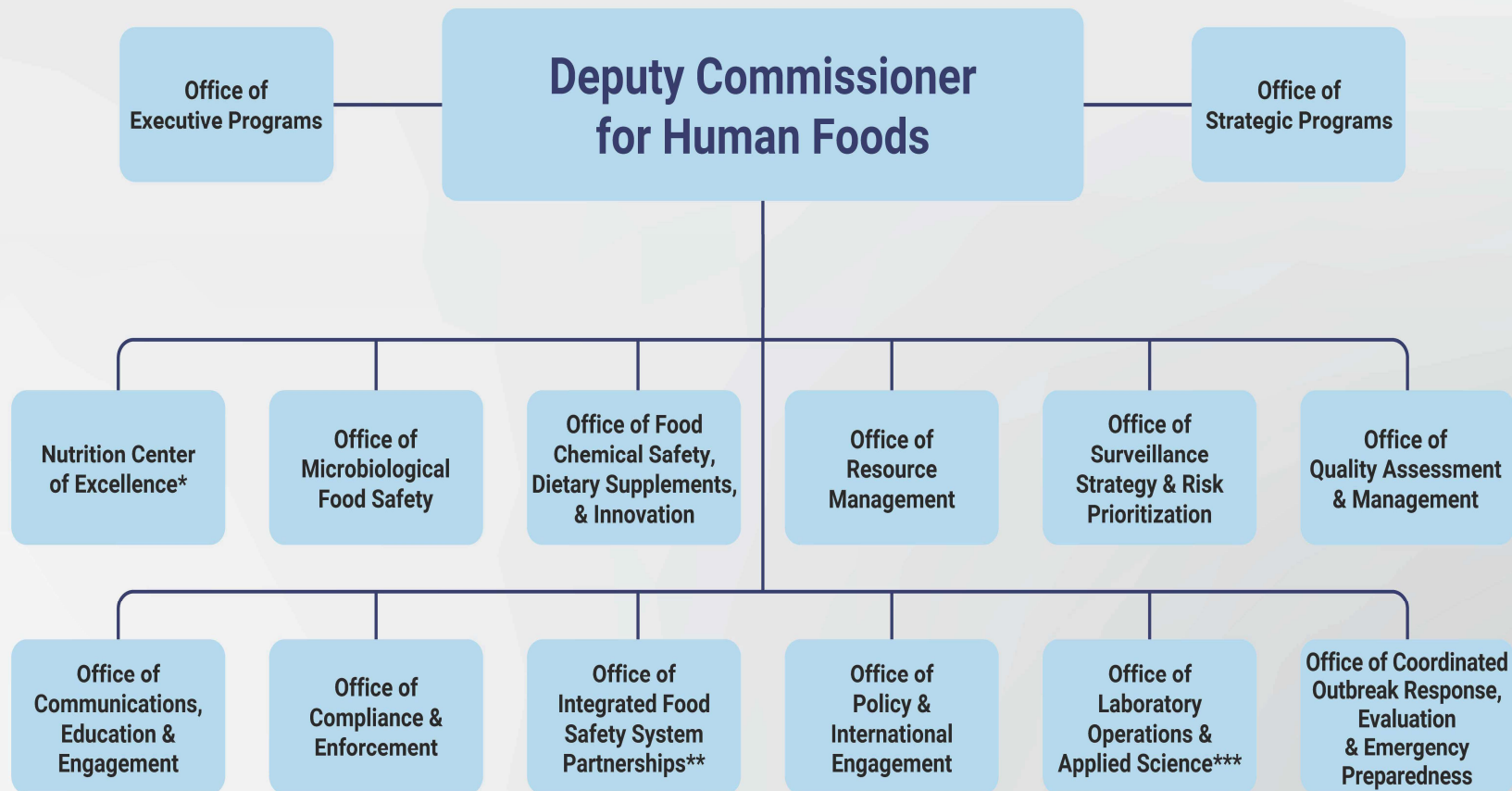


# Approved FDA Organization Chart - Human Foods Program<sup>†</sup>

Implementation planned for Oct. 1, 2024<sup>†</sup>

**Legend:**  
 Directly impacted by reorganization (i.e., shifts of functions, resources and/or personnel)

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



<sup>†</sup>The elements of the reorganization are the same as those proposed in December 2023.

<sup>†</sup>The changes reflected here will be implemented when all required reorganization steps have been met.

\*Includes Office of Critical Foods

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

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



# Approved FDA Organization Chart - Associate Commissioner for Inspections and Investigations\*

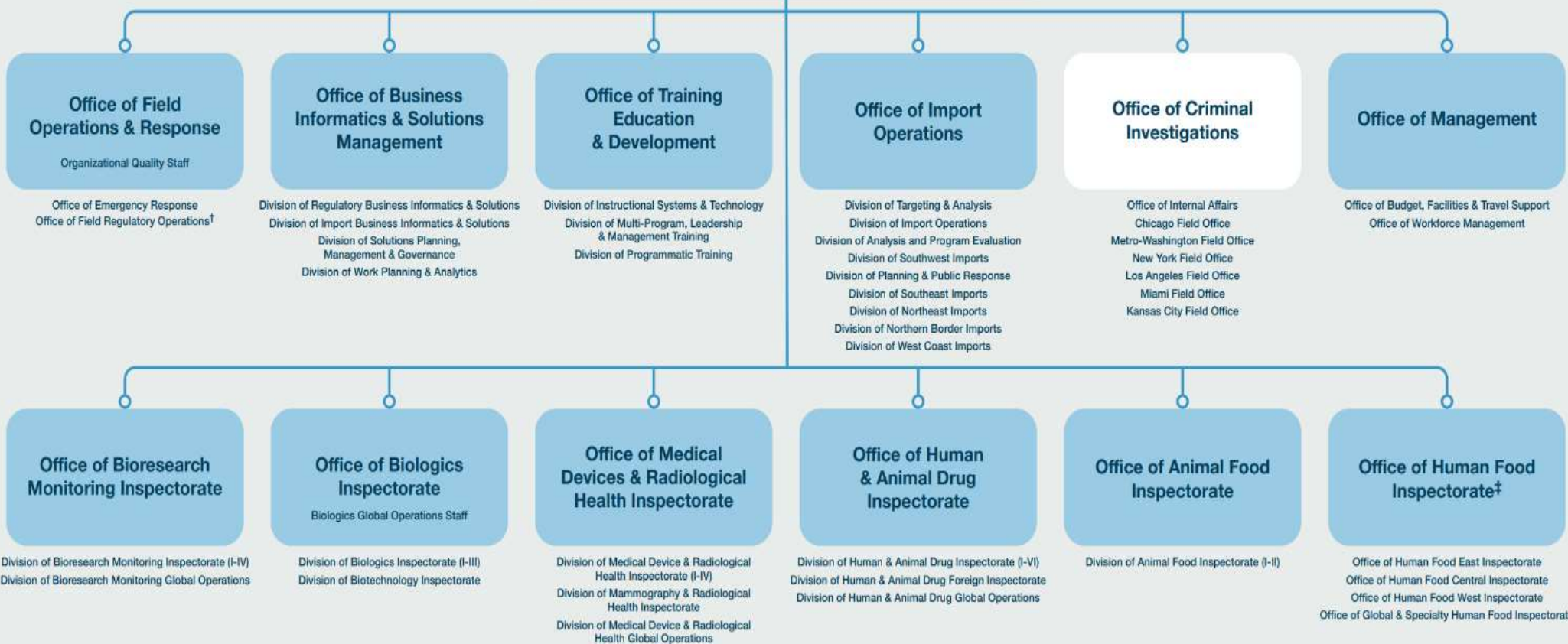
Implementation planned for Oct. 1, 2024\*\*

