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FDA FSMA Update

Presentation Overview

- FDA authority and key elements of its regulatory framework
- FSMA rules impacting the grain and feed industry
- Recent FDA inspection activity
- What's next from FDA
- Compliance resources

FDA Authority

- **U.S. Law: Definitions**
  - Section 201(f) Federal Food, Drug and Cosmetic Act (FFDCA):

    “The term “food” means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.”

Food Adulteration

- **According to the FFDCA, a food shall be deemed to be adulterated if it:**
  - is not produced and distributed in conformance with applicable FDA regulations
  - is missing a valuable constituent
  - contains any poisonous or deleterious substance which may render it injurious to health
  - contains any added poisonous or added deleterious substance that is unsafe or pesticide residue that is unsafe
  - contains any additive or animal drug that is unsafe
  - consists of any filthy, putrid, or decomposed substance or it has been prepared, packed, or held under insanitary conditions

Food Misbranding

- **According to the FFDCA, a food shall be deemed to be misbranded if:**
  - its labeling is false or misleading in any particular
  - it is offered for sale under the name of another food
  - it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard
  - any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon

Key Elements of U.S. Grain and Feed Industry Regulatory Framework

- FFDCA provides FDA broad authority to issue emanating regulations and inspect to ensure compliance
  - General provisions of FFDCA
  - Adequate sanitation – ensure food is not “adulterated” during manufacturing, packing or storage
  - FDA action, advisory, guidance levels for mycotoxins
  - BSE-Prevention Regulations
  - Records access in the event of food-related serious adverse health consequence
  - FDA Food Facility Registration
  - FDA Reportable Food Registry
  - FDA Recordkeeping Requirements for Food
  - Medicated Feed Current Good Manufacturing Practices (CGMPs)
  - Rules associated with Food Safety Modernization Act

FDA Food Facility Registration

- Food facilities that manufacture, process, pack or hold food intended for consumption in the United States are obligated to register with FDA as food facilities
  - Re-registration is to occur during even numbered years, during the Oct. – Dec. timeframe
  - Beginning in the 2020 renewal period, the registration process requires a Dun & Bradstreet Data Universal Numbering System (DUNS) number for each facility
  - Upcoming FDA webinar: Aug. 11, noon central

FDA Recordkeeping Requirements

- Facilities that manufacture, process, pack or hold food are to establish and maintain records to:
  - Identify immediate previous sources of all food received
  - Identify immediate subsequent recipients of all food released
  - Use reasonably available information to link specific inbound shipments of ingredients or raw materials to specific outbound shipments of finished product
  - For manufacturers, processors, packers, records must identify lot numbers (if they exist) of ingredients used to produce finished products

FDA Reportable Food Registry

- Food facilities are obligated to file a report with FDA within 24 hours through an electronic portal 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”

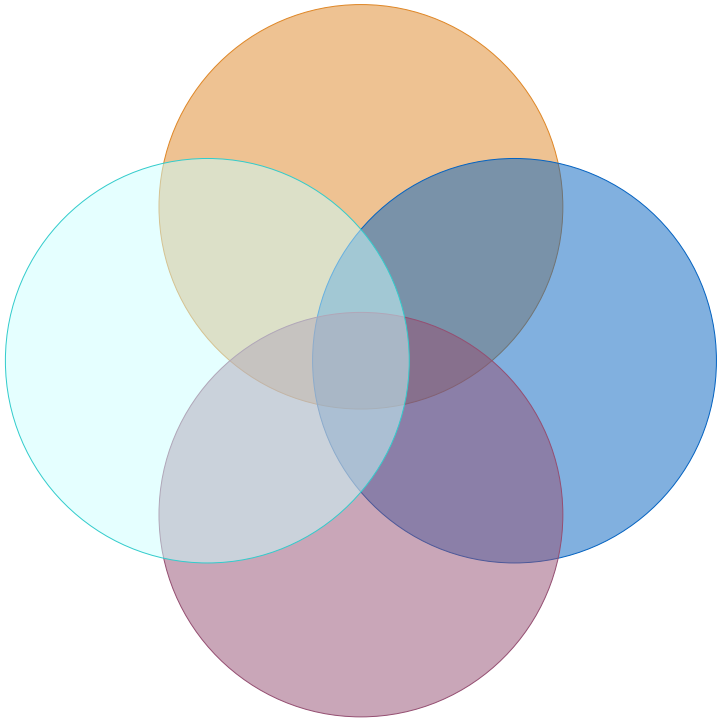
Food Safety Modernization Act of 2011

- Amended Federal Food Drug and Cosmetic Act and greatly expanded FDA's authority to regulate the U.S. food supply
  - Mandated that FDA create a **new prevention-based regulatory system** to ensure the safety of food products
  - Granted new authorities to FDA to ensure food safety
  - Directed FDA to implement several new, major food safety regulations

