Overview of FDA’s Animal Feed Safety System (AFSS)
July 2019

Feed Safety Background

In 1906, Congress passed the Pure Food and Drug Act, giving the Food and Drug Administration (FDA) its start in developing safety regulations for food and feed. Then, in 1938, Congress passed the Federal Food, Drug, and Cosmetic Act (F&DC Act), which incorporated and expanded the provisions of the 1906 Act and became the basic federal law giving FDA the authority to regulate food, including food for animals, as well as drugs for humans and animals. In 2011, the Food Safety Modernization Act (FSMA) made the most significant changes to the regulation of animal and human food safety since the 1938 law. FSMA changed the regulatory emphasis to one of preventing rather than reacting to food safety problems.

Animal food produced and used in the United States has a strong safety record. But problems have still occurred over the years. Because of that, the importance of FSMA – with its emphasis on prevention – can’t be overstated. And FSMA has provisions that apply to domestic as well as international feed safety issues. FSMA is mentioned several times throughout this document.

AFSS Purpose and Scope

FDA is the primary federal regulatory agency responsible for the safety of animal food. FDA manages this responsibility under the Animal Feed Safety System (AFSS), and the Center for Veterinary Medicine (CVM) manages the AFSS.

AFSS covers these aspects of animal food safety:

1. Regulatory activities:
   - pertaining to all aspects of animal food safety – pre-approval requirements, establishing limits on feed hazards, manufacturing, labeling, packaging, storing, distributing

2. Enforcement:
   - performing inspections and investigations
   - taking enforcement actions to remove unsafe animal food from the marketplace and to address firms failing to comply with FDA regulations

3. Information dissemination:
   - providing education and training, conducting research

4. Cooperation:
• establishing partnerships with other government agencies with responsibility for feed safety

AFSS Operating Principles

These operating principles form the basis for AFSS:

1. Animal food and animal production industries are responsible for safe animal food, including production, packaging, distribution, and use;
2. Federal and state regulatory agencies provide the rules, guidance, and oversight to assist industry in producing and distributing safe animal food ingredients and mixed feed;
3. Rules and guidance provide flexibility in the approaches that individual animal food producers can use to meet acceptable safety criteria;
4. Federal and state regulatory agencies cooperate on all aspects of animal food regulation;
5. Federal and state feed regulatory agencies conduct inspections of animal food manufacturers, conduct reviews of product labels, take samples, analyze animal food for hazards, analyze animal food for compliance with label guarantees, and take appropriate actions to address violations;
6. FDA uses risk-based decision-making approaches to determine which animal food hazards to focus on for inspection or enforcement, which require more research, and which are the best methods for addressing the hazards;
7. FDA directs its regulatory resources to those animal food hazards that are a risk to animal and public health;
8. Animal food defense measures to prevent or respond to intentional acts of animal food contamination are part of the AFSS;
9. Training is critical for ensuring that industry and regulatory agencies have the most up-to-date knowledge about FDA rules and guidance, and that enforcement by FDA and states is consistent and conducted in an appropriate manner;
10. All animal food, including pet food and livestock feed, are included under AFSS; and
11. AFSS covers animal food establishments, including all facilities, equipment, and conveyances involved in the production, packaging, storage, and distribution of individual animal food ingredients and mixed feed, as well as animal feeding.

State Partners

State feed control officials help FDA by doing much of the animal food manufacturer inspections and enforcing state and federal laws. In addition, states have programs to minimize economic losses for feed purchasers, such as programs ensuring that feed products meet label guarantees for nutritional components.

State feed control officials work cooperatively through the Association of American Feed Control Officials (AAFCO) to put uniform rules in place on manufacturing, distributing, labeling, and selling animal foods. AAFCO was founded in 1909. It provides a forum for the feed industry, academia, consumers, and government to identify, discuss, and resolve animal feed and animal food safety issues. AAFCO membership includes FDA, USDA,
the Canadian Food Inspection Agency, Puerto Rico, and Costa Rica, as well as all states in the United States.

AAFCO annually updates its Official Publication, a book that contains definitions of feed terms, official names and definitions for feed ingredients, model regulations for states, and proceedings from its regular meetings. AAFCO also publishes an on-line version of the Official Publication, so it can be updated more frequently than the printed version.

