

Wisconsin Crop Management Conference

Regulatory Update: *Food Safety Modernization Act*

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Who is AFIA?

- **AFIA provides:**
 - **Leadership on legislative and regulatory issues concerning feed industry firms from a state, national and global perspective**
 - **Education, training and networking services for the industry**

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 Provide Expert Legislative & Regulatory Leadership.



Our 4 Promises to our members...

We Will Offer Unparalleled Member Services



Our 4 Promises to our members...

We Will Offer Confidential Individual Staff Expertise on Demand.



Who is AFIA?

- 
- AFIA is a non-profit organization representing over 575 animal feed and pet food manufacturing and supplier companies, regional and state associations and international firms.
 - Member companies represent over 75% of all commercial feed manufactured and supplied to the U.S. market.

Raw Ingredients Used in U.S. Feed

RAW MATERIALS USED IN FEEDS:

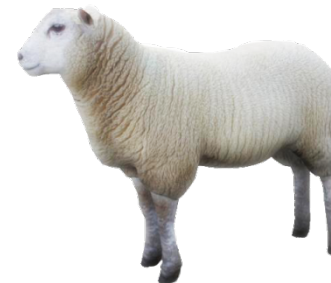
	2013	SOURCE:
Corn	4,335 million bushels	USDA/WASDE Report, March 2014
Wheat	388 million bushels	USDA/WASDE Report, March 2014
Barley	59 million bushels	USDA/WASDE Report, March 2014
Oats	98 million bushels	USDA/WASDE Report, March 2014
Soybean Meal (Domestic Use)	29,031 thousand short tons	USDA/WASDE Report, March 2014
Sorghum/Milo	93 million bushels	USDA/WASDE Report, March 2014
DDGS	35.5 million metric tons	RFA, 2014 Annual Report
Total Forage Production	281,810 thousand tons	2013 Summary Report, USDA-NASS
Alfalfa Production	57,581 thousand tons	2013 Summary Report, USDA-NASS
Corn Silage Production	117,851 thousand tons	2013 Summary Report, USDA-NASS
Other Hay Production	78,365 thousand tons	2013 Summary Report, USDA-NASS



