NGFA Guidance on FDA Regulations Applicable to the Grain, Feed and Processing Industry

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Foreword

This document, developed by the National Grain and Feed Association (NGFA), provides guidance to assist the grain, oilseed, feed and processing industry in understanding and complying with the U.S. Food and Drug Administration's (FDA) requirements.

The topics discussed and guidance contained in this document are not intended to be formal recommendations or advice. Nor is this document intended to be a comprehensive compilation of all of FDA food safety requirements that apply to all sectors of the agricultural and food industry. Rather, it is intended to summarize several of the major food safety regulations and requirements established by FDA that apply to companies encompassed within the NGFA's membership – namely, grain elevators, feed mills, feed ingredient manufacturers, grain processors, livestock and poultry integrators, and transporters.

As outlined in the table of contents, this document includes:

- An **Executive Summary** section that includes a table indicating the general applicability of FDA requirements for different types of grain, feed and processing operations and facilities. Readers are cautioned, though, that the table provides *only a summary* of general applicability, and its contents should not be relied upon to definitively determine whether a specific facility is subject to a given regulation or requirement. Further, several of FDA's regulations include exemptions and/or modified requirements for certain subsets of types of facilities that otherwise would be subject to a given regulation. More detailed information concerning applicability issues, exemptions and modified requirements is provided within sections of the document that describe individual regulations. In addition, readers are encouraged to refer to the Code of Federal Regulations and FDA's official guidance documents as listed in the **References** section of this document to obtain more complete information on regulatory requirements.

- An **FDA Regulations and Guidance** section that provides information on relevant provisions, regulations and agency guidance associated with FDA's authority, aside from those related to the Food Safety Modernization Act (FSMA), to regulate the grain, feed and processing industry. FSMA-related requirements are addressed in other sections of this document.

- Sections that address **FDA's Authority to Inspect Facilities** and **The FDA Inspection Process**. These sections describe FDA's right to inspect facilities to evaluate whether human food, animal feed and pet food, and ingredients and raw agricultural commodities used to make such products are being held (stored), processed, packed and distributed in accordance with the agency's requirements. In addition, the sections provide information on the process used by FDA during an inspection and how facilities may choose to prepare for and react to inspections.

- Numerous sections that provide a comprehensive overview of the **Food Safety Modernization Act** (FSMA) and the regulations issued by FDA to implement the provisions contained within this expansive food safety law.

- A **References** section that provides electronic access to more information pertaining to FDA's requirements.

- A **Sample Animal Food Safety Plan Template** section that contains example templates firms may wish to consider when developing a food safety plan at an animal food facility. The example animal food safety plan template consists of an abridged plan that is not complete and contains both content that is optional and required by FDA's rule for current good manufacturing practice and preventive controls for animal food. Please note that facilities covered by FDA's rules for current good manufacturing practice and preventive controls for animal food and/or human food are obligated to develop and implement written food safety plans that adequately address the regulatory requirements associated with their specific operations.

We hope you find the information presented in this guidance document useful in understanding and complying with FDA's requirements and inspectional authority that apply to your operation. The NGFA encourages member companies to contact the Association with any additional questions related to their specific business operations. NGFA members may send inquiries via email to dfairfield@ngfa.org.

Executive Summary

The U.S. Food and Drug Administration (FDA) has broad authority under the Federal Food Drug and Cosmetic Act (FFDCA) to regulate the safety of food. This authority extends not only to human food, but also to animal feed and pet food and their components, such as grains, oilseeds, animal- and plant-based ingredients, minerals, vitamins and other items.

Further, FDA has general authority to inspect human food, animal food and grain-handling facilities to evaluate whether human food, animal food, and raw agricultural commodities, such as grains and oilseeds, are being held (stored), processed, packed and distributed in accordance with the agency's requirements.

The Food Safety Modernization Act of 2011 (FSMA) – signed into law on Jan. 4, 2011 – significantly expanded FDA's authorities and regulatory reach, and mandated that the agency issue significant new prevention-orientated regulatory requirements for the food and feed industry, including facilities in the grain, animal feed and feed ingredient, grain processing, pet food, biofuels and export sectors.

The law generally, but not in all cases, applies to operations required to register with FDA as food facilities under the Bioterrorism Act of 2002. It also applies to food, feed, and grain products regardless of whether they are shipped in interstate or intrastate commerce. FDA's "cornerstone" FSMA rules are the current good manufacturing practice (CGMP) and preventive controls rules for human food and animal food. If covered by these rules, facilities are to adhere to specified CGMP requirements and develop and implement a written food safety plan. The written food safety plan is to include an evaluation of food safety hazards associated with the facility and implementation of preventive controls for hazards that, based on the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard would occur in the absence of a preventive control, require such a preventive control.

If a facility covered by the CGMP and preventive controls rule for human food or animal food determines through its hazard evaluation that its operation does have a hazard requiring a preventive control, then the facility is required to implement management components to manage the preventive control. The required management components include monitoring, corrections or corrective actions, verification and records. In addition, facilities that identify the need for a preventive control are required to develop a written recall plan.

Significantly, a "facility" solely engaged in the holding (storage) and/or transportation of raw agricultural commodities is exempt from the CGMPs established by FDA's CGMP and preventive controls rules for human food and animal food. In addition, a "facility" solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing is exempt under FSMA from the preventive controls requirements established by both rules. Therefore, if a "facility's" food-related activities consist solely of those performed by a grain elevator that meet both of these qualifying conditions, the facility (grain elevator) is exempt from all requirements established by FDA's rules for CGMP and preventive controls for human food and animal food.

Importantly, the exemption for the CGMPs is available only to a grain elevator when it is located at a "facility" whose ***only*** food-related activity is being "solely engaged" in the storage and/or transportation of raw agricultural commodities. Further, the exemption for the preventive controls is available only to a grain elevator when it is located at a "facility" whose only food-related activity is being "solely engaged" in the holding (storage) of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.

As such, FDA's definition of "facility" is relevant to determining whether a grain elevator's operations are exempt from the rules for CGMP and preventive controls for human food and animal food. FDA defines the term "facility," within its regulations, which states in relevant part: "Facility means any establishment, structure, or structures under one ownership at one general physical location…that manufactures/processes, packs, or holds food for consumption in the United States. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership."

To provide guidance on what constitutes a single facility, FDA states, "one factor for determining whether a business is one or two facilities is through real estate records, because a property line could demonstrate that several buildings are on the same lot, and therefore, are the same facility."

Based on the "facility" definition, FDA states one facility could have several operations in separate physical structures. For example, a single facility may store raw agricultural commodities in one structure (e.g., grain elevator) destined for animal food and manufacture animal food in another structure (e.g., feed mill). In this example, FDA says the facility is not "solely engaged" in the holding of raw agricultural commodities and, as a result, the grain elevator located at the facility is ***not*** exempt from requirements established by the rule for CGMP and preventive controls for animal food.

Therefore, if a facility consists of a grain elevator plus other food-related operations that involve more than storing and distributing raw grains or oilseeds (e.g., grain processing, feed processing, human food processing), then FDA does not consider such a facility to be "solely engaged" in storing and transporting grain. As such, the grain elevator (and other food-related activities) at the facility is not considered to be exempt from requirements established by the rules for CGMPs and preventive controls for human food and/or animal food.

The following table on page 6 indicates the general applicability of FDA regulations and requirements for different types of grain-, feed- and processing-related operations when performed at a single facility. The page citations alongside each topic reference the page numbers within this document where more information is available. However, this table provides ***only a summary*** of general applicability, and its contents should not be relied upon to definitively determine whether a specific operation or facility is subject to a given regulation or requirement. Further, several of FDA's regulations include exemptions and/or modified requirements for certain operations and subsets of types of facilities that otherwise would be subject to a given regulation.

More detailed information concerning applicability issues, exemptions and modified requirements is provided within other sections of this document that describe individual regulations. In addition, the Code of Federal Regulations and FDA's official guidance documents as listed in the **References** section of this document may be reviewed to obtain more complete information on regulatory requirements.

Overview of Applicability of FDA Regulations/Guidance to Different Types of Grain, Feed and Processing Operations

FDA Regulation or Guidance (page where discussed in this guidance)	Type of Operation(s) Performed at Single Facility								
	Grain Elevator (only)	Grain Elevator and Feed Mill (co-located)	Feed Mill	Pet Food	Fuel Ethanol Animal Food Distillers Grains	Grain Processor Human and Animal Food	Importer of Foreign Human/Animal Food – With Facility	Importer of Foreign Human/Animal Food – No Facility	Transporter of Animal or Human Food
General Provisions of Federal Food Drug and Cosmetic Act (FFDCA) (Page 7)	X	X	X	X	X	X	X	X	X
FDA Mycotoxin Action Limits and Guidance (Page 8)	X	X	X	X	X	X	X	X	
FDA Limits on Addition of Mineral Oil for Dust Suppression (Page 8)	X	X	X		X	X	X	X	
Current Good Manufacturing Practice Medicated Feed (Page 8)		X	X						
Veterinary Feed Directive (Page 8)		X	X						
Bovine Spongiform Encephalopathy (BSE) (Page 8)	X	X	X	X	X	X	X	X	X
Bioterrorism Act Food Facility Registration (Page 9)	X	X	X	X	X	X	X		
Bioterrorism Act Establishment and Maintenance of Records (Page 9)	X	X	X	X	X	X	X	X	X
Bioterrorism Act Prior Notice of Imported Food (Page 9)							X	X	
Reportable Food Registry (Page 9)	X	X	X	X	X	X	X		
Mitigation Strategies to Protect Food Against Intentional Adulteration (Page 22)						X (Applies to human food facilities only)	X (Applies to human food facilities only)		
Accreditation of Third-Party Certification Bodies (Page 23)							X (If importing "high risk" foreign food and/or participating in VQIP)	X (If importing "high risk" foreign food and/or participating in VQIP)	
Additional Food Traceability Requirements (Page 23)	FDA on Nov. 15, 2022 issued a final rule to establish additional traceability requirements for certain foods as identified within FDA's "Food Traceability List" or FTL. Grains and oilseeds are not included in the FLT. In addition, the final rule does not establish additional traceability requirements for animal feed or pet food. Nor do the additional traceability requirements apply to animal foods that contain foods (or by-products from the production of food) identified in the FTL.								
Testing of Food by FDA-Accredited Laboratories (Page 23)	Applies to the owner or consignee of human and/or animal food when such food is subject to the food testing requirements established by the rule.								
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (Page 25)							X	X	
Sanitary Transportation of Human and Animal Food (Truck and Rail) (Page 30)	X	X	X	X	X	X	X	X	X
Current Good Manufacturing Practice and Preventive Controls for Human Food (Page 39)						X	X		
Current Good Manufacturing Practice and Preventive Controls for Animal Food (Page 42)		X	X	X	X	X	X		

FDA's Role in Overseeing Safety of the U.S. Food and Feed Supply

The FDA, as authorized by the federal Food, Drug and Cosmetic Act (FFDCA)[(1)] and the Public Health Service Act, regulates the safety of foods, including animal feed and pet food, other than the meat, poultry and egg products (which are under the jurisdiction of the U.S. Department of Agriculture). FDA also is responsible for the safety of human drugs, medical devices, biologics, cosmetics and radiation emitting devices.

To oversee the safety of human food, animal feed and pet food, and components of such foods, FDA activities are divided between two centers:

- The **Center for Food Safety and Applied Nutrition** (CFSAN) is responsible for promoting and protecting the public's health by ensuring that the nation's human food supply is safe, sanitary, wholesome and honestly labeled, and that dietary supplements and cosmetic products are safe and properly labeled.

- The **Center for Veterinary Medicine** (CVM) is responsible for ensuring that animal drugs are safe and effective, and that food for animals – which includes animal feed, pet food, and pet treats, as well as ingredients and agricultural commodities used to produce such products – is safe, stored and made under sanitary conditions, and is properly labeled.

FDA's authority to regulate human food, animal feed and pet food and their components is provided by the FFDCA. The FFDCA defines "food" as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." As such, the term "food" encompasses human food, animal feed and pet food, and components used to make such products, such as grains, oilseeds, animal- and plant-based ingredients, minerals, vitamins and other items.

FDA has broad authority provided under the FFDCA to establish regulations to ensure food products are not "adulterated" or "misbranded."

- **Adulteration** is a legal term used by FDA to define a condition under which a food is deemed to be unfit for its intended use. Among other things, FDA may deem a food to be adulterated if it: 1) is missing a valuable constituent; 2) contains a poisonous or deleterious substance that may render the food injurious to health; 3) has been prepared, packed or held under insanitary conditions; and 4) is not produced and distributed in conformance with applicable FDA regulations.

- **Misbranding** is a legal term used by FDA to define a condition whereby a food is not labeled properly. Among other things, FDA may deem a food to be misbranded if: 1) it is labeled in a false or misleading manner; 2) it is offered for sale under the name of another food; and 3) any word, statement, or other information required by FDA to appear on the label or labeling is not prominently placed thereon.

FDA Regulations and Guidance

The following are among relevant provisions, regulations and agency guidance associated with FDA's authority for the grain and feed industry:

- **FDA Guidance Levels for Mycotoxins:** FDA has established action and guidance levels for aflatoxin, deoxynivalenol (vomitoxin) and fumonisin.[(2)]

- **Addition of Dust Suppressants:** As provided in 21 Code of Federal Regulations (CFR) 172.878, white mineral oil meeting the established specifications may be used as a dust-control agent for wheat, corn, soybean, barley, rice, rye, oats and sorghum at a level of not more than 0.02 percent by weight of grain (200 parts per million). In addition, white mineral oil meeting the established specifications and with ISO 100 oil viscosity may be applied as a dust-control agent for rice at a level of no more than 0.08 percent by weight of the rice grain (800 parts per million).[(3)]

- **Current Good Manufacturing Practices (CGMPs) for Human Food:** 21 CFR Part 117 modernizes FDA's long-standing CGMPs for the manufacture and distribution of human food.[(4)] The CGMPs establish required conditions and practices that are to be present at human food facilities to ensure that food will not become adulterated while it is manufactured, processed, packed or stored.

- **CGMPs for Medicated Animal Feed:** FDA's CGMPs for the manufacture and distribution of medicated animal feed are found at 21 CFR Part 225.[(5)] FDA uses Form FDA 2481[(6)] when conducting inspections of feed mills holding an approved medicated feed mill license, which is necessary for the use of Category II, Type A medicated articles and the use of Category I, Type A medicated articles when manufacturing certain medicated free-choice and/or liquid feeds. FDA investigators use a Non-Licensed Medicated Feed Establishment Inspection Form[(7)] when conducting medicated feed inspections at facilities that do not hold an approved medicated feed mill license.

- **Veterinary Feed Directive:** FDA's Veterinary Feed Directive (VFD) regulation – 21 CFR 558.6 – requires that animal drugs designated with a VFD marketing status may be used only in or on animal feed under the professional supervision of a licensed veterinarian.[(8)]

- **CGMPs for Animal Drugs:** 21 CFR Part 226 provides CGMPs for the manufacture and distribution of animal drugs.[(9)]

- **Prevention of Bovine Spongiform Encephalopathy (BSE):** 21 CFR Part 589.2000 and 21 CFR Part 589.2001 specify FDA's BSE-prevention regulations.[(10)] These regulations generally apply to animal feed and feed ingredients, including corn and other raw agricultural commodities, intended to be fed to ruminants, such as cattle. When

performing inspections to evaluate compliance with the BSE-prevention regulations, FDA uses Form FDA 3719. [(11)]

- **Food and Drug Administration Amendments Act (FDAAA) of 2007 – Reportable Food Registry:** This Act amended the FFDCA to provide for the Reportable Food Registry.[(12)] Under FDAAA, responsible parties at food facilities registered with FDA under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) are obligated to report to FDA through the agency's electronic portal as soon as possible, but no later than 24 hours, after determining that a food is "reportable." A food is "reportable" if it is an article of food (other than dietary supplements or infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.

- **Bioterrorism Act:** The Bioterrorism Act authorizes FDA to take actions to protect the nation's food supply against the threat of intentional contamination. In accordance with the law, FDA has developed and implemented food, animal feed and pet food safety measures, including the following major regulations:

  - **Registration of Food Facilities**[(13)]. Domestic or foreign facilities that manufacture, process, pack, or hold food for consumption by humans or animals in the United States are to register with FDA as a "food" facility. This registration requirement took effect on Dec. 12, 2003. Covered facilities include those involved in grain handling, grain processing, feed manufacturing, grain exporting and others. Facilities may register through FDA's web-based electronic portal. In addition, covered facilities are required to reregister with FDA to renew and update such registrations every two years. The registration renewals are required to occur between Oct. 1 and Dec. 31 of even-numbered years.

  - **Prior Notice of Imported Food**[(14)]**:** Beginning Dec. 12, 2003, importers were required to provide FDA with advance notice of each shipment of food (including human food, animal feed and pet food, and components used to make such products, such as grains, oilseeds, animal- and plant-based ingredients) being offered for import into the United States.

