



FDA FOOD SAFETY MODERNIZATION ACT

& THE CALIFORNIA FEED INDUSTRY

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



CALIFORNIA DEPARTMENT OF
FOOD & AGRICULTURE

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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.



PROPOSED RULE

- 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



PROPOSED cGMP REQUIRMENTS

- 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



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

A screenshot of the FDA website, specifically the FSMA (Food Safety Modernization Act) section. The header shows the U.S. Department of Health & Human Services logo and the FDA logo with the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". A navigation bar includes links for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco. The "Food" section is highlighted. Below the navigation bar, there is a breadcrumb trail: Home > Food > Guidance & Regulation > Food Safety Modernization Act (FSMA). A sidebar on the left lists "Guidance & Regulation" with links for "Food Safety Modernization Act (FSMA)", "The Law, Rules & Guidance", and "How to Comment on FSMA". The main content area features the title "FSMA Proposed Rule to Establish Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals" and a brief description: "Preventive Standards under the FSMA Main Page Stay connected with FSMA E-mail updates!".



FSMA & the Feed Inspection Program

- 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.



AMENDMENT TO THE COMMERCIAL FEED LAW:

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

Feed Inspection Program – Field Operations	SAFE Program
Feed Sampling	CA GMP Inspections
CA GMP Inspections	SAFE Audits
BSE Inspections	HACCP Audits
TR Investigations	High Violation Binders
Livestock Drug Inspections	Mixer Profiles - at feedmills
Complaint/Follow-up	Mixer Studies - on farm
Violation Follow-up	Outreach/Education
Quarantines	Workshops
Label Review/Inspection/Activities	On-site consulting
Training (staff)	Feed Safety Results
Delinquent Feed Licensee follow-ups	



FSMA & the Feed Inspection Program

The Feed Inspection Program will encompass these three critical areas:

1. Process Verification	2. Enforcement and Compliance	3. Industry Outreach/Training (SAFE)
Process Verification Inspections (CGMP's and Prerequisite program)	Label Review/Inspection/Activity	On-site Training/consulting
Tissue Residue Investigations	Delinquent Feed Licensee follow-up	Workshop
BSE/FEED Inspections	Feed Sampling (1000)	Mixer Profiles/Studies
FDA Regulations Audits	Complaint follow-up	Feed Safety Sample Results
Verification Sampling (200)	Quarantine	Surveys stats etc..
Violation follow-up	Violation follow-up	High Violations Summary
Training	Livestock Drug Inspections	Training/meetings



FEED INSPECTION PROGRAM

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**



RISK ASSESSMENT: ***CA Firms***

Criteria is as follows: 429 in-state firms

High Risk Firm: (55 identified)

- Mix two or more ingredients **and** use drugs/medications
- Vitamin/mineral premix's
- All regulated under CA-GMP's
- Handle prohibited materials

