FSMA Implementation Update 2018

Summer 2019 Pet Food Alliance Meeting
June 27, 2019

Jenny Murphy, M.S.
Outline

• Major FDA/CVM Personnel Changes
• FSMA Updates
  – 2018 data
  – 2019 data (to date)
• Key/Emerging Hazards and Research Gaps
• Need for Collaborative Approach
Major FDA/CVM Personnel Changes
FSMA Updates
FSMA Implementation Update

CGMP Inspections (FY18): General Findings

• Approximately 400 CGMP 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))
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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): Numbers to Date*

<table>
<thead>
<tr>
<th>Type of Inspection</th>
<th>Number of Inspections</th>
<th>Percent of 483’s issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>CGMP</td>
<td>156</td>
<td>14%</td>
</tr>
<tr>
<td>PC (by FDA)</td>
<td>75</td>
<td>27%</td>
</tr>
<tr>
<td>PC (by State)</td>
<td>14</td>
<td>Unknown</td>
</tr>
<tr>
<td>Sanitary Transportation</td>
<td>25</td>
<td>5%</td>
</tr>
<tr>
<td>FSVP</td>
<td>2</td>
<td>0%</td>
</tr>
</tbody>
</table>

*Data reported up to mid-June, 2019*
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*Inspections (FY19): General Findings for PC inspections*

- 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
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Inspections (FY19): General Findings for PC inspections

• Common inspection citations:
  – Failure to identify/implement a preventive control
  – Hazard analysis
  – No written food safety plan
  – Food safety plan not done/overseen by PCQI
  – Failure to establish/implement corrective action procedures
  – Failure to validate preventive control
  – Failure to conduct a reanalysis
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Inspections (FY19): General Findings on PC inspections

• Perspectives from Investigators:
  – Hazard analysis
  – Pre-requisite programs
  – Corporate plans vs. facility specific plans
Key/Emerging Hazards and Research Gaps
Pathogens in Pet Food

• Key pathogens of concern:
  – *Salmonella* spp.
  – *Listeria monocytogenes*
  – *E. Coli*

• Concern for all pet food

• Data trends
Pathogens in Pet Food

• Research gaps:
  – Adequate controls in raw pet food
  – Post kill step contamination issues (ingredients and final product)
  – Transportation best practices (primarily unpackaged ingredients)
Pentobarbital

• FDA withdrawal of CPGs
• FDA method available for detection in tallow
• FDA developing method for detection in:
  – Meat
  – Finished product
Pentobarbital

• Research Gaps
  – Widespread vs. local problem
  – Appropriate control
    • Supply chain?
    • Process?
  – Humane euthanasia alternatives
Dilated Cardiomyopathy

• FDA updated released 6-27-19
  – Update on number of cases/reports
  – “Case” definition
  – Current data and findings including data from VetLIRN labs
  – Released raw case data as received
Dilated Cardiomyopathy

• Research Gaps:
  – Is there a causal link between diet and DCM?
  – Formulation data
  – Medical data (cardiac, bloodwork) from animals that meet the case definition
African Swine Fever Virus

- Highly virulent virus that impacts pigs
- Rapid spread through Asian continent in past year
- Foreign animal disease
- Catastrophic impact if reaches U.S. swine herd
African Swine Fever Virus

• Research Gaps:
  – Natural contamination
  – What does a “positive” test mean in feed
  – Appropriate control
Need for Collaborative Approach to Research
Thank you!

Center for Veterinary Medicine
Protecting Human and Animal Health