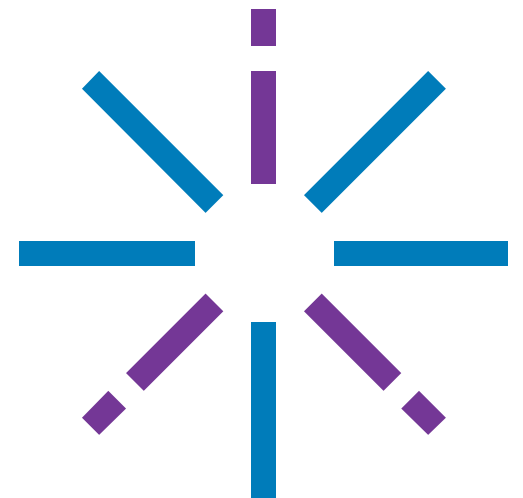


Update on FDA's Office of Inspections and Investigations

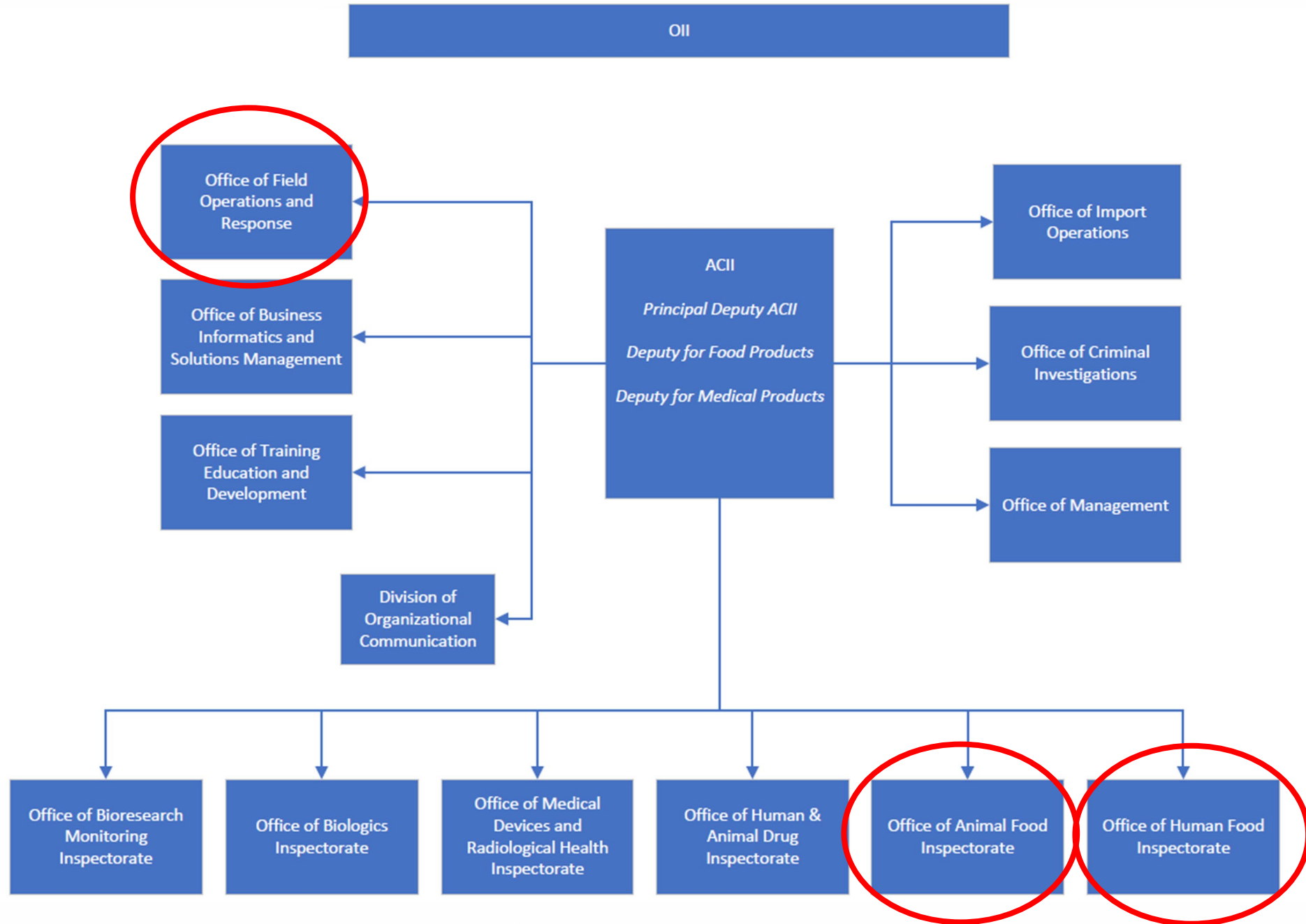
Ronald Pace
Division Director
Human Food Inspectorate East 1