Legend:

Directly impacted by reorganization (i.e., shifts of functions, resources and/or personnel)

Department of Health And Human Services  
Food and Drug Administration  
Office of Inspections and Investigations

## Associate Commissioner for Inspections and Investigations



\*The elements of the reorganization are the same as those proposed in December 2023.  
\*\*The changes reflected here will be implemented when all required reorganization steps have been met.

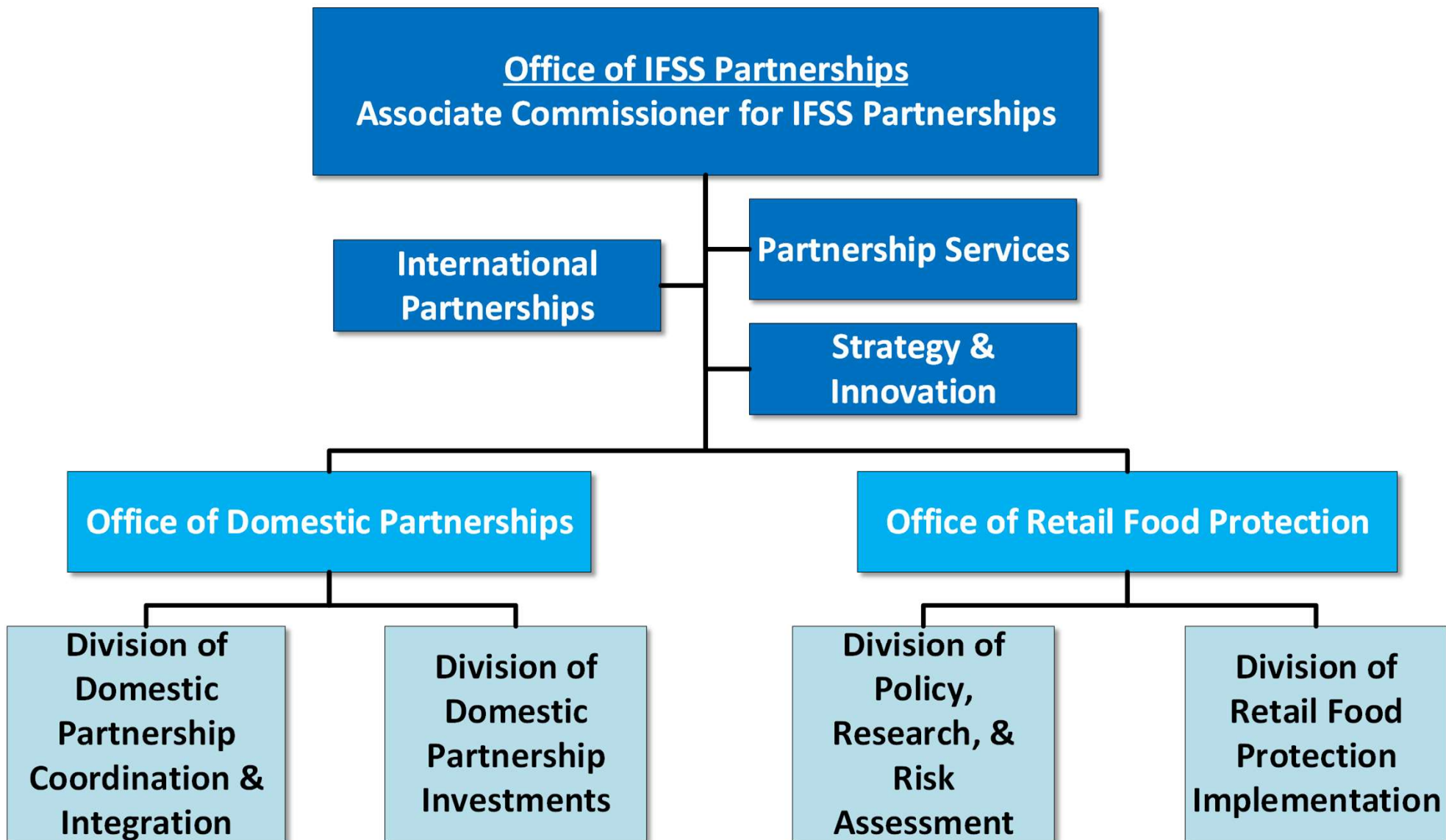
†Includes Division of Tobacco Inspectorate  
‡Includes specialized teams for products such as infant formula

