FOOD RECALL PLAN

PURPOSE

To outline the methods for product withdrawal and recall.

SCOPE

Applies to all product withdrawals and recalls.

RESPONSIBILITY

Recall Team

PROCEDURE

Product Recall:

The removal of product shipped by Food Group International from the retail and wholesale market that the FDA or other government agency considers in violation of the laws it regulates. FGI chooses to recall products before the FDA requires it.

Recall Communications

Food Group International is responsible for promptly notifying each of its affected direct accounts about the recall. A recall communication should be brief and to the point.

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The Importance of Preparing for A Recall

We provide the maximum protection for our clients through our exclusive "Food Safety & QA Program". Yet, there are no guarantees when it comes to product recalls.

In the rare event FGI and one of our clients are involved in a recall, we have consulted with consumer product safety experts to develop a recall plan that minimizes any negative impact of a recall for our clients. Due to the potentially significant business consequences, a plan to quickly and effectively react is necessary to protect our clients, their brand, and the people who have received the products involved.

This plan, therefore, will help us manage through the steps of a defective product analysis and how to remove unsafe products quickly and completely from the market.

In order to mitigate human and economic damage, we must all be clear about roles and responsibilities, procedures, and important regulatory information and be prepared to move promptly as soon as we become aware of an unsafe product we have sold.

Roles and Responsibilities

Recall Coordinator

1. Manage activities related to recall.
2. Convene Recall Team meeting and coordinate activities.
3. Keep recall master file. Maintain Recall Plan.

Shipping & Receiving Coordinator

1. Stop all in-transit shipments of questionable material and arrange for return of product to collection points.
2. Prepare inventory and distribution status of product showing where, when, to whom, and quantity shipped.

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QA Coordinator (SQF Practitioner)

1. Prepare lot identification.
2. Halt production of product if related to problem.
3. Investigate cause of problem; check all records.
4. Clear product only upon recommendation of COO
5. Keep records of any destruction.
6. Conduct traceability exercises twice a year, finding 100% product in less than 4 hours.
7. Analyze mock traceability tests and resolve any nonconforming issues.
8. Obtain lot identification and samples.
9. Obtain product analysis to determine if pick up or destruction necessary.
10. Coordinate all action until problem is resolved.
11. Consult with Lab.
12. Consult with regulatory agencies if a recall occurs.

Consumer Affairs and Legal Counsel

1. Prepare response for consumers.
2. Answer all customer inquiries.
3. Handle all press releases and media.
4. Handle legal implications.

Chief Operations Officers

1. Notify sales managers, buyers, and all recall contacts. Arrange for pick up at all end users. Arrange proper credit to be given.
2. Aid in contacting customers.

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Recall Team/Emergency Contacts/Responsibility List

Member	Position	Contacts	Responsibility
Bladimiro Valbuena	COO	bvalbuena@foodgroupinternational.com	Team Chairman
Deidania Sanchez	Recall Coordinator	Quality@foodgroupinternational.com	Ensures products produced are traceable for recall. Coordinates Total Recall Plan
Hector Martinez	Shipping & Receiving Coord.	Logistic@ foodgroupinternational.com	Production records, shipping and receiving records, lot numbers.
SQF	Certification Body	?	To be contacted within 24 hours
Wanda Torres	FDA	Orahafeast4recalls@FDA.hhs.gov	To be contacted within 24 hours

Recall Procedures

The recall procedure outlines the activates that the FGI will take to manage the recall of our product(s) which has/have been determined to be defective, unsafe, and/or subject to regulatory action.

A defect could be the result of a Raw materials or production error; or it could result from the handling of, or the materials used in, the product. A defect could also occur in a product's contents, manufacturing, finishing, packaging, Labeling, warnings, and/or instructions.

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The company's recall procedure is carried out through four steps:

1. Product evaluation

2. Location of products

3. Notification of affected parties

4. Product Removal

Step 1: Product Evaluation

The first step in the recall process is evaluating the product called into question. The steps involved in the evaluation process are:

1. Receive the complaint–A file should be stored that contains all product defect complaints the company receives.
2. Information that should be maintained in the product complaint file is:
    - Contact information for complainer
    - Reported problem with the product
    - Product identification numbers
    - Supplier information
    - Product purchase date and location
    - Illness and Injury details
3. Provide the complaint to the Recall Coordinator for initial evaluation. If an initial assessment indicates a recall may be necessary, the Recall Coordinator assembles the Recall Team for a full evaluation.
4. The Recall Team should evaluate all necessary criteria and determine whether the product should be recalled.