OII Acronyms

Acronym	
ACII	Associate Commissioner for Inspections and Investigations
OII	Office of Inspections and Investigations
OHFI	Office of Human Food Inspectorate
OAFI	Office of Animal Food Inspectorate
OFOR	Office of Field Operations and Response
OHFI Central	Office of Human Food Inspectorate Central
OHFI East	Office of Human Food Inspectorate East
OHFI West	Office of Human Food Inspectorate West
OGSHFI	Office of Global and Specialty Human Food Inspectorate
DHFI	Division of Human Food Inspectorate
SSA	Supervisory Senior Advisor



Reorganization New Model for Field Operations



The Office of Regulatory Affairs (ORA) became the Office of Inspections and Investigations (OII) on October 1, 2024.

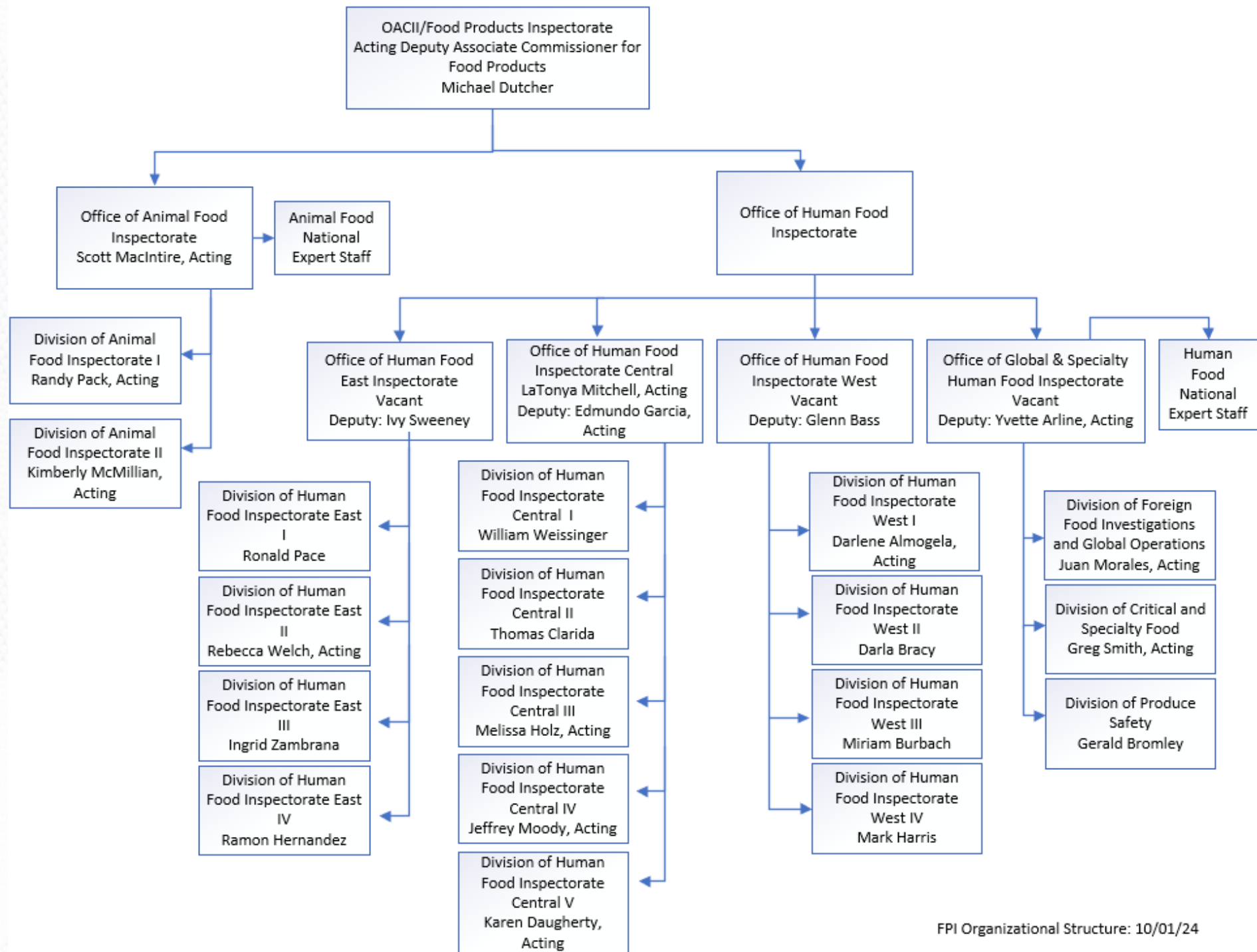
Office of Human and Animal Foods Operations will change names as follows:

