

(Name of Company) recall team coordinates and manages recalls and has prepared a withdrawal and recall procedure describing the methods, responsibilities and procedures they implement in the event of a recall. The recall team consists of the:

A product recall applies when a product is found to be unsafe or otherwise in breach of regulatory requirements and is withdrawn from public use and the consumer market is advised not to use or consume that product.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

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when a dispatched product is found not to meet safety or quality requirements, is deemed not suitable for sale and is withdrawn from the distribution chain before it has reached the consumer.

Some reasons for a recall or withdrawal are as listed:

A. Microbiological

Presence of:

1. Salmonella
2. Listeria monocytogenes
3. E. Coli
4. Other bacteria, toxins, viruses

B. Chemical

Presence of:

1. Banned substances, i.e. antibiotics
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C. Quality

1. Presence of foreign material, i.e., glass, wood, dirt, infestation
2. Incorrect labeling which could lead to customer illness
3. High temperature, i.e., loss/lack of refrigeration
4. Incorrect labeling which does not pose a food safety risk.

In the event of a potential withdrawal or recall the following steps should be followed.

1. Investigation

An initial investigation needs to be performed to determine the severity of the incident including what type of contamination or quality issues are involved and how much product is affected.

An investigation also needs to be performed to determine the root cause. Appropriate corrective action needs to be implemented.

2. Evaluation

The food safety/quality risk needs to be evaluated to determine the recall class. E.J. Dairy Marketing Inc. uses the FDA's definition of recall classes.

- **Class I recall:** 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:** 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:** a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.
- **Market withdrawal:** occurs when a product has a minor violation that would not subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing or distribution problems would be a market withdrawal.

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Communication: The recall team is responsible for obtaining all the relevant information needed in the recall process and for communicating with external organizations and internal personnel. The recall team needs to conduct frequent meetings during a recall to ensure no information is shared with external organizations (including the media) without all team members being aware of it. Clear communications must also be maintained internally in managing non-conforming product and product disposal. At no time during a recall shall any external agent, including regulatory agents, be allowed to tour the plant unattended.

Recall Contact Information The list of customers, regulators and other essential contacts that need to be notified in the event of a withdrawal (*) or recall needs to be up-to-date.

Name	Address	Phone/Fax	Email
FDA			
Media			
Legal			

Artisan Dairy Producer Food Safety Initiative

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Mock Recalls

The recall reviews and tests the withdrawal and recall procedure (mock recall) twice a year on finished product and once a year on raw materials and primary packaging materials.

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.

Non-conformances identified during the exercise must be investigated by the team and required corrective action completed, with a follow up test completed to ensure that corrective actions are effective. .

The traceability system allows a test to be completed in a reasonable amount of time (maximum 4 hours). It also allows the team to trace 100% \pm 2% of all finished product.

Reportable Food Registry

All food safety related incidents involving withdrawal or recall need to be reported to the FDA via the Reportable Food Register (RFR). This is an electronic portal for the industry to report when there is reasonable probability that an article of food will cause serious health consequences.

END

Date	Action	Approved By
	New Document	