

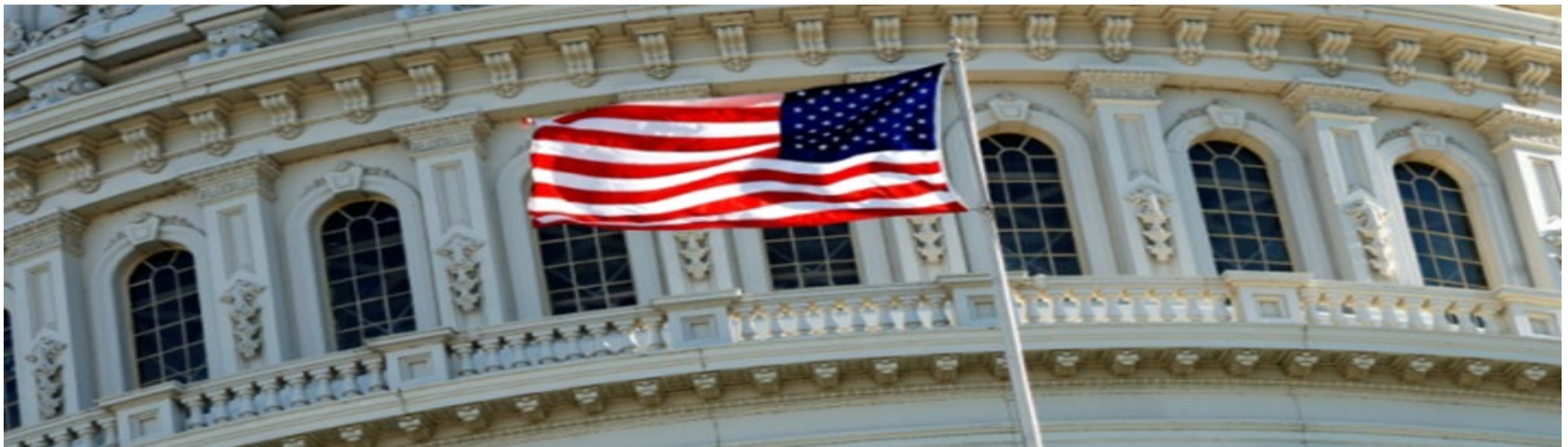
FDA Office of Partnerships and Division of Standards Implementation

Updates

AFDOSS

Asheville, NC

August 28, 2023



Speakers

- Abe Brown, Senior Advisor, Office of Partnerships
- Guy Delius, MFRPS Specialist, Division of Standards Implementation (DSI)



Objectives

- Office of Partnerships 2023
 - FDA Foods Program Reorganization
 - OP Support and Funding Initiatives
- Updates from DSI
 - DSI 2023 Outreach
 - Staffing/Management Status
 - Planning for the 2025 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.”

Office of Partnerships
Organization Chart
June 2023

FTE Ceiling: 114
On-board: 106
Vacancies: 08

Office of Partnerships
Barbara Cassens, Director
Alan Tart, Deputy Director

DCIHB

Abe Brown III, Senior Advisor
Yetunde Ijaodola, Senior Advisor
Maria Reed, QSM
Justin Carr, QSM
Bill Miller, Executive Assistant

Partnership Services Group (PSG)

Matthew Avis, J.D., Manager
Anthony Whalen, J.D., Team Lead

Adam Betman
Ciara Edward
Crystal Ford
Brenda Stewart-Munoz
Erik Smith
Jolene Gordon
Jamal Tull
Mercedes Laddon
Iphdeller Bookard

Division of Integration (DI)

DCIHBB

Division of Information Disclosure Programs (DIDP)

DCIHBD

Division of Partnership Investments and Agreements (DPIA)

DCIHBA

Division of Standards Implementation (DSI)

DCIHBC

Timothy Mueller, J.D., Director

Domestic Mutual Reliance Team

Priscilla Neves
Deborah Nebenzal
Mari Carpenter

Integration Group

Rebecca Dreisch, Manager

Heika Tait
Jessica Kimbrough
Suzette Kuhn
Ilyse Garman
VACANT
VACANT

International & Federal Engagement Group

Francis Kalush, Ph.D., Manager

David Kelly
John Sproul
Tammy Hancock
LCDR Jay Wong

Lisa Bellows, Director

Jennifer Rosero
Mark Barnes

Testimony Team

Jessica Whiting
Tobi Erskine
Whitney White

Disclosure Branch

Melissa Pickworth, Branch Chief

HQ FOIA Team

Christa Kiggundu
David Ruiz-Pineyro
Latrice Gilliard
VACANT

Special Projects Team

Jason Schilling
Mariah Jackson
Juan Gonzalez
Elisa Beard

DCIHBD3

FOIA Branch I (Pharma and Biologics)

Tamara Coley, Branch Chief

Biologics Team

Kimberly Morris
Janice Straight
Cara Minelli
Ko Min

Pharma Team

Louise Miranda
Cynthia Turner
Mayra Rivera
Sarah Bailey
Nancy Mabie
Monika Borkowska

DCIHBD1

FOIA Branch II (Foods and Devices)