- Food Products Inspectorate (FPI – formerly OHAFO)
- Office of Human Food Inspectorate East (OHFIE – formerly OHAFO East)
- Office of Human Food Inspectorate West (OHFIW – formerly OHAFO West)
- Three New Offices
 - Office of Human Food Inspectorate Central (OHFIC)
 - Office of Global and Specialty Human Food Inspectorate (OGSHFI)
 - Office of Animal Food Inspectorate (OAFI)

OHFI and OAFI will have new geographical boundaries

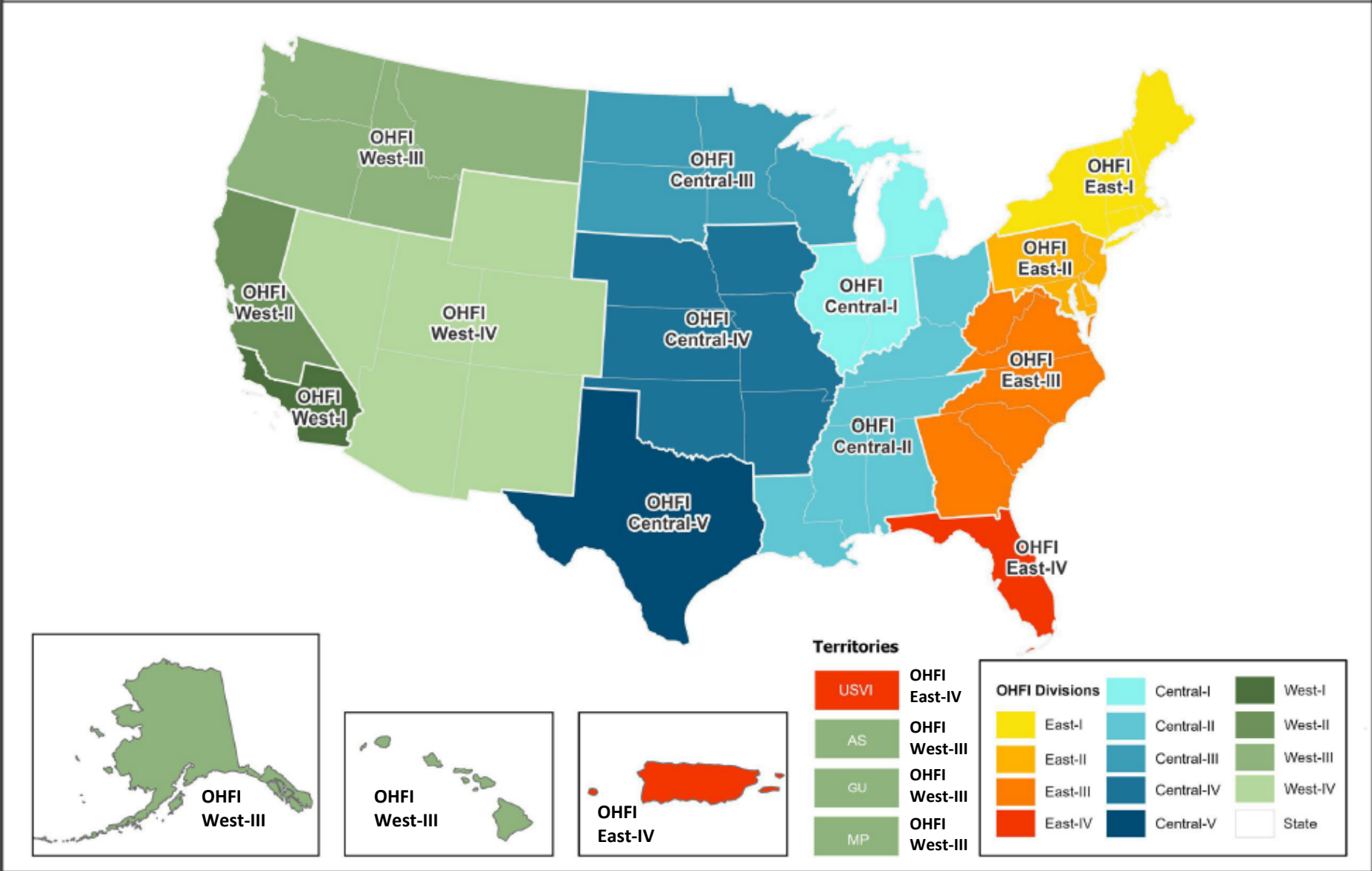
OHFI and OAFI will work closely with Compliance in the Human Food Program (HFP) and Center for Veterinary Medicine (CVM)