FSMA Snapshot

Prevention

Enhanced Partnerships



Inspections, Compliance, and Response

Import Safety

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Major FSMA Rules

1. Current Good Manufacturing Practice (CGMP) and Preventive Controls (PC) for Animal Food
2. CGMP and PC for Human Food
3. Produce Safety
4. Foreign Supplier Verification Programs (FSVP) for Importers
5. Sanitary Transportation of Human and Animal Food
6. Accredited Third-Party Certification
7. Mitigation Strategies to Protect Food Against Intentional Adulteration

FSMA Rules – Who's Covered

Rules Applicable to Animal Food	Rules NOT Applicable to Animal Food
Animal Food CGMP and PC	Human Food CGMP and PC
Foreign Supplier Verification Program	Produce Safety
Accredited Third-Party Certification	Intentional Adulteration
Sanitary Transportation	

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FSMA Rules – Who's Covered

FSMA Rule	Type of Operation(s) Performed at Single Facility			
	Grain Elevator (only)	Grain Elevator and Feed Mill (co-located)	Feed Mill – Animal Food	Grain Processor – Human and Animal Food
Animal Food CGMP and PC		XXX	XXX	XXX
Human Food CGMP and PC				XXX
Sanitary Transportation	XXX	XXX	XXX	XXX
Intentional Adulteration				XXX

FDA Inspections

- FDA is authorized to:
  - Enter “any factory, warehouse, or establishment in which food [is] manufactured, processed, packed, or held …” and “any vehicle….”
  - Inspect “at reasonable times and within reasonable limits and in a reasonable manner”
  - Inspect “all pertinent equipment, finished and unfinished materials, containers, and labeling thereon”
  - **No** warrant necessary for inspection