VACANT, Branch Chief

Food Team

Patrick Kaelin
Barbara Recupero
Ashley Gonzalez
Michele Beckett
Natasha Johnson
Dana Carter

Devices Team

Sandra Williams
Annette Ellis
Isabel Carter
Klara Jenkins

DCIHBD2

Wendy Campbell, Director

Teresa Bills
Anh Lac

Human and Animal Food Branch

VACANT, Branch Chief

VACANT
Brenita Walker
Isaiah Isakson
Jocelyn Ramos
LCDR James Betz
Gerald Berg
Graham Giesen
Thanh Andrews

Retail Team

Maribeth Niesen
Jenice Butler

DCIHBA1

Laboratory, Medical Products & Innovation (LMPI) Branch

Erin Woodom-Coleman, Branch Chief

CAPT Mei-Ying Li
Ron Winter
VACANT
Christina Chrysogelos
Janna Hutchinson

DCIHBA2

Produce Branch

Alicia Schroder, Branch Chief

LDCR Doreen Gubbay
CDR Nicola Areshenko
Danielle Head
Adrianna Vargo
Jeanette Fredrick
Andrea Schmidt

DCIHBA3

Michelle Motsinger, Director (Acting)

Cooperative Programs Team

Belinda Clifton, CSO
Michael Antee, CSO
Barbara Kitay, CSO

Rapid Response Team

Travis Goodman
Lisa Joseph
LCDR Quynh Anh Tran

Regulatory Program Standards Group (RPS)

VACANT, Manager

Jennifer Godwin
Timothy Tyson
Kathryn Blackshear
LCDR Mark Chen
Lara Snyder
Angela Kohls
Guy Delius
Richard (Travis) Jensen
VACANT

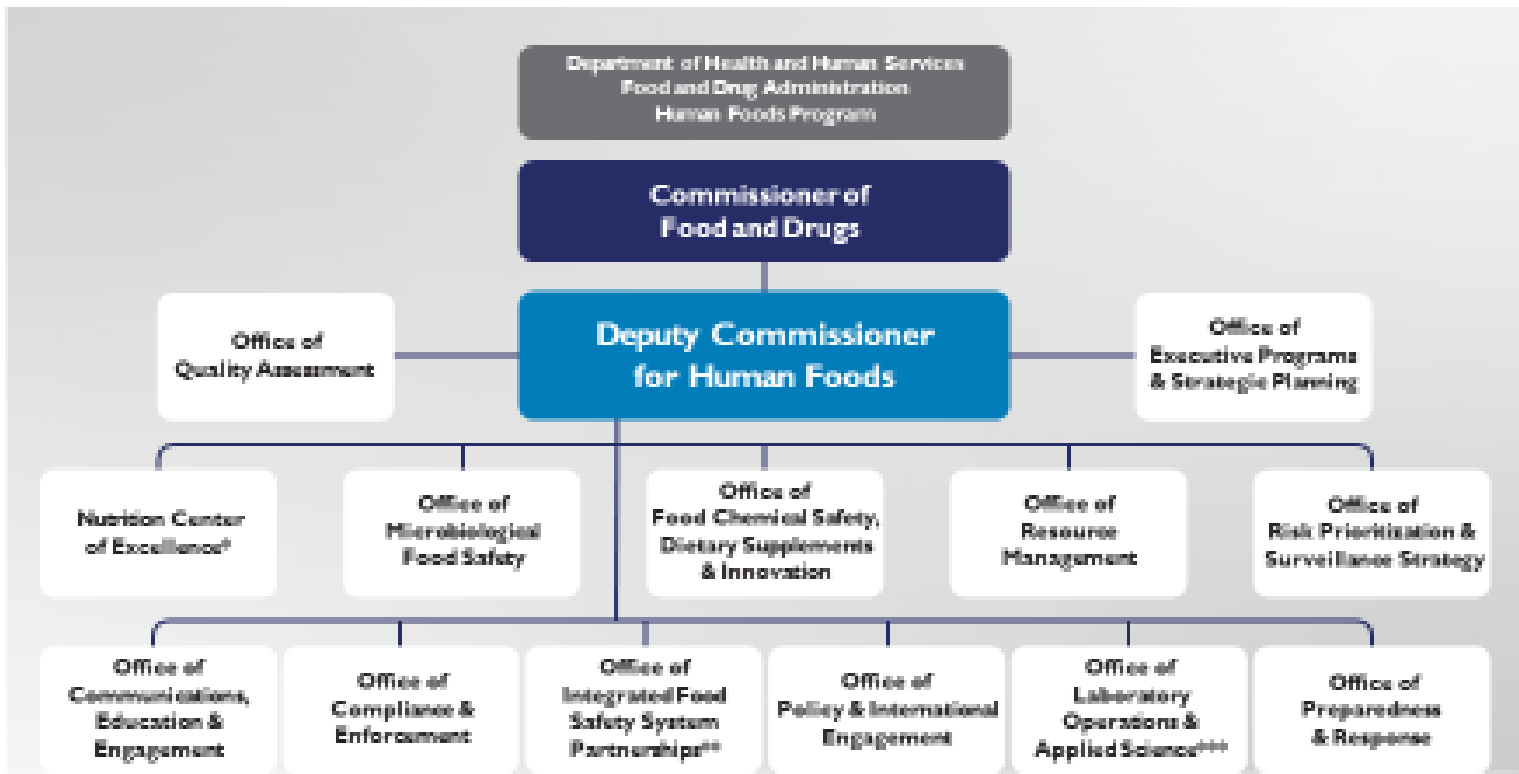
Update on Proposal for Unified Human Foods Program



