Jenna Areias, Program Supervisor
Feed and Livestock Drugs Inspection Services Branch

2014 CGFA Convention

FDA FOOD SAFETY MODERNIZATION ACT

&

THE CALIFORNIA FEED INDUSTRY

Maui, Hawaii
April 24, 2014
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WHAT IS FSMA?

- FSMA: Food Safety Modernization Act

- Signed into law on Jan. 4, 2011 – President Obama

- Expands FDA’s authority to regulate the U.S. food supply
  - Mandates that FDA create a new prevention-based regulatory system to ensure the safety of food/feed products.
  - Feed is considered food per the Food, Drug and Cosmetic (FD&C) Act
  - Requires FDA to develop and issue more than 50 regulations and/or guidance documents over the next three-plus years.
• October 25, 2013 proposed regulations were released for public comment:
  – CDFA submitted official comments to the Docket on March 28, 2014

• 21 CFR Part 507:
  – Current Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.
FOOD SAFETY MODERNIZATION ACT: Legislative Intent

- Requires U.S. feed facilities to have a documented, written food/feed safety plan that:
  - Evaluates hazards
  - Implements risk-based preventive controls
  - Performs monitoring activities
  - Documents corrective actions
  - Performs verification activities
  - Establishes and maintains records
SUMMARY OF REQUIREMENTS

• Establishing, for the first time, Good Manufacturing Practices for ALL animal food.
  – Previously established cGMP’s were only required for certain types of medicated feed manufactures.
  – No distinction between livestock feed and pet food manufacturing

• Hazard Analysis and Risk-Based Preventive Controls:
  – Each facility will be required to implement a written food safety plan that focuses on preventing hazards in animal feed and human food.
WHO IS COVERED?

• Facilities that manufacture, process, pack or hold animal food
• In general, facilities required to register with FDA under sec. 415 of the FD&C Act
• Applies to domestic and imported food
• Some exemptions and modified requirements are being proposed – very limited.
HUMAN VS. ANIMAL
PREVENTIVE CONTROLS

- Very similar with some exceptions
- Animal PC established CGMPs for all feed
- Human PC modifies some CGMPs
- Allergens not a hazard in Animal PC
- Animal PC does include nutrient imbalances
- Different definitions of very small business

Section 1. FSMA
PROPOSED cGMP REQUIREMENTS

- Personnel
- Plant and grounds
- Sanitary operations
- Sanitary facilities and controls
- Processes and controls
- Equipment and utensils
- Warehousing and distribution
PROPOSED cGMP REQUIREMENTS

• Personnel
  – Follow good hygiene practices
  – Protection of food from contamination from personal effects

• Plant and grounds
  – Including proper cleaning, maintenance, and pest control
PROPOSED cGMP REQUIREMENTS

• Sanitary operations
  – Includes maintaining clean and sanitary conditions of food contact surfaces, proper use and storage of toxic cleaning compounds, and exclusion of pests.

• Sanitary facilities and controls
  – Such as the plant's water supply, plumbing, and toilet and hand-washing facilities
PROPOSED cGMP REQUIREMENTS

- Processes and controls includes:
  - Following adequate sanitation principles
  - Proper labeling of ingredients and finished animal food
  - Ensuring the safety of raw materials
  - Prevention of contamination of animal food during processing
PROPOSED cGMP REQUIREMENTS

- Equipment and utensils
  - Includes the cleaning and maintenance of such items and protecting animal food from contamination

- Warehousing and distribution
  - Includes protecting animal food against contamination and deterioration

Section 1. FSMA
QUALIFIED INDIVIDUAL

• Must have successfully completed training in the development and application of risk-based preventive controls
  – At least equivalent to that received under a standardized curriculum recognized as adequate by FDA or
• Be otherwise qualified through job experience to develop and apply a food safety system
OTHER FACTS:
FSMA

- Re-register every two years starting in 2012
  - Requirements for revoking registration established
  - Re-registration for your firms will need to occur October 1 – December 1, 2014.

