Agenda

➢ Background on FSMA

➢ Highlights of Proposed Animal Feed Rule
  ➢ Coverage and Definitions
  ➢ Current Good Manufacturing Practices
  ➢ Hazard Analysis & Risk-Based Controls

➢ Florida’s FSMA Rules Response Program

➢ Key Considerations
Foundations of FSMA

- To better protect human and animal health
- Prevention not reaction
- Partnerships
- Seven primary rules
Proposed Rules

- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Docket FDA-2011-N-0921) *(Produce Safety)*

- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based *Preventive Controls* for Human Food (Docket FDA-2011-N-0920)

- *Foreign Supplier Verification* Programs for Importers of Food for Humans and Animals- (Docket FDA-2011-N-0143)
Proposed Rules Continued

- Accreditation of *Third-Party Auditors*/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications (Docket FDA-2011-N-0146)

- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for *Animal Food* (Docket FDA-2011-N-0922)
Proposed Rules Continued

- Focused Mitigation Strategies to Protect Food Against *Intentional Adulteration* (Docket FDA-2013-N-1425)

- *Sanitary Transportation* of Human and Animal Food (Docket FDA-2013-N-0013)
History Of Animal Food Incidents

- 2005 contaminated corn
- 2007 melamine to elevate protein levels
- 2007 *Salmonella* in pet food and humans
- Nutrient imbalances
Animal Feed Rule- Coverage

- Facilities required to register with FDA under Section 415 of the FD&C Act: facilities that manufacture, process, pack or hold animal food
- Domestic and foreign facilities

**Farms and some retail are exempt**
Definitions and Impact

- Farm - Classical vs Current
- Ownership - Raising of own and other
- Farm mixed-type facility
- Raw Agricultural Commodities (RACs)
- Business sizes and ‘Qualified’ components
Current Good Manufacturing Practices (CGMPs)

- Personnel Practices and Training
- Facility Operations, maintenance, and sanitation
- Equipment & utensil design, use and maintenance
- Processes and controls
- Warehousing and Distribution
Exemptions to CGMPs

- Activities within farm definition
  - Including those activities that are covered by the Produce Safety rule

- Facilities that store RACs
Hazard Analysis and Risk-Based Preventive Controls (HARBPC)
Hazard Analysis and Risk-Based Preventive Controls (HARBPC)

- Analysis of hazards
- Preventive Controls of identified hazards
  - Mandatory recall plan
- Monitoring procedures
Hazard Analysis and Risk-Based Preventive Controls (HARBPC)

- Corrective actions
- Verification activities
- Record keeping

![Corrective action form](image)
Hazard Analysis & Preventive Controls

Exemptions

- Modified exemptions - must be qualified facility and follow preventive controls

- Animal food sales <$500K/yr for last three years & Qualified end-user sales exceed sales to other

- Very small business
Hazard Analysis & Preventive Controls
Exemptions

- Low-acid canned foods
- Facilities that store animal food
- Farm activities
- Low-risk activities
- Specified storage facilities
Florida FSMA Rules Response

- Research Impacted Parties
- Gather input
  - Cross-pollination of ideas
  - Feedback to FDA
  - Issue comments
- Continued communication
Working Group Topics

- Usage of Culls
- Back grounding cattle
- Aquaculture
- Coverage for pet food vs livestock
- Citrus processing
Florida Citrus Discussion

- Ten processing plants with mills
- ~58% juice weight, 42% excess
- Pellets sold regionally/internationally
- Existing safety programs
- Landfill options are not viable/tonnage
Citrus Cull Usage

- Use of culls from packinghouses and processing facilities
- Historic and safe
- Quality of fruit
- Nutritious
Florida Animal Feed
Tour March 2014
Florida Animal Feed Tour
March 2014
FDA Requests on Proposed Rule

- Finished product testing
- Environmental testing
- Review of customer complaints
Summary of Key Concerns

- Current food system
- Resource restrictions
- Risk-based and science-based
- Definition inconsistencies
- Inequities in supply
Summary of Key Concerns Continued

- Economic impact - funding
- Education, research, training
- Formal agreements
Anticipated FDA Next Steps

- Re-opening portions of rule
- Creation of programs
- Final rule issuance
Further Information

- http://www.fda.gov/fsma
- http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm
Contact Information

Susan Caime Mardenborough
Florida Department of Agriculture and Consumer Services

susan.mardenborough@freshfromflorida.com
850.694.4911