FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

27th Distillers Grain Technology Council CVM Updates

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Today's Menu

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- Guidance & Rulemaking
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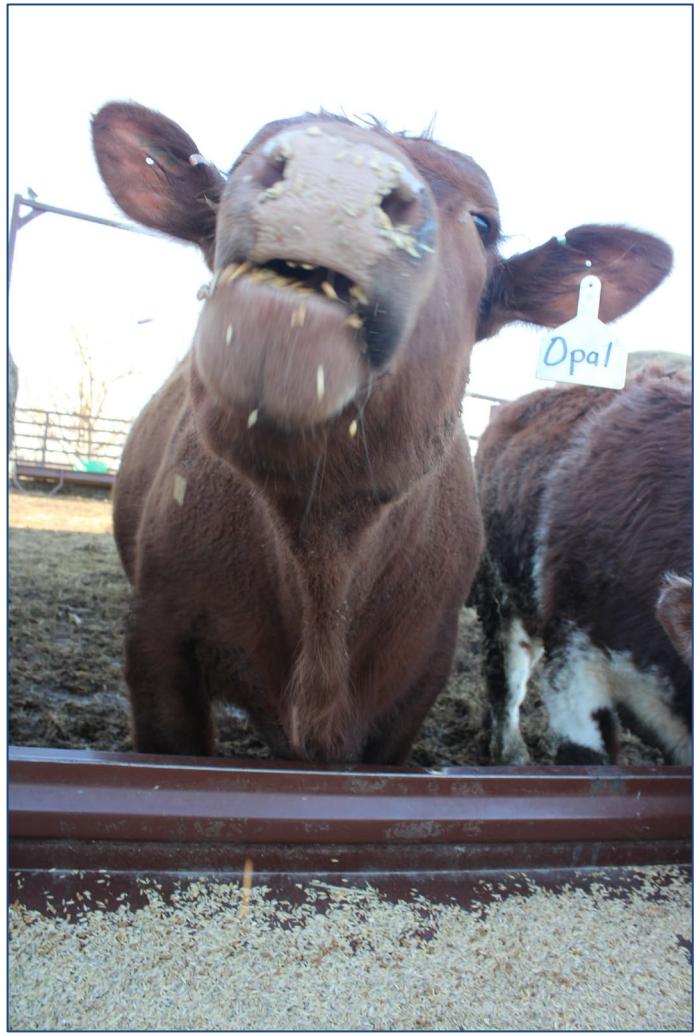
  - Upcoming Rulemakings & Guidance



Comprehensive Inspections

Animal Food Program Evolution

Past Approach

- Medicated Feed CGMPs
- BSE
- VFD
- Separate compliance programs
- Separate inspections
- State or FDA

Interim Approach

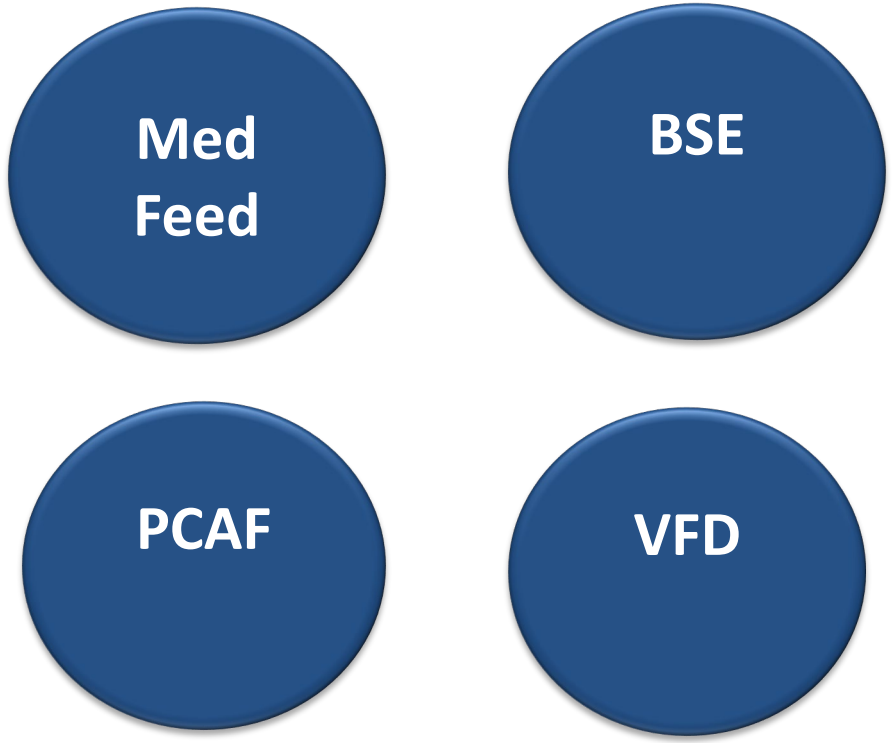
- PCAF CGMPS and PC inspections implemented
- Introduced comprehensive approach for FDA
- Encouraged comprehensive inspections for States