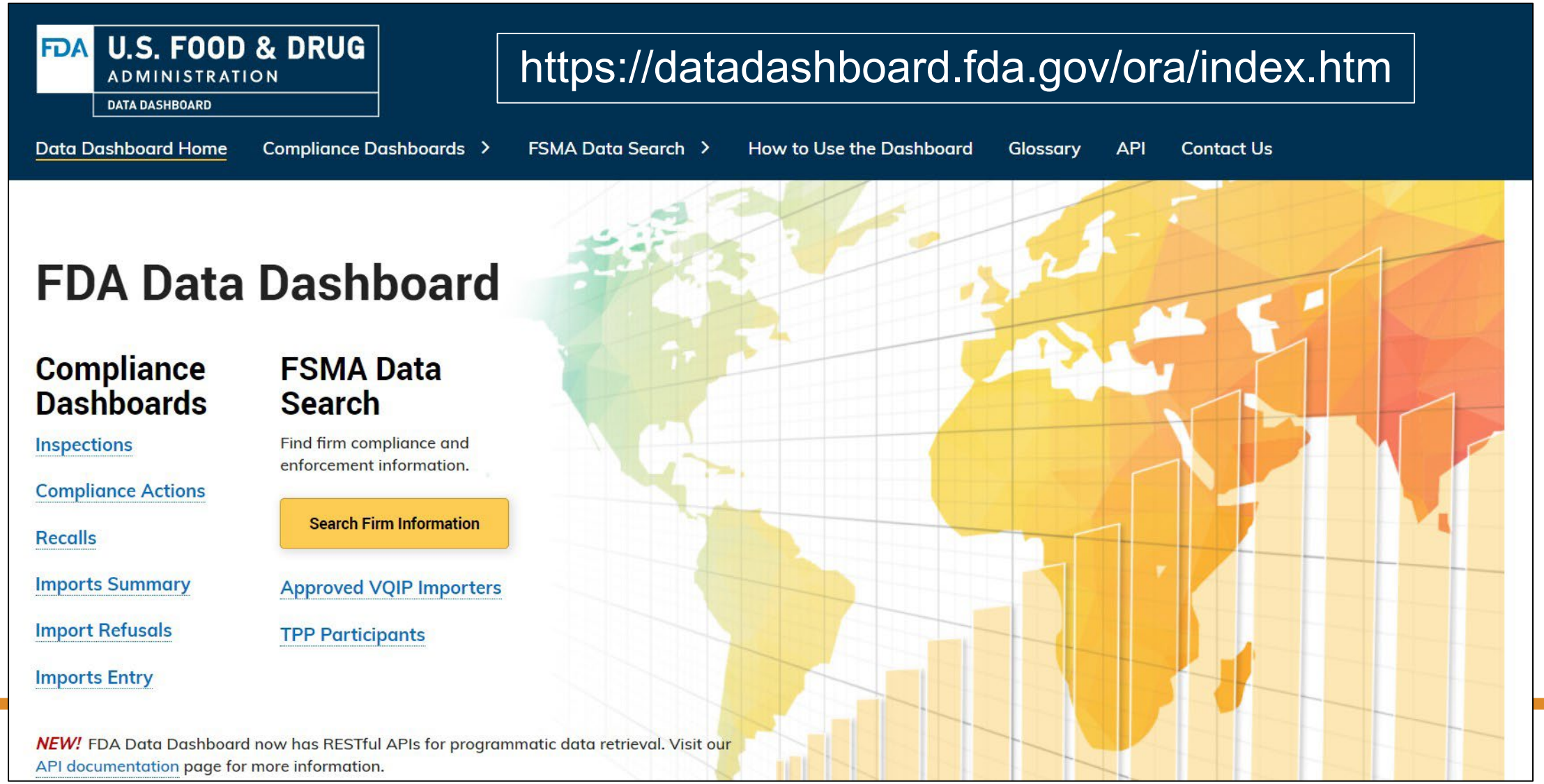
The Inspection Process

- Be prepared for “comprehensive” inspections
- Be prepared to respond to requests for information or records that are not expressly required by regulation
  - Customer complaints files
  - Lists of top customers and suppliers
  - Business volume information
  - Organizational charts
- Be prepared to deal with “grey” issues
  - Employee interviews
  - Pictures
  - Providing copies of records, confidential records
  - Signing affidavits/declarations

