Recall Program

Assessment sheet

Revision date	Changes to the program	Changed by name	Changed by title
01/06/24	Annual assessment, no changes.	Yundong Chi-Zhang, Ph.D.	QC Consultant
01/06/24		**JOE MANGANELLA**	**MANAGER**

Product Identification, Traceability and Recall Plans and Procedures

1. Finish product identification code: Lot number, code date and sell by date
2. Finish product lot identification: per lot is per day's production.

a. The recall team members:

Name	Position	Telephone number	Responsibility	Alternative
Joseph Manganella	Recall coordinator	973-417-6420	Initiating and managing a product recall or withdrawal. Recall coordinator, public relation spokesperson. Provide resources to the team to ensure that the food recall is properly conducted; instruct sales team to contact customers at timely manor; inform other ownerships or steak holders within the company, instruct purchasing agents to contact vendors or suppliers if applicable, responsible for internal communication	Dr. Chi-Zha
Joseph Manganella	Recall coordinator	973-417-6420	Initiating and managing a product recall or withdrawal. Coordinate recall meetings; Alternative coordinator as the recall team leader in the event of recall situation; responsible for internal communication and external communication	Designated Law Firm
Dr. Yundong Chi-Zhang	QA Director/ Consultant/ Crisis coordinator / Process Authority, Food Safety Expert	Cell: 908-803-0089 Email: Yundong@aol.com Fax: 866-888-6236	Investigating a product recall or withdrawal. Expert advice. Alternate person to be the coordinator, notify regulatory agents	Dr. Chi-Zha office
Dr. Yundong Chi-Zhang	QA Director/ Consultant/ Crisis coordinator / Process Authority,	Cell: 908-803-0089	*Public speak person *Media contact person *Provide legal advice in a crisis situation	

Name	Position	Telephone number	Responsibility	Alternative
	Food Safety Expert			

b. Recall procedures:

We will review all production records, test results (if applicable), reason to recall and decide on what to be recalled with the amount affected if there is a need to recall the products.

c. Evaluation of health hazards:

We will collect and evaluate any information regarding the nature and extent of the associated health risks. The following factors will be assessed when submitting recall information to FSIS Recall Committee during the preliminary recall evaluation:

1. Whether any disease or injuries have already occurred from the use of the product.
2. Assessment of the hazard to various segments of the population. Such as children, elderly, immune-compromised individuals, etc. who are expected to be exposed to the product being considered for recall, with particular attention paid to the hazard to those individuals who may be at greatest risk.
3. Assessment of the relative degree of seriousness of the health hazard to which the population at risk would be exposed.
4. Assessment of the likelihood of occurrence of the hazard.
5. Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

d. **Scope of Recall**

The amount recalled will be determined based on a few factors and at each specific case: such as from clean-up to clean-up, coding system, the pathogen of concern, the processing and packaging, the equipment, the HACCP plan monitoring and verification records and activities, microbial testing results, SSOP records, different production lines, etc.

e. Records

Invoices or bill of lading identify the product name, EST#, lot number, and amount received. Shipping log identifies the amount shipped and to which customers. The records will be maintained for minimum 1 year.

f. Depth of Recall

We will determine the depth of the recall based on the shipping records. The four depths are:

1. Whole sale level – the product has been distributed to a warehouse or distribution center where it is not under the direct control of the producing company. This the distribution level between the manufacture and the retailer.
2. Retail level – the product has been received by retailers for sale to household consumers but has not yet been sold to consumers.
3. HRI level – The product has been received by hotels, restaurants, and other institutional customers.
4. Consumer level – the product has been sold to household consumers, although identifiable quantities may remain under the control of retailers.

g. Recall communications: We will first initiate phone call to the customers, and then followed by fax. Sample letters are listed from page 32-34 of the FSIS