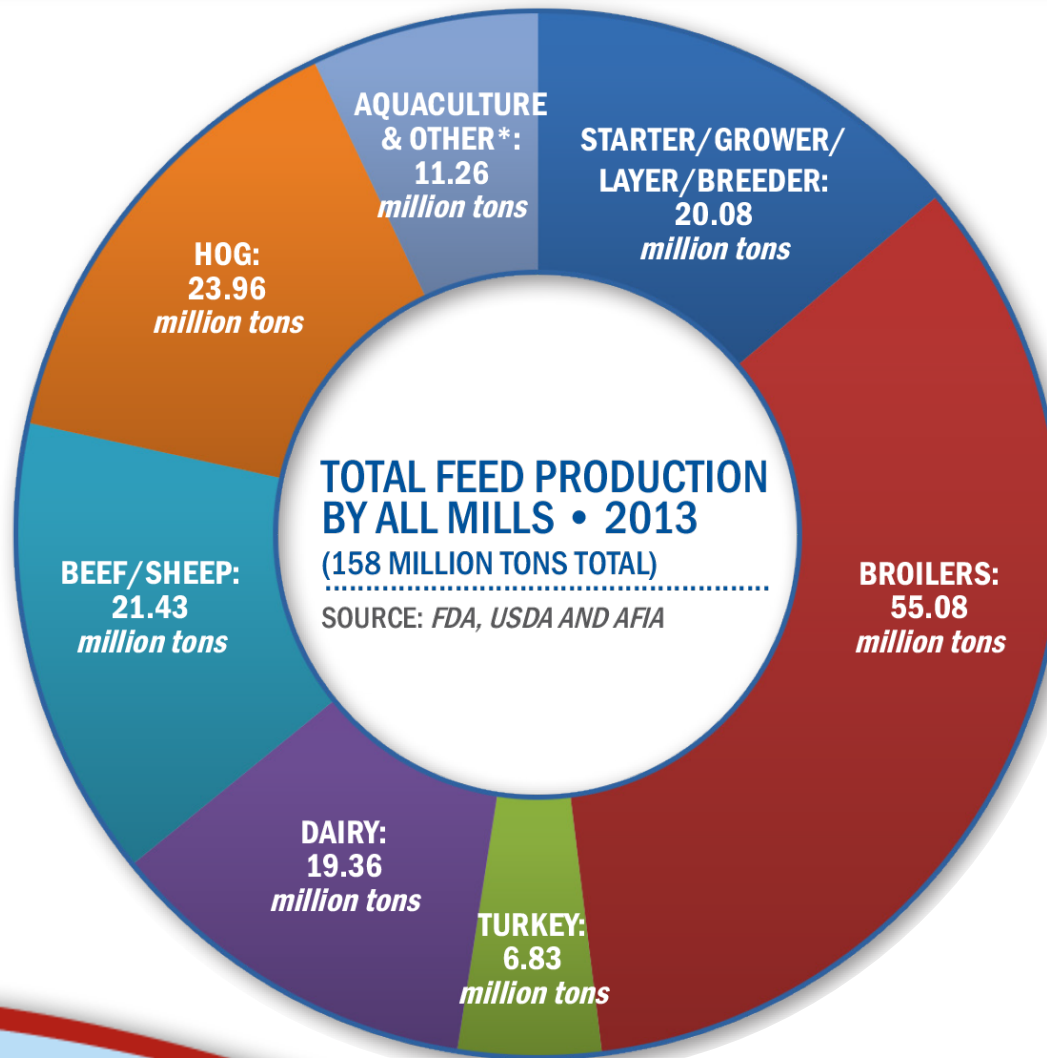
U.S. Animal Production

TOTAL NUMBER OF HEAD:

	2013	SOURCE:
Broilers	8.515 billion head	<i>National Chicken Council: March 2014</i>
Layers	351 million head	<i>USDA-NASS, as of Feb. 2014</i>
Market Hogs	60.2 million head	<i>USDA-NASS, as of March 2014</i>
Breeding Hogs	5.76 million head	<i>USDA-NASS, as of March 2014</i>
Dairy Cattle - Cows that calved	9.2 million head	<i>USDA-NASS, as of Jan. 2014</i>
Beef Cattle - Cows that calved	29.0 million head	<i>USDA-NASS, as of Jan. 2014</i>
Cattle on Feed	10.8 million head	<i>USDA-NASS, as of Feb. 2014</i>
Sheep & Lambs	5.21 million head	<i>USDA-NASS, as of March 2014</i>
Turkeys	242 million head	<i>USDA-NASS, as of Sept. 2013</i>