**AFSS and Feed Safety**

This document provides an overview of the elements that make up AFSS. Each AFSS feed safety program is discussed below in more detail.

**Ingredients and the Approval Process**

The Federal Food, Drug, and Cosmetic Act (F&DC Act) gives FDA the authority to regulate ingredients and additives used in animal food.* Food ingredients that are demonstrated to be safe and effective are approved as Food Additive Petitions. Notice of approvals appear as regulations in the Federal Register. All FDA-approved food additives for use in animal feed are listed in 21 CFR 573.

Animal food ingredient suppliers can also use the Generally Recognized as Safe (GRAS) Notification procedure if information about the ingredient is not confidential. In 2016, FDA issued the GRAS Final Rule, saying that FDA can be notified of a conclusion that a substance is GRAS under the conditions of its intended use in human or animal food. FDA evaluates GRAS notices when filed and determines whether FDA has questions about the GRAS conclusion. These notices can be found in CVM’s GRAS Inventory. FDA neither approves nor confirms the GRAS status for intended conditions of use. Instead, a GRAS status is the notifier’s conclusion and responsibility. GRAS approved substances are listed 21 CFR 582 and 21 CFR 584.

FDA also accepts animal food ingredients as defined in the AAFCO Official Publication and uses the name in the Official Publication as the common or usual name of the ingredients (see Compliance Policy Guide [CPG] 665.100).

FDA has also developed a Memorandum of Understanding (MOU) with AAFCO explaining the roles of both organizations in adding or modifying feed ingredient definitions. The MOU is also in the AAFCO Official Publication.

**Production, Storage, and Distribution of Safe Animal Food Feed Ingredients and Mixed Feed**

The AFSS Team reviewed the U.S. feed safety system before FSMA was passed in 2011 and found that the system lacked baseline requirements for producing safe animal food, including Current Good Manufacturing Practice (CGMP) requirements. So FSMA’s final

* Some articles added to feed fall under the purview of other Federal agencies. Feed-through pesticides are regulated by the Environmental Protection Agency, and vaccines added to feed are the responsibility of the USDA.
rule calls for animal food and ingredient producers to comply with CGMPs that address manufacturing, processing, packing, and holding animal food. FSMA also requires hazard analysis and risk-based Preventive Controls for Animal Food for many animal food manufacturers to prevent illness or injury to animals or to humans consuming food derived from animals.

FDA has developed “Guidance for Industry” documents, including the following that address hazard analysis and preventive controls:

- Guidance for Industry #235: “Current Good Manufacturing Practice Requirements for Food for Animals.”
- Guidance for Industry #245: “Hazard Analysis and Risk-Based Preventive Controls for Food and Animals”
- Guidance for Industry #246: “Hazard Analysis and Risk-Based Preventive Controls for Food for Animals: Supply-Chain Program”
- Guidance for Industry #239: “Human Food By-Products for Use As Animal Food”.

Animal food and ingredient manufacturers are typically required to comply with FSMA’s animal food preventive-control rule if they are also required to register with FDA as food facilities under the Bioterrorism Act (formally known as the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 Act). The Act calls for food facilities that manufacture, process, pack, or hold food or feed for consumption in the United States to register with FDA. FSMA requires them to register under the Bioterrorism Act every other year.

Farms are typically exempt from the Bioterrorism Act, and, therefore, from FSMA, too. For exempt farms, CVM has developed a guidance document, Guidance for Industry #203, “Ensuring Safety of Animal Feed Maintained and Fed On-Farm,” that provides information that animal producers can use to help them make sure their animals’ health is not adversely affected by feed hazards and that human food derived from their animals does not compromise human health.

Animal Food Hazards
Not all animal food hazards carry the same risk for adverse consequences to animal or human health. The Agency needs a systematic process whereby it can distinguish among animal food hazards based on the risks each hazard poses to animal or human health.

During public meetings, held September 12, 2006, May 22, 2007, and May 14, 2008, CVM made presentations about risk, risk-ranking, potential animal food hazards, health consequence, and exposure scoring for chemical and microbiological feed hazards. FDA incorporated information gathered from discussions at the meetings into its process for building a relative risk ranking tool.