Issues that should be discussed during the meeting should be as follows:

- What is the defect that causes the product hazard?
- What was the cause of the product defect?
- Where are the unsafe products? How many are there?
- Did the product fail to comply with government safety regulations? How?
- Was the appropriate regulatory body informed about the defect?

- Has the supplier discontinued production and shipments of affected product (s) to clients?

4. If a recall is deemed as being necessary:

o Determine the product removal strategy appropriate to the threat and location in commerce.
o Maintain a log of the events of the recall including information such as dates, actions, communications, and decisions.
o Contact the appropriate regulatory authorities.
o Alert legal counsel, insurance, etc. as appropriate.
o What is the company's estimate of the cost of the product recall campaign?
o How will the company prepared to deploy manpower and/or fund efforts necessary to provide replacement for defective products?
o What steps if any are underway to upgrade the company's quality control or risk analysis procedures to prevent a similar product recall in the future.

Step 2: Identify Implicated Products

FGI must ensure the identity of all products and quantities of products implicated in the recall. In addition, related products from the supplier should be evaluated to determine possible links to the defective product.

Information about the product and its distribution should be prepared and documented. The product should be identified through description, style, color, brand, UPC code, lot number, item number, and date of manufacture or import.

The distribution list should at minimum identify:

• Customer that received the recalled product(s)
• Customer addresses
• Contact names
• Contact telephone numbers
• Type of account
• Amount of product received/shipped

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• Product ship date(s)
• Amount of product returned
• Amount of product consumed

Step 3: Notification to Affected Parties

Notifications during a recall must be done in a timely manner. These notifications should be delivered to the appropriate regulatory agencies, the distribution chain, and consumers when necessary.

Recall notices are typically used to notify regulatory agencies and those businesses in the distribution chain. Press releases are generally oriented to consumers but may be used to notify any affected party.

• *Regulatory Agencies* - should be notified at the earliest opportunity after the decision has been made to conduct a recall. The regulatory authority should be updated throughout the recall process.

- *Distribution Chain* – suppliers and clients must be notified by appropriate means. It is recommended that a written recall notice be provided to all consignees. A record of all account communication should be maintained.
- *Consumers* - should be notified by the most effective method available such as a hotline or signs. If appropriate, a press release can be used to notify consumers.

Considerations for preparing a press release include:

- name and location of the recalling company
- name of the product
- number of products involved
- A description of the hazard
- number of incidents involving the product
- Detailed description of the product, including lot numbers, colors, sizes, and labeling
- A line drawing or photograph of the product
- Major retailers and where and when the product was sold
- Complete instructions for consumers on how to participate in the recall

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Notification of the FDA

When it is determined to contact the FDA, call the FDA emergency number:
1-866-300-4374

FDA Recall Coordinator for the State of Florida:

Wanda Torres
466 Fernandez Juncos Avenue
San Juan, PR 00901-3223
Email: Orahafeast4recalls@FDA.hhs.gov
Phone: 787-729-8826

Also, the FDA website should be consulted for any changes. The FDA will assist Food Group International

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Step 4: Product Removal

The procedure for product removal can be divided into five components including: removal, control, and disposition of affected product, recall effectiveness, and recall termination.

1. Removal

All reasonable efforts must be made to remove affected products from commerce.

- Products in commerce should be detained, segregated, and handled in a manner determined by FGI.
- Products that are still in FGI's control (e.g., inventory located onsite, in transit, in off-site storage, and in offsite distribution) should be detained, and segregated.
- All quantities and identification codes shall be documented to assist in the reconciliation of product amounts.

2. Control of Recalled Product

When Food Group International chooses to retain recalled product, control must be regained to prevent reentry of the product into commerce.

▪ All affected product returned will be clearly marked, not for sale or distribution, and stored in an area that is separated from any other products.

▪ All quantities and identification codes shall be documented to assist in the reconciliation of product amounts.

3. Product Disposition

The final disposition of the recovered product must be determined. The final disposition must be reviewed and approved by the regulatory agency.

Options include:

- Redirection – Products may be redirected for uses other than human consumption.
- Destruction - Products determined to be unsafe for human consumption may be destroyed or denatured and disposed by appropriate means.

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- Recondition – Products may be reworked to remove the safety risk.
- All quantities, identification codes, and disposition shall be documented.

4. Recall Effectiveness

FGI is responsible for determining whether the recall is effective. Recall effectiveness check verifies that all consignees have been notified and have taken the appropriate action.

Steps include:

▪ Verifying that all clients have received the notification.

▪ Verifying that clients have taken appropriate action.

▪ If the response from our client is less than 100%, then the recall strategy should be reassessed.

