



Food Recall Process

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LEGAL ISSUES



Code of Federal Regulations

- 21 CFR Part 7, Subpart C: Recalls (Including Product Corrections) – Guidelines on Policy, Procedures, and Industry Responsibility

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=7>

- Passed in 1978
- Acknowledges a recall is a voluntary action by a firm
- Guidance on development of recall strategy (depth, public warning, effectiveness checks) and on recall communications with customers and FDA



Code of Federal Regulations

- 21 CFR Part 107, Subpart E – Infant Formula Recalls

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=107&showFR=1&subpartNode=21:2.0.1.1.7.5>

- Passed in 1985
- When the Food and Drug Administration determines that an adulterated or misbranded infant formula presents a risk to human health, a manufacturer **shall** immediately take all actions necessary to recall that formula, extending to and including the retail level, consistent with the requirements of this subpart.



Other laws that enhance FDA's ability to monitor recalls

- 2002 Bioterrorism Act: regulations requiring persons who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain records. These records identify the immediate previous source of all food received, as well as, the immediate subsequent recipient of all food released.



Other laws that enhance FDA's ability to monitor recalls

- 2007 The Food and Drug Administration Amendments Act directs the FDA to establish a Reportable Food Registry for Industry.
- Industry must report on products that might sicken or kill people or animals.



Poll Question

Should FDA be given broader authority to
order recalls of food?

Yes ✓

No ✗



If firms will not recall...

- FDA Requested Recall
- FDA Publicity
- Legal action (seizure, injunction)
- FDA seeking wider recall authority



Let's Pause for Two Questions from the Audience





DEFINITIONS



Definitions (21 CFR 7.3)

- *Recall* means a firm's removal or correction of a marketed product(s) that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure.



Focus on Recall definition: “correction” and “marketed”

- Removal or correction: *Correction* means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.
- Marketed: Product has left the firm's control

Focus on “Recall” definition: “food”



- Product: FDA has jurisdiction over all foods that have moved in interstate commerce except those which are specifically regulated by USDA
- United States Department of Agriculture (USDA) regulates meat and poultry; FDA regulates fish, shellfish, reptiles, amphibians and exotic species.
- Dept. of Treasury regulates alcoholic beverages

Focus on “Recall” definition: “food”



- Environmental Protection Agency (EPA) determines which pesticides may be used on specific foods (“tolerances”). FDA enforces the tolerances established by EPA.
- Consumer Product Safety Commission (CPSC) has jurisdiction over harmful packaging that does not adulterate the food



Pop quiz

FDA regulates ground beef
FDA regulates whiskey
FDA regulates monkey meat
Recalls are always voluntary
USDA regulates infant formula

Place clip art in the boxes to the left!



Recall Classification

- Numerical designation, i.e., I, II, or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.



Recall Classification

- **Class I:** reasonable probability of serious adverse health consequences or death.
- Examples: undeclared allergens such as peanuts, eggs, or milk; pathogens such as Salmonella, Listeria monocytogenes and E. coli O157:H7; botulism.



Recall Classification

- **Class II:** temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- Examples: undeclared wheat; undeclared FD&C Yellow #5 or #6; foreign objects that pose a physical hazard



Recall Classification

- **Class III:** not likely to cause adverse health consequences.
- Examples: short weight; insect parts; non-pathogenic yeasts and molds



Let's Pause for Two Questions from the Audience





FDA Recall Process



FDA Offices Involved in Recalls

- Office of Regulatory Affairs
- Center for Food Safety and Applied Nutrition (for human food)
- Office of Public Affairs (Press Office)



Office of Regulatory Affairs (ORA)

- Consists of headquarters unit and field offices (20 district offices)
- District office has investigations and compliance branches
- Field laboratories

ORA's Regional and District Offices





ORA District Role in Recalls

- Districts have an individual or staff designated as recall coordinator
- Receive notification of all recalls from regulated industry in their district
- Advise firms on their recall strategy
- Monitor the progress of firm's recalls
- Forwards information to ORA HQ, Press Office and appropriate Center



