AFIA®
American Feed Industry Association

Our Industry. Our Passion. Our Voice.

Overview of Completed FSMA Inspections

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American Feed Industry Association

AFIA members include:

- Ingredient Suppliers
- Feed Manufacturers
- Associations
- Industry Support
- Pet Food Manufacturers
- Educational Institutions
- Pharmaceuticals
- Equipment Manufacturers
- Media

Represents **75%** of the feed (236 million tons) in the U.S.A. and **70%** of the non-grain ingredients

Nearly 700 members

Founded in 1909

Based in Arlington, VA

FSMA Snap Shot

Signed into law January 4, 2011

- **The current food safety system has opportunity for improvement.**
  - —1 in 6 Americans (48 million) sickened, 128,000 hospitalized, 3,000 die each year from foodborne diseases (CDC, 2011);
  - —**Identified by FDA as the most sweeping reform of food safety laws in more than 70 years.**
  - —GOAL: Aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it.

Preventive Controls for Animal Food Timeline

- January 2011: FSMA signed into law
- October 2013: First version issued (Proposed Rule)
- September 2014: Second version issued (Revised Rule)
- September 2015: Final rule published

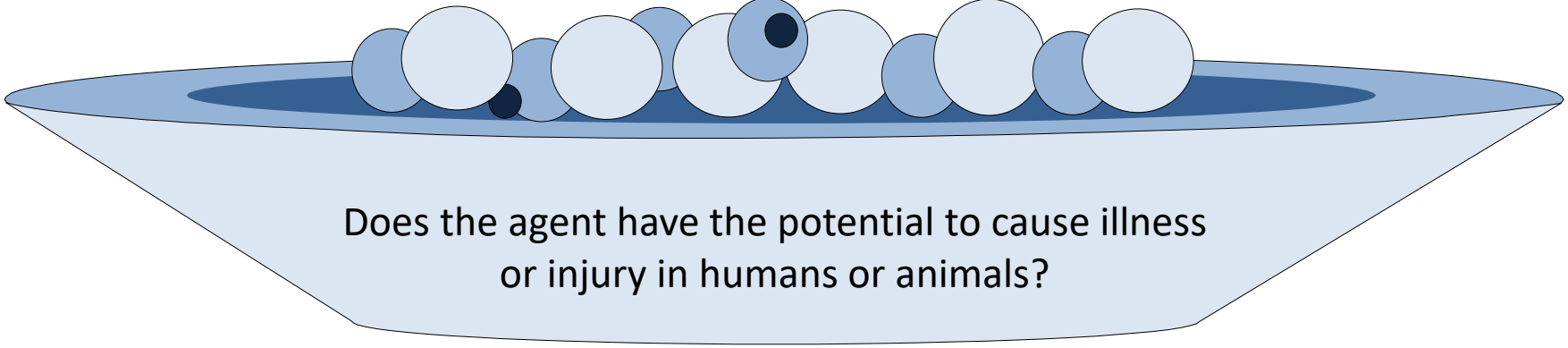
Business Size	Subpart B Current Good Manufacturing Practice	Subpart C Hazard Analysis and Risk-Based Preventive Controls
All Others (>500 FTE)	Sept. 19, 2016	Sept. 18, 2017
Small Businesses (< 500 FTE)	Sept. 18, 2017	Sept. 17, 2018
Very Small Businesses (< $2.5 million/year)	Sept. 17, 2018	Sept. 17, 2019

What Does FSMA Require?

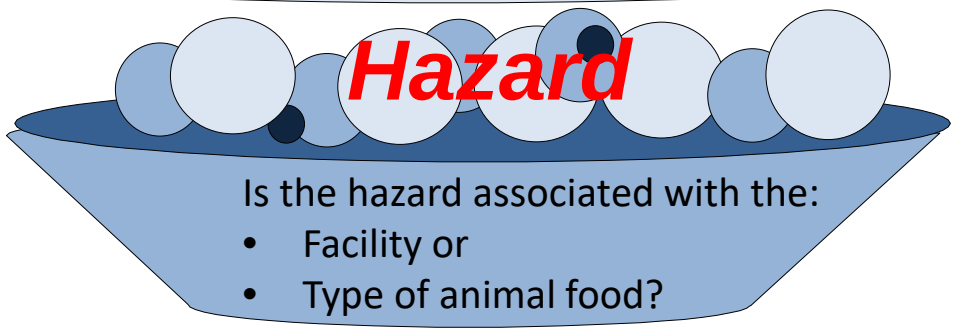
- **Facilities that manufacture, process, pack or <u>hold</u> animal food must (includes retail):**
  - Comply with CGMP requirements
  - Train Qualified Individuals (almost everyone working in a mill)
- **Facilities that <u>manufacture, process or pack</u> must also:**
  - Designate and train a Preventive Controls Qualified Individual (PCQI)
  - Conduct a Hazard Analysis
  - Develop a written Food Safety Plan to address the hazards identified

What is a FSMA Hazard Analysis?

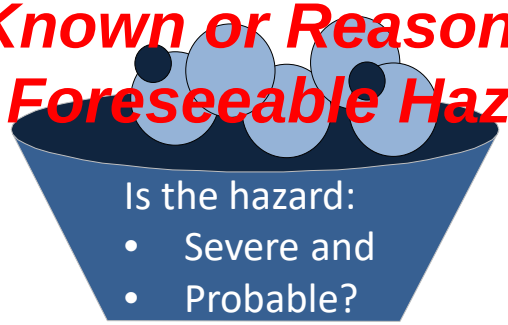
- Varies by facility
- Consider ingredients and processes
- Identify hazards to animals as well as humans
- Most difficult part of FSMA compliance



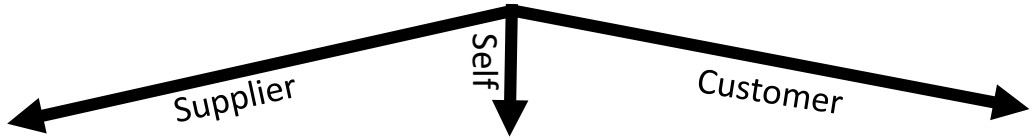
Hazard



Known or Reasonably Foreseeable Hazard



Hazard Requiring a Preventive Control



Supply-Chain-Applied Controls

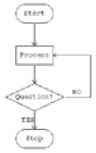
Process, Sanitation, Other Controls

21 CFR 507.36

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Hazard Analysis Process

1. List Ingredients and Steps/Equipment within the Process Flow (recommended)

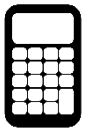


2. Identify *Known or Reasonably Foreseeable Hazards*

3. Assess Severity of Illness or Injury if Hazard were to Occur

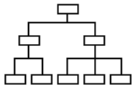
4. Assess Probability that the Hazard will Occur in the Absence of Preventive Controls

5. Determine if the Hazard Requires a Preventive Control



6. Justify the Classification of the Hazard

7. Determine the Control for the *Hazard Requiring a Preventive Control*



8. Assign a Preventive Control Number (recommended)

Required Documentation

All of your food safety information should be assembled into a written Food Safety Plan

- The format is flexible
- Describes the facility's risk-based approach to managing the identified hazards

Complete Framework of FSMA for Animal Food

- **Preventive Controls for Animal Food (Part 507)**
  - CGMPs
  - Hazard Analysis
  - Food Safety Plan
- **Foreign Supplier Verification Program (FSVP) for Importers**
- **Sanitary Transportation of Human and Animal Food**
- **SF/SF can help**

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FSMA Inspections FDA FY2019
What We've Learned