# Human Foods Program (HFP) Office of Domestic Partnerships (ODP) Overview

Informational Update



# HFP OIFSSP - Organization Structure



# What Functions Are Staying?

**Support for HAF-related Domestic Inspections & Sample Collections via Contracts & Cooperative Agreements (CAs)**

**Oversight of all IFSS-related grants/CAPs to SLTT/association partners**

**Enhancement of SLTT laboratory capacity & capabilities**

**Oversight of IFSS-related domestic partner formal agreements (including tribes)**

**Administration/oversight/technical support for non-retail Regulatory Program Standards (MFRPS, AFRPS, ERPS, PRPS)**

**Oversight/technical support for Domestic Mutual Reliance (DMR)**

**(Gaining org in parentheses)**

# What Functions Are Leaving the Current OP?

Oversight & Issuance of  
FDA Commissions to  
SLTT officials (to  
OIFSSP/Partnership  
Services Staff - PSS)

Oversight of medical  
products-related  
contracts (CDRH)

Information disclosure  
programs/FOIA/20.88s/  
20.85s (OC/OO/OEMS)

International  
engagement [OIFSSP IO  
(HAF) & OII (Medical  
Products)]

Medical products  
partner formal  
agreement oversight  
(OII)

Coordination of certain  
OTED HAF training for  
SLTT partners (OIFSSP  
PSS)

SLTT data  
analysis/dashboard  
creation (OIFSSP PSS)

(Gaining org in parentheses)



# **Supporting our Mission Through Federal Agency Partnerships**

**Centers for Disease Control**

**National Institutes of Standards and Technology**

**U.S. Department of Defense**

**U.S. Occupational Safety and Health Administration**

**U.S. Postal Service**

# **DIVISION OF DOMESTIC PARTNERSHIP INVESTMENTS (DDPI)**

# Funding Approach

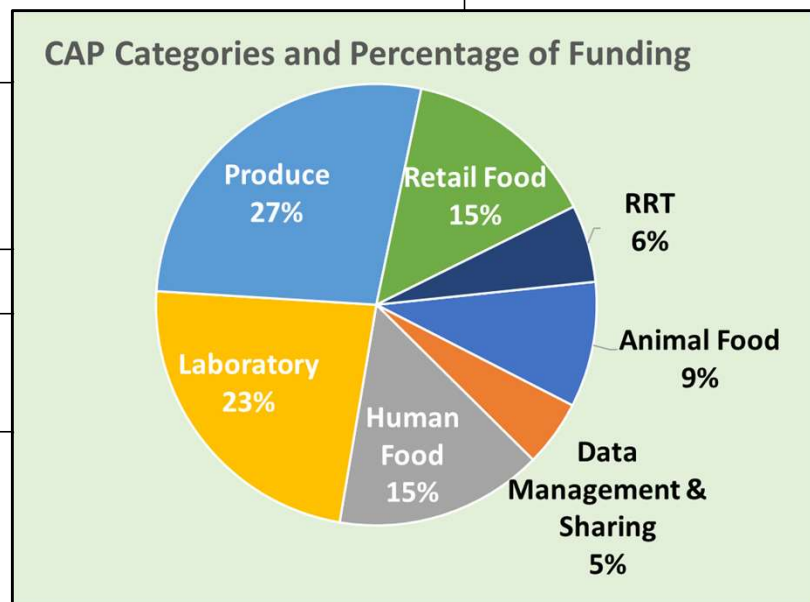
**Holistic funding portfolio**  
**Collaboration with association partners**  
**Program & funding flexibility customized to partner needs**  
**Minimize administrative burden through flexible funding models & automation technology**  
**Funding prioritization**  
**Demonstrating ROI/ROV & monitoring program performance through data visualization**



# ORA's FY23 Federal-State Initiative CAPs

12 major CAPs can be grouped into 7 buckets:

Category	Value	Includes
Produce	\$27M	State Produce Implementation and Produce Association
Laboratory	\$23.1M	Laboratory Flexible Funding Model (Lab FFM) and Lab Association
Human Food (excluding retail)	\$15.1M	Manufactured Food Regulatory Program Standards (MFRPS), Food Protection Task Forces, Grade A Dairy, Shellfish, Egg Standards, and Integrated Food Safety System Alliance
Retail Food	\$14.2M	Retail Flexible Funding Model and Retail Collaborative
Animal Food	\$9.1M	Animal Food Regulatory Program Standards (AFRPS) and Feed Standards Coordination
RRT	\$5.6M	Rapid Response Teams (RRT)
Data Management & Sharing	\$4.8M	SAFHER, FoodSHIELD, and Scientific Conference Grant



# Milk-Shellfish Subawards – FY 23

Current sub-awards in FY24:

- Milk
  - \*Training – 50 grants \$1,634,48
  - \*Equipment – 35 grants \$559,081
- Shellfish
  - \*Training – 30 grants \$717,605
  - \*Equipment – 26 grants \$489,089
- 2024 - CFSAN-35 grants \$21, 256 MDRS



## Objectives of the RFFM Grants

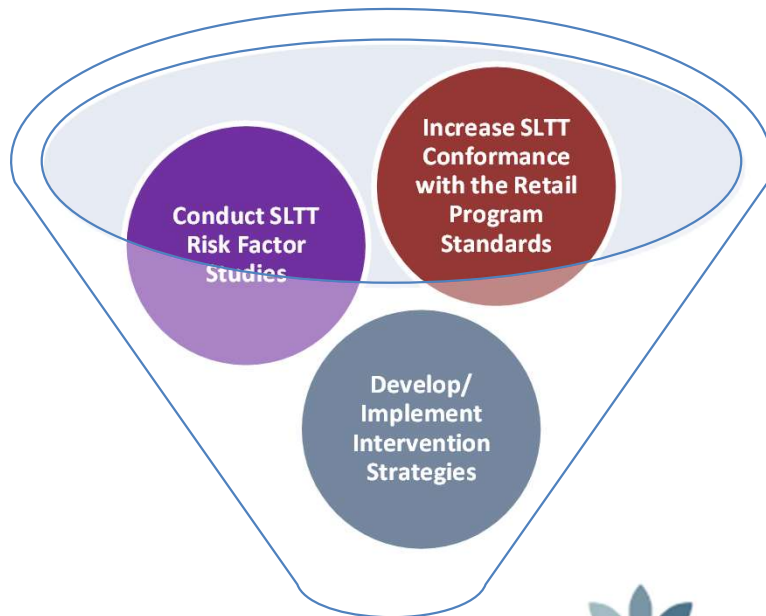
- Reduce Foodborne Illness Risk Factors
- Move toward full conformance with the Retail Program Standards
- Fully leverage our State, Local, Tribal, and Territorial Partners