New Approach

- One all-encompassing inspection program
- True comprehensive inspections
- Based on lessons learned during interim approach from field/states

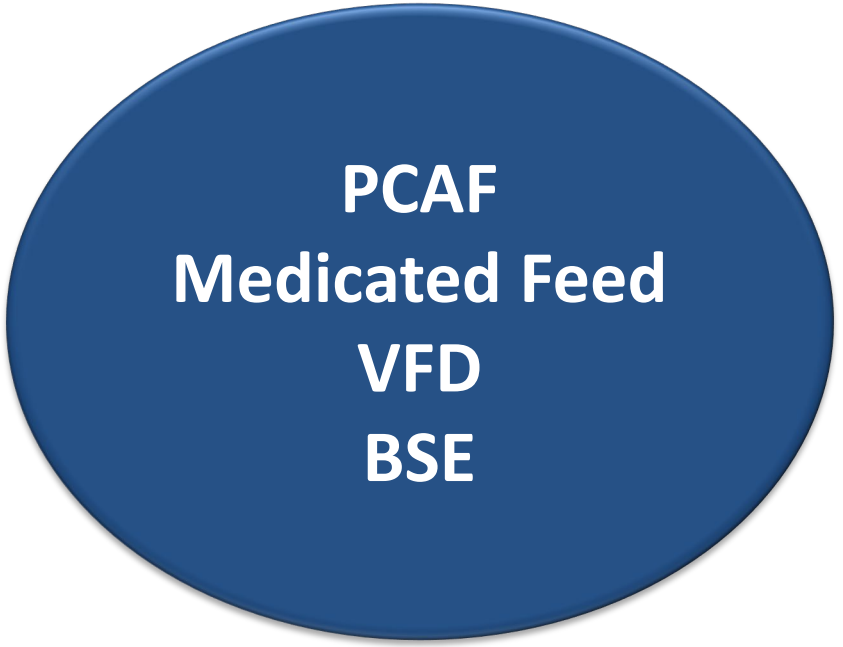
Animal Food Program Evolution

Old Approach



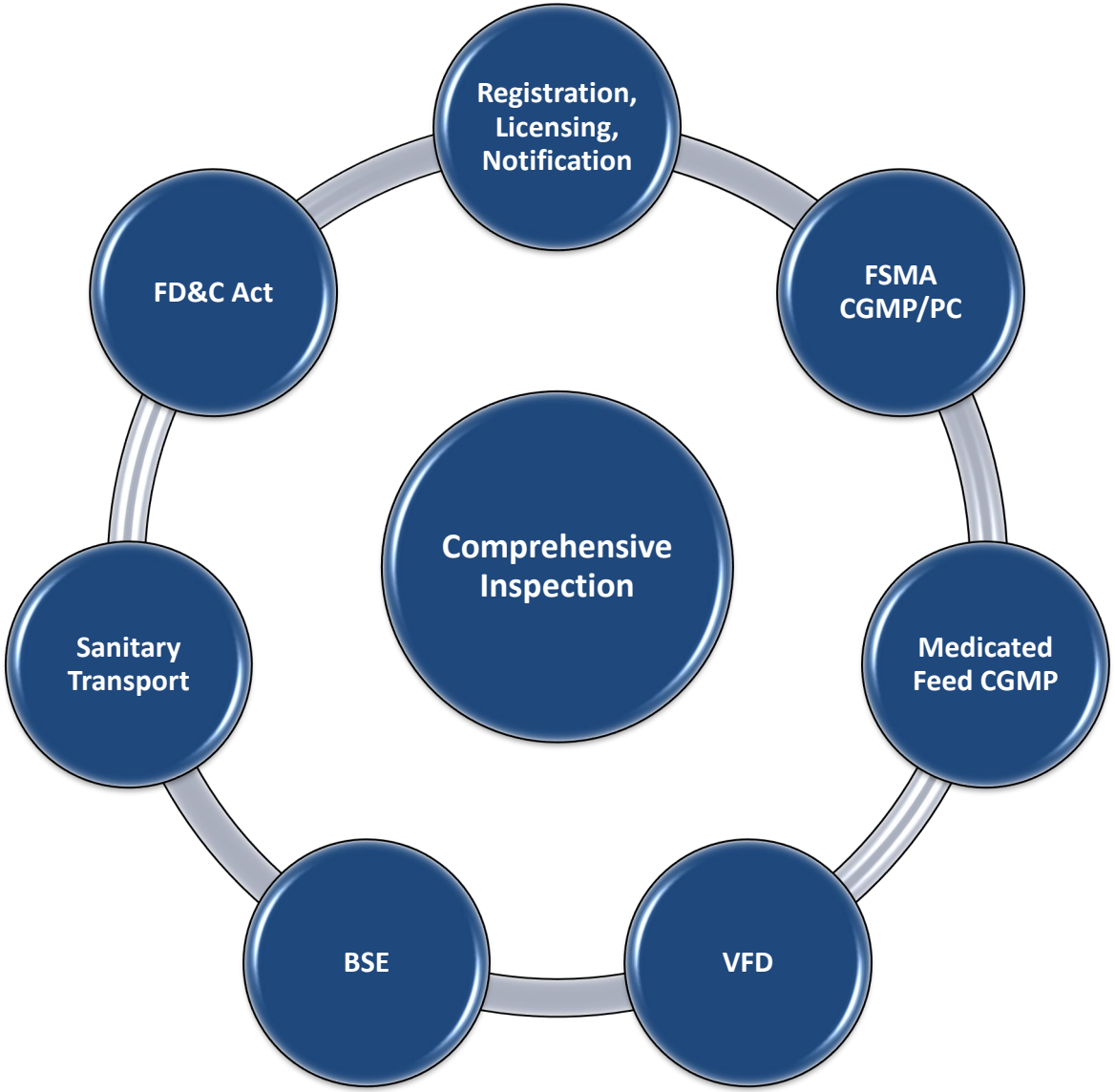
Up to 4 separate inspections

New Approach



1 comprehensive inspection

Comprehensive Inspection



Comprehensive Inspection Approach

Facility Example	Applicable Requirements
Non-licensed medicated feed mill **Required to register as a food facility** **Handles prohibited materials** **Handles VFD drugs** **Ships in bulk**	• Non-licensed Medicated Feed CGMP Requirements • PCAF CGMPs and Preventive Control Requirements • BSE Requirements • VFD Requirements • Sanitary Transportation Requirements
Licensed medicated feed mill on a farm **Not required to register as a food facility (meets the definition of a farm)** **Does not handle prohibited material, or VFD**	• Licensed Medicated Feed CGMP Requirements