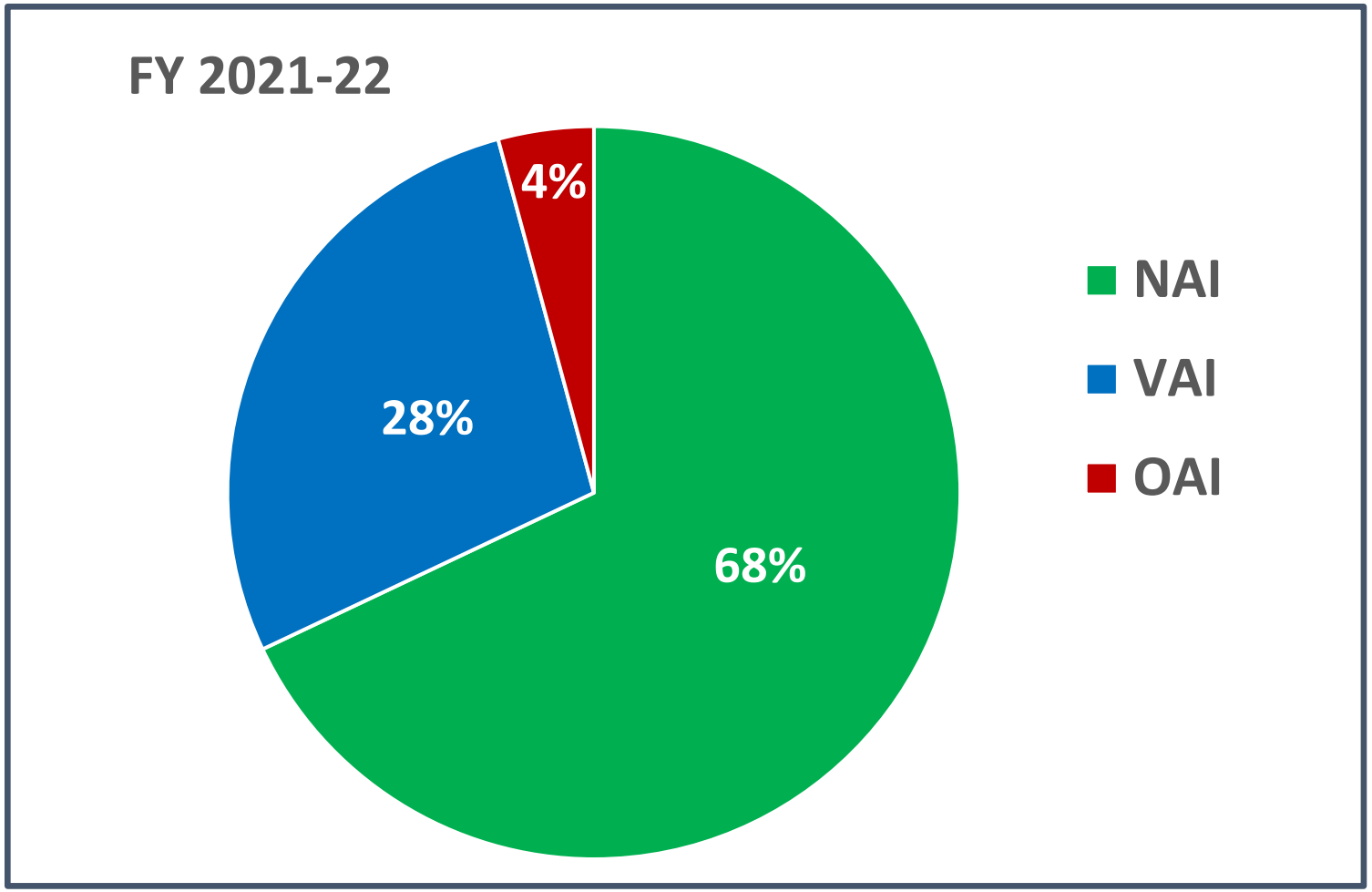
The Inspection Process

- FDA uses “Form FDA-483” to document inspectional observations (alleged violations)
- Inspections are classified as:
  - No Action Indicated (NAI)
  - Voluntary Action Indicated (VAI)
  - Official Action Indicated (OAI)
- If FDA believes enforcement action is warranted, the agency typically does not impose monetary penalties; instead, it has authority to:
  - Detain product
  - Mandate recalls
  - Seek consent decrees
  - Suspend facility registration

FDA Inspection Activity



Animal Food Facility Inspections Classifications



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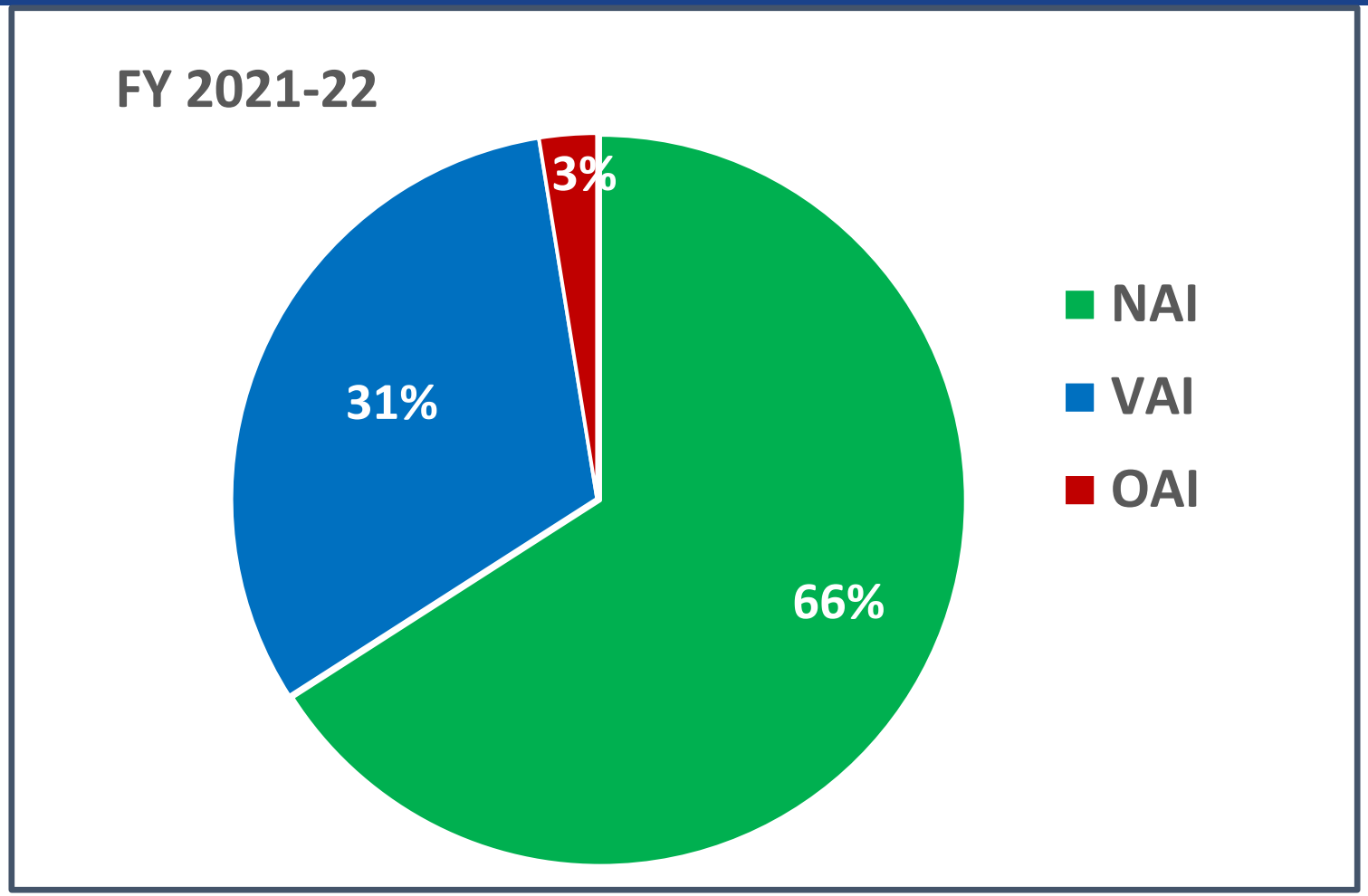
Top Animal Food Citations