VOICE


REPRESENTATION


EXPERTISE

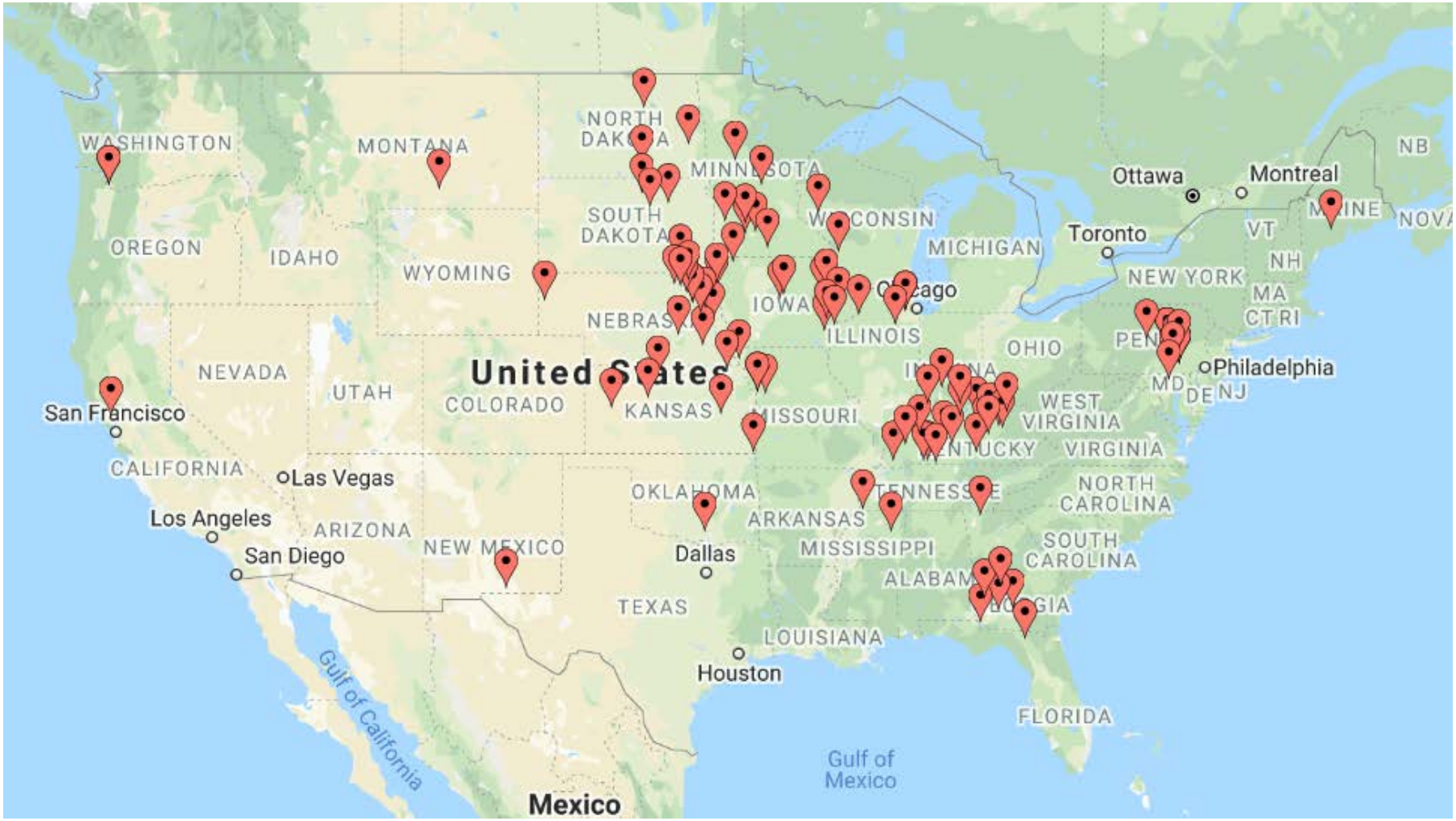

ENGAGEMENT

FDA CGMP Inspections & FOIA Data

- 626 inspections performed and completed during calendar year FDA FY2019
- Inspections held in 37 states, Brazil, Canada, China, India, Ireland, Mexico & Morocco
- 69% feed/integrators; 11% pet food; 16% ingredients/renderers; 3% warehouses; 1% food & beverage or other/unknown
- 51 Form 483s were issued, 25 NAIs were issued, 14 were not classified; 11 VAI and 1 OAI
- AFIA has copies of most 483s issued
- Facility type and geographic diversity consistent