Directive 8080.1 Rev. 6, Attachment 1. The phone calls will include the followings:

g.i. That the product in question is subject to a recall;
g.ii. That further distribution or use of any remaining product should cease immediately;
g.iii. Where applicable and required as part of the recall strategy, that the direct consignee should in turn notify its consignees that received the product about the recall;
g.iv. Instructions regarding what to do with the product; and
g.v. Contact information for questions.

h. Recall communication implementation – by phone than followed by fax.
i. Recall communication content –

TO BE COMPLETED BY THE FIRM: TODAYS DATE:_____
ESTABLISHMENT NUMBERS: EST._____P-_____
ESTABLISHMENT NAME:_____
ADDRESS:_____
COMPANY RECALL COORDINATOR (name, title, telephone)_____
COMPANY MEDIA CONTACT (name, title, telephone)_____
REASON FOR RECALL:_____
IDENTIFY RECALL PRODUCTS SEPARATELY BY:

BRAND NAME			
PRODUCT NAME			
PACKAGE (Type & Size)			
PACKAGE CODE (Use By/Sell By)			
PACKAGING DATE			
CASE CODE (Identifying)			
COUNT/CASE			

PRODUCTION DATE			
AMOUNT (lbs./cases) PRODUCED			
AMOUNT HELD AT ESTABLISHMENT			
AMOUNT (lbs./cases) DISTRIBUTED			
DISTRIBUTION LEVEL (institutional/retail/etc)			
DISTRIBUTION AREA			
CHILD NUTRITION (CN, AMS Contract)	**(YES) (NO)**	**(YES) (NO)**	**(YES) (NO)**
DEPT. OF DEFENSE (DPSC, Commissary, etc.)	**(YES) (NO)**	**(YES) (NO)**	**(YES) (NO)**
INTERNET OR CATALOG SALES	**(YES) (NO)**	**(YES) (NO)**	**(YES) (NO)**

RECALL NOTIFICATION FORM

To:
Date:
Re: Recall products
Via: Fax, phone calls

Our company name requests that you immediately segregate and cease to sell any inventory you may have of the product listed below.

We have discovered that the following products may show a deficiency; specifically *Packaging materials was contaminated with unknown chemicals.*

Description	Product Code	Brand	Pk/Size	Date Code	Lot Number

To fulfill our mutual responsibility to provide a safe and wholesome food product we require your assistance in the removal of this product from distribution. This is a class _____ Recall.

1. We request that you review our products from your inventory, and segregate and hold all products meeting the size and code description in this notice.

2. Please complete the attached Recall Return Information Form. Fax the completed form to _____, recall coordinator. Please also send the completed form via Fax to:_____.

3. If you can identify who you may have sold the product to please call the Recall Coordinator at _____ so your customer can be contacted.

A representative will contact you upon receipt of this form to arrange for retrieval and replacement of the product.

Thank you for your cooperation.

Recall Coordinator

MODEL RECALL NOTIFICATION LETTER

DATE

CUSTOMER FIRM NAME & ADDRESS

ATTN: ***CONTACT PERSON NAME & TITLE***

Re: RECALL OF ***TYPE OF PRODUCT***

Dear Sir or Madam:

This letter is to confirm our telephone conversation that ***Company Name*** is recalling the following product because ***Specify Recall Reason.***

Describe the product, including name, brand, code, package size and type, establishment number, 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 all of the 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.

We are undertaking this action in cooperation with the Food Safety and

Inspection Service (**FSIS**) of the U.S. Department of Agriculture. **FSIS** officials may contact you to confirm that you have received this notice and are cooperating in this action.

Your prompt action will greatly assist ***Company Name*** in this action. If you have any questions, please do not hesitate to contact ***Company Recall Coordinator*** at ***Phone Number***.

Thank you for your cooperation.