1. Inadequate hazard analysis
2. Failure to identify and implement necessary preventive controls
3. No food safety plan
4. Inadequate sanitation and pest control
5. Failure to establish/implement appropriate corrective action procedures

Human Food Facility Inspections Classifications



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Top Human Food Citations

1. Inadequate sanitation and pest control
2. Failure to control microorganism and/or allergen contamination
3. Inadequate hazard analysis
4. Inadequate equipment/utensil design to protect against allergen contamination
5. Personnel practices are not adequate

Compliance Topics

- Increasing expectations by FDA for testing to control:
  - Mycotoxins
  - Nutrient deficiencies and toxicities
  - Pathogens in pet food
- Pathogenic viruses and feed – an emerging issue
  - African Swine Fever, Porcine Epidemic Diarrhea, High Pathogenic Avian Influenza

Compliance Topics

- Sanitary Transportation – Prior Cargoes
  - NGFA-led ag shipper group worked with Railinc to release an online application that provides the three most recent loaded waybills on covered hopper railcars
    - No one-time or on-going fees if the user's company has an existing Railinc Mark or Company ID

What's Next

- FDA Requirements for Additional Traceability Records for Certain Foods – Final Rule, anticipated Nov. 2022
- Revisions to Food Facility Registration Requirements – Notice of Proposed Rulemaking, anticipated Sept. 2022
- Guidance documents for final rules
  - Animal Food Supply Chain
  - Human Food By-Products Used as Animal Food

FSPCA

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Menu

FSPCA Home

COMMENTS, COMPLIMENTS & CONCERNS

The Food Safety Preventive Controls Alliance (FSPCA) is a broad-based public private alliance consisting of industry, academic and government stakeholders whose mission is to develop curricula, and training and outreach programs to support compliance with the prevention-oriented standards of the Food Safety Modernization Act (FSMA).

FSPCA 2022 ANNUAL CONFERENCE

Keeping Food Safe

In an Increasingly Challenging Business Environment

OCTOBER 19-20 VIRTUAL

Training

- List of FSPCA Participant Courses
- FSPCA Preventive Controls for Human Food
- FSPCA Preventive Controls for Animal Food
- Foreign Supplier Verification Programs (FSVP)
- Intentional Adulteration

The Alliance

- NEW! FSPCA Executive Advisory Board (EAB)
- Committees, Subcommittees, Work Groups

Quick Links

- Apply to Become a Lead Instructor
- FSPCA Advertising Requirements for Lead Instructors (Human Food)
- FSPCA Advertising Requirements for Lead Instructors (Animal Food)
- FSPCA Advertising Requirements for Lead Instructors (FSVP)
- FSPCA Advertising Requirements for Lead Instructors (IA VA)
- FSPCA Bookstore
- FSPCA Amazon Bookstore
- FSPCA Community
- FSPCA Lead Instructor Listing
- FSPCA Materials

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NGFA FDA Guidance

NGFA Guidance on FDA Regulations Applicable to Grain, Feed and Processing Industry

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