  - **Establishment and Maintenance of Records**[(15)]: Domestic persons that manufacture, process, pack, transport, distribute, receive, hold or import food are required to create and maintain records to identify the immediate previous sources and the immediate subsequent recipients of food (i.e., where the food came from and who received the food). The term "persons" includes individuals, partnerships, corporations and associations. In addition, the records established and maintained by facilities that manufacture, process or pack food must include lot or code numbers or other identifiers if such information exists. The records are to include

information that is "reasonably available" to assist in identifying the specific source of each ingredient that was used to make each lot of finished product.

- **Food Safety Modernization Act:** The Food Safety Modernization Act of 2011 (FSMA) established significant regulatory requirements for operations involved in the storing, production and distribution of human food, animal feed and pet food products, and raw agricultural commodities, including grains and oilseeds. Among the major regulations established by FDA as mandated by FSMA are:
  - Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
  - Mitigation Strategies to Protect Food Against Intentional Adulteration
  - Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications
  - Additional Food Traceability Requirements
  - Testing of Food by FDA-Accredited Laboratories
  - Foreign Supplier Verification Programs for Importers of Food for Humans and Animals
  - Sanitary Transportation of Human and Animal Food
  - Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food
  - Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals

  These FSMA-related regulations are reviewed in subsequent sections of this document.

In addition to federal requirements, states also have laws and regulations to govern the production and distribution of human food, animal feed and pet food products. Most state laws and regulations are modeled after those established by the FFDCA.

FDA's Authority to Inspect Facilities

FDA's general authority to inspect human food and animal food facilities is found within section 704 of the FFDCA.[(16)]

Based upon this general authority, it is a "prohibited act" for regulated facilities to refuse to permit access to or copying of any record required under FDA's regulations, or to refuse to permit entry or inspection of a facility or vehicle. FDA is not obligated to have a warrant for conducting an inspection. Warrants may be obtained if inspection has been refused completely or when refusals have been encountered during the inspection.

Under its inspection authority, FDA is authorized to: 1) enter "any factory, warehouse, or establishment in which food [is] manufactured, processed, packed, or held …" and "any vehicle….;" 2) inspect "at reasonable times and within reasonable limits and in a reasonable manner;" and 3) inspect "all pertinent equipment, finished and unfinished materials, containers, and labeling thereon."

FDA's authority provides the agency's investigators with the right to inspect facilities to evaluate whether human food, animal feed and pet food are being stored, processed, packed and distributed in accordance with provisions of the FFDCA and its associated regulations.

In addition, FDA has special authority to inspect facilities and access records in the event of a human food, animal feed or pet food safety incident, as follows:

- **Reportable Food Registry:** FDA may inspect records related to "each report received, notification made, and report submitted" to FDA through the Reportable Food Registry for up to two years. Therefore, a company should have appropriate procedures governing the reporting of a reportable food.

- **Inspection Authority under the Bioterrorism Act:** If FDA has a reasonable belief that a human food, animal feed or pet food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, then, in addition to its general inspection authority, FDA is allowed to have access to and copy records relating to that food, and foods that may be affected similarly. This authority applies to records: 1) pertaining to manufacture, processing, packing, distribution, receipt, holding or importation of such food; 2) associated with Reportable Food Registry reports and notifications; and 3) held in any format – including paper and electronic form.

  FDA's records access authority under the Bioterrorism Act does <u>not</u> extend to: 1) recipes (formulas); 2) financial data; 3) pricing data; 4) personnel data; 5) research data; and 6) sales data – other than shipment data pertaining to sales of the food in question.

  To invoke this authority, FDA is to present a special written "Notice of Inspection – Request for Records" (Form FDA 482c).

In response to inspection findings, FDA has authority to take both administrative and judicial enforcement actions, including injunctions, seizure and condemnation, statutory penalties and criminal prosecution.

Under its authority, FDA may conduct various types of inspections, including:

- **For Cause:** For cause inspections pertain to public health concerns or animal illness and/or death.

- **Pre-Approval:** Some inspections are conducted to pre-approve a facility to manufacture and distribute certain foods or animal feeds. For example, FDA conducts pre-approval inspections at facilities that apply for a medicated feed mill license.

- **Surveillance:** FDA conducts routine surveillance inspections to evaluate compliance with its regulations. For example, inspections at animal feed and grain-handling facilities may address compliance associated with the following topics:
  - Medicated animal feed current good manufacturing practices.
  - Prevention of BSE.
  - Sanitation Inspections: Either state or FDA investigators may conduct these inspections, which generally are limited to evaluating facilities for unsanitary conditions or conditions that have the potential to result in an adulterated product. Sanitary inspections primarily are made in the human food industry, but food as defined in the FFDCA includes animal feed (regardless of whether it is medicated) and raw agricultural commodities, such as grains and oilseeds.

- **Compliance:** These inspections are conducted because FDA has information that suggests problems may or do exist at a facility. The types of information that may generate a compliance inspection include sample analyses, prior inspections, reported information, etc.

- **Criminal:** FDA conducts criminal inspections when information suggests to the agency that serious willful and/or egregious violations of applicable requirements are occurring within a facility.

FDA Inspection Process

An FDA-regulated facility should be prepared to undergo an inspection at any time during normal business operations. Typically, facilities do not receive advance notice that an FDA inspection will occur. As such, a facility should consider developing a comprehensive plan on how to handle the inspection. The facility's inspection plan should, among other things, anticipate the scope of the inspection, questions that may be asked, and how to handle requests for copies of records and policies. In addition, the plan should outline the responsibilities that individuals within the facility will have during the inspection.

The following information pertains to FDA investigators and suggestions that facilities may wish to consider when preparing for and undergoing an FDA inspection.

- **FDA Investigators:** FDA titles a person conducting an inspection as an "investigator," which has a higher governmental ranking than "inspector." FDA investigators generally are based at local FDA district offices, although investigators may be accompanied by

other FDA employees from other district offices or from the FDA's Washington, D.C.-area headquarters. State regulatory officials also may be credentialed to conduct inspections on behalf of FDA. Currently, state regulatory officials conduct about 60 percent of FDA animal feed-related inspections. FDA investigators or FDA-credentialed state officials should carry an FDA-issued badge.

FDA investigators are trained to make observations during an inspection, but not necessarily to make conclusions as to whether a condition constitutes a violation. However, FDA investigators may offer their own thoughts on what they observe during the inspection, as well as suggestions on how they believe procedures and practices could be changed at the facility to improve compliance. Facilities may wish to consider the suggestions offered, but also should be mindful that the primary purpose of the inspection is for the investigator to gather information to support findings of alleged violations.

- **Receiving the Investigator:** The FDA investigator should present a badge and credentials upon arrival at the facility. The facility should keep a record of the investigator's credentials when presented. If the investigator does not present a badge or credentials, the facility may consider not allowing the inspection to proceed on grounds that the individual may not have authority to inspect.

  Upon initiating the inspection, the FDA investigator should present the facility with a Notice of Inspection – Form FDA 482. Facilities should keep a copy of this form. While presenting the Notice of Inspection, the investigator should state the purpose of the visit and/or inspection. If the investigator does not offer this information, it is appropriate for the facility to ask for it. It also is acceptable for the facility to ask how long the investigator believes the inspection will last.

  If the investigator presents a warrant, facilities are obligated to comply with its content. If a warrant is presented, it strongly is recommended that the facility contact its legal counsel immediately.

  Facility management should ensure that the first point of contact within the facility is prepared for the investigator's arrival. The first point of contact should:

  - Know who to contact at the facility when the investigator arrives.
  - Request that the investigator sign the facility's Visitor's Log.
  - Escort the investigator to a designated place within the facility until the person assigned to escort the investigator is available.

- **Facility Representative(s) Designated to Accompany Investigator:** It is advisable that the facility have a plan that assigns appropriate personnel to escort the investigator at

all times. Frequently, the appropriate person may be the individual responsible for regulatory affairs or quality assurance at the facility. The designated person should:

- Know the company and its operations well.

- Not be a senior officer of the company.

- Inform the investigator of all relevant visitor and safety policies established for the facility. The investigator should be required to use the clothing and personal protective equipment used by employees in the facility. As applicable, this may include dust masks, gloves, shoe coverings, etc.

- Accompany the investigator at all times (except for restroom or lunch breaks).

It is recommended to have at least two trained individuals accompany the investigator, and one of the individuals should take detailed notes about questions asked, responses, corrective actions taken or promised, areas inspected and any other relevant details.

The absence of the designated person during regular business operations generally does not provide a legitimate basis for refusing the inspection. Facilities should have a secondary individual(s) trained to accompany an investigator in the event that the primary designated person is not available.

- **Specific Inspection Issues:** Following is information pertaining to specific issues that may be encountered during an inspection.

  - **Investigator Requests to Interview Employees:** The FFDCA does not expressly provide FDA the authority to interview facility employees. Therefore, it is advisable for facilities to develop a policy on how to address this issue.

    Because of the potential for employees to not provide a thorough or accurate response to requests for information, the facility may choose to establish a policy that prohibits employee interviews during inspections. In this case, the designated person should expressly inform the investigator of such a policy and that the designated person will respond to any questions posed during the inspection.

    If the facility policy does allow investigators to interview employees, it is advisable for the designated escort person to be present during the interview and available to immediately correct any inaccurate, inadequate or incomplete responses provided by an employee.

  - **Access to and Copies of Records:** Facilities should have a written policy that designates those records the investigator will be allowed to see and copy, if

requested. FDA generally is entitled to copies of labeling and can review and copy records required by regulations.

Generally, an investigator's authority to review and have access to records is limited by the FFDCA, which states that FDA may inspect "within reasonable limits and in a reasonable manner." This is subjective language, and the facility's inspection policies should address the extent to which the facility will provide access and copies of its records.

In addition to its general inspection authority, if FDA has a reasonable belief that a food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, the agency is allowed to have access to and copy all records relating to the implicated food and those foods that FDA reasonably believes may be affected similarly.

As previously noted, this authority applies to records:

- pertaining to manufacture, processing, packing, distribution, receipt, holding (storage) or importation of such food.
- associated with Reportable Food Registry reports and notifications.
- held in any format, including paper and electronic forms.

FDA's records-access authority in such situations does not extend to:

- recipes (formulas);
- financial data;
- pricing data;
- personnel data;
- research data; and
- sales data, other than shipment data regarding sales.

FDA investigators also may, upon written request, have access to and copy records showing the movement in interstate commerce of any food or the holding of any food during or after such movement, and the quantity, shipper and consignee thereof.

Facilities should make two copies of whatever records are given to the investigator. One copy should be provided to the investigator, and the other retained for the facility's inspection file. Importantly, facilities should stamp confidential documents given to the investigator as "Confidential."

- **Use of Cameras and Photographs:** The use of cameras and taking of photographs by an investigator during an inspection is a difficult legal issue. FDA does ***not*** have express legal authority to take photographs during an inspection. But the agency's current position is that photographs are a reasonable part of the inspection process. Therefore, investigators may insist they have a right to use a camera. However, the use of photography is controversial because photos taken by an investigator may be misleading in that they do not show the entire context of a situation within the facility.

  FDA's current inspection procedures state that if a company refuses to allow the taking of photos during an inspection, investigators are to "obtain name and contact information for the firm's legal counsel, and advise [the FDA] district management immediately."

  It is advisable that facilities develop a policy that addresses the use of cameras and taking of photographs during inspections. If there is a possible hazard to using a camera within the facility – e.g., the flash might cause an explosion hazard – this provides a valid reason for the facility to not allow the taking of photographs. A written policy for photographs is advisable, so the investigator may be directed to the policy before the inspection begins.

  If photographs are allowed, the facility should consider having a camera accessible and take pictures of whatever the investigator photographs and do so from the same camera angle/point of view. Such duplicate photos should be retained in the facility's inspection file.

- **Taking Samples:** The FFDCA authorizes FDA investigators to obtain samples. If samples are taken during the inspection, the facility should request the investigator, prior to leaving the premises, to provide a receipt describing the samples obtained – FDA Form 484 – Receipt of Samples.

  If a sample is taken, the designated person should request that the investigator "split" the sample so that the facility can keep a retention sample of the regulatory sample. Typically, the investigator will do this; however, if not, the designated person should obtain a duplicate sample from the same lot of product, if possible.

  If a sample is taken and if an analysis is made of the sample "for the purpose of ascertaining whether such food consists…of any filthy, putrid, or decomposed substance, or is otherwise unfit for food," FDA is obligated to provide the facility with a copy of the analysis. The facility should ask the investigator what tests will be performed on the sample and the expected timing of the test results. The facility also should establish a policy regarding whether the lot of sampled product will be withheld from distribution until test results are received.

The facility may request that the investigator pay for the samples' value; however, the investigator then may ask for records to substantiate what the fair value is for the samples.

- **Affidavits:** An investigator may write one or more affidavits of varying content for facility personnel to sign as part of the inspection process. There is no legal requirement for facility personnel to sign such affidavits. The facility's policy towards affidavits should reflect the degree of cooperation that it chooses to extend in this area. If affidavits are signed, a copy should be retained. Incidentally, FDA will not sign an affidavit if asked to do so by the facility.

- **Inspecting the Facility:** At the outset of an inspection, the investigator typically will request a tour of the facility. During this tour, designated personnel always should accompany the investigator. The designated person(s) should answer questions as the investigator poses them. Such personnel should never give the investigator false information. If the answer is not known, the designated person should say so and commit to obtaining the requested information and providing it later.

  After the initial facility tour, the investigator typically will focus on individual departments or processes. The investigator may stay hours or even several days in a particular department. The investigator has authority to conduct the inspection at "reasonable times," which correlates to normal business operating hours. However, the investigator does **not** have authority to disrupt the facility's normal operations. For example, an investigator is not authorized to mandate that the facility start or stop a production line for inspectional purposes.

  If the investigator raises an issue of concern during the inspection to which the designated escort person agrees, it is appropriate for the designated person to remedy the issue immediately, if possible, in the investigator's presence.

- **Requests for Records:** If the investigator requests to review documents or records, it is advisable to have the investigator review the information in a designated space. Any copies of confidential documents or records provided to the investigator should be stamped "Confidential." It is advisable for the facility to make the requested copies themselves – although the investigator should be allowed to observe the copying, if requested. Facilities are not required to create any documents; investigators are entitled to only relevant documents that already exist.

  If an investigator desires access to an unreasonably large quantity of records, or seeks to review and copy records beyond those designated by the facility's written policy, it is advisable to ask the investigator to provide a list in writing of the requested documents, along with reasons as to why access is desired, so that the list can be reviewed by facility management and/or legal counsel, as appropriate. This allows the facility to consider and balance FDA's legal authority, the benefits of cooperating with the investigator, the

investigator's need for the information requested, the confidentiality of the information and other factors.

As previously noted, it is advisable that the facility develop a written inspection plan that clearly outlines those facility documents and records for which the investigator has authority to review upon request so as to minimize the need to seek review by facility management and/or legal counsel during the inspection.

- **Interacting with the Investigator:** It is advisable for the designated person not to volunteer information to the investigator during the inspection. Designated personnel should answer in a direct manner only those questions asked.

  In addition, facility personnel should:

  - Interact with the investigator in a pleasant and professional manner.
  - Not become argumentative or hostile towards the investigator.
  - Freely ask the investigator questions to clarify the investigator's comments or requests.
  - Display a cooperative attitude toward the investigator, to the degree possible. If it is perceived that the facility is being "uncooperative," the investigator may become suspicious and more zealous during the inspection.
  - Attempt to limit the scope of the investigator's inquiries. For example, if an investigator asks to review complaint files associated with medicated feed, ask the investigator for what specific time period or particular product they desire to review.
  - Emphasize to the investigator that the facility intends to comply with all applicable regulations.
  - Always provide truthful information to the investigator.

- **Inspection Exit Interview:** At the end of the inspection, the investigator will ask to meet with facility management to discuss the findings of the inspection. The designated person also should attend the exit interview.

  During the exit interview, the investigator will discuss the findings and typically present a Form FDA 483 – Inspectional Observations. Despite its title, Form FDA-483 is used to provide a written statement of what the investigator believes are objectionable matters. The investigator should discuss each of the objectionable conditions and provide facility management with an opportunity to comment. Facility management should inform the investigator of any corrective action taken and ask that it be included in the investigator's notes. Facility management also should carefully explain its position pertaining to any area of disagreement. The investigator likely will document any responses provided by management.

Facility management should not secretly record the exit interview meeting. If it is believed to be desirable to record the session, notify the investigator in advance and document the fact that notification was provided. Normally, the investigator will not want the inspection exit interview to be recorded.

Investigators often will request that company employees or officials sign an Affidavit or Declaration during the exit interview. However, there is no requirement for employees or officials to sign such documents. In addition, it is advisable that Affidavits or Declarations not be signed by company officials unless such documents have been reviewed by competent legal counsel in advance. Companies should consider establishing a policy on signing Affidavits or Declarations and using this policy as the basis to respond to investigator requests.

When officials refuse to sign an Affidavit or Declaration, the investigator may read the document and ask whether it is true. In response, it is advisable that company officials not acknowledge or comment on the correctness of any information presented.

During the exit interview, facility management should specifically request a copy of the Establishment Inspection Report (EIR) – the investigator's written report. Many investigators will provide this upon request, although some reports only are obtained through a Freedom of Information Act (FOIA) request. Upon receiving the EIR, facility management should review the document carefully for inaccuracies or trade secret information that should be stricken before the public potentially obtains copies.

