

Black Sheep

FOODS

Procedure Name: Handling a product withdrawal and recall SOP		
Document ID: A2023.01.19	Date: 01/19/23	Created by: SN
Facility: San Diego, CA	Version #: 1	Approved by: VG

Handling a food withdrawal and recall SOP

1. OBJECTIVE:

- 1.1. This standard operating procedure applies to employees who are involved in preparation, storage, and distribution of the product.
- 1.2. This standard operating procedure mentions details to prevent food borne illness in an event of a product recall.
- 1.3. This standard operating procedure establishes responsibility for investigating during product withdrawal or recall.

2. GLOSSARY:

- 2.1. Product Withdrawal: When a dispatched product is found not to meet safety requirements, is deemed not suitable for sale, and is withdrawn from the distribution chain before it has reached the customer.
- 2.2. Product Recall: The process to remove a product from the market if the product is found to violate laws that the FDA administers and enforces, and the consumers are advised to not consume the product.
- 2.3. CLASS I: Recalls for products that could cause serious injury or death.
- 2.4. CLASS II: Recalls for products that might cause serious injury or temporary illness.
- 2.5. CLASS III: Recalls for products that are unlikely to cause injury or illness but violates FDA regulations.

3. REGULATORY HIGHLIGHTS:

- 3.1. 21CFR Part 7, Subparts A and C

4. RECALL MANAGEMENT TEAM:

- 4.1 The Recall management team is responsible to effectively organize and manage the recall of the food product that presents a threat to the public health and violates laws that FDA administers and enforces and ensures that the procedures in this SOP are carried out in an event of a recall and that the effectiveness of this procedures to be tested out at least annually.



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The Recall Management Team is as follows:

Sunny Kumar	CEO	(847) 868-6639
Viswas Ghorpade	Head of Operations	(269) 209-2724
Alice Wistar	Chief of Staff	(215) 718-5101
Shruti Nikam	Quality and Regulatory Specialist (FSQA & SQF Practitioner)	(312) 863-9758
Michael Dye	Sales Lead	(925) 383-7462

5. PROCEDURES:

5.1. The recall team will identify the problem with the product. The following factors to be considered:

- a. The health hazards
- b. The root causes
- c. What level of the distribution chain will the recall be extended to
 - Consumer or user level
 - Retail level
 - Wholesale level
- d. Public warning
- e. Recall or withdrawal of product

5.2. The recall management team will identify the specific products that are affected by the recall, including product name, size, batch, and lot numbers.

5.3. Once the problem has been identified Sunny Kumar will inform FDA, California Department of Public Health and other regulatory agencies involved as soon as possible.

- a. Food and Drug Branch Recall Coordinator - (916) 650 6500 or FDB-ERU@cdph.ca.gov
- b. FDA's Office of Regulatory Affairs (ORA) Division Recall Coordinator.

5.4. The recall management team will review the food recall notice and specific instructions that have been identified.

5.5. The recall management team will provide the designated investigation documentation to be filled and maintained by Sunny Kumar and/or designee.

- a. Recall management team meeting logs and meeting notes.
- b. The product traces
- c. Distribution reports.
- d. Notification letter.



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- e. List of contacts affected by recall and/or product withdrawal.
- f. Recall update notifications.
- g. Corrective and Preventive action plan

5.6. Shruti Nikam (FSQA/SQF Practitioner) and/ or designee will perform a trace to determine the location and disposition of the affected product.

5.6.1. The following documents will be collected to begin the product trace:

- a. Incoming and Receiving records.
- b. Customer pick up/distribution records.
- c. Invoices records.
- d. Final product storage records.
- e. Production records.
- f. The affected product names and lot numbers will be identified.
- g. The materials and lot numbers used to produce the affected product will be identified.
- h. The location internally and externally of the product will be identified.
- i. The number of cases and ship dates will be identified.
- j. Impacted products and materials still in the inventory will be put on hold.
- k. All records supporting the trace will be filed together with the summary page detailing each point of the trace to start the withdrawal and/or recall process.

5.7. Viswas Ghorpade will instruct the facility to hold the recalled product using the following steps:

- Physically segregate the product, including any open containers, leftover products and food products in current production that contains recalled product.
- Inform employees and shipping team to not use the product and or distribute it. It will be segregated with “DO NOT TOUCH” or “DO NOT USE” signs.

5.8. Alice Wistar will contact distributors and retailers who have received the affected products and instruct them to remove the product from their storage and shelves and return it to the manufacturer.

5.9 The Sales Coordinator will provide a distribution report detailing the affected lot codes, quantity of affected products and ship dates.

5.10. The FSQA/ SQF Practitioner and/or designee will provide a list of suppliers with address, emails, and contact numbers.

5.11. The FSQA/ SQF Practitioner and/or designee will notify the FDA and submit the product withdrawal and/or recall notification letter within 24 hours of the identification of the event.



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5.12. The Sales Lead will contact the consumers. Or it can be accomplished with a press release. She will distribute the withdrawal and/or recall notification letter by email to all contacts in receipt of the product within 24 hours of the identification of the event.

5.13. The Sales Lead and/ or designee will call each of the customers who have not responded within 24 hours of the first notification.

5.13. The Sale Lead will obtain accurate inventory count of the recalled product from distributors, retailers, and clients, including the amount in their inventory and the amount used.

5.14. The FSQA/ SQF Practitioner will account for all recalled product by verifying inventory counts against the records of product distribution of the company.

5.15. The FSQA/ SQF Practitioner and/ or designee will provide monthly updates on the recall and/ or product withdraw to the FDA until the product withdraw and/ or recall has been closed out.

5.16. The FSQA/ SQF Practitioner and/ or designee must complete the Reportable Food Registry to the FDA.

5.17. The HACCP or food safety plan will be reassessed, and changes will be made as required.

5.18. Once the product has been removed from the market, the recall team will investigate the root cause of the problem to prevent it from happening again in the future.

6. CORRECTIVE AND PREVENTIVE ACTION:

6.1. Determining the hazards of a product.

6.2. Evaluation of the recovered product and root cause analysis.

6.3. The product was disposed of in a legal manner. Contact local FDA District Recall Coordinator prior to product destruction.

6.4. Regular evaluations of product quality failure may call for improvements or revisions to the way the product is processed.

