State of California
Department of Food and Agriculture
Safe Animal Feed Education Program

Recall and Complaint Procedures

*A firm's removal or correction of a marketed product that FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g. seizure. Does not include market withdrawal and stock recovery.**

Recall

Objective:

Preventing the continued use, locating, and retrieving all adulterated material is the first priority in the event of a recall. The objective is to perform this task as quickly and efficiently as possible, limiting the consumption of adulterated product.

Person Responsible:

Plant Manager or employee designated as Recall Coordinator

General Information (Refer to the 2014 Feed Additive Compendium):

Companies are required to report violative feed problems to the Reportable Feed Register of FDA within 24 hours, in the event that a situation presents that is "a threat of serious adverse health consequences or death in humans or animals is adulterated or misbranded".

Include the identity of the product; the reason for its removal or correction and the date and circumstances under which the deficiency or possible deficiency was discovered; an evaluation of the risks associated with the product; total amount of the product produced and distributed; all distribution information; a copy of the firm's recall communication efforts; a proposed strategy for resolution, and the name and contact information of the primary contact for the firm.

An *External Recall* is, removal of a product in which the distribution has exceeded the direct control of the firm.

An *Internal Recall* or product withdrawal, is the removal of a product from the market, none of which has left the firms control.

A *Retention* is the temporary holding of product from the market for further processing or disposal (Refer to the Holding Procedure standard operating procedure.)

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Class I recall, an emergency situation involving a product that may have an immediate or long-rang effect on life. (A firm experiencing a Class I recall involving Category II medicated feed is required to notify FDA.)

Class II recall, a priority situation involving a potential health hazard.

Class III recall, a situation that involves a product that does not pose a health hazard.

Procedure:

Contact chief executive officer and other appropriate regulatory agencies if human or animal health is at risk, see Recall Contacts sheet.

Initiate an investigation and access all records and documents that include the ingredient or finished feed that is being recalled (i.e. lot numbers, production and receiving records, order forms, batching logs, etc.). Determine source of adulterated material.

In the event of alleged illness or fatality record; name, address, and phone numbers of affected person(s), name and phone number of doctor, veterinarian, or other health authority involved, the doctor's or veterinarian's assessment of the case, and a complete identification of product involved.

Establish communication with all departments, including; sales, production, quality assurance, legal and regulatory, and public relations to identify any locations that recalled product was distributed to or in contact with, as well as the proper proceedings for each department to take.

Identify all recalled product with a label and remove ALL products from the facility storage areas.

Sample and analyze recalled product to confirm the source of adulterated material.

Dispose of all material as designated by the Plant Manager or by regulatory agency oversight, if necessary. (landfill, spread and disk, compost, etc.)

The Plant Manager will contact all customers to notify them of the recalled product and discontinue use of product.

Contact approved supplier if recalled product is determined to have originated from the supplier.

Sample and analyze approved supplier product from the same lot to confirm the source of adulterated material.

If a product involved in a recall is discovered to have been used in a formula feed, stop production of all formulas using that product and recall all affected formula feed.

NOTE: In the event of a recall, it benefits the firm to have an accurate traceability program. The ability to locate all products including formula feeds containing recalled ingredients in the event of an incident will ensure less overall product being recalled and less overall loss to the firm.

Example: If a firm does not have a traceability program/lot tracking program in place there may be a need to recall an entire day's worth or up to a months' worth of product, leading to the unnecessary recall of products. The accuracy of a firm's traceability program can directly correlate to the loss taken in the event of a recall.

Frequency:

Every time a product is recalled.

Corrective Action:

A corrective action will be documented describing the cause of the recall as well as any relevant material.

Related Documents:

Facility Recall Contacts List

Mock Recall

Recall Forms

All Production Records

Bulk Receiving Form

Bagged Receiving Form

Recall Label

**Code of Federal Regulations*