- **After the Inspection:** Following is information pertaining to post-inspection activities and suggestions for facilities to consider:

  - The facility should compile and organize an inspection file that includes any documents, records and samples made available to the investigator during the inspection. A detailed written report should be prepared and provided to company management.

  - If a Form FDA-483 was issued, the facility should begin to prepare a response immediately. While there is no legal obligation for the facility to formally respond to a Form FDA-483, it may be beneficial to do so. In this regard, FDA has established a policy that allows 15 days for companies to respond in writing to the agency after issuance of an observation on Form FDA-483. The company's written response must be received by FDA in the allotted time period if the company wishes to have its comments considered when FDA determines whether to initiate enforcement action based upon the observations.

  - If FDA believes it is warranted based upon the inspection findings, the agency may issue either an "Untitled Letter" or "Warning Letter"[(17)] to the facility. FDA uses Warning Letters for violations that may lead to enforcement action if they are not

corrected promptly and adequately. FDA uses Untitled Letters for violations that are not as significant as those that trigger Warning Letters. Unlike a Warning Letter, an Untitled Letter does not include a statement warning that failure to promptly correct a violation may result in an enforcement action.

- If a facility receives an Untitled Letter or Warning Letter after an inspection, it is obligated to provide a formal response to FDA within the time frame prescribed within the letter. A response to an Untitled Letter or Warning Letter should be sent to the FDA District Office, with a copy also sent to the investigator.

- When an Untitled Letter or Warning Letter is received after an inspection, the facility should use all necessary resources to appropriately address the issues made in the letter and to prepare a response within the designated time frame. An unanswered or inadequately answered Untitled Letter or Warning Letter will lead almost certainly to further FDA enforcement action. It is advisable that the facility's response to an Untitled Letter or Warning Letter be reviewed by competent legal counsel before sending it to FDA.

- The facility should comment on each observation made on the Form FDA-483 when responding to an Untitled Letter or Warning Letter. Frequently, observations listed on the Form FDA-483 are cited as "for example," so it is advisable that the response not just address the specific example, but also address the relevant issue more broadly.

- The facility should not admit to violations of the law or regulations in its response. Instead, the facility should note the observation and clearly state how it has or will address the condition or observations made. When corrective actions are taken, it is advisable for the facility to provide information in its response to demonstrate that the corrective action has been implemented effectively. In all cases, the facility should convey to FDA that it is concerned with the inspection findings and/or particular observation, and is committed to appropriately resolving issues of non-compliance.

- Within its response, the facility may disagree with an observation. If so, the facility should provide the reasons it believes the observation is incorrect. Attempts to reconcile disagreements with observations should be made first with FDA District Office personnel. If an agreement is not reached, it may be appropriate to pursue the issue with compliance personnel located at FDA's Washington, D.C.-area headquarters.

- If more time is needed to remedy a condition documented within the Untitled Letter or Warning Letter, the facility should provide that response and indicate that another update on facility actions will be forthcoming. Facilities should take FDA's documented observations seriously and always follow through on actions that it

indicates to FDA will be taken to remedy non-compliant conditions. Otherwise, depending upon the significance of the non-compliant condition, FDA may initiate further enforcement actions, such as seizures, injunctions or consent decrees.

FDA's inspection protocol is outlined within the agency's Investigations Operations Manual.[(18)] In addition, FDA's Comprehensive Animal Food Inspection Compliance Program Guidance Manual[(19)] provides specific information on inspectional approaches and compliance expectations for each of the agency's animal food compliance programs.

Food Safety Modernization Act

The Food Safety Modernization Act of 2011 (FSMA)[(20)] – signed into law on Jan. 4, 2011 – significantly expanded FDA's authorities and regulatory reach, and mandated that the agency issue significant regulatory requirements for the human food and animal food industries, including facilities in the grain, animal feed and feed ingredient, grain processing, pet food, biofuels and export sectors.

The law generally, but not in all cases, applies to facilities required to register with FDA as food facilities under the Bioterrorism Act of 2002. It also applies to food, feed and grain products, regardless of whether they are shipped in interstate or intrastate commerce

Farms as defined by FDA, with a few notable exceptions, are exempt from FSMA. Under the Bioterrorism Act, a farm is exempt from FDA food facility registration if its operation is under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term "farm" includes operations that, in addition to the aforementioned activities: 1) pack or hold raw agricultural commodities (such commodities may be grown on a farm under a different management); and 2) manufacture or process food, provided that all food used in such activities is consumed on that farm or another farm under the same management.

Increased Authorities to FDA under FSMA

Among the increased authorities granted to FDA under FSMA are:

- **User Fees[(21)]:** FDA is required to assess fees to: 1) compensate the agency for the cost of reinspecting facilities that fail an original inspection, with the cost not to exceed the actual cost of reinspection (capped at $25 million annually); 2) compensate for the actual cost of conducting mandatory recalls (capped at $20 million annually); 3) implement a voluntary qualified importer program (VQIP) that provides for expedited entry of food imports from trusted suppliers; and 4) compensate for costs of issuing export certificates for food and animal feed/ingredients (capped at $175 per certificate).

- **Records Access**[(22)]**:** FDA is authorized to access existing facility records associated with foods for which it has a "reasonable belief" present a threat of serious adverse health consequences or death to humans or animals, plus records for other foods for which the agency "reasonably believes" are "similarly" affected. Importantly, FDA's access is limited to records relating to the manufacture, processing, packing, distribution, receipt, storage or import of products that meet these aforementioned criteria and danger threshold. FDA also is required to provide written notice before accessing such records.

- **Administrative Detention**[(23)]**:** FDA is authorized to administratively detain a product when it has "reason to believe" that it is adulterated or misbranded.

- **Mandatory Recalls**[(24)]**:** FDA is authorized to issue mandatory recalls if it determines there is a "reasonable probability" that an article of food (other than infant formula) is adulterated or misbranded, and that use of, or exposure to, the product would cause serious adverse health consequences or death to humans or animals.

- **Suspension of Facility Registration**[(25)]**:** FDA has authority to suspend a facility's registration – in essence, shutting it down – if it determines there is a "reasonable probability" that its products could "cause serious adverse health consequences or death" to humans or animals. If this statutory threshold is met, FDA has the authority to suspend the registration of: 1) the facility(ies) that created, caused or otherwise was responsible for the adulteration; or 2) any facility that packed, received or stored such products and knew of, or had reason to know, that it was handling such a product.

Major Regulations Issued by FDA under FSMA

Among the major regulations issued by FDA as mandated by FSMA are:

1. **Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption**[(26)]**:** FDA on Nov. 27, 2015 published its final rule that establishes science-based minimum safety standards for farms and other operations involved with growing, harvesting, packing and holding of fruits and vegetables grown for human consumption.

2. **Mitigation Strategies to Protect Food Against Intentional Adulteration**[(27)]**:** FDA on May 27, 2016 published final regulations to require domestic and foreign food facilities that are required to register under the Bioterrorism Act to address hazards that may be introduced with the intention to cause wide-scale public health harm. Covered food facilities are required to conduct a vulnerability assessment to identify significant vulnerabilities and actionable process steps and implement mitigation strategies to significantly minimize or prevent significant vulnerabilities identified at actionable process steps in a food operation. Such mitigation strategies also are required to be monitored and verified, with corrective actions taken when warranted.

FDA's final rule exempts from the intentional adulteration requirements facilities that solely manufacture, process, pack or store animal feed and pet food. In addition, the final rule exempts facilities, such as grain elevators, that solely store food that may be destined for human consumption. The exemption also expressly applies to the storage of mineral oil in liquid storage tanks and its application to raw, whole grains or oilseeds. However, the final rule does stipulate that facilities that store and apply mineral oil on other food products, such as baked goods, condiments, spices or confectionary products, evaluate mineral oil storage and use when conducting vulnerability assessments required under the regulations.

3. **Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications**[(28)]**:** On Nov. 27, 2015, FDA published a final rule that provides for FDA accreditation of third-party certification bodies to conduct food safety audits of foreign food entities, including registered foreign food facilities, and to issue food and facility certifications under FSMA. These certifications are required for participation in the voluntary qualified importer program (VQIP) – a voluntary, fee-based program mandated by FSMA to allow the expedited review and importation of foods into the United States from importers who achieve and maintain a high level of control over the safety and security of their food supply chains. In addition, when FDA has determined that an imported food is subject to certification under FSMA because of the risk it poses to public health, the agency may require a certification under this rule as a condition for admitting the food into the United States.

4. **Additional Food Traceability Requirements**[(29)]**:** FDA on Nov. 15, 2022 issued a final rule to establish additional traceability requirements for certain foods. The final rule standardizes the data elements and information covered entities are to establish, maintain, and communicate to the next entity in the supply chain to facilitate rapid and accurate traceability of foods identified within FDA's "Food Traceability List" (FTL). Among the foods included by FDA within the final FTL are soft and semi-soft cheeses, leafy greens, fresh cut fruits and vegetables, some types of fish, shell eggs, and nut butters. Grains and oilseeds are not included in the FLT. Significantly, the final rule does not establish additional traceability requirements for animal feed or pet food. Nor do the additional traceability requirements apply to animal foods that contain foods (or by-products from the production of food) identified in the FTL.

5. **Testing of Food by FDA-Accredited Laboratories**[(30)]**:** FDA on Dec. 1, 2021 issued a final rule that establishes a program for the testing of food by FDA-accredited laboratories as required by FSMA. The rule is intended to improve the accuracy and reliability of certain food testing through the uniformity of standards and enhanced FDA oversight of participating laboratories.

   The final regulations require owners and consignees of human and animal food to use an FDA-accredited laboratory for food testing under the following circumstances:

- To support removal of a food from an import alert through successful consecutive testing requirements;

- To support admission of an imported food detained at the border because it is or appears to be in violation of the FFDCA;

- As required by existing FDA food safety regulations, when applied to address an identified or suspected food safety problem (i.e., certain tests of shell eggs, sprouts, and bottled drinking water);

- As required by a directed food laboratory order, a new procedure being implemented in this final rule that will allow FDA to require use of an FDA-accredited laboratory to address an identified or suspected food safety problem in certain, rare circumstances; and

- When conducted in connection with certain administrative processes, such as testing submitted in connection with a mandatory food recall order or an appeal of an administrative detention order.

Regarding a directed food laboratory order, FDA under the rule may require the owner or consignee to conduct food testing, or to have food testing conducted on their behalf, to address an identified or suspected food safety problem, as FDA deems appropriate. FDA states repeatedly in the preamble of the rule that a directed food laboratory order will generally be limited to the rare situation when the agency has reason to question the accuracy or reliability of past or present test results and where an identified or suspected food safety problem exits. When issued, the directed food laboratory order will specify the food product or environment to be tested; whether the food testing may be conducted using an FDA-accredited laboratory that is owned, operated, or controlled by the owner or consignee; the timeframe in which the food testing must be conducted; and the manner of the food testing, such as the methods that must be used.

Significantly, the final rule does not apply to all food testing that a facility may perform. Food testing, including environmental testing, is only required to be conducted by an FDA-accredited laboratory under the certain circumstances specified in the rule. In addition, for facilities covered by the FSMA-related human or animal food preventive controls rules, the rule does not require testing done as a routine prerequisite program and/or verification activity to be performed by an accredited laboratory.

FDA within the rule specifies eligibility requirements that accreditation bodies and laboratories wishing to voluntarily participate in the program need to satisfy, as well as procedures for how the agency will manage and oversee the program. When there is sufficient FDA-accredited laboratory capacity for the food testing covered by the final rule, the agency will publish a document in the ***Federal Register*** giving owners and consignees 6 months' notice that they will be required to use an FDA-accredited

laboratory for such food testing. FDA states it also will maintain an online public registry listing of recognized accredited bodies and accredited laboratories when the rule is fully implemented.

6. **Foreign Supplier Verification Programs for Importers of Food for Humans and Animals**[(31)]**:** FDA on Nov. 27, 2015 published its final rule to establish foreign supplier verification programs (FSVP) for importers of food for humans and animals to ensure the safety of imported food. The regulation requires importers to verify that food they import into the United States is: 1) produced in compliance with the hazard analysis and risk-based preventive controls requirements established under other FSMA-related rules; 2) not adulterated; and 3) not misbranded.

   The FSVP rule covers a wide variety of entities involved with importing food, including importers of raw agricultural commodities (e.g., grain and oilseeds), animal feed and feed ingredients, and human food and food ingredients.

   Within the rule, "importer" means the U.S. owner or consignee of an article of food that is being offered for import into the United States. Further, as defined by the rule, "U.S. owner or consignee" means the person in the United States who, at the time of U.S. entry, either owns the food, has purchased the food or has agreed in writing to purchase the food. If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer as required under the rule.

   Significantly, the rule covers importers regardless of whether they are required to register with FDA as a food facility under the regulations established by the Bioterrorism Act.

   Exemptions from FSVP: The requirements in the final rule apply to all food imported or offered for import into the United States and to the importers of such food except:

   - Food that is transshipped or imported for processing and export.

   - Food that is manufactured/processed, raised, or grown in the United States, exported, and returned to the United States without further manufacturing/processing in a foreign country.

   - Meat, poultry, and egg products subject to USDA regulations.

   - Juice, fish and fishery products that are imported from a foreign supplier that is required to comply with, and is in compliance with, the FDA's juice and seafood hazard analysis and critical control point regulations.

- Food imported for research or evaluation.

- Food imported for personal consumption.

- Alcoholic beverages imported from a foreign supplier that is subject to permitting requirements established by the Federal Alcohol Administration and is required to register with FDA as a food facility.

In addition, FDA on Jan. 24, 2018 issued a guidance document that extends enforcement discretion regarding the application of the FSVP rule to certain importers of raw agricultural commodities that FDA classifies as "grain." FDA defines "grains" to mean the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are grown and processed for use as meal, flour, baked goods, cereals and oils rather than for fresh consumption (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). FDA examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, cotton seed, sunflower seeds and soybeans. In contrast, FDA classifies the following raw agricultural commodities as "fruit" and not "grain": lentils, kidney beans, pinto beans, lima beans, coffee beans, cocoa beans, peanuts, tree nuts and seeds for direct consumption.

FDA's enforcement discretion applies to those importers of "grain" that: 1) are solely engaged in the storage of grain intended for further distribution or processing; or 2) do not take physical possession of the grain they import, but instead arrange for the delivery of the grain to others for storage, packing, or manufacturing/processing. This means that FDA does not intend to enforce the FSVP requirements for importers of grain meeting either of the two specified conditions. Further, it is anticipated that FDA will engage in rulemaking to revise its regulations to codify the enforcement discretion within the FSVP rule in the future.

Required Components for FSVP: Covered importers are responsible for developing and implementing a written FSVP that includes analysis of hazards and implementation of risk-based controls. To do so, the rule requires a "qualified individual" to develop, implement and oversee the plan.

The rule defines a "qualified individual" to mean a person who has the education, training or experience (or a combination thereof) necessary to perform an activity required under the rule, and can read and understand the language of any records that the person must review in performing this activity.

The importer's FSVP is to include:

- **Foreign Supplier Approval:** The importer is required to establish and follow written procedures to ensure that foods are imported only from foreign suppliers that have been approved based on the evaluation conducted under the rule's requirements (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods are subject to adequate verification activities before importing the food). The importer is required to document the use of the written procedures.

  "Foreign supplier," as defined by the rule, means the establishment that manufactures/processes the food, raises the animal or grows the food that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a *de minimis* nature.

  Therefore, a foreign facility that simply stores food within the supply chain is not a foreign supplier for the purposes of the rule because it does not manufacture, process or grow the food. As an example, an importer may import grain into the United States from a foreign grain elevator that stores the grain. In this case, the grain elevator is not the foreign supplier because it did not manufacture or grow the grain. Instead, the foreign supplier for purposes of the final rule is the producer(s) who grew the grain.

- **Hazard Analysis**: A written hazard analysis is to be conducted by the importer's "qualified individual" to identify and evaluate "known or reasonably foreseeable hazards" associated with the food and its foreign supplier. The hazard analysis is to include an evaluation of the hazards to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of controls.

- **Foreign Supplier Verification:** If an importer conducts a hazard analysis and appropriately determines that the foreign supplier and food have no hazards requiring a control, then the importer does not need to conduct supplier- approval and verification activities. This exemption from further supplier- approval and verification activities does not apply if the food is a raw agricultural commodity that is a fruit or vegetable that is "covered produce" as defined by FDA's produce safety rule.

  An importer may rely on an entity (other than the foreign supplier) to determine and perform appropriate supplier verification activities so long as the importer reviews and assesses that entity's relevant documentation in accordance with the rule's requirements.

If the hazard analysis does establish that there is a hazard requiring a control, then the hazard must be controlled by either: 1) the foreign supplier; or 2) the importer (when the importer is subject to FDA's preventive controls rule); or 3) the importer's customer.

In cases where the importer controls the hazard, importers subject to and in compliance with FDA's final rules that established preventive controls requirements for human and animal food are deemed to be in compliance with the FSVP requirements if the importer, in accordance with the preventive controls rules, has implemented preventive controls to address the hazard(s) in the food.

