

**Virginia State Feed Association**

**New Challenges to Feed Mills:**  
*Food Safety Modernization Act & Veterinary Feed Directive (VFD)*

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**Topics to be Presented**

- **Food Safety Modernization Act:**
  - The feed rules have arrived and they are huge!
  - How to prepare for implementation
- **Veterinary Feed Directive or VFD**



**New Law Applies To**



All Ingredient Processing



All Feed Manufacturing



Pet Food



Feed & Ingredient Imports



Transportation




**Main Component of FSMA**

**SEC. 103. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS.**

(a) In General- Chapter IV (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

**SEC. 418. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS.**

(a) In General- The owner, operator, or agent in charge of a facility shall, in accordance with this section, evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 or misbranded under section 403(w), monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice.



### Food Safety Modernization Act

- FDA required reregistration of all feed, ingredient and pet food facilities by **January 31, 2013**. Make sure your firm has re-registered
- Farms and feed mills on farms are exempt if feeding animals on the land owned by the feed mill/farm



### Food Safety Modernization Act

- **Timeframe:** Rules are out, 120 days comment, final rules out June 2015
- **Implementation** is 1, 2, or 3 years depending on size or annual sales
- **Feed rules** will also have GMP rules
- **AFIA** has asked and been granted a comment extension until March 31



### What Should You Do?



AFIA offers training, education and certification programs to support compliance with FSMA

[www.safefeedsafefood.org](http://www.safefeedsafefood.org)



### Preparing For FSMA Compliance

AFIA provides multiple *Safe Feed/Safe Food* certification options for its anyone



## Preparing For FSMA Compliance

### cGMP's and Preventive Controls for Animal Food


Proposed rule applies to facilities that manufacture, process, pack, or hold animal food and are required to register as a food facility under section 415 of the FD&C Act. This rule does not apply to farms that manufacture food for their own animals (on their own land) or other food facilities not required to register.

<p><b>New cGMP's</b></p> <ul style="list-style-type: none"> <li>• Hygienic personnel practices and training;</li> <li>• Facility operations, maintenance, and sanitation;</li> <li>• Equipment and utensil design, use, and maintenance</li> <li>• Processes and controls; and</li> <li>• Warehousing and distribution</li> </ul>	<p><b>Food Safety Plan</b></p> <ul style="list-style-type: none"> <li>• Hazard Analysis</li> <li>• Risk-Based Preventive Controls</li> <li>• Recall Plan</li> <li>• Monitoring</li> <li>• Corrective Actions</li> <li>• Verification</li> <li>• Records</li> </ul>
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## Preparing For FSMA Compliance

*"FSMA is like an on-coming train!!"*




*We need to prepare the tracks!!*

Animal Food  
cGMP's (Pre-requisites)  
Animal Food Safety Plan  
Hazard Analysis  
Preventive Controls  
Records

FSMA "touches" all aspects of "animal food" manufacturing, processing and distribution

Compliance expected by FDA in 2015-16



## Preparing For FSMA Compliance

### Animal Food Safety Plan

(written food safety plan is required)

- Hazardous analysis
- Preventive controls (PC's) for identified hazards
- Recall plan
- PC's monitoring procedures
- Correction action procedures
- Verification procedures with frequency performed



## Preparing For FSMA Compliance



<p><b>FSMA-PR Food Safety Plan</b></p> <p>Requirements of a <b>Written</b> Food Safety Plan</p> <ol style="list-style-type: none"> <li>1. Conduct a Hazard Analysis Establish CCP's, if any;</li> <li>2. Establish Preventative Controls;</li> <li>3. Write a Recall Plan;</li> <li>4. Monitor Performance of Preventative Controls;</li> <li>5. Establish Corrective Actions for Preventative Controls;</li> <li>6. Establish Verification and Validation Procedures for Preventative Controls. (Validate the Method, Verify the Process.)</li> </ol>	<p><b>HACCP Hazard Analysis</b></p> <p>Principles 1 through 7:</p> <ol style="list-style-type: none"> <li>1. Conduct a Hazard Analysis;</li> <li>2. Identify Critical Control Points, CCP's, if any;</li> <li>3. Establish Critical Limits;</li> <li>4. Establish (CCP) Monitoring Requirements;</li> <li>5. Establish (CCP) Corrective Actions;</li> <li>6. Establish (CCP) Verification Procedures;</li> <li>7. Establish Record Keeping Procedures; Establish Recall Policies and Procedures.</li> </ol>
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## Preparing For FSMA Compliance