ORA Headquarters Recall Unit

- Headquarters unit: Office of Enforcement, Division of Compliance Management and Operations, Recall Staff
- Establish agency-wide recall policies and procedures
- Receive notification of all recalls from FDA field offices
- Advise field offices and coordinate field's response to recalls
- Inter-agency and international coordination
- Authority to publish firm recall press releases on the FDA website, along with photos of recalled products if available

CFSAN Role in Recalls

FDA Center for Food Safety and Applied Nutrition



- Receives information on all food recalls from district offices
- Decides whether firm's action meets the definition of a recall
- Comments on firm's and FDA's recall strategies, including effectiveness checks and audit checks
- Performs health hazard evaluation and classifies recall



Press Office Role in Recalls

- Assists in review of firm's press releases
- Assists in writing/clearance/issuance of FDA press releases
- Responds to media inquiries on recalls
- Posts firm's and FDA's press releases on FDA website, along with photos of recalled products
- Publishes weekly Enforcement Report



Recall info on FDA's website

- FDA's home page has a link to "Recalls & Safety Alerts"
- Recall page has firm's and FDA's press releases for significant recalls and also links to recall guidance documents
- Consumer Updates and Information
- FDA Enforcement Report



Let's Pause for Two Questions from the Audience





Assessing recall effectiveness



Effectiveness checks conducted by firms

- The purpose of an effectiveness check is for recalling firms to verify their recall notification was received by the customer, that the customer read and understood the letter and followed the recall instructions. The effectiveness check should also verify the recall reached the appropriate level in the distribution chain.



Audit checks conducted by FDA, state and local governments

- In addition to the effectiveness checks conducted by recalling firms, FDA may also contact a percentage of customers (referred to as audit checks) as a means of assuring the recalling firm and its consignees are carrying out their recall responsibilities.



Audit check process

- Audit checks are normally begun by FDA after the firm has initiated its recall and consignees have been notified
- The percentage of consignees to be audited is usually proposed by the district auditing the recall and approved by CFSAN



Audit check process (cont.)

- Depending on the circumstances, audit checks may be conducted at secondary accounts and beyond. For example, if the primary consignee is a distributor, the audit check will obtain a list of retail stores and a percentage of the retail stores will be audited.



Audit check process (cont.)

- The audit check assignment is issued by the district monitoring the recall and may assign audits to other FDA district offices.
- The individual conducting the audit check fills out FDA form 3177 (see example at <http://www.fda.gov/downloads/ICECI/Inspections/IOM/ucm127471.pdf>). The check is endorsed as effective or ineffective and returned to the district monitoring the recall.



Firm's status reports

- The recalling firm will be asked to provide Recall Status Reports after initiating a recall (usually on a monthly basis but more frequently when indicated) to the FDA District office monitoring the recall. The reports requested will usually include the following information:
 - - Dates customers notified
 - - Number of customers notified
 - - Number of customers responding
 - - Quantity of RECALLED product returned or accounted for
 - - Details of firm's recall effectiveness checks



Ineffective recalls

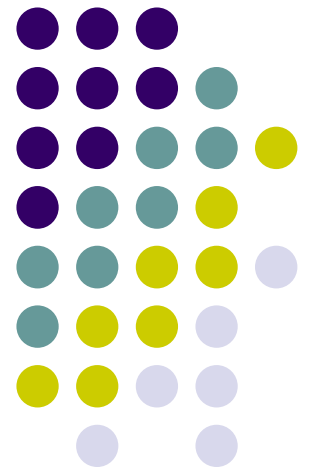
- FDA can ask firm to re-issue recall notifications or to re-issue press
- Possible FDA actions
 - FDA press
 - Ineffective Recall letter
 - FDA Requested recall



Recall Termination

- FDA will terminate (consider it completed and closed out) a firm's recall after reviewing the results of audit checks, the firm's status reports, and the disposition of recalled product.

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