- Establishing ORA's core mission as conducting investigations, inspections and imports for all FDA-regulated products, with assignments planned in partnership with the HFP and other product programs or Centers.
- Merging compliance functions currently managed within ORA into the HFP and the product Centers' existing compliance functions
- Realigning the eight Human and Animal Food laboratories that are currently managed by ORA into the HFP.
- Transitioning certain functions under the Office of Security and Emergency Management, currently in the Office of Operations, to ORA.
- As previously shared, unifying state and local food safety partnership functions and certain aspects of international food safety partnerships into an Office of Integrated Food Safety System Partnerships in the HFP.
- Reviewing support functions across ORA and proposing realignment of certain resources and personnel to support these changes.
- Prioritizing recruitment, retention and training opportunities for field-based employees with the availability of Title 21 hiring authority.



Proposed Human Foods Program Organization Chart

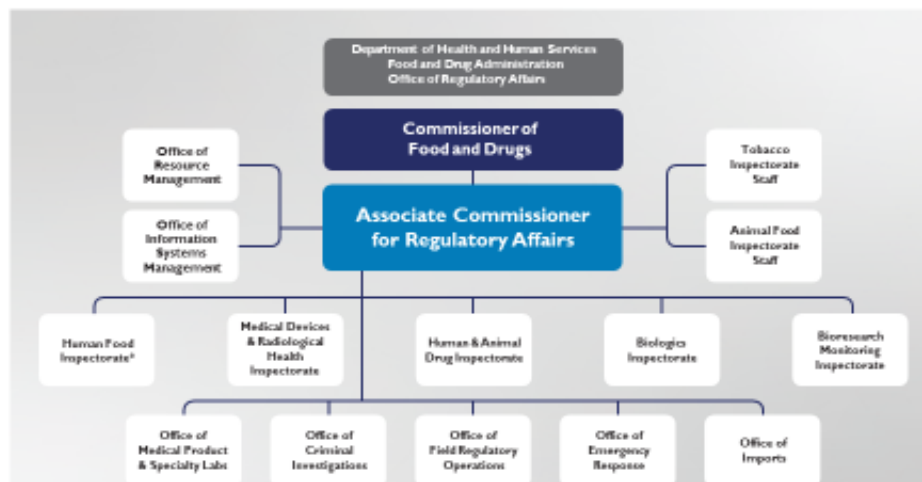


*Includes Office of Orphan Foods
**OIFSSP will work in close coordination with the Center for Regulatory Modernization
***OLOAS will work in close coordination with the Office of the Chief Science and Officer for Veterinary Medicine

Descriptions of proposed HFP offices:



Proposed Office of Regulatory Affairs Organization Chart



*Includes special interest programs such as infant formula

Descriptions of proposed ORA offices:

The **Associate Commissioner for Regulatory Affairs (ACRA)** will report directly to the FDA Commissioner with responsibility of overseeing the agency's field force who carry out inspections, investigations, and import operations in support of the FDA's product centers and programs. The ACRA will work closely with other FDA executives to ensure priorities are appropriately coordinated and advanced.

Commodity Inspection Functions: Aligning inspection resources with center and program priorities

- The **Inspectorate Offices and Staffs** will carry out inspections and other field activities for their individual portfolios. These offices include Human Food, Animal Food, Medical Devices and Radiological Health, Human and Animal Drugs, Biologics, Bioresearch Monitoring, and Tobacco.

Overview of the Reorganization Process



- FDA identifies all changes to structure and functions to incorporate into proposal to support agency effectiveness and efficiency
- FDA develops:
 - Proposed organization charts
 - Proposed staffing charts and crosswalks*
 - Proposed budget tables
 - Proposed functional statements

**A required element in a proposed reorganization package showing current list of employees/vacancies and future list of employees/vacancies for each office impacted by proposed reorganization.*

- FDA assembles/finalizes reorganization package
- FDA leadership officially approves package
- FDA submits to HHS **in Fall 2023**

- HHS officials review/clear reorganization package
- HHS routes package to OMB for review/clearance
- HHS Secretary officially approves package
- HHS works with FDA to send official notification to Congress
- Congress conducts/completes review (at least 30 days)

- FDA notifies employees/unions that reorganization is approved
- FDA initiates bargaining with union as appropriate
- FDA announces reorganization in Federal Register
- FDA initiates implementation of new structure (after all steps above), including changes to administrative (e.g., SF-50 notifications, ITAS) and budget systems

FY24 FSI Funding

- Our goal is to provide the needed financial support for all programs and partners
- Projecting \$116,312,000 will be available
- Ideal FSI budget is >\$135M