A relative risk ranking project using an animal food database consists of developing a risk score for a number of hazards and then ranking them based on the risk scores.
Because different species respond to hazards in different ways and consume species-specific diets, the ranking is done for a given species, class of animal, and a given diet.

The AFSS risk ranking team originally developed the tool in EXCEL, but it outgrew that platform. A contractor (RTI) converted the model to a Microsoft Access database platform. The new animal food database is referred to as aFRED, for Animal Food Risk Evaluation Database.

FDA provided to the contractor, in spreadsheet format, tables that communicated the desired aFRED table structure. In addition, the spreadsheet provided example data for each table to facilitate the design and implementation of the aFRED structure.

The contractor constructed the aFRED database and provided it to CVM in September 2017. CVM continues to update and refine the tool.

The aFRED database has these features:

- It has a graphical user interface (GUI);
- It has multiple user entry screens with prompts for input;
- An associated EndNote database (literature, graphs, etc.) to query for relevant information to use as input;
- Available for user-supplied information, which the user should add to the EndNote data warehouse to continually update the database; and
- Storage for results for a hazard, loop through the model for the next hazard, and aggregate the results for all hazards evaluated into one report showing the rankings.

**Limits for Animal Food Hazards**

Environmental, agricultural, industrial, or other sources can contaminate animal food and food ingredients, causing serious adverse effects to animal and human health and creating problems in the market. Contamination can happen at any stage of the animal food production system – harvest, manufacture, storage, or transportation. It can even happen because of on-farm feeding practices.

Existing, low-level animal food contaminants that could create food hazards can be increased to deleterious or toxic levels by certain harvesting or manufacturing practices, storage, or transportation conditions. Contaminants could also be added deliberately to animal food to cause serious adverse animal and human health and economic problems.

When limits are needed for animal food ingredients or mixed food, the analytical method must be rapid, inexpensive, and reliable. FDA has developed a Standard Operating Procedure (SOP) so that analytical methods can be validated and made available to industry and government. The SOP uses established criteria for FDA’s limits for feed hazards. (See Appendix II.)
**Antimicrobial Drugs**

Until 1996, antimicrobial drugs were largely approved for use in feed or water as over-the-counter drugs. By then, though, science had improved to provide more information about bacterial resistance to antimicrobial drugs. Therefore, since 1996, as provided in Animal Drug Availability Act, antimicrobial drugs approved for feed use were approved as Veterinary Feed Directive (VFD) drugs.

FDA believes that antimicrobial drugs are important to protect the health of animals. But in some cases, drugs used for human health were the same drug used in animals, potentially leading to the threat of bacterial resistance in humans and animals because of non-judicious use of antimicrobial drugs. As a result, the animal drug industry with the guidance of CVM changed the status of drugs important in human medicine from over the counter to VFD. And the use of the antimicrobials would have to be ordered by a qualified veterinarian. Water use antimicrobials were changed to prescription use. Veterinarians have the scientific and clinical training to know how to use antimicrobials judiciously, thus reducing the likelihood of resistance.

**Reporting of Unsafe Animal Food**

Information about adulterated or misbranded animal food comes from a variety of sources, including the feed industry, animal producers, practicing veterinarians, and the public. It’s important for FDA to have access to that information, so the FDA Amendments Act (FDAAA) of 2007 called for the establishment of a “Reportable Food Registry.” A reportable product is any animal food that has left the control of a company last handling it and that is likely to lead to illness or injury to humans or animals.

Reports can be sent to the Registry via a Safety Reporting Portal. Anyone with an Internet connection who can access the FDA Website can make the report a problem animal food to the Registry.

Responsible parties – food establishments that have registered with FDA as required by the Bioterrorism Act – must file reports to the Registry. The Portal is also open to anyone else – federal, state, local public health officials, and consumers – to file voluntary reports.

The Registry is explained in a pair of videos. One video discusses voluntary reporting of animal feed and pet food problems (“Voluntary Reporting of Animal Food Problems”). The other discusses the mandatory reporting requirements for certain feed manufacturers (“Mandatory Reporting of Animal Food Problems”). Both videos are available through CVM’s SafeFeed Web page.

