



# Preventive Controls for Animal Food Inspections and Compliance

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# FSMA Applicability to Animal Food

Rules <u>applicable</u> to Animal Food	Rules <u>NOT applicable</u> to Animal Food
Preventive Controls for Animal Food	Preventive Controls for Human Food
Foreign Supplier Verification Program	Produce Safety
Accredited Third-Party Certification	Intentional Adulteration
Sanitary Transportation	

# Compliance Dates for Animal Food

Business Size	CGMP Compliance	PC Compliance
Large	Sept 19, 2016	Sept 18, 2017
Small	Sept 18, 2017	Sept 17, 2018
Very Small	Sept 17, 2018	Sept 17, 2019

- Compliance dates for training provisions (21 CFR 507.4) coincide with date a facility is first subject to either CGMPs or PC

# 2017 CGMP Inspections

- Conducted ~230 CGMP inspections
- Inspections were more conversational (and will continue to be so)
- Questions were asked (and will continue to be) about PC readiness
- Overall inspectional findings were positive
- Most common finding – pest control issues

# 2018 CGMP Inspections

- Increased number of inspections from 2017
- CGMP inspections may be combined with BSE inspections
- We will continue to “Educate Before and During” Regulation
- Overall inspectional findings are positive

# CGMP Inspection Concerns

- Most common industry concerns
  - Why do investigators ask to see complaint files?
  - Why do investigators ask to see pest management records?
- General response to these concerns
  - That is standard procedure for all FDA inspections
  - Procedures are in the Investigations Operations Manual (IOM), available online:  
<https://www.fda.gov/iceci/inspections/iom/default.htm>

# 2019 CGMP and PC Inspections

- Continue CGMP inspections
  - Now at all business sizes
- Begin PC inspections
  - Focus on hazard analysis to ensure that all known or reasonably foreseeable hazards are identified and evaluated
- If a facility is subject to several regulations, all of the requirements will likely be covered during one inspection
  - Could include: PCAF CGMPs/PC, Medicated Feeds, VFD, BSE, Sanitary Transportation

# Inspection Considerations

- End goal is safe animal food that is free from contamination
- FDA is training Investigators in systems thinking approach so that they can evaluate the food safety system holistically
- Several guidance documents are available to help companies understand the regulations



# FDA FSMA Website

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/>

Rules and Related Programs



Guidance Documents



Training and Technical Assistance



Compliance and Implementation Tools



FSMA Background



FSMA's Impact on Public Health





# Feed Industry View of CGMP Inspections by FDA

**Richard Sellers, PAS, Dipl., ACAN**  
**Sr. Vice President, Public Policy & Education**  
**American Feed Industry Association**