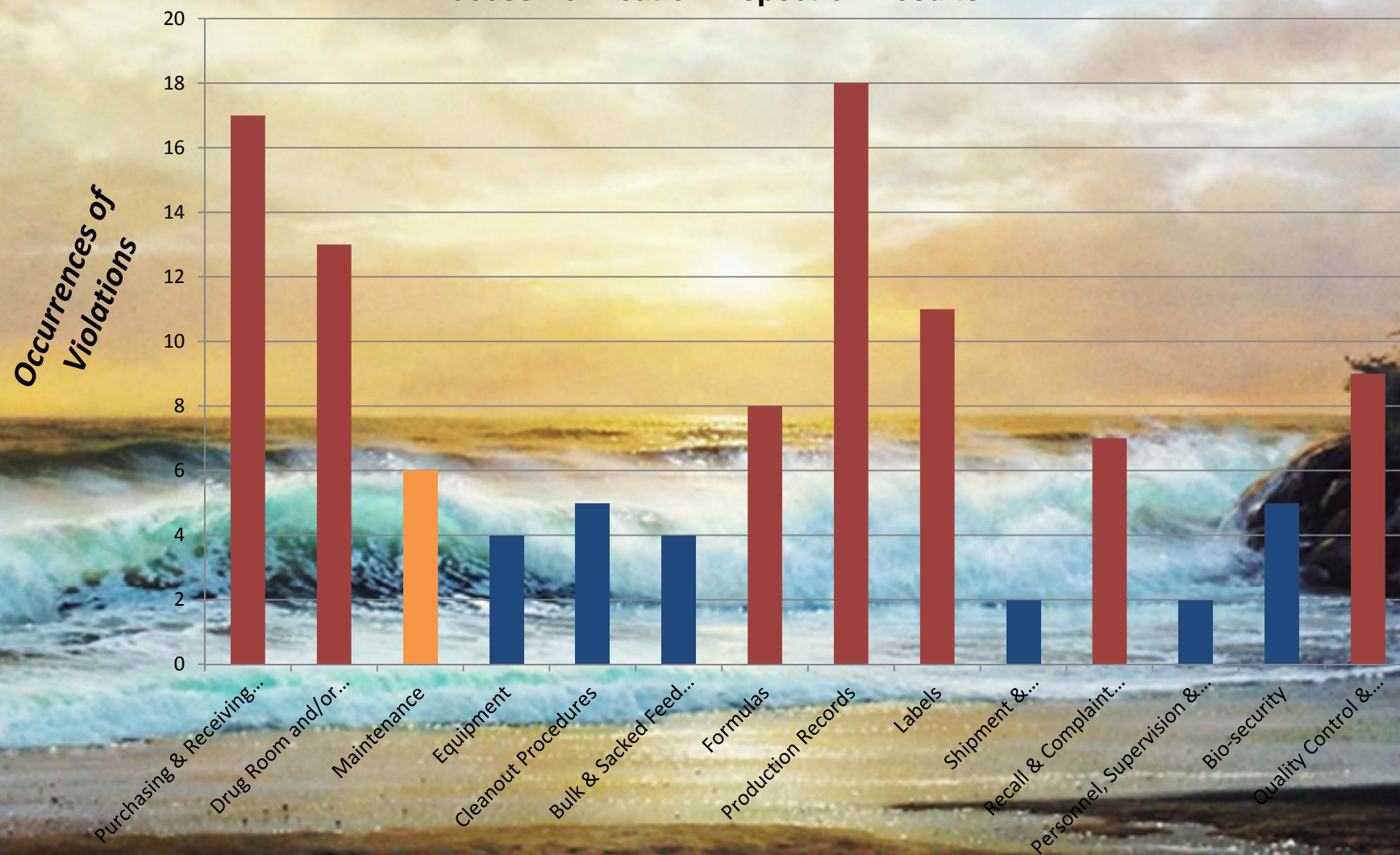
Medium Risk Firm: (244 identified)

- Any firm that mixes two feed ingredients or more 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