## Advancing Retail Food Protection

- Largest FDA Retail Food Protection Investment in History
- RFFM has defined metrics to measure advancement of retail food protection

Access to the grant portal and additional information can be found at [neha.org/retailgrants](https://neha.org/retailgrants)

# Retail Food Flexible Funding Model (RFFM)



**GOAL: Reduction in the Occurrence of Foodborne Illness Risk Factors**



**\$34M awarded over 3 years (2021 thru 2024)**

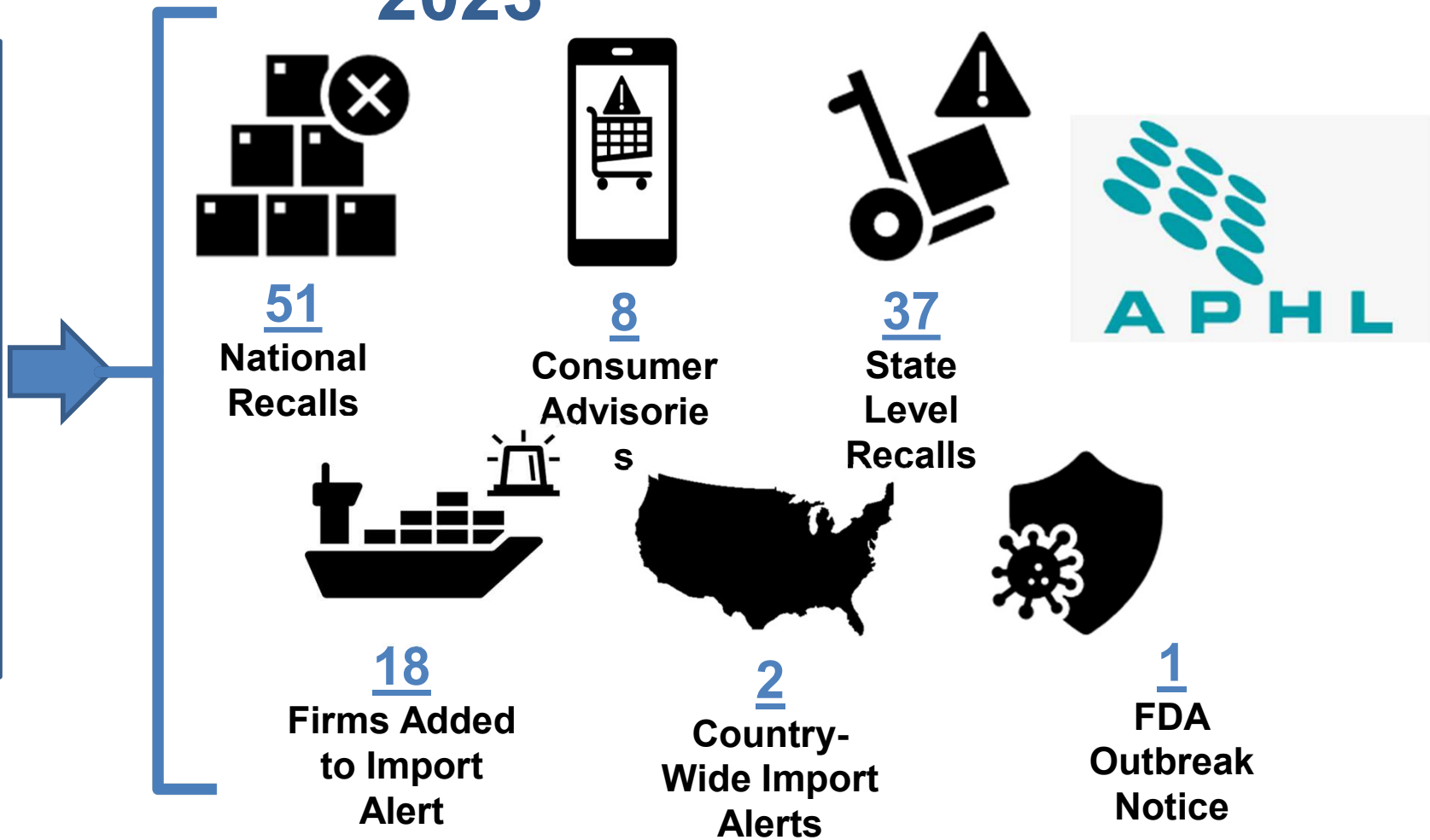
## Applications/Awards Across the RFFM

Year	Applications	Awards
2022	486	446
2023	502*	397*
2024	619	530*

\*68 awards from 2022 were for three years. They are not included in this total for 2023 or 2024. They did not need to reapply in following years.