- FSMA provides for FDA to collect a variety of fees
  - Support and establish 3rd party certification
  - Re-inspection fees for domestic and imported products
    - Re-inspection hourly rate for domestic travel: $237.00
    - Re-inspection hourly rate for foreign travel: $302.00
FDA Information Available

- Website: http://www.fda.gov/fsma
- Subscription feature available
- Send questions to FSMA@fda.hhs.gov
• Recognize that the branch needs to evolve
• Know that US FDA’s FSMA implementation will occur over the next 2-3 years
• Identified areas of opportunities for increased effectiveness and change
• Realize that under the current CDFA “umbrella” law/regulation changes will need to occur.
• The Feed, Livestock Drugs and SAFE programs will be working through this transition in workload/organizational activities to assist the industry in compliance with FSMA.
IN 2013:

SEC 14903: The secretary shall establish, by regulation, such good manufacturing practices, **Hazard Analysis and Preventive Control measures**, as he/she determines are reasonably necessary to carry out the purposes of this chapter. The good manufacturing practices, **Hazard Analysis and Preventive Control measures**, **including verification and validation activities for all commercial feeds**, and **additives** regulation for additives, including medicated feed premixes and medicated feeds shall be based upon those established pursuant to the federal food and drug laws and regulations, unless the secretary determines that such laws and regulations are not appropriate to the conditions which exist in this state. The regulations adopted pursuant to this section shall assure that drug usage under this chapter shall not conflict with the provisions of Chapter 4 (commencing with section 14201) of this division.
## Feed Inspection Program – Current Field Operations

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<th>SAFE Program</th>
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<td>CA GMP Inspections</td>
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<td>Quarantines</td>
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<td>Label Review/Inspection/Activities</td>
<td>On-site consulting</td>
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<td>Training (staff)</td>
<td>Feed Safety Results</td>
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<td>Delinquent Feed Licensee follow-ups</td>
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The Feed Inspection Program will encompass these three critical areas:

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<td>Process Verification Inspections (CGMP’s and Prerequisite program)</td>
<td>Label Review/Inspection/Activity</td>
<td>On-site Training/consulting</td>
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<tr>
<td>Tissue Residue Investigations</td>
<td>Delinquent Feed Licensee follow-up</td>
<td>Workshop</td>
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<td>BSE/FEED Inspections</td>
<td>Feed Sampling (1000)</td>
<td>Mixer Profiles/Studies</td>
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<td>FDA Regulations Audits</td>
<td>Complaint follow-up</td>
<td>Feed Safety Sample Results</td>
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<td>Verification Sampling (200)</td>
<td>Quarantine</td>
<td>Surveys stats etc.</td>
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<td>Violation follow-up</td>
<td>Violation follow-up</td>
<td>High Violations Summary</td>
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<td>Training</td>
<td>Livestock Drug Inspections</td>
<td>Training/meetings</td>
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1. Process Verification Workload:

Re-aligning the Feed Program focus on “front-end” inspections these will be conducted by FDA Commissioned Special Investigators

They will Include:

» Incoming ingredients review
» Production record review
» Assurance of SOP’s at all critical areas of manufacturing
» Process controls review
» Sampling for verification of identified hazards and other feed safety related issues
» contract work: Tissue Residue Investigations, BSE Inspections and FDA Regulations (FSMA) work

Performing process verification work, as well as supporting the SAFE Program in working with feedmills to gain compliance with FSMA regulations

Investigators trained to perform HACCP and Process Verification Inspections

Starting with the 55 “high risk” firms
SAFE PROGRAM

3. Industry outreach/training

– SAFE will continue to have a consulting role with all feedmill facilities who fall under the FDA regulations (FSMA)
– Provide the CA feed industry with the minimum compliance standards developed by FDA’s Feed Safety Alliance and will facilitate workshops or “Train-the-Trainer” seminars
– Research on new feed ingredients and other feed/food safety related issues, through a Technical Advisory Sub-Committee
– Provide training for proper on-farm antibiotic use, for the dairy industry
– SAFE audits will now be conducted by “Process Verification” staff
NATIONAL WORKING GROUP PARTICIPATION

- **US FDA Animal Food and Feed Safety Alliances (2)** – Mike Davidson represents CDFA and AAFCO on the National Alliance. The purpose of this alliance is to develop outreach and training material to the feed industry, pertaining to FSMA regulations.

