



Recall Plan

7169 E. Pleasant Valley Road
Independence, OH 44131
216-642-4605

Table of Contents

Introduction	3
Recall Coordinator/Recall Team	3
Mock Recall:	5
Product Recall Terminology:	5
Types of Recalls:	6
Determining if a Recall Action is Necessary:	6
Product Recall Procedure:	7
Disposition of a Recalled Product:	7
Product Recall Documentation:	7
Release of Information:	8
Records:	8

Introduction

In the event that Signature Sauces needs to perform a Product Recall, Market Withdrawal or Stock Recovery, this program will identify the specific responsibilities that must occur to successfully manage the situation to allow for the complete identification and recovery of suspect product in a timely fashion while providing the necessary safeguards to the customer.

PURPOSE:

To provide direction and assign responsibilities for the rapid identification, confirmation and removal of Signature Sauce® products from the marketplace.

Recall Coordinator/Recall Team

When a Signature Sauces employee is alerted to the fact that a regulatory agency, (e.g. FDA/USDA), is considering recall of product, or becomes aware that product may be adulterated, misbranded, or contain a health hazard, he/she shall promptly notify the **Recall Coordinator**:

Signature Sauces Recall Coordinator:

COO Ken Palladino

Work: 216-642-4605

Cell: 330-472-7483

Responsibilities:

- Will be advised immediately in the event a product complaint indicated a potential health hazard.
- Will obtain complete identification of the product type, item code, code date, lot, or other identifying information, location of the product, person(s) involved, medical or health department involved, and all other information required to determine that a problem does exist.
- Will immediately notify the Recall Team if the information indicates a potential health hazard exists and it warrants a product recall, withdrawal or recovery. A meeting must be called within 12 hours of being made of the situation.
- If a market withdrawal or a product recovery is warranted, he will immediately notify the Recall Team for proper action.
- Will coordinate implementation of the decided plan and maintain records concerning the action taken.
- Will recommend to the Recall Team whether it is necessary to advise the FDA/USDA that a recall is being conducted and will work with the FDA/USDA to satisfy their requirements.

Signature Sauces Recall Team:

<u>Title:</u>	<u>Name:</u>	<u>Contact Information:</u>
CEO	Perry Stancato	Work: 216-642-4605 ext. 18 Cell: 216-509-9541
COO	Ken Palladino	Work: 216-642-4605 ext. 13 Cell: 330-472-7483
Project Manager	Justin Scharf	Work: 216-642-4605 ext. 35 Cell: 440-554-1266
QA Manager	Ted Bienas	Work: 216-642-4605 ext. 38 Cell: 216-404-8204
Quality Compliance	Kelly Sobonya	Work: 216-642-4605 ext. 37 Cell: 216-403-0526
Purchasing/Logistics	Alex Litten	Work: 216-642-4605 ext. 20 Cell: 440-343-4607
Legal Counsel	Robert B. Casarona	Work: 440-337-9083
FDA Recall Coordinator	N/A	Orahafeast5recalls@fda.hhs.gov

Responsibilities are:

- To recommend the appropriate recall classification (Class I, II, or III).
- To determine the strategy for conducting the recall.
- To implement the recall strategy.
- To monitor the recall, prepare and disseminate information concerning the recall, and maintain records concerning the recall.
- To complete the recall and report the results of the recall.

Mock Recall:

To ensure that unsafe product can be accounted for and removed from circulation as quickly as possible, Signature Sauces' Food Safety team will perform mock recalls bi-annually on selected finished and raw products. Mock recalls must be completed within a two-hour window with 100% traceability. Any issues that arise or problems identified during these mock recalls will be documented and corrective actions will be engineered.

Product Recall Terminology:

A **Product Recall** is a firm's removal or correction of a marketed product. It may be firm-initiated, or FDA/USDA requested, and occurs where:

- FDA considers the product to be in violation of laws that it administers and
- FDA would take legal action against the product.

1. Class I Recall

- a) Recall at all depths to be as complete and expeditious as possible.
- b) Placed on public recall list as Class I.
- c) Issuance of public warnings via press and media.

2. Class II Recall

- a) Recall at retail, food service and wholesale levels done completely and promptly.
- b) Placed on public recall list as Class II.
- c) Possible issuance of press release, depending on circumstances.

3. Class III Recall

- a) Recall generally to distribution level only.
- b) Placed on public recall list as Class III recall.
- c) Normally no press release although FDA/USDA generally responds to questions from press or public.

A **Market Withdrawal** is a firm's removal or correction of a distributed product where:

- There is no violation, or
- There is only a minor violation, which would not be subject to FDA legal action.

