

What does FSMA mean to an Ethanol Plant?

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Food Safety Modernization Act

- Signed into law January 4, 2011
- NPRM issued October 2013 by FDA;
 - **Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals**
- The proposed rule would establish Part 507 with the following Subparts related to the ethanol industry;
 - **Subpart B** Current Good Manufacturing Practice (CGMPs)
 - **Subpart C** Hazard Analysis and Risk Based Preventive Controls
 - **Subpart F** Requirements Applying to Records That Must Be Established and Maintained

Food Safety Modernization Act

- Comments received had specific concerns related to the interpretation of the current good manufacturing processes (CGMPs) as being too much like the human food regulations
- FDA issued a proposed supplemental notice to Current Good Manufacturing Practice and Hazard Analysis and Risked-Based Preventive Controls for Animal Food
- The supplemental addressed comments received from the original October 2013 proposed rule
- We are still waiting on the rule due to be finalized this summer

FSMA; Supplemental Proposed Rule

- CGMPs are now more applicable to animal food industry and provide flexibility for a wide diversity in the types of animal food facilities
- The NPRM resembled too closely the HACCP regulations, whether a known or reasonably foreseeable hazard was "reasonably likely to occur." HACCP regulations focus on critical control points (CCPs) to control hazards. FDA eliminated the term "hazard reasonably likely to occur" throughout the proposed requirements to reduce the potential for a misinterpretation that all necessary preventive controls must be established as CCPs
- A new term "significant hazard" in its place, would be linked to the facility's hazard analysis, which addresses both the severity of a potential hazard and the probability that the hazard will occur. This term would reflect the risk-based nature of the requirements.
- The revised regulations provide additional flexibility relative to the previous proposal by providing that a facility can take into account the nature of a preventive control in determining when and how to establish and implement appropriate preventive control

Who is Covered under FSMA?

- Facilities that manufacture, process, pack or hold animal food
- In general, facilities required to register with FDA under Sec. 415 of the FD&C Act
- Small Businesses - a business employing fewer than 500 persons (total workforce all facilities) would have to comply two years after the publication of the final rule, expected to be finalized by August 2015
- Applies to domestic and imported food for animals
- Some exemptions and modified requirements are being proposed

Current Good Manufacturing Practice (CGMPs)

Personnel

- Follow good hygiene practice
- Protection of food from contamination from personal effects,

Plant and grounds

- Proper cleaning and maintenance of facility
- Pest control program
- Adequate restrooms
- Safe lighting
- Adequate ventilation

CGMPs continued

Sanitation

- Includes maintaining clean and sanitary conditions of food contact surfaces, proper use and storage of toxic cleaning compounds
- Pest Control
- Proper storage of garbage and trash

Water supply and plumbing

- Plant's water supply, plumbing, and toilet and hand-washing facilities are adequate
- Adequate drainage, proper sewage disposal
- No cross connections or backflow between waste water or sewage and process waters

CGMPs continued

Equipment and Utensils

- All plant equipment and utensils must be designed and of such material and workmanship to be adequately cleanable, and must be properly maintained
- Instruments and controls maintained



CGMPs continued

Plant operations

- All operations in the manufacturing /processing, packing, and holding of animal food (including operations directed to receiving, inspecting, transporting, and segregating) are conducted in accordance with the CGMPs
- Chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures or possible animal food contamination (mycotoxins)
- Raw materials and ingredients must be inspected to ensure that they are suitable for manufacturing/processing into animal food and must be handled under conditions that will protect against contamination
- Rework procedures

CGMPs continued

Holding and distribution

- Protect against contamination and minimize deterioration
- Proper labeling
- Transport vehicle inspection procedures prior to loading



Hazard Analysis and Risk Based Preventive Controls

- A facility must prepare, or have prepared, and implement a **written food safety plan** prepared by (or its preparation overseen by) a **qualified individual**.
- Components of the plan must include;
 - Hazard Analysis as required
 - Preventive Controls
 - Supplier Program
 - Recall Plan
 - Procedures for Monitoring the Implementation of the Preventive Controls
 - Corrective action procedures
 - Verification procedures

Hazard Analysis

- **Known or reasonably foreseeable hazard** means a biological, chemical (including radiological), or physical hazard that has the potential to be associated with the facility or the food.
- **Significant hazard** means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing/processing, packing, or holding of animal food would, based on the outcome of a hazard analysis, establish 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 food, the facility, and the control.