ORA's State Inspection Contracts Overview

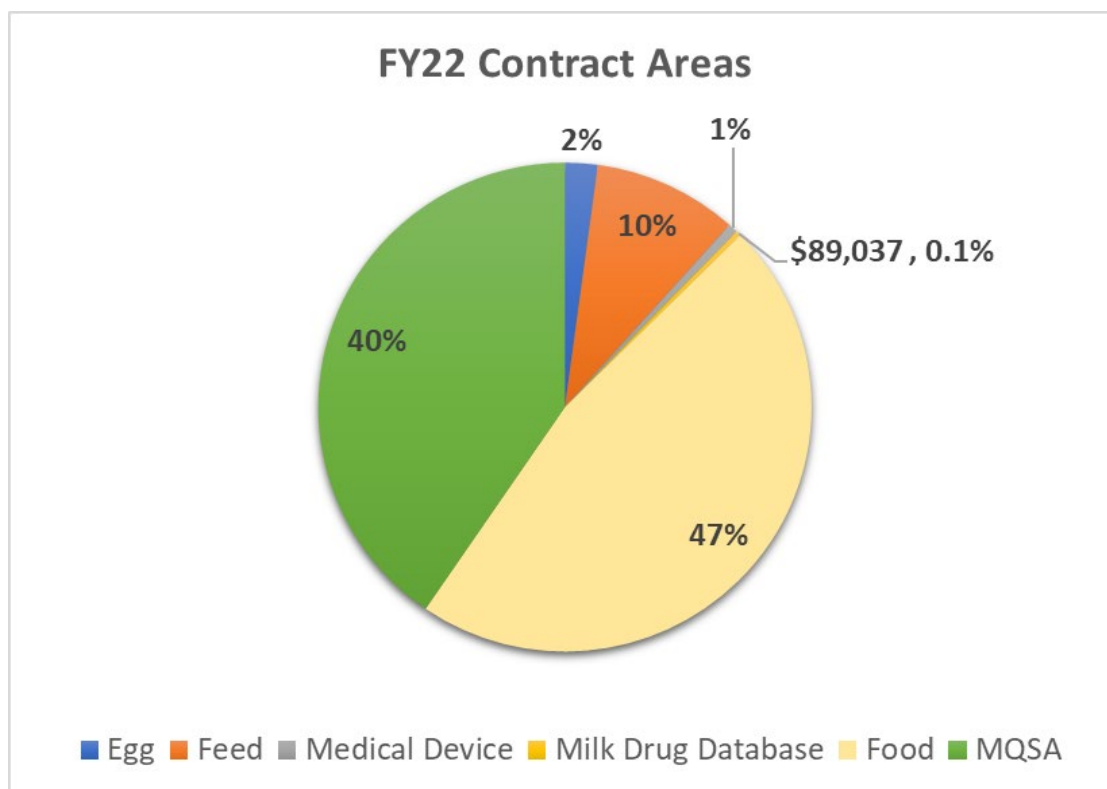


- In FY22, ORA funded 5 state contract programs to protect the public health*

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

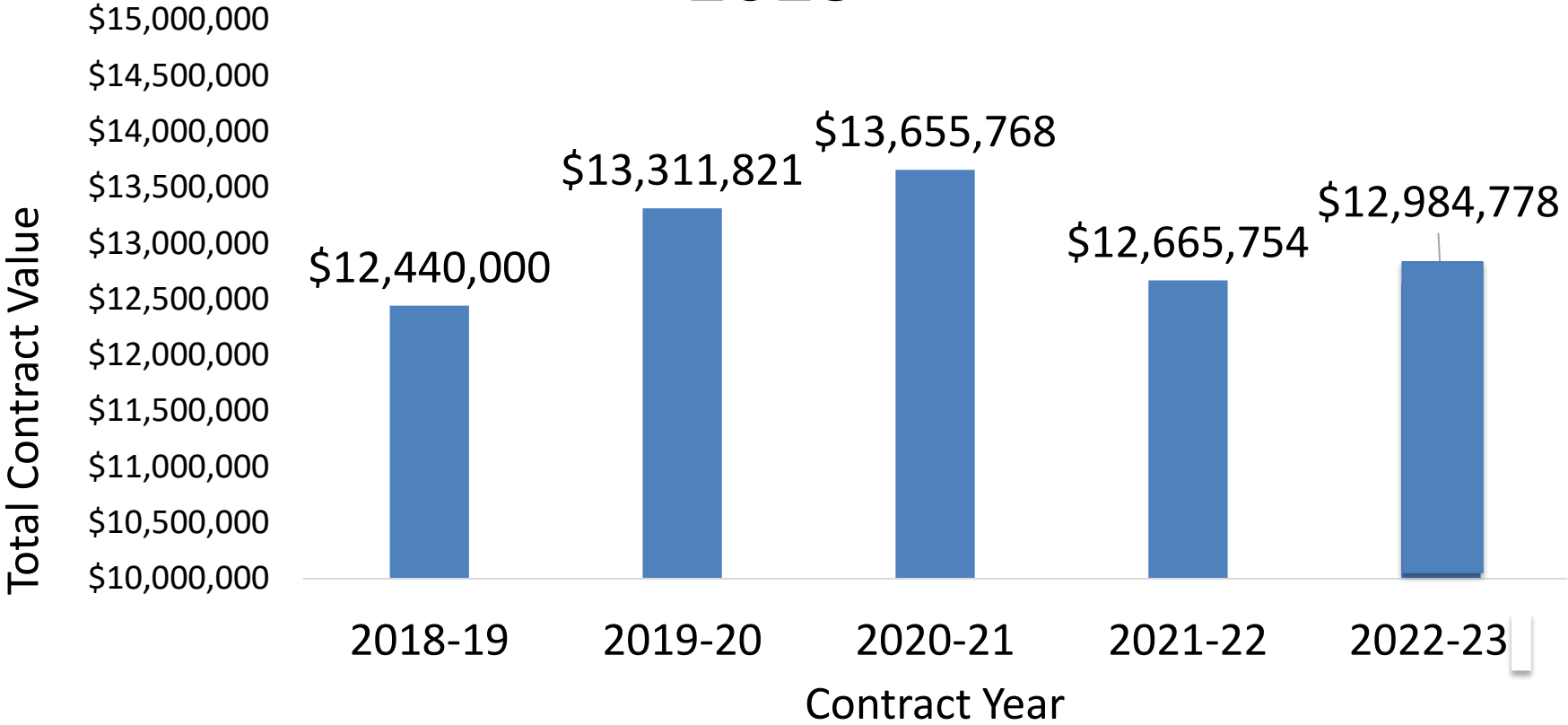
- FY22 FSI Contract Funding

