	Document#: P-260	Title: **Product Identification, Trace, Withdrawal and Recall**
	Rev#: A	Prepared/Revised By: Erik Beaty
		Approved By: Felix Ho
Standard: **SQF Code, clause 2.6**		

1.0 Purpose

1.1 This procedure describes the process for raw material, work in progress and product identification and traceability and performing a product recall or withdrawal.

2.0 Responsibilities

2.1 Top management is responsible for ensuring an effective method is in place to provide product traceability from raw material, packaging and other inputs through to the customer.

2.2 Top management is responsible for ensuring there is an effective recall and withdrawal system in place.

2.3 Top management and the SQF Practitioner are responsible for determining the need for a product recall or withdrawal.

2.4 The SQF Practitioner is responsible for initiating a product recall or withdrawal.

3.0 Definitions

4.0 Product recall: A recall action is taken by a firm to remove a product from the market that is, or is considered to be, in violation of Federal, State, or Local food laws. Recalls may be conducted on a firm's own initiative, by USDA request, or by USDA order under statutory authority.

5.0 Instructions

5.1 Identification

5.1.1 All Materials used in the process are verified for lot codes and recorded by the Production Manager or designee.

5.1.2 If the Raw Material doesn't have a lot code at receiving, then receiving will assign an internal lot number.

5.1.3 An inspection is conducted at the beginning of a production run to make sure that the correct raw material is being used and that the use by date has not expired.

5.1.4 A lot number must always be labeled on every raw material.

5.1.5 Rework or work in process must always have a lot number assigned and labeled.

5.2 Production line checks

5.2.1 The production lead conducts a line check/line clearance at the beginning of each shift and the beginning of each new production run for:

a) Cleaning and sanitation.
b) Product and packaging from previous run is removed.
c) Correct packaging is used.
d) Correct labeling is being applied to the packaging.
e) Line checks are documented on production forms.
f) Line checks are completed are completed by the SQF Practitioner, Production Manager or an authorized employee.
g) Once the finished product label is approved, packaging may begin.

h) Once a product is produced, production shall verify that a finish product label is attached and that the proper customer requirements have been met. All finished product is required to have lot coding prior to releasing for shipping.

5.2.2 Lot Code System:

a) Use the Type of Vinegar, Date for Lot code: Example- XX/XX/XX/XX Type/Day/Month/YR.

5.3 Customer specifications determine which packaging to use.

5.4 **Traceability**

5.5 The following steps are taken during the receiving, production and shipping processes in order to maintain traceability of all raw materials and finished product.

5.5.1 A receiving log is completed with the vendor, lot number, Kosher certification and item description.

5.5.2 It is verified that the lot number is labeled on each raw material container.

5.5.3 The lot code on the raw material is transferred to the receiving material logbook.

5.5.4 The lot number, date consumed, and amount consumed is documented in the nutrient's logbook.

5.5.5 The lot number is put on the label of the 55-gallon drum or the 280-gallon tote.

5.5.6 The lot code is entered to the Certificate of Analysis (COA) with the grain strength from the Aceto Scan readings.

5.5.7 The invoice is sent to customer with lot codes along with the COA.

5.6 The HACCP Team performs a test of the traceability system once per year.

5.6.1 A forward trace (raw material to finished product) and a backward trace (finished product to raw materials) are performed once per year each.

5.7 **Withdrawal and Recall**

5.8 **GUIDELINES**

5.8.1 Allegations of products failing to meet applicable the Company product safety or quality standards are very serious and require immediate attention.

5.8.2 Operating management responsible for a product that has been cited or seized, or which is below company standards, shall fully investigate the matter and promptly report its findings to the Legal Consult (as needed).

5.8.3 The facility will identify a Product Removal Team and develop, establish and maintain an action plan for product removals that is in accord with the Company Product Removal General Procedures.

5.9 **PRODUCT REMOVAL CLASSIFICATIONS**

5.9.1 **Types of Recalls**

a) **Class I** is a situation in which there is a reasonable probability that the use of, or exposure to, a volatile product will cause serious adverse health consequences or death.

b) **Class II** is a situation in which use of, or exposure to, a volatile product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences are remote.

c) **Class III** is a situation in which use of, or exposure to, a volatile product is not likely to cause adverse health consequences

5.9.2 **Other Types of Removals**

a) **Stock Recovery**: A firm's removal for any reason of a product that has not left the company's direct control. This is not a recall and regulatory agents do not have to be notified

b) **Market Withdrawal**: A firm's removal on its own initiative of distributed product, which involves a minor violation that would not warrant legal action by FDA or which involves no violation or health hazard. This is not a recall and regulatory agents do not have to be notified (FDA 1-888-463-6332)

6.0 INITIATING A PRODUCT REMOVAL PROCESS

6.1.1 When it is confirmed through the President that a product removal may be warranted, the SQF Practitioner will initiate the product removal process by convening their respective Product Removal Team. – **CEO will be in charge of the process.**

6.1.2 A Product Removal Team will be in place based on functional positions at the Facility Level along with supporting members in the facility. The Teams are responsible for managing and investigating the product removal process for their respective areas. The degree of involvement by various members will depend on the scope of the specific removal process.

