Good Manufacturing Practices (GMPs) – Background Information
FSMA Overview

Patrick Clark, Ph.D.

patrick@c6advantage.com
NUMBER OF FEED MILLS IN THE U.S.
- 5,970 TOTAL FEED MILLS
- 932 FACILITIES PRODUCING MEDICATED FEED
- 542 PET FOOD FACILITIES
SOURCE: APRIL 25, 2016 FDA LIST

TOTAL NUMBER OF HEAD

<table>
<thead>
<tr>
<th></th>
<th>2015</th>
<th>SOURCE:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Broilers</td>
<td>8.932 billion head</td>
<td>National Chicken Council: April 2016</td>
</tr>
<tr>
<td>Layers</td>
<td>303 million head</td>
<td>USDA-NASS, as of April 2016</td>
</tr>
<tr>
<td>Market Hogs</td>
<td>66.7 million head</td>
<td>USDA-NASS, as of March 2018</td>
</tr>
<tr>
<td>Breeding Hogs</td>
<td>6.20 million head</td>
<td>USDA-NASS, as of March 2018</td>
</tr>
<tr>
<td>Dairy Cattle - Cows that calved</td>
<td>9.32 million head</td>
<td>USDA-NASS, as of Jan. 2016</td>
</tr>
<tr>
<td>Beef Cattle - Cows that calved</td>
<td>30.3 million head</td>
<td>USDA-NASS, as of Jan. 2016</td>
</tr>
<tr>
<td>Cattle on Feed</td>
<td>13.2 million head</td>
<td>USDA-NASS, as of Jan. 2016</td>
</tr>
<tr>
<td>Sheep and Lambs</td>
<td>5.32 million head</td>
<td>USDA-NASS, as of Jan. 2016</td>
</tr>
<tr>
<td>Turkeys</td>
<td>237.5 million head</td>
<td>USDA-NASS, as of April 2016</td>
</tr>
</tbody>
</table>
April 16, 2018
Rose Acre Farms recalls over 206 million eggs
22 related illnesses have been reported

Rose Acre Farms is voluntarily recalling 206,749,248 eggs because they have the potential to be contaminated with Salmonella Braenderup, the U.S. Food and Drug Administration (FDA) announced on April 13.

The eggs were distributed from Rose Acre’s farm in Hyde County, North Carolina, and reached consumers in the following states: Colorado, Florida, New Jersey, New York, North Carolina, Pennsylvania, South Carolina, Virginia, and West Virginia through retail stores and restaurants via direct delivery.
As of the time the recall was reported, 22 illnesses in the U.S. had been reported.

Source: Wattagnet.com
Food Safety Modernization Act (FSMA)

- 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)
- Foreign Supplier Verification requirements
- Domestic supplier verification
- Over 50 new regulations, guidance documents and reports
Food Safety Modernization Act (FSMA) - OVERVIEW

• Subpart A—General Provisions
• Subpart B—Current Good Manufacturing Practice
• Subpart C—Hazard Analysis and Risk-Based Preventive Controls
• Subpart D—Withdrawal of a Qualified Facility Exemption
• Subpart E—Supply-Chain Program
• Subpart F—Requirements Applying to
• Records That Must Be Established and Maintained
• Foreign Supplier verification
• Sanitary Transportation
FDA Background:

- “... to better protect human and animal health by helping to ensure the safety and security of the food and feed supply.”

- “... embraces preventing food safety problems as the foundation of a modern food safety system and recognizes the need for a global approach to food and feed safety.”
New Law Applies To
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.
What defines “Feed”? 

• “Food” means “articles used for food or drink for man or other animals” as defined in section 201(f) of the federal Food, Drug and Cosmetic Act and includes raw materials and ingredients.

