



Updates in Animal Food and Feed: State Changes, GRAS, and FSMA

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FSMA Animal Food Rule: *Inspections*

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FSMA Animal Food Rule: *Broad Overview*

- Subpart B - Current Good Manufacturing Practices (CGMPs) establish baseline standards for sanitary operations
- Areas of focus:
 - Plant, grounds, personnel, management and training, sanitation, water supply & plumbing, equipment and utensils, plant operations, holding and distribution

CGMP requirements apply to all facilities (except grain elevators) regardless of whether Preventive Controls are required

FSMA Animal Food Rule: *Broad Overview*

- Subpart C – Hazard Analysis and Risk-Based Preventive Controls
- Unless exempt or “qualified,” facilities must conduct a hazard analysis
- If the hazard analysis identifies a “hazard requiring a preventive control,” then the facility must implement preventive controls

- **Small and very small businesses subject to modified requirements**
- **Some “low risk” activities exempt (e.g., on farm processing, storage)**

FSMA Animal Food Rule: Implementation Timeline

- Sept. 17, 2015 – Final Rule published
 - Established staggered implementation deadlines for CGMPs & Preventive Controls

Entity Type	CGMPs	Preventive Controls
Not “small” or “very small”	Sept. 16, 2016	Sept. 18, 2017
“Small” - < 500 employees	Sept. 18, 2017	Sept. 17, 2018
“Very small” – < \$2.5 M animal food sales	Sept. 17, 2018	Sept. 17, 2019

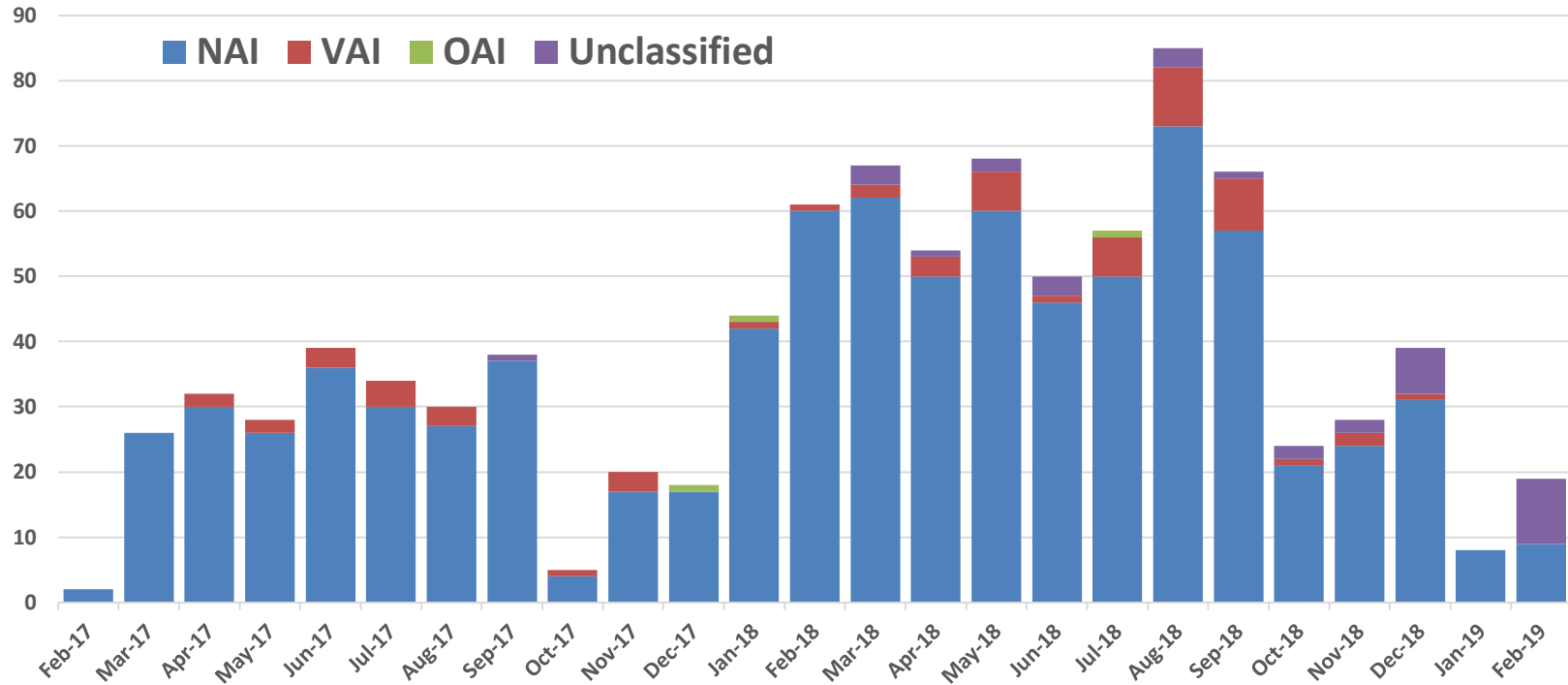
FOIA Data:

CGMP Inspections

- Feb. 15, 2017 – First CGMP Inspection
- Through Feb 2019 – 942 inspections*
- Classification:
 - No Action Indicated – 90% (845)
 - Voluntary Action Indicated – 6% (59)
 - Official Action Indicated – < 0.5% (3)
 - Not yet classified – 4% (35)
- 5% (48) resulted in issuance of FDA Form 483

* This figure includes inspections where CGMPs were referenced in the inspection, even if CGMPs were not the primary focus (e.g., veterinary feed directive inspections)

CGMP Inspections



FOIA Data:

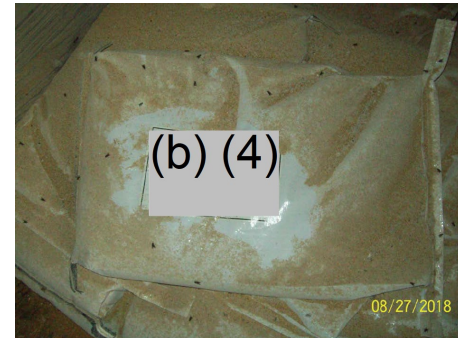
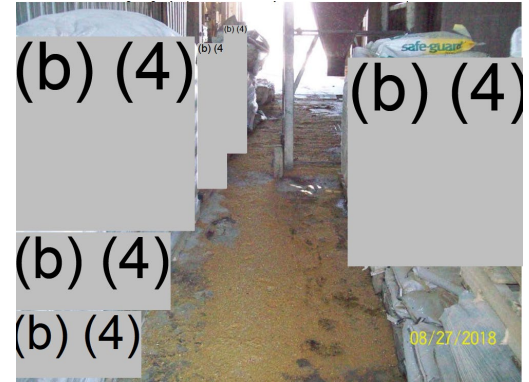
Preventive Control Inspections

- July 26, 2018 – First PC inspection
 - November 7, 2018 – Second PC Inspection
- 21 PC inspections conducted through Feb. 2019
- 48% (10) inspections resulted in FDA Form 483

Month	NAI	VAI	OAI	Unclassified	Total
July 2018	0	1	-	-	1
Nov 2018	1	1	-	4 (2 483s)	6
Dec 2018	1	1	-	3 (2 483s)	5
Jan 2019	2	-	-	-	2
Feb 2019	1	-	-	6 (4 483s)	7

Inspection Insights: *CGMP Inspections*

- Common issues
 - Rodents and rodents
 - Pest attractants
 - Water in storage
 - Insanitary storage
 - Employee training records



Inspection Insights:

PC Inspections

- Focus on Hazard Analysis
 - Failure to address Fumonisin in corn
 - Food Safety Plan addressed Aflatoxin, but facility failed to follow sampling protocol
 - Food safety plan identified Vitamin D as a “critical” hazard, but did not treat it as a hazard requiring a preventive control
 - Measures intended to address Vitamin D deficiency did not address root cause

FSMA Animal Food Rule: *Inspections*

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Updates in Animal Food

FDLI Annual Conference
Jenny Murphy, M.S.
FDA – Center for Veterinary Medicine
May 2, 2019

FSMA Implementation Update

CGMP Inspections (FY18): General Findings

- Approximately 400 inspections conducted in FY18
- 60% by FDA, 40% by State agencies
- Approximately 6% of inspections resulted in observations documented on an FDA Form 483
- 1 FDA Warning Letter issued for CGMP violations

FSMA Implementation Update

CGMP Inspections (FY18): General Findings

- General Feedback from Investigators
 - Pest Management
 - House Keeping
- Most Frequent FDA Form 483 Findings
 - Plant Management (21 CFR 507.25(a) and (b)(1))
 - Pest Management (21 CFR 507.19(e))

FSMA Implementation Update

Inspections (FY19): What to Expect

- CGMP inspections are being conducted at all business sizes
- Routine PC inspections started in October 2018 for “large” businesses
- Routine PC inspections at “small” businesses will begin in fall 2019; however are conducting some “for cause” inspections in FY 19
- Inspections will consider the various regulations that may apply at a facility

FSMA Implementation Update

Inspections (FY19): General Findings

- Continue to “Educate Before and During” regulation
- Significant public health concerns result in advisory or enforcement action
- Findings to date:
 - Not enough data yet to draw conclusions
 - Pre-requisite program implementation

Ingredient Safety

- Challenges within the ingredient review process
 - Limited CVM resources
 - Completeness of submissions
 - Consistency within submissions
- Impacts on industry
 - Less predictable review timing
 - Questions on data requirements

Ingredient Safety

Opportunities for Cooperation

- Solutions to challenges, what are we doing
 - Evaluating our processes
 - Flexibility: each submission is different
- Solutions to challenges, how you can help
 - Opportunities for increased resources
 - Interaction prior to any submission

**Center for Veterinary Medicine
Protecting Human and Animal Health**

Thank you!