Inspection Priorities/Basis

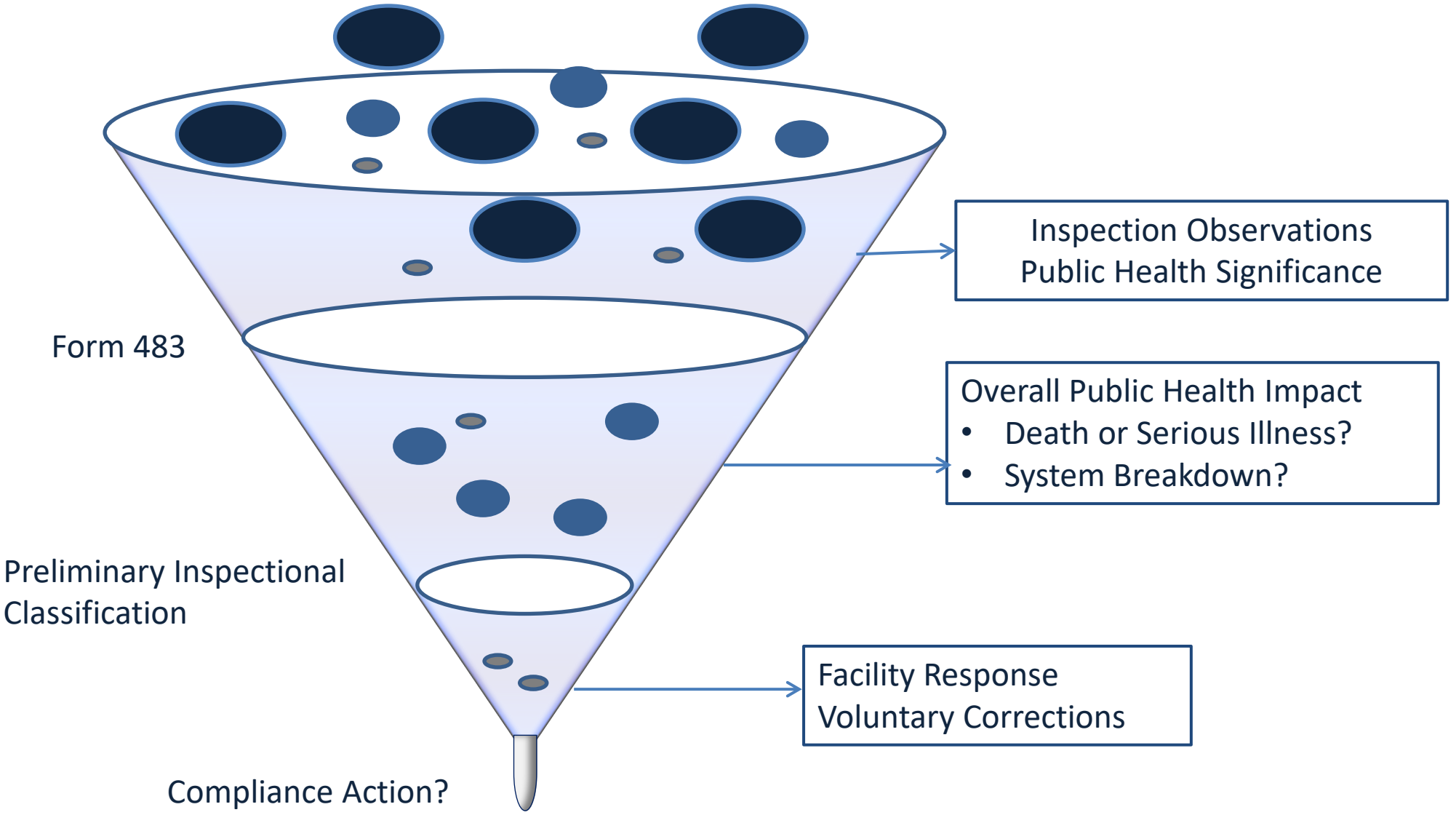
What to Expect During an Inspection

- Display Credentials Notice of Inspection
- Initial Interview
- Requests to review documents
- Walk through the facility
- Questions, questions, questions

What to Expect During an Inspection

- What are we looking for during an inspection?
  - Overall food safety system and culture
  - Food safety plan
    - Decisions you've made in the FSP (e.g., pre-requisites, use of compliance with other regulations, hazard evaluation outcomes)
    - Your approach to identifying and controlling hazards
    - How you verify hazards are controlled and perform corrective actions and reanalyze as needed
- Inspection Close-out Discussion
    - Significance of findings, if any.