U.S. Feed Production by Species

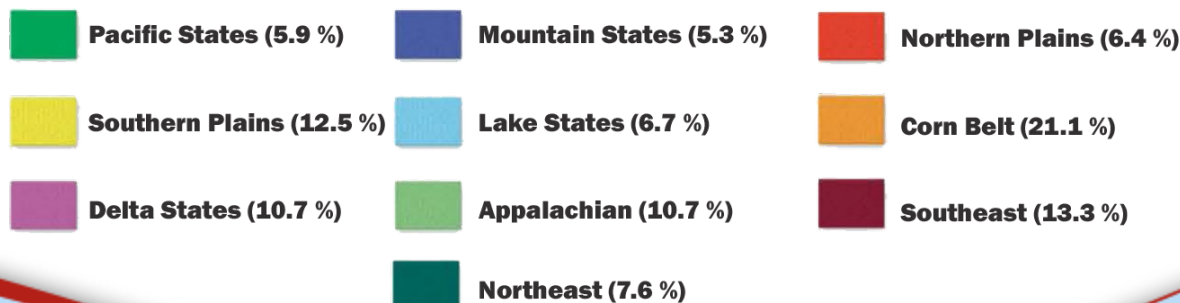
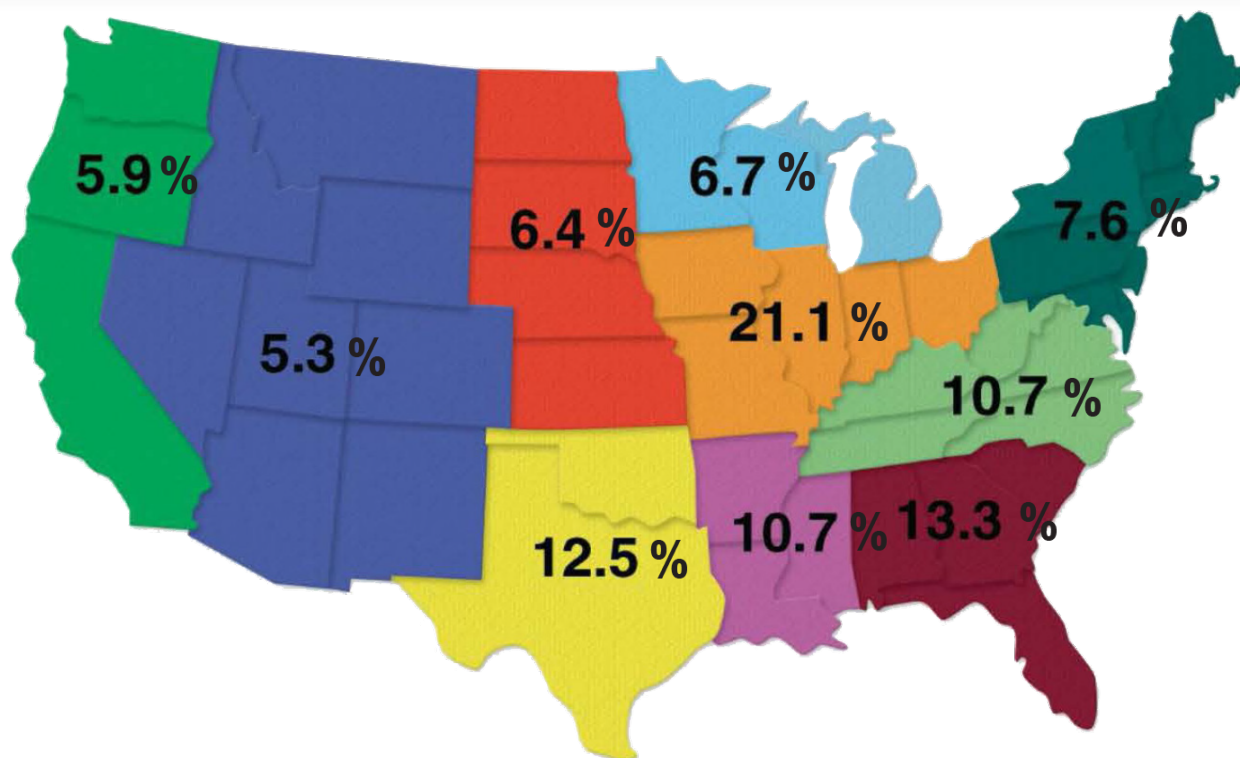


* Does not include dog & cat food

Animal & Feed Production by Region

**ESTIMATED
PRIMARY FEED
PRODUCTION
REQUIRED
TO SUPPORT
ANIMAL
INVENTORY**

SOURCE: Feedstuffs, 2012
Reference Issue and Buyers
Guide, Sept. 12, 2012,
Number 39, Page 6



Total Feed Mills Nationwide

Total Number of Feed Mills in the U.S.

(Source: January 15, 2014 FDA List)

Medicated: 1,012

Non-Medicated: 5,215

Pet Food: 491

TOTAL 6,718

Food Safety Modernization Act

- Signed into law January 2011
- All facilities covered by this law unless a “farm”
- Broadened administrative detention authority
- New mandatory recall authority
- Requires reregistration of all facilities in even numbered years (Oct – Dec 2014)
- Foreign Supplier Verification requirements
- Domestic Supplier Verification requirements

Historical times for animal feeds and feed ingredients.

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 issued CGMP and Preventive Control Rule for Animal Food – Oct. 29, 2013**
 - **Comment period closed March 31, 2014**
 - **FDA used human food rule as basis**
- **Revised FSMA rule issued Sept. 29, 2014**
 - **Comment period closed Dec. 15, 2014**
 - **Supplier Verification**
 - **Product Testing**
 - **Environmental Monitoring**

New

General Provisions

Subpart A

- **Applicability**

- All registered facilities (manufacture, process, pack or hold animal food)
- Medicated feed must still follow 21 CFR 225 CGMPs
- ~~Human food facility co-products: follow 21 CFR 117 if Food Safety Plan includes hazards for animals~~
- Human food facilities: by-products that are packed or held for animal food are exempt if:
 - In compliance with subpart B of part 117
 - Does not further manufacture/process the by-products