Recall Coordinators will continue to have the same responsibilities as pre-reorganization

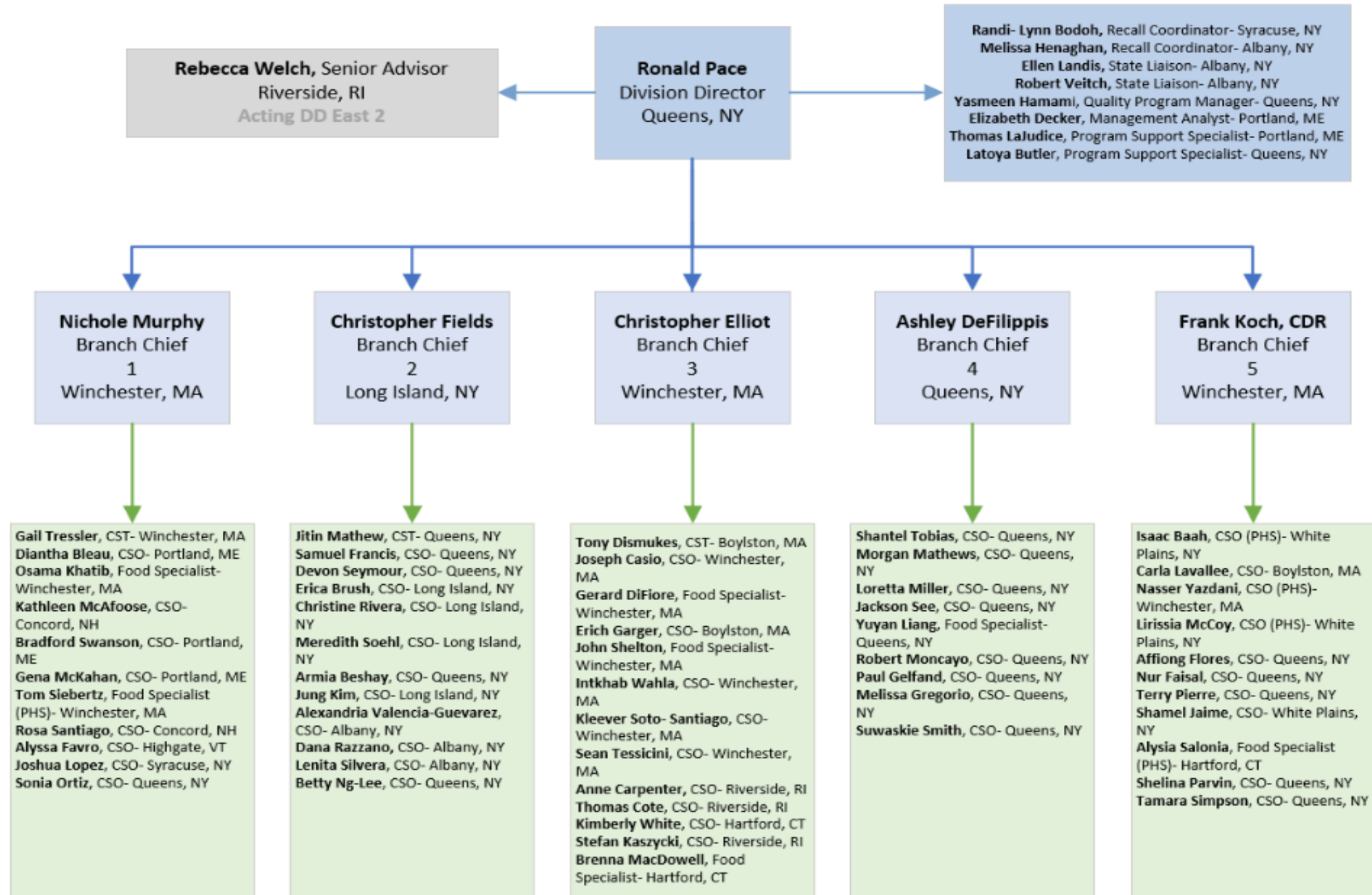




Office of Human Food Inspectorate (OHFI)



