



Basic Information on Recalls and Recall Plans

This handout provides basic information and recommendations to help firms handle most aspects of a product recall, as well as product removals and corrections that do not meet the definition of a recall under **21 CFR 7.3 Enforcement Policy: Recall**. The handout also helps identify what information the firms should provide to the Oregon Department of Agriculture (ODA) and/or the Food and Drug Administration (FDA) and how they should notify their customers about product recalls.

DEFINITIONS

Recall means a firm's removal or correction of a marketed product that the FDA 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 CFR, Part 7.3(g)]

Market Withdrawal means a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc. [21 CFR, Part 7.3(j)]

Stock Recovery means a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e., the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use. [21 CFR, Part 7.3(k)]

CLASSIFICATIONS

The classification of recalls is assigned by the FDA based on the relative degree of health hazard presented by the product being recalled.

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

PROCEDURES

Most product recalls are undertaken voluntarily by manufacturers or distributors, either after self-discovery of a problem or as a result of findings from another source. In 2011 the Food Safety Modernization Act (FSMA) gave the FDA mandatory recall authority for foods if there is a reasonable probability that the food is adulterated or misbranded under the Federal Food, Drug, and Cosmetic (FD&C) Act where the food could

cause serious illnesses or death. The FDA must give the responsible party an opportunity to conduct a voluntary recall before ordering a mandatory recall. Cooperation between the FDA and its regulated industries has proven over the years to be the fastest and most reliable way to remove unsafe and defective products from the market.

When a firm conducts a Class I recall, the firm is required to file a report through the FDA's Reportable Food Registry (RFR) electronic portal as soon as practicable, but in no case later than 24 hours after the recall is initiated.

The firm's recall objectives include:

- Providing consumer protection
- Providing accurate information to the customers and relevant regulatory agencies
- Locating the product
- Removal and/or correction of the product
- Proper disposal of the product
- Investigating the root cause and steps to prevent reoccurrence

21 CFR Part 7 Subpart C contains guidance on policy, procedures, and industry responsibility for firms to follow when recalling product under the FDA's jurisdiction. The firm needs to take full responsibility for product recalls including promptly notifying its affected direct accounts and conducting effectiveness checks to verify that all consignees have received notification and have taken appropriate action. Firms must immediately notify the FDA when a recall is initiated including submitting periodic recall status reports during the recall.

IMPORTANT INFORMATION TO COLLECT

In the event a firm is involved in a product recall the following information may be necessary for conducting an effective recall:

- Identity of the product involved
- Reason for the removal or correction of the product and date and circumstances under which the deficiency was discovered
- Evaluation of the risk associated with the deficiency
- Total amount of products produced and timespan of production
- Total amount of product estimated to be in distribution channels
- Distribution information, including the number of direct accounts and, where necessary, the identity of the direct accounts
- Proposed recall communication
- Proposed strategy for conducting the recall
- Name and telephone number of the firm official, who should be contacted concerning the recall

A recall can be disruptive to a firm's operations and business, but there are several steps a prudent firm can take in advance to minimize this disruptive effect [21 CFR, Part 7.59]:

- (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 such 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.

RECALL PLAN

A recall plan is required for any food with a hazard requiring a preventive control [21 CFR, Part 117.139]:

- (a) The firm must establish a written recall plan for the food.
- (b) The written recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility:
 - (1) Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;
 - (2) Notify the public about any hazard presented by the food to protect public health;
 - (3) Conduct effectiveness checks to verify that the recall is carried out; and
 - (4) Appropriately dispose of recalled food - e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.

It is recommended that the recall plan contains a trace-forward and traceback procedure and the business performs a mock recall annually to determine the adequacy of the plan and to provide an opportunity to evaluate the thoroughness of the plan.

Contacting your local ODA Food Safety Inspector is highly recommended for assistance during any recall situation. Assistance from ODA personnel is a resource available to Oregon food facilities at no charge. To locate your local ODA Food Safety Inspector, please check the following website:

<https://oda.direct/FindFoodInspector>

RESOURCES

21 CFR Part 7 Enforcement Policy:

<https://oda.fyi/CFRPart7>

21 CFR Part 117.139 Recall plan:

<https://oda.fyi/CFRTitle21>

Guidance for Industry: Product Recalls, Including Removals and Corrections

<https://oda.fyi/ProductRecalls>

Guidance for Industry and FDA Staff: Questions and Answers Regarding Mandatory Food Recalls:

<https://oda.fyi/RecallsGuidance>

Reportable Food Registry (RFR):

<https://oda.fyi/RFR>