- **Definitions**

General Provisions

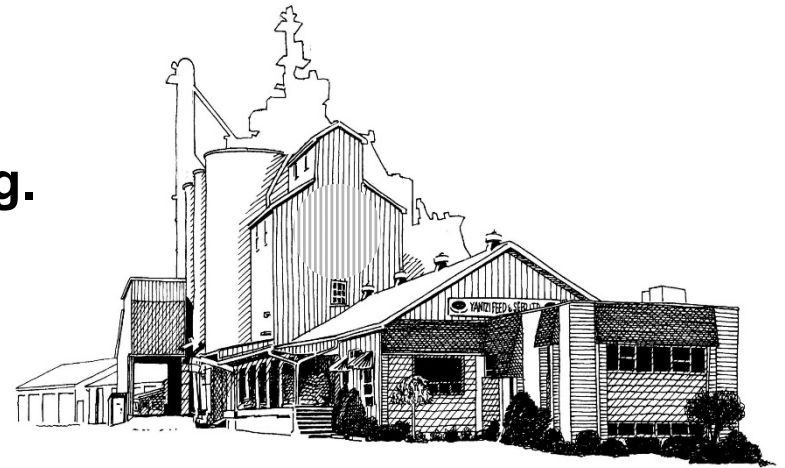
Subpart A

- **Exemptions**
 - Farms, other facilities not required to register
 - LACF – exempt from microbial hazards - Subpart C
 - Qualified facility (VSB or ~~< \$500,000~~ total annual sales)
< \$2.5 million
- Requirements that apply to a “qualified” facility
- Applicability of Subpart C to facility solely engaged in storage of animal food not exposed to the environment

FSMA: Proposed Rule for Animal Food

Subpart B: Current Good Manufacturing Practices (CGMPs)

- 507.14 Personnel.
- 507.17 Plant and grounds.
- 507.19 Sanitation.
- 507.20 Water supply and plumbing.
- 507.22 Equipment and utensils.
- 507.25 Plant operations.
- 507.27 Holding and distribution.
- 507.28 Holding and distribution of human food by-products for use in animal food.



CGMPS

Subpart B

507.14 Personnel

- Illness/lesion? = No access to animal food
- Maintain adequate cleanliness

507.17 Plant and grounds

- Adequate facilities for sanitation, operation
- Maintain grounds, proper drainage, litter removal

507.19 Sanitary operations

- Measures to exclude pests
- Maintained in a sanitary condition

CGMPS

Subpart B

(Re-Proposed)

FDA requested comments:
“Is there adequate flexibility?”

507.14 Personnel

- ~~Illness/lesion? = No access to animal food~~
- Maintain adequate cleanliness

507.17 Plant and grounds

- Kept in condition that will protect against contamination of animal food

507.19 Sanitary operations

- Measures to exclude pests
- Good repair to prevent contamination

CGMPS

Subpart B

507.20 Water supply and plumbing

- Sufficient water supply from adequate source
- Adequate toilet/handwashing facilities
- **Water must be safe for its intended use**

507.22 Equipment and utensils

- **Maintained in such a way as to facilitate cleaning**
- kept in sanitary condition, **if applicable**

CGMPS

Subpart B

507.25 Plant Operations

- ~~Operations conducted with adequate sanitation~~
Reasonable precautions avoid contamination
- Raw materials . . . stored under conditions
 - ~~Inspected and segregated~~ **that will protect against**
 - ~~Washed to remove dirt~~ **contamination**
- Labeling of finished product for safe use

507.27 Warehousing and distribution

- Must protect against contamination/deterioration

CGMPS

Subpart B

507.28 Holding and distribution of human food by-products for use as animal food *(NEW)*

- Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination.

CGMPS

Subpart B

EXAMPLE: AFIA recommendations to FDA

§ 507.25 Plant operations

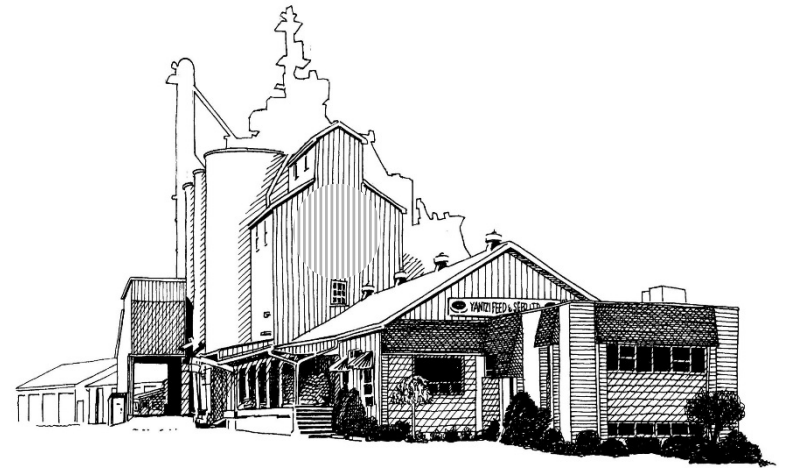
(b) Raw materials and ingredients

(3) And all rework, must be held in ~~containers designed and constructed in a way that protects against contamination, and must be held under conditions, e.g., appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and in a manner that prevents the animal food from becoming adulterated;~~

