Recalls

Policies and Procedures

OFFICE OF THE TEXAS STATE CHEMIST
Texas Feed and Fertilizer Control Service • Agriculture Analytical Service

FDA and FSIS Recall Policies and Procedures

- FDA information is in 21 CFR Part 7.0
- FSIS Directive 8080.1 Revision 4.

FSMA

- FD&C Act Section 423 Mandatory Recall Authority
- Rules for animal feed

Recall

- Class I is a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

Recall

- Class II is a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Recall

- Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Recall – Guidelines on Policy, Procedures and Industry Responsibilities

- A recall is an effective method of removing or correcting consumer products that are in violation of laws administered by FDA. A Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective.

Recall is

- Voluntary recalls can be undertaken at any time by manufacturer and distributor, or at the request of FDA.
- More appropriate and affords better protection for consumers than seizure, when many lots of product have been widely distributed.
- Mandatory if the Secretary determines, based on the information gathered through the reportable food registry under section 417 (of the Act) or through any other means, that there is a reasonable probability that tan article of food is adulterated under section 402 or misbranded under section 403(w) and the use of or exposure to such article will cause serious adverse health consequences or death.

Recall Strategy

- **A recall strategy takes into account the following factors**
  - Results of health hazard evaluation
  - Ease in identifying the product
  - Degree to which the product's deficiency is obvious to the consumer or user
  - Degree to which the product remains unused in the marketplace.

Elements of a recall strategy

- Depth of recall
- Public warning
- Effectiveness checks

FSMA Rule § 507.38: Recall Plan

(a) For animal food

(1) Establish a written recall plan

(2) Assign responsibility for performing all procedures

(b) The written recall plan must include procedures that describe the steps to perform:

(1) Directly notify direct consignees including how to dispose
(2) Notifying the public
(3) Conducting effectiveness checks
(4) Proper disposal

Public Notification for a Mandatory Recall

In conducting a recall under this section (§423(g))

(1) ensure that a press release is published regarding the recall, as well as alerts and public notices, as appropriate, in order to provide notification
  (a) Of the recall to consumers and retailers
  (b) That includes, at a minimum
    (i) The name of the article of food subject to the recall
    (ii) A description of the risk associated with such article
    (iii) The extent practicable, information for consumers about similar article of food that are not affected by the recall

FDA requested recall

- **The commissioner of FDA or designed may request a firm to initiate a recall**
  - Product presents a risk of illness or injury
  - The firm has not initiated a recall of the product
  - Agency action is necessary to protect the public health and welfare
- **Notification**
- **Upon receipt of a request to recall, firm to provide information to FDA**

Firm Initiated Recall

- Identity of product
- Reason
- Evaluation of the risk
- Total amount of product
- Total amount of product in distribution
- Distribution information
- A copy of firm's recall communication
- Proposed strategy
- Firm official name handling recall

Procedure for Recalls & Holds

- Written & in sufficient detail to that individuals know their responsibility and authority
- Complete commitment for authority and priority by top executives and contains their approval
- Audit the recall by initiating a mock recall
- Include a preamble stating the objective
- Definitions: internal, external, retention
- Establish recall classification to clarify priorities
- May or may not notify FDA

Recall Procedures:

- **Immediate verify the facts**
- **Alert CEO if warranted**
- **If an alleged illness or fatality obtain**
  - Person's address and phone
  - Contact information for vet or doctor
  - Doctor's or vet's assessment of the case
  - Complete identification of the product
  - Who to involve internally
- **Who to involve**
  - Research, Production, Sales, Quality, Insurance
  - Legal and regulatory, Public relations

Recall Procedures cont.

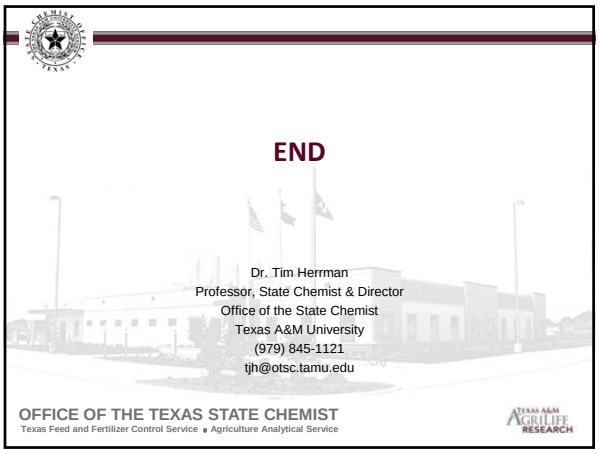
- Method to trace material and contact customers
- Arrangements for product return or disposal if required
- Record all steps taken on Corrective Action Sheet

Anticipate Potential Recalls

- A significant nutrient or drug "off assay"
- Discrepancy in the drug inventory
- Drug residues in meat
- Pesticide or other chemical
- Wrong or inaccurate labeling

Summary

- A key to effectiveness of the entire program depends upon all pertinent information being channeled through one individual
- Verify the facts
- Responsibilities are clearly assigned and understood
- Continual follow-up
- Complete records of ongoing recall activity
- Communicate
- Required under FSMA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