In March 2014, CVM added the Livestock Food Reporting Portal. It accepts reports about animal foods for farm animals, including horses, cattle, swine, poultry, and fish. Anyone, including veterinarians, with concerns about the safety of an animal food can file a report.

The FDAAA also required FDA to establish a Pet Food Early Warning Surveillance System to detect adverse events associated with pet food. Consumer complaints are the
primary source of reports, which come through the Safety Reporting Portal and through consumer complaint coordinators in FDA’s District Offices.

Beginning in 2009, the Partnership for Food Protection began developing the Integrated Food Safety System, which allows states and the federal government to share information about contaminated pet food products. Under the system, food safety professionals from federal, state, and local governments coordinate work in food, feed, epidemiology, laboratory testing, animal health, environment protection, and public health.

The Partnership was also instrumental in the development of CVM’s Pet Event Tracking Network, or PETNet, which was officially launched in August 2011. In PETNet, information is shared over a secure information network with state and federal regulatory agencies that have jurisdiction over pet food products. PETNet disseminates information to regulators – typically state officials – who are in the best position to take quick action to protect the health of pets as information becomes available to FDA. (PETNet is for government use only. It is not accessible by the public.)

In late 2010, CVM’s Office of Research initiated the Veterinary Laboratory Investigation and Response Network (Vet-LIRN). It began to collaborate with veterinary diagnostic laboratories to exchange scientific information, build laboratory capacity for routine and emergency responses, and train scientists. CVM’s goal is for participating laboratories to be ready to investigate potential problems with animal feed and animal drugs, providing a rapid response to reports of animal injury. In a cost-effective way, Vet-LIRN has leveraged the resources of state-of-the-art veterinary diagnostic laboratories to provide FDA with rapid information about animal feed contamination events.

**Regulatory Oversight**

The primary purpose of regulatory oversight is to determine whether establishments and products comply with federal and state regulations. Surveillance inspections determine whether the operation is adequately controlled, thus in compliance. Compliance inspections, on the other hand, are used to document observations that could support enforcement actions against an establishment.

Regulatory compliance efforts often rely on education leading to voluntary compliance. But when education and voluntary compliance don’t work, FDA has other options, such as sending Untitled Letters or Warning Letters; holding informal meetings or mediations; applying civil penalties; holding administrative hearings; or conducting injunctions, seizures, and criminal prosecutions. (See Appendix IV for more information.) An Untitled Letter is an initial correspondence with a company in the regulated industry that cites violations that do not meet the threshold of regulatory significance for a Warning Letter. A Warning Letter includes a requirement that the firm take a specific action to address the violation.

For foreign firms exporting human or animal food to the United States, FDA is now allowing the use of third-party certification. These certification programs are not intended to take the place of inspections performed by a regulatory agency. In fact, enforcement action would not be taken based on information from third-party certifiers. Nor could
third-party certifiers launch an enforcement action against a feed or food firm. But if a firm participates in a recognized third-party certification program, it is likely to be at a lower risk for problems than a non-participant. The final rule on third-party certification bodies took effect on January 26, 2016. The rule establishes a process for accreditation of third-party auditors, to allow them to certify qualified human and animal food manufacturers.

Under FSMA, regulatory oversight has been extended to include transportation with the final rule on the Sanitary Transportation of Human and Animal Feed, implemented in April 2016. The rule establishes requirements for the use of sanitary practices by human and animal food shippers, loaders, transporters, and haulers that use motor or rail carriers.

Research
CVM’s Office of Research conducts research to support CVM’s ability to ensure the safety of animal food in the United States. The Office of Research, located in Laurel, MD, on a 167-acre plot of land, can accommodate several types of animals and fish. The Office of Research is a multidisciplinary, scientific organization with a staff capable of working on a wide array of issues.

Its three main areas of work are these:

- Analytical research for compounds that pose a health risk if found in animal tissue or animal food;
- Basic and applied research in animal health and medicine in support of current and evolving regulatory issues; and
- Basic and applied research regarding microorganisms potentially harmful to animals and humans.