FSMA: Proposed Rule for Animal Food

SUBPART C: Hazard Analysis and Risk-Based Preventive Controls

- 507.31 Food safety plan.
- 507.33 Hazard analysis.
- 507.36 Preventive controls.
- **507.37 Supplier program.**
- 507.38 Recall plan.
- 507.39 Preventive control management components.
- 507.40 Monitoring.
- 507.42 Corrective actions and corrections.
- 507.45 Verification.
- **507.47 Validation.**
- **507.49 Verification of implementation and effectiveness.**
- **507.50 Reanalysis.**
- 507.51 Modified requirements that apply to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment.
- **507.53 Requirements applicable to a qualified individual and a qualified auditor.**



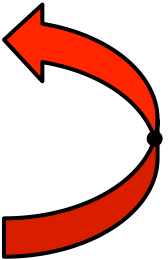
Preventive Controls

Subpart C

- Requirement for the animal food safety plan (written)
 - Hazard analysis
 - Preventive controls
 - **Supplier verification program**
 - Recall plan
 - **Written procedures for monitoring**
 - Correction action program
 - **Written verification procedures**
 - Records

Preventive Controls

Subpart C

- Hazard analysis (written)
 - ~~Reasonably likely to occur~~ Reasonably foreseeable
 - Each type of animal food at facility
 - Naturally occurring or unintentionally introduced
 - Biological
 - Chemical
 - Physical
 - Radiological
- Moved under Chemical
- 

Changes or Additions to FSMA

CGMP's

- Distinguishing between livestock feed and pet food.
- **Exempts** human food manufacturers from animal food CGMP's and preventive controls.
- Removed requirement for **“ill employees”**.
- From **“sanitation”** of equipment to **“cleaned, maintained and stored”** as necessary.

Changes or Additions to FSMA

Hazard Analysis & Preventive Controls

- Replaced reasonably “likely to occur” to reasonably “foreseeable”.
- From hazard “reasonably likely to occur” to “significant hazard”.
 - Hazard analysis of known or reasonably foreseeable hazards
 - Establish controls to significantly minimize the hazard

Changes or Additions to FSMA

“Very Small Businesses”

- Total annual sales of **\$2.5 million**
- Provided more time than a larger business (**3 years vs. 1 year**)
- FDA believes this represents only **2 percent** of the companies qualify as **VSB**.

Changes or Additions to FSMA

Product Testing

- Implemented as a **verification step** and effectiveness of preventive controls.

Changes or Additions to FSMA

Environmental Monitoring

- Animal food facilities must conduct environmental monitoring **as appropriate** for the facility.
- Five potential provisions:
 - Part of Hazard Evaluation for product exposed to environment
 - **Verification of preventive controls**
 - Records
 - Written procedures
 - Corrective actions required

Changes or Additions to FSMA

Supplier Controls

- Required for ingredients identified with a **significant hazard** where it is controlled before receipt.
- Requires verification activities that materials are provided by **approved suppliers**.
- Requires verification activities to ensure significant **hazards are minimized** or prevented.
- Requires an **annual audit** for hazards that result in a **serious** or adverse health consequence.

Changes or Additions to FSMA

Supplier Controls (continued)

- Alternative verification activities for “qualified suppliers.”
- On-site audits must be completed by a qualified individual (training and/or experience).
- FDA, officially recognized, or equivalent food safety authority may substitute for an on-site audit.
- Records required for various activities for verification.