Process Verification Inspection Results





LOOKING AHEAD

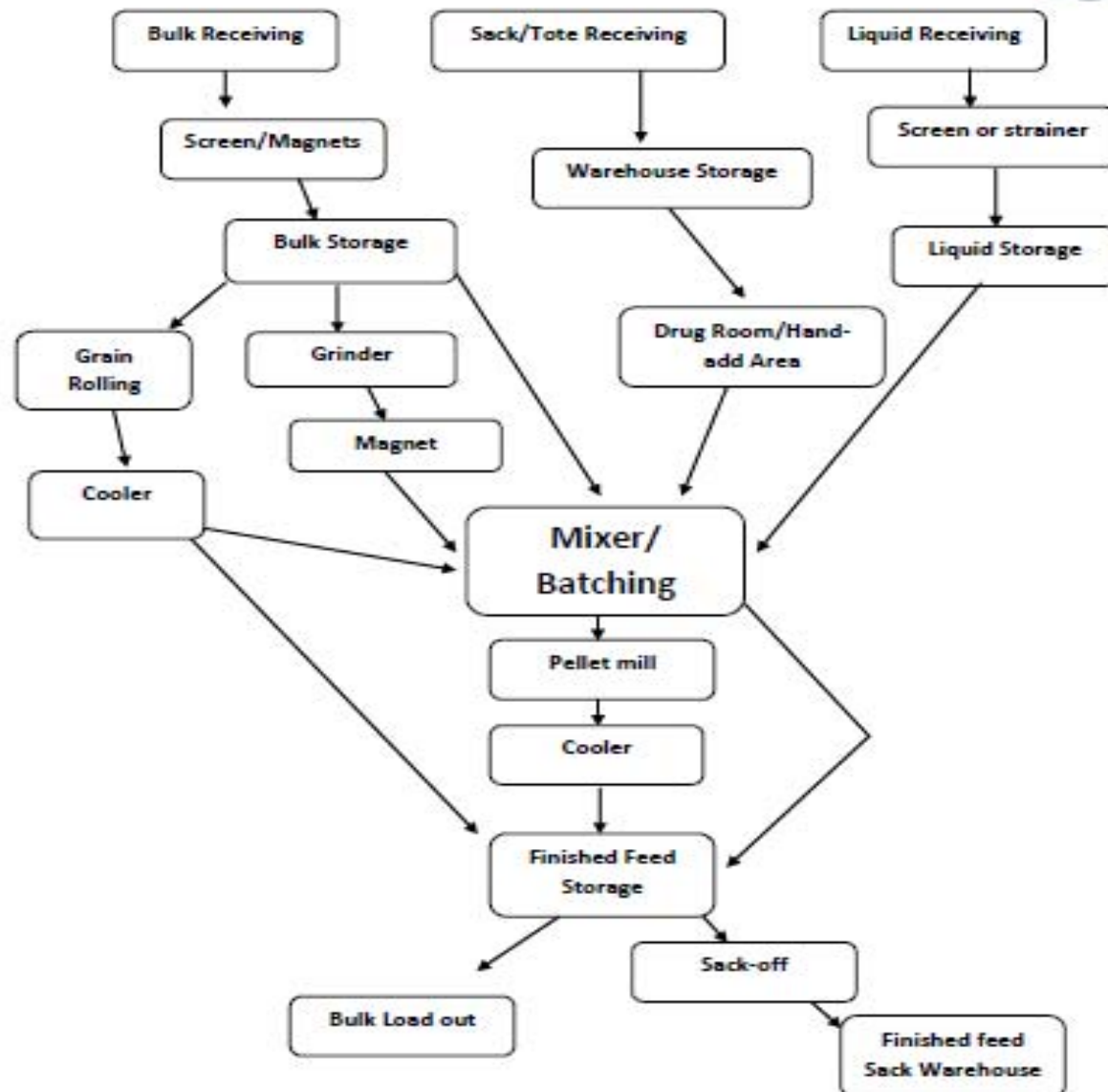
Prepare the Feed Inspection Program to carryout
FSMA audits on licensees in CA; recognized by
the US-FDA

