

Purpose

The purpose of this plan is to ensure that in the case of a recall, the Recall Team can lead a smooth efficient recall of all product in question.

Scope

This plan covers the steps of performing a product recall.

Responsibility

It is the responsibility of the Recall Coordinator in conjunction with the Recall Team to facilitate a Recall if the situation should arise.

Procedure

Once alerted to an issue:

Step 1: Hazard analysis - perform a full hazard analysis of affected product(s). Analysis may involve a third-party laboratory for product testing and evaluation.

Step 2: Classification - per analysis findings classify the recall according to USDA or FDA guidelines:

- I: Serious or Dangerous
- II: Potentially Dangerous
- III: Least Dangerous

Then inform the appropriate regulatory agency of the recall

Step 3: Production Stop

1. Immediately stop production of products affected under recall.
2. Remove inventory from your distribution channels so that it cannot leave the facility. Place all materials of Safety Hold in Galileo.
3. If immediate threats are present, quarantine the affected products away from others.

Step 4: Customer Notification - Notify customers who may have purchased the product to ensure a means to verify receipt of these notifications

Step 5: Product Collection - Once customers have received the recall notification, document that all recalled product has been collected and received.

- Amount of affected inventory in facility
- Amount of product that went out through distribution channels
- Amount of product sent back to the facility

Document depository measures taken to address the recalled product

Step 6: Investigation and corrective action - Following the notification, collection and handling of affected products complete a root cause investigation.

Investigation should include

- A determination of the root cause
- Creation of corrective action
- Delegation and tracking of corrective action
- Disciplinary or legal actions, if applicable

During this process, compile a detailed report providing the following:

- Product details (name, qty., manufacturer, etc.)
- Label and packaging information
- Lot numbers affected by the recall
- Root cause of the recall
- Timeline of events (when issue was discovered, when notification go out, etc.)
- Information regarding the amount of product recalled, reprocessed and destroyed
- Copies of all communications sent out to customers, distributors and regulators
- Contact information for the recall team member(s)