A **Stock Recovery** is a firm's removal or correction of a product that has not been marketed or has not left the direct control of the firm.

Types of Recalls:

FDA/USDA Initiated Recall

1. FDA/USDA normally initiates recalls under two circumstances:
 - a) FDA/USDA determines that a violation exists and notifies the company. A recall, even if company initiated or initiated at a later time, is still considered to be FDA/USDA initiated.
 - b) When the product poses imminent danger or significant consumer deception, FDA/USDA can notify the firm of their determination and mandate immediate product recall.
2. FDA/USDA recall notification should include details of the violation, recall classification, recall strategy, and other information.
3. Notification generally occurs by an official letter. Oral communications should be followed by a written confirmation.

Firm Initiated Recalls

1. A firm can initiate a product recall, withdrawal, or recovery at any time. The local FDA field office should be contacted immediately with evidence to justify the action. The action will be considered a recall by FDA/USDA only if the product violates policy and warrants legal action.
2. If the FDA/USDA determines the event to be a recall per FDA procedures and definitions, the company shall send completed Recall Regulatory Submission Email Form (Reference Document:) to the FDA/USDA

Determining if a Recall Action is Necessary:

Problem Reported by	Initial Action	Decisions	Actions
Regulatory Agency believing your product is causing illness	Assemble recall team and ask agency if recall is recommended	Evaluate situation; decide if, what and how much product to recall	If no recall is needed: document why not and action
News media story on problem with a type of sauce you produce	Assemble recall team, review internal records		If recall is needed: <ul style="list-style-type: none"> • Assign responsibilities • Gather Evidence • Analyze evidence • Get word out • Monitor recall • Dispose of product • Apply for termination of recall • Assemble recall team and debrief • Prepare for legal issues
Internal QA or customer information suggest a potential problem	Assemble recall team and review internal records		
Health Department believes your produce is causing illness	Assemble recall team, contact appropriate regulatory agency		

Doc #: 601.01
Version: 103

Updated: 6.1.20
Supersedes: 7.16.18

Author: Kelly Sobonya

Product Recall Procedure:

1. The Quality Assurance department, the Production Manager, COO, and CEO will be notified about an issue needing a recall (whether it be an internal or external reason for a recall)
2. Quality Assurance will gather information on why the recall is occurring and how the issue came about
3. The type of recall needed will then be determined by the Food Safety Team
4. Quality Compliance will perform a product trace on the affected item to see where it is and whether it has been used in any productions. This data will be saved onto the server and be used to trace all destinations of the affected product
5. The affected product and any runs it was used in will be immediately put on hold during investigation
6. The relevant agencies and customers that received potentially contaminated product will then be contacted by phone and email using the Regulatory Submission Form, Response Notification sheet, and the Recall Customer Notification Sheet or the Withdrawal Customer Notification sheet (**Reference Documents: 601.07, 601.05, 601.04, 601.08**)
7. SQFI and Merieux Nutrisciences will be notified within 24 hours at Foodsafetycrisis@sqfi.com and Certification@MXNS.com.
8. Notes will be taken throughout the recall process using the recall notes sheet to summarize what happened during the recall using the Recall Notes Sheet Form (**Reference Document: 601.6**). These notes will be saved onto the server for reference.

NOTE: Whenever deliberate sabotage or product tampering is suspected, the local FBI Office should be notified immediately. The FBI may give further instructions that must be followed. The offending object or suspected evidence must be preserved in as close to its original condition as possible.

Disposition of a Recalled Product:

All movement, reconditioning and/or destruction of recalled product must be monitored by responsible personnel to assure close control and to avoid inadvertent product release to the public. Recalled product should not be disposed of through commercial salvage operations, charities, institutions, etc. The FDA/USDA should be notified of the firm's method of recalled product disposition prior to its actual disposition so as not to further complicate the recall situation.

Product Recall Documentation:

All events, activities, decisions and communications that occur prior to and during the recall should be documented in a chronological, concise, and objective manner. Specifically, this document should contain the causal factors precipitating the recall, administrative/technical successes and failures that occurred during the

recall, and description of the corrective measures that were instituted to prevent a recurrence of the recall situation.

Release of Information:

Unless specifically authorized to do so by the COO, no company employee will release any information or make any statements concerning a product recall program. All information concerning a product recall will be treated as CONFIDENTIAL so that the recall can be conducted in an orderly manner and to protect the company's legal rights and potential claims. All press communications will be handled by the Vice President or his designee.

Records:

The "Product Recall Program" will be tested on a bi-annual basis and the results will be kept in the Quality Assurance Office. The records will document what the percentage of recovery /identified product was and the corrective action steps that were put into action to address any program deficiencies.