

FDA is developing an Animal Feed Safety System that minimizes the risk to animal and public health through the use of risk-based, preventive, and comprehensive animal feed control measures. As part of this process we have established the following draft outline containing the essential components of a safe feed system.

ELEMENTS OF AN ANIMAL FEED SAFETY SYSTEM

The following bullets are some basic elements of any animal feed safety system. Every feed and/or feed ingredient transporter, processor, distributor, and user should be incorporating these elements into their animal feed business process. The detail and extent to which any of these elements apply to a specific product or line of products will depend on the product itself, its' use, the facility structure and equipment, and the distribution and feeding mechanism.

Each element is identified with a number and includes bulleted items below to provide some context and explanation of the element.

1. Incoming materials - know what you are getting
 - a. Assure identity of material. If Certificates of Analysis [COAs] are used, consider periodic audits of suppliers of COAs.
 - b. Is the material susceptible to any contamination? Do you need additional assurance such as testing
 - c. Receiving procedures - control measures [when does it occur, who does it, is the equipment dedicated], clean-out
 - d. Storage - labeled bins, designated bins, clean-out between receipt of different shipments, what else is stored with or near materials
 - e. Inventory and periodic accountability
 - f. Written SOPs

2. Processing/Manufacture
 - a. What are critical steps to the process? Are the mix times adequate? Are there other time and/or temperature/pressure requirements? Do you need in-line specifications? Do you need production schedules? Are there cross-contamination possibilities that need to be controlled? IS this a simple mix operation or are there special processes such as pelleting?
 - b. Equipment maintenance - what equipment is needed? Is it in working order? Are there QC checks that should be done on the equipment; how and how often? Is equipment specified for particular production runs or products? What are the clean-out steps and when it clean-out done?

- c. Product Labeling - labels on file; who prepares labels; how are labels verified; are checks needed to assure the correct label is on the product
 - d. Written SOPs
3. Record Keeping
- a. Records of important steps in receipt, production, distribution maintained.
 - b. Specify the minimum records and the information in each record [take from BSE, GMPs, etc.]
 - c. Written SOPs about how to keep records
4. Distribution/Transportation/Feeding
- a. Know who, what, when, where, and how much for distribution of material. Distribution should include feeding of product to food-producing animals.
 - b. How is material transported? Are special precautions needed? What was transported previously? Do you need to have clean-out between transport?
 - c. Procedures for identifying and controlling product that is not sold, used, or fed.
 - d. Procedures to get product back from marketplace if needed [recall]
 - e. Written SOPs
5. Inspection/Audit/Corrective Action
- a. Establish procedures to periodically conduct internal inspection and audit of control systems and test results - are SOPs being followed? Are internal specifications being met? Are labels current and accurate? Were deviations investigated?
 - b. Maintain a complaint file and review, evaluate, and implement corrective action when problems are identified. Do you need to provide notification of a corrective action [such as recall] to a regulatory agency.
 - c. Written SOPs
6. Responsibilities
- a. Determine responsible individuals for controls and corrective action throughout the receipt, processing, and distribution.
 - b. Establish criteria that assures the individuals are trained and understand their responsibilities.
 - c. Include responsibilities in written SOPs
7. Training
- a. Provide training to employees on regular basis - level and extent of training and oversight will depend on product and product ingredients and individual employee responsibilities
 - b. Include government requirements in training
 - c. Written SOPs