In the case when the importer relies on the foreign supplier to control the hazard in the food, the rule establishes that the importer is to develop written supplier verification activities and conduct such activities to provide assurance the hazard requiring a control in the food has been significantly minimized or prevented. The rule specifies that such supplier-verification activities may include:

- Annual on-site audits of the foreign supplier's facility. An annual on-site audit generally is required when there is a reasonable probability that exposure to a hazard controlled by the foreign supplier will result in serious adverse health consequences or death to humans or animals (called a "SAHCODHA" hazard). When conducted, audits are to be performed by a "qualified auditor" as defined by the rule. However, the importer can choose a means of verification other than an audit provided the importer documents that the alternate choice is appropriate and provides adequate assurances that the foreign supplier is producing the food in accordance with applicable U.S. safety standards.

- Sampling and testing.

- A review of the supplier's relevant food safety records.

- Other appropriate supplier-verification activities, as provided by the rule.

In cases where the importer relies on its customer to control the hazard, the importer is not required to conduct supplier verification activities if they disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]". Significantly, after issuing the FSVP rule, FDA announced its intent to use enforcement discretion and not require importers to also obtain annual written assurances from customers controlling the hazard as specified within the regulation. In addition, FDA has indicated that it expects to initiate rulemaking to remove the customer written assurance requirements from the regulation in the future.

- **Reevaluation of Foreign Supplier's Performance and the Risk Posed by a Food:** Under the final rule, the importer is required to reevaluate the risk associated with a food at least every three years – or sooner if new information becomes available about the factors associated with the food's hazard analysis.

- **Corrective Actions:** An importer is required to promptly take appropriate corrective actions if it determines that a foreign supplier of imported food does not produce the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under applicable U.S. safety standards. Under the rule, such a determination could be based on a review of consumer, customer or other complaints related to food safety; the verification activities conducted; a reevaluation of the risks posed by the food and the foreign supplier's performance; or any other relevant information. The appropriate corrective actions to be taken will depend upon the circumstances, but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance have been addressed adequately. All corrective actions taken are to be documented.

- **Modified FSVP Requirements:** The final rule provides for modified requirements for very small importers and importers of food from certain small foreign suppliers. The rule's definition of "very small importer" is consistent with the definition of "very small business" in FDA's rules for current good manufacturing practice and preventive controls for human and animal food – average annual sales of less than $1 million for human food, plus the market value of human food manufactured, processed, packed or held without sale, and average annual sales of less than $2.5 million for animal feed and pet food, plus the market value of animal food manufactured, processed, packed or held without sale.

  Small foreign suppliers as specified by the rule include: 1) facilities subject to modified requirements under the current good manufacturing practice and preventive controls rules for human food and animal food because they are qualified facilities; 2) farms that are not covered farms under the produce safety rule because they average $25,000 or less in annual produce sales or because they meet requirements for a qualified exemption; and 3) shell egg producers with fewer than 3,000 laying hens.

  Under the modified requirements, the rule generally establishes that very small importers and importers of food from certain small foreign suppliers do not have to conduct hazard analyses and are able to verify their foreign suppliers by obtaining written assurances from the supplier.

7. **Sanitary Transportation of Human and Animal Food[32]:** FDA on April 6, 2016 published final regulations mandated under the Food Safety Modernization Act (FSMA) that establish requirements for shippers, loaders, carriers, and receivers engaged in the

transportation of human and animal food by truck or rail to use sanitary transportation practices to ensure food and feed safety. The requirements do not apply to transportation by water vessel or air because of legal limitations established by the Sanitary Food Transportation Act of 2005.

Among the many operations covered by the rule are shippers, loaders, carriers and receivers involved with motor or rail vehicle transportation of raw agricultural commodities (e.g., grains and oilseeds), animal feed and feed ingredients, and human food and food ingredients.

With some exemptions (listed below), the final rule applies to shippers, receivers, loaders and carriers who transport food in the United States by motor or rail vehicle, regardless of whether the food is offered for or enters interstate commerce. Significantly, a given entity may be subject to the rule's requirements in multiple capacities, e.g., the shipper may also be the loader and the carrier, if the entity also performs the functions of those respective parties as defined by the rule. In such cases, the entity is responsible for meeting the applicable requirements for each function performed.

The final rule also applies to: 1) persons (e.g., shippers) in other countries who ship food to the United States directly by motor or rail vehicle (from Canada or Mexico), or by ship or air, and arrange for the transfer of the intact container onto a motor or rail vehicle for transportation within the United States, if that food will be consumed or distributed in the United States; and 2) transportation activities associated with food intended for export until the shipment reaches a port or U.S. border.

Operations Exempted from the Rule: The requirements of the rule do not apply to shippers, receivers, loaders, or carriers when they are engaged in transportation operations of:

- Food that is transshipped through the United States (e.g., from Canada or Mexico by truck or rail) to another foreign country; or

- Food that is imported for future export, in accordance with the FFDCA, and that is neither consumed nor distributed in the United States; or

- Food when it is located in food facilities that are regulated exclusively by the U.S. Department of Agriculture under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act.

"Non-covered businesses" also are exempt from the rule's requirements. FDA's rule defines a "non-covered business" as "a shipper, loader, receiver, or carrier engaged in transportation operations that has less than $500,000, as adjusted for inflation, in average annual revenues, calculated on a rolling basis, during the three-year period

preceding the applicable calendar year. For the purpose of determining an entity's three-year average revenue threshold as adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011."

The rule defines "transportation operations" to mean "all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container except a food that requires temperature control for safety, compressed food gases, food contact substances as defined in section 409(h)(6) of the FFDCA, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. In addition, transportation operations do not include any transportation activities that are performed by a farm."

As established by the definition, "transportation operations" do not include transportation activities performed by a farm. Therefore, transportation operations performed by a farm (defined by 21 Code of Federal Regulations Part 1.227) are exempt from the rule's requirements. As such, farms that transport commodities (e.g., grains and oilseeds) in their vehicles to storage or processing facilities are exempt. By contrast, non-farm carriers that transport commodities from the farm are subject to the rule, unless they are considered to be non-covered businesses.

In addition, given FDA's definition of "transportation operations," activities associated with transportation of food that is "completely enclosed in a container" that does not require temperature control for safety are exempt from the rule's requirements. This exemption extends to transportation activities for grain, grain byproducts, animal feed, pet food, human food and other food products that meet these criteria.

Within the preamble of the final rule, FDA says it considers a "completely enclosed container" to be one that physically separates the food from the [transportation] environment and functionally protects the food from environmental contamination during transportation. FDA says that examples of such containers include a metal can, a glass or plastic bottle, or a sealed bag or box. In contrast, if the food comes into contact with the bulk vehicle or transportation equipment (e.g., hopper trailer, rail car, or intermodal container), FDA does not consider the food to be protected from the transportation environment and does not consider the food to be "completely enclosed by a container."

Further, "transportation operations" do not include any activities associated with the transportation of human food byproducts transported for use as animal food without further processing. Therefore, transportation activities associated with such products are exempt from the rule's requirements. However, this exemption does not extend to

human food byproducts transported to an animal feed manufacturer where it is to be used as an ingredient in a manufactured animal food or to be further processed.

Although the previously specified operations are exempt from the rule's requirements, the adulteration provisions of the FFDCA are applicable to any food transported or offered for transportation in the United States, including by any shipper, loader, carrier by motor vehicle or rail vehicle, or receiver subject to FDA's rule for Sanitary Transportation of Human and Animal Food.

General Requirements for Vehicles and Transportation Equipment: FDA defines "vehicle" and "transportation equipment" as follows within the rule:

- "Vehicle" means a land conveyance that is motorized, such as a motor vehicle, or that moves on rails, such as a railcar, which is used in food transportation operations.

- "Transportation equipment" means equipment used in food transportation operations and includes items such as bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems, and unloading systems. Transportation equipment also includes a railcar not attached to a locomotive or a trailer not attached to a tractor.

FDA's final rule establishes requirements that vehicles and transportation equipment used in transportation operations are to be designed of such material and workmanship so as to be suitable and adequately cleanable for their intended use to prevent the food they transport from becoming unsafe. In addition, the sanitary condition of vehicles and transportation equipment is to be maintained to prevent food from becoming unsafe during transportation operations. Further, vehicles and transportation equipment are to be stored in a manner that prevents it from harboring pests or becoming contaminated in any other manner that could result in unsafe food.

Significantly, the rule does not prescribe how the sanitary condition of vehicles and transportation equipment is to be maintained. For instance, FDA does not prescribe methods (e.g., sweeping, washouts) for the cleaning and maintenance of vehicles and equipment. Nor does the agency establish required intervals for cleaning operations. Instead, FDA states that firms may employ any cleaning procedures and intervals that satisfy the requirements of the rule.

In addition, the rule does not prescribe the use of seals on vehicles and transportation equipment during transportation operations. FDA states in the preamble of the rule that establishing requirements for the use of seals is outside the scope of the regulation, since the purpose of the rule is to establish sanitary transportation practices, which is distinct from the issue of security of food transportation.

General Requirements for Transportation Operations: The general requirements for transportation operations established by the rule apply to all covered shippers, carriers, loaders and receivers engaged in transportation operations. However, a party subject to the rule may reassign in a written agreement its responsibilities under the rule to another entity that is subject to the rule.

The general requirements for transportation operations require that:

1. Competent supervisory personnel be assigned to ensure transportation operations are carried out in compliance with all requirements of the rule.

2. Effective measures, such as segregation, isolation or other protective measures, such as hand washing, be taken to protect food transported in bulk vehicles or food not completely enclosed by a container from contamination and allergen cross-contact during transportation operations.

   Significantly, FDA states that this provision does not require persons who handle animal feed or feed ingredients to always wear gloves and/or wash their hands. Instead, FDA states the rule provides flexibility to determine which measures are necessary to protect food transported in bulk vehicles or food not completely enclosed by a container from contamination during transportation operations.

   In addition, FDA defines the term "allergen cross-contact" to mean the unintentional incorporation of a food allergen as defined in section 201(qq) of the FFDCA into food, except animal food. Therefore, the rule does not require transportation operations to be conducted under conditions and controls to prevent allergen cross-contact in animal food.

3. Food that requires temperature control for safety be transported under adequate temperature control.

4. If a shipper, loader, receiver, or carrier becomes aware of an indication of conditions that may render the food unsafe during transportation, the food is not to be sold or otherwise distributed, and these persons are to take appropriate action. These actions are to include, as necessary, communication with other parties to ensure that the food is not sold or otherwise distributed unless a determination is made by a qualified individual that the condition did not render the food unsafe.

5. The type of food, e.g., animal feed, pet food, human food, and its production stage, e.g., raw material, ingredient or finished food, be considered in determining the necessary conditions and controls for the transportation operation.

Requirements for Shippers: FDA's final rule places most of the responsibility on the shipper for ensuring sanitary transportation of food and feed. In the preamble to the

rule, FDA states its belief that shippers should be charged with developing and implementing written procedures that address how the safety of food they ship will be assured relative to the "three major focus areas" of the rule: 1) assurance that the vehicles and equipment used in the shipper's transportation operations are in appropriate sanitary condition; 2) assurance that, for bulk cargo, a previous cargo does not make the food unsafe; and 3) assurance that, for foods that require refrigeration for safety, the food is transported under adequate temperature control.

As defined within FDA's rule, a "shipper" means "a person, e.g., the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially."

In addition to the previously referenced general requirements that apply to all covered parties engaged in transportation operations, specific requirements established within the rule for shippers include:

1. Shippers, in all cases, are to develop and implement written procedures adequate to ensure that vehicles and equipment used in transportation operations are in appropriate sanitary condition for the transportation of the food, i.e., they will prevent the food from becoming unsafe during the transportation operation. The shipper may perform the measures to implement these procedures themselves, or they may be accomplished by the carrier or another party subject to the rule under a written agreement.

2. Unless the shipper itself implements written procedures adequate to ensure that vehicles and equipment used in transportation operations are in appropriate sanitary condition for the transportation of the food, shippers are to specify to the carrier and, when necessary, the loader, in writing, all necessary sanitary specifications for the carrier's vehicle and transportation equipment, including any specific design specifications and cleaning procedures. A one-time notification is sufficient unless the design requirements and cleaning procedures required for sanitary transport change based upon the type of food being transported, in which case shippers are to notify the carrier in writing before the shipment.

   FDA states in the preamble of the final rule that it expects the "default arrangement" shippers typically will use to comply with this requirement of the rule is for them to provide instructions to the carrier and, when necessary, the loader to ensure the vehicle and equipment meet appropriate sanitary conditions (i.e., a one-time notification that is updated when necessary), while also allowing for alternative arrangements whereby the shipper itself ensures that the specifications are met. In doing so, FDA says the latter option provides flexibility in situations when the shipper does not have a relationship with the carrier or another party to provide instructions relative to the necessary sanitary condition of the vehicles and equipment by allowing the shipper itself to ensure that necessary conditions are

met. Accordingly, the requirement to specify to the carrier and, when necessary, the loader, in writing, all necessary sanitary specifications for the carrier's vehicle and transportation equipment applies to shippers in the instance when the shipper itself does not perform the written procedures necessary to ensure that vehicles and equipment used in transportation operations are in appropriate sanitary condition.

Further, FDA states in the preamble of the rule that this requirement allows the shipper to use reasonable judgment in deciding what information must be communicated to a carrier to meet the requirements of the rule, and that the agency understands that a shipper could reasonably determine that it is not necessary to specify procedures that are already commonly understood by carriers.

3. If food is shipped in bulk, shippers are to develop and implement written procedures adequate to ensure that a previous cargo does not make the food unsafe. The shipper may perform the measures to implement these procedures themselves, or they may be accomplished by the carrier or another party subject to the rule under a written agreement.

   Significantly, the rule does not require the shipper to identify the previous cargo(es) transported with the bulk vehicle or transportation equipment. Instead, the rule provides flexibility to shippers when developing written procedures adequate to ensure that a previous cargo does not make the food unsafe by allowing them to use any effective means to make such a determination.

   In addition, in the preamble to the rule, FDA notes that its current good manufacturing practice regulations for human food and animal food already require that storage and transportation of food occur under conditions that protect against allergen cross-contact in human food, as well as against biological, chemical (including radiological) and physical contamination that would cause human or animal food to become unsafe.

Requirements for Loaders: The rule defines a “loader” as “a person that loads food onto a motor or rail vehicle during transportation operations.”

In addition to the previously referenced general requirements that apply to all covered parties engaged in transportation operations, the rule establishes that loaders are to determine that the vehicle or transportation equipment is “in appropriate sanitary condition for the transport” (e.g., “in adequate physical condition and free of visible evidence of pest infestation and previous cargo that could cause the food to become unsafe during transportation”) for the type of food to be shipped prior to loading onto a vehicle or into transportation equipment considering, as appropriate, any specifications provided by the shipper, except in instances where the food is completely enclosed by a container. The rule provides that this determination may be accomplished by any appropriate means.

Requirements for Receivers: A "receiver," as defined by the rule, means "any person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food."

In addition to the previously referenced general requirements that apply to all covered parties engaged in transportation operations, the rule establishes that receivers are to take steps to adequately assess that food requiring temperature control for safety under the conditions of shipment was not subjected to significant temperature abuse during transport.

Requirements for Carriers: The rule defines a "carrier" to mean "a person who physically moves food by rail or motor vehicle in commerce within the United States, excluding persons who transport food while operating as a parcel delivery service."

The previously referenced provisions within the rule for vehicles and transportation equipment and general requirements for transportation operations apply to carriers. The requirements established by these provisions apply regardless of whether there is a written agreement under which the carrier has agreed to be responsible, in whole or in part, for sanitary conditions during the transportation operation.

However, the other specific requirements for carriers within the rule only apply to the carrier when the carrier and shipper have established a written agreement that the carrier is responsible, in whole or in part, for sanitary conditions during the transportation operation.

When a shipper-carrier agreement has been established, the carrier is responsible for the following functions as applicable under the agreement:

- A carrier is to ensure that vehicles and transportation equipment meet the shipper's specifications and are otherwise appropriate to prevent the food from becoming unsafe during the transportation operation.

- If requested by the shipper, a carrier that offers a bulk vehicle for food transportation is to provide information to the shipper that identifies the previous cargo transported in the vehicle.

- If requested by the shipper, a carrier that offers a bulk vehicle for food transportation is to provide information to the shipper that describes the most recent cleaning of the bulk vehicle.

- A carrier is to develop and implement written procedures and maintain records that:

- ❖ Specify practices for cleaning, sanitizing if necessary, and inspecting vehicles and transportation equipment that the carrier provides for use in the transportation of food to maintain the vehicles and the transportation equipment in appropriate sanitary condition.

- ❖ Describe how it will comply with the provisions for the use of bulk vehicles pertaining to identifying the previous cargo transported in the vehicle and describing the most recent cleaning of the vehicle.

Carriers that have a contract with the shipper to be responsible for any sanitary conditions during transportation are to provide adequate training for personnel involved in food transportation operations. The carrier training is to be provided when personnel for food transportation operations are hired and as necessary thereafter. The training content is to provide an awareness of potential food safety problems that may occur during food transportation, basic sanitary transportation practices to address those potential problems, and the responsibilities of the carrier under the rule. Records are to be established and maintained to document the required training. To assist carriers in providing training to personnel, FDA has made available on its website a free training module[(33)] that covers the required training elements.