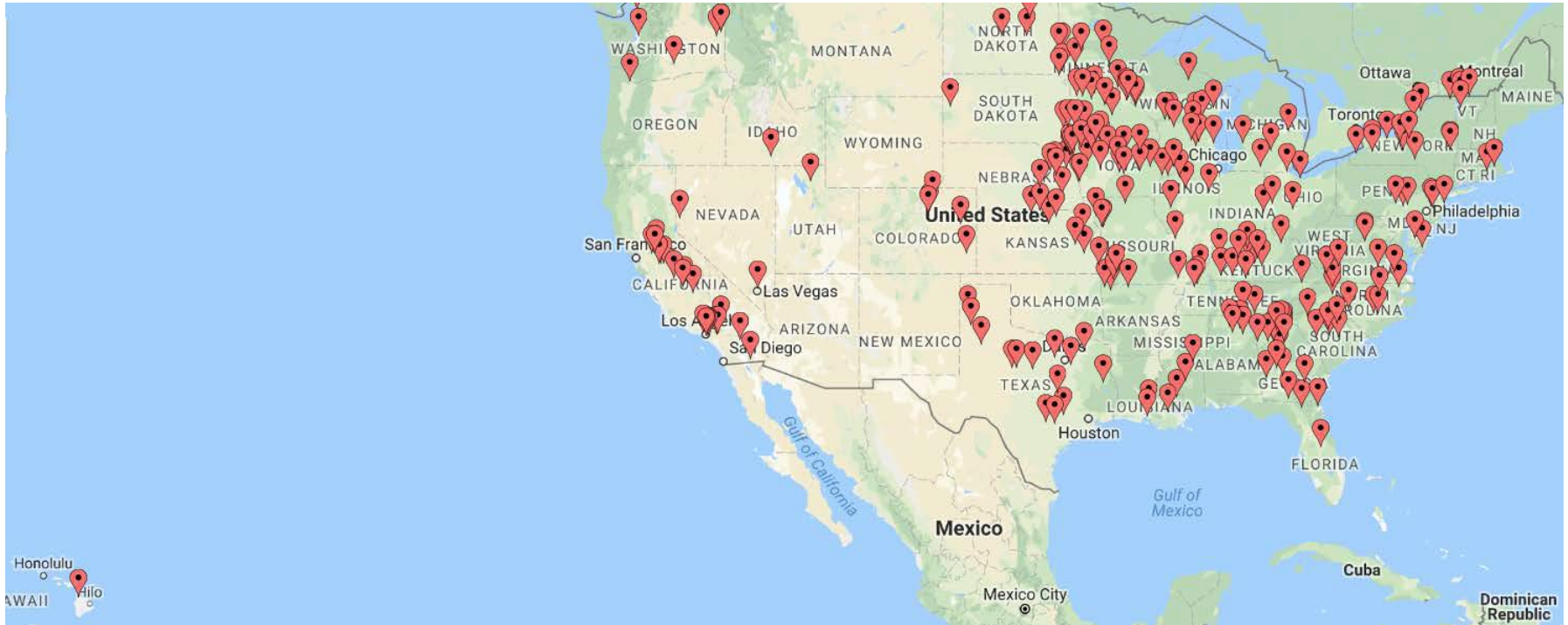
# Inspection Data thru April 3<sup>rd</sup>

- 278 inspections conducted with 14 (5%) receiving a FDA Form 483
  - 7 of 14 (50%) were classified as VAI
  - 1 of 14 (7.15%) was NAI
  - 1 of 14 (7.15%) was OAI
  - 5 of 14 (35.7%) had no classification reported

# Inspection Data thru April 3<sup>rd</sup>

- 278 inspections are in seven categories
  - Feed mfr. 115 41.37%
  - Integrator 49 17.63%
  - Ingredients 34 12.23%
  - Pet Food 31 11.15%
  - Renderer 26 9.35%
  - Distributor 19 6.83%
  - Retail 4 1.44%

# Inspection Data thru April 3<sup>rd</sup>



# Inspection Data thru April 3<sup>rd</sup>

- 39 states had inspections:
  - IA 26 9.35% occurred in IA
  - CA 23 8.27% occurred in CA
  - GA 21 7.55% occurred in GA
  - MN 19 6.83% occurred in MN
  - TX 18 6.47% occurred in TX
  - WI 15 5.40% occurred in WI
  - KY, NY 13 each 4.68% (each) occurred in KY & NY
  - MO 10 3.60% occurred in MO
  - KS, NE 9 each 3.24% (each) occurred in KS & NE

# Inspection Data thru April 3<sup>rd</sup>

- 39 states had inspections (continued):
  - VA 8 2.88% occurred in VA
  - NC 7 2.52% occurred in NC
  - ND, SC, WA 6 each 2.16% (each) occurred in ND, SC, & WA
  - AL, CO, SD, TN, VT 5 each 1.80% (each) occurred in AL, CO, SD, TN, & VT
  - AR, IL, LA, MI, OH, PA 4 each 1.44% (each) occurred in AR, IL, LA, MI, OH, & PA
  - FL, NJ 3 each 1.08% (each) occurred in FL & NJ
  - IN, MD, MS, NV 2 each 0.72% (each) occurred in IN, MD, MS, & NV
  - HI, ID, MA, OR, RI, UT 1 each 0.36% (each) occurred in HI, ID, MA, OR, RI, & UT
- More than 53% of all inspections occurred in the top 8 states or 20.5% of the states that had inspections

# Top Topics of Concern

- AFIA members report inspections to an e-portal, here are a list of concerns:
  - Request for pest inspection records—rule does not require data to be maintained
  - Request for complaint files—rule does not require data to be maintained
  - Knowledge of HA/PC part of rule—not in effect until later
  - QI training records—AFIA members use AFIA training video
  - Unlabeled containers and trash cans—observational inspection
  - PCQI and training—compliance dates have not occurred
  - Asking for several records for which not entitled to view