

Regulatory Oversight

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Objective

Develop a framework for use in prioritizing and allocating inspection and enforcement resources to minimize risks to animal and human health.

Scope

The process should apply to FDA's feed regulatory program activities (e.g., label review, education, inspections, enforcement and information sharing) and to similar state actions conducted using FDA authority.

Inspection Program

The primary purpose of an inspection is to determine a firm's or product's degree of compliance with applicable regulations.

- Surveillance
- Compliance

Surveillance Inspections

Surveillance inspections are conducted to determine whether a firm is substantially in compliance with the regulations and operating “under control.”

Compliance Inspections

Compliance inspections are conducted to evaluate a firm's compliance with the provisions of the regulations and to document inspectional observations supporting possible enforcement action.

Federal/State Interaction

Because the majority of inspections of feed manufacturing and distribution establishments that fall under the jurisdiction of FDA are done by state agencies using federal or state authority, a strong working relationship with state counterparts should be a significant component of the FDA's Animal Feed Safety System.

Risk-Based

A scientific- and risk-based approach should be utilized to improve the agency's ability to prioritize and allocate inspection resources by targeting firms, facilities, products and processes that have been identified as posing the greatest risks to animal or human health.

Enforcement

FDA has a variety of enforcement options available. Regulatory enforcement often focuses on voluntary compliance with the law and regulations. When voluntary compliance and education are unsuccessful, the agency has other enforcement options that are available.

Identified Gaps

- Establishing Priorities
- On-Farm Manufacturing
- Transportation
- Inspector Training

Identified Gap 1

Establishing Priorities

- The agency has established priorities for inspections under the BSE inspection program based on a combination of risk factors.
- CVM is currently developing a risk-based inspectional approach for other feed-related inspections, which is not expected to be completed until FY 2006.

CVM's Risk-Based Inspection System

- In 2004, CVM was charged with developing a risk-based method for determining the feed products, processes and/or facilities that presented the greatest risks to animal and human health.
- CDER had just developed their risk-based model for prioritizing GMP drug inspections (September 2004).
- CVM's Risk Based Inspection System Team is headed by Ibrahim Kamara.

CVM's Major Compliance Programs

The Risk-Based Inspection System will include:

- Drug pre-approval inspections
- Drug GMP inspections
- Drug post-approval inspections
- Medicated feed cGMP inspections
- BIMO inspections
- BSE inspections
- Feed contaminants inspections (pesticides, dioxin, mycotoxins, microbes, heavy metals, etc.)
- Inspections for drug, pesticides and dioxin residues in tissues

Identified Gap 2

Part A On-Farm

- Regulatory oversight has focused principally on the commercial medicated feed industry even though there has been a major shift to more on-farm production of all types of feed.
- Some on-farm operations are making more feed than most commercial feed companies.

Identified Gap 2

Part B -Transportation

- Vehicles that are used to transport feed are also not receiving much inspectional scrutiny. This can be a significant cross-contamination issue.
- Dept Transportation Act 1990 - Safeguarding Food From Contamination During Transportation

Identified Gap 3

Inspector Training

Ensuring the competency and proficiency of FDA field and state inspectors, compliance officers and program personnel regarding animal feed regulations, policies and program directives is essential.

Questions