Intra-Company Transportation Activities: Intra-company shipments of food are not exempt from the rule's requirements. However, shippers, carriers, loaders and receivers that are under the ownership or operational control of a single legal entity can rely on compliance with common, integrated written procedures for transportation activities as an alternative to developing written procedures and agreements as specified in the FDA regulations. The rule has a specific provision that loaders involved in intra-company shipments must continue to ensure that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food.

Transloading Operations: Within the preamble of the final rule, FDA clarifies how the rule's requirements apply to transloading operations. FDA states that an entity that only transfers food cargo from one mode of transportation to another, e.g., from a railcar to a truck, would be subject to the rule as a receiver of food arriving by rail vehicle and as a loader of food onto trucks. The entity would not be considered to be a shipper if it simply holds the food pending truck transport and does not arrange for its transport by the trucking firm.

Record Requirements: Shippers, receivers, loaders and carriers are to establish and maintain required records as indicated in the following table.

Required Records	Description
Information provided by shippers to carriers.	Shipper records are to demonstrate that the shipper provided, as a regular part of transportation operations, specifications and operating temperatures to carriers.
Written agreements and the written procedures of a shipper.	The shipper's written agreements and written procedures are to meet the rule's requirements.
Written procedures of a carrier.	The carrier's written procedures are to meet the rule's requirements.
Any written agreements subject to the rule that are not otherwise noted.	Written agreements that assign tasks required by the rule to another person.
Records documenting required training by carriers.	The training records are to: 1) include the date of training, the type of training, and the persons trained; and 2) be established and maintained in accordance with other records requirements.
Written procedures of firms that operate in more than one capacity under the rule, under the ownership or operational control of a single legal entity, for example, as a shipper and a carrier.	The written procedures are to be common integrated procedures that ensure the sanitary transportation of food consistent with the requirements of the rule.

All required records are to be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records. Significantly, records established and maintained to satisfy requirements of the rule are exempt from FDA's onerous Part 11 electronic records and signatures requirements.

Required records are to be retained as follows:

1. Records of written procedures and written agreements (except as described in the next paragraph) for a period of 12 months beyond when the procedures or agreements are in use for transportation operations.

2. Records of written agreements that assign tasks required by this rule to another party for a period of 12 months beyond the termination of the agreements.

3. Records that demonstrate that shippers provide specifications and operating temperatures to carriers as a regular part of their transportation operations for a period of 12 months beyond the termination of the agreements with the carriers.

4. Carriers training records for a period of 12 months beyond when the person identified in the record stops performing the duties for which the training was provided.

The required records are to be made available to an FDA investigator or other duly authorized individual promptly upon oral or written request.

8. **Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food**[(34)]**:** On Sept. 17, 2015, FDA published a final rule (referred to hereafter as the "preventive controls rule for human food") that modernized the long-standing current good manufacturing practice (CGMP) requirements already in place for human food and established new requirements for covered facilities to implement a food safety system that includes an analysis of hazards and implementation of risk-based preventive controls.

   Under the preventive controls part of the rule, covered facilities are required to develop and implement a written food safety plan that includes prescribed components. These preventive controls components are similar to those required within written food safety plans that are to be established at covered facilities to comply with the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (referred to hereafter as the "preventive controls rule for animal food"). This document details requirements associated with written food safety plans under the section that reviews the preventive controls rule for animal food.

   The preventive controls rule for human food generally applies to foreign and domestic establishments that are required to register with FDA as food facilities because they manufacture, process, pack or store human food for consumption in the United States.

   Operations Exempted from the Rule: A "facility" *solely engaged* in the holding (storage) and/or transportation of raw agricultural commodities is exempt from the CGMPs established by the preventive controls rules for human food and animal food. In addition, a "facility" solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing is exempt from the preventive controls requirements established by both rules. Therefore, if a "facility" consists ***solely*** of a grain elevator that meets both of these qualifying conditions, the facility (grain elevator) is exempt from all requirements established by the preventive controls rules for human food and animal food.

   Importantly, the exemption for the CGMPs is available only to a grain elevator when it is located at a "facility" whose ***only*** food-related activity is being "solely engaged" in the

holding (storage) and/or transportation of raw agricultural commodities. Further, the exemption for the preventive controls is available only to a grain elevator when it is located at a "facility" whose ***only*** food-related activity is being "solely engaged" in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.

Therefore, if a "facility" consists of a grain elevator plus other food-related operations that entail more than storing and distributing grain (e.g., grain processing, feed processing, human food processing), then such a "facility" is not considered by FDA to be "solely engaged" in storing and transporting grain. As such, the grain elevator (and other food-related activities) at the facility is not exempt from requirements established by the preventive controls rules for human food and/or animal food.

FDA Interpretations of "Storage", "Facility Solely Engaged" and "Raw Agricultural Commodities (Other than Fruits and Vegetables)":

- **Storage:** As noted previously, FDA in its rules uses the term "holding" to define "storage." The agency defines "holding" to mean "storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the FFDCA. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators and liquid-storage tanks."

  In addition to those activities listed within the "holding" definition, the following are other examples of activities that FDA considers incidental to the safe and effective storage of food and therefore may be performed by facilities that are exempt from the CGMP and preventive control requirements:

  - Cleaning grain, and distributing the resulting screenings as an animal feed ingredient.
  - Treating stored grain with protectant chemicals and pesticide alternatives (other than by fumigation) to control infestation.
  - Using modified atmosphere treatments to control pests.
  - Using biological controls for pests.
  - Applying chemical preservatives to grain to prevent growth of mycotoxin-producing molds.

- Weighing grain.
- Blending grain.
- Sampling and grading grain.
- Aerating grain to control temperature.

- **Facility Solely Engaged:** To assist in determining whether a "facility" meets the "solely engaged" criteria, FDA states that the plain meaning of "solely" is "only, completely, entirely; without another or others; singly; alone."

  FDA defines the term "facility" in 21 CFR 1.227, which states in relevant part: "Facility means any establishment, structure, or structures under one ownership at one general physical location … that manufactures/processes, packs, or holds food for consumption in the United States. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership."

  FDA states this means that one facility could have several operations in separate physical structures. For example, a single facility may hold raw agricultural commodities in one structure (e.g., grain elevator) for use as animal food and manufacture animal food in another structure (e.g., feed mill). In this example, FDA says the facility is not "solely engaged" in the holding and/or transportation of one or more raw agricultural commodities. Therefore, the grain elevator located at the facility is not exempt from requirements established by preventive controls rules for animal food.

  To provide guidance on what constitutes a single facility, FDA states "one factor for determining whether a business is one or two facilities is through real estate records, because a property line could demonstrate that several buildings are on the same lot, and therefore, are the same facility."

- **Raw Agricultural Commodities (Other than Fruits and Vegetables):** The exemption from the preventive controls requirements is available only to facilities that are solely engaged in storing raw agricultural commodities, other than fruits and vegetables, as defined by FDA. When issuing its regulations, FDA stated that its intent is to exempt from preventive controls requirements, for example, facilities that only store whole grains. For the purposes of the rules' requirements, FDA defines grains to mean the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are grown and processed for use as meal, flour, baked goods, cereals and oils rather than for fresh consumption (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of products that are included within FDA's definition of "grain" are barley,

dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, sunflower seeds and oilseeds for oil extraction.

Among the products that FDA classifies as "fruit" are lentils, kidney beans, pinto beans, lima beans, coffee beans, cocoa beans, peanuts, tree nuts and seeds for direct consumption. Under the rules, facilities that store such "fruits" are exempt from FDA's CGMP regulations, but are not exempt from the requirements established within the agency's regulations for hazard analysis and risk-based preventive controls. However, FDA since publishing the rule has issued policy and guidance documents that extend enforcement discretion from the hazard analysis and risk-based preventive controls regulations to facilities solely engaged in the storage of pulse crops, e.g., dry beans, broad beans, dry peas, chick-peas, cow peas, pigeon peas, lentils, bambara beans, vetches, and lupins, intended for further distribution or processing. Therefore, FDA does not expect facilities solely engaged in storage of grains and/or pulse crops intended for further distribution or processing to comply with either the CGMP or hazard analysis and risk-based preventive controls requirements established by the animal food and human food rules.

9. **Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals[(35)]:** FDA on Sept. 17, 2015 published a final rule that established CGMP and preventive controls requirements for animal food. FDA defines "animal food" to mean "food for animals other than man and includes pet food, animal feed, and raw materials and ingredients." As such, the term animal food includes grains and oilseeds, and products derived therefrom, that are used for animal food. The final rule also establishes requirements for covered facilities to implement a food safety system that includes an analysis of hazards and implementation of risk-based preventive controls, including a written food safety plan.

   The preventive controls rule for animal food generally applies to foreign and domestic establishments that are required to register with FDA as food facilities because they manufacture, process, pack or hold animal food for consumption in the United States.

   Operations Exempted from the Rule: Animal food facilities ***solely engaged*** in the following activities are not subject to the rule's CGMP requirements 1) holding and/or transportation of one or more raw agricultural commodities; 2) hulling, shelling, drying, packing and/or holding nuts and hulls (without manufacturing/processing, such as grinding shells or roasting nuts); or 3) ginning cotton (without manufacturing/ processing, such as extracting oil from cottonseed).

   In addition, preventive control requirements established within the animal food rule do not apply to facilities ***solely engaged*** in:

1. Storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing; and

2. Storage of unexposed packaged animal food that does not require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens (e.g., facilities that are solely engaged in storing and distributing packaged animal food that does not requirement time/temperature control to ensure its safety).

See the previous section of this document addressing Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food for further information on FDA's interpretations of "holding (storage)," "facility solely engaged" and "raw agricultural commodities other than fruits and vegetables."

Employee Training and Qualification Requirements: Under both the preventive controls rules for human food and animal food, individuals at facilities subject to either rule who manufacture, process, pack, or hold (store) food are required to be qualified, i.e., have the education, training or experience (or a combination thereof) necessary to ensure safe human and/or animal food as appropriate to the individual's assigned duties. The preventive controls rule for animal food specifically establishes that such individuals (including full-time employees, seasonal employees, temporary employees, and outside contractors) are to be appropriately trained on the principles of animal food hygiene and animal food safety, including the importance of personnel health and personal hygiene. Although the rule does not prescribe the content of training or its frequency, FDA expects training to occur before an individual works in production operations and periodic refresher training thereafter. In addition, training records are to be established and retained for at least two years after the date of the training. NGFA has made available a separate qualified individual training guidance[(36)] document that details FDA's requirements.

Within the preambles of the rules, FDA states that it expects much of the required training to be provided in-house by knowledgeable employees already working at facilities. In addition, FDA states that the training material developed by the Food Safety Preventive Controls Alliance (FSPCA)[(37)] will be useful to facilities when conducting in-house training. The FSPCA has completed standardized training curriculums for the preventive controls rule for human food[(38)] and the preventive controls rule for animal food[(39)].

Facilities are required to keep records that document the training on the principles of food hygiene and food safety for those who supervise and/or perform manufacturing, processing, packing, or holding activities for food. The facility can generate training records in a format that is convenient, for example: 1) training check-list for new employees/individuals; 2) sign-in sheets for specific trainings; or 3) computerized training records.

Required records are to include: 1) information adequate to identify the plant or facility; 2) the date and, when appropriate, the time of the activity documented; and 3) the signature or initials of the person performing the activity. The required training records should provide sufficient information to document the training. Examples of additional information that may be included in such a record are: 1) a list of the person(s) trained; 2) a description of the content of the training; and 3) the name and qualifications of the trainer. Required records are to be retained at the plant or facility for at least two years after the date they were prepared.

Major Components of Rules: The preventive controls rules for human food and animal food have three distinct subparts that establish requirements for covered facilities to: 1) adhere to specified CGMPs; 2) conduct a hazard analysis and implement risk-based preventive controls; and 3) implement a supply-chain program to verify that its supplier of a raw material or ingredient controls a hazard requiring a preventive control if the facility relies on the supplier to control such a hazard.

- **Animal Food CGMPs:** The animal food CGMPs establish baseline standards for facility operations and conditions. The regulation contains approximately 85 provisions and requires covered facilities to address issues such as hygienic personnel practices and training; facility operations, maintenance and sanitation; equipment design, use, and maintenance; processes and controls; and warehousing and distribution. Among the key requirements established by the animal food CGMPs are:

  - Personnel are to maintain adequate personal cleanliness, including washing hands thoroughly in an adequate hand-washing facility as necessary and appropriate to protect against animal food contamination.

  - The overall cleanliness of the plant is to be under the supervision of one or more competent individuals assigned responsibility for this function.

  - Materials not used in animal food or those not necessary for plant and equipment maintenance and operation (e.g., fertilizers and pesticides) must be stored in an area of the plant where animal food is not manufactured, processed or exposed.

  - Raw materials and other ingredients:

    - Must be examined to ensure they are suitable for manufacturing and processing into animal food and must be handled under conditions that will protect against contamination and minimize deterioration.

- ❖ Susceptible to contamination with mycotoxins or other natural toxins must be evaluated and used in a manner that does not result in animal food that can cause injury or illness to animals or humans.

- ➢ Water must be adequate for the facility's operations, must be derived from an adequate source, and must be safe for its intended use.

- ➢ Plumbing must be designed, installed and maintained to avoid being a source of contamination to animal food, water supplies, equipment or utensils, or creating an unsanitary condition.

- ➢ Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle.

- ➢ Animal food returned from distribution must be assessed for animal food safety to determine the appropriate disposition. Returned animal food must be identified as such and segregated until assessed.

Importantly, the CGMPs are an overarching set of requirements for all animal food. Therefore, facilities producing medicated animal feeds are subject to both the preventive control for animal food CGMPs and FDA's existing CGMP regulations for medicated feeds.

Significantly, the only record requirements associated with the animal food CGMPs are those that document required qualified individual training on the principles of animal food hygiene and animal food safety. Facilities are not required to submit the required training records to FDA, but are to make them promptly available to an FDA investigator for official review and copying upon oral or written request.

FDA has issued final guidance[(40)] to further inform covered facilities about the CGMP requirements established by the animal food rule.

- **Hazard Analysis and Risk-Based Preventive Controls:** The final rule requires covered facilities to establish and implement an animal food safety system that includes an analysis of hazards and, as necessary, implementation of risk-based preventive controls. To do so, the rule requires a "preventive controls qualified individual" to develop and implement a written food safety plan for the facility.

  The rule defines a "preventive controls qualified individual" to mean 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."

Therefore, a preventive controls qualified individual may be qualified by successfully completing training under a standardized curriculum recognized as adequate by FDA or by job experience. The standardized curriculum referred to within FDA's definition has been developed by the FSPCA for both animal food(41) and human food(42) and may be electronically downloaded at no cost.

The preventive controls qualified individual responsible for developing and implementing the food safety plan may be, but is not required to be, an employee of the facility.

The required written animal food safety plan mandated by the rule is to include:

- **Hazard Analysis:** A written hazard analysis is to be conducted by the facility to identify and evaluate "known or reasonably foreseeable hazards" within their operation. The hazard analysis is to include an evaluation of the hazards to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls. Determinations made during the hazard analysis are to be justified.

  For purposes of the hazard analysis, FDA defines a "hazard" to mean "any biological, chemical (including radiological) or physical agent that has the potential to cause illness or injury in humans or animals." Further, FDA defines a "known or reasonably foreseeable hazard" to mean "a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the animal food."

  The hazard analysis is to identify and evaluate, based on experience, illness data, scientific reports and other information, known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held (stored) at the facility to determine whether there are any hazards requiring a preventive control. The hazard analysis is required to be written, regardless of its outcome.

  The hazard identification process is to consider known or reasonably foreseeable hazards that include:

  1. Biological hazards, including microbiological hazards such as parasites, environmental pathogens and other pathogens;
  2. Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient deficiencies or toxicities (i.e.,

inadequate thiamine in cat food, excessive vitamin D in dog food, and excessive copper in food for sheep); and

3. Physical hazards (such as stones, glass and metal fragments).

In addition, the hazard identification process is to consider known or reasonably foreseeable hazards that may be present in the animal food because the hazard: 1) occurs naturally; 2) may be unintentionally introduced; or 3) may be intentionally introduced for purposes of economic gain.

Significantly, the hazard analysis at animal food facilities does not need to consider allergens.

During the evaluation of identified known or reasonably foreseeable hazards, the effect of the following on the safety of the finished animal food for the intended animal(s) are to be considered:

1. The formulation of the animal food;
2. The condition, function, and design of the facility and equipment;
3. Raw materials and other ingredients;
4. Transportation practices;
5. Manufacturing/processing procedures;
6. Packaging activities and labeling activities;
7. Storage and distribution;
8. Intended or reasonably foreseeable use;
9. Sanitation, including employee hygiene; and
10. Any other relevant factors, such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins).

- **Preventive Controls:** Preventive controls are required to be implemented for those identified hazards that the preventive controls qualified individual determines require a preventive control to be significantly minimized or prevented.

  As defined by the final rule, a "hazard requiring a preventive control" means a "known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing or holding (storage) of animal food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the

absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in an animal food and components to manage those controls (such as monitoring, corrections or corrective actions, verification and records) as appropriate to the animal food, the facility, and the nature of the preventive control and its role in the facility's food safety system."