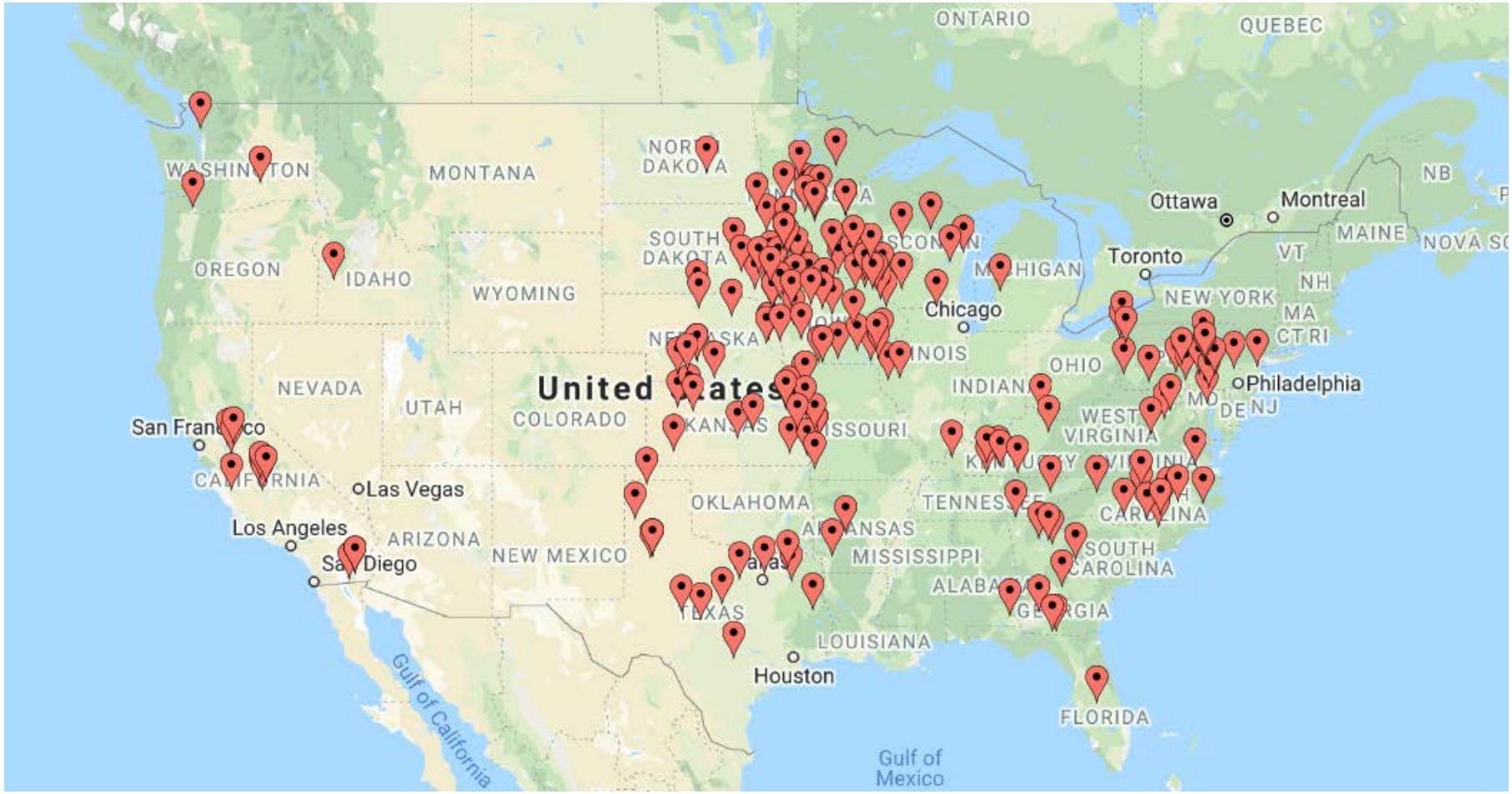
FDA CGMP Inspections by location

Q1 2019



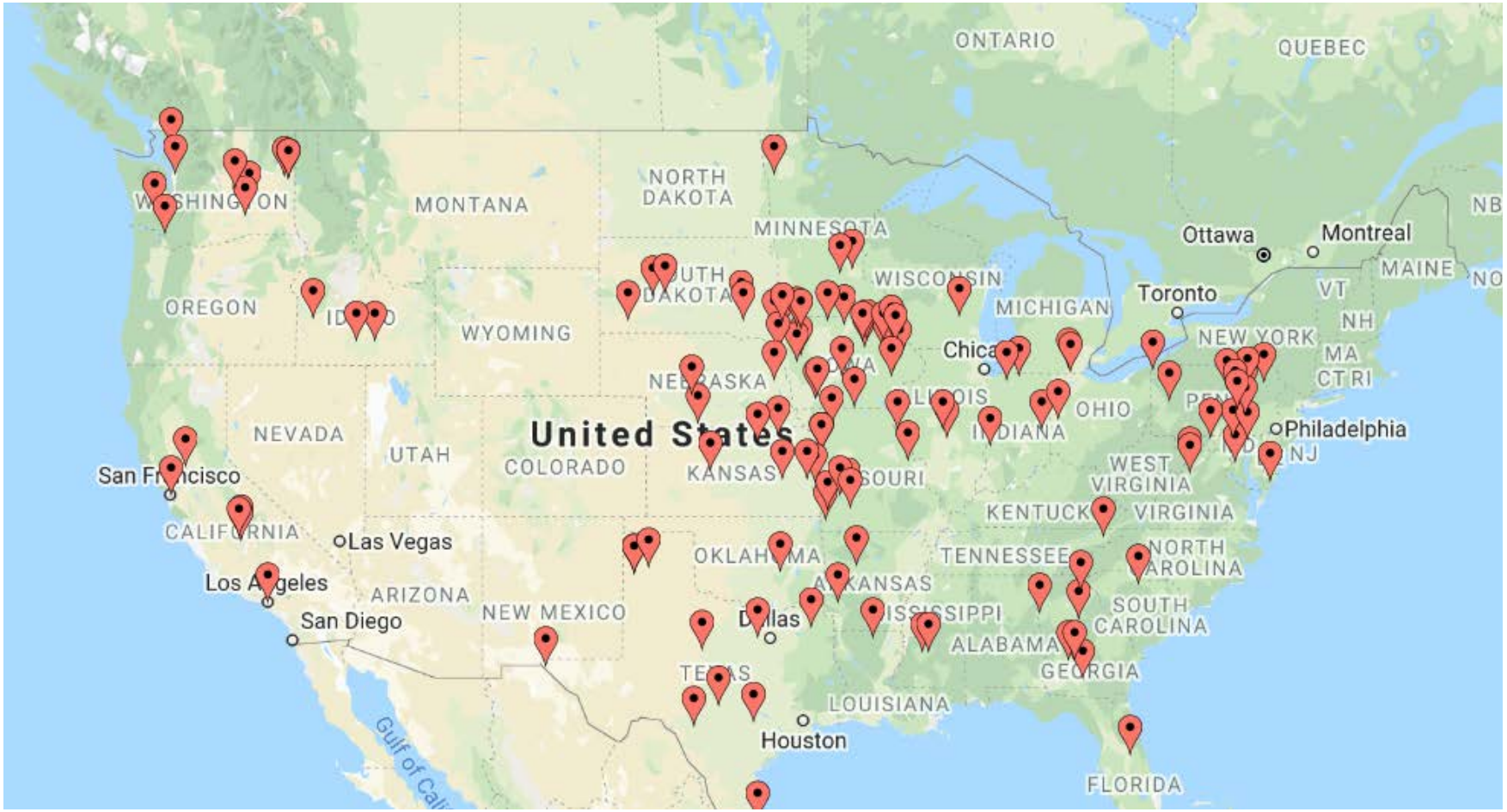
FDA CGMP Inspections by location

Q2 2019



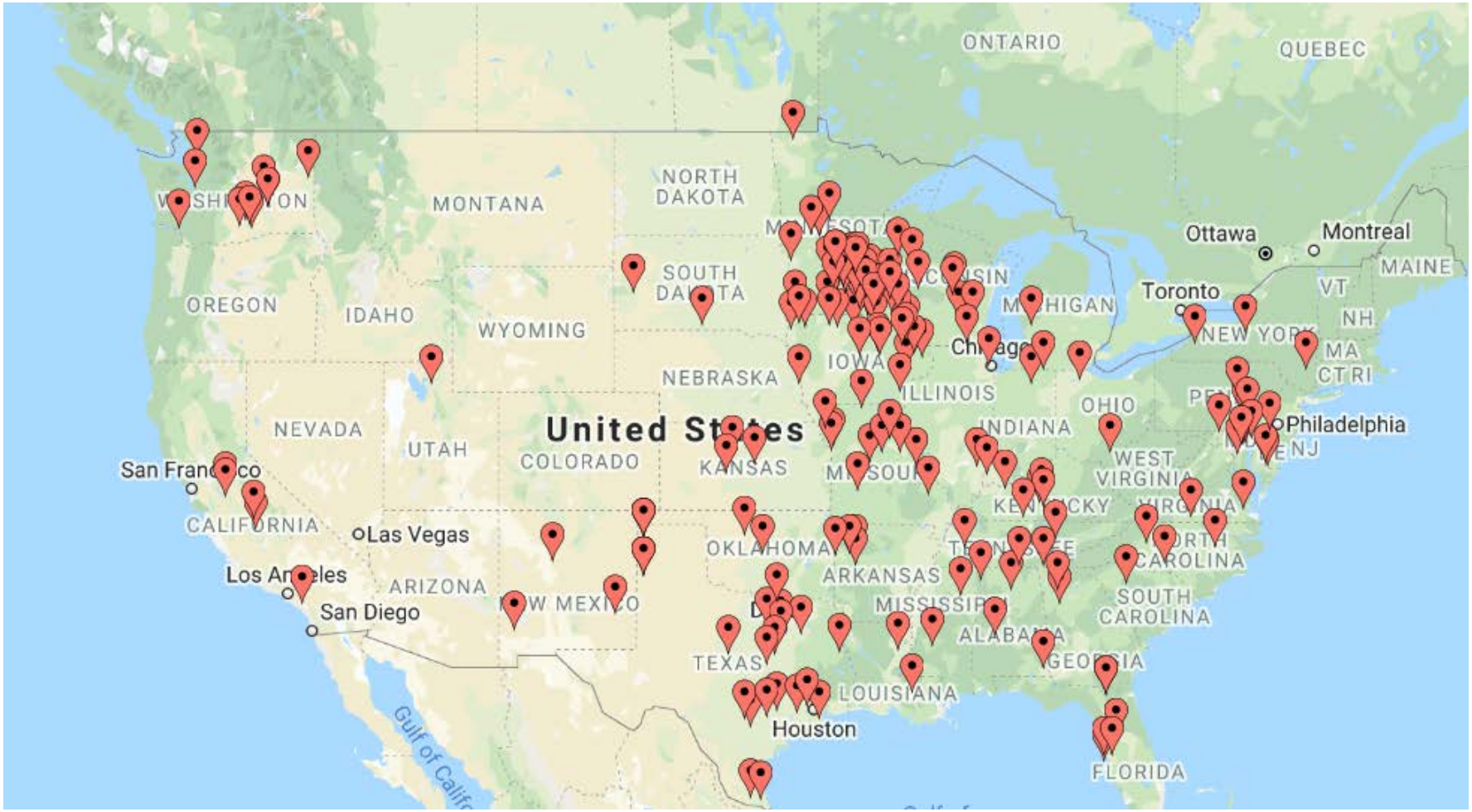
FDA CGMP Inspections by location

Q3 2019



FDA CGMP Inspections by location

Q4 2019



CGMP Inspection Activity Calendar 2018

- **What we've learned so far:**
  - They usually do a thorough walk-thru of the plant
  - Pest control seems to be a major focus
  - Unlabeled containers and trash cans is a frequent observation
  - They are asking to see QI training documentation
  - They are asking about the PCQI and training
  - They have visited several retail commodity blenders
  - Frequently, they are asking to see records for which they are not entitled to see
- **The best preparation for an inspection is familiarity with the rule**

FDA CGMP Inspection 483s

- 51 Form 483s were issued; most have been viewed by AFIA Staff via FOIA
  - Pest Control
    - Spilled feed (of various amounts)
    - Bird droppings
    - Rodents (live and dead)
    - Bird nests
    - Cat urine/feces
    - Cockroaches

FDA CGMP Inspection 483s Con't

- 51 Form 483s were issued
  - Equipment not properly installed to allow for cleaning