### Hazard Analysis



- Identify and evaluate known or reasonably foreseeable hazards
- Consider hazards that may occur naturally or may be unintentionally introduced including physical, chemical, biological and radiological
- Determine whether the hazards are reasonably likely to occur, including an assessment of the severity of the illness or injury
- The hazard analysis must consider the effect of the following on the safety of the finished animal food:
  - Formulation, facility/equipment, ingredients, manufacturing, packaging or labeling, storage/distribution, intended use, cleanliness or housekeeping, and any other factors

## Preparing For FSMA Compliance

### Preventive Controls (PC's) for Identified Hazards




- Must identify and implement PC's (including CCP's, if any) to provide assurances that hazards reasonably likely to occur will be significantly minimized or prevented, and will not be adulterated
- Must be written with parameters (max/min) that will significantly minimize or prevent a hazard
- When necessary, cleanliness or sanitation must be included in procedures for the control of hazards (biological)

## Preparing For FSMA Compliance

### Recall Plan



- Must develop a written recall plan for animal food with a hazard that is reasonably likely to occur and assign responsibility for performing all actions in the plan
- Plan must include procedures for:
  - Customer notification about how to return or dispose of the product
  - Public notification about any hazard, when necessary
  - Verify the recall has been completed, and evaluate its effectiveness.
  - Proper disposition of any recalled animal food

## Preparing For FSMA Compliance

### Preventive Control Monitoring

- Must implement written procedures for monitoring the preventive controls
  - Who? What? When? How?
- Frequency must provide assurance that the preventive controls are consistently performed
- Personnel must be trained and qualified to complete the work
- Records, records, records

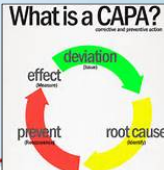




## Preparing For FSMA Compliance

### Corrective Action Procedures

- Implement written corrective action procedures that must be taken if preventive controls are not properly implemented
  - Identify and correct a problem
  - All affected animal food is evaluated for safety
- If a specific corrective action procedure has not been established, or a preventive control is ineffective, you must:
  - Take corrective action
  - Evaluate all affected animal food for safety and take appropriate action
  - Reanalyze the food safety plan

**What is a CAPA?**  
corrective and preventive action







## Preparing For FSMA Compliance

### Verification

- Validate that the preventive controls "work" and are completed by qualified individuals
- Include collecting and evaluating scientific and technical information
- Verify that Monitoring is conducted as required and appropriate decisions about corrective actions are being made
- Verify that the preventive controls are consistently implemented and are effective
- Establish and implement written procedures, as appropriate, for the frequency of calibration
- Records, records, records

## Preparing For FSMA Compliance

### Safe Feed/Safe Food Certification

**Education and Training**

- Feed manufacturing
- Premix blending
- Ingredient suppliers
- International
- Transportation

**Certification**

- Feed manufacturing
- Premix blending
- Ingredient suppliers
- Transportation

**Certification**

- Feed manufacturing
- Premix blending
- Ingredient suppliers
- Pet Food

**Certification**

- Internationally recognized







## Preparing For FSMA Compliance

### Foreign Supplier Verification Program (FSVP)

**Importers would be required:**

- Review the compliance status of the food and the potential foreign supplier before importing the food
- Analyze the hazards associated with each food (reasonably likely to occur)
- Assure hazards are adequately controlled
- Onsite audits; sampling and testing; and periodic review of foreign supplier food safety records; or other appropriate risk-based procedures
- Implement a corrective action program and review supplier verification and PC's, if necessary
- Reassess Foreign Supplier list at least every 3 years
- Obtain a DUNS number for company identification
- Records, records, records




## Preparing For FSMA Compliance

### Accreditation of Third-Party Auditors

This proposal contains requirements for accreditation bodies seeking as well as third-party auditors. These requirements will help ensure the competence and independence of the accreditation bodies and third-party auditors participating in the program.

The proposed rule would require accreditation bodies to:

- Assess third-party auditors for accreditation
- Monitor performance of the third-party auditors it accredits
- Assess and correct any problems in its own performance
- Submit reports and other notifications to FDA
- Protect against conflicts of interest
- Records, records, records








## Preparing For FSMA Compliance

### Accreditation of Third-Party Auditors

The FDA would require accredited auditors to:

- Ensure their audit agents are competent and objective
- Conduct rigorous audits
- Submit reports of reports of audits used for certification purposes
- Notify any condition posing a serious risk to the public health
- Assess and correct any problems in performance
- Protect against conflicts of interest
- Records, records, records