OII HFI East 1 Organizational Chart





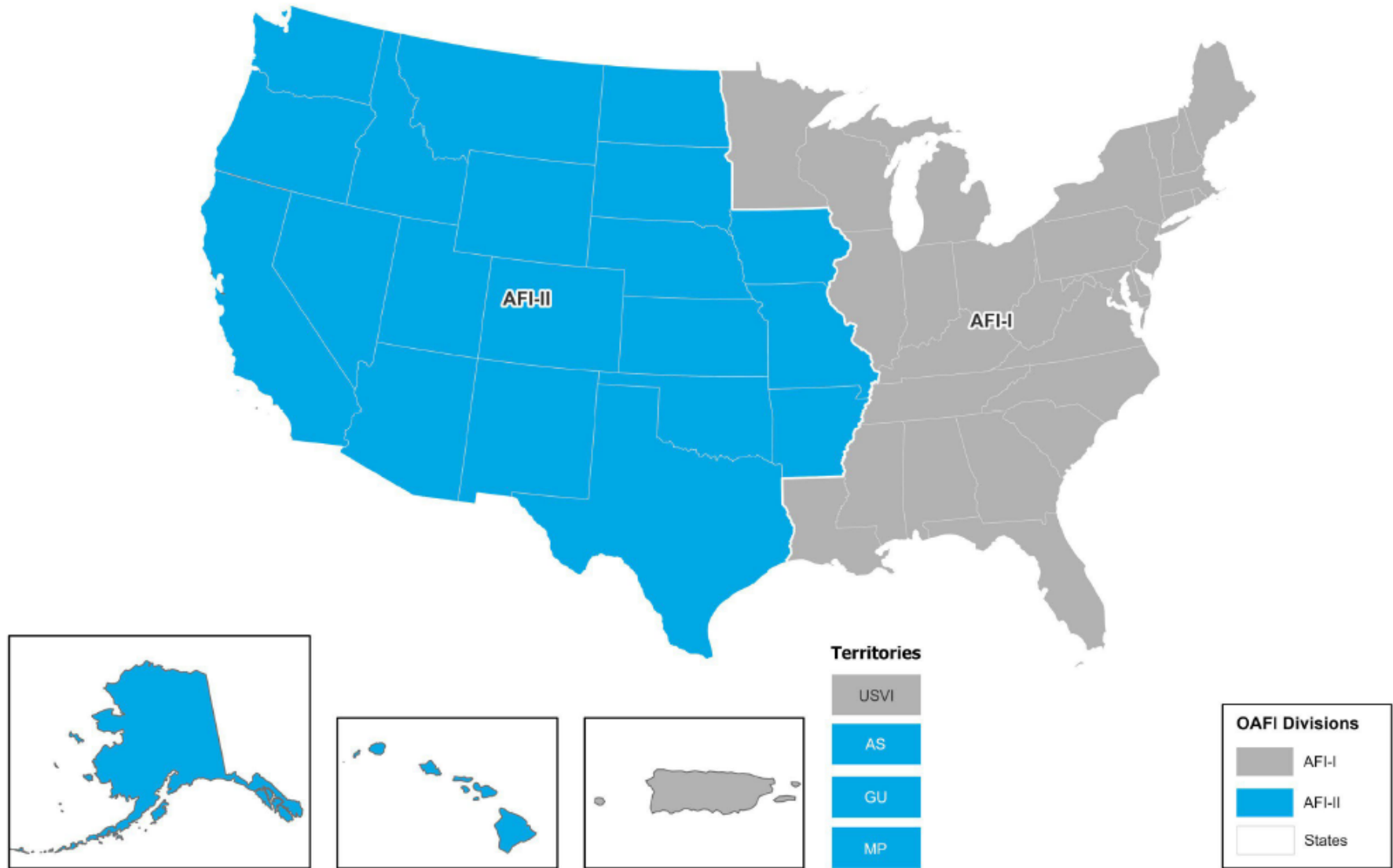
New OII/OHFI Division	Human Food State Liaisons
HFI East 1	Ellen Landis (NY, NH); Rob Veitch (CT, MA, VT, RI, ME)