  - Failure to identify toxic chemicals
    - That would prevent contamination of animal food
  - Animal food contact surfaces made from improper materials or improperly maintained
    - Unprotected, non-shatter proof light bulbs
    - Roof leak
  - Failure to maintain plant in "clean manner" to prevent animal food from contamination
  - Improper storage of utensils and equipment

CGMP Inspections: Frequent 483 Citations

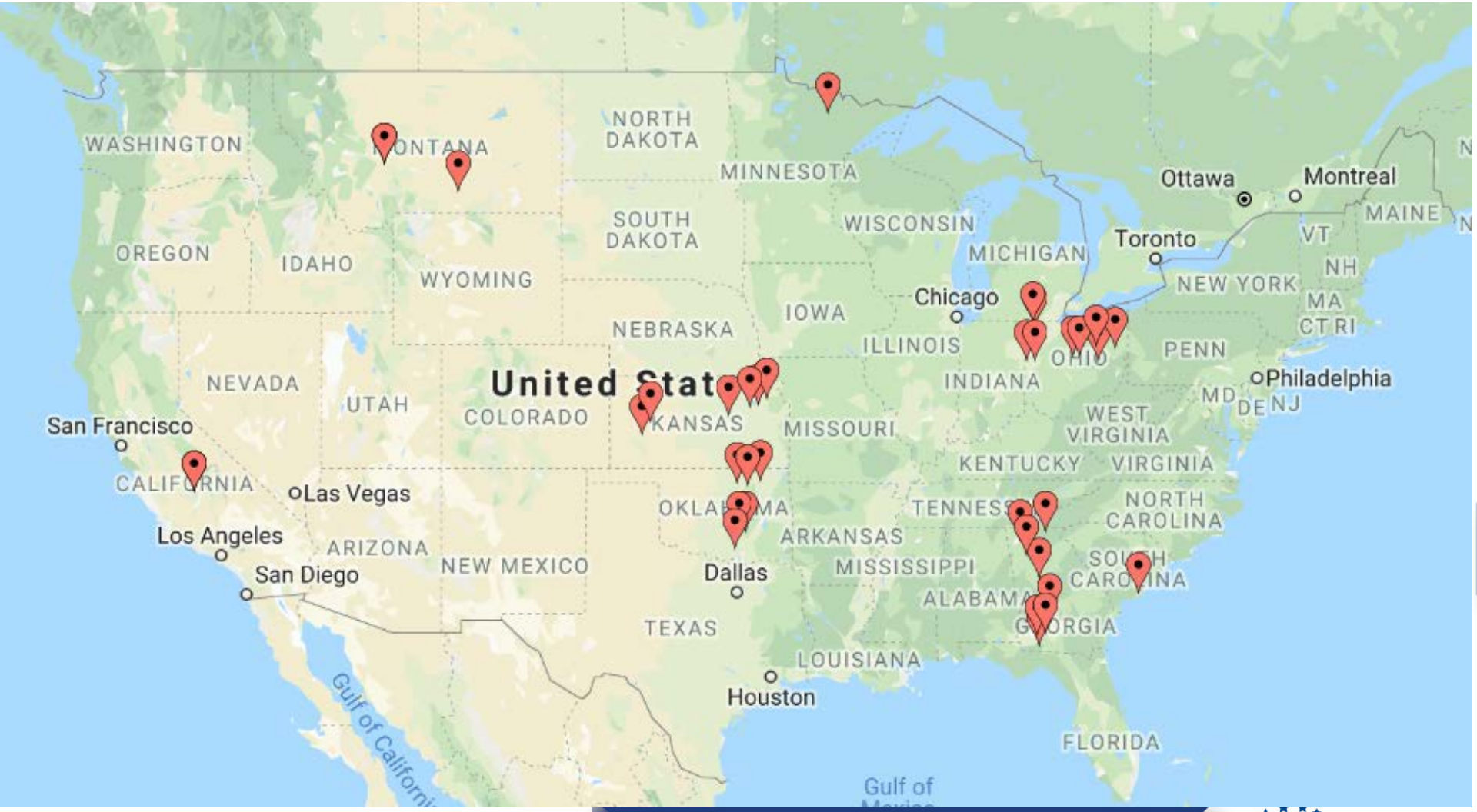
- 21 CFR 507.25(a): Plant Operations
  - Unlabeled containers
  - Easy catch all for various perceived violations
- 21 CFR 507.19(a): Plant Maintenance
- 21 CFR 507.19(b): Plant Sanitation
  - Plant housekeeping
- 21 CFR 507.19(e): Pest Control
  - Evidence of insect or rodent infestations
  - Pest Control program in place
- 21 CFR 507.25(b)(1): Raw Material Control
  - Ingredient/raw material examination
  - Mycotoxin program

FDA VFD Inspections FOIA

- 598 inspections performed and completed during FDA FY2019
- Inspections held in 35 states, with more than 60% in IA, MN, KS, NE and OH
- 71% Distributors (Retailers), 24% Farms and 4% at Veterinary facilities
- 49 Form 483s were issued, 12 VAIs were issued, 7 were not classified; 30 were NAI
- Facility type and geographic diversity questionable