Sincerely,

Company Official Name and Title

MODEL PRESS RELEASE – FOREIGN OBJECT

[State] Company Recalls [Product] That May Contain Glass

[City], [Date]—[Company], a [City, State], establishment, is voluntarily recalling approximately [number of pounds] of [product] because the product may contain [hazardous material, e.g., glass]. Consumption could cause [lacerations]. Specific information on how to identify the product (e.g., the type of container [plastic/metal/glass], size or appearance of the product, product brand name, establishment number and location on package, flavors, codes and expiration dates, etc.).

Product was distributed [Listing of the states and areas where the product was distributed and how it reached consumers (e.g., through retail stores, mail order, direct delivery)].

Status of the number of and types of related illnesses that have been confirmed to date (e.g., "No illnesses have been reported to date").
Brief explanation about what is known about the problems, such as how it was revealed, and what is known about its source. An example of such a description: "The recall was the result of the plant finding several pieces of glass on routine examination of the product. The company immediately contacted **FSIS** and has ceased distribution of the product as **FSIS** and the company continue their investigation as to what caused the problem."
Because of the potential hazard, [name of company] urges consumers who have purchased these products not to eat them but to return them to the place of purchase.

Information on what consumers should do with the product and where they can get additional information (e.g., "Consumers who have purchased Brand X are urged not to eat the product but to return it to the place of purchase for a full refund).

Consumers with questions about the recall may contact [name and position or company division], at [phone number], or the consumer hotline at [toll free number]. Media with questions may contact [name and position] at [phone

number].**MODEL PRESS RELEASE – ALLERGEN**

[State] Company Recalls [Product] Because Of Undeclared Allergen

FOR IMMEDIATE RELEASE

DATE

COMPANY CONTACT AND PHONE NUMBER

FOOD CO. ISSUES ALLERGY ALERT ON UNDECLARED ALLERGEN IN PRODUCT

[Company Name] of [City, State] is recalling [Quantity and Type of Product], because it may contain undeclared [specific type of allergen, e.g., egg, milk, etc]. People who have an allergy or severe sensitivity to [specific type of allergen run the risk of serious or life-threatening allergic reaction if they consume these products.

Specific information on how the product can be identified (e.g., the type of container [plastic/metal/glass], size or appearance of the product, product brand name, establishment number and location on package, flavors, codes, expiration dates, etc.).

Product was distributed [Listing of the states and areas where the product was distributed and how it reached consumers (e.g., through retail stores, mail order, direct delivery)].

Status of the number of and types of related illnesses that have been confirmed to date (e.g., "The company has received two reports from consumers allergic to [specific allergen] of mild adverse reactions.").

Brief explanation about what is known about the problem, such as how it was revealed, and what is known about its source. An example of such a description: "The recall was initiated after it was discovered that product containing (the allergen) was distributed in packaging that did not reveal the presence of (the allergen)."

Information on what consumers should do with the product and where they can get additional information (e.g., "Consumers who have purchased Brand X are urged to return it to the place of purchase for a full refund. Consumers with questions may contact the company at **1**-800-XXX-XXXX").

j. Responsibility of recipient – Consignees that receive a recall communication should immediately carry out all instruction set forth therein and, where necessary, extend the recall to their consignees.
k. Public notification – General public notification by press release through USDA website.
l. Firm's effectiveness checks –

- How much product is implicated in the recall?
- How is this product identified to customer or retailers such as lot marking?
- How much product is within the firm's control?
- How much product has left the firm's control?
- How many locations did the firm ship the product to, and where are those locations?
- How did the firm communicate the product removal action to those who received the product, did the firm document this contact, and did the firm ask for and receive a written response acknowledging receipt of the information?
- What actions were taken with the product and by whom?
- If product was destroyed, was destruction witnessed and documented; was Agency personnel present?
- Is there a written record of when the issue was identified, when customers were notified, and when the firm received notification that product was either placed on hold or was no longer in a customer's control?
- Can the firm account for most of the product? Does the math add up?

m. Returned product control and disposition – All returned recalled items will be placed with Hold for QC tag and stored in designated area. Contact FSIS inspector before destroying the products.
n. Recall simulations – Mock recall will be conducted at least yearly on the end product.