What to Expect After an Inspection



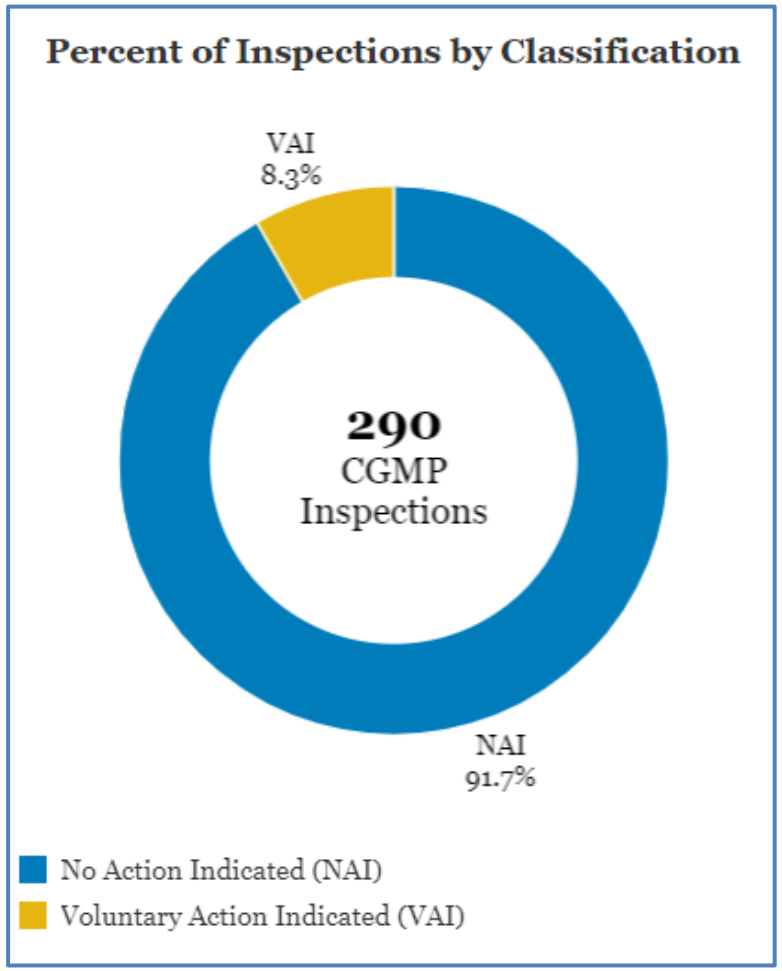
Inspectional Updates

Inspectional Classifications

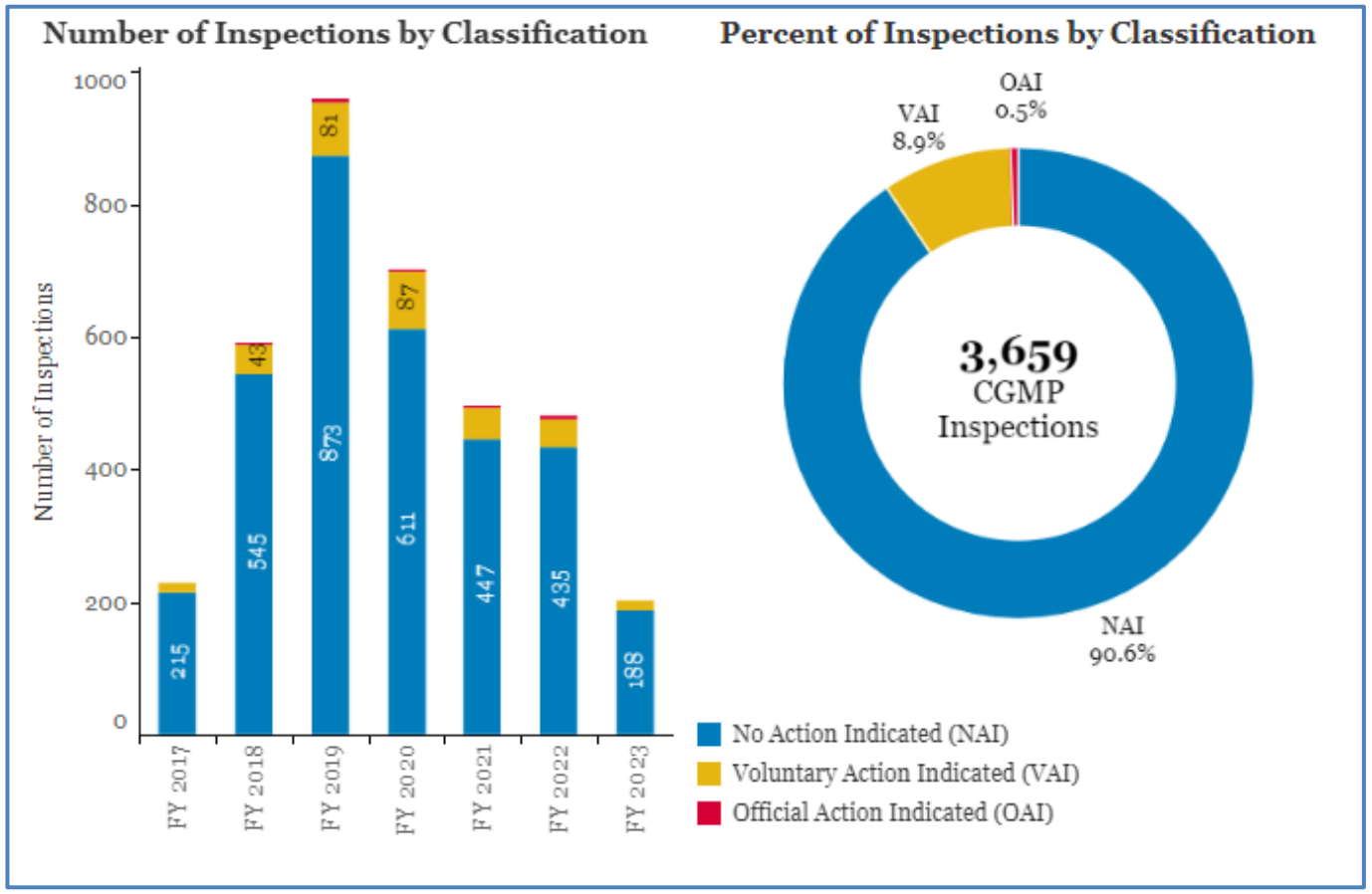
- No Action Indicated (NAI)
  - No objectionable conditions or practices were found during the inspection (or the significance of the documented objectionable conditions found does not justify further action).
- Voluntary Action Indicated (VAI)
  - Objectionable conditions were found and documented but the Agency is not prepared to take or recommend any of the regulatory actions since the objectionable conditions do not meet the threshold for regulatory action.
- Official Action Indicated (OAI)
  - Objectional conditions were found, and regulatory action should be recommended.