▪ All verifications shall be documented.

5. Termination of a Recall

Termination of the recall process may be considered after all reasonable efforts have been made to remove the affected products from commerce, including reconciliation, recall effectiveness, and disposition.

A termination of the recall may be requested by submitting a written request to the regulatory authorities.

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Recall Review / Follow-up

Based upon the Recall Summary, The Recall Team will take actions to prevent a re-occurrence of the conditions and practices that created the recall. Also, the performance of the Recall will be appraised.

The product withdrawal and recall system shall be reviewed, tested and verified as effective at least annually.

Investigation shall be undertaken to determine the root cause of a withdrawal or recall or mock recall and details of investigations and any action taken shall be documented.

Mock Recall

In addition to an annual verification of the recall plan, Food Group International will conduct a mock recall annually or whenever there are significant changes to the plan or personnel. The mock recall will include the following elements:

- Selecting a product which has reached the consumer market.
- Tracing the product from the raw ingredient (e.g. source) level to the finished product in the marketplace.
- Verifying communications systems (e.g. contact information, test emails and faxes, etc.) to outside contacts.
- Modifying the recall plan to correct any problems encountered during the test.
- Records of these mock recalls will be documented and filed appropriately.

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SAMPLE NOTIFICATION

Food Group International
1335 NW 98th Ct, Unit 11
Miami FL 33172

ATTN: CONTACT PERSON NAME & TITLE

Re: RECALL OF TYPE OF PRODUCT

Dear Sir or Madam:
This letter is to confirm our telephone conversation that Food Group International is recalling the following product because of REASON:

PRODUCT DESCRIPTION, LOT NUMBER, PACK TYPE, ETC.

We request that you review your inventory records and segregate and hold the above product. If you have shipped any of this product, we request that you contact your customers and ask them to retrieve the product and return it to you. Once you have retrieved the entire product, please contact us. We will arrange to have the product shipped to our facility. Please do not destroy the product. We will credit your account for product returned.

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We are undertaking this action in cooperation with the United States Food and Drug Administration. FDA officials may contact you to confirm that you have received this notice and are cooperating in this action.

Your prompt action will greatly assist Food Group International in this action. If you have any questions, please do not hesitate to contact us.

Thank you for your cooperation.

Sincerely,

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Appendix B – Templates

1. Communication Templates

i. Model Press Releases (FDA)

a. Allergens (Allergy Alert)

b. Listeria monocytogenes

c. Clostridium botulinum

d. Salmonella (all serotypes)

e. E. coli 0157:H7

2. Recall Events Log (should include the following information):

i. Name of the person creating the action

ii. Dates

ii. Actions

iv. Communications

iii. Decisions

vi. Product disposition

3. Recalled Product Information Data Sheet (should include the following information):

i. Product description: brand, product name, size, etc.

ii. Lot codes

iii. Quantity of recalled product

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iv. Date of the action

v. Action taken for each product

4. Model Product Complaint Report

Issue Date: 02-15-2022

Version: Initial Release

Document: QA-SOP-RP

HANDLING A FOOD RECALL

SOP

Policy: In the event of a food recall, all employees will take proper steps to prevent foodborne illness.

Procedure:

General Guidelines:

1. Food Group International employees must be trained on using the procedures in this SOP.
2. All State or local health department requirements must be followed.
3. Once a food has been recalled, review the food recall notice and specific instructions that have been identified in the notice.
4. Communicate the food recall notice to the appropriate administrators and health department officials.
5. Check receiving documents, perpetual inventory, requisitions, production records, and shipping record to identify product matching the product code and lot numbers identified in the recall notice.
6. Obtain accurate inventory counts of the recalled product including the amount in inventory and amount used.
7. Hold the recalled product using the following steps:
8. Physically segregate the product, including any open containers, leftover product, and food items in current production that contain the recalled product.
9. If an item is suspected to contain the recalled product, but label information is not available, label as suspect and do not use and do not discard.
10. Mark recalled product “Do Not Use” and “Do Not Discard.” Inform the entire staff not to use the product.

HANDLING A FOOD RECALL

SOP

11. Do not destroy any recalled product until proper authorization is received.

Monitoring:

1. Food Group International employees and managers will visually observe that the recalled product has been segregated and secured. Confirm segregated product label information matches recall notice information

The managers will:

1. Ensure all employees are trained in this procedure.
2. Verify appropriate action as outlined in this procedure is followed in the event of a food recall
3. Document and confirm segregated product label information matches recall notice information.
4. Work with media should they become involved.
5. Maintain all documents relating to a food recall for at least 1 year.