Office/Division	Recall Coordinators	Recall Email
HFI East 1	Randi-Lynn Bodoh and Melissa Henaghan	oiihfeast1recalls@fda.hhs.gov

Office/Division	ERCs	Coverage Area
OER	Milan McGorty	New York
OER	Kim Langelo	CT, MA, ME RI, NH, VT



Office of Animal Food Inspectorate (OAFI)



Office of Animal Food Inspectorate (OAFI) Division Boundaries



New OII/OAFI Division	States	Districts
AFI 1	CT, MA, ME, NH, NY, RI, VT, DE, NJ, PA, MD, DC, VA, WV, GA, NC, SC, FL, PR, VI, IL, IN, MI, OH, KY, TN, LA, AL, MS, WI, MN	NWE-DO, NYK-DO, PHI-DO, NWJ-DO, BLT-DO, ATL-DO, FLA-DO, SJN-DO, CHI-DO, DET-DO, CIN-DO, NOL-DO, MIN-DO
AFI 2	ND, SD, IA, KS, MO, NE, AR, OK, TX, CA, AS, GU, MP, HI, AK, ID, MT, OR, WA, AZ, NV, CO, UT, NM, WY	MIN-DO, KAN-DO, DAL-DO, LOS-DO, SAN-DO, SEA-DO, DEN-DO

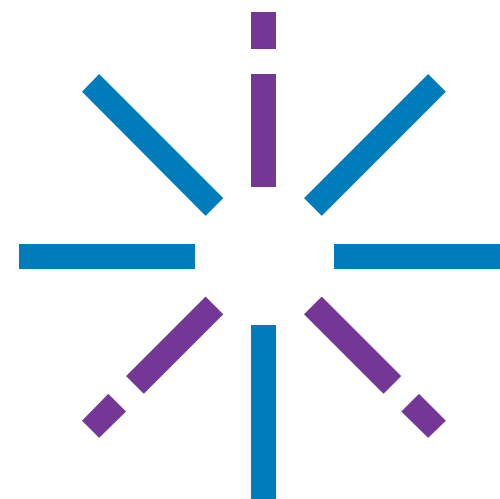
Office of Animal Food Inspectorate (OAFI)

Division State Liaisons



New OII/OAFI Division	Animal Food State Liaisons
AFI 1	William Murray (CT, NJ, MD, PA, VA, WV, NC, DC, DE, MA, ME, NH, NY, RI); Adam Williams (TN, AL, FL, GA, SC, LA, MS, PR, VI); Vacancy (KY, IL, IN, MI, MN, OH, WI)
AFI 2	Alcee Tavarez (MO, NE, TX, AR, OK); Julie Vosilus (IA, KS, SD, WY); Suzanne Crotty, Acting (NM, CO, UT, ID, MT, NV, AZ); Lisa Nakagawa (ND, CA, WA, GU, HI, OR)

Office of Field Operations and Response



Office of Field Operations and Response

Office of Emergency Response (OER)