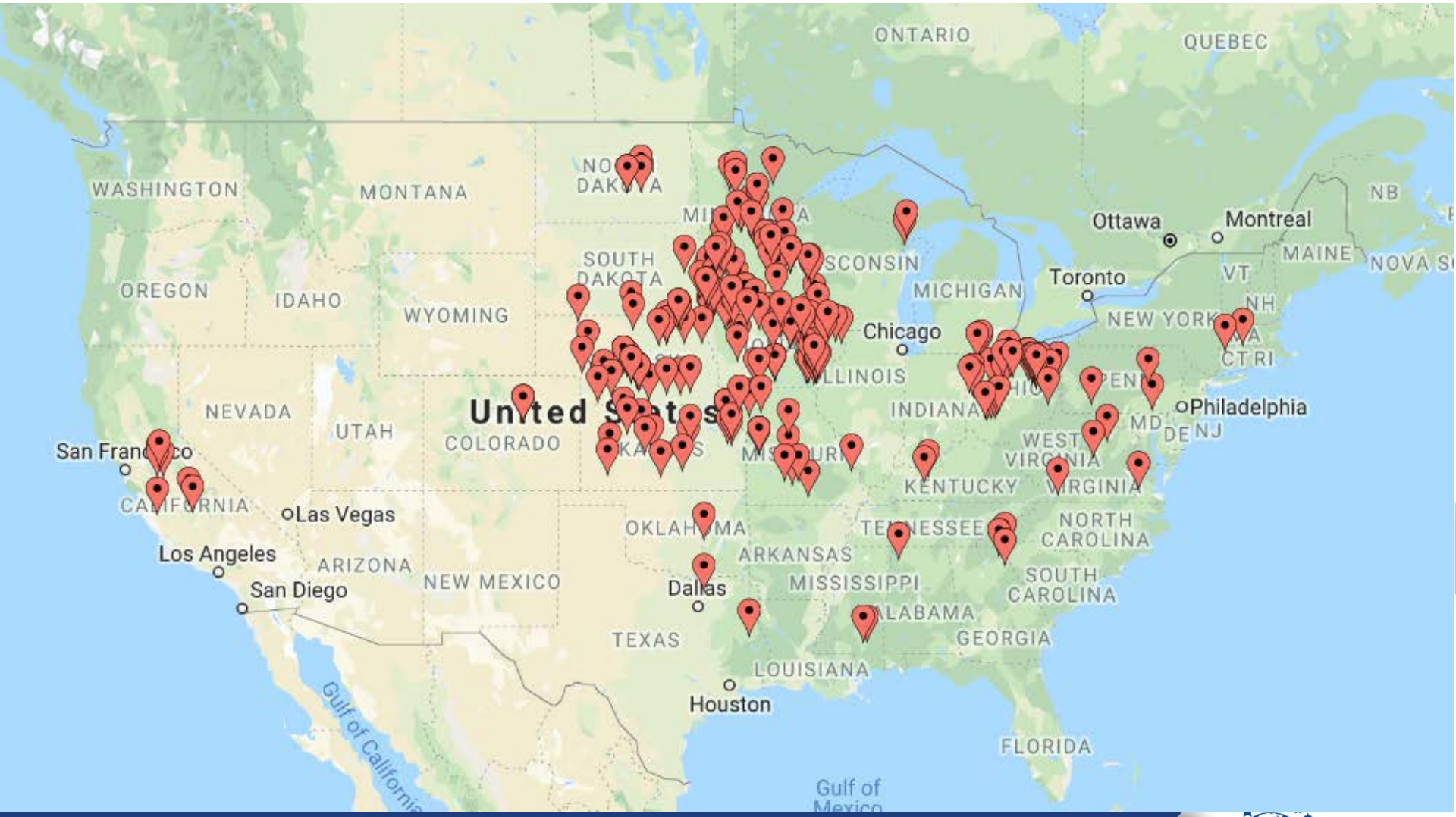
FDA VFD Inspections by location

Q1 2019



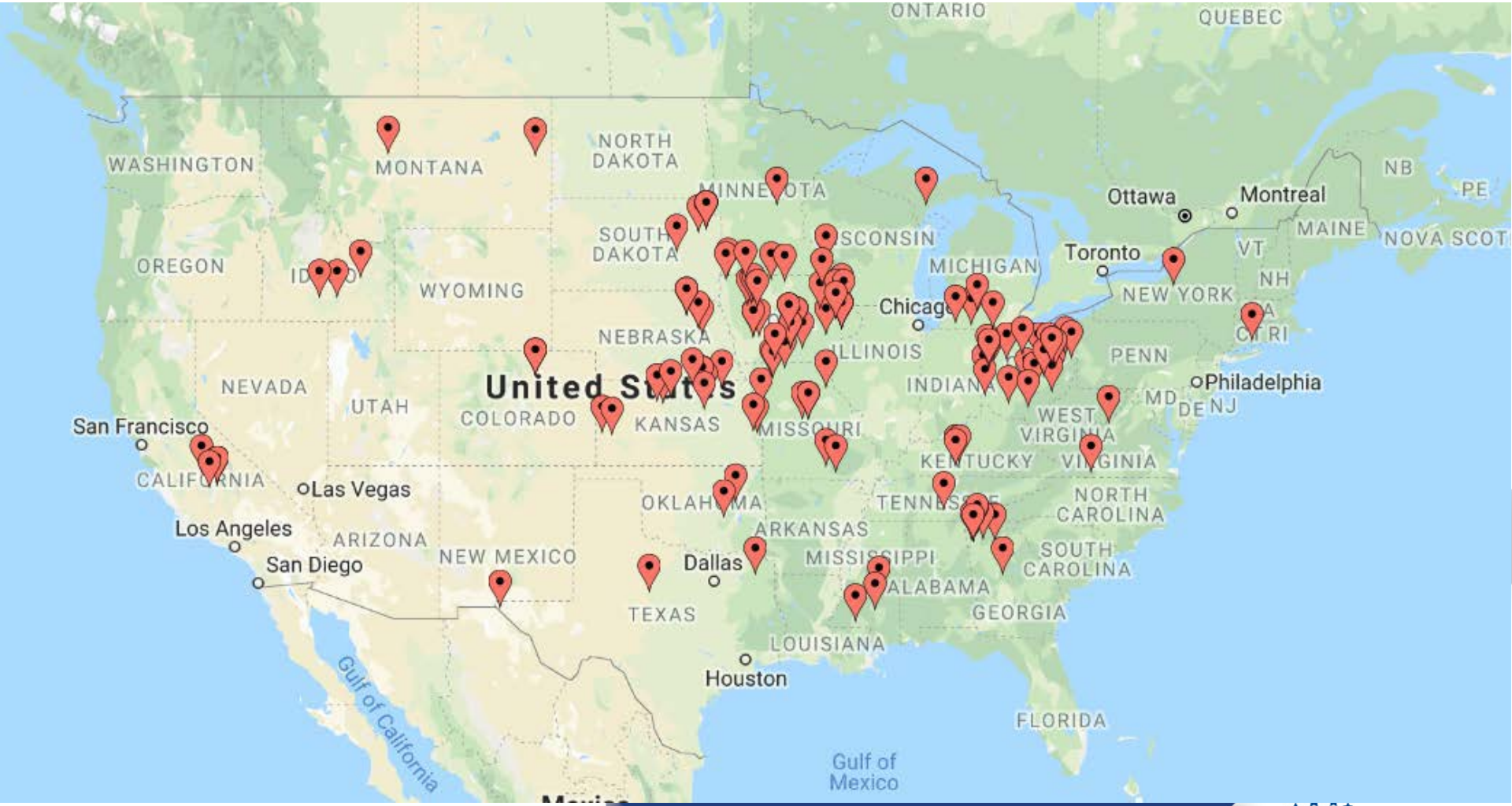
FDA VFD Inspections by location

Q2 2019



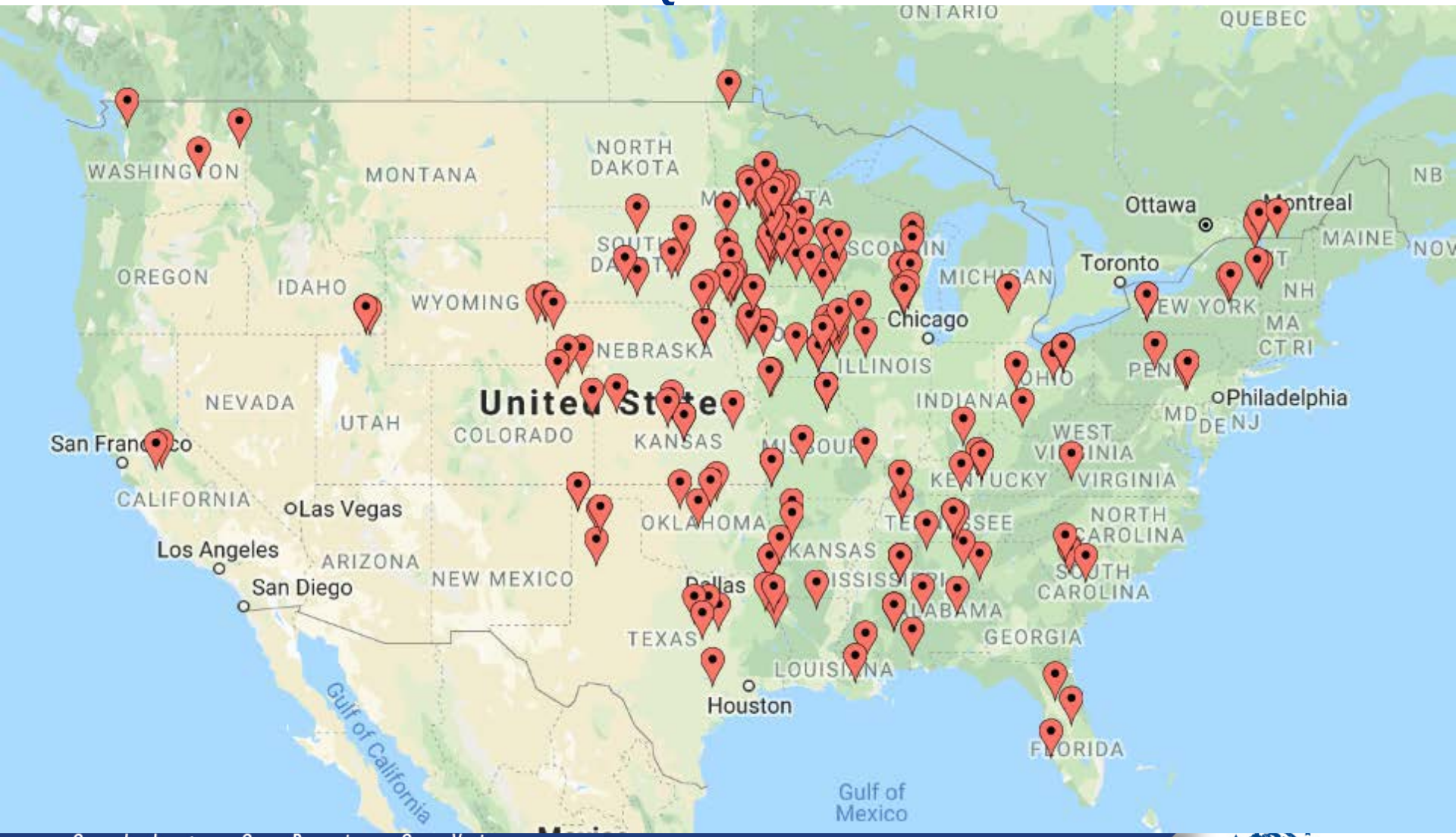
FDA VFD Inspections by location

Q3 2019



FDA VFD Inspections by location

Q4 2019



FDA HA/PC Inspections FOIA

- 189 inspections performed and completed during FY 2019
- Inspections held in 36 states, PR, Brazil, Canada, China, Germany, Japan, Thailand & Vietnam
- 60% Feed/Integrator, 21% Renderer/Ingredients, 1% Distributor and 18% Pet Food facilities
- 42 Form 483s were issued, 21 VAI, 5 NAI, 3 OAI balance unclassified
- Evidence suggests first facilities inspected (7) may have had recent Animal Food Safety incident.

FDA HA/PC Inspections Learnings

- Multiple day inspections
- Documents thoroughly reviewed:
  - Food Safety Plan
  - Hazard analysis
  - Supplier approval program
  - Training documentation (PCQI and QI)
  - Others related to other parts of the inspections (medicated feed, BSE, CGMP)
- Federal and State investigators
- Seem to be in “educate” mode…but issue 483

HA/PC Inspections: Frequent 483 Citations

- 21 CFR 507.34(a)(1): Preventive Controls
  - Investigator feels facility needs to identify a PC
- 21 CFR 507.33(a): Hazard Analysis
  - Investigator feels facility hasn't identified a hazard
- 21 CFR 507.31(a): Food Safety Plan
  - No written food safety plan
- 21 CFR 507.31(b): Food Safety Plan
  - No PCQI identified
- 21 CFR 507. 38(b): Recall Plan
  - Plan doesn't meet all requirements

FDA HA/PC Inspection Plan

- Large firms – compliance as of Sept. 2017
  - Delayed inspections until Oct. 2018
    - New FY and inspections should be occurring
- Small firms – compliance Sept. 2018
  - Inspections will start fall of 2019
- May do CGMP and HA/PC inspections at same time
  - May add in BSE, medicated feed inspections
  - Sanitary transportation readiness questions
  - This intent was reaffirmed during IPPE

FDA Guidance Available for the Animal Food Rule

- FDA finalized **GFI #235** for CGMP Compliance in October 2017
  - AFIA filed comments that impacted the GFI
- FDA released draft **GFI #245** on Hazard Analysis and Risk-Based Preventive Controls in January 2018
  - AFIA filed 36 pages of comments in July
  - This GFI needs a lot of work; meetings with CVM