The definition of a "hazard requiring a preventive control" has the following significant components:

1. The "knowledgeable" person referenced in the definition is the preventive controls qualified individual. Therefore, it is the preventive controls qualified individual who is responsible for making the determination as to whether given "known or reasonably foreseeable hazards" rise to the level of being a "hazard requiring a preventive control."

2. The assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls are key factors in determining whether a hazard is a "hazard requiring a preventive control." If a given hazard has a high probability of occurring in the absence of a preventive control and a high severity of injury or illness if it were to occur, then the hazard is more likely to require a preventive control. Conversely, if a given hazard has a low probability of occurring in the absence of a preventive control and a low severity of injury or illness if it were to occur, then the hazard is less likely to require a preventive control.

   During the hazard analysis, a facility may appropriately determine that properly implementing a prerequisite program, such as a CGMP, will decrease the probability that a known or reasonably foreseeable hazard will occur in the absence of a preventive control or decrease the severity of the illness or injury if the hazard were to occur. When the probability of a hazard occurring or the severity of the illness or injury is sufficiently reduced due to proper implementation of a prerequisite program, a facility may conclude that the hazard does not require a preventive control. If the facility concludes in its hazard analysis that the hazard is not a "hazard requiring a preventive control," the facility does not need to establish preventive controls, or preventive control management components, for these hazards.

   If a facility determines through its hazard analysis that a preventive control is not needed because of an existing prerequisite program, such as a CGMP, then the facility should be prepared to demonstrate to FDA upon request that the prerequisite program is effective in addressing hazards and has been implemented properly.

3. The need for components to manage the effective control of a given hazard (such as monitoring, corrections or corrective actions, verification, and records) is a key consideration when determining whether a given hazard is a "hazard requiring a preventive control." If the level of rigor associated with these management components is not necessary to effectively control the hazard, then it is less likely that the hazard requires a preventive control.

A "preventive control" is defined to mean "those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis."

The final rule requires preventive controls to be written and may include, as appropriate to the facility and animal food:

1. Process controls. Process controls include procedures, practices and processes to ensure the control of parameters during operations such as heat processing, irradiating and refrigerating of animal food. Process controls are to include, as appropriate to the nature of the applicable control and its role in the facility's food safety system:

    a. Parameters associated with the control of the hazard; and

    b. The maximum or minimum value, or combination of values, to which any biological, chemical or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.

2. Sanitation controls. Sanitation controls include procedures, practices and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards like environmental pathogens and biological hazards due to employee handling or cross contamination. Sanitation controls are to include, as appropriate to the facility and the animal food, procedures, practices and processes for the:

    a. Cleanliness of animal food-contact surfaces, including animal food-contact surfaces of utensils and equipment; and

    b. Prevention of cross-contamination from insanitary objects and from personnel to animal food, animal food-packaging material and other animal food-contact surfaces, and from raw product to processed product.

3. Supply-chain controls. Supply-chain controls include the supply-chain program as described later in this document.

4. Recall Plan: For those animal foods associated with a hazard requiring a preventive control, the facility is required to establish and implement a recall plan to effectively withdraw products from the market; notify consumers and, as necessary, the public; conduct recall effectiveness checks; and evaluate affected products for proper disposition. An example recall plan and templates are components of the sample animal food safety plan included as an appendix to this guidance.

5. Other preventive controls. These include any other procedures, practices, and processes determined to be necessary by the preventive controls qualified individual. Examples of other controls could include hygiene training and other current good manufacturing practices.

- **Preventive Control Management Components:** If a facility determines through its hazard analysis that it has one or more hazards requiring a preventive control, then the facility is to incorporate the following management components within its written food safety plan to ensure the effectiveness and proper implementation of the preventive control:

  - **Monitoring Procedures:** Written monitoring procedures are to be developed and implemented to provide assurance that the preventive control is performing as necessary and operating within intended parameters, as applicable.

  - **Verification Activities:** These written procedures are required to ensure the preventive control is consistently implemented and effective. They are to include validating with scientific evidence that the control is capable of effectively controlling an identified hazard; confirming implementation and effectiveness; verifying that monitoring and corrective actions (if necessary) are being conducted, and reanalysis of the food safety plan, as required.

    Validation of the preventive control, if applicable, is to take place before its implementation. If that is not possible, validation is to take place within 90 days of implementing the control unless a longer time can be justified.

    Verification of implementation and effectiveness of the preventive control involves verifying that the preventive control identified in the food safety plan is being consistently applied and is significantly

minimizing or preventing the hazard.

Examples of verification of implementation and effectiveness activities for a preventive control include:

- ✓ Calibration of instruments (such as thermometers and scales) to ensure their accuracy;
- ✓ Product testing (such as for pathogens or nutrient deficiencies or toxicities); and
- ✓ Environmental monitoring (such as for pathogens).

Verification of monitoring, corrective action and correction records is to occur within seven working days after the records are created, unless a longer time can be justified. Verification of calibration of equipment (e.g., scales and thermometers), product testing and environmental monitoring activities associated with preventive controls are to occur within a reasonable time after the records are created, as determined by a preventive controls qualified individual.

Verification of the food safety plan through reanalysis is to occur at least every three years, and more frequently if: 1) significant changes occur to the activities conducted at the facility; or 2) the facility becomes aware of new information about potential hazards associated with the type of animal food it makes; or 3) the facility finds that a preventive control, combination of preventive controls, or the food safety plan is ineffective.

- ❖ **Corrective Actions and Corrections:** Corrections are steps to be taken to timely identify and correct a minor, isolated problem that occurs during animal food production. Corrective actions include actions to be taken to identify a problem that occurred with preventive control implementation, reduce the likelihood the problem will recur, evaluate affected animal food for safety, and prevent it from entering commerce. Facilities are to develop written corrective action procedures for hazards requiring a preventive control. Records documenting corrective actions and corrections, when taken, are to be established and maintained and are subject to verification activities.

FDA has issued final guidance[(43)] to further inform facilities about the hazard analysis and preventive controls requirements established by the animal food rule.

- **Supply-Chain Program:** The final rule requires that an animal food facility have a

risk-based supply-chain program for those raw materials or other ingredients for which the facility has identified a hazard requiring a preventive control that will be controlled by the supplier of the raw material or ingredient. Animal food facilities that control such a hazard requiring a preventive control within their own operations, or who follow requirements applicable when relying on a customer to control such a hazard, do not need to have a supply-chain program for that hazard.

Importantly, the rule's definition of "supplier" plays a key role in how and whether a facility may implement a supply-chain program as a preventive control to control a hazard requiring a preventive control associated with a raw material or ingredient that it receives. The definition of a "supplier" is "the establishment that manufactures/processes the animal food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/ processing by another establishment, except for further manufacturing/ processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature."

Therefore, an establishment that provides a raw material or other ingredient to a receiving facility is a "supplier" only if it manufactures/processes the raw material or ingredient, raises the animal, or grows the raw material or ingredient that is provided to a receiving facility without further manufacturing/processing by another establishment.

As an example of how the "supplier' definition works in practice, consider the supply chain for corn used by a feed mill that consists of many farmers delivering corn to a country grain elevator, then the country grain elevator delivering corn to a terminal grain elevator, and then the terminal grain elevator delivering corn to the feed mill.

In this supply chain scenario, the country grain elevator and terminal grain elevator are not "suppliers" because these establishments only held (stored) the corn and did not manufacture/process the corn. So, for this supply chain, the farmers are the "suppliers," since the farmers are the establishments that grew the corn, and no further manufacturing/processing of the corn occurred prior to receipt by the feed mill. Further, the suppliers of the corn to the feed mill likely are not only the farmers who delivered corn to the country elevator, but also the farmers whose corn was stored at the terminal elevator, and which was commingled with corn received from the country elevator.

The practical application of the definition of "supplier" is important because if a facility chooses to rely on a supply chain program as a preventive control, the facility must approve the supplier of the raw material or ingredient according to the preventive controls rules. As illustrated by the supply chain example above,

within a complex supply chain where raw materials or ingredients are obtained from multiple sources, handled in a commingled nature and stored by one or more entities, it may be difficult, if not impossible, to identify the "supplier" of the raw material or ingredient.

If there is a hazard requiring a preventive control associated with a supplier's raw material or ingredient and the facility relies on the supplier to control the hazard, the rule requires that the facility:

- Receive that raw material or ingredient only from approved suppliers, or on a temporary basis from unapproved suppliers whose raw materials or ingredients are subject to verification activities before being accepted for use. The facility must approve the supplier of the raw material or ingredient and cannot rely on another entity to perform this approval. In addition, the facility is to develop and implement written procedures to ensure that the raw material or ingredient is received only from approved suppliers.

- Perform activities to verify that the supplier or other designated entity is adequately controlling the hazard, including, as appropriate to the raw material or ingredient and its supplier:

  - Conducting onsite audits of the supplier's operations.
  - Sampling and testing of the raw material or ingredient, which may be conducted by either the supplier or receiving facility.
  - Reviewing the supplier's relevant animal food safety records.
  - Other appropriate supplier verification activities based upon the risk associated with the ingredient and the supplier.

  Significantly, for a raw material or ingredient with a hazard requiring a preventive control and for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the supply-chain program requires that an annual onsite audit be conducted of the supplier unless there is a written determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazard is controlled. The onsite audit is to be conducted by a qualified auditor that is an employee of the receiving facility or a separate third-party organization.

FDA has issued draft guidance[(44)] for the supply-chain requirements established by the animal food rule.

- **Recordkeeping Requirements:** Facilities are required by the final rule to document its hazard analysis and the management activities associated with

controlling hazards that require a preventive control as part of its written food safety plan. If a facility relies on a supply-chain program to control a hazard requiring a preventive control, then verification activities performed to control the hazard are to be documented. In addition, facilities are to document required training of qualified employees and other individuals.

All records required are to be retained at the facility for at least two years after the date they were prepared. However, except for the food safety plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of FDA request for official review. However, the food safety plan is to remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location. Importantly, the rule also provides that records established or maintained to satisfy the requirements of the rule are exempt from FDA Part 11 computer validation and electronic record requirements.

All records required by the rule are to be made promptly available to an authorized representative of FDA for official review and copying upon oral or written request.

Very Small Businesses: Under the final rules, facilities that meet the definitions of a "very small business" are subject to modified requirements for hazard analysis and risk- based preventive controls and supply-chain programs. However, a very small business still is obligated to comply with the rules' CGMP requirements.

- **Animal food Very Small Business** means, for purposes of this part, a business (including any subsidiaries and affiliates) averaging less than $2.5 million, adjusted for inflation, per year, during the three-year period preceding the applicable calendar year in sales of animal food, plus the market value of animal food manufactured, processed, packed or held without sale (e.g., held for a fee or supplied to a farm without sale). The baseline year for calculating the adjustment for inflation is 2011.

- **Human food Very Small Business** means, for purposes of this part, a business (including any subsidiaries and affiliates) averaging less than $1 million, adjusted for inflation, per year, during the three-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed or held without sale (e.g., held for a fee). The baseline year for calculating the adjustment for inflation is 2011.

Generally, under the regulations for preventive controls and supply-chain programs, a facility that is a very small business is required to:

- Attest the facility is a very small business; and

- Attest that the facility has identified hazards and that preventive controls have been implemented and are being monitored; or
- Attest that the facility is in compliance with an applicable non-federal food safety law.

Sample Plans: The last section of this document provides a Sample Animal Food Safety Plan Template that firms may wish to consider when developing an animal food safety plan at a facility. Please note that the sample plan is abridged and not complete. Facilities are required to develop and implement a complete plan that adequately addresses the regulatory requirements associated with their specific operations.

In addition, the FSPCA has made available a guide for creating a livestock food safety plan[(45)]. This guide outlines steps to create an animal food safety plan that is structured in a different format and provides an example plan for a facility that produces medicated feeds for swine and broilers.

Compliance Dates for Major FSMA Rules

Generally, the compliance dates established for the major FSMA-related rules are staggered based upon business size. In addition, the preventive controls rule for animal food provides covered facilities with one additional year to comply with the preventive controls requirements after being required to be in compliance with the CGMP requirements.

The following table summarizes compliance dates established for the major FSMA rules. Note that all compliance dates for the rules have already passed. As such, if a new food/feed facility begins operation, FDA expects such a facility to be in compliance with applicable rules at the time of start-up. That is, FDA provides no compliance "grace" period for new operations.

Summary of Compliance Dates for Major FSMA Rules

Final Rule	Date Issued	Compliance Date Large Business*	Compliance Date Small Business**	Compliance Date Very Small Business***
CGMP and Preventive Controls for Human Food	Sept. 17, 2015	Sept. 19, 2016†	Sept. 18, 2017†	Sept. 17, 2018
CGMP and Preventive Controls for Animal Food	Sept. 17, 2015	Sept. 19, 2016 (CGMP) Sept. 18, 2017 (PCs)†	Sept. 18, 2017 (CGMP) Sept. 17, 2018 (PCs)†	Sept. 17, 2018 (CGMP) Sept. 17, 2019 (PCs)
Produce Safety	Nov. 27, 2015	Jan. 26, 2018‡	Jan. 26, 2019‡	Jan. 26, 2020‡
Foreign Supplier Verification Program	Nov. 27, 2015	May 30, 2017§	Not applicable	Not applicable
Third Party Accreditation and Certification	Nov. 27, 2015	Requirements go into effect after FDA publishes Model Accreditation Standards – Issued Dec. 6, 2016		
Sanitary Transportation of Human and Animal Food	April 6, 2016	April 6, 2017	April 6, 2018	Not applicable
Intentional Adulteration	May 27, 2016	July 26, 2019	July 26, 2020	July 26, 2021

* **Large Business Definitions:** *All Rules* – Business that does not meet the definitions for "small business" or "very small business"

**** Small Business Definitions:**

- *CGMP and Preventive Control Rules for Human and Animal Food*: Business with less than 500 full-time equivalent employees
- *Produce Safety*: Business with more than $250,000 but no more than $500,000 in average annual produce sales
- *Sanitary Transportation*: Businesses, other than a motor carrier, that are not also shippers and/or receivers, employing fewer than 500 persons and motor carriers having less than $27.5 million in annual receipts
- *Intentional Adulteration*: Business with less than 500 full-time equivalent employees

***** Very Small Business Definitions:**

- *Preventive Controls Human Food*: Business with less than $1 million in annual human food sales, plus market value of human food not sold;
- *Preventive Controls for Animal Food*: Business with less than $2.5 million in animal food sales, plus market value of animal food not sold;
- *Produce Safety*: Business with more than $25,000, but not more than $250,000, in average annual produce sales
- *Intentional Adulteration*: Business averaging less than $10 million in annual human food sales, plus market value of human food not sold

† **Supply Chain Program Compliance**: *Human Food* – Later of: 1) six months after supplier is required to comply with the applicable rule; or 2) March 17, 2017 (large business) or Sept. 18, 2017 (small business); *Animal Food* – Later of: 1) six months after supplier is required to comply with the applicable rule; or 2) Sept. 18, 2017 (large business) or Sept. 17, 2018 (small business)

‡ **Produce farms** have an additional two years to comply with certain water-related requirements. Separate compliance dates applicable to sprouts.

§ **All importers** are to comply with FSVP requirements 18 months after the final rule or six months after their foreign suppliers' reach their FSMA compliance deadlines, whichever is later. "Very small importers" (importers with average annual sales of less than $1 million for human food and $2.5 million for animal food plus market value of human food or animal food not sold) and "importers of food from very small foreign suppliers" are subject to modified requirements.

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Sample Animal Food Safety Plan Template

The Sample Animal Food Safety Plan Template section of this document contains example templates firms may wish to consider when developing an animal food safety plan at a facility. The sample animal food safety plan template consists of an abridged plan that is not complete and contains both content that is optional and required by FDA's current good manufacturing practice and preventive controls rule for animal food. Please note that facilities covered by FDA's rules for current good manufacturing practice and preventive controls for animal food and/or human food are obligated to develop and implement written food safety plans that adequately address the regulatory requirements associated with their specific operations.

For operations covered by FDA's rule for Foreign Supplier Verification Programs (FSVP), importers of the foreign human and/or animal food are required to develop and implement a foreign supplier verification program for each food and its foreign supplier. Several of the required components of such a program are similar to those described within this sample animal food safety plan template section, but they are **not** identical. Importers covered by the FSVP rule are required to develop and implement a FSVP in accordance with the requirements of that rule.

In addition, a written food safety plan is not required for the major FSMA-related rule issued for Sanitary Transportation of Human and Animal Food. However, that rule does require records to be established and maintained in accordance with the regulation's provisions.

The specific format of a food safety plan is not defined by the preventive controls rules for human and animal food. However, for facilities covered by the regulations, the food safety plan must contain all the required elements. Each facility may organize the required information in a manner that suits their systems, the needs of their employees, and the requirements of the regulations.

As specified by the preventive controls rules for human and animal food, a required food safety plan must be prepared by, or be prepared under the oversight of, one or more preventive controls qualified individuals. In addition, the preventive controls qualified individual is responsible for performing, or overseeing, activities associated with: 1) validation of the preventive controls, 2) records review and 3) reanalysis of the food safety plan.

Although the preventive controls qualified individual is responsible for developing and implementing the plan, the preventive controls rules for human and animal food require that the owner, operator or agent in charge of the facility sign and date the food safety plan upon initial completion and upon any modification. Generally, the owner, operator or agent in charge of the facility is the individual that has management authority to enable adequate resources to be made available to develop and implement an effective food safety plan.