Compliance Deadlines

Very Small Business

3 yrs. after publication

- Less than \$2.5 million total annual sales

Small Business

2 yrs. after publication

- Employ fewer than 500 persons & do not qualify for exemption

Other Businesses

1 yr. after publication

- Businesses not considered VSB or SB

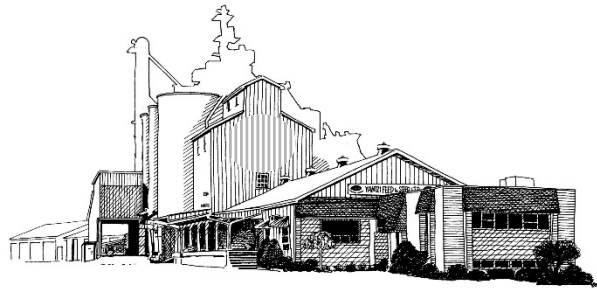
Operating Under FSMA

- **Inspections:**
 - **TODAY:** For cause; reviews for compliance (BSE, medicated feed CGMPs)
 - **FSMA*:** Audit based, review of records
- **High Risk:**
 - **TODAY:** No differences
 - **FSMA*:** Increased inspection frequency and sampling, additional record keeping

* Dependent on congressional funding

FSMA: Proposed Rule for Animal Food

What's next?



Anticipate and Prepare

“Remain calm and carry on”

August 31, 2015

FDA Deadline

Food Safety Modernization Act

BENEFIT: Certified facilities are considered lower risk.

END RESULT: More facilities will obtain 3rd party certifications for quality & food safety to ensure compliance with FSMA requirements

GOAL: Develop a proactive program to reduce potential animal food safety risks versus a reactive approach to failures or nonconformities

More Quality & Food Safety Certifications



What Should You Do?



www.safefeedsafefood.org

Safe Feed/Safe Food: Historical Perspective



Alignment with Safe Quality Food Institute (SQFI)
Global Food Safety Initiative (GFSI) recognition
Reciprocal certifications discontinued

International Safe Feed/Safe Food certification established
with FAMI-QS alignment



2010

2011

Pet Food Manufacturing Facility Certification
Pet Food Ingredient Facility Certification



2006

Safe Feed/Safe Food program updated
to site audits completed every 2 years
Auditor training strengthened

2004

Safe Feed/Safe Food certification established by AFIA
Site audits completed every 4 years



Current Safe Feed/Safe Food Certification Programs

2004

Safe Feed/Safe Food

2014

International Safe Feed/Safe Food

- Internationally recognized program that aligns with FAMI-QS
- Designed for feed additives and premixes

FSC32 Manufacture of Pet Food

- GFSI recognized program that meet FSMA regulatory requirements
- Designed for pet food manufacturers or ingredient suppliers

FSC34 Manufacture of Animal Feeds

- GFSI recognized program that meet FSMA regulatory requirements
- Designed for feed manufacturers

FSC36 Safe Feed/Safe Food

- Fundamentals for compliance with FSMA
- Designed for North American feed manufacturers