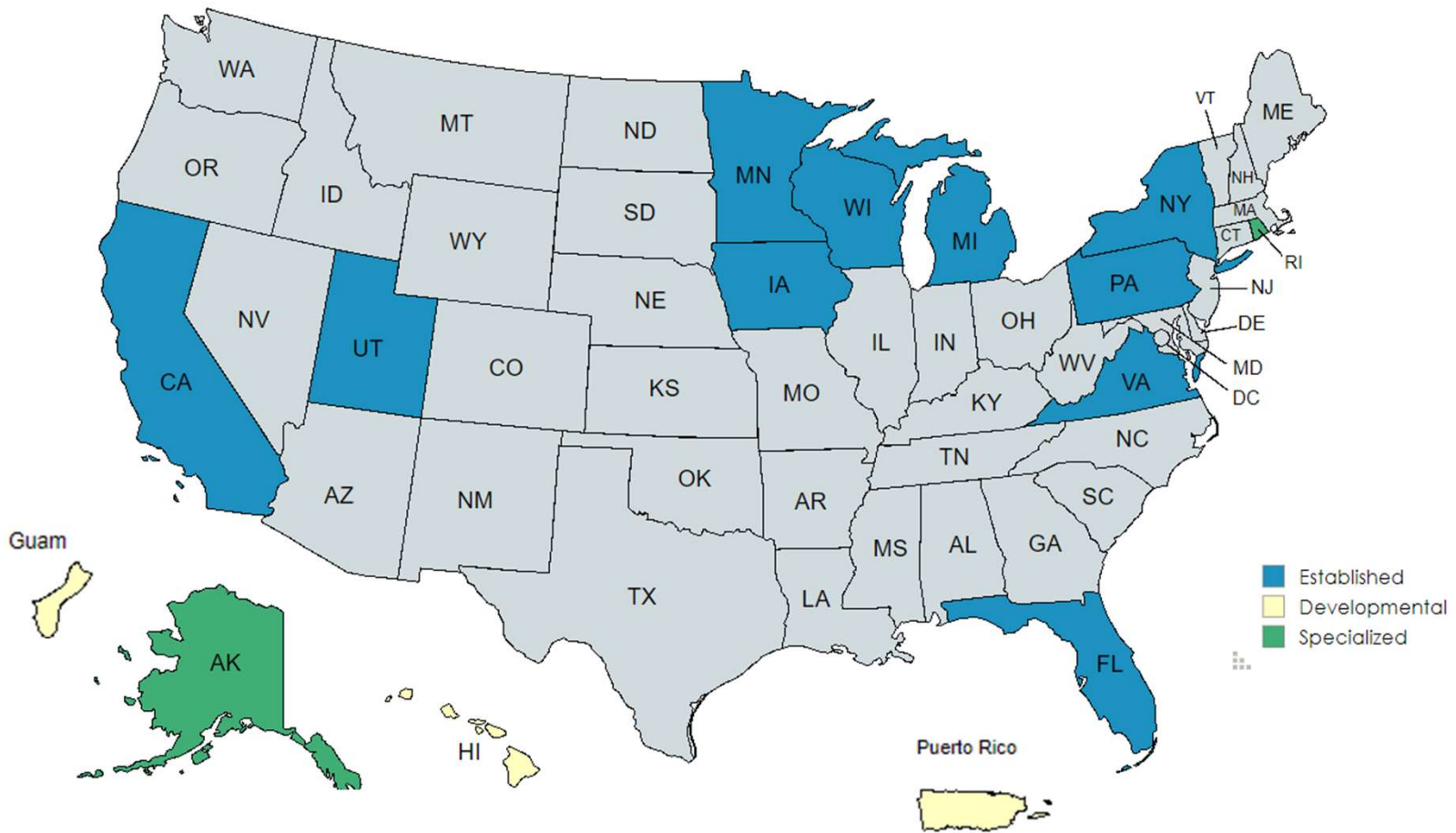
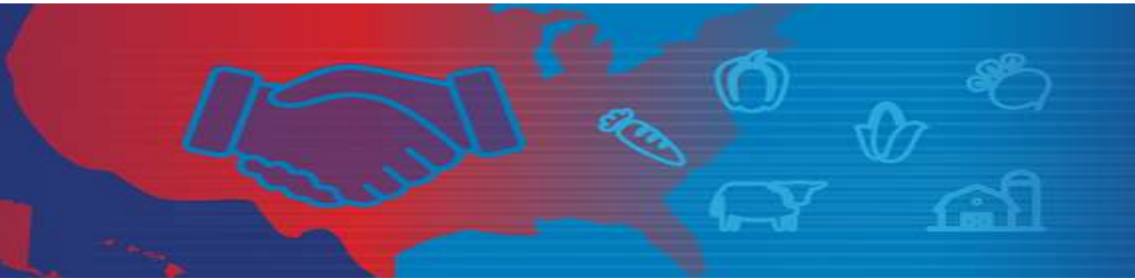
# Lab FFM Regulatory Actions 2020 - 2023

  
**57,642 Human & Animal Food Samples Analyzed**  
**15,280 Food/Environmental**





# Domestic Mutual Reliance





# **DIVISION OF DOMESTIC PARTNERSHIP COORDINATION & INTEGRATION (DDPCI)**

# DDPCI - Moving into the Future

- DSI name is changing to Division of Domestic Partnership Coordination and Integration (DDPCI)
- DSI is growing to incorporate parts of the Division of Integration (DMR-Partnership Agreement staff)
- Our MFRPS meetings will soon include aspects of DMR/Partnership Agreement touch Points.
- Your contacts (MFRPS, AFRPS, EGG) should largely remain unchanged



# DSI Updates

- Michelle Motsinger named DSI Director!
  - Details for the vacant DSI MFRPS Manager
  - 25 states visited and/or MFRPS meetings held
  - 23 states visited and/or AFRPS meetings held
  - Quarterly Regional Coordinator calls
  - Educational webinars provided
  - MFRP Alliance (Little Rock) planned and successfully held