FSMA Metrics – CGMP Inspections

FY23 FDA and State CGMP Inspections

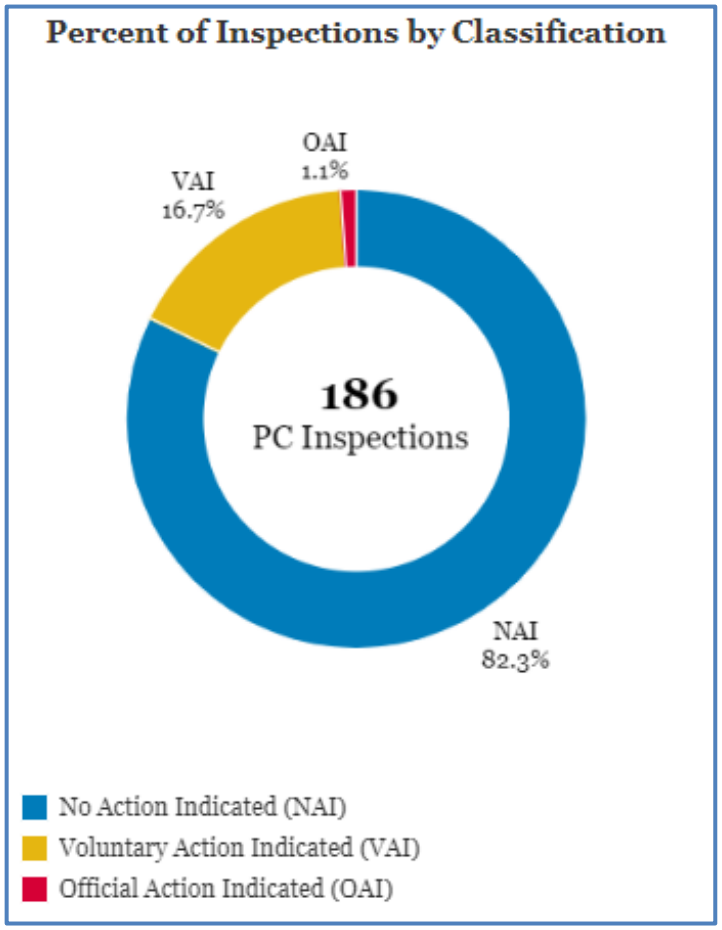


Historical FDA and State CGMP Inspections

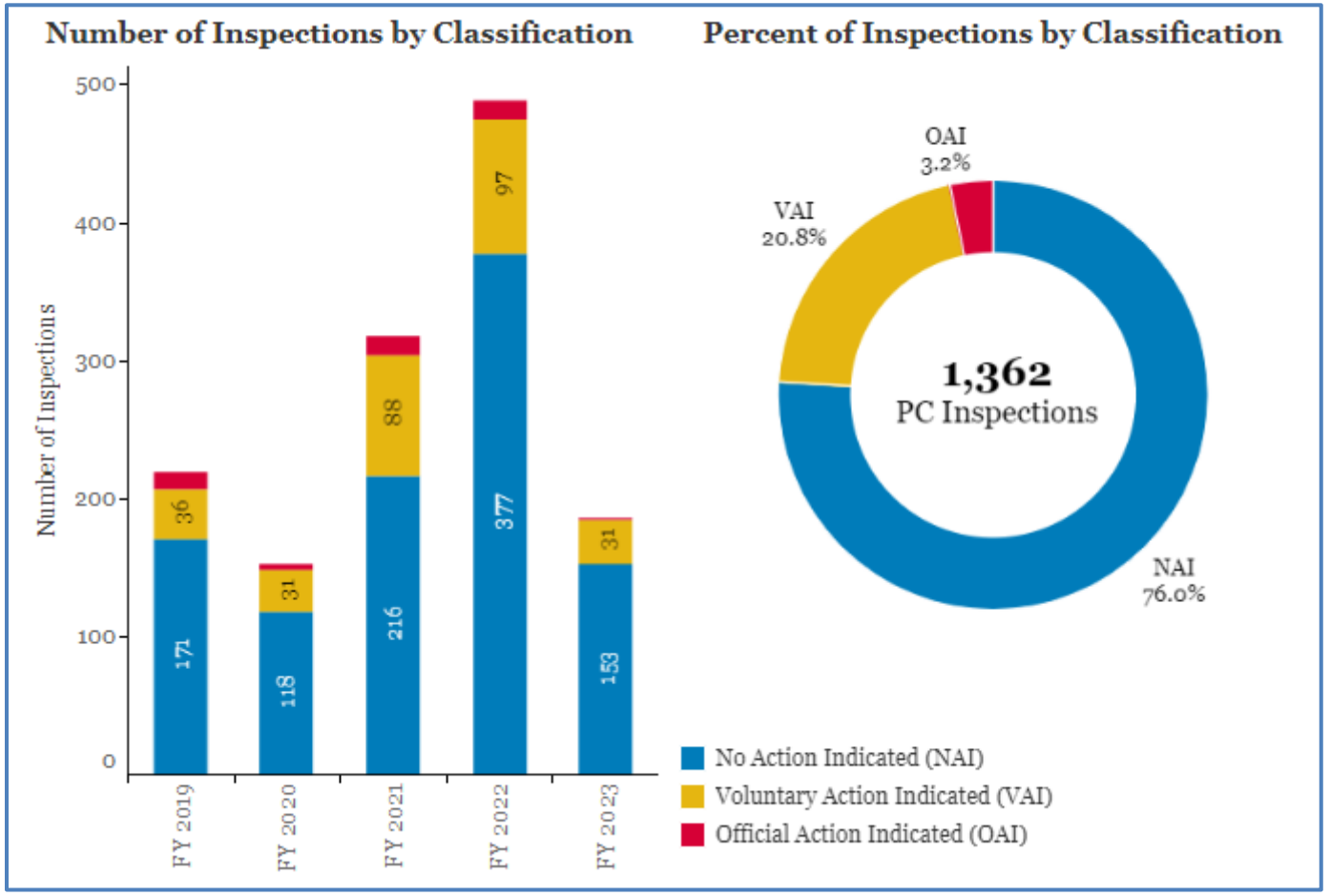


FSMA Metrics – PC Inspections

FY23 FDA and State PC Inspections



Historical FDA and State PC Inspections



Common Food Safety Observations

- CGMP Observations
  - Evaluation of raw materials/ingredients
  - Take adequate precautions to ensure plant operations do not result in contaminated animal food

Common Food Safety Observations

- PC Observations
  - Failure to identify/implement PCs
    - Includes failures in design and implementation of pre-requisite programs
  - No written Food Safety Plan
  - No written hazard analysis or evaluation of each known or reasonably foreseeable hazard

