U.S. FOOD & DRUG ADMINISTRATION

Office of Inspections and Investigations
Office of Human Food Inspectorate
Office of Human Food Inspectorate Central

Food & Drug Administration Updates

MCAFDO Educational Conference
December 3, 2025

Dr. LaTonya Mitchell, Acting Office Director
Office of Human Food Inspectorate - Central
Office of Inspections and Investigations

Today's Topics

1. Office of Inspections and Investigations (OII) and Food Products Inspectorate (FPI) Overview
2. Overview & Boundary Maps
3. Contacts for Human Food
   Contacts for Animal Food
4. Risk Based Inspection Under FSMA
5. Enhanced Technologies and Future Landscape
6. Reporting a Product Problem

OFFICE OF INSPECTIONS AND INVESTIGATIONS (OII) AND FOOD PRODUCTS INSPECTORATE (FPI) OVERVIEW

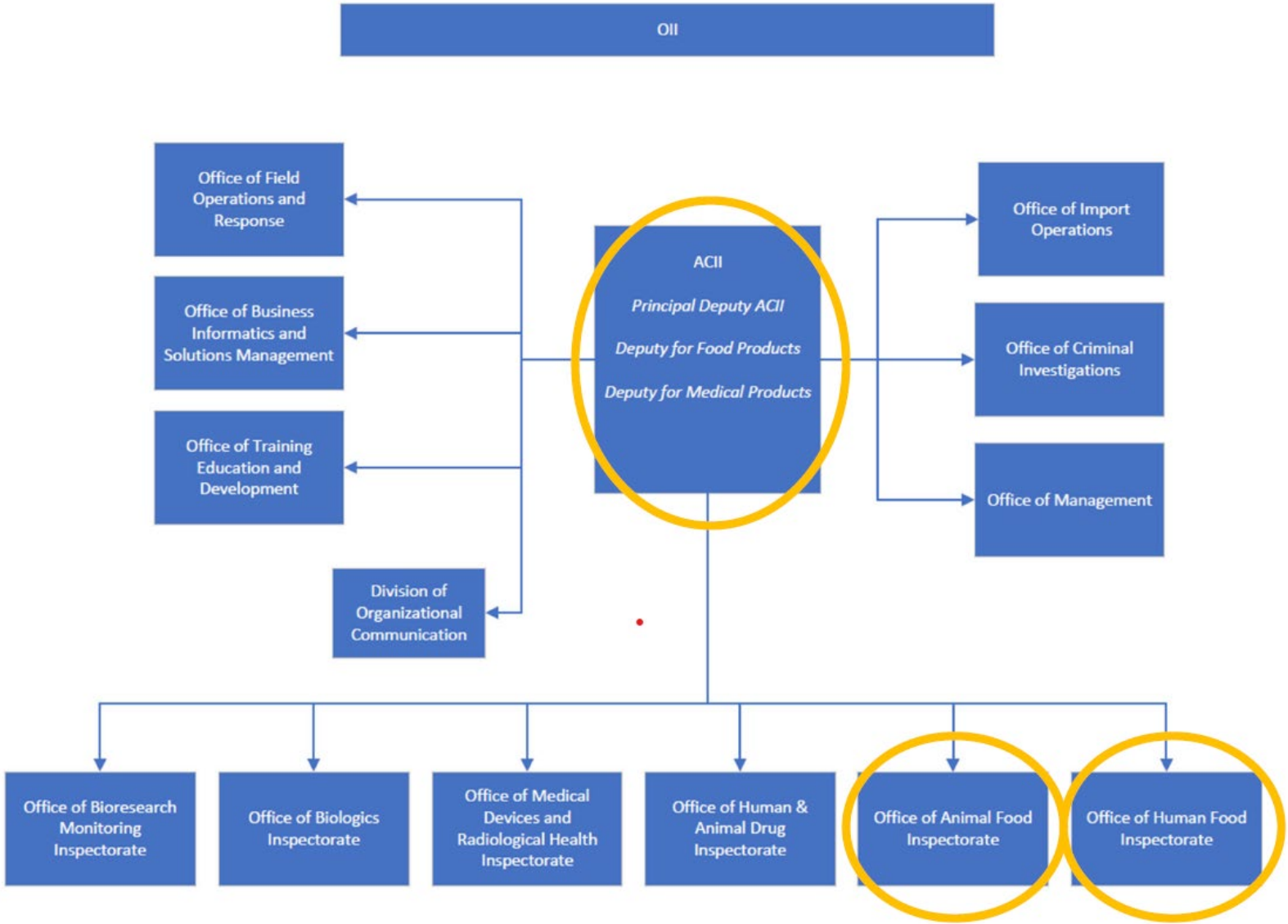
Office of the Associate Commissioner for Inspections and Investigations