VIDEO

- FSMA AND THE CA FEED INDUSTRY

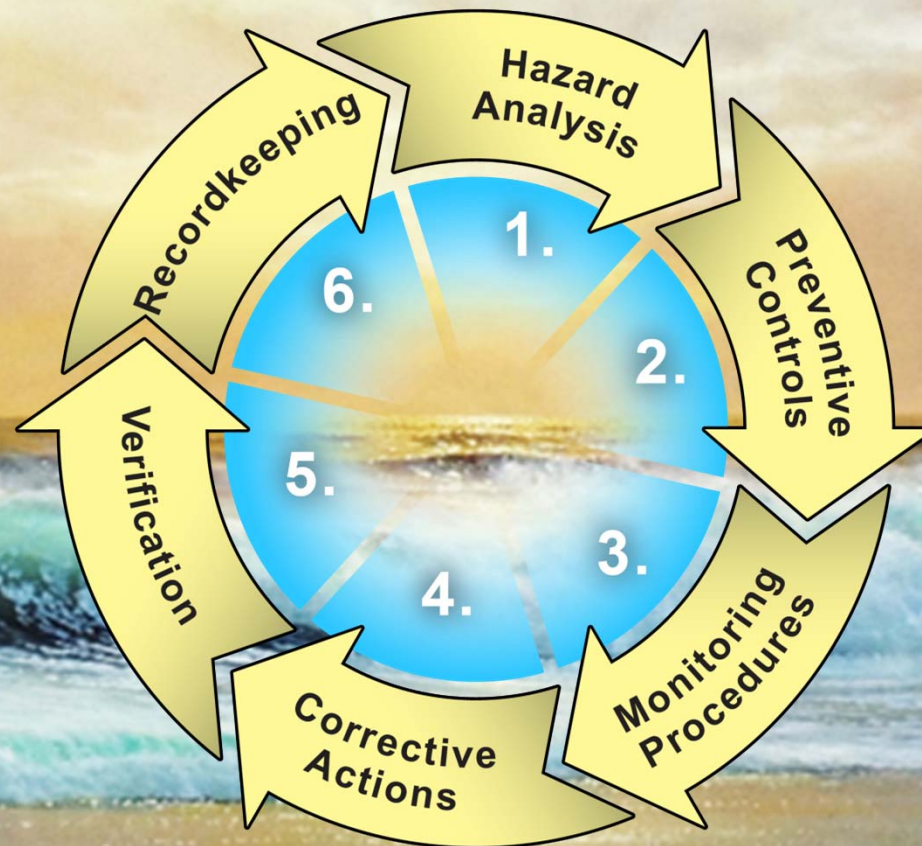


SAFE Feedmill Flow Diagram



HAZARD ANALYSIS & RISK-BASED PREVENTIVE CONTROLS

2014
CGFA
Convention





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.”



HAZARD GUIDE:

IDENTIFYING *FEEDMILL SPECIFIC* HAZARDS

Biological

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

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

Physical

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





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

2014
CGFA
Convention

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

Recommendation
for FSMA plan at a
Feed mill

Considerations for
being addressed in
HACCP plan

Likelihood of Occurrence

* HACCP: A Systematic Approach to Food Safety



HAZARD ANALYSIS

Product:

INGREDIENT/ PROCESSING STEP	POTENTIAL HAZARD INTRODUCED	IS THIS A SIGNIFICANT HAZARD? SEVERITY: LIKELIHOOD				JUSTIFICATION FOR SIGNIFICANCE		WHAT CONTROL MEASURED DO YOU HAVE IN PLACE TO PREVENT
		ANIMAL		HUMAN		ANIMAL	HUMAN	
	Biological	Severity	Likelihood	Severity	Likelihood			
	Chemical							
	Physical							
	Radiological							

HAZARD ANALYSIS EXAMPLE FOR CORN

Product: Corn,(Whole, Flaked, Crimped)

INGREDIENT/ PROCESSING STEP	POTENTIAL HAZARD INTRODUCED	IS THIS A SIGNIFICANT HAZARD? SEVERITY: LIKELIHOOD				JUSTIFICATION FOR SIGNIFICANCE		WHAT CONTROL MEASURE DO YOU HAVE IN PLACE TO PREVENT HAZARD:
		ANIMAL		HUMAN		ANIMAL	HUMAN	
1A Receiving, Bulk Ingredients	Biological BSE	Severity High	Likelihood Low	Severity Moderate	Likelihood Low	BSE contaminated feed that could lead to an outbreak of disease.	No significant risk	Approved Supplier List Truck inspection upon arrival.
	Contaminants from rodent or bird excrement	Low	Low	Low	Low	All feed and ingredients coming from an outside source will be from a supplier that produces a safe and clean feed.	↓	↓
	Chemical Pesticide residues	High	Low	High	Low	Contaminate feed leading to animal sickness	Pesticide residues can reside in meat and milk products and can lead to human illness	Approved Supplier List Testing upon arrival
	Naturally occurring toxins	Moderate	Low	High	Low	Climate not conducive for fungal/Mycotoxin growth	Toxins through milk can lead to toxicity, causing illness	Limits placed on naturally occurring toxins such as Mycotoxins, as well as scheduled testing
	Physical Trailer previously hauled trash, glass, or metal shards.	Moderate	Low	No significant risk	No significant risk	Physical non-food objects in feed could lead to animal injury	No significant risk	Approved Supplier List Visual Inspection
	Radiological No significant risk							