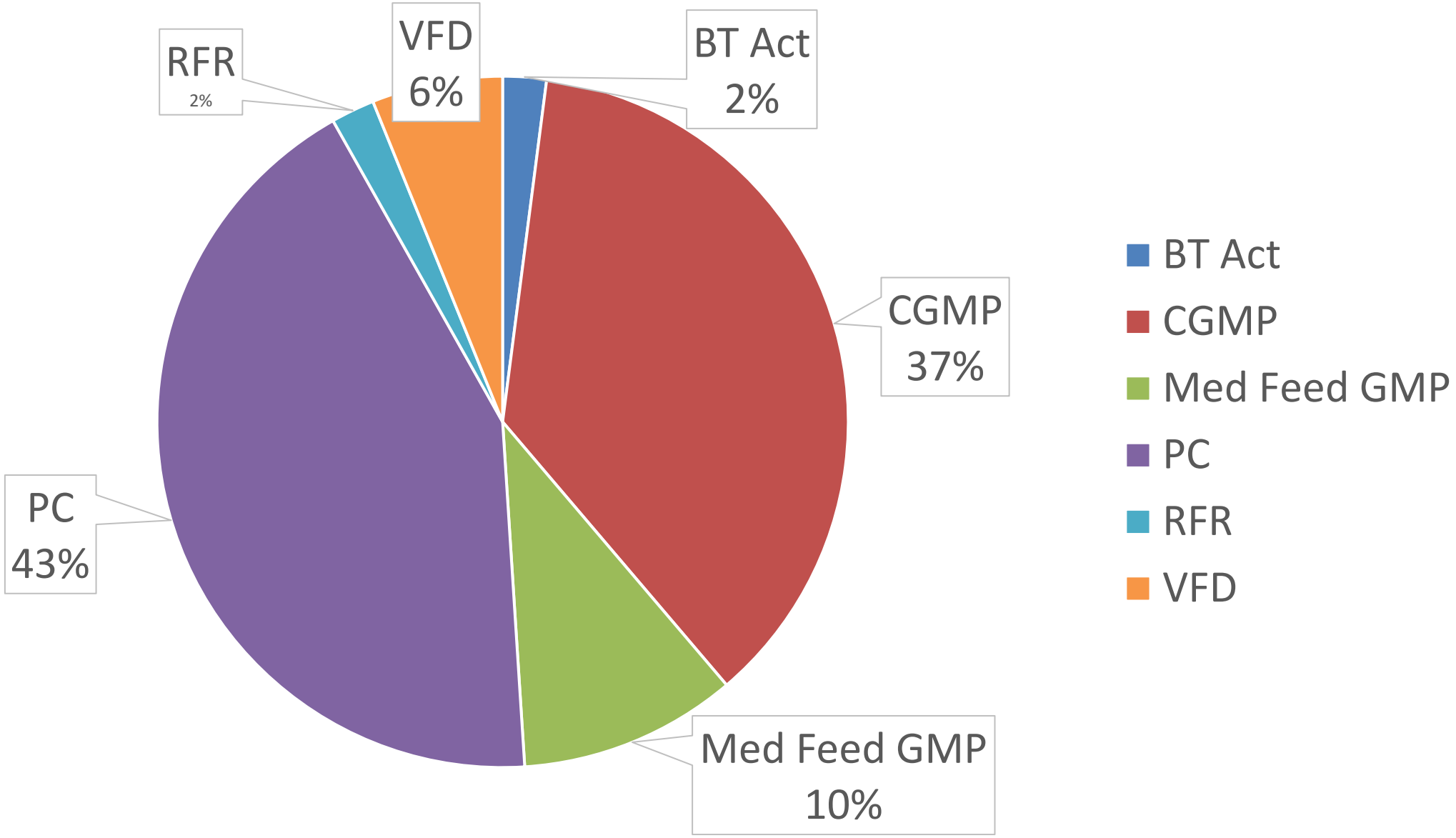
Pre-Requisite Programs

- Used to reduce probability a hazard will occur in the absence of a preventive control. Frequently used for hazards such as:
  - Aflatoxin and other mycotoxins
  - Drug carryover and nutrient deficiency/toxicities
- Must be robust & consistently implemented to support hazard analysis determinations
- Pre-requisite program design and implementation failures have been a frequent root cause of recall and compliance situations

Common Non-FSMA Citations

- Medicated Feed – Drug Components
  - Not properly identifying, storing, handling, or controlling drugs to maintain their integrity and identity (licensed medicated feed mills)
  - Drug components are not identified and stored in a manner such that their identity, strength, quality and purity will be maintained (non-licensed feed mills)
- Medicated Feed – Assays/Investigations
  - Not conducting three periodic assays (licensed medicated feed mills)
  - Not conducting an investigation when assays of drug components do not meet permissible drug levels (non-licensed feed mills)
- VFD
  - Failure to file a VFD Distributor Notification with FDA

Citations by Requirements



Mycotoxins

Mycotoxin CGMP & PC Requirements

- CGMPs
  - Evaluate Raw Materials & Ingredients (507.25(b)(2))
  - Maintain appropriate storage conditions (507.25(c)(1))
- PC Requirements
  - Identify known or reasonably foreseeable hazard (507.33(b)(1))
  - Assess the severity and probability (507.33(c)(1))

Sampling & Regulatory Information

- Surveillance Sampling
- Multi-analyte method development
  - Currently developed for human food matrices and corn
  - Development ongoing for animal food matrices
  - Regulatory action levels and guidance can be found at the link below
  - Mycotoxins | FDA

Mycotoxin Sampling

- Currently we have 2 primary sampling streams