# DSI Updates Continued

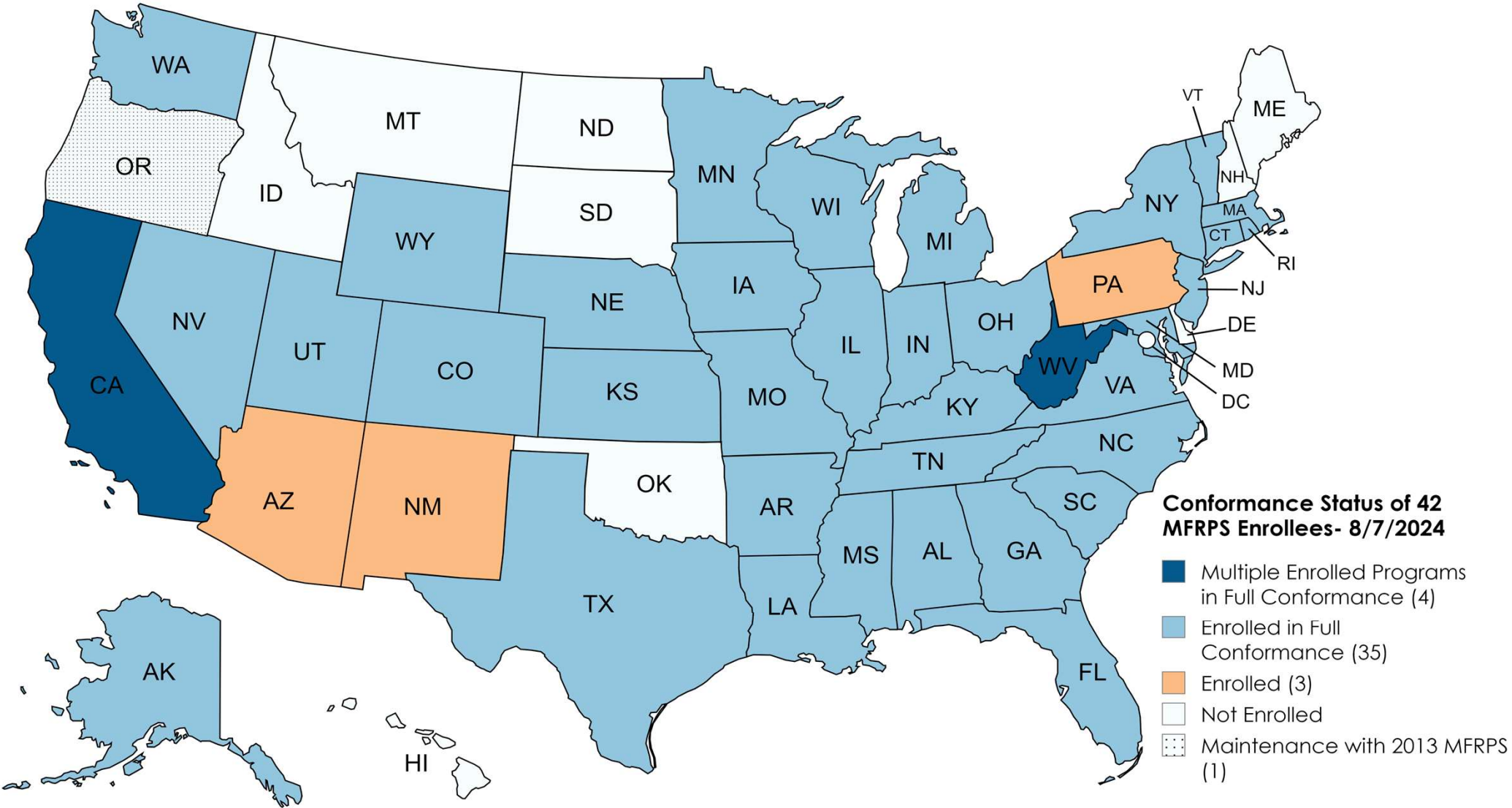


# MFRPS 2022-2025



- Standards remain successful and strong foundation for IFSS
- 42 Programs enrolled and 39 in Conformance
- Enrolled state programs having similar systems now
- Next steps underway to leverage states success with Standards.

# MFRPS 2024



# MFRPS 2025

- Recommended and approved changes are being drafted into the 2025 standards.
- Formatting, 508 compliance and OMB process on the way.
- A “Summary of Changes” document will be on the way to highlight all changes.
- The 2025 MFRPS standards will Roll out in Oct. 2025.





# MFRPS Reporting Dates 2024-2025

- September 30, 2024: SF 424 (Federal Financial Report) due for 2023-2024 Budget Period
- October 30, 2024: For states with a No Cost Extension for 2022-2023 only: end of project report (Final RPPR)
- January 30, 2025: Mid Year Reports
- January 30, 2025: Mid Year SF 424 new requirement
- End of Year Reports: May 1, 2025 (RPPR)

# MFRPS FFM CAP Awards

- Year 2 awards provided in August 2024
- Awards are limited to the “current” award ceilings - \$150K, \$225K, and \$300K
- Reduction of Dietary Supplement (DS) track to max of \$50K for states performing DS contract inspections
- Fund Food Protection Task Forces (FPTF)- \$15k
- Very limited, if any, special projects



# FFM Contact Information

## Office of Partnerships (OP)

Jocelyn Ramos, Project Manager

*Alaska, Arkansas, Arizona, California (H), California (A), Colorado, Iowa, Illinois, Kansas, Louisiana, Minnesota, Missouri, Mississippi, Nebraska, New Mexico, Nevada, Oklahoma, Texas, Utah, Washington, Wisconsin, Wyoming*

[Jocelyn.Ramos@fda.hhs.gov](mailto:Jocelyn.Ramos@fda.hhs.gov)

(510) 337-6894

Nicola Areshenko, Project Manager

*Alabama, Connecticut, Florida, Georgia, Indiana, Kentucky, Massachusetts, Maryland, Michigan, North Carolina, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, South Carolina (H), South Carolina (A), Tennessee, Virginia, Vermont, West Virginia (H), West Virginia (A)*

[Nicola.Areshenko@fda.hhs.gov](mailto:Nicola.Areshenko@fda.hhs.gov)

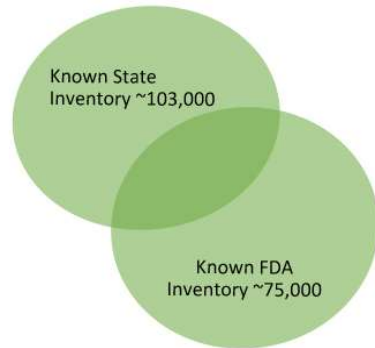
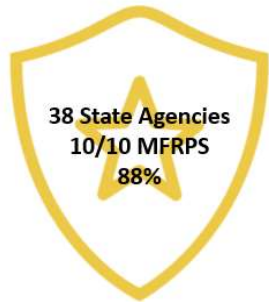
(253) 259-6915

## Office of Acquisitions & Grants Services (OAGS)

Terrin Brown, Grant Management  
Specialist

[Terrin.Brown@fda.hhs.gov](mailto:Terrin.Brown@fda.hhs.gov)