Elizabeth Miller, Pharm. D.
Associate Commissioner for Inspections and Investigations

Michael Dutcher, DVM
Deputy Associate Commissioner for Food Products

Vinetta Howard-King
Acting Deputy Associate Commissioner for Medical Products Inspectorate

OII Organizational Chart



Office of Inspections and Investigations (OII)

- Lead office for all FDA field activities
- Primary Function – Conduct inspections of FDA regulated facilities
  - Domestic and internationally – approximately 30,000 inspections a year
- Includes foods, human and animal drugs, cosmetics, medical devices, biologics, and tobacco

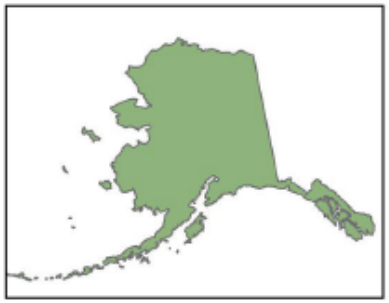
Food Products Inspectorate (FPI)

- Food facility inspections
  - Domestic and foreign
    - Food inspections, including animal food, ITP and cosmetics
    - Infant formula, Produce, Cell cultured foods and Food Defense
    - Emerging new and novel food products
- FSMA implementation
- Outbreak Response

Office of Human Food Inspectorate (OHFI)