- Human Food \$13M
- Animal Food \$2.5M
- Egg \$580,029
- Medical Device \$170,027
- *Milk Drug Database \$89,037
- MQSA \$11M

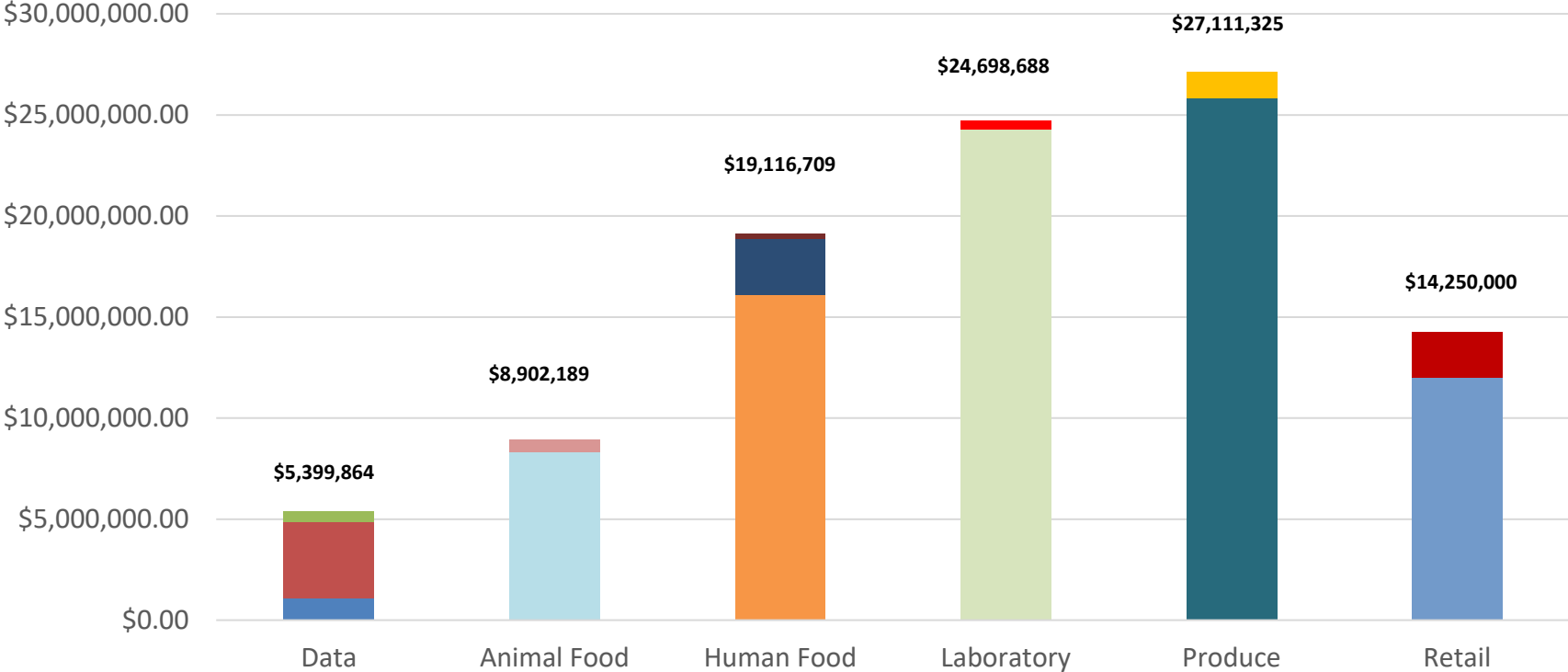


***The milk database contract does not cover inspections; however, it funds the collection of national milk sample data**

