Product Recalls

Protecting Public Health

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Overview

Agency’s Mission Office of Field Operation (OFO)

FSIS Directive 8080.1 Rev 5

Recall Effectiveness Checks

Closure
Effective Method of removing from commerce any product that may be adulterated or misbranded.

Manufacturer, distributors, retail stores, warehouse and importers can be involved.

Recalls are voluntary, FSIS has detention and seizure authority to remove adulterated products from commerce.
Quick View

- OFO samples products, O157:H7 & Lm or is notified of significant event
- Electronic notification of results (BITES)
- OFO Verify hold status/trace back activities
  - OFO acts if not held 2-hours from positive findings
Quick View

- OFO notifies Recall Management Staff (RMS)
- OFO gathers product information
- Conference call to evaluate the need for a recall.
Quick View

- FSIS recommends a recall
- Industry decides to initiate action
- Press release issued
- FSIS recall effectiveness begins
FSIS Directive 8080.1 Rev.5

Background

- Protect Public Health
- Prevent USDA detention or seizure
- Verification by USDA
Recall- voluntary removal of product from commerce.

Recall classifications

Class I- will cause serious, adverse health consequences or death.

Class II- remote probability of adverse health consequences.

Class III- will not cause adverse health consequences. (GRAS ingredient not on label)
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Depth of Recall

- Wholesale level
- Retail level
- HRI level
- Consumer level
Scope

- Amount and kind of product in question
- Factors - lotting, clean up to clean up, rework and epidemiological investigations
Recall Committee

Representatives from various FSIS offices and staffs. They respond to health hazards reported to Recall Management Staff (RMS).

RMS distributes information about recalls to committee members.
Primary Committee Members

- District Recall Officer (DRO) - Deputy District Manager in a District.

- Health Hazard Evaluation Board (HHEB) - Explains regulatory codes and policies.

- Congressional and Public Affairs (Media Relations) - Gathers info and generates press release.
DRO coordinates the inquiry to determine need for recall:

- Collects information
- Documents chronology
- Discussions with FSIS field inspection.
- Contacts company
Determining the need for Recall (con’t)

- Interview consumers
- Collects samples
- Contacts State and Local Health Departments
- Analyses epidemiological data
Preliminary Recall Evaluation

Committee evaluates information received

Make recommendations

Determine whether plants are to recall product
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Preliminary Recall Evaluation

Factors in Recall Evaluation:

- Nature of defect
- Occurrence of illness
- Likelihood of illness
- Type of illness
Recall Determination (Questions)

- Is product adulterated or misbranded?
- Is product in commerce and available to consumers?
- Is FSIS prepared to detain or move to seize product?
Recall Press Release will contain:
- Whether firm is recalling product
- Reason for the recall
- Recall classification
- Depth of recall/ Scope of recall
- Ability to identify product
- Estimated amount of product
Recall Approval

AA/OFO approves recall recommendation

RMS contacts firm to request recall

RMS will follow up with confirmation letter

Public Affairs will confirm info for press release

DRO will begin effectiveness checks
Recall Effectiveness

- OFO gathers initial distribution
- OFO gathers further distribution
- OFO performs effectiveness and product disposition checks with help from some MOU states
- OFO determines success of recall
Recall Effectiveness

Recall classification  Following the initiation of a recall, FSIS verification activities should begin as soon as possible within a period of:

- **Class I**  3 days
- **Class II**  5 days
- **Class III**  10 days

Completed within a period of:

- **Class I**  10 days
- **Class II**  12 days
- **Class III**  17 days
Recall Effectiveness

Disposition

The firm’s action with respect to product to correct a situation leading to the recall.

Rework, re-cook, re-label, destruction depending on the hazards associated with the product being recalled.
Recall Effectiveness

If firm decides not to accept the agency’s recommendation to recall product:

- FSIS will detain all product subject to recall found in commerce
- Press release to inform public (Class I and II)
Questions?