- **US FDA Animal Food GMPs Alliance** – Jenna Areias represents CDFA on the national Alliance. The purpose of this alliance is to develop training and outreach materials to the feed industry, specific to the new cGMP’s.

- **US FDA National Animal Food Safety Systems (AFSS) Committee** – Jenna Areias represents CDFA on this national committee. Its Purpose is to provide education and training; conducting research; performing inspections, taking enforcement for ensuring the removal of unsafe feed from the marketplace and to ensure compliance with Agency regulations; and establishing partnerships with other agencies with responsibility for feed safety.
IMPLEMENTATION OF STANDARDS FOR REGULATORY PROGRAMS

AFRPS – Animal Feed Regulatory Program Standards

1. REGULATORY FOUNDATION
2. TRAINING
3. INSPECTION PROGRAM
4. AUDITING
5. FEED-RELATED ILLNESS or DEATH and EMERGENCY RESPONSE
6. ENFORCEMENT PROGRAM
7. OUTREACH ACTIVITIES
8. PLANNING and RESOURCES
9. ASSESSMENT and IMPROVEMENT
10. LABORATORY SERVICES
11. SAMPLING PROGRAM
Criteria is as follows: 429 in-state firms

High Risk Firm: (55 identified)
• Mix two or more ingredients \textit{and} use drugs/medications
• Vitamin/mineral premix's
• All regulated under CA-GMP's
• Handle prohibited materials

Medium Risk Firm: (244 identified)
• Any firm that mixes two feed ingredients or more \textit{and does not} use drugs/medications or concentrated selenium products

Low Risk Firm: (132 identified)
• Any firm that sells or distributes whole commodities including co-products from food processing facilities
Prepare the Feed Inspection Program to carry out FSMA audits on licensees in CA; recognized by the US-FDA
VIDEO

• FSMA AND THE CA FEED INDUSTRY
HAZARD ANALYSIS & RISK-BASED PREVENTIVE CONTROLS

1. Hazard Analysis
2. Preventive Controls
3. Monitoring Procedures
4. Corrective Actions
5. Verification
6. Recordkeeping
HAZARD ANALYSIS

- Facilities will be required to conduct and document a written analysis of hazards to evaluate:
  - “Known or reasonably foreseeable hazards that may be associated with the facility”
  - Biological, chemical, physical and radiological hazards
  - Includes hazards that occur naturally, and those that “may be intentionally introduced, including by acts of terrorism.”

Section 3. FSMA
HAZARD GUIDE:  
IDENTIFYING FEEDMILL SPECIFIC HAZARDS

Biological

- Viral, prior/prion and bacterial infectious diseases
- Salmonella
- E.coli 0157
- Food borne contaminants
- Avian Influenza/Newcastle disease
- Parasitic Agents
- Campylobacter
- Clostridium Botulinum
- Clostridium Perfringens
- Staphilococcus Aureus

Physical

- Any foreign object/clips/twist-ties
- Glass
- Metal
- Stones
- Nuts/bolts
- Wood
- Plastics

Chemical

- Aflatoxins/Mycotoxins
- High Risk Minerals - Selenium
- Medication/drug residues
- Heavy metals
- Copper – Sheep
- Pesticide residues
- Nitrates
- Toxic Weeds – Alkaloid

Gossypol – Free
- Non-Protein Nitrogen – Horses, Rabbits, Pigs
- Dioxins
- Allergens (Not required under FSMA)
- Color Additives
- Lubrication/cleaning/ sanitization agents
HAZARD ANALYSIS

When building your Hazard Analysis, remember:

- Complete it for every manufacturing step and/or Category of ingredients.
- Clear and easy to follow through entire manufacturing process, use a flow diagram to help organize your thoughts, if needed.
- Identify both animal and human hazards.
- Refer to “Severity: Likelihood to Occur” diagram
- Refer to your prerequisite programs and use them to your advantage!
HAZARD ANALYSIS

Severity
High          H-R    H-L    H-M    H-H
Medium        M-R    M-L    M-M    M-H
Low           L-R    L-L    L-M    L-H
Remote        Low    Medium  High

Likelihood of Occurrence

Recommendation for FSMA plan at a Feed mill
Considerations for being addressed in HACCP plan