# State's Capacity and Capability at a Glance



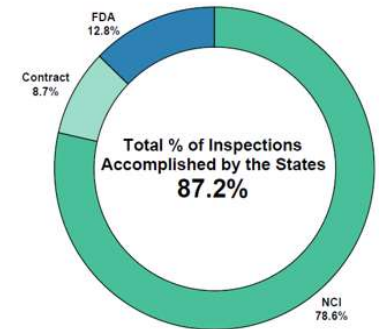
State Non-Contract Inspections: **53,950**

State Contract Inspections FY23: **5,959**

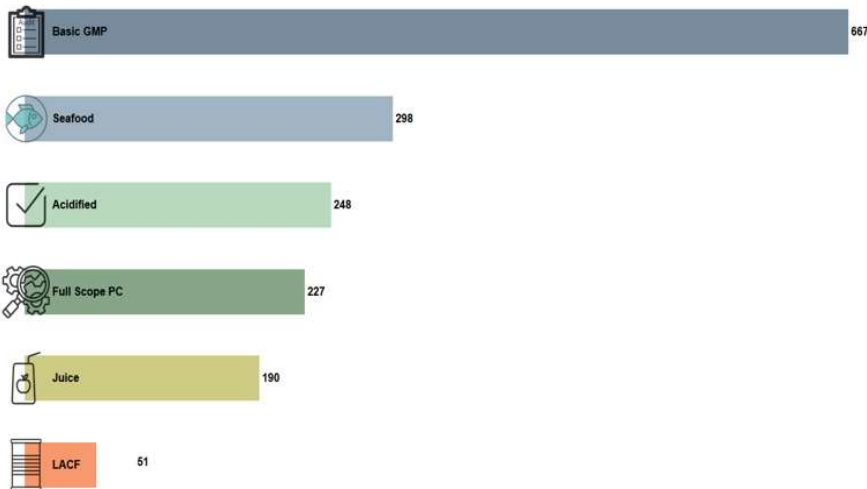
FDA Inspections FY 23: **8,755**

Total Manufactured Food

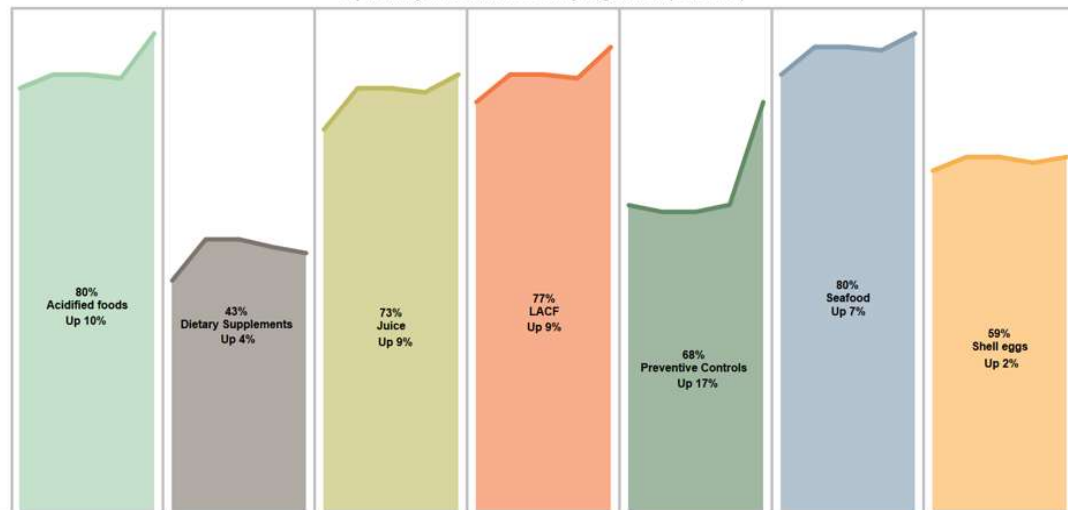
Inspections by FDA and State: **68,664**



Fully Trained Staff Across the Nation



Equivalency to Federal Food Safety Regulations (2018-2023)