Human Food Contract National Trends 2018-2023



ORA FY22 Federal-State Initiative CAPs



- FoodSHIELD
- AFRPS
- Integrated Food Safety System Alliance
- Building an Integrated Lab System
- Retail FFM
- SAFHER/State Database
- Animal Food Association
- Eggs
- Retail Collaborative
- Scientific Conference
- MF FFM
- Lab FFM
- Produce Grower Implementation

Milk-Shellfish Subawards – FY 23

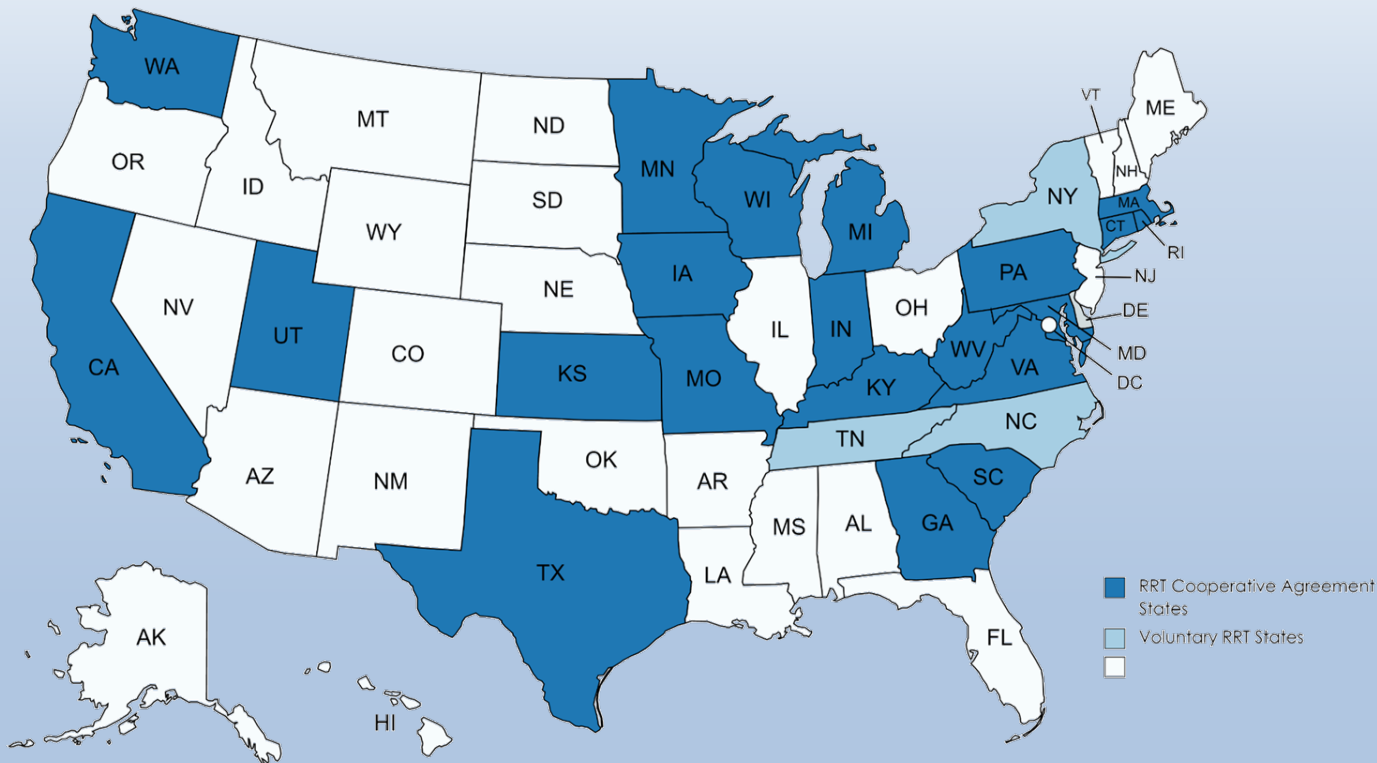
- Nov. 2022 training portal:
 - Milk training: \$1,277,275.00
 - Shellfish training: \$511,322.00
- Biennial conference portal:
 - NCIMS conference: \$203,943.00
 - ISSC conference: \$92,150.00
- Milk sampling assignment: \$23,165.00
(Funded via CFSAN admin. supplement)



Retail Flexible Funding Model

- Starting Year 3 of the RFFM (Year 2 of sub-awarding)
 - \$7.5M across 477 grants sub-awarded
 - 31 States, 193 Local, 3 Territorial, and 3 Tribal retail regulatory agencies were funded.
 - Largest number of participants in the mentorship program ever – 15 mentors and 50 mentees
 - Portal expected to open in mid-August 2023
- Training and standardization survey
- Retail Program Standards Symposium