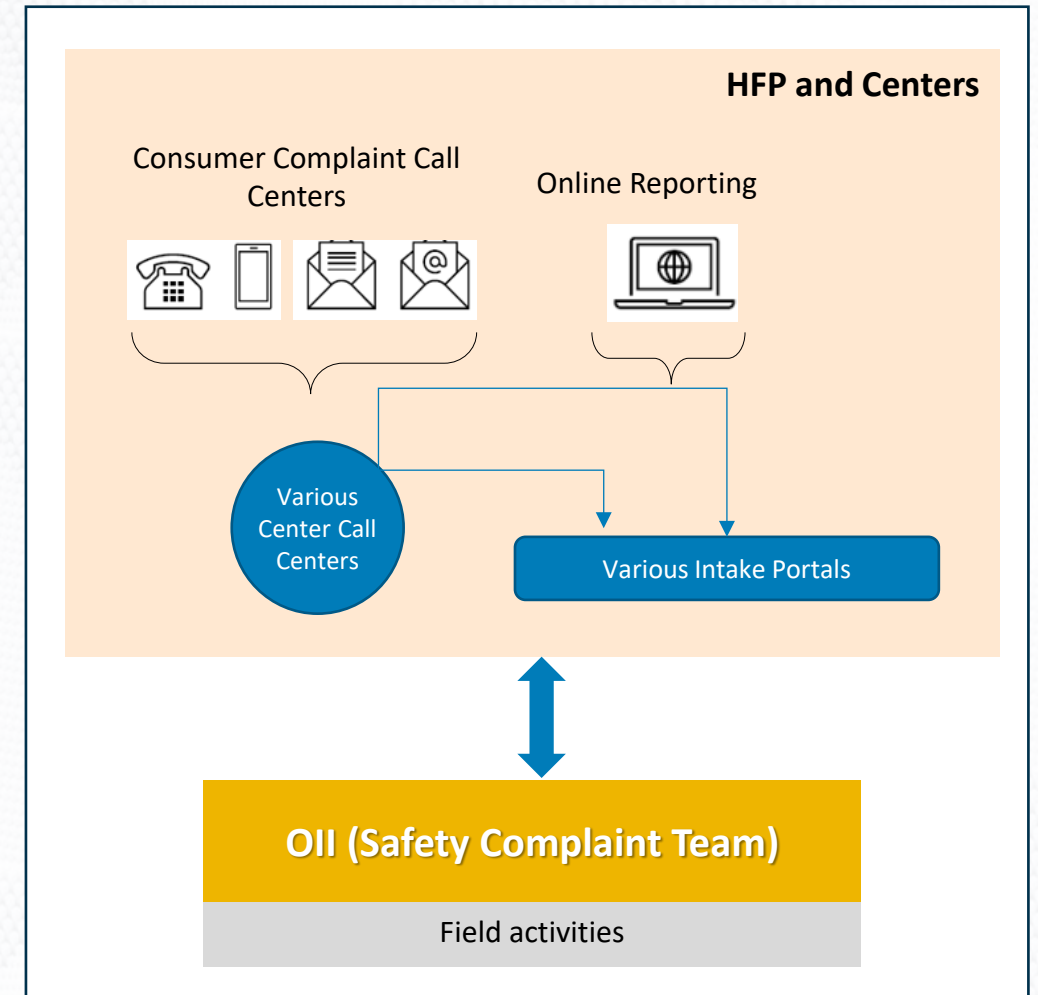
- ERCs will continue to cover the same States as pre-reorganization
- ERCs will continue to have close relationships with their local and State counterparts (including RRTs)
- ERCs will continue to have close relationships with all OII program areas as well as CORE.
- Consolidated emergency coordination leadership structure
- Emergency.operations@fda.hhs.gov

FDA's New Complaint Handling Approach



The FDA is streamlining its handling of consumer complaints to be more efficient and responsive to public health concerns.

- HFP and Centers will be responsible for the intake, evaluation, and triage of consumer complaints and inquiries.
- HFP and Centers will refer complaints to OII to collaborate on field follow-up activities as needed.



How Should Consumers Submit a Complaint?



- Consumers wishing to submit a complaint directly to FDA should be directed to the new *SmartHub* or call 1-888-INFO-FDA (1-888-463-6332).
 - **Action:** Please make sure all your agency's *public-facing* webpages and materials are updated accordingly.
- All prior ORA Consumer Complaint Coordinators numbers and dedicated complaint email boxes will be decommissioned. Calls will be routed to 1-888-INFO-FDA and the prior email boxes will not be monitored.