Scott MacIntire
OHFI West
Director

Glenn Bass
Acting OHFI
East Director



LaTonya Mitchell, Ph.D.
Acting OHFI Central Director

Prepared by ORA GIS Program, DAES, 2024

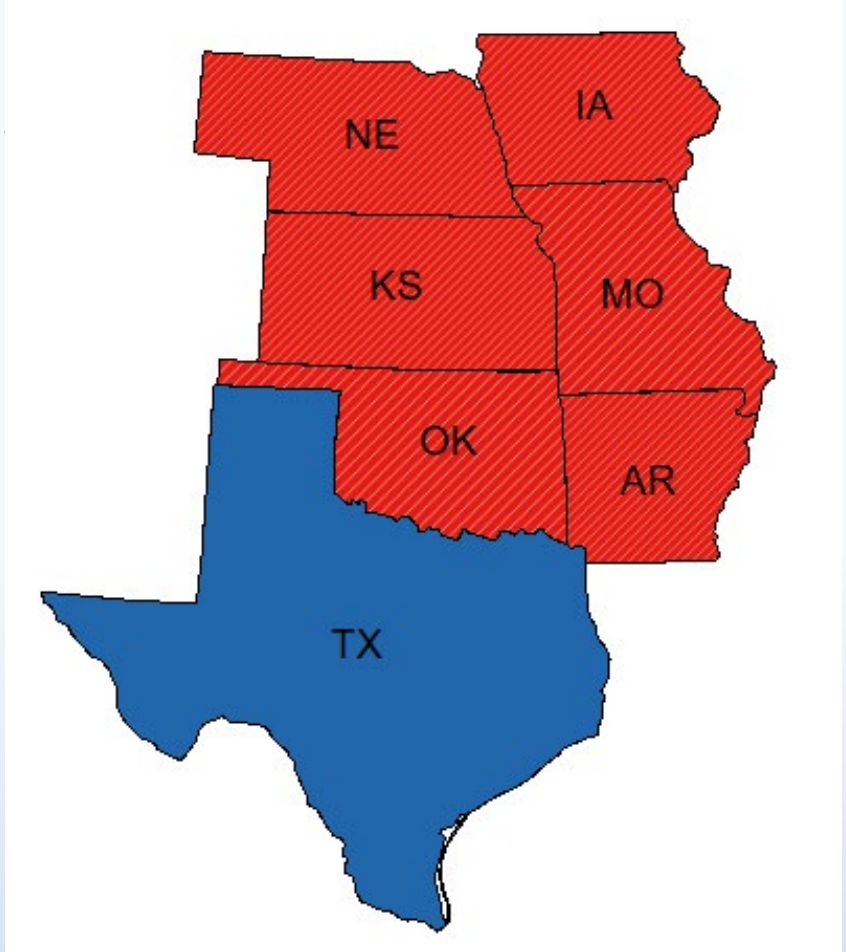
FDA Human Food Contacts

- Central Division 4 –

  IA, KS, MO, NE, OK, AR