Hazard Analysis

- Identify and evaluate known or reasonably foreseeable hazards for each type of animal food manufactured /processed, packed, or held at your facility to determine whether there are significant hazards (facility specific)
- Hazards that include:
 - Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens
 - Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient imbalances
 - Physical hazards
- Our industry will continue to look at new ways to reduce costs, improve efficiencies or possibly create new feed products. We will use new enzymes, yeasts, cleaning chemicals and process aids that may or may not be GRAS or acceptable. Facilities will need to understand their “ingredients” and only use approved ingredients.

Hazards that may be present in the animal food for any of the following reasons:

- The hazard occurs naturally;
- The hazard may be unintentionally introduced; or
- The hazard may be intentionally introduced for purposes of economic gain.

Preventative Controls

- Must identify and implement preventive controls, to provide assurances that significant hazards will be significantly minimized or prevented and the animal food manufactured, processed, packed, or held by your facility will not be adulterated
- Preventive controls required as appropriate to the facility and animal food:
 - Controls at critical control points (CCPs), if there are any
 - Controls, other than those at CCPs that are also appropriate for animal food safety.

Supplier Program

- The receiving facility must implement a risk-based supplier program for those raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of the raw material or ingredient.
- The receiving facility is not required to establish and implement a supplier program for raw materials and ingredients for which:
 - There are no significant hazards;
 - The preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the significant hazards; or
 - The receiving facility relies on its customer to control the hazard and annually obtains from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard.

Risk Based Preventive Controls continued

- **Recall plan** for animal food for which there are hazards that are reasonably likely to occur
- **Preventive control management components**
- **Monitoring procedures** that would provide assurance that preventive controls are consistently performed
- **Corrective actions** that would be used if preventive controls are not properly implemented
- **Verification activities** to ensure that preventive controls are consistently implemented and are effective. Verification activities might include records review of monitoring, correction actions, or instrument calibration.
- **Validation** of the preventative controls
- **Verification of implementation and effectiveness** ; calibrations, record reviews for product testing
- **Reanalysis** of the food safety plan every three years
- **Implementation Records** , establish and maintain specified records related to the above activities

Records That Must Be Established and Maintained

Facility maintains the following records;

- written food safety plan, including the written hazard analysis, preventive controls, monitoring procedures, corrective action procedures, verification procedures, and recall plan
- records that document the monitoring of preventive controls
- records that document corrective actions
- records that document verification, including, as applicable, those related to validation; monitoring; corrective actions; calibration of process monitoring and verification instruments; records review; and reanalysis
- records that document applicable training for the qualified individual

Who is Responsible for Developing a Plan?

- A facility must prepare, or have prepared, and implement a **written food safety plan** prepared by (or its preparation overseen by) a **qualified individual**
- Qualified individual performs
 - Preparation of the food safety plan
 - Validation of the preventive controls
 - Review of records
 - Reanalysis of the food safety plan

Requirements for a Qualified Individual

- To be a qualified, individual, must have 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 be otherwise qualified through job experience to develop and apply a food safety system.
- Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility.

How to Get Your Staff Qualified

Animal Food Safety Preventive Control Alliance

- RFA participates in the Alliance with key industry, academic and FDA stakeholders helping develop a nationwide core curriculum, training and outreach programs to assist companies producing animal food in complying with the animal preventive controls regulations that are part of FSMA
- The Alliance is active and we have a draft training curriculum we are reviewing next month

Animal Food Safety Preventive Control Alliance

The Alliance will:

- Develop standardized hazard analysis and preventive controls training and distance education modules for the animal food industry and regulatory personnel
- Design and deliver a state-of-the-art distance learning training portal
- Develop “train-the-trainer” materials and student education delivery systems
- Create a technical assistance network for small- and medium-sized animal food companies
- Develop commodity / industry sector-specific guidelines for animal preventive controls
- Assess knowledge gaps and research needs for further enhancement of the animal preventive control measures
- Identify and prioritize the need for, and compile, maximum or minimum values for widely used preventive controls

Animal Food Safety Preventive Control Alliance

Expected Deliverables

- Animal Training Curriculum
 - Will include examples of Food Safety Plans for different segments of the animal food industry, tentatively including plans for dry food, liquid feed, animal co-products, plant co-products, pet food, and minerals, vitamins and micro-ingredients.
- Guidance
 - Addresses possible hazards in animal food ingredients and manufacturing processes

Thank you

