

## Oregon Department of Agriculture Information on Recall Plans for Small Firms

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**Recall** - a firm's removal or correction of a marketed product 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. Recall does not include a market withdrawal or a stock recovery. [21 Code of Federal Regulations, Part 7.3 (g)]

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The Federal Food, Drug and Cosmetic Act (the law) does not generally authorize FDA to "order" a manufacturer to recall a food product. The Agency may request a product recall if the firm is not willing to remove dangerous products from the market without FDA'S written request. Most product recalls are done voluntarily, either after self-discovery of a problem or as a result of findings from another source. If a company does not voluntarily recall the identified product, FDA can seek legal action under the FD&C Act. These legal actions can include seizure of product and/or injunctions against the firm. Cooperation between FDA and its regulated industries has proven over the years to be the fastest and most reliable way to get unsafe and defective products out of consumer's hands.

**Market withdrawal** involves a minor violation such as failure to put the zip code on your label or improper labeling or net weight. Market withdrawal involves only distributed product. FDA may or may not be involved with a market withdrawal. **Stock recovery(s)** generally involve bringing product back that is still within the control of the company. FDA is usually not involved with stock recoveries.

Title 21 of the Code of Federal Regulations, part 7 contains guidelines for companies to follow when recalling product under FDA's jurisdiction. In the guidelines it is clear the firm needs to take full responsibility for product recalls including follow-up checks to see that the recall was successful. These guidelines also include instructions to contact FDA when a recall is initiated and to make progress reports during the recall.

When a food product has been deemed unsafe or adulterated an evaluation of the health hazard will be assessed and based on the findings a classification for the recall will be assigned, i.e., Class I, Class II or Class III. Class I – dangerous or defective products that predictably could cause serious health problems or death. (e.g., food found to contain botulinal toxin, undeclared allergens) Class II – products that might cause a temporary health problem, or pose only a slight threat of a serious nature. (e.g., bacteria contamination or undeclared ingredients on the label) Class III – products are unlikely to cause any adverse health reaction, but violate FD labeling or manufacturing regulations. (e.g., container defect like plastic delaminating or a lid that does not seal, off flavor, color or leaks and lack of English labeling in a retail food) FDA develops a strategy for each recall that determines how extensively it will check on the firm's performance in recalling the product. For a Class I recall, FDA could check to make sure that each defective product has been recalled or reconditioned. For a Class III recall, FDA may decide to spot check to make sure the product is off the market.

In the event a firm is involved in a product recall the following information may be necessary.

- Identity of the product involved

- Reason for the removal/correction of the product and date the deficiency was discovered
- Evaluation of the risk involved with the deficiency
- Total amount of products produced and timespan of production
- Total amount of product estimated to be in distribution channels
- Distribution information
- Proposed communication for the firm during the recall
- Proposed strategy for conducting the recall
- Name and telephone number of the firm's contact information during the recall

**General Industry Guidance – [21 Code of Federal Regulations, Part 7.59]**

A recall can be disruptive of a firm's operation and business, but there are several things that prudent business cans do to facilitate a recall action.

- (a) Prepare and maintain a current written contingency plan for use in initiating and effecting a recall.
- (b) Use sufficient coding of regulated products to make possible positive lot identification and to facilitate effective recall of all violative lots.
- (c) Maintain product distribution records as are necessary to facilitate location of products that are being recalled. Such records should be maintained for a period of time that exceeds the shelf life and expected use of the product and is at least the length of time specified in other applicable regulations concerning record retention.

**Each plan should include the following:**

- Legal name of the firm
- Mailing address of the firm
- Phone and fax numbers of the firm
- Emergency phone numbers for the firm
  - Oregon Dept of Agriculture main office
  - Local Health Department
  - FDA local and regional offices
- Complete list of all approved sources, their phone numbers and addresses
- Complete list of customers, their phone numbers and addresses
- Current copies of all labels that are in distribution
- Complete list of current ingredients for food products in distribution
- Written explanation for any coding that appears on food products in distribution
- Copies of relevant microbiological and/or toxicological tests
- A narrative or flow diagram on how the public will be notified in the event of a recall
- How will the public contact the firm?
- How will the product be returned to the firm and where will it be stored?
- Copies of SSOP's, SOP's, HACCP plan, monitoring logs, production logs and test results
- Name of retail coordinator (should be the person that handles all complaints for the firm)

This document is intended as a guide in developing a recall plan. Not all variables in a food processing firm's distribution can be accounted for globally without individual consideration. It is recommended that a mock recall be performed annually to both determine the adequacy of the plan and to provide an opportunity to evaluate the thoroughness of the plan. FDA's web page for more information may be found at [www.fda.gov](http://www.fda.gov).