  - Jeffrey Moody, Acting Division Directo
  - Sam Gibbons and Steve Allen, State Liaisons
  - Melissa Simanton, Recall Coordinator

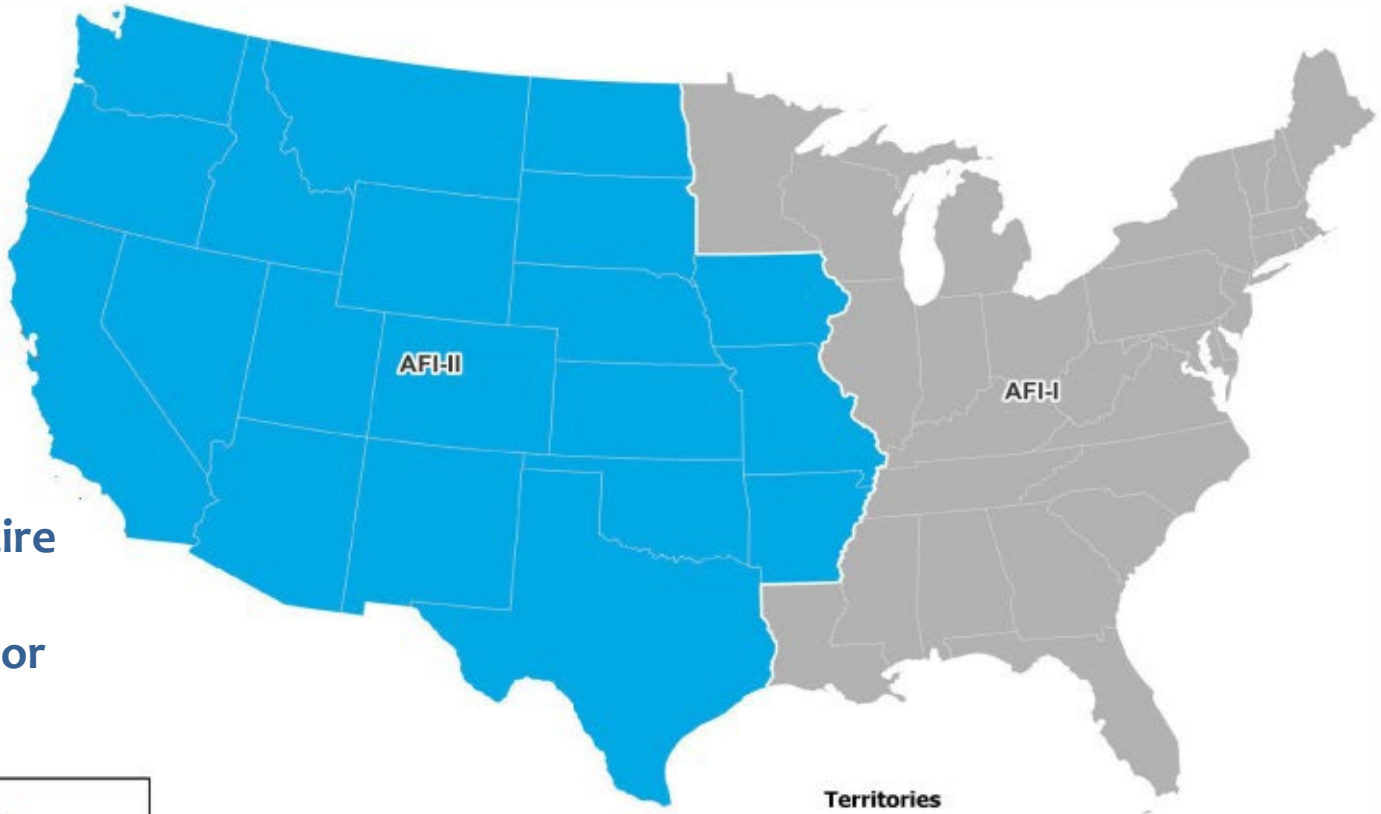
- Central Division 5 – TX
  - Edmundo Garcia, Division Director
  - Lourdes Genera, State Liaison
  - Brandi Williams, Recall Coordinator