Mock Recall Summary Sheet

REPORT DATE: REASON FOR RECALL TEST ACTUAL

PRODUCT RECALLED

ITEM # LOT # PRODUCTION DATE:

LOT CODE DETAILS (Attach Copies of Code Format and Code Locations on Cartons, Retail Packages)
Ingredient Forward Back Trace Forward Customer Back to Ingredient
RECALL FROM (Circle One)
Packed Lot Back Pack Lot to Distributor Pack Lot to Customer

INGREDIENT STATEMENT: (Attach Product Label)

COMPONENT LIST: (Attach Copies of Production Records showing Lot #'s of each ingredient and each packaging component. For ingredient or packaging initiated recalls, attach documents showing amount received, lotnumber, amount used in or on product, and amount in inventory. Show percent recovery of the component.)

CASES PRODUCED: (Attach Detail Showing Units Packed, Warehouse Receipts, Floor Losses, Samples, Incubation, Retained, Test, Hold)

CASES SHIPPED: (Attach Detail Showing Warehouse Location, Copies of BOL's, Confirmation of Receipt, Etc)

CASES ON HAND: (Attach Detail Showing Location, Hold, Test, Etc)

PERCENT RECOVERY:
START TIME: _____ FINISH TIME: _____ ELAPSED TIME: _____

EXPLAIN ANY DISCREPENCY:

PRODUCTION RECORDS REVIEW:

EXCEPTIONS:

UNUSUAL EVENTS:

INVESTIGATION:

% RECALLED:

Terminology

A. Recall. A firm's voluntary removal of distributed meat or poultry products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA). "Recall" does not include a market withdrawal or a stock recovery.

B. Market Withdrawal. A firm's removal or correction on its own volition of a distributed product that involves a minor infraction that would not warrant legal action by **FSIS** and constitutes no health hazard.

C. Stock Recovery. A firm's removal or correction of product that has not been marketed or that has not left the direct control of the firm. For example, product is located on premises owned by, or under the control of, the firm, and no portion of the lot has been released for sale or use.

D. Recall Classifications. **FSIS** assesses the public health concern or hazard presented by a product being recalled, or considered for recall, whether firm-initiated or requested by **FSIS**, and classifies the concern as one of the following:

1. Class I. This is a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death. An example of a Class I

recall is the presence of pathogens in ready-to-eat product or the presence of *E. coli* O157:H7 in raw ground beef.

2. Class II. This is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product. An example of a Class I recall is the presence of undeclared allergens such as very small amounts of potential allergenic substance (soy) or small sized non-sharp edged foreign material (plastic).

3. Class III. This is a situation where the use of the product will not cause adverse health consequences. An example of a Class III recall is the presence of undeclared generally recognized as safe non-allergenic substances, such as excess water.

E. Depth of Recall. The level of product distribution to which the recall is to extend:

1. Consumer - This includes household consumers, as well as all other levels of distribution.

2. Retail level – This includes all retail sales of the recalled product.

3. User level - This includes hotels, restaurants, and other food service institutional consignees.

4. Wholesale level - The distribution level between the manufacturer and the retailer. This level may not be encountered in every recall situation; i.e., the recalling firm may sell directly to the retail or consumer level.

F. Scope. This defines the amount and kind of product in question. There are several factors used in determining the scope, such as the plant's processing and sanitation procedures, the definition of a lot, any finished product reincorporated into fresh product (rework). For example, in the absence of additional data, all products produced under a single HACCP plan between performance of complete cleaning and sanitation procedures (clean up to clean up), or all products including any reworked product added to subsequent days' production, may be included in a recall. The findings of epidemiological investigations that link certain lots of product with foodborne illnesses will also affect the scope of a recall.

G. Disposition. The firm's action with respect to product to correct a situation leading to the recall, such as relabeling, recooking, reworking, or destroying product.