Ingredients that have a completed Hazard Analysis

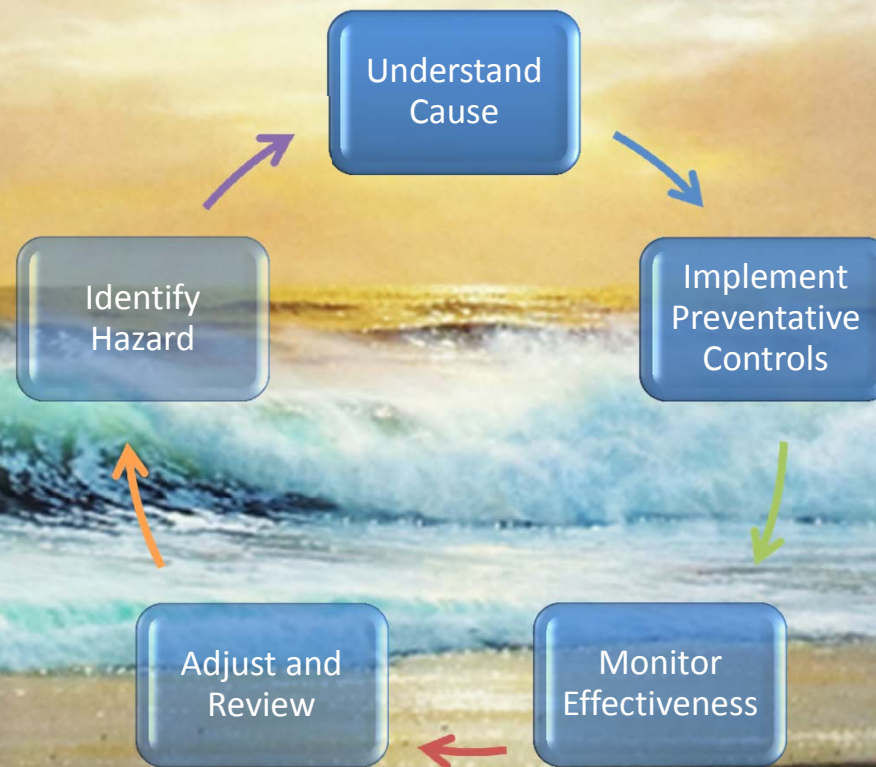
- Baled:
- Suncured Alfalfa
- Suncured Forage Hay (oat, wheat, barley)
- Bulk:
- Alfalfa Pellet
- Almond Hulls
- Bakery
- Barley (Whole, Flaked)
- Canola Meal/Pellet
- Cargill PI Milk Plus
- Corn (Whole, Flaked Crimped)
- Corn Germ Meal
- Corn Gluten 60%
- Corn Gluten Feed
- Cottonseed, Whole
- Dairy 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
- Ammonium Chloride
- Apple Aid
- All Pro Biotics
- Ammonium Sulfate
- Animate
- Ascorbic Acid 100
- Availa 4
- Availa Cu 100
- Avizyme 1320
- Beef Vitamin Premix
- Beet Pulp Pellets
- Bentonite Sod
- Bio-Chlor
- Bioplex Zinc 15
- Biotin 1%
- Biotin 100 Mg/Lb
- Blood Meal (Pork or Beef)
- Buffer Pellet
- Broiler Vitamin Premix
- Calcium Carbonate
- Calcium Iodate
- Calcium Sulfate
- 885 Calf 2X
- Calf PI R160
- Carniking 10%
- Carophyll Red
- Carrots Dehydrated
- Choline Chloride 60%
- Chromium Tripicolinate
- Cobalt Carb 46%
- Cobalt Sulfate 7.5% Premix
- Copper Carbonate
- Copper Oxide-75
- Copper Sulfate
- 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
- Fibrozyme
- 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%
- Manganous Oxide-60
- 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
- Santoquin 66.6%
- Selenium 0.06%
- Selnosource AF 2000
- Sheep Trace Mineral
- Sodium Sesquicarb
- SoyChlor
- Stock Joy Flavor
- Storamate 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 D3 500K IU
- Vitamin E 20 M U/Lb
- Vitamin E 25%
- Vitamin E 125
- Vitamin E 227M U/Lb
- Vitamin/Mineral Pellet
- Wheat Starch
- Whey Powder
- Yea Sac
- 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
- Carbadox 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:



HAZARD ANALYSIS & RISK-BASED PREVENTIVE CONTROLS

- 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.