• This is the very broad federal definition under the Food & Drug Administration’s (FDA) jurisdiction - consider the terms “food” and “feed” to be synonymous.
Adulteration

The presence of any poisonous or deleterious substance at a level that may render feed and/or feed ingredients injurious to human or animal health. (AAFCO)

- **Biological** – microbiological; parasites; prohibited mammalian protein; decomposition
- **Chemical** – drugs; pesticides; industrial contaminants; toxins (including plant toxins); heavy metals; minerals, unapproved feed ingredients or food additives
- **Physical** – stones, wood, metal, glass, plastic
Compliance Deadlines

Very Small Business 3 yrs. after publication 2018
- Less than $2.5 million total annual sales

Small Business 2 yrs. after 2017 publication
- Employ fewer than 500 persons & do not qualify for exemption

Other Businesses 1 yr. after publication 2016
- Businesses not considered VSB or SB
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
  • 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
• Applicability

Facilities “Solely Engaged” in storing grain and oilseeds (i.e. a facility consisting only of a grain elevator), ARE EXEMPT from both Human Food and Animal Food Current Good Manufacturing Practice (cGMP) and Preventative Controls (PC)

1. Importers of grain that are solely engaged in the storage of grain intended for further distribution or processing; and 2. Importers of grain that do not take physical possession of the grain they import ARE EXEMPT
Subpart B-CGMPs - Flexibility

• Provides flexibility in a variety of ways with words like;
  • “suitable”
  • “appropriate”
  • “adequate”
  • “as necessary”
  • “where necessary”
  • “when necessary”
FSMA: Proposed Rule for Animal Food

- 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.
Qualified Individual (QI)

• A person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual’s assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.
Qualified Individual (QI)

• All individuals who manufacture/process/pack/hold animal food must be qualified to perform their assigned duties:
  • Includes temporary and seasonal workers
  • Must be a Qualified Individual as defined by § 507.3
    • Have education, training, experience, or a combination thereof, to complete duties in a way that results in safe food.
    • Receive training on animal food hygiene and safety, including importance of employee health and personnel hygiene as appropriate.

• The responsibility for this assurance changes:
  • Subpart B: Management of an establishment
  • Subpart C: Owner, operator, or agent in charge of the facility
Preventative Controls Qualified Individual (PCQI)

• A Qualified Individual who has 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 is otherwise qualified through job experience to develop and apply a food safety system.
Preventative Controls Qualified Individual (PCQI)

Must oversee:

1. Preparation of the food safety plan
2. Validation of the preventive controls
3. Determination that validation is not required
4. Review of records
5. Reanalysis of the food safety plan
6. Written justification for validation to be performed in a timeframe that exceeds the first 90 calendar days of production
7. Written justification for review of records of monitoring and corrective actions within a timeframe that exceeds 7 working days
8. Determination that reanalysis can be completed and additional preventive controls validated as appropriate to the nature of the preventive control and its role in the facility’s food safety system, in a timeframe that exceeds the first 90 calendar days of production
CGMPS

Subpart B

(a) Plant management must take all reasonable measures and precautions to ensure that all persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices to the extent necessary to protect against contamination of animal food. The methods for maintaining cleanliness include:

1. Maintaining adequate personal cleanliness;
2. Washing hands thoroughly in an adequate hand-washing facility as necessary and appropriate to prevent contamination;
3. Removing or securing jewelry and other objects that might fall into animal food, equipment, or containers;
4. Storing clothing or other personal belongings in areas other than where animal food is exposed or where equipment or utensils are cleaned; and
5. Taking any other necessary precautions to protect against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.
(b) Personnel responsible for identifying sanitation failures or animal food contamination should have a **background of education or experience**, or a combination thereof, to provide a level of competency necessary for production of clean and safe animal food. Animal food handlers and supervisors should receive appropriate **training in proper food handling techniques and food-protection principles** and should be informed of the danger of poor personal hygiene and insanitary practices.

(c) Responsibility for ensuring compliance by all personnel with all requirements of this subpart must be **clearly assigned to competent supervisory personnel**.
(a) The grounds surrounding an animal food plant under the control of the operator must be kept in a condition that will protect against the contamination of animal food. Maintenance of grounds must include:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests;

(2) Maintaining driveways, yards, and parking areas so that they do not constitute a source of contamination in areas where animal food is exposed;

(3) Adequately draining areas that may contribute to contamination of animal food; and

(4) Treating and disposing of waste so that it does not constitute a source of contamination in areas where animal food is exposed.
CGMPS

Subpart B

(b) Buildings, structures, fixtures, and other physical facilities of the plant must be suitable in size, construction, and design to facilitate cleaning, maintenance, and pest control to reduce the potential for contamination of animal food, animal food-contact surfaces, and animal food-packaging materials. This includes:

1. Providing adequate space between equipment, walls, and stored materials to permit employees to perform their duties and to allow cleaning and maintenance of equipment;

2. Being constructed in a manner such that drip or condensate from fixtures, ducts, and pipes does not serve as a source of contamination;

3. Providing adequate ventilation or control equipment to minimize vapors (for example, steam) and fumes in areas where they may contaminate animal food; and locating and operating fans and other air-blowing equipment in a manner that minimizes the potential for contaminating animal food;
(4) Providing adequate lighting in hand-washing areas, toilet rooms, areas where animal food is received, manufactured/processed, packed, or stored, and areas where equipment or utensils are cleaned;

(5) Providing safety-type light bulbs, fixtures, and skylights, or other glass items suspended over exposed animal food in any step of preparation, to protect against animal food contamination in case of glass breakage; and

(6) Protecting animal food stored outdoors in bulk by any effective means, including:
   (i) Using protective coverings;
   (ii) Controlling areas over and around the bulk animal food to eliminate harborages for pests; and
   (iii) Checking on a regular basis for pests and pest infestation.
Sub-Part C  FSMA

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.**
To Cover or Not To?
Sanitary Transportation

The rule was mandated by the Sanitary Food Transport Act (SFTA) to prevent practices during transportation that create food safety risks such as:

- Failure to properly refrigerate food
- Inadequate cleaning of vehicles between loads
- Failure to properly protect food

Implementation of the SFTA provisions was included in the FDA Food Safety Modernization Act (FSMA). Consistent with our “educate before and while we regulate” approach to FSMA implementation, the agency is focusing on supporting compliance through education in these initial months.
Sanitary Transportation

Q. Do I need to provide documentation to identify/verify the three previous loads in a bulk container?

A. In the original proposed rule this was a proposed requirement. However, in the final rule, the requirement was lowered to identifying only one previously hauled load if requested by the shipper. Section § 1.908 (e)(4) reads:

(4) If requested by the shipper, a carrier that offers a bulk vehicle for food transportation must provide information to the shipper that identifies the previous cargo transported in the vehicle.
Sanitary Transportation

I have to comply with the rule - what are my requirements?

• **Vehicles and transportation equipment:** The design and maintenance of vehicles and transportation equipment to ensure that it does not cause the food that it transports to become unsafe.

• **Transportation operations:** The measures taken during transportation to ensure food safety, such as adequate temperature controls, preventing contamination of ready-to-eat food by raw food, protection from food contamination by non-food items in the same load or a previous load on the vehicle, and the protection of food from cross-contact, i.e., the unintentional incorporation of a food allergen.

• **Training:** Training of carrier personnel in the awareness of potential food safety problems and basic sanitary transportation practices required by the rule, and documentation of the training. This training is required when the carrier and shipper agree that the carrier is responsible in whole or part, for sanitary conditions during transport.

• **Records:** Maintain records of shipper-to-carrier communication, written procedures, agreements and training (required of carriers). The required retention time for these records depends upon the type of record and when the covered activity occurred, but except for training documentation, does not exceed 12 months.
• Q. Are there specific cleanout procedures for vehicles and transportation equipment required in the regulations?

• A. No, the regulations do not require specific cleaning procedures for vehicles or transportation equipment for transporting animal food. The regulations provide flexibility through the use of terms like “suitable,” “adequate,” “appropriate” and “when, or as necessary,” and there is no specific definition of a “clean truck.”

• Each shipper has the ultimate responsibility of determining the necessary sanitary specifications required to prevent the animal food from becoming unsafe during transportation. These specifications defined by the shipper will determine what would be considered a “clean vehicle.” These specifications should be in the form of written procedures required by the shipper to prevent the animal food from becoming unsafe during transportation.
Q. Do I need specific written Current Good Manufacturing Practices (CGMPs) or is having them in my standard operating procedures (SOPs) enough?

A. CGMPs do not need to be written out as long as they are covered in SOPs. It will be easier to demonstrate compliance with written procedures for CGMPs, but there is no requirement for documentation of CGMPs in 21 CFR part 507.
Questions?

Patrick Clark, Ph.D.
patrick@c6advantage.com