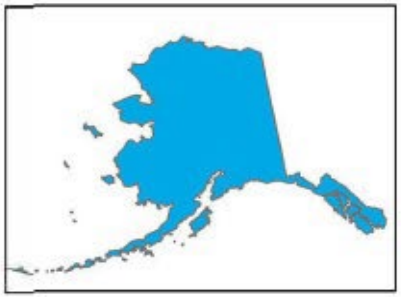
- Central 4 & 5
  - Erin Dugan, Emergency Response Coordinator



Office of Animal Food Inspectorate (OAFI)

Scott MacIntire
OAFI Acting
Office Director



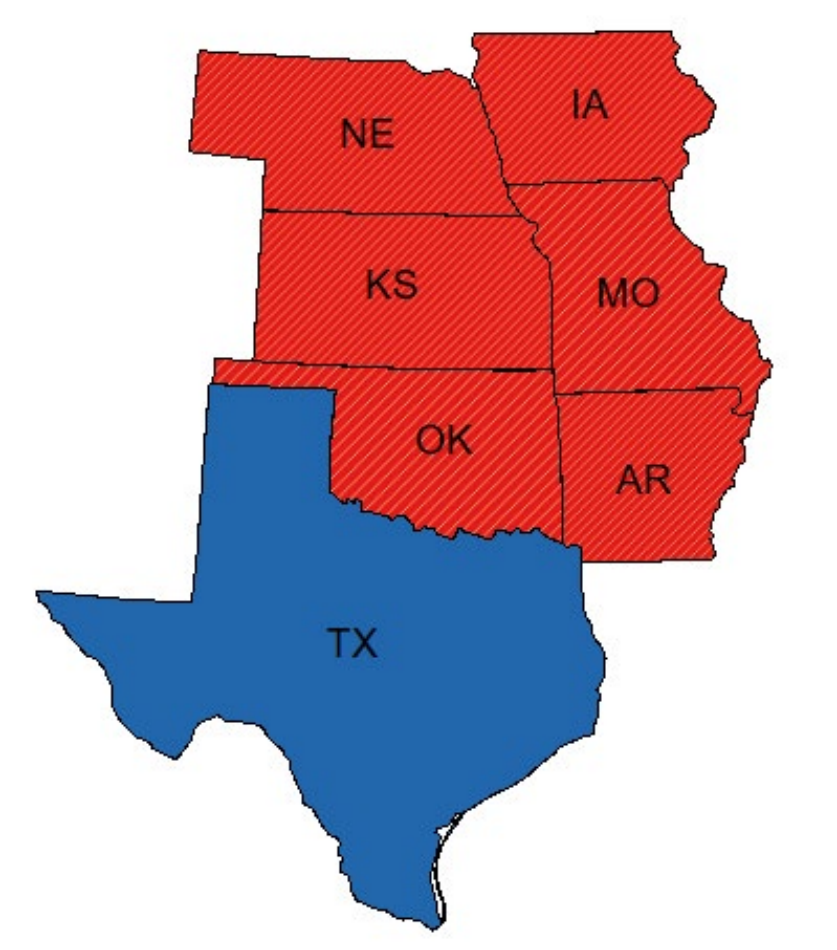


Territories
USVI
AS
GU
MP

OAFI Divisions
AFI-I
AFI-II
States

FDA Animal Food Contacts

- **Animal Food Inspectorate II**, includes IA, KS, MO, NE, OK, AR
  - Randy Pack, Acting Division Director
  - Alcee Tavarez, State Liaison for TX, NE, MO
  - Julie Vosilus, State Liaison for KS and IA
  - Nina Patel, Recall Coordinator



FY2026 Lapse in Funding

- During the lapse, FDA continued to ensure vital activities critical to ensuring public health and safety.
  - Food inspections
  - For-cause Inspections
    - Monitoring and responding to outbreaks
    - High-risk food product recalls

FDA'S RISK- BASED INSPECTIONS UNDER FSMA MANDATES

Using a Risk- Based Approach

- Focus on the highest risks
  - Targeting vulnerable food products
  - Focusing on facilities with a history of non-compliance
- Resource Planning
  - Directing staff to most critical needs
- Clear Decision-Making
  - Faster decision-making
  - Can quickly respond to new problems

Using a Risk- Based Approach

- Outbreaks and Recalls
  - Risk-based approach allows for quicker response to outbreaks as well as ensuring timely removal of unsafe food from distribution
- Emergency response
  - Working with the Human Foods Program and Emergency Response
  - Ensures inspection staff can spend time to prevent the most serious food safety problems.

Inspections under FSMA Mandates

- Using the risk-based approach
  - Prioritize facilities
    - Food type, processing methods, consumer vulnerability, and compliance history
- Inspection Frequency Requirements
  - High-risk facilities
    - Inspected every 3 years
  - Non-High-risk facilities
    - Inspected every 5 years
- Data-Driven Decision Making
  - The inspection frequency can increase –
    - Issues during previous inspections
    - Outbreaks
    - Recalls
    - Violative samples

FSMA Section 204: Food Traceability

- Original compliance date: January 20, 2026 – extended to July 20, 2028
- Establishes new recordkeeping requirements
- Persons who manufacture, process, pack, or hold foods on the Food Traceability List (FTL)
- Covers the entire food supply chain
- Includes both foreign and domestic entities
- Full and partial exemptions may apply

Food Traceability List

Cheese (made from pasteurized milk), fresh soft or soft unripened	Tomatoes (fresh)
Cheese (made from pasteurized milk), soft ripened or semi-soft	Tropical tree fruits (fresh)
Cheese (made from unpasteurized milk), other than hard cheese	Fruits (fresh-cut)
Shell eggs	Vegetables (fresh-cut)
Nut butters	Finfish (histamine-producing species) (fresh, frozen, and previously frozen)
Cucumbers (fresh)	Finfish (species potentially contaminated with ciguatoxin) (fresh, frozen, and previously frozen)
Herbs (fresh)	
Leafy greens (fresh)	Finfish, species not associated with histamine or ciguatoxin (fresh, frozen, and previously frozen)
Leafy greens (fresh-cut)	Smoked finfish (refrigerated, frozen, and previously frozen)
Melons (fresh)	Crustaceans (fresh, frozen, and previously frozen)
Peppers (fresh)	Molluscan shellfish, bivalves (fresh, frozen, and previously frozen)
Sprouts (fresh)	Ready-to-eat deli salads (refrigerated)

Enhanced Technologies and Future Landscape

Implementing Enhanced Technologies

- Observation and Corrective Action Report (OCAR)
  - Enhances the process for facilities
  - Submit documentation to address observations
  - Phasing in a voluntary Industry Portal
  - Real time, secure and private exchange of information between FDA and industry
- Keeping up with technology
  - Implementing mobile tools and AI
  - Mapping tools