  - FDA samples over the last 6 years
    - 39 samples of distillers grain products in last 6 years, analyzed for aflatoxin (32), fumonisin (4), vomitoxin (9) and zearalenone (2)
  - Lab Flexible Funding Model (LFFM) samples from participating states over the last 3 years
    - 71 samples of distillers grain products in last 3 years, analyzed for aflatoxin (61), fumonisin (61), vomitoxin (22), zearalenone (38) and ochratoxin (1)

Fumonisin Esterase

- Speaking of fumonisin, FDA approved fumonisin esterase as a food additive for use in animal food in August 2022
- It's purpose is to degrade fumonisins in swine feed and details are found in 21 CFR 573.485
- Represents an advance in feed ingredient technology, but is limited to use in swine and poultry feed that does not contain more than 10 ppm total fumonisin
- Not a silver bullet to manage fumonisin in the corn crop, but possibly a glimpse of the types of technology on the horizon

Rulemaking & Guidance

Final GFI #245

- Hazards
  - Appendix E -> Use Chapter 3
  - Included broad discussion of viruses as a type of biological hazard
- Reanalysis
  - Examples about when a reanalysis would be required and when it would not
- Prerequisite Programs
  - Adequate information about the program must be in your HA evaluation
- Additional information on hazards – e.g., more recent recalls

Future Rulemaking & Guidance

- FDA-TRACK: Unified Agenda-TRACK | FDA
  - Amendments to Registration of Food Facilities (i.e., farm definition)
  - Current Good Manufacturing Practice and Risk-Based Preventive Controls for Food for Animals (Written Assurances)
  - Other (e.g., Co-manufacturing/Supply-Chain)
- Guidances Under Development for 2022 | FDA
  - Diversion and Reconditioning (#277)
  - Human Food By-Products (#239)
  - Supply-chain (#236)
  - Veterinary Feed Directive (#120)

Questions?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