# Integrated Manufactured Food Project (IMFP)

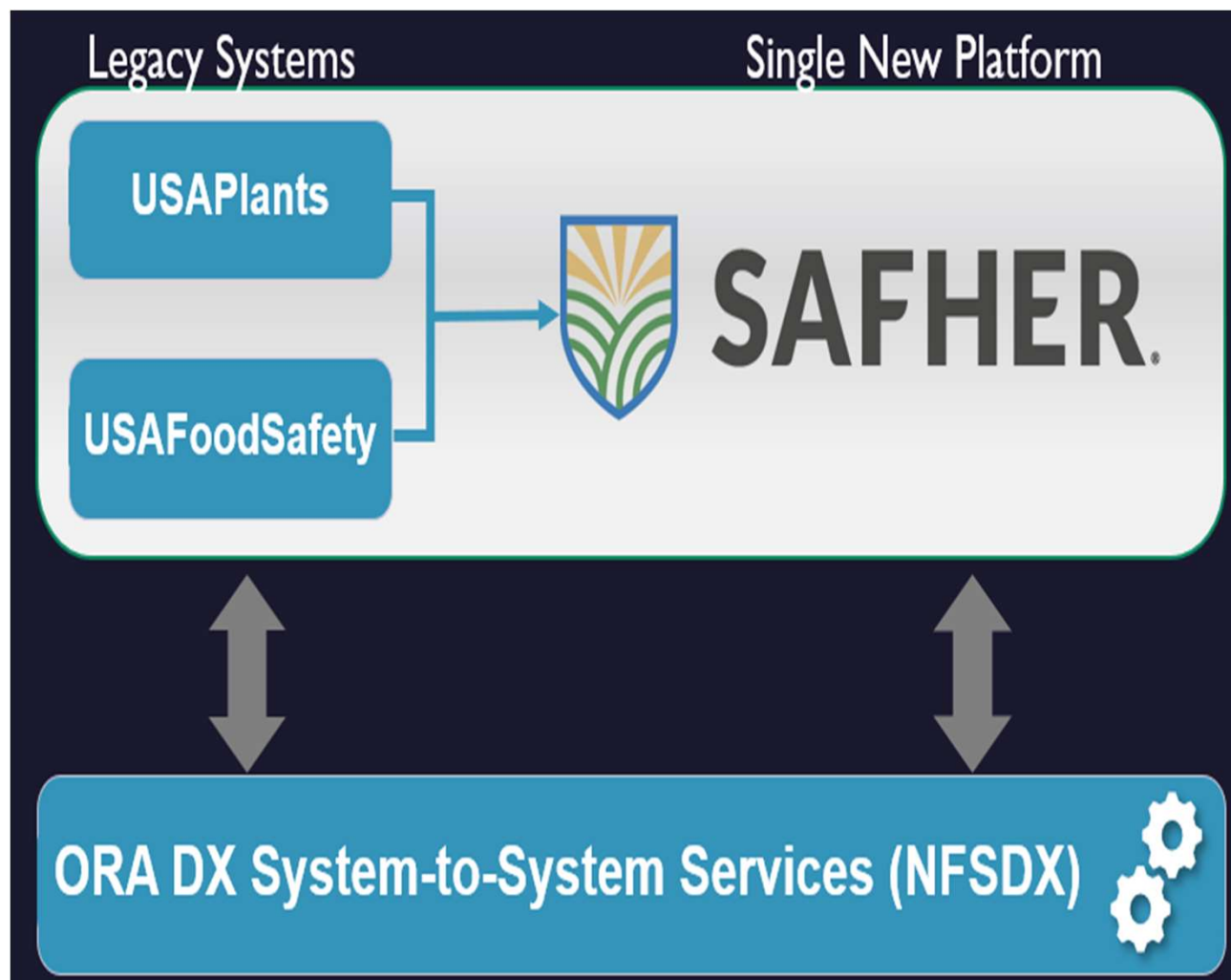


# Integrated Manufactured Food Project (IMFP)



- Dedicated cross sectional research and development team stood up
- Streamline FDA and State programs into one consolidated cooperative agreement to possibly include HAF contracts, MFRPS, FPTF, NCI and other projects
- Reduce administrative burden to States and FDA
- Move closer to one agency workforce model
- Initial Pilot of 5 states
- Timeline: NOFO posted 2025; Roll out in 2026
- Secure state feedback
- Update and roll out to larger group in 2029

- Comprehensive regulatory data management system
  - Firm inventory
  - Inspections
  - Lab data
  - Enforcement and compliance
  - Complaints
  - Supports conformance with the MFRPS and AFRPS
  
- SAFHER and ORA DX System-to-System integration planned



What are we  
hearing so far?

Strong engagement  
Optimism and curiosity  
Respect for each other  
Better collaboration  
Easy data exchange is key  
Improved efficiency  
May require more work  
Many challenges and questions

- Risk categorization
- Inspection frequencies
- Workplanning
- Inventory reconciliation
- Funding levels
- Reporting requirements



## OP's Continued Support

- Continued support to partners
- Leverage resources and intelligence for mutual advancements
- Focus on *Moving the Needle* further towards an IFSS and Improving food safety in the United States
- Thank you – it is your work, dedication, flexibility, and partnership that makes our programs succeed
- Together, we will continue to find innovative ways to support our shared vision of an IFSS that protects public health and advances food safety

# Questions



# Speaker Contact Information



Guy Delius: [Guy.Delius@fda.hhs.gov](mailto:Guy.Delius@fda.hhs.gov)

# 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](mailto:OP.Feedback@fda.hhs.gov)





# ORA's State Inspection Contracts Overview



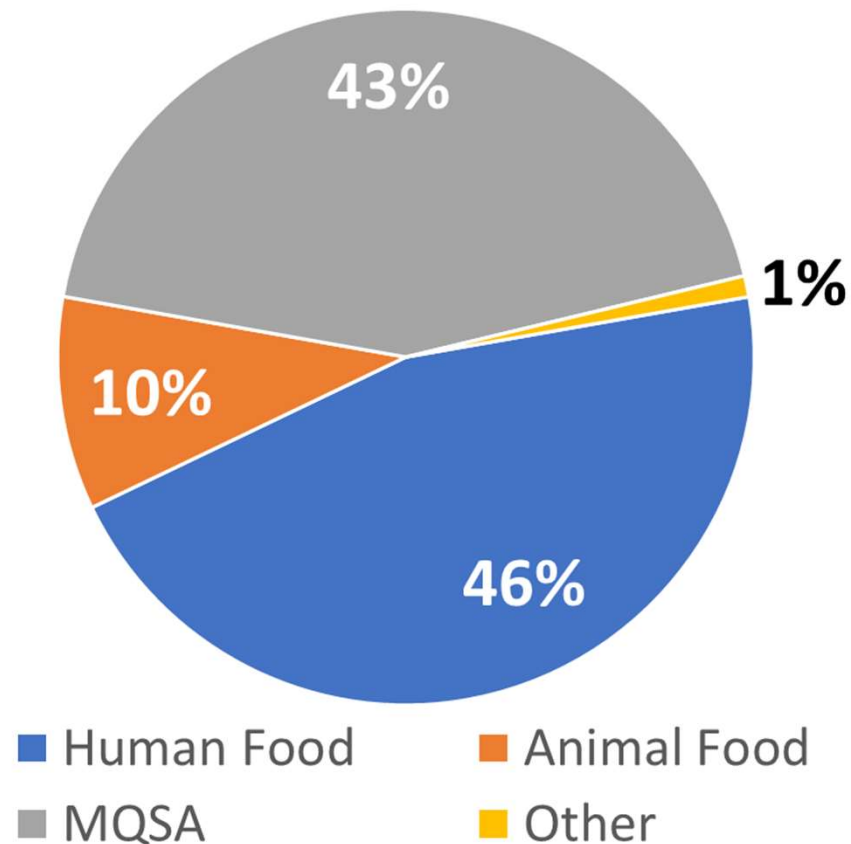
- In FY23, ORA funded 5 state contract programs to protect the public health\*

- Human Food
- Animal Food
- Egg Safety
- Medical Devices
- Milk Database\*
- MQSA

- FY23 FSI Contract Funding

- Human Food \$13.6M
- Animal Food \$2.9M
- MQSA \$12.9M
- Other Contracts \$291k

FY23 Contract Areas



\*The milk database contract does not cover inspections; however, it funds the collection of national milk sample data