Product Withdrawal & Recall

Definition

Recall is the action taken to remove from sale, distribution and consumption foods which may pose a safety risk to consumers. A recall removes food product from the market when there is reason to believe that the product is contaminated, adulterated, and/or mis-branded.

Recalls are often voluntary; however, in some instances regulatory agencies may mandate a recall. In some countries, withdrawal is used as recall.

Applicable Code Requirements

1. 2.6.1
2. 2.6.2
3. 2.6.3

Review Glossary Terms

1. Food Safety Event

Implementation & Audit Guidance

What does it mean?

A product recall applies when a product is found to be unsafe or otherwise in breach of regulatory requirements and is withdrawn from public sale and the consumer market is advised not to use or consume that product. Recalls may be mandatory (i.e., initiated by a regulator), retailer driven, or voluntary (i.e., initiated by the supplier).

A product withdrawal applies when a dispatched product is found not to meet safety requirements, is deemed not suitable for sale, and is withdrawn from the distribution chain before it has reached the consumer.

A product recall and withdrawal procedure must be prepared, implemented, and regularly reviewed to ensure everyone involved in the recall process understands their role and their responsibility in the event of a recall or withdrawal.

Why is it in the Code & why is it important?

This is a mandatory clause.

The supplier must have a management committee in place to coordinate and manage recalls and must prepare a withdrawal and recall procedure describing the methods, responsibilities, and procedures they implement in the event of a product withdrawal or recall. There must be senior management involvement in the recall committee, as well as departmental and division managers with the authority to make decisions.

The procedure may contain a description of incidents specific to the supplier's product that may trigger a withdrawal or recall and must include an up-to-date list of customers, regulators and other essential contacts that need to be notified in the event of a withdrawal or recall.

The SQFI and the supplier's certification body (CB) must be included on the communication list. The supplier is required to notify the CB and SQFI in writing within 24 hours of a food safety incident of a public nature (i.e., requiring public notification) or a product recall for any reason. The SQFI contact is foodsafetycrisis@sqfi.com).

It must also outline the methods the supplier will implement to investigate the cause of a withdrawal or recall (refer to 2.5.3). The supplier shall review and test their withdrawal and recall procedure at least annually and verify that the instructions continue to be relevant, that it is effective and efficient and that everyone understands their role. Annual testing should be varied and carried out on products from different shifts, lines, sizes, bulk items that are shipped from a wide range of customers.

Records of any/all recalls and withdrawals must be maintained, along with the results of testing of the withdrawal and recall procedure. Records for testing must include all supporting documentation used to identify product included within the recall/withdrawal. These records may include production records, raw materials receiving records, rework records, product holds, and product storage and distribution records. The supplier should test product that has already been released so that full distribution traceability can be verified.

Non-conformances identified during the exercise must be investigated by the site and required corrective action completed, with a follow up test completed to ensure that corrective actions are effective. A recall and withdrawal exercise should be able to demonstrate linkage of raw materials through the process to the facilities first customer. This review of the system is also a review of the trace back system as outlined in 2.6.2.

The supplier must also be aware of the recall targets set by retail customers. Some may require effectiveness checks and 100% identification and quarantine of affected product within hours or recall notification. Regulatory recall requirements must also be considered.

See RIO Chart on following page.

RIO Road to Audits (Records, Interviews, and Observations)

Records	Interviews	Observations
The following are examples of records and/or documents to assist in the implementation and review of this topic:	The following are examples of people to interview to assist in the implementation and review of this topic:	The following are examples of observations to assist in the implementation and review of this topic:
- The recall plan including communication plan. - The members of the recall team and contact list. - The last recall or test of the program including how the recall was communicated. - Corrective actions that were identified. - Bills of lading, product identification and lot control logs. - Any specific customer requirements as how recalls are to be tested and /or managed.	- Recall team including the coordinator. The following are examples of questions to ask to assist in the implementation and review of this topic: - Who is on the recall team? - Who is included on the contact list? How is contact initiated? - Has there been a recall within the past 12 months? / When was the last time the recall plan was tested? - Describe the outcomes of the last recall or test.	- Product identification and lot control system. - Bulk storage areas and how lot control is managed in these areas.

Additional References

- FDA - Recalls, Outbreaks & Emergencies:
  https://www.fda.gov/Food/RecallsOutbreaksEmergencies/default.htm
- FMI - Crisis Communications Manual:
  https://www.fmi.org/industry-topics/crisis-continuity
- SQF Tip Sheet 15: Product Identification, Traceability and Withdraw and Recall:
  https://www.sqfi.com/wp-content/uploads/2018/10/Tip-Sheet-15-Product-Identification-Traceability-and-Withdraw-and-Recall.pdf