The screenshot shows the FDA's 'Report a Product Problem' page. At the top, there is a dark blue header with the FDA logo and 'U.S. FOOD & DRUG ADMINISTRATION'. Below the header, the page title 'Report a Product Problem' is displayed, along with buttons for 'Mandatory Reporters Pathway' and 'Español'. A paragraph explains that the tool is for reporting human or animal product problems (defects, safety issues, adverse health experiences, etc.). Below this, there is a note about digital accessibility and a contact information section. The main content area features a grid of 12 categories, each with a representative image and a 'Report Here' button. The categories are: Food, Infant Formula, Dietary Supplements, Human Drugs, Medical Devices, Vaccines, Blood, and Biologics, Pet Foods/Treats and Livestock Food, Veterinary/Animal Drugs, Cosmetics, Tobacco Products, and Other Safety Issues. A 'Menu' button is visible in the top right corner of the page.

Report a Product Problem Mandatory Reporters Pathway Español

This navigation tool will lead you to the reporting forms where consumers, healthcare professionals and industry members can report human or animal product problems (defects in the quality or safety of the product, or labeling issue), adverse health experience (injury, illness, other health-related issues, or even death associated with an FDA-regulated product), and facility issues (an FDA regulated facility issue such as a whistleblower report or sanitation issue). The FDA appreciates your contribution to the safety of America's food supply, medicines, and other products that touch us all.

FDA is committed to ensuring digital accessibility for people with disabilities. We are continually improving the user experience for everyone and applying the relevant accessibility standards. FDA is partially conformant with WCAG 2.0 level AA. Partially conformant means that some parts of the content on our websites do not fully conform to the accessibility standards.

If you have difficulty accessing information on this site, please contact us at 1-(888)-463-6332 or SRPSupport@fda.hhs.gov.

If this is a life-threatening emergency, please call 911.

All Categories

- Food
- Infant Formula
- Dietary Supplements
- Human Drugs
- Medical Devices
- Vaccines, Blood, and Biologics
- Pet Foods/Treats and Livestock Food
- Veterinary/Animal Drugs
- Cosmetics
- Tobacco Products
- Other Safety Issues

Food Report Here

Infant Formula Report Here

Dietary Supplements Report Here

Human Drugs Report Here

Medical Devices Report Here

Vaccines, Blood & Biologics Report Here

Pet Foods & Livestock Food Report Here

Veterinary/Animal Drugs Report Here

Cosmetics Report Here

Tobacco Products Report Here

Other Safety Issues Report Here

[SmartHub - Safety Intake Portal - Report a Product Problem \(hhs.gov\)](https://www.safetyreporting.hhs.gov/smarthub#/)
<https://www.safetyreporting.hhs.gov/smarthub#/>

How Should SLTT Partners Forward Complaints?



- SLTT partners should forward complaints directly to FDA using these email addresses.
 - ***Action:*** Please make sure all your *internal protocols only* are updated with this information accordingly.
- If you have any problem or concern, notify the *FDA National Consumer Complaint Coordinator* at NCCComplaints@fda.hhs.gov

Human Foods & Dietary Supplements
HFPComplaints@fda.hhs.gov

Vaccines, Blood, Cell and Gene Therapies
OCOD@fda.hhs.gov

Human Drugs
DrugInfo@fda.hhs.gov

Human Medical Devices
CDRHDeviceAllegations@fda.hhs.gov

Veterinary Drugs, Devices and Foods
AskCVM@fda.hhs.gov

Tobacco Products
AskCTP@fda.hhs.gov

Cosmetics
OCSComplaints@fda.hhs.gov

How Will the Complaint Response be Coordinated?



- If SLTT partners forward a complaint, HFP and the Centers may follow up directly with you or the complainant for more information.
- If FDA decides that field activities are needed, OII's new Safety Complaint Team (SCT), OII Inspectorates, and/or CORE Team will coordinate with all the appropriate FDA groups, including relevant FDA state liaisons and emergency response coordinators. FDA state liaisons will involve state counterparts, as necessary.
- HFP will share milk/dairy and molluscan shellfish related complaints with the Milk/Shellfish specialists in the Office of Microbiological Food Safety. The Milk/Shellfish specialists will continue to share the complaints with the States under the cooperative agreement.

Questions

