REYKJAVIK CREAMERY

Food Safety and Quality Management System
Standard Operating Procedure (SOP)

PROCEDURE:	**Product Recall Plan**	**ISSUE DATE:** 4/21/26
AUTHORIZED FOR USE AT RC:	**1422 CENTER ROAD NEWVILLE, PA 17241**	**SUPERSEDES: 2**
ISSUED BY:	**JEFF THOMPSON**	**REVIEWED BY: S. Tandle**
PROCEDURE NO.	**RC-PITWR-02**	**REVISION NO. 3**

PURPOSE:

Effectively manage, document, and perform recalls when necessary including final resolution of recall. Gathering all necessary information on product(s) involved in the recall, including explanation of coding. Notifying regulatory agencies, consignees, customers, and consumers of the recall.

DEFINITIONS:

Product Recall

Reykjavik Creamery will voluntarily remove from marketing and distribution channels, those products which are adulterated or miss-branded to the extent of which are subject to seizure under current policy and guidelines of the United States Department of Agriculture (USDA) or the Federal Drug Administration (FDA). Product recall is an effective means of removing mass quantities of product from the marketplace. Seizures or other legal action by regulatory agencies is the alternative to a product recall.

Market Withdrawal

Reykjavik Creamery will voluntarily remove product from the market where no violation is involved or the violation is minor and the product is not subject to seizure under FDA or USDA policy and guidelines.

Stock Recovery

Reykjavik Creamery will voluntarily remove from stock, product that may or may not be subject to seizure under FDA and USDA guidelines. This product has not left the direct control of the manufacturer or primary distributor. This type of action would be a product recall or market withdrawal if the product were in distribution channels.

Effectiveness Checks

Reykjavik Creamery will verify that proper contact was made by the direction of regulatory agencies to ensure that the recall has been effective.

Mock Recall

Reykjavik Creamery will review, test, and verify the recall plan annually that is at a minimum 1 step forward (finished product) and 1 step back (incoming materials). The mock recall is to be performed on finished products and for materials that are used across a range of products.

PROCEDURES:

1. Assemble recall team in an event of potential recall and perform Initial Action. See table below for potential recall scenarios.

Problem Reported By	Initial Action	Decisions	Actions
Regulatory Agency believes 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 the action
News media story on problem with a food we produce	Assemble Recall team and review internal records		If Recall is Needed: 1. Assign Responsibilities 2. Gather Evidence 3. Analyze Evidence 4. Get Word Out 5. Monitor Recall 6. Dispose of Product 7. Apply for termination of Recall 8. Assemble Recall team and debrief 9. Prepare for legal issues
Internal QA/QC or customer information suggest a potential problem	Assemble Recall team and review internal records		
Health Department believes your product is causing illness	Assemble Recall team, and contact appropriate Regulatory Agency		

2. If recall is necessary, fill out corresponding forms with all known information as well as gather all necessary product labeling for FDA Communication. All forms are found in the recall documents folder in the recall document forms spreadsheet.
   Information FDA Communication:
   Product Information:
   - Modify the "Product Description, Distribution, Consumers, and Intended Use" form as needed to reflect only the product involved, including:
     - Product Name (including brand name and generic name)
     - Product number/UPC or product identification
     - Remove any names of products that are not involved in the recall

   - Assemble TWO COMPLETE SETS OF ALL labeling to the local FDA District Recall Coordinator. Include the following:
     - Product Labeling (including ALL private labels)
     - Individual package label
     - Case label (photocopy acceptable)
     - Package inserts (if applicable)

  - Directions for Use
  - Promotional Material (if applicable)

- Lot Identification Codes
  - UPC codes
  - Lot numbers involved
  - Lot numbers coding system (Describe how to read our product code)
  - Expected Shelf life or BBD of our product

3. In the event of a food safety event requiring public notification the information that has been sent to the FDA is to also be sent to the SQFI and the certification body within 24 hours of identifying the event. Must be communicated in writing.

4. With shipping logs determine all consignees for the affected product(s) and gather all appropriate information. Fill out corresponding forms for consignee lists.

5. Decide on recall strategy by deciding who will be involved with the recall; wholesaler, distributor, customer, etc. Fill out corresponding form for who's involved.