6.1.3 **Legal and Expert Advice will be contacted to ensure that the proper decisions are made for the safety of the marketplace and company integrity. CEO will be the point person to contact the legal and expert advice. NOTE: Contact numbers are in the Master Contact List.**

6.1.4 After a determination has been made that a product removal may meet the requirements of a Recall, versus a Stock Recovery or Market Withdrawal, the CEO- Product Removal Coordinator will confer with the SQF Practitioner. In some situations, it will be necessary to coordinate recall efforts with a Quality representative of our customer's. (Store brand or co-manufacturing). Customers will be notified of the impending recall action prior to any press release to the public.

6.1.5 When the required coordination is complete, including the information listed immediately below, the Product Removal Coordinator or designee will promptly notify the appropriate USDA District office for guidance and assistance in confirming the Class of Recall and the specific communication required to the public (press release) After confirmation of the required action, the Product Removal Team through the Product Removal Coordinator will work with the USDA Compliance Officer to complete all required steps in conducting and documenting the Recall.

6.1.6 The following information should be available prior to the initial contact:

a) Complete and accurate product identity, including product labels
b) The reason for the recall and details about when and how any defects or deficiencies were discovered
c) An evaluation of the risk associated with the consumption of the product and how the evaluation was made, **note the USDA will ultimately make the final determination of risk**
d) How much of the product in question was produced and during what period of time
e) An estimate of how much product is in distribution, address locations and ship to dates
f) The area of geographical distribution of the recalled product by state and if exported
g) A copy of any proposed press release (see attachment) **Note that many customers require prior approval of any press release that mentions the name of their company or label**

6.1.7 After confirmation of the required action the Product Removal Coordination or a designee will work with the USDA compliance officer to complete all required steps in conducting the recall.

6.1.8 SSS Vinegar will notify Legal Services, the FDA/USDA if Applicable and, as a store brand supplier, applicable customer representatives will be used to seek input and advice related to meeting the requirements of an effective recall.

6.2 COMMUNICATION

6.2.1 The Product Removal Coordinator or designee will initiate immediate notification of the affected customer group based on product labels. The 24 hr. Emergency Contact Customer list is a source of key individuals to notify when a recall action is required. The USDA, SQFI and the certification body will be notified in writing within 24 hours of the recall. SQFI will be notified by e-mailing foodsafetycrisis@sqfi.com.

6.2.2 The following information should be available prior to contact:

a) Product /brand name
b) Product code
c) Package/case size
d) Lot number
e) UPC
f) An explanation of the health risk involved if the product is consumed
g) Recall reason and hazard involved
h) Specific instructions relating to product disposition
i) 24 hr. emergency Contact information in the event of any questions

6.3 INVESTIGATION

6.3.1 Product removal or mock recall must be investigated for root cause with documentation of the investigation findings and corrective action plan.

6.3.2 The Product Removal process shall be reviewed, tested and verified at least annually.

6.4 **RECORDS**

6.4.1 A record of each product removal incident will be maintained in a secure, recoverable location and will be kept for a minimum of 2 years.

6.5 **Product Removal Procedure**

6.5.1 All Product Removals Must Approved By the CEO.

6.5.2 Each incident is unique and requires an individualized approach. The following is a guideline.

a) Assess the incident to determine if a hazard, potential hazard or violation exists.
b) Assemble the Team.
c) Determine appropriate action and review it with SQF Practitioner.
d) Implement action after Discussion
e) Take action to complete product removal on a timely basis.
f) Confirm the effectiveness of the product removal.
g) Dispose of product in a manner that is legal and responsible.

6.6 **CEO**

6.6.1 Will serve as Product Removal Coordinator and will coordinate the activities of the Product Removal Team.

6.6.2 Assures all quality assurance records, (including all regulatory agency visits and sanitation reports) pertinent to the product under consideration are readily available and accessible.

6.6.3 Provides, with the assistance of Consumer Affairs, consumer complaint data for:

A. Occurrences of complaints similar to those precipitating product removals.
B. Early clues.
C. Complaint distribution patterns.