Although not elements required by the preventive controls rules for human and animal food, facilities may wish to consider incorporating the following information within a food safety plan:

1. **Food Safety Team:** The use of a food safety team in developing and implementing a food safety plan is not a regulatory requirement. However, for facilities where feasible, the use of a team of employees from different backgrounds and areas of expertise may be helpful in establishing an effective food safety plan.

2. **Facility Overview:** A general description of the facility and its operations is not a required element of a food safety plan, but may be useful when communicating with other parties, such as regulatory authorities and customers, about the facility's food safety plan. The level of detail included is optional, but the facility overview could include information that describes the facility age and operational hours, general description of products handled and distributed, and a basic overview of its manufacturing processes.

3. **Product Description:** Although not a required component of a food safety plan, it may be useful to document a general description of finished products distributed by the facility. This description could include: 1) important food safety characteristics; 2) product ingredients, as applicable, 3) type of packaging used, if any; 4) intended use of the product; 5) shelf life of the product, as applicable; 6) general labeling instructions; and 7) storage and distribution methods. The product description may be used when performing the hazard analysis and identification of preventive controls, if necessary, when developing the food safety plan.

4. **Process Flow Diagram:** The required elements for the food safety plan do not include a process flow diagram. But such an illustration may be useful to systematically consider where hazards may be introduced, amplified, and/or significantly minimized or prevented within the facility's operations. Generally, it is recommended that the process flow be illustrated in a block flow diagram that summarizes the facility's operations from start to finish.

The following sample animal food safety plan template provides example templates and format that could be used when developing an animal food safety plan at a facility. As previously noted, it is an abridged plan that is not complete and contains both content that is optional and required by the preventive controls rule for animal food. Each facility covered by the FDA's rules for current good manufacturing practice and preventive controls for animal food and/or human food is required to develop a written food safety plan that adequately addresses the applicable regulatory requirements associated with its specific operations. Additional explanatory notes are provided as necessary within the forms and are noted as such.

Explanatory note: This animal food safety plan template is only an example. The sample plan is abridged and is not complete and contains both required and optional information. For the purposes of regulatory compliance, each facility obligated to comply with FDA's preventive controls regulation for animal food is required to develop a written animal food safety plan that applies to its own specific operations and the animal food it manufactures/processes, packs or holds. Further, for regulatory purposes, the animal food safety plan is to be prepared by, or under the oversight of, a preventive controls qualified individual.

Animal Food Safety Plan for *[Name of Facility]*

Reviewed by: _____ Date: _____
Owner, Operator, Agent-in-Charge

Explanatory note: The owner, operator or agent in charge of the facility must sign and date the food safety plan upon initial completion and upon any modification.

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Food Safety Team

Explanatory Note: Although not a required element of the food safety plan, consider establishing a food safety team that will assist in the development and implementation of the food safety plan. If a team is utilized, list team members such as:

- Plant manager
- Maintenance supervisor
- Production operations supervisor
- Quality assurance supervisor
- Formulation supervisor

Facility Overview

Explanatory Note: Although not a required element of the food safety plan, consider including a general description of the facility that provides basic information on facility age, operational hours, general description of products handled and distributed, and a basic overview of its manufacturing and distribution processes. The following is an example of a basic facility overview:

- Facility Description: The facility was built in 1988 and operates two shifts, five days per week.

- Product Description: The facility manufactures approximately 300,000 tons of medicated and non-medicated finished animal feed per year. The finished animal feed is intended to be fed to swine, poultry and beef cattle, and is distributed in bulk and bag quantities.

- Manufacturing/Distribution Process: The facility receives a variety of raw materials and ingredients used in the manufacture of finished products. Some ingredients are ground prior to mixing with other ingredients. The manufacturing process utilizes a batching system that consists of automated scaling of major dry and liquid ingredients, hand-weighing of premix ingredients and a 6-ton horizontal mixer. Mixed feed may be pelleted and/or packaged prior to distribution. All finished feeds are distributed by truck.

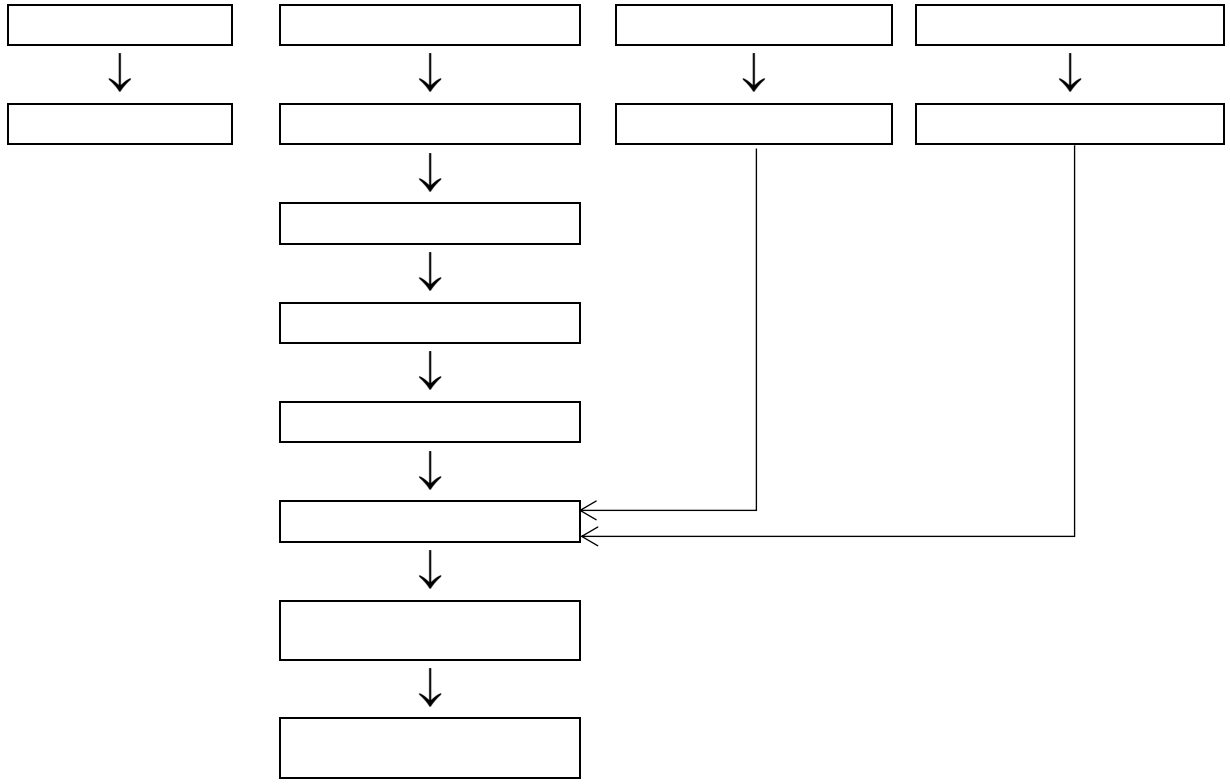
Product Description

Explanatory Note: Although not a required component of a food safety plan, it may be useful to document a general description of finished products distributed by the facility.

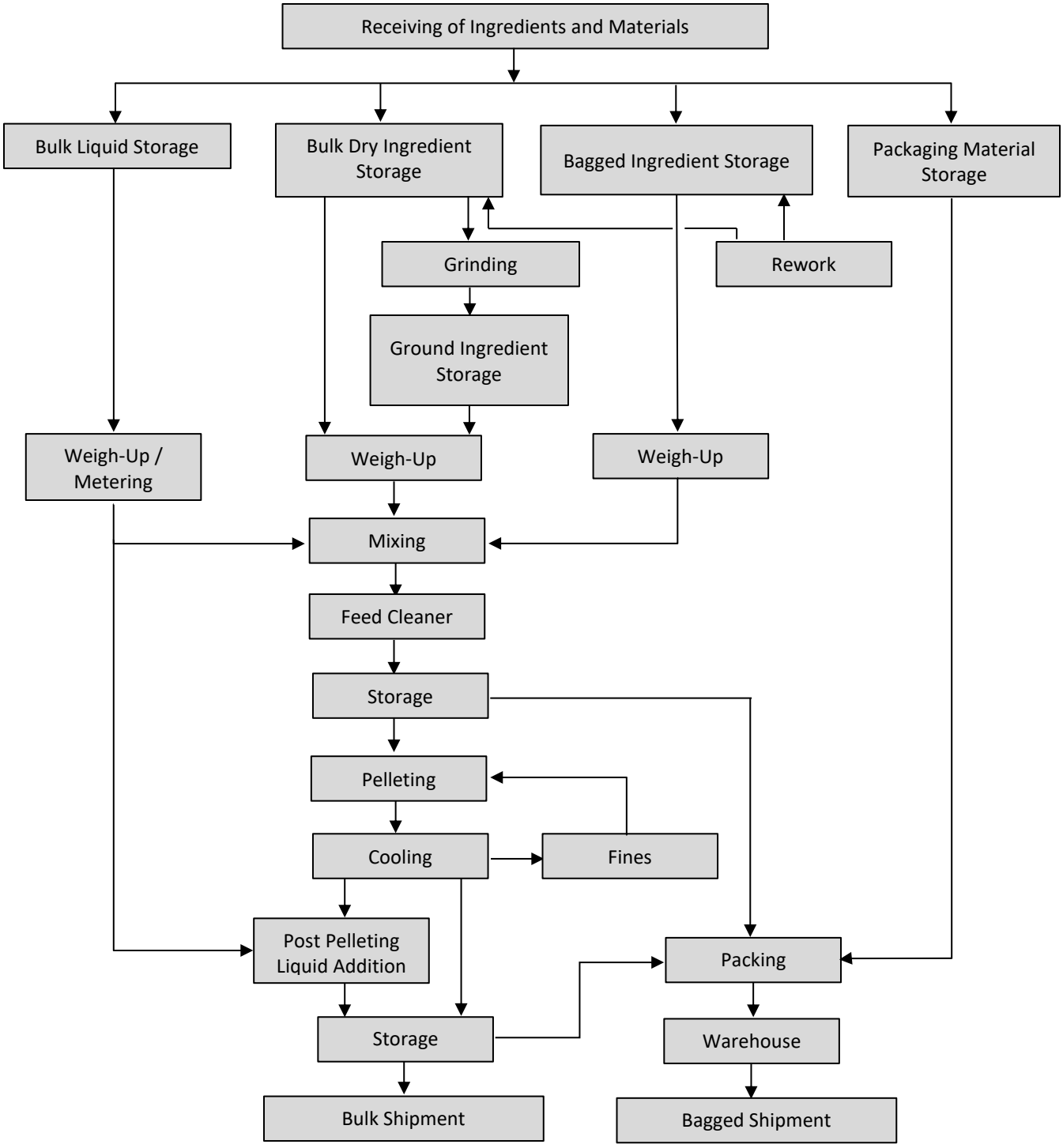
Product Name(s)	
Product Description, including Important Food Safety Characteristics	
Ingredients	
Packaging Used	
Intended Use	
Shelf Life	
Labeling Instructions	
Storage and Distribution	
Signature:	**Date**:

Process Flow Diagram

Explanatory Note: Although not a required element within a food safety plan, such an illustration may be useful to systematically consider where hazards may be introduced, amplified, and/or significantly minimized or prevented within the facility's operations. Generally, it is recommended that the process flow be illustrated in a block flow diagram that summarizes the facility's operations from start to end. For example, as indicated below, text boxes and arrows could be used to create a block flow diagram.



Example Process Flow Diagram



Rework will be added appropriately (bulk or bagged) to avoid adulteration and contamination of finished products.

HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS

Explanatory Note: The following hazard analysis tables with suggested columns are provided as examples only. A facility's hazard analysis may include all or only some of the illustrated steps, and may include additional steps not indicated in the example tables.

Table 1: Information about the hazard analysis and risk-based preventive controls may be listed in Table 1 as follows:

- **Column 1 = Ingredient or Processing Step:** List the facility's ingredients and processing steps from the Process Flow Diagram to be assessed.
- **Column 2 = Identify Known or Reasonably Foreseeable Hazards:** Identify all known or reasonably foreseeable food safety hazards that are introduced by the ingredient, or introduced, controlled or enhanced by the process step. The hazard identification process is to rely on experience, illness data, scientific reports, and other information and is to consider hazards that may be present in the food or process because the hazard occurs naturally, or the hazard may be unintentionally introduced, or the hazard may be intentionally introduced for economic gain. In addition, the following types of hazards are to be considered:

  B = Biological hazards, including bacteria, viruses, parasites, and environmental pathogens.

  C = Chemical hazards, including radiological hazards, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.

  P = Physical hazards, including potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.
- **Column 3 = What is the Severity for the Hazard?** The hazard analysis is to evaluate, based on experience, illness data, scientific reports and other information, known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at the facility to determine whether there are any hazards requiring a preventive control. The evaluation of known or reasonably foreseeable hazards also is to consider the effect of the following on the safety of the finished animal food for the intended animal(s):

  1. The formulation of the animal food;
  2. The condition, function, and design of the facility and equipment;
  3. Raw materials and other ingredients;
  4. Transportation practices;
  5. Manufacturing/processing procedures;
  6. Packaging activities and labeling activities;

7. Storage and distribution;
8. Intended or reasonably foreseeable use;
9. Sanitation, including employee hygiene; and
10. Any other relevant factors such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins).

In addition, the evaluation is to include an assessment of the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

Severity in this plan is assigned to one of four categories:

- **High** = Hazard poses imminent and immediate danger of death or severe illness or injury. It is likely to affect both humans and animals.
- **Medium** = Hazard poses danger of illness or injury that may be severe, but it is not imminent or immediate. It is likely to affect animals, but only has a limited impact to humans.
- **Low** = Hazard poses potential for illness or injury, but impact is limited and reversible. It is likely to affect animals, but unlikely to affect humans.
- **Very Low** = Hazard poses potential for minor illness or injury. It is possible that the hazard impacts animals, but it is unlikely to affect humans.

- **Column 4 = What is the Probability that the Hazard Will Occur?** Determine the probability of occurrence for each known or reasonably foreseeable hazard in the absence of a preventive control. Probability of occurrence in this plan is assigned to one of four categories:

  - **High** = Immediate danger that the hazard will occur without a preventive control.
  - **Medium** = Hazard probably will occur over time without a preventive control.
  - **Low** = Hazard possibly will occur over time without a preventive control.
  - **Very Low** = Hazard is unlikely to occur; or it is determined that it will not occur, in the absence of a preventive control.

- **Column 5 = Does the Hazard Require a Preventive Control?** Determine whether any known or reasonably foreseeable hazards require a preventive control. A risk matrix (Figure 1 below) may be used to access the known and reasonably foreseeable hazards to make this determination. The risk matrix is an example method, and its use is not a requirement. The matrix is used as a tool to help justify or explain the evaluation of whether a known or reasonably foreseeable hazard is a hazard requiring a preventive control.

Figure 1: Risk Assessment for the Hazard

SEVERITY / PROBABILITY In absence of a preventive control		High	Medium	Low	Very Low
		Hazard poses imminent and immediate danger of death or severe illness or injury. Likely to impact both humans and animals	Hazard poses danger of illness or injury that may be severe, but it is not imminent or immediate. Likely to impact animals, limited impact to humans	Hazard poses potential for illness or injury, but impact is limited and reversible. Likely to impact animals, unlikely to impact humans.	Hazard poses potential for minor illness or injury. Possible impact on animals, unlikely impact on humans.
High	Immediate danger that the hazard will occur	High-High	High-Medium	High-Low	High-Very Low
Medium	Hazard probably will occur over time	Medium-High	Medium-Medium	Medium-Low	Medium-Very Low
Low	Hazard possibly will occur over time	Low-High	Low-Medium	Low-Low	Low-Very Low
Very Low	Hazard is unlikely to occur; or determined that it will not occur	Very Low-High	Very Low-Medium	Very Low-Low	Very Low-Very Low

As the evaluation of the hazard moves toward a higher probability and severity (High-High), the hazard is more likely to require a preventive control. Conversely, as the hazard evaluation moves toward a lower severity and probability of occurrence (Very Low-Very-Low), the hazard is less likely to require a preventive control.

- **Column 6 = Justify the Response in Column 5; if Hazard does not Require a Preventive Control, Describe other Mitigation Measures in Place (if applicable).** For each known or reasonably foreseeable hazard, provide justification based upon the risk assessment, experience, illness data, scientific reports and/or other information as to whether the hazard requires a preventive control. Though not required if the hazard does not require a preventive control, other mitigation measures in place to address the hazard may be described when appropriate. Such a mitigation measure could be used to justify the ranking of severity and/or probability of occurrence made during the risk assessment.
- **Column 7 = What are the Preventive Controls for the Hazard?** List processes or procedures taken to significantly minimize or prevent the hazard requiring a preventive control. If the hazard does not require a preventive control, list "not applicable (n/a)."
- **Column 8 = Hazard Preventive Control Number.** Each preventive control should be assigned a number for traceability and identification within the food safety plan.

