

# Health and Human Services Agency California Department of Public Health



### What Are My Responsibilities During A Food Recall?

A food recall is the removal of an adulterated or misbranded product from commerce. A food recall is undertaken voluntarily by the manufacturer or distributor of a product; however, once a recall has been initiated every firm that has received or distributed the affected product must take action. The California Department of Public Health - Food and Drug Branch (CDPH-FDB) recommends firms prepare in advance for a food recall by developing and implementing a formal Recall Plan. You can access a sample "Food Recall Plan" template at: <a href="Sample Recall Plan">Sample Recall Plan</a>.

If your firm does not currently have a Recall Plan, it is recommended that you take the following actions identified below, at a minimum to assure the efficient and effective removal of the recalled product from commerce:

#### If your company is the recalling firm:

- 1. Identify, isolate and stop selling the affected product(s). You must consider all products that could be involved in the event. For instance, if a problem is found in a single lot of product, are you reasonably assured other lots are not affected?
- 2. Prepare a Press Release and send it to the Associated Press or other appropriate media agency. If needed, firms may request CDPH-FDB's assistance with drafting a Recall Notice and/or Press Release. CDPH-FDB requests a review of your draft Recall Notice and/or Press Release before they are issued.
- 3. Within 24 hours, develop a Recall Notice to inform all customers who received the recalled product. Your customers must be advised of the reason for the recall and the specific product(s) affected. Instruct your customers to isolate and stop selling the product and to notify all their customers who have received the recalled product. The Recall Notice should include a method to contact you to confirm that the Recall Notice was received and appropriate actions were taken.
- 4. Conduct a "root cause analysis" to investigate the cause of the recall and initiate steps to prevent further recurrence of the problem. You may be required to file a report through the U.S. Food and Drug Administration (FDA) Reportable Food Registry on-line portal if the recalled food item may cause serious adverse health consequences.
  - Infant formula and dietary supplements are excluded from the requirements of the Reportable Food Registry (RFR). Individuals recalling infant formulas and supplements should seek additional information from the appropriate <u>FDA Recall</u> Coordinator.



- 5. Prepare a Customer Distribution List (e.g., Excel or other database) that identifies all customers to whom your firm shipped the recalled product. CDPH-FDB recommends that a distribution list be prepared within four hours after the recall has been initiated. A template may be obtained by sending an email to <a href="mailto:fdberu@cdph.ca.gov">fdberu@cdph.ca.gov</a> or call (916) 650-6500 and ask for the Food Recall Team.
- 6. Return the completed "Customer Distribution List" template to CDPH–FDB at <a href="mailto:fdberu@cdph.ca.gov">fdberu@cdph.ca.gov</a>. The list must include the following information:
  - Type of customer (Distributor, Manufacturer, Wholesaler, Retailer, Retail Distribution Center, Food Service etc.)
  - Customer name
  - Customer street address, city, state, zip code, telephone and fax numbers, contact person's name and email address
  - Date and quantity shipped
  - Brand Names, Lot Codes and/or UPC Codes
- 7. Efforts should be taken to reconcile production and/or distribution amounts with products returned. This information will be included in your reports to CDPH-FDB.
- 8. As the recalling firm you have the responsibility to assure the effectiveness of the recall by monitoring responses from all customers who have received the recall notice.
- 9. Contact CDPH-FDB concerning requests for product disposition. Requests may include: destruction, reconditioning or redirection to non-food usage.
- 10. Contact CDPH-FDB to discuss formal termination of the recall.
- 11. For additional information including sample recall Press Releases and Customer Distribution Lists, refer to the Food and Drug Branch's Food Recall webpage.

For your convenience, a reference document has been included on the last page. Please post the document in a visible location for reference during a food recall.

#### If your firm received a recalled product from a supplier:

1. Identify, isolate and stop selling the affected product (s).

You may be required to file a report through the FDA Reportable Food Registry on-line portal if the recalled food item may cause serious adverse health consequences. Infant formula and dietary supplements are excluded from the requirements of the Reportable Food Registry (RFR). Individuals recalling infant formulas and supplements should seek additional information from the appropriate FDA Recall Coordinator.

- 2. Notify your customers of the recall as soon as possible, but within 24 hours upon notification from the recalling firm.
- 3. Prepare a "Customer Distribution List" (e.g., Excel or other database) that includes all customers to whom your firm shipped the recalled product. CDPH-FDB recommends that a distribution list be prepared within four hours upon notification from the recalling firm. A template can be obtained at: <a href="mailto:fdberu@cdph.ca.gov">fdberu@cdph.ca.gov</a> or call (916) 650-6500 and for the Food Recall Team. The list must also include the following information:
  - Type of customer (Distributor, Manufacturer, Wholesaler, Retailer, Retail Distribution Center, Food Service etc.)
  - Customer name
  - Customer street address, city, state, zip code, telephone and fax numbers, contact person's name and email address
  - Date and quantity shipped
  - Brand Names, Lot Codes and/or UPC Codes
  - Return the completed "Customer Distribution List" template to CDPH–FDB at: fdberu@cdph.ca.gov
- 4. All firms involved in a recall have the responsibility to assure the effectiveness of the recall by monitoring responses from all customers who have received the recall notice.
- 5. Efforts should be taken to reconcile production and/or distribution amounts with products returned. This information will be included in your reports to CDPH-FDB.
- 6. Contact your supplier for disposition instructions.
- 7. Contact CDPH-FDB to discuss formal termination of the recall.
- 8. For additional information, refer to the Food and Drug Branch Food Recalls webpage.

For your convenience, a reference sign has been included on the next page. Please post the document in a visible location for reference during a food recall.

## What Are My Responsibilities During A Food Recall?

- 1. Identify, isolate and stop selling the affected product(s).
- 2. Refer to your firm's Recall Plan.
- 3. Notify your customers about the recall as soon as possible, but within 24 hours upon notification.
- 4. Prepare a Distribution List (e.g., Excel or other database) that includes all customers to whom your firm shipped the recalled product. CDPH-FDB recommends that a distribution list be prepared within four hours after a firm has initiated a recall or is notified of a recall. A template can be obtained by sending an email to: <a href="mailto:fdberu@cdph.ca.gov">fdberu@cdph.ca.gov</a> or call (916) 650-6500 and ask for the Food Recall Team.
- 5. Return the completed "Customer Distribution List" template to CDPH–FDB at <a href="mailto:fdberu@cdph.ca.gov">fdberu@cdph.ca.gov</a>.
- 6. You may be required to submit a safety report to the Federal Food and Drug Administration (FDA) at <u>FDA Reportable Food Registry</u> for more information. Infant formula and dietary supplements are excluded from the requirements of the Reportable Food Registry. Firms recalling formula or supplements should seek additional information regarding FDA's requirements for reporting any serious adverse events from <u>FDA's website</u>.
- 7. Assure the effectiveness of the recall by monitoring responses from all customers who have received the recall notice.
- 8. Efforts should be taken to reconcile production and/or distribution amounts with products returned. This information will be included in your reports to CDPH-FDB.
- 9. Contact CDPH-FDB concerning requests for product disposition.
- 10. Contact your supplier for disposition instructions.
- 11. Contact CDPH-FDB to discuss formal termination of the recall.
- 12. For additional information, refer to Food and Drug Branch's Food Recall Webpage.

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