Rapid Response Teams



**24 states participate (21 funded, 3 unfunded/voluntary),
involving 11 FDA HAF Divisions**

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



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

DSI Updates

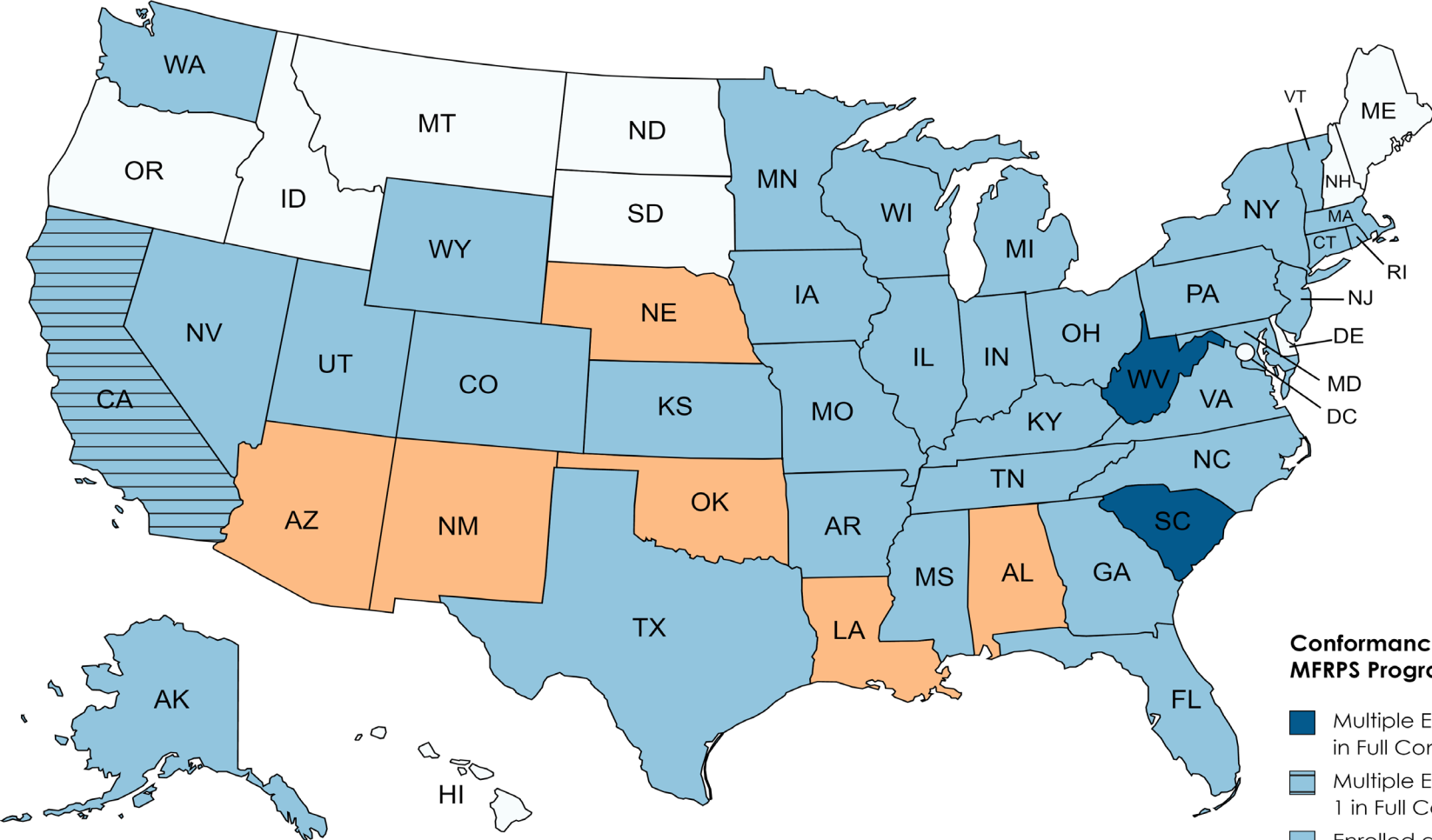
- DSI Director long-term detail named!
 - Michelle Motsinger
- Pending long-term detail for the vacant DSI MFRPS Specialist
 - Help alleviate increasing workload for staff
 - Help provide additional personalized service and attention to states
 - Provide additional service to critical program developments within DSI



DSI Updates

- DSI Outreach and Accomplishments
 - 23 states visited and/or MFRPS meetings held
 - Quarterly Regional Coordinator calls
 - Educational webinars provided
 - MFRP Alliance (Kansas City) planned
 - Partnership for Food Protection leadership
 - 2 MFRPS Specialists served as at the Council for Food Protection Parliamentarians
 - Many workgroups and committees
 - Roll out of 2022 MFRPS
 - MFRPS, AFRPS, ERPS and Produce Standards
 - 2023 AFRPS approved by OMB
 - Much More!

MFRPS 2023



Conformance Status of 44 MFRPS Programs- 1/17/23

- Multiple Enrolled Programs in Full Conformance (4)
- Multiple Enrolled Programs, 1 in Full Conformance (2)
- Enrolled and in Full Conformance (32)
- Enrolled (6)
- Not Enrolled

MFRPS 2025



- Proposals will be solicited starting **July 1, 2023**
- Submission deadline will be **September 1, 2023**



MFRPS 2025

- Any Alliance Member or FDA Representative may submit a proposal
- Proposals must be submitted on the form provided by the MFRPA:
- Clearly identify the standard element or job aid to be modified;
- Include the proposed language / modification; and
- Provide the basis for the modification.