* HACCP: A Systematic Approach to Food Safety

Section 3. FSMA
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<tr>
<th>INGREDIENT/PROCESSING STEP</th>
<th>POTENTIAL HAZARD INTRODUCED</th>
<th>IS THIS A SIGNIFICANT HAZARD? SEVERITY: LIKELIHOOD</th>
<th>JUSTIFICATION FOR SIGNIFICANCE</th>
<th>WHAT CONTROL MEASURED DO YOU HAVE IN PLACE TO PREVENT</th>
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<tr>
<td>Biological</td>
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<td>Radiological</td>
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## HAZARD ANALYSIS EXAMPLE FOR CORN

**Product:** Corn, (Whole, Flaked, Crimped)

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<th>INGREDIENT/ PROCESSING STEP</th>
<th>POTENTIAL HAZARD INTRODUCED</th>
<th>IS THIS A SIGNIFICANT HAZARD? SEVERITY: LIKELIHOOD</th>
<th>JUSTIFICATION FOR SIGNIFICANCE</th>
<th>WHAT CONTROL MEASURE DO YOU HAVE IN PLACE TO PREVENT HAZARD:</th>
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<td>1A Receiving, Bulk Ingredients</td>
<td>Biological BSE</td>
<td>Severity High</td>
<td>Likelihood Low</td>
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Ingredients that have a completed Hazard Analysis

**Baled:**
- Baled Suncured Alfalfa
- Baled Suncured Forage Hay (oat, wheat, barley)

**Bulk:**
- Alfalfa Pellet
- Almond Hulls
- Bakery
- Barley (Whole, Flaked)
- Canola Meal/Pellet
- Cargill PI Milk Plus
- Corn (Whole, Flaked Crimped)
- Corn Germ Meal
- Corn Gluten 60%
- Corn Gluten Feed
- Cottonseed, Whole
- Dairy Grain
- Dried Distillers Grains w/Solubles
- Ground Grain
- Linseed Meal/Pellet
- Milo-Whole
- Oats (Whole, Ground, Crimped)
- Rice Bran
- Safflower Meal
- Soybean Hulls/Pellet
- Soybean Meal
- Soy Best
- Soy Plus
- Sunflower Meal
- Wheat Midds, Midds Pellet
- Wheat Starch
- **Bagged:**
- Active Dry Yeast
- Amaferm

For More Information, please contact

- CR Corn For Tx Sys
- Diatomaceous Earth
- Dicalcium Phosphate
- Diamond V XPC
- Diamond V Yeast XP
- DL- Methionine
- Dried Molasses
- DTI 3 MVP Premix
- Eddi 42 Gm/Lb
- Energy I
- Energy II
- Extruded Soybeans
- EZ-Keep
- Fat Sprayed
- Feather Meal
- Ferrous Sul 30
- Fibroyme
- Fish Meal
- Fish Meal Sealac
- Fish Premix
- Flavor Plus NM
- Garlic Powder
- Gold Dye
- Gold Flavor
- Green Flavor
- Green Dye
- Herd Builder Flavor
- 36% Horse Pellet
- 776- Horse PMX5098
- Iron Carbonate
- Iron Oxide- Brown
- Iron Oxide- Red
- Iron Oxide- Yellow
- Kerry Kreeme
Ingredients that have a completed Hazard Analysis