Feed Standards
In 2016, the FDA and state partners took on the task of revising the Animal Feed Regulatory Program Standards (AFRPS), used by state feed control programs. The feed standards do not apply to manufacturers, but instead were developed for use by state animal feed regulatory programs. FDA continues to audit the states’ progress under AFRPS and will assist with its implementation. AFRPS are updated every 3 years. They were last updated in 2017. The current set of standards expires in on January 31, 2020. A copy of the 2017 standards is available.

Risk Assessments
In 2010, CVM, FDA’s District Office in Minneapolis, and states within that district (Wisconsin, Minnesota, North Dakota, and South Dakota) established a pilot program for assigning feed manufacturer inspections based on risk. Since then, the pilot program has been refined to the point that it is now fully accepted by FDA and being implemented by FDA’s Office of Regulatory Affairs. In addition, many states that adopted the AFPRS have also adopted the relative risk ranking process developed through the pilot program.
Education and Outreach

Educational materials and guidance documents need to be distributed in a timely way for animal food companies and producers as FSMA is implemented. It is critical to have program and inspection staff well trained in all facets of FDA’s animal food safety program, as well as an industry that also knows the rules. Education and outreach initiatives need to be understandable and widely available.

AFSS emphasizes education and outreach programs for use in conjunction with enforcement activities to bring about compliance with safe animal food rules and policies. Delivering the message using formats that are familiar to the industry and other stakeholders is another key to success. A significant step in this effort is FDA’s animal feed Web page. The page has links to all pertinent animal food safety information and is arranged by audience – animal food and pet food manufacturers, animal producers, consumers, state regulatory officials, and veterinarians.

Also, CVM has developed a Web-based system that houses the most up-to-date approved Blue Bird labels for Type B and C medicated feeds. CVM uses the term Blue Bird Labels for representative labels to be used as a guide for information that must be included by the feed manufacturer in preparing Type B or Type C medicated feeds. Type A medicated articles are feed-use drugs in their most concentrated form, not suitable to be fed to livestock. Type B and Type C are medicated feeds, but only Type C feed can he fed to animals. Typically, Type B is an intermediate medicated feed.

The Web-based Blue Bird label system, which was made available in June 2009 for a number of approved drugs, provides the medicated feed industry examples of information required to be on labels. The Blue Bird label system gives the industry the best opportunity to develop and use accurate labeling. By using resources available on the Internet, licensed medicated feed mills will be operating in compliance with the requirement of 21 CFR 515.10 by having in their possession current approved Type B or Type C medicated feed labeling before they receive Type A medicated articles. CVM continues to add new Blue Bird labels to the system.

Videos

CVM has produced videos about animal food safety and U.S. animal food standards, thus making the information available to domestic as well as international audiences. The videos include these topics:

- How pet food is regulated (“FDA and Pet Food”)
- Safe animal feed
- How to safely handle pet food in the home (“Pet Food and Treats in your Home”)
- Medicated feed labels (“Helping Animal Producers Understand Medicated Feed Labels,” and “Medicated Feed Labeling for Manufacturers – Getting it Right”)
- The role of feed manufacturers in producing safe medicated animal feed (“Medicated Feed Rules for Animal Feed Manufacturers”)
- Reporting feed problems to FDA (“Mandatory Reporting of Animal Food Problems” and “Voluntary Reporting of Animal Food Problems”)


• BSE ("U.S. Measures to Protect Against BSE")
• Guidance for Industry #203, Ensuring Safety of Animal Feed Maintained and Fed On-Farm (Information for Animal Producers about Safe On-Farm Feeding)

All of the videos are available on the Safe Feed web page.
Appendix I

Processes:
1. Food Additive Petition
2. New Animal Drug Application
3. Generally Recognized As Safe (GRAS) Petition
4. Color Additive Petition
5. AAFCO Ingredient Definition Process (See AAFCO Official Publication)
6. Common or Usual Names for Non-Standardized Animal Foods
8. AAFCO Feed Labeling Model Regulations and Guides (food-producing animals and pet animals) (See AAFCO Official Publication)

