REGULATORY ISSUES/FSMA IMPACTS ON PRODUCTION & SALE OF DDGS

Leah Wilkinson
American Feed Industry Association
lwilkinson@afia.org

Dallas, TX
May 15, 2014
Topics to be Presented

• **Food Safety Modernization Act:**
  • What the feed rule said
  • AFIA’s concerns
  • What happens next

• **Biotech labeling**
New Law Applies To

- All Ingredient Processing
- All Feed Manufacturing
- Pet Food
- Feed & Ingredient Imports
- Transportation

AFIA
American Feed Industry Association
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
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:

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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.
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Food Safety Modernization Act

- FDA issued CGMP and Preventive Control Rule for Animal Food – Oct. 29, 2013
- Comment period closed March 31
- FDA used human food rule as basis
- AFIA’s main concerns:
  - Who’s covered
  - No separate rules: where appropriate/for intended use
  - Compliance dates
Preparing For FSMA Compliance

CGMP’s and Preventive Controls for Animal Food

New CGMP’s
- Hygienic personnel practices and training;
- Facility operations, maintenance, and sanitation;
- Equipment and utensil design, use, and maintenance;
- Processes and controls; and
- Warehousing and distribution

Preventive Controls
- Hazard Analysis
- Risk-Based Preventive Controls
- Recall Plan
- Monitoring
- Corrective Actions
- Verification
- Records
FSMA Trivia

What products are covered in “animal food” and therefore fall under the rule?

a) Livestock feed
b) Pet food
c) Ingredients and raw materials
d) Co-products from human food
e) All of the above
The proposed rule says _______ is necessary to meet the personnel hygiene requirements?

a) Working toilets in sufficient number  
b) Hairnets/beardnets for employees  
c) Sick employees cannot handle feed/pet food  
d) Employees must maintain adequate cleanliness  
e) Handwashing facilities before entering production  
f) Some of the above  
g) All of the above
The proposed rule says ______ is necessary to meet the personnel hygiene requirements?

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True or False?

The hazard analysis must consider hazards that may occur naturally or may be unintentionally introduced.

**TRUE**

Chemical, physical, biological and radiological
The proposed rule says ______ are forms of a chemical hazard?

a) Pesticides
b) Drug residues
c) Natural toxins
d) Decomposition
e) Unapproved food additives or color additives
f) Nutrient imbalances
g) Some of the above
h) All of the above
The proposed rule says ______ are forms of a chemical hazard?

a) Pesticides
b) Drug residues
c) Natural toxins
d) Decomposition
e) Unapproved food additives or color additives
f) Nutrient imbalances
   Nutrient toxicity and deficiency
g) Some of the above
h) All of the above
• Need trained qualified individual(s)
• True or False?

The training required for a qualified individual can be via a course with standardized curriculum OR through on the job experience to develop and apply a food safety system.

TRUE
FSMA Compliance Dates

• When will all of this go into place?
  • Final rule issued by August 30, 2015
  • Effective 60 days post publication
  • Compliance dates for CGMPs and PCs:
    • Large and other firms: 12 months post publication
    • Small (less than 500 employees): 2 years
    • Very Small: 3 years
  • Should CGMPs and PCs be phased in?
    • AFIA says YES: 1, 2, 3 years CGMPs; 2, 3, 4 years PCs
<table>
<thead>
<tr>
<th>FDA or AFIA</th>
<th>Size</th>
<th>Firm Description</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
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<tbody>
<tr>
<td>FDA</td>
<td>Large</td>
<td>&gt;500 employees</td>
<td>CGMPs/PCs</td>
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<tr>
<td>AFIA</td>
<td>Large</td>
<td>&gt;500 employees</td>
<td>CGMPs</td>
<td>PCs</td>
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<tr>
<td>FDA</td>
<td>Small Business</td>
<td>&lt;500 employees</td>
<td>GMPs/PCs</td>
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<tr>
<td>AFIA</td>
<td>Small Business</td>
<td>&lt;500 employees feed business only</td>
<td>CGMPs</td>
<td>PCs</td>
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<tr>
<td>FDA</td>
<td>Very Small Business</td>
<td>$500K; $1M; 2.5M (above threshold, PCs not required)</td>
<td>CGMPs/modified PCs not subject to inspection</td>
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<tr>
<td>AFIA</td>
<td>VSBs</td>
<td>&lt;$10,000</td>
<td></td>
<td>CGMPs</td>
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Work Is Not Done...

• Reopening of portions of AF rule:
  – Supplier verification, testing, byproducts (human food, brewers), CGMPs

• Methodology on High-Risk Foods – May 22

• Sanitary Transportation – May 31

• Reportable Food Public Notification – June 9

• Intentional Adulteration (animal food exempt) – June 30
What Should You Do?

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

www.safefeedsafefood.org

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<th>TIMING</th>
<th>TOPIC</th>
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<td>Phase I</td>
<td>Summer-Fall 2014</td>
<td>Overview of the Food Safety Modernization Act Proposed Rules and AFIA Recommendations; Fundamentals for Complying with FSMA</td>
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<td>Phase II</td>
<td>Spring 2015</td>
<td>Completing an Effective Hazard Analysis; Implementing Preventive Controls; Requirements for Effective Corrective Actions</td>
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<tr>
<td>Phase III</td>
<td>Summer-Fall 2015</td>
<td>Developing an Effective Animal Food Safety Plan</td>
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As of 5/8/14

2014 Biotech Food Labeling Activity

- States with GM Labeling Laws
- States Introducing GM Labeling Bills in 2014
- Ballot Initiative Qualified
- Ballot Initiatives Threatened
- Legislation Defeated, Withdrawn or Held

States Introducing GM Labeling Bills in 2014

- CA
- CO
- ID
- ME
- MT
- NE
- ND
- OR
- UT
- WI
- WV
- WY

States with GM Labeling Laws

- AK
- AZ
- HI
- NV
- OR
- WA
- WY

Initiative State with Introduced Bill

- AK

State Initiative, defeated state bill

- HI

Ballot Initiative Qualified

- MA

Ballot Initiatives Threatened

- VT

Legislation Defeated, Withdrawn or Held

- CT

Not certified for ballot

- MA

Maine – GM Food Labeling signed into law 1/10/14.

Safe and Accurate Food Labeling Act

• Introduced by Rep. Pompeo (R-KS) – HR 4432
  – Cosponsors: G.K. Butterfield (D-NC), Marsha Blackburn (R-TN), Jim Matheson (D-UT) and Ed Whitfield (R-KY)
• Mandatory FDA notification
• Labeling if material differences
• Sets voluntary labeling guide
• Requires FDA to define “natural”
• Will need assistance with additional cosponsors
Thank you!
Questions/Discussion
AFIA’s 4 Promises to Our Members...

We Will Provide Expert Legislative & Regulatory Leadership.

We Will be the Active Voice for the Total Feed Industry.

We Will Offer Unparalleled Member Services.

We Will Offer Confidential Individual Staff Expertise on Demand.