PREVENTIVE CONTROL MEASURES

INGREDIENT/ PROCESSING STEP	IDENTIFIED HAZARD	PREVENTATIVE MEASURE IN PLACE	MONITORING			VERIFICATION ACTIVITIES	RECORDS
			WHAT	WHO	FREQUENCY		

PREVENTIVE CONTROL MEASURES

INGREDIENT/ PROCESSING STEP	IDENTIFIED HAZARD	PREVENTATIVE MEASURE IN PLACE	MONITORING			VERIFICATION ACTIVITIES	RECORDS
			WHAT	WHO	FREQUENCY		
<u>Ingredient:</u> Section 3, pages: <i>ALL</i> Section 4, pages: 1,2,4,6- 23,27-30 <u>Processing:</u> Section 10, pages: 1,2,4,10,11,16	Mycotoxins/ Aflatoxins/ Fumonisin	Yes	Critical Control Point # 1	Plant Manager Designated Employee	Twice Yearly	Samples sent to outside lab	Kept for 2 years
<u>Ingredient:</u> Section 6, pages: 7 <u>Processing:</u> Section 10, pages: 8, 38	Water Quality	Yes	Sampling Testing City Water Quality Report	Plant Manager Designated Employee	8 hours of Boiler use Annually	In house testing City Water Testing	Kept for 2 years Printed Annually
<u>Processing:</u> Section 10, pages: 9,20,21, 22,40	Magnet Efficiency	Yes	Magnet Efficiency Test	Plant Manager Designated Employee	Twice Yearly	In house testing	Kept for 2 years



MONITORING ACTIVITIES

- 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.

CORRECTIVE ACTIONS

- 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.



CORRECTIVE ACTIONS

- 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.



VERIFICATION OF PREVENTIVE CONTROLS

- 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.





EXAMPLE: Verification Schedule

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



RECALL PLAN

- 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.

The image shows a two-page recall form template. The left page is titled 'Recall' and contains fields for 'Person Initiating Recall', 'Date', 'Feed/Ingredient Recalled', 'Lot # (s)', and 'Reason for Recall'. It also has a section for 'List all feeds and formulas manufactured that contain this ingredient:' with multiple lines for entry. At the bottom, there are checkboxes for 'Retrieve all relevant production records (circle)', 'COMPLETED', and 'NOT COMPLETED'. The right page is titled 'Recall 2' and contains sections for 'List all feeds produced and the lot #s:', 'Yield reconciliation at on site (bags or bulk still on site)', 'List of facilities that recalled feed was delivered and amount that was delivered:', and 'Identify the location, amount, and lot # of the recalled product:'. Both pages have a footer with the text 'Recall | 1' and 'Recall | 2' respectively.

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 firms “qualified individual”

NOTE – Once all pre-requisite program are in place
CDFA can conduct a SAFE audit to verify your firms
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

