

Process Control For the Production of Feed Ingredients and Mixed Feed

Animal Feed Safety System Public Meeting
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Process Control - Objective

- To ensure the safe manufacture, packaging, storage, distribution or use of all feed ingredients and mixed feed.

Process Control - Scope

- Firms and individuals involved in manufacturing, packaging, storage, distribution or use of feed ingredients and mixed feed, including on-farm operations.

Process Control

■ Why?

- To prevent, eliminate or reduce to an acceptable level risks to animals and humans that might occur during the processing of feed ingredients and mixed feed.

Process Control

■ What?

- A systematic approach designed to ensure feed safety.

Process Control

■ How?

- By identification and use of appropriate controls (within an established feed safety program) to prevent, eliminate or reduce to an acceptable level risks to animals and humans.

and

Process Control

■ How?

- By establishing procedures to verify that the controls established within the feed safety program are effective.

A Systematic Approach

- How do we* design this systematic approach?

*we – Public comment sought.

Approaches Utilized by FDA

- cGMPs – Type A Medicated Articles
- cGMPs – Medicated Feed (Applicable wherever medicated feed is made)
- cGMPs – Low Acid Canned Food
- HACCP – Seafood and Juice
- SSOP – Seafood and Juice (Sanitary Standard Operating Procedures)

We are not advocating any of these approaches for this issue

Identified Gap

- No current regulatory approach to govern the controls used to address feed safety concerns associated with the manufacture, packaging, storage, distribution or use of non-medicated feed ingredients and mixed feed.

Identified Gap cont.

■ Comments to Docket

- Identified Gap is not correct. The Gap is focused solely on the medicated feed industry. (this is not our intent)
- Very important for the agency to extend feed safety programs up and downstream from the commercial feed manufacturer – this means ingredient suppliers and animal feeders.

Identified Gap cont.

- Comments to Docket
- Identified gap contradicts the concept of flexibility embodied in one of the core concepts contained in FDA's draft definition of "comprehensive".

Identified Gap cont.

■ Comments to Docket

- Specifically, the fourth component of the definition stated that the AFSS should “have the flexibility to be process- or product-oriented, depending on the situation.”

Identified Gap cont.

- Something to think about.
- What does “process- or product-oriented” mean to you within the context of the identified Gap for Component #3 – Process Control?

Basic Elements of AFSS

Process Control*

- Incoming materials (6 sub elements)
- Processing/Manufacturing (4 sub elements)
- Record Keeping (3 sub elements)
- Distribution/Transportation/Feeding (5 subs.)
- Inspection/Audit/Corrective Action (3 subs.)
- Responsibilities (3 sub elements)
- Training (3 sub elements)

Basic Elements of AFSS

Process Control cont.

- For each of the seven elements, the final sub element listed was an indication for written SOPs.

Basic Elements of AFSS

Process Control cont.

■ Comments to Docket

- Most comments are specific to each sub element of an element.
- One repeating comment specific to the indication for written SOPs.

Comments to Docket Cont.

- Written SOPs should be dependent upon the type, size, complexity of the operation or number of personnel involved.
- SOPs are advisable in most cases, but may be inappropriate for extremely small commercial or on-farm establishments where one or two persons are responsible for the manufacture and/or feeding of products.

Comments to Docket Cont.

- Something to think about.
- In a risk-based approach for human and animal feed safety, how are risks dependent upon the type, size, complexity of the operation or number of personnel involved?

THE END