6.6.4 Initiates "Hold Order" on all suspected product still under Company control to prevent further distribution to retail outlets. If it is determined to remove product outside of our control, will request notification of all involved accounts.

6.6.5 Provides statistical sampling plan for analysis of previous and subsequent date codes to ascertain extent of product (ingredient and/or material) problem. Assures that sampling plan will provide results, which are statistically valid.

6.6.6 Initiates necessary physical/chemical tests; arranges for additional analytical support when needed.

6.6.7 Maintains close liaison with Production, Legal, Regulatory Compliance and other Facility Management in all product removal situations, particularly in product removals where Regulatory involvement is a reality or is anticipated

6.6.8 Provides any other information relating to previous quality assurance activities, special investigations or reports which may be pertinent to the situation.

6.6.9 Will issue, in conjunction with other Product Removal Team members, periodic reports to Management in order to update the progress of a product removal.

6.6.10 Coordinate with Regulatory Compliance in the development of instructions for disposition of affected product. Since the actual product(s) in question may involve regulatory agencies, e.g., FDA and/or EPA, it is imperative that disposition and/or destruction be coordinated with Regulatory Compliance.

6.6.11 At termination of product removal will issue, in conjunction with other Product Removal Team members, a comprehensive report to Management covering all aspects of the removal.

6.6.12 The specific responsibilities include but are not limited to:

a) Preparation of press releases to the media.
b) Organize to handle media telephone calls.
c) Compile a list of anticipated questions from the media.
d) Assist in compiling answers to anticipated consumer inquires.

6.6.13 Work with Regulatory Compliance with respect to contacts with the Regulatory press office.

7.0 SQF Practitioner

7.1.1 Stops movement to trade of affected product.

7.1.2 Establishes storage facilities or collecting areas for holding removed product; assures adequate separation and identification of returned product; puts hold order on returned products until final disposition is determined.

7.1.3 Provides, as needed, replacement product (unaffected and approved for sale) for any product removed from the trade.

7.1.4 Provide all pertinent marketing and sales information and records related to the affected product.

7.1.5 Shall generate letters to field Sales personnel explaining Company actions.

7.1.6 Will direct the physical removal of all affected product from the trade and will determine method for most expeditious removal of product.

7.1.7 Shall provide personnel to effect physical removal of product from trade. However, this Procedure does not restrict physical removal to Sales/Customer Development personnel. Other personnel selected for this purpose, however, shall come under the direct supervision of Sales/Customer Development during the actual physical removal.

7.1.8 Coordinate with Distribution the collection and storage of affected product.

7.1.9 Shall maintain close contact with the Plant regarding progress and problems.

7.1.10 Will provide all pertinent manufacturing information and records related to the product problem. This information will include, but not be limited to:

a) Total cases (units of the affected product manufactured).
b) If problem is determined to be caused by ingredients, equipment, materials, etc., provides receiving and usage reports.
c) Process control records.

7.1.11 Provides information requested. This information should include but not be limited to:
a) Total quantity produced.
b) Inventory on hand in plant warehouse and outside storage under plant control.
c) Record of shipments to customers' warehouses and Distribution Centers.

7.1.12 If product problem is related to a manufacturing plant error, initiates corrective action to prevent recurrence.

7.1.13 Provides all pertinent distribution information and records related to the product problem. This information shall include, but not be limited to:
a) Quantities of affected product in plant warehouses, Distribution Centers, and other warehouses under Company control.
b) Identify customers that may have received affected product.
c) Mode of transportation.

7.1.14 Provides total inventory of product scheduled for removal.

7.2 **Legal Consult**

7.2.1 Legal Consult serves as a main function to advise the company on what to do and what to say in order to protect the company and the brand name.

7.3 All Numbers for parties mentioned above are on the Emergency Contact List in Certdox.

7.4 Record all activities on the activity log.

7.5 Recalled or withdrawn products are held under supervision until they are destroyed, or other disposition is determined.

7.6 Once the recall is completed, evaluate the effectiveness.

7.6.1 Determine the cause of the recall. Initiate corrective action.

7.6.2 Determine if any changes need to be made to the recall process.

7.7 Test recalls are performed to validate the recall process every 12 months. Records maintained and results evaluated by the recall team and the food safety team.

7.8 A 98% recovery on a mock recall is considered to be successful.

8.0 Forms and Records

8.1 F-260-001 Production Record

8.2 F-260-002 Mock Recall Trace Sheet

8.3 F-260-003 Mock Recall

8.4 F-260-004 Recall and Withdrawal

8.5 F-260-005 Sample Letters

Review Log

Reviewed By	Reviewed Date
Tim Campbell-Director of Operations	4/6/2020