- FDA released draft **GFI #246** on the Supply-Chain Program in June 2018
  - AFIA found very few issues with this GFI
  - We filed comments in December

Applicable FDA FSMA Guidance Documents: Guidance for Industry

#235 Current Good Manufacturing Practice Requirements for Food for Animals

- No real surprises or enlightening interpretations
- Final document after comment period not bad
- Almost all of AFIA's suggestions were accepted
- Good explanation about the different types of facilities
- Does a good job highlighting flexibility of the rule
- Best part of the document is Appendix B – Self-Assessment Tool (Inspection Checklist)

Applicable FDA FSMA Guidance for Industry

#245 Hazard Analysis and Risk-Based Preventive Controls for Food for Animals

- This document is still in the draft stage (169 pages)
- AFIA submitted 36 pages of comments (lots of issues!)
- A lot of the language was devoted to hazards not relevant to most of the industry (pet vs livestock)
- Not enough qualifying language on the intended use of the animal food
- The list of hazards in Appendix E is concerning

Applicable FDA FSMA Guidance for Industry

#246 Hazard Analysis and Risk-Based Preventive Controls for Food for Animals: Supply-Chain Program

- This document is also still in the draft stage (53 pages)
- It addresses Subpart E (not very relevant to animal food)
- Not nearly as many issues as GD #245
- AFIA submitted comments in December
- It's unlikely feed mills will have a supply chain applied control

Available AFIA Resources

- **Qualified Individual Training Video**, Handout and Quiz
- **PCQI Training** –Course in Nashville, TN in July 2019; Private courses available for AFIA members (2.5 days F2F)
- **Hazard Analysis Tool** – Literature Database and User Guide
- **Sample Animal Food Safety Plan** – Available on website
- **FSMA Updates** – As needed and archived on the website
- **FSMA Webinar Recordings** – Available on website until April
- **Safe Feed/Safe Food Program** – FSC36 certification supports FSMA compliance
- **L&R Staff Support** – Available to answer your questions

Expected Length of Inspections

- Expect different types of inspections to be stacked for efficiency
  - CGMP
  - HA/PC
  - BSE
  - Medicated Feed
  - FSVP
  - Sanitary Transportation
- FSMA CGMP – 2-3 Days
- FSMA HA/PC – 4-5 Days
- FSVP and Sanitary Transportation - ??