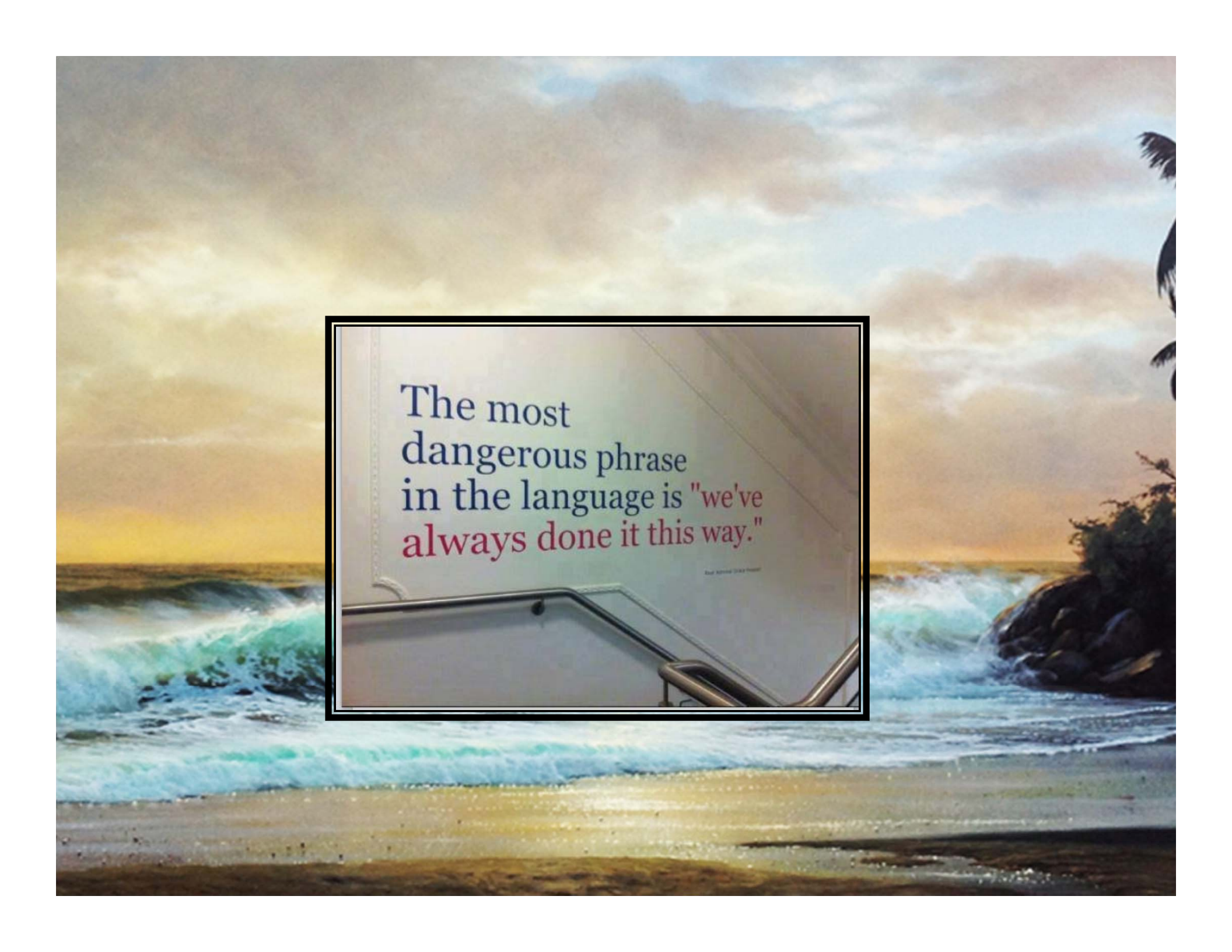
Step 7 – Validate preventive controls

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 background of the entire image is a painting of a beach at sunset. The sky is filled with soft, golden clouds, and the ocean waves are depicted with vibrant turquoise and white foam. In the foreground, the sandy beach is visible. On the right side, there are dark, silhouetted palm trees and some coastal vegetation. Overlaid on the center of this scene is a rectangular inset with a black border. Inside this inset is a photograph of a white wall in a hallway, with a staircase railing visible at the bottom. The wall features a large, printed quote in a serif font. The text is arranged in five lines, with the first four lines in dark blue and the final line in a dark red color. A small, faint signature is visible in the bottom right corner of the inset image.

The most
dangerous phrase
in the language is "we've
always done it this way."

Paul Aronson (2014) Project



Thank You, Questions?

Jenna Areias, Program Supervisor

Feed and Livestock Drugs Inspection Program
Division of Inspection Services
California Department of Food and Agriculture

(916) 900-5022 | jenna.areias@cdfa.ca.gov

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