- Lactomil
- Lacto Sac
- Lactose
- Lamb Premix Pellet
- Layer Vitamin Premix
- Limestone
- L-Lysine HCL
- L-Threonine
- Magnesium Oxide
- Magnesium Sulfate
- Magnesium Sulfate 9.9%
- Manganese Oxide
- Mega Lac R
- Mega Lac Plus w/ 6% Methionine
- MGK Chelate Trace Mineral
- MGK Cheated
- Micro Aid
- Milk Plus Premix
- Min Ad
- Mono Dicalcium Phosphorous
- Mono Prop
- MTB 100
- Niacin-99%
- Oyster Shell
- Oyster Shell Flour
- Papain Enzyme
- PCC Custom Calf Blend
- PCNS Dairy Fortifier
- Pell Tuff
- Pellunite
- Phosphorous Monoammonium
- Phosphorous Monosodium 25
- Pig Nectar
- Potassium Carbonate
- Potassium Ch50
- Potassium Iodide
- Potassium/Magnesium/Sulfate
- Poultry Trace Mineral Premix
- Protein Pellet
- Quadra 4 Alltech
- ReaShure Choline
- Red Flavor
- Rout Mold Inhibitor
- ROP- Royal Optimum Powder
- Salt
- Sana Kreeme
- Santequin 66.6%
- Selenium 0.06%
- Selnosource AF 2000
- Sheep Trace Mineral
- Sodium Sesquicarb
- SoyChlor
- Stock Joy Flavor
- Storagemate Dry
- Thiamine Mono
- Trace Mineral Premix
- Turkey Vitamin Premix
- UNF-40
- Urea
- Vitamin A 30M U/G
- Vitamin A 650M U/G
- Vitamin D3 30 M U/G
- Vitamin E 20 M U/Lb
- Vitamin E 25%
- Vitamin E 125
- Vitamin E 227M U/Lb
- Wheat Starch
- Whey Powder
- Yeast-Dried Brewers
- Yucca Powder
- Zinc Oxide- 72
- Zinc Sulfate
- Zin-Pro 100
- Zinpro 4 Plex ‘C’
- Liquid:
- Aliment
- EZ Flake
- EZ Glo 3-70
- Fat
- Molasses
- Soy Oil
- Vegetable Oil
- Water
- Medicated:
- Amprol 25%
- Amprol Ethorpbate
- Aureozol- 500
- Bac MD-50 RX
- Bambermycin 4G
- BMD-60
- Calf Pellet 25 Rum 1400g RX
- Carboxad 10
- Coban- 60 RX
- CTC- Aureo 50 RX
- Decoquinate 6%
- Fenbendazol 20%
- Lasalocid 68G RX
- Linco-50
- 3 Nitro 20
- Poloxalene 53%
- Pyram Tart- 48
- Rabon 2.1%
- Rumensin 90g (Monesin) RX
- Salinomycin 60 G
- Tylosien-40 RX
PREVENTIVE CONTROL MEASURES

- FDA’s General Approach to Preventive Controls:
  - Understand Cause
  - Identify Hazard
  - Implement Preventative Controls
  - Adjust and Review
  - Monitor Effectiveness

Section 3. FSMA
• Ingredients and/or processing steps that have a hazard that is likely to occur and have a high severity should be assigned a preventive control.

• Preventive controls should be implemented to minimize, eliminate, or monitor these hazards.
PREVENTIVE CONTROL MEASURES

- For Example:
- Medicated feed preventive controls would be identified by:
  - Daily inventory reconciliation
  - Flush/sequencing/cleanout procedures
  - Medicated feed SOP’s established and being followed.
<table>
<thead>
<tr>
<th>INGREDIENT/PROCESSING STEP</th>
<th>IDENTIFIED HAZARD</th>
<th>PREVENTATIVE MEASURE IN PLACE</th>
<th>MONITORING</th>
<th>VERIFICATION ACTIVITIES</th>
<th>RECORDS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>WHAT</td>
<td>WHO</td>
<td>FREQUENCY</td>
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## PREVENTIVE CONTROL MEASURES

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<th>RECORDS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingredient: Section 3, pages: ALL</td>
<td>Mycotoxins/ Aflatoxins/ Fumonisin</td>
<td>Yes</td>
<td>Critical Control Point # 1</td>
<td>Plant Manager</td>
<td>Twice Yearly</td>
</tr>
<tr>
<td>Processing: Section 10, pages: 1,2,4,10,11,16</td>
<td></td>
<td></td>
<td></td>
<td>Designated Employee</td>
<td></td>
</tr>
<tr>
<td>Ingredient: Section 6, pages: 7</td>
<td>Water Quality</td>
<td>Yes</td>
<td>Sampling Testing</td>
<td>Plant Manager</td>
<td>8 hours of Boiler use</td>
</tr>
<tr>
<td>Processing: Section 10, pages: 8, 38</td>
<td></td>
<td></td>
<td>City Water Quality Report</td>
<td>Designated Employee</td>
<td>Annually</td>
</tr>
<tr>
<td>Processing: Section 10, pages: 9,20,21, 22,40</td>
<td>Magnet Efficiency</td>
<td>Yes</td>
<td>Magnet Efficiency Test</td>
<td>Plant Manager</td>
<td>Twice Yearly</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td>Designated Employee</td>
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</tbody>
</table>
• All Preventive controls must have a monitoring step.
• Parameters should be set for each hazard, whether it is zero tolerance or has a range of acceptance.
  – EX: 20 ppb for aflatoxin level would be a parameter
• All monitoring must be recorded and reviewed regularly
• All preventive controls will have a SOP that describes the monitoring that needs to take place.
In the event that a processing error occurs or a parameter is not met:

- Corrective actions should be documented.
- Form should outline the who, what, where, etc. of the failure
- Document how it was corrected and by whom.

Section 3. FSMA
Corrective actions are not a failure of your plan. They are proof that your FSMA plan is working. Shows your ability to catch your mistakes before they leave the facility, which would then result in a recall. An effective plan will always have corrective actions.
Example of Medicated Feed Verification procedures should include:

- Flush verification
- Mixer profiles
- Finished feed sampling and analysis
- Production tonnage compared to load-out scale or bag count

***These steps are required for every hazard indentified in the manufacturing process.***
### Verification Schedule

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>FREQUENCY</th>
<th>RESPONSIBILITY</th>
<th>REVIEWER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verification Activities Scheduling</td>
<td>Annually or upon HACCP/FSMA System change</td>
<td>Person designated by the HACCP/FSMA Coordinator</td>
<td>Plant Manager</td>
</tr>
<tr>
<td>Verification of CCP Monitoring as described in the plan (Ex: monitoring of time &amp; Temp. for cooking meat &amp; bone meal)</td>
<td>According to HACCP/FSMA Plan</td>
<td>According to HACCP/FSMA Plan or Plant Supervisor</td>
<td>HACCP/FSMA Plan designated Quality Assurance employee</td>
</tr>
<tr>
<td>Review of monitoring, corrective action Records</td>
<td>Monthly</td>
<td>HACCP/FSMA designated Quality Assurance employee</td>
<td>HACCP/FSMA Team</td>
</tr>
<tr>
<td>Comprehensive HACCP/FSMA System Verification</td>
<td>Annually</td>
<td>Independent Experts/SAFE Program Audit</td>
<td>Plant Manager</td>
</tr>
</tbody>
</table>

Section 3. FSMA
A recall plan should include:
- A standardized form that is easily followed
- Critical steps in performing the recall should be identified
- Key individuals that should be notified and involved
- Document progress of your recall and conclusion and findings.

Routinely conduct mock recalls at your facility.

Lot tracking -
The better your lot tracking system is, the less feed you will need to recall.
FDA TIMELINE FOR IMPLEMENTATION:

FSMA Timelines:

- Mandated by a court order - Final rule to be published: August 30, 2015
  - Businesses will have 1 year to fully comply
  - Small businesses will have 2 years to fully comply
  - Very small businesses will have 3 years to fully comply

Where do you and your company fit into this picture??
HOW DO YOU START?

Your role as management:

Step 1 – Send a clear message of commitment and support

Step 2 – Establish your FSMA team (these are usually your “Hi-Per/Hi-Po” employees)

Step 3 – Complete a review of all pre-requisite programs and identify areas of improvement
HOW DO YOU START?

Your role as management:

**Step 4** – Designate your firm’s “qualified individual”

**NOTE** – Once all pre-requisite program are in place CDFA can conduct a SAFE audit to verify your firm’s readiness for Hazard Analysis.

**Step 5** – Identify your hazards and establish preventive controls measures.
HOW DO YOU START?

Your role as management:

Step 6 – Monitor those activities
Step 7 – Validate preventive controls
Step 8 – Review and Retain all records for two years
Step 9 – periodically revisit and revise your food safety plan. This is a fluid document.

NOTE – DOCUMENT EVERYTHING!
The most dangerous phrase in the language is "we've always done it this way."
Thank You,
Questions?

Jenna Areias, Program Supervisor
Feed and Livestock Drugs Inspection Program
Division of Inspection Services
California Department of Food and Agriculture

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(559) 978-6276 | cdfa.ca.gov/FFLDRS