6. Prepare for Consignee Notification
- Write instructions on how consignees will be notified (i.e. by mail, phone, facsimile, email). Note: It is advisable to include a written notification so customers will have a record of the recall and your instructions. Include the following:
- How letters will be sent to customers (overnight mail, first class mail, certified mail, facsimile, etc.)
- Draft recall letter example seen on page 5 of this document. Blanks found in Recall Letters Blanks forms. Save copy for each specific recall.
- Draft phone script, if you decide to use phone. Note: If initial notification is by phone, be prepared to provide a copy of the phone script to FDA.
- Draft recall notification for website and instructions for posting it, if applicable. Note: The web is NOT recommended as a sole means of customer notification.
- Draft instructions for consignees on what to do with recalled product. If there is a recall, FDA will want a copy of final instructions.

7. Determine if destruction or reconditioning of the product is the final disposition of the product.
- Provide a proposed method of destruction, if applicable
- If the product is permitted to be "reconditioned", explain how and where the reconditioning will take place. It is recommended that you provide details of the reconditioning plan to our local FDA District Recall Coordinator before implementation. All reconditioning must be conducted under any applicable GMPs.
- Describe how reconditioned product will be identified so it is not confused with recalled (pre-conditioned) product.

- It is recommended that we contact our local FDA District Recall Coordinator prior to product destruction. FDA will review our proposed method of destruction and may choose to witness the destruction.
- We and our customers should keep adequate documentation of product destruction (and whether or not destruction was witnessed by an FDA investigator)
- Field corrections, like product relabeling, should be performed by only by our own facility, or under our supervision and control. We need to contact our FDA District Recall Coordinator prior to release of reconditioned goods.

8. Fill out Consignee Contact Effectiveness form when notice is sent to each consignee as well as when consignee responds. Make note of each method of contact is used and when each method of contact was sent.
9. As recall product information comes back from consignee and unsold product is returned to facility update the Consignee list's Quantity Sold, Quantity on Hold, and Quantity Unaccounted for.
    - All Product returned to facility will be placed on Hold
    - Ensure we receive verification that each consignee has performed the appropriate actions. Documenting all verifications and interactions.
10. Once all unsold accounted for product is back in the facility perform final disposition that was agreed upon earlier within step 6. Either Destruction of product or reconditioning of product. Documenting steps up to and including product final disposition.
11. After determining all product was destroyed or reconditioned draft Termination of Product Recall letter, example seen on page 6 of this document. Use same recall letters forms used when drafting notification of recall letter. Submit to regulatory agency for approval.
12. Send Termination of Product Recall to consignees

RECORDS:

Records shall be maintained of withdrawal and recall tests, root cause investigations into actual withdrawals and recalls, and corrective and preventative actions applied.

REFERENCES:

Recall Program Forms Spreadsheet
Recall Letters Blank forms
Crisis Event Check Sheet
NSF Food Safety Incident Form

(Date)

RE: Notification of Product Recall

Dear (*Customer Name)*:

Effective *(**Date**)*, Reykjavik Creamery is conducting a voluntary recall of the following product(s) and lot(s). Further distribution of the following product should cease immediately. Customers are asked to remove all product with the codes listed below out of distribution immediately. Customers may call the number listed below for further instruction on what to do with the product.

Product Name and Item #	Description	Lot Number

This product is being recalled due to _____.

The specific hazard involved is _____.

All products subject to this recall should be isolated and _____.

No other Lot Codes, or any other Reykjavik Creamery products, are involved in this action.

(If Accurate) We have not received any reports of illness associated with this product, but we are voluntarily recalling this product out of an abundance of caution

Please direct all questions to the recall coordinator during regular business hours of Monday to Friday 7am-5pm EST, or via the email listed below.

Contact Name*:*
Title:
Phone:
E-Mail:

Please respond to this communication by _____.
Thank you for your immediate attention to this matter.

Sincerely,

Name
Title
Reykjavik Creamery, LLC

Date:

To All Involved Parties:

TERMINATION OF PRODUCT RECALL

This is an official notice of the termination of recall for product(s) based on the following information:

Date of Recall:

Reason for recall (problem or concern):

Product Identification and Amount:

Corrective Action Taken and Completed:

Plant Information/Contact Person:

Thank you for your cooperation and support during this recall procedure. All corrective action required has been acted upon and completed which concludes the recall of the product.

Any questions or concerns should be addressed to:

Sincerely,

Name
Title
Reykjavik Creamery, LLC