**OBJECTIVE: Consistency and Credibility**








## VFD: The Law

- Offered as alternative to Rx feed
- Enacted in 1996 as part of the Animal Drug Availability Act (ADAA)
- First drug was approved in 1996 for swine
- Now five NADAs: 2 swine, 2 fish, 1 beef
- Basically, requires more documentation for control/use of drug in feed
- VFD is both the drug and the form

## VFD: The Process

- Simple process; involves veterinarian
- Feed mill purchases drug premix from supplier, which triggers "use" letter to FDA and letter to supplier about agreeing to comply with requirements
- Lawful VFD form is required from veterinarian → producer → feed mill/dealer before drug can be delivered

### VFD: The Process (cont'd.)

- VFD has three parts; all which must be maintained for two years post-distribution
- One part for vet; one for producer and the original one is for the feed mill OR dealer
- A VFD form is specific for the drug and amounts and indications for use
- NO deviations from these levels, indications, species or age class are allowed
  - Would constitute a violation



### VFD: The Process (cont'd.)

- Three documents are required:
  1. Any firm can receive a VFD drug if it provides the distributor of the drug with an acknowledgement letter (one-time letter) stating the recipient will abide by the rules and not provide the drug to any firm without a lawful VFD or similar letter of acknowledgement



### VFD: The Process (cont'd.)

2. After receiving the VFD drug, a firm (not producer) must send a notification letter to FDA indicating the firm has the drug. This is also a one-time letter
3. To ship/sell a medicated feed containing a VFD drug to a producer/user, a lawful, original VFD must be presented by the producer



### VFD: The Process (cont'd.)

- The VFD form must contain (some are pre-printed):
 

<ul style="list-style-type: none"> <li>• Drug name</li> <li>• Amount</li> <li>• Indications for use</li> <li>• Location</li> <li>• Number and kind of animals</li> <li>• Amount of feed to be mixed</li> <li>• Name/address/phone of veterinarian</li> <li>• Treatment date</li> </ul>	<ul style="list-style-type: none"> <li>• VFD date</li> <li>• Feeding instructions</li> <li>• Withdrawal time</li> <li>• Warning and/or cautionary statements</li> <li>• Veterinarian's signature</li> <li>• Veterinarian's license # and state</li> </ul>
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### VFD: Practical Issues

- Original VFD form goes to producer then to feed mill/dealer.
  - Faxes (and limited electronic) VFDs are allowed, but must be followed by an original with a signature within five days for a fax and none for approved Internet transmissions.
- Phone-in VFDs are not allowed
- Feed mills can deliver smaller amounts than on VFD and save rest for later



### VFD: Practical Issues (cont'd.)

- If VFD form is incorrect, it's unlawful and will not be "filled" by feed mill
- All VFD drugs are Category II animal drugs, requiring license for Type A
- This means purchasers (feed mills or producers) cannot buy Type A articles (premixes) without an approved Medicated Feed Mill License (MFML)



### VFD: Current Challenges

- Feed Mills are policing the veterinary profession by reviewing the form and assuming the form is lawful (e.g. vet is licensed, etc.).
  - However, FDA recently clearly stated vets are responsible.
- AFIA members say failure to return the original VFD forms by vets for faxes and electronic VFDs is problematic and leaves the feed mill vulnerable for violations



### VFD: Current Challenges (cont'd.)

- More VFD approvals increases paperwork load and review times for feed mills
- AFIA members say feed mills put at disadvantage when producer customer cannot be served appropriately due to form problems





### VFD: The Future

- FDA has published proposed VFD rule changes; took all of AFIA's suggestions
  - Will remove amount of feed to be mixed
  - Will remove vet license # and state
  - Will allow faxes without hard copies
  - Will allow pdfs without hard copies
  - Will not allow oral/verbal VFDs



### VFD: The Future Challenges

- How will this happen: all drugs VFD overnight, phase-in???
- Will FDA required training for vets?
- Will there be a list of trained vets?
- Where will more vets come from?
- Agree with AVMA's changes.
- Will there be enforcement against vets?



Commissioner of Food & Drugs Dr. Margaret Hamburg (left) and Secretary of HHS Kathleen Sebelius



Thank you!  
Questions/Discussion



## Contact Information

**Safe Feed/Safe Food:**

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- Henry Turlington ([hturlington@afia.org](mailto:hturlington@afia.org))
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**FSMA and VFD:**

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## AFIA's 4 Promises to Our Members...

Our 4 Promises to our members...  
We Will Provide Expert Legislative & Regulatory Leadership.

Our 4 Promises to our members...  
We Will Offer Confidential Individual Staff Expertise on Demand.

Our 4 Promises to our members...  
We Will be the Active Voice for the Total Feed Industry.

Our 4 Promises to our members...  
We Will Offer Unparalleled Member Services