AFIA Safe Feed/Safe Food Certifications



FSC36 Safe Feed/Safe Food



FSC32 Manufacture of Pet Food

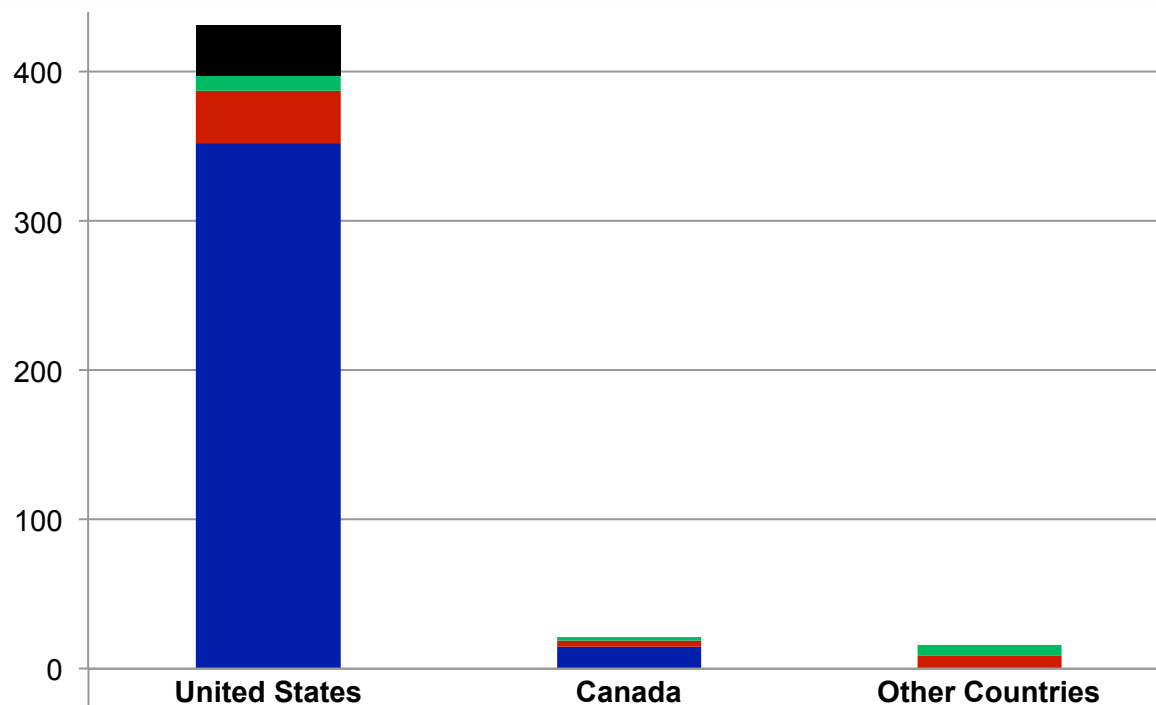
FSC34 Manufacture of Animal Feeds

International Safe Feed/Safe Food



AFIA Safe Feed/Safe Food Program by Certifications

- FSC36, 34, & 32 administered by SQF
- I-SF/SF administered by FAMI-QS

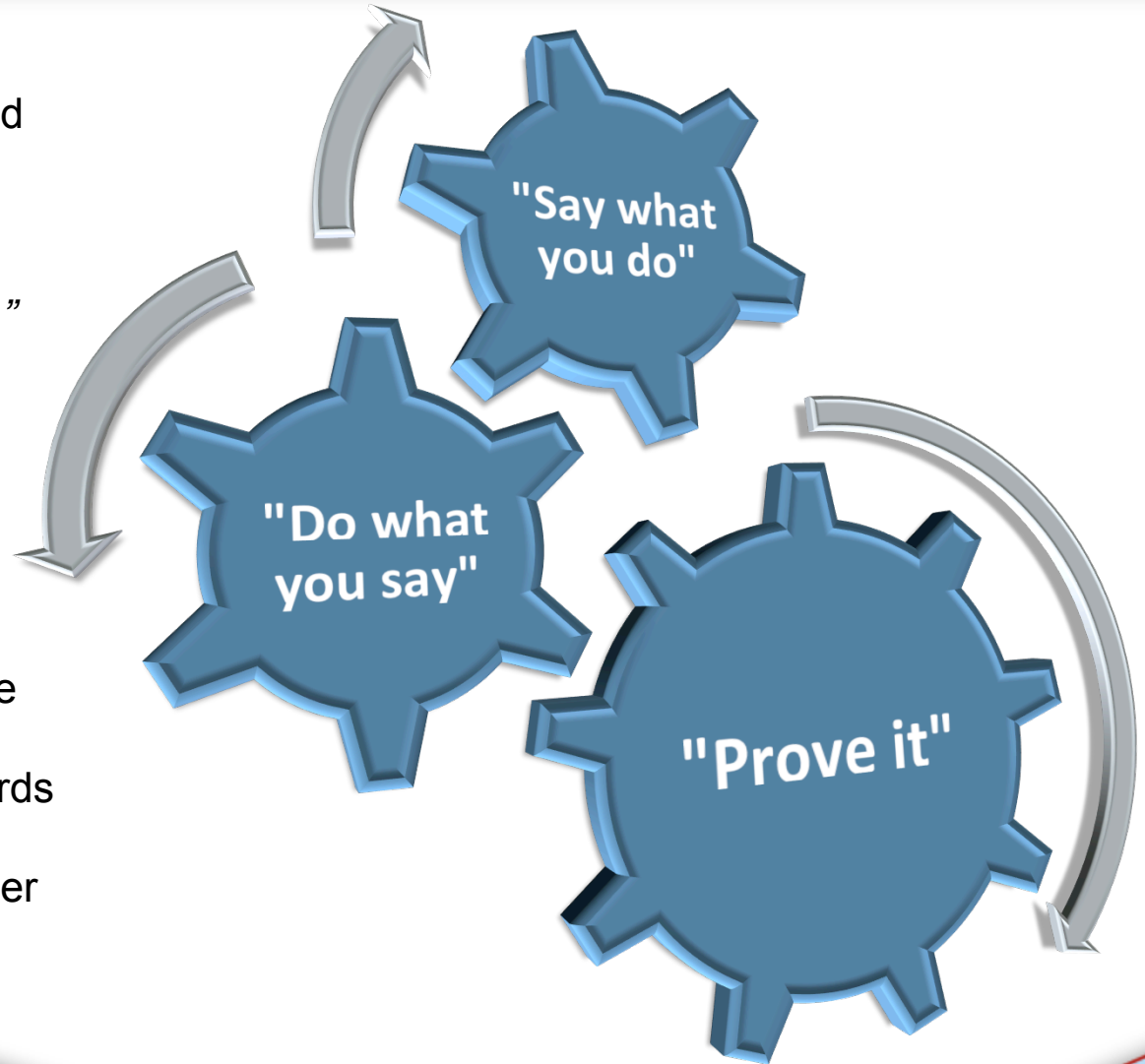


	United States	Canada	Other Countries
■ International Safe Feed/Safe Food	34		
■ FSC34 Animal Feed Manufacturing Animal Feed Ingredient	10	2	7
■ FSC32 Pet Food Manufacturing Pet Food Ingredient	35	4	9
■ FSC36 Safe Feed/Safe Food	352	15	

AFIA & SQFI, June 2014

Safe Feed/Safe Food Program

- Document – prepare policies, procedures, work instructions and specifications that address the relevant elements of the FSC36 guidance document Version 6.0. In other words “*say what you do.*”
- Implement – put into place the prepared policies, procedures, work instructions and specifications. In other words, “*do what you say.*”
- Provide Records – keep records to demonstrate compliance to the relevant elements of the FSC36 guidance document. These records provide evidence of the function and control of the System. In other words, “*prove it.*”





JOIN/RENEW

[Join Safe Feed/Safe Food](#)

[Renew Certification](#)



Printer-friendly version

Join Safe Feed/Safe Food

If your business involves livestock feed or pet food, consider joining the Safe Feed/Safe Food Certification Program today. Look below for information on how to achieve certification for your facility.

Review the following documents before you begin the application process:

- [Hazard Guidelines](#)
- [Guidelines for Record-Keeping and Product Tracking](#)
- [Definitions](#)
- [FSC 36 Safe Feed/Safe Food Guidance Document](#)
- [FSC 36 Safe Feed/Safe Food Checklist](#)