MFRPS 2025

MANUFACTURED FOOD REGULATORY PROGRAM ALLIANCE	
PROPOSAL TO MODIFY MANUFACTURED FOOD REGULATORY PROGRAM STANDARD	
SUBMITTER NAME:	DATE:
AGENCY:	
EMAIL:	PHONE:
STANDARD YOUR PROPOSAL SEEKS TO MODIFY:	
DESCRIBE THE CURRENT STANDARD REQUIREMENT:	
DESCRIBE YOUR PROPOSED CHANGE & PROVIDE YOUR PROPOSED LANGUAGE:	

MFRPS 2025

- MFRPA Board will assign the proposals to one of four workgroups:
 - WG1: Standards 1, 2, 8, & 9
 - WG2: Standards 3, 4, & 6
 - WG3: Standards 5 & 7
 - WG4: Standard 10



MFRPS 2025

- AFDO will be soliciting Workgroup volunteers in August 2023.
- AFDO will work with DSI and Audit staff to ensure an appropriate representative will be able to participate in each workgroup to provide technical input related to the proposed modifications.
- Workgroups will meet in September, October, and November (if late proposals are received)

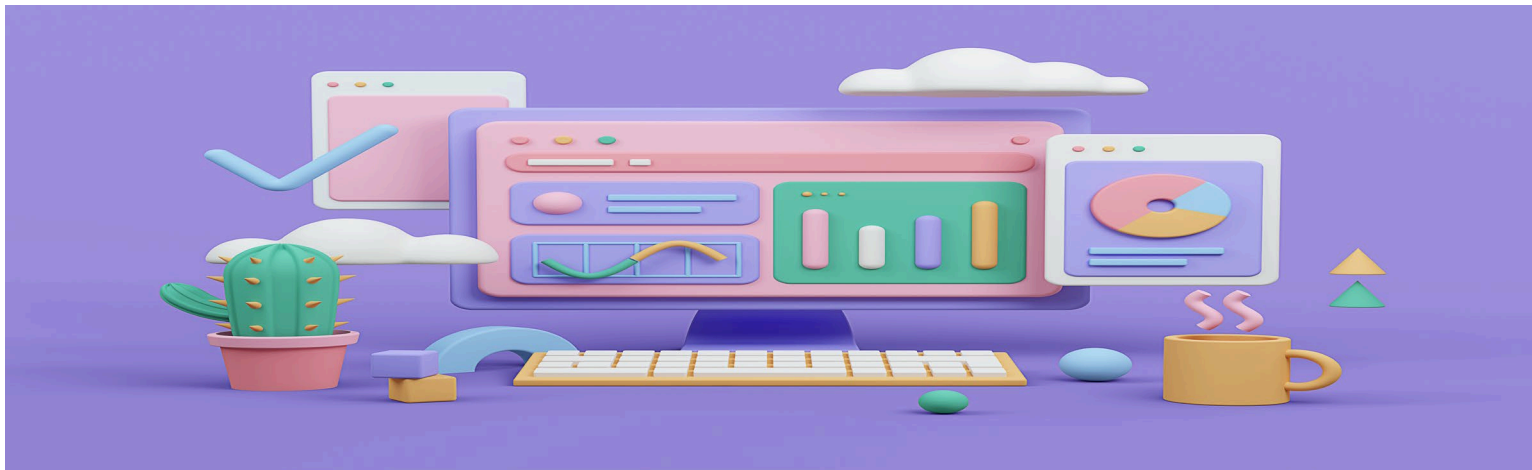


MFRPS 2025

- Voting Members will be assembled at the MFRPA Annual Meeting to vote on the proposals.
 - Must be a Voting Member (Program Manager) or a manager that was delegated the responsibility by the program manager. This is generally not the MFRPS Coordinator.
 - Final language to be voted on will be disseminated to voting members prior to the voting session.

MFRPS Reporting

- Deadline Date for the End of Project Report (Final RPPR) – **October 30, 2023**
- If you have a No Cost Extension (NCE) Approved – **Report will be due 120 days after the NCE ends.**
- SF-425 – Due Sept. 30, 2023, unless a NCE was approved.



MFRPS FFM CAP Awards



- Objective review panels have been completed and Funding announcements are being issued soon!
- Projected funding
 - New awards will be 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	jocelyn.ramos@fda.hhs.gov (510) 337-6894
Thanh Andrews, Project Manager	thanh.andrews@fda.hhs.gov (202) 815-0889
Office of Resource Management Operations (ORMO)	
Aaron Dagues, Program Official	aaron.dagues@fda.hhs.gov (513) 322-0607
Office of Acquisitions & Grants Services (OAGS)	
Janelle Fundersburg, Grant Management Specialist	janelle.fundersburg@fda.hhs.gov (301) 796-2533
Kimberly Pendleton, Director	kimberly.pendleton@fda.hhs.gov (240) 402-7610

Questions



Speaker Contact Information



Abe Brown: Abe.Brown@fda.hhs.gov

Guy Delius: 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