TABLE 1. HAZARD ANALYSIS & PREVENTIVE CONTROLS

Identification			Evaluation				Preventive Control(s)	
(1)	(2)		(3)	(4)	(5)	(6)	(7)	(8)
List Ingredients and Steps/Equipment Within Process Flow	Identify Known or Reasonably Foreseeable Hazards (B, C, P)		Assess Severity of Illness or Injury of the Hazard to Humans or Animals	Assess Probability that Hazard Will Occur in Absence of a Preventive Control	Determine if Hazard Requires a Preventive Control (Yes or No)	Justify the Classification for the Hazard in Column 5; Describe Other Mitigation Measures in Place (if applicable)	Determine the Appropriate Control for any Hazard Requiring a Preventive Control	Assign a Preventive Control Number
	B							
	C							
	P							
	B							
	C							
	P							
	B							
	C							
	P							
	B							
	C							
	P							

PREVENTIVE CONTROLS

Explanatory Note: Table 2 is used to describe management components associated with any hazards identified as requiring a preventive control. The following is a description of the columns listed in Table 2:

- **Column 9 = Hazard Requiring a Preventive Control:** The hazard evaluated as requiring a preventive control, if any, is carried over from Table 1, columns 2 and 5 into this column.

- **Column 10 = Preventive Control for the Hazard:** The preventive control used to significantly minimize or prevent the hazard, if any, identified in Table 1, column 7 is carried over for identification purposes.

- **Column 11 = Preventive Control Number.** The number of the preventive control, if any, established in Table 1, column 8 is carried over for identification purposes.

- **Column 12 = Preventive Control Category.** The preventive control category is identified in this column. The typical categories associated with preventive controls are: 1) process control; 2) sanitation control; 3) supply-chain-applied control; and 4) other control.

- **Column 13 = Parameters (if applicable):** List the parameters (e.g., critical limits) associated with process preventive controls (when applicable) for the preventive control of the hazard. Parameters are those maximum or minimum values, or combination of values, to which any biological, chemical or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.

- **Column 14 = Monitoring:** Written monitoring procedures are to be developed and implemented to provide assurance that the preventive control is performing as necessary and operating within intended parameters, as applicable**.** Monitoring procedures are to specify what will be monitored, how it will be monitored, the frequency of the monitoring activity and who will perform the monitoring.

- **Column 15 = Corrective Actions:** This column is used to describe the actions that will be taken when control of the hazard requiring a preventive control is not adequate. For hazards requiring a preventive control, written corrective action procedures are to be developed to describe actions to: 1) be taken to correct a problem that occurred with preventive control implementation; 2) reduce the likelihood the problem will recur; 3) evaluate affected animal food for safety; and 4) prevent it from entering commerce.

- **Column 16 = Records:** List information to describe the records established and maintained to document the management components associated with the preventive controls.

TABLE 2. DESCRIPTION OF PREVENTIVE CONTROLS

Preventive Control(s)					Preventive Controls Management Components					
(9)	(10)	(11)	(12)	(13)	(14)				(15)	(16)
					Monitoring					
Hazard Requiring a Preventive Control (from Table 1, Columns 2 and 5)	**Appropriate Control for Hazard Requiring a Preventive Control (from Table 1, Column 7)**	**Preventive Control Number (from Table 1, Column 8)**	**Type of Preventive Control**	**Parameters (if applicable)**	**What**	**How**	**Frequency**	**Who**	**Corrective Actions**	**Records**

Explanatory Note: Table 3 is used to describe verification activities associated with any hazards identified as requiring a preventive control. The following is a description of the Table 3 columns:

- **Column 17 = Hazard Requiring a Preventive Control:** The hazard evaluated as requiring a preventive control, if any, is carried over from Table 2, column 9 into this column.
- **Column 18 = Preventive Control for the Hazard:** The preventive control used to significantly minimize or prevent the hazard, if any, identified in Table 2, column 10 is carried over for identification purposes.
- **Column 19 = Preventive Control Number.** The number of the preventive control, if any, listed in Table 2, column 11 is carried over for identification purposes.
- **Column 20 = Preventive Control Category.** The preventive control category established in Table 2, column 12 is carried over into this column. The typical categories associated with preventive controls are: 1) process control; 2) sanitation control; 3) supply-chain-applied control; and 4) other control.
- **Column 21 = Type of Validation:** Describe how the preventive control was validated, if applicable, in this column. Validation of the preventive control is to occur before its implementation. If that is not possible, validation is to take place within 90 days of implementing the control, unless a longer time can be justified.
- **Column 22 = Assurance that Monitoring and Corrective Actions/Corrections are Completed:** Describe the activities used to verify that monitoring and corrective action/corrections are occurring as necessary. Verification of monitoring and corrective action/correction records is to occur within seven working days after the records are created, unless a longer time can be justified.
- **Column 23 = Verification of Implementation and Effectiveness:** Describe methods used to verify implementation and effectiveness of the preventive control. This involves verifying that the preventive control is being consistently applied and is significantly minimizing or preventing the hazard. Examples of verification of implementation and effectiveness activities for a preventive control may include: 1) calibration of instruments (such as thermometers and scales) to ensure accuracy; 2) product testing (such as for pathogens, nutrient deficiencies or toxicities); and 3) environmental monitoring for pathogens. Review of verification records associated with calibration of equipment, product testing and environmental monitoring activities associated with preventive controls is to occur within a reasonable time after the records are created as justified by the preventive controls qualified individual.
- **Column 24 = Reanalysis of Food Safety Plan:** A description of when reanalysis of the food safety plan will occur is listed in this column. Verification of the food safety plan through reanalysis is required to take place at least every three years, and more frequently if: 1) significant changes occur to the activities conducted at the facility; or 2) the facility becomes aware of new information about potential hazards associated with the type of animal food it makes; or 3) the facility finds that a preventive control, combination of preventive controls, or the food safety plan is ineffective.

TABLE 3. DESCRIPTION OF PREVENTIVE CONTROL VERIFICATION ACTIVITIES

Preventive Control(s)				Description of Verification Activity			
(17)	(18)	(19)	(20)	(21)	(22)	(23)	(24)
Hazard Requiring a Preventive Control (from Table 2, Column 9)	**Appropriate Control for Hazard Requiring a Preventive Control (from Table 2, Column 10)**	**Preventive Control Number (from Table 2, Column 11)**	**Type of Preventive Control (from Table 2, Column 12)**	**Type of Validation**	**Assurance that Monitoring and Corrective Actions/ Corrections are Completed as Necessary**	**Verification of Implementation and Effectiveness**	**Reanalysis of Food Safety Plan**

SUPPLY-CHAIN-APPLIED PREVENTIVE CONTROLS

Explanatory Note: If a facility relies on its supplier of a raw material or ingredient to control a hazard requiring a preventive control prior to receipt by the receiving facility, then the food safety plan is to include a supply chain program.

When a supply-chain-applied control is used within the food safety plan, then the facility is to develop and implement written procedures to ensure that it only receives the raw material or ingredient from approved suppliers. In addition, the facility is to identify and implement appropriate verification procedures that provide assurances that the supplier is effectively controlling the hazard. Such verification procedures may include, as appropriate to the supplier and the raw material or ingredient: 1) conducting annual onsite audits of the supplier's operations; 2) sampling and testing of the raw material or ingredient, which may be conducted by either the supplier or receiving facility; 3) review of the supplier's relevant food safety records; and 4) other appropriate supplier verification activities based on the risk associated with the ingredient and the supplier.

Supply-Chain-Applied Preventive Controls Program

Raw Material or Ingredient (requiring supply-chain-applied control)	*[Name of Raw Material or Ingredient]*	*[Name of Raw Material or Ingredient]*	*[Name of Raw Material or Ingredient]*
Approved Supplier and Location			
Approval Date			
Hazard Requiring a Supply-Chain-Applied Control			
Preventive Control(s) Applied by the Supplier			
Type(s) of Supplier Verification			
Verification Procedures			
Verification Records			

Written Procedures for Ingredients Requiring a Supply-Chain-Applied Control

[Develop and implement written procedures used to ensure that raw materials or ingredients requiring a supply-chain-applied control are only received from approved suppliers.]

RECALL PLAN

Explanatory Note: For those animal foods associated with a hazard requiring a preventive control, the facility is required to establish and implement a recall plan to effectively withdraw products from the market, notify consumers and, as necessary, the public, conduct recall effectiveness checks, and evaluate affected products for proper disposition. The preventive controls rule for animal food does not require a specific format to be used for the recall plan. The rule only requires that all required elements be present within the plan. This sample recall plan contains information and templates that may be used to develop an individualized, facility-specific plan.

Recall Team: The recall plan should identify and assign responsibility to those individuals who are necessary to effectively conduct a recall.

Assignment	Person	Contact Information
Recall Coordinator: Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx
Responsibility: The recall coordinator generally has the following duties: • Directs product recalls. • Directs the recall team and coordinates actions and communications. • Ensures appropriate documentation related to the affected product is collected. • Determines the location and quantity of affected product involved in the recall. • Reports the status, findings and recommendations related to the recall situation to senior management. • Notifies pertinent regulatory agencies. • Maintains the facility's written policies associated with the recall plan and its activities.		
Publicity and Public Relations: Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx
Responsibility: As directed by recall coordinator, communicates with customers, the public and regulatory agencies.		
Sales & Marketing: Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx
Nutritionist or Veterinarian: Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx
Purchasing: Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx
Quality Assurance / Food Safety: Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx
Accountant: Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx
Attorney: Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx
Administrative Support:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx
FDA Recall Coordinator:		Office: xxx-xxx-xxxx
State Recall Coordinator:		Office: xxx-xxx-xxxx

Determining if Recall Action is Necessary: The following are suggested actions to take to determine whether a recall is necessary.

Problem reported by	Initial Action	Decisions	Actions
Regulatory agency believes product is causing illness or injury.	Assemble recall team and ask agency if recall is recommended.	Evaluate situation; decide if, what and how much product to recall	**If no recall is needed**: Document why not and action taken.
News media story on problem with a type of animal food distributed by the facility.	Assemble recall team, review internal records.		**If recall is needed**: • Assign responsibilities • Gather evidence • Evaluate evidence • Initiate communications • Monitor recall • Determine appropriate disposition of affected product • Work with regulatory agencies to determine when recall should end • Assemble recall team and debrief • Prepare for legal issues
Internal or customer information suggests a potential food safety issue.	Assemble recall team and review internal records.		

Regulatory Agency Communication

Explanatory Note: The following are suggestions to facilitate communications with regulatory agencies in the event of a recall.

Product Description Form:

Modify the **Product Description** form developed as a component of the food safety plan as necessary to reflect only the product involved in the recall, including:

- Product name (including brand name and generic name).
- Product labels.
- Removal of any names of products that are not involved in the recall.

Product Labeling:

Assemble two complete sets of product labeling to provide to the regulatory agency recall coordinator. Include:

- Product labeling (including all private labels).
- Individual package label.
- Bag label (or photocopy).
- Package inserts.
- Directions for use.
- Promotional material (if applicable).

Codes (Lot Identification Numbers):

Identify the lot numbers of the affected product:

- Lot number(s) involved: _____
- Lot numbers coding system: Describe how to read the product's code:

  _____

  _____
- Expected shelf life of product: _____

Recall Company Contacts

Provide the following contact information for company personnel associated with the recall to the relevant regulatory agencies:

Manufacturer name: *[Name and address]*

Position	Name, Title	Contact Information
Recall coordinator		Office: XXX-XXX-XXXX Mobile: XXX-XXX-XXXX Email:
Most responsible individual		Office: XXX-XXX-XXXX Mobile: XXX-XXX-XXXX Email:
Public contact:	*May be one of the above or another individual. If possible, it is useful to name a different individual to allow the coordinator to focus on retrieving product and resolving the issue*	Office: XXX-XXX-XXXX Mobile: XXX-XXX-XXXX Email:

Notification of the Public

Explanatory Note: The following press release template could be used to notify the public of a recall.

Example Press Release Template

[*Company Name]* Voluntarily Recalls *[insert summary info]* Representing
[X quantity] [--No Other Products Affected--]

Contact Number for Consumers: XXX-XXX-XXXX

Contact Number for Media: XXX-XXX-XXXX

FOR IMMEDIATE RELEASE – *[date]* – *[Company name]* is voluntarily recalling *[xx]* Lot Codes of *[COMPANY/BRAND name] [insert specific product name and description]*, representing *[insert quantity]. [Insert reason for recall*].

This action relates only to *[Company name]* products with any of these Lot Codes printed on the package:

- *[Insert lot codes]*

No other Lot Codes, or any other *[Company name]* products, are involved in this action.

Only these specific Lot Codes are subject to the recall. Customers are asked to remove from distribution immediately all product with codes listed below. Customers may call the number listed or visit our website for instructions on what to do with the product.

PRODUCT	LOT CODE	ITEM NO.
[Company Name] [insert product name(s)]	*[insert product codes(s)]*	*[insert item number(s)]*

[Company name] is voluntarily recalling *[insert product name(s)]* due to [*insert reasons, or although no reports of illness have been received associated with this product, we are voluntarily recalling this product out of an abundance of caution]*.

For more information or assistance, please contact us at XXX-XXX-XXXX (Monday to Friday, 9:30 a.m. to 5 p.m. CST) or via our website at www.xxx.com.

Evaluation/Description of Recall

Explain in detail how product is defective or violative.	
Explain how the defect affects the performance and safety of the product, including an assessment of a health risk, if any, associated with the deficiency.	
If the recall is due to the presence of a foreign object, describe the foreign objects' size, composition, hardness and sharpness.	
If the recall is due to the presence of a contaminant (e.g., toxin, metal, medication, prohibited animal protein), explain the level of contaminant in the product. Provide labeling, a list of ingredients and the Safety Data Sheet for the product.	
If the recall is due to failure of the product to meet product specifications, provide the specifications and report all test results. Include copies of any sample analysis.	
If the recall is due to a label/ingredient issue, provide and identify the correct and incorrect label(s), description(s), and formulation(s).	
Explain how the problem occurred and the date(s) it occurred.	
Explain if the problem/defect affects all lot(s) subject to recall, or just a portion of the lot(s) subject to recall.	
Explain why this problem affects only those products/lots subject to recall.	
Provide detailed information on complaints associated with the product/problem: • Date of complaint • Description of complaint -include details of any injury or illness • Lot Number involved	
If a regulatory agency is involved in this recall, identify agency and contact.	

Quantity of Recalled Product

Total quantity of affected product	
Date(s) produced	
Quantity distributed	
Date(s) distributed	
Quantity on hold	
Indicate how the product is being quarantined	
Estimate amount remaining in marketplace • Distributor level • Customer level	
Provide the status/disposition of marketed product, if known, (e.g., used, used in further manufacturing, or destroyed).	

Describe Product Distribution Methods

Type of Accounts	Number
• Wholesalers/distributors	
• Repackers	
• Manufacturers	
• Retail	
• Consumers (internet or catalog sales)	
• Foreign consignees (specify whether they are wholesale distributors, retailers or users)	
• Geographic areas of distribution, including foreign countries	

Consignee List for Affected Product and Product Status

Name	*Street Address*	*City*	*State*	*Recall contact name*	*Contact phone number*	*Recalled product was shipped?*	*Recalled product was sold?*	*Recalled product may have been shipped or sold*

Notification of Customers

Explanatory Note: It is recommended that written procedures be developed on how consignees will be notified (i.e., by mail, phone, facsimile, e-mail, etc.). It is advisable to include a written notification so customers will have a record of the recall and instructions. Such procedures may include:

- How letters will be sent to customers (e.g., overnight mail, first class mail, certified mail, facsimile, email).
- Draft phone script, if notification includes use of phone. Note that if initial notification is by phone, be prepared to provide a copy of the phone script to FDA.
- Draft recall notification for website and instructions for posting notification, if applicable. Note that it is not recommended that the website be used as the sole means of customer notification.
- Draft instructions for consignees on what to do with recalled product. In the event of a recall, FDA will want a copy of final instructions.
- How to address notifications to out-of-business distributors.

Effectiveness Checks

Effectiveness checks by account: Fill in the consignee's recall contact name and information to facilitate contact.

Consignee	Recall contact		Date contacted	Method of contact				Date of response	Number of products returned or disposed
	Name	Contact info		Phone	Email	Fax	Letter		

Effectiveness check summary: To be provided to FDA periodically.

Date of notification	Method of notification	Number of consignees notified	Number of consignees responding	Quantity of product on hand when notification received	Number of consignees not responding and action taken	Quantity accounted for	Estimated completion date

Appropriate Disposition of Recalled Animal Food

- Provide a proposed method of disposition, if applicable.

- It is recommended that the local FDA District Recall Coordinator be contacted prior to product destruction. FDA will review the proposed method of destruction and may choose to witness the destruction.

- Adequate documentation of product destruction (and whether destruction was witnessed by an FDA investigator) should be established and maintained.

- If the product is to be reconditioned, explain how and where the reconditioning will take place.

- It is recommended that details of the reconditioning plan be provided to the local FDA District Recall Coordinator before implementation. Describe how reconditioned product will be identified so it is not confused with recalled product that has not been reconditioned yet.

- All reconditioning must be conducted in accordance with applicable regulatory requirements. Notify the local FDA District Recall Coordinator prior to release of reconditioned products.

- Field corrections, like product relabeling, only are to be performed by recalling firm representatives, or under their supervision and control.