Future Landscape

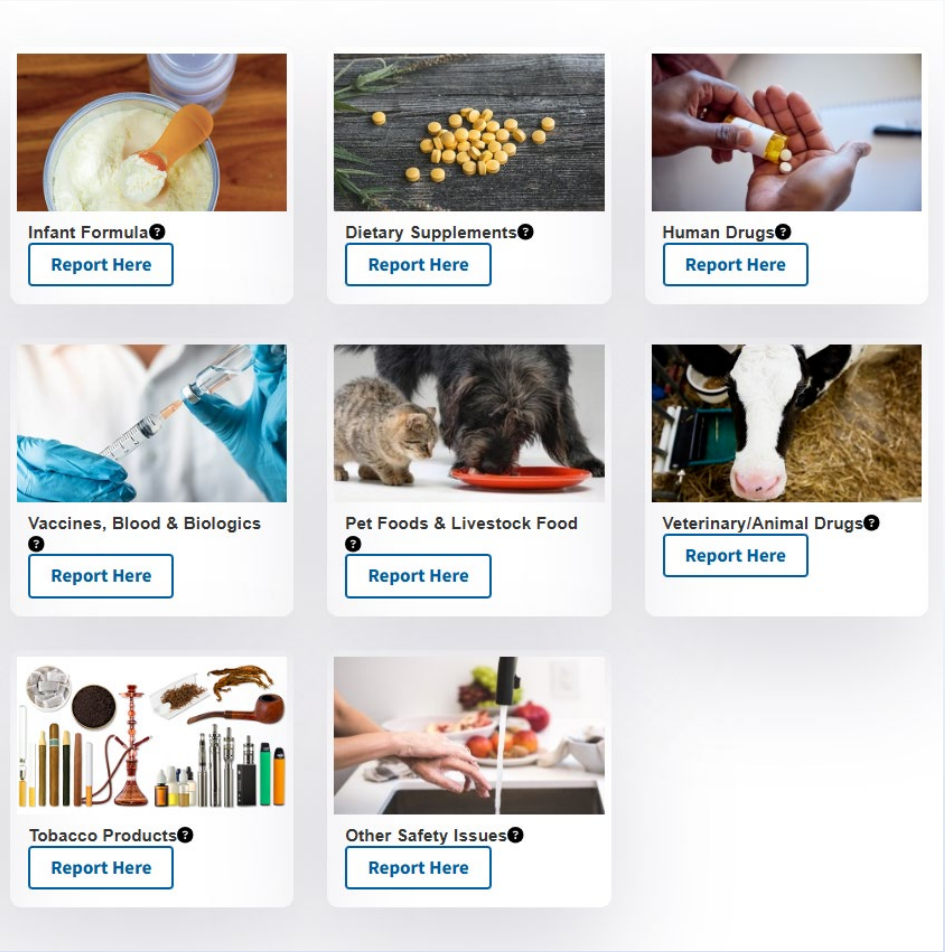
- Process Improvement
  - Modernizing inspection methods and models
  - Improve both quality and quantity of inspections
  - Scaling our inspectional capacity to keep pace with expanding global food chain
  - Monitor performance data

- The BRIDGE Project
  - Better Regulatory Inspections for Dynamic Government Efficiency

Report a Product Problem – Consumer Complaints and RFRs

Consumer Complaints

- Submit complaints via two methods:
- Visit FDA's SmartHub safetyreporting.fda.gov/smarthub
- Call 1-888-INFO-FDA



Reportable Food Registry (RFR)

Electronic Portal for Industry and Government Officials

Safety Reporting Portal

www.safetyreporting.hhs.gov

Who Should Use the Reportable Food Registry?

Registered Food Facilities that manufacture, process, pack, or hold food for human or animal consumption are required to report when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals.

Federal, state, and local government officials may voluntarily use the RFR portal to report information that may come to them about reportable foods.

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