Ingredient/Additive Listings:
1. Food Additives Permitted in Feed and Drinking Water for Animals
2. New Animal Drugs for Use in Animal Feeds
3. Generally Recognized of Safe (GRAS) Substances, and Affirmed as GRAS in feed and drinking water
4. Color Additives exempt from certification, and subject to certification
5. Feed Ingredient Definitions (See AAFCO Official Publication)
6. Substances Prohibited for Use in Food and Feed
7. Animal Food Labeling
8. Common or Usual Names for Animal Feed Ingredients (Compliance Policy Guide Sec. 665.100)
9. Packaging material

Other Products Approved for Use in Feed:
1. EPA Tolerances and Exemptions for Pesticide Chemical Residues in Food (40 CFR 180)
2. Biological Products Approved by USDA for Use in Animal Feed (9 CFR 101-123)
Appendix II

Processes: Procedures for establishing limits for contaminants in feed and feed ingredients include the following:
1. Setting tolerances, action levels and regulatory limits for feed contaminants in packaging material, unavoidability (21 CFR 509.4 through 509.7)
2. Setting guidance levels are described in FDA’s Good Guidance Practices Regulations

Contaminant Limits: FDA has established Limits on contaminants in food and feed:
1. Aflatoxin action levels (FDA’s Compliance Policy Guide 683.100);
2. Pesticides in Animal Feed and Pesticide Residues in Food and Feed – Enforcement Criteria and Action Levels (CPG 575.100)
3. Temporary tolerances for PCB’s
4. Substances prohibited from use in animal food or feed
5. Tolerances established for drugs in food
6. Salmonella in Food for Animals
Appendix III

Operations/Manufacturing Process Listings:
1. Medicated Feed CGMPS are found by clicking here.
2. Type A Medicated Article CGMPS
3. Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals
4. AAFCO Model
5. Good Manufacturing Practice Regulations for Feed and Feed Ingredients (AAFCO Official Publication)
6. Low acid canned food regulations
7. Codex Code of Practice for Good Animal Feeding
8. HACCP; (seafood 21 CFR 123; juice 21 CFR 120)
9. SSOP (21 CFR 120.6 and 123.11)
Appendix IV

Inspection and Enforcement Descriptions: Inspections (FDCA Subchapter 701)

1. Enforcement information under FDCA Subchapter 704-706 is found in Investigations Operations Manual (IOM) under Chapter 2 Regulatory, Chapter 7 Recall Activities and Chapter 3 Federal State Cooperation by going to the following website:


2. The regulatory procedures manual is located on the following website:

   - this FDA Website

Inspection and Enforcement Listings:

1. Information on administrative actions in the CFR can be found on the following FDA websites

   - 21 CFR Part 12 Formal Evidentiary Public Hearing FDA Website
   - 21 CFR Part 511 New Animal Drug For Investigational Use FDA Website
   - 21 CFR Part 514 New Animal Drug Applications FDA Website
   - 21 CFR Part 571 Food Additive Petitions FDA Website

2. FDA and AAFCO Enforcement Guidelines are found on the following website:

   - AAFCO Official Publication Website

3. Inspection priorities are found on the following website

   - BSE Compliance Plan 7371.009 FDA Website

4. FDA Compliance Program Guidance Manual on Feed contaminants is found on the Program 7371.003 Feed Contaminant Program FDA Website.

5. FDA Compliance Program Guidance manual, Program 7371.004 Feed Manufacturing Compliance Program

6. CVM GFI #69 Small Entities Compliance Guide for Feeders of Ruminant Animals with On-Farm Feed Mixing Operations

7. CVM GFI #70 Small Entities Compliance Guide for Feeders of Ruminant Animals Without On-Farm Feed Mixing Operations

8. Veterinary Feed Directive Requirements for Distributors Who Manufacture VFD Feed

9. Veterinary Feed Directive Requirements for Distributors Who Do Not Manufacture VFD Feed

10. FDA Compliance Program Guidance Manual: Type A Medicated Articles

11. BSE/Ruminant Feed Ban Inspections

12. Illegal Residues in Meat, Poultry, Seafood, and Other Animal Derived Foods