For detailed information on registration and certification for FSC36 Safe Feed Safe Food, please use the following user guide: [FSC36 SFSF SQF Reliance System User Guide - Registration to Certification](#)

To register your company, or companies, with the SQF Assessment Database, [click here](#).

A **NEW FSC36 Safe Feed/Safe Food Guidance Document** is now available. A new FSC36 Safe Feed/Safe Food Checklist will be coming soon. The requirements for the program are the same; however, the program has been organized into a more user-friendly format. The new guidance document will take effect on MARCH 1, 2015:

- **NEW FSC 36 Safe Feed/Safe Food Guidance Document **** IMPLEMENTATION DATE IS MARCH 1, 2015 ******

Please review the new guidance document and provide us with your feedback prior to March 1st. Primary changes in the program are as follows:

Requirements for FSC36 Safe Feed/Safe Food

77 elements or sub-elements with requirements for compliance divided among 9 areas

QUALITY & FOOD SAFETY AREAS	CLAUSES
SF/SF 1 MANAGEMENT COMMITMENT AND RESPONSIBILITY	6
SF/SF 2 QUALITY AND FEED SAFETY MANAGEMENT SYSTEM	4
SF/SF 3 PERSONNEL AND TRAINING	5
SF/SF 4 INFRASTRUCTURE	9
SF/SF 5 PRODUCT REALIZATION	23
SF/SF 6 PURCHASING PROCESSES AND CONTROLS	5
SF/SF 7 VALIDATION AND VERIFICATION	13
SF/SF 8 ANIMAL FOOD SAFETY PLAN	11
SF/SF 9 SAFE FEED/SAFE FOOD SEAL REQUIREMENTS	1
TOTAL	77



QUESTIONS

For Safe Feed/Safe Food information, contact:

- Henry Turlington (hturlington@afia.org)
- Shakera Daley (sdaley@afia.org)
- www.afia.org
- www.safefeedsafefood.org

Veterinary Feed Directive (VFD)

- 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, 0 poultry
- Basically, requires more documentation for control/use of drug in feed and a DVM order
- Lawful VFD form is required before drug can be delivered
veterinarian → producer → feed mill/dealer

Thank you!

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