FDA FY 2020 Regulatory Strategy

- Voluntary Compliance
- Educate before and while we regulate
- FDA issues Warning Letters to firms in violation of new requirements and other regulations
- FDA continues to use other enforcement tools such as regulatory meetings to obtain prompt voluntary compliance

FDA FY 2020 Inspection Goals

- CGMP - 589
  - Domestic - 180
  - State - 409
- HA/PC - 455
  - Domestic - 330
  - Foreign - 30
  - State - 95
- FSVP - 75
- Sanitary Transportation - 84

Information can be Valuable!

How do You Prepare for FDA ?

- Before the Inspection
- During the Inspection
- After the Inspection

Hopefully it will end like this:

But…
With poor preparation it could end like this:

You want to avoid it ending like this:

Before the Inspection

- **Always be prepared**
  - FDA has the authority to come in unannounced, as long as your open for business
  - Be thoroughly familiar with the regulations and what you are required to do and FDA can do
  - Decide who is the designated employee(s) to accompany the inspector
  - Be familiar with your company policies
    - What can I sign
    - What can I show
    - Photography
    - Copying documents

Before the Inspection

- **Develop corporate policies on how to handle FDA inspections**
  - Policies should be regularly reviewed by senior management
  - Policies should be regularly reviewed by legal counsel
  - Policies should be regularly reviewed with local management staff to be sure they **know what to do**

Before the Inspection

- **Policies you should consider - Photography**
  - Consider a policy that prohibits photography and videotaping without corporate approval
  - For safety reasons, only allow explosion-proof cameras and flash equipment
  - FDA's authority to take photos is unsettled
  - FDA's own policy states that investigators should not take photos except to document an issue
  - If you allow photos, always take duplicates

Before the Inspection

- **Policies you should consider – Documents & Records**
  - FDA's authority to review and copy documents is limited
  - FDA believes if they can review a document, they can copy it; likely to be contentious point for FSMA
  - Establish in your policy what FDA can see
  - Require exceptions to obtain corporate approval
  - Mark "CONFIDENTIAL" on proprietary documents
  - **Be careful!**

During the Inspection

- **You should always:**
  - Be professional
  - Be honest
  - Be nice
  - Be cooperative
  - Be respectful
  - Be calm
  - **Be on guard!**

During the Inspection

- **You should always:**
  - Notify corporate management when an investigator(s) arrive
  - Ask for appropriate identification
  - Receive a form FDA-482 “Notice of Inspection”
  - Ask about the nature of the inspection - CGMP/PC & HA/BSE/Medicated Feed/Complaint/Etc.
  - They may not say, but you can ask

During the Inspection

- **Other things to be aware of:**
  - You should not be expected to interrupt production “business as usual”
  - If an investigator collects a sample
    - Collect two duplicate samples
    - Ask for a Form FDA-484 “Receipt of Samples”
  - Make sure the investigator is aware of company safety procedures and insist they are followed
  - Don’t answer anything or show anything you’re unsure about without consulting management

During the Inspection

- **Exit conference:**
  - Inform the investigator of corrective actions taken
  - Ask the investigator about any areas of concern
  - Adopt a policy that all Affidavits must be reviewed by legal counsel before signing
  - Form FDA-483 “Inspectional Observations” may be given
    - Point out clear, factual mistakes
    - Don’t argue at this time
    - Do not lie; if you don’t know say so
    - Lying to a federal officer is a felony

After the Inspection

- **After the inspection concludes:**
  - Prepare and submit a report to management
    - Include appropriate details
    - Include documentation provide by investigator
  - Respond in writing to a Form-483 or Warning Letter
    - Ask for assistance from AFIA if needed
    - Coordinate response with corporate management
    - Consult legal counsel is appropriate

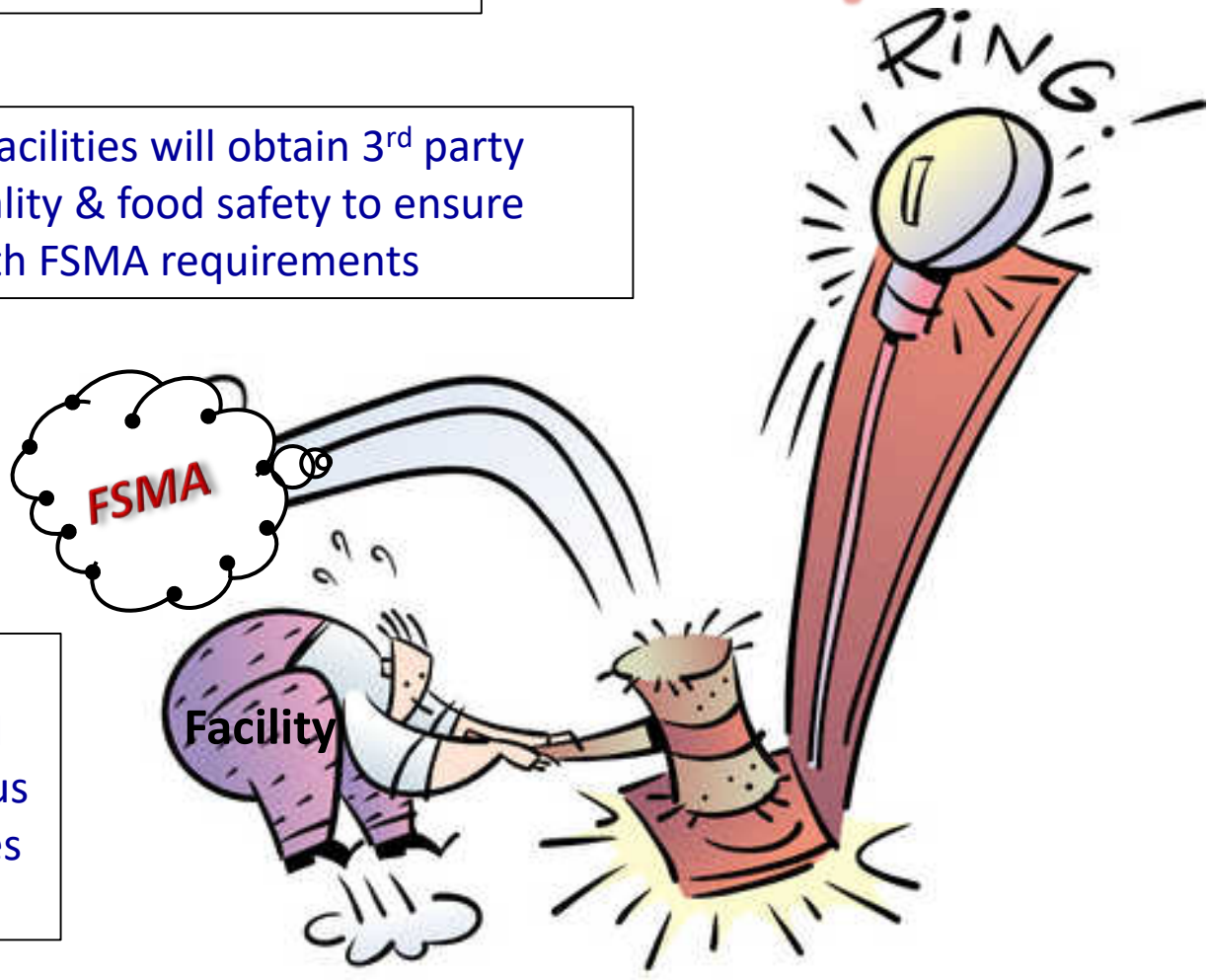
Don’t be ‘Allergic’ to Inspections!

