

	Section: Product Identification, Trace, Withdrawal and Recall	Issue Date: April 20, 2015	Document Number: 2.6.3
	Subject: Product Withdrawal and Recall	Supersedes:	Revision:

Goal:

The following procedure will give guidelines for the proper and consistent completion and documentation of a Product Recall or Product Traceability.

Scope:

All raw materials, primary packaging material and finished product manufactured at Mascot Incorporated

Procedure:

1.0 [FDA RECALL](#) CLASSES DEFINED

When the US Food and Drug Administration (FDA) recalls a product, they classify it into three classes based on the relative health risk: Regardless of the classification level of a recall, consumers are advised to take each of them seriously and follow the instructions provided by the agency responsible for the recall.

- **Class I Recalls** by the US Food and Drug Administration (FDA) are the most severe type of FDA recall. In a Class-I recall there is a potential for serious injury or death.
- **Class II Recalls** are issued on products that have a lower chance of causing major injuries or death, but where there is still the possibility of serious enough adverse events to have irreversible consequences.
- **Class III Recalls** are not very likely to cause adverse health consequences, but there is still a chance and therefore the product is being recalled.

2.0 In the event of a withdrawal or recall the Office Manager is responsible for initiating, managing conducting the investigating the nature of the incident

3.0 Depending on the product being recalled: whether it is a pecan, confectionary product or raw material, the proper investigation protocol will be followed:

- Pecan/Confectionary Products – If it is a customer generated recall, the first step would be collect all the information from the customer related to product identification. If the customer is not able to provide such information, then the investigation would be initiated by reviewing the customer order history. Once the product information has been collected and/or retrieved, the work order is pulled to identify what lots are involved in the production of that particular product (Please see 2.6.1 – Product Identification and Traceability Procedure)
- Raw Material or Packaging Components – Most likely initiated by the supplier, in this case the main point would be to identify where the ingredients or packaging components where used, this is done by locating the purchase order number

associated with that particular material to determine the lot numbers used and the products these components were used into

- 5.0** Once the purchase order or work order has been identified a report is run on SL Dynamics software program that will provide the identity of the customer it was shipped to, and the quantity.
- 6.0** Once the customer has been identified the Office Manager or its designee will contact the customer by either phone call or notification letter.
- 7.0** The notification letter will contain the following information:
 - 7.1 Formal Recall Letter shall include:
 - 7.2 Date of notification of contamination from supplier.
 - 7.3 Description of contamination suppliers name, address, phone number and personnel responsible of the information.
 - 7.4 Date of production of contaminated product.
 - 7.5 A list of all distributors affected by the contamination, including addresses and phone numbers, and personnel to be contacted.
 - 7.6 Outline steps taken (Corrective Action) to eliminate further contamination of other products.
 - 7.7 A list of all personnel in charge of handling the recall program.
- 8.0** Mock Recall and Traceability Exercises will be conducted annually.

Responsibilities:

Danna Rogers Recall Coordinator (912) 237-3260 cell (912) – 654-2195 - Office

Responsibility: Will orchestrate the recall as a whole, including to identify the product/material involved, inventory, product destination and corrective actions deemed necessary.

Kristin MacSorley Recall Assistant (912) 237-5162 - cell (912) – 654-2195 - Office

Responsibility: Will obtain all documentation necessary to locate and verify product inventory, product destination, vendors and quarantine documents; will utilize other key people in other departments.

Amy Vizcarra Recall Assistant (912) – 237-8160 – cell (912) – 654-2195 - Office

Responsibility: Will obtain all documentation necessary to locate and verify product inventory, product destination, vendors and quarantine documents; will utilize other key people in other departments.

Kenny Tarver Spokesperson (912) – 237-2380 – cell (912) – 654-2195 - Office

Responsibility: Will remain in direct contact with the Recall Coordinator; will conduct all means of communication with the open public, regulatory and media outlets

Sources and Notifications:

- In the event of a recall Mascot Incorporated will notify in writing within 24 hours of the event SQFI at foodsafetycrisis@sqfi.com and the certification body providing the SQF certification services to Mascot Incorporated
- **Certification Body**
GSR, LLC
7420 Stone Valley Ln
New Albany, OH 43054
614-822-0958 Phone
www.globalstandardsresource.com
- **SQFI**
2345 Crystal Drive
Suite 800
Arlington, VA 22202
202-220-0635
foodsafetycrisis@sqfi.com
- **Legal Counsel**
Dick Wood
847-234-7500
- **Regulatory Contact**
Department of Health and Human Services – FDA
Atlanta District Office
60 Eight Street, NE
Atlanta, GA 30309
404-253-1161
- **Expert Advice**
SQF Consultants
Chilton Consulting Group – SQF Consultants
P.O. Box 129
Rocky Face, GA 30740
706-694-8325

9.0 A root cause analysis will be conducted in the event of a recall to determine the basis of the recall and the overall goal to prevent reoccurrence. If it is a recall initiated by a supplier, root cause analysis may not be required.

Reference:

SQF Code 7.2

Documents:

Recall Record

Production Work Orders

Notification Letter

<u>Document History of Changes / Amendments</u>	<u>Date</u>	<u>Name</u>
Procedure created to meet SQF Code, 7.2 Edition requirements	April 20, 2015	Amy Vizcarra