How Can Safe Feed Safe Food Help?

BENEFIT: Certified facilities are considered lower risk.

More Quality & Food Safety Certifications

END RESULT: More facilities will obtain 3rd party certifications for quality & food safety to ensure compliance with FSMA requirements



GOAL: Develop a proactive program to reduce potential animal food safety risks versus a reactive approach to failures or nonconformities

Safe Feed/Safe Food: Historical Perspective

2004

Safe Feed/Safe Food certification established by AFIA
Site audits completed every 4 years

2010

International Safe Feed/Safe Food certification established with FAMI-QS alignment

2011

Pet Food Manufacturing Facility Certification
Pet Food Ingredient Facility Certification

2013

Alignment with SQFI
Two GFSI benchmarked certifications added

2015

FSC36 Safe Feed/Safe Food Updated
Alignment with NRA's Code of Practice
Support Compliance with FSMA

FSC36 Safe Feed Safe Food Certification

- **Important Tools**
  - FSC36 Safe Feed Safe Food Process Document
  - FSC36 Safe Feed Safe Food Guidance Document
  - FSC36 On-Site Audit Checklist

FSC36 Safe Feed/Safe Food

FSC36 Safe Feed/Safe Food Registration and Certification

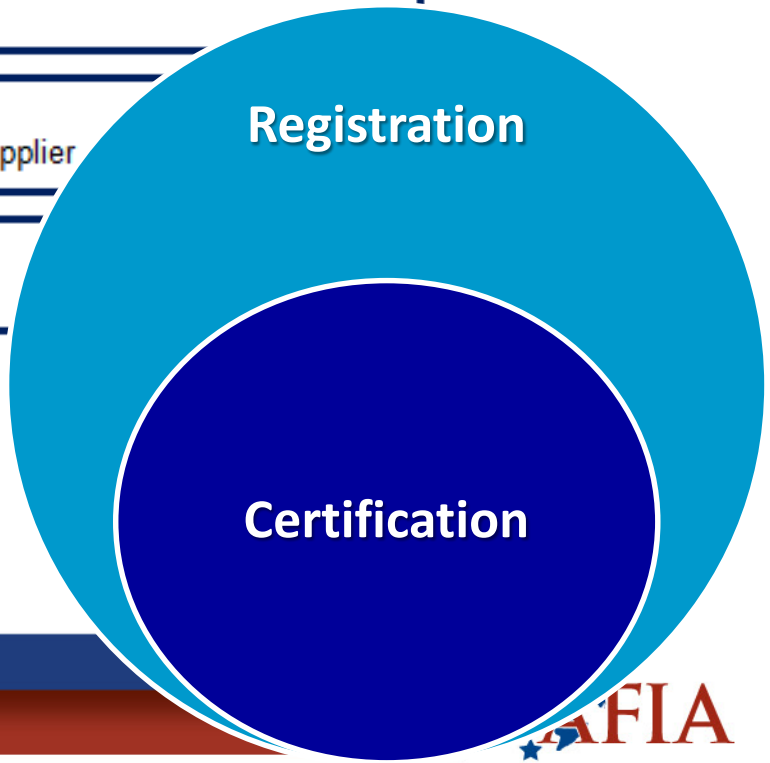
Step 1
- Review the FSC36 Safe Feed/Safe Food Guidance Document
- Complete preparation for FSC36 Safe Feed/Safe Food certification

Step 2
- Complete registration within the SQFI website
- Certification Body should be selected

Step 3
- Notify Certification Body that registration has been completed
- Arrange for audit by Certification Body

Step 4
- Auditor from the Certification Body completes the audit
- Any nonconformance activities shall be corrected by the supplier

Step 5
- Certification Body will notify SQFI when certification issued
- Certified locations shall be listed on AFIA website



"Registration" and "Certification" are independent activities

FSC36 Safe Feed/Safe Food Program

Registration and Certification Steps

- **FSC36 Safe Feed/Safe Food is a 2-year certification.** Certification issued after on-site audit on **Year 1**. Remote audit (surveillance audit) completed on **Year 2** to ensure compliance with Mandatory Elements.

- On-site audit ***may*** be completed during Year 2.
  - Facility's choice
  - Change in CB
  - Due to results from on-site audit from Year 1.

- Remote audit follows the year of an on-site audit.
  - On-site audit not required.

- **Registration is completed each year ($250).**

Certificate of Compliance

eurofins

Eurofins hereby certifies that

KENT NUTRITION GROUP, INC. - WATERLOO

Has been reviewed by an authorized representative of the American Feed Industry Association and is certified under the Safe Feed/Safe Food Certification Program for the following site:

2233 W. Airline Highway

Waterloo, Iowa, UNITED STATES, 50704-0718

Date of issue: Mar 16, 2015
Expiration: Mar 16, 2017
Authorized by: Eurofins
Issuing Officer: Gary Smith
Certificate Number: 50087-002

Signature

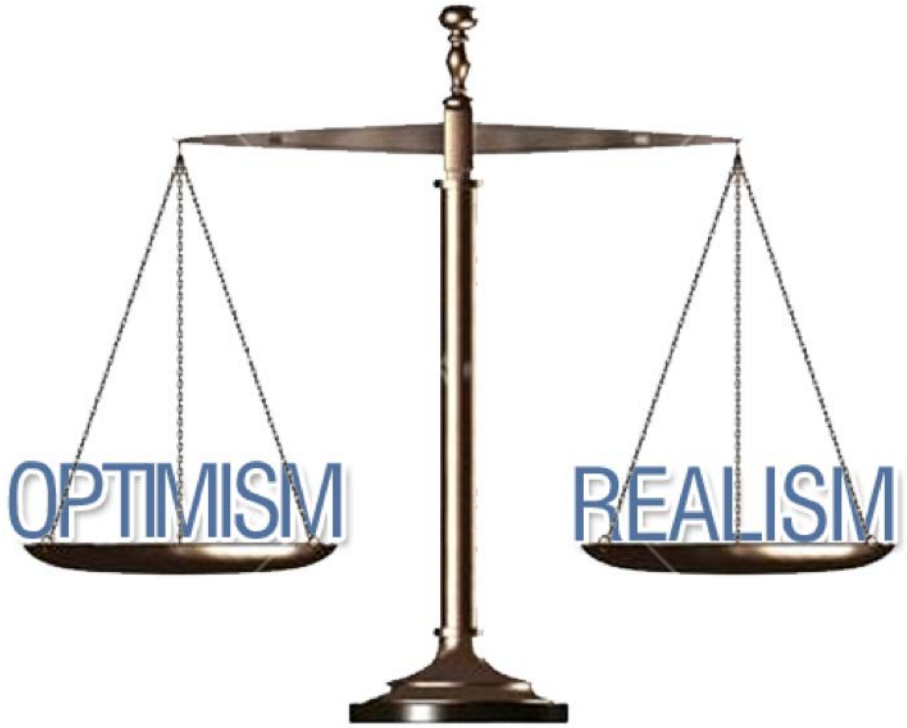
Valid for a period of 2 years from the date of issue.
Audit was conducted with checklist in effect March 2015.

AFIA

FSC36 Safe Feed/Safe Guidance Document Version 7.0

- AFIA's Animal Food Safety and Quality Committee Oversees FSC36 Program
- Began a Comprehensive Review of Program after FSMA Animal Food Rule (507) was released
- Released Version 7.0 of the FSC36 Safe Feed Safe Food Guidance Document

Optimism vs Realism




QUESTIONS

THANK YOU

AFIA'S 4 PROMISES

VOICE

REPRESENTATION

EXPERTISE

ENGAGEMENT

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