OUR COMPANY'S Recall Plan

OUR COMPANY'S Recall Plan outlines the activities that our company will take to manage the recall of our product(s) which has/have been determined to be unsafe and/or subject to regulatory action. Our Company's recall plan shall be reviewed annually and revised as necessary when personnel, procedures, processes, suppliers, or as other factors change. The Plan will also be reviewed after any company recall.

VERSION: _____

Approved by: Signature
Name of approver
Title

Date approved: mmddyy

This document is provided as a model for helping a food company develop a recall plan. The company's actual plan will contain information that is more detailed and will be specific to that enterprise.

Referenced for this sample plan:

USDA How to Develop A Meat & Poultry Product Recall Plan (Small Plant News Guidebook Series)
http://www.fsis.usda.gov/wps/wcm/connect/d87d635d-75fa-4a9b-8301-378675435a68/RecallPlanBooklet_0513.pdf?MOD=AJPERES
Oregon Department of Agriculture Information on Recall Plans for Small firms:
http://www.oregon.gov/ODA/FSD/docs/pdf/pub_recalls.pdf
California Department of Public Health Sample Recall Plan:
http://www.cdph.ca.gov/pubsforms/Documents/fdbRIgde23.pdf
North Carolina Food Protection Task Force: Recall Enhancement Committee
http://www.foodsafetytaskforce.nc.gov/Recall_Enhance_Committee.aspx
Penn State Creamery: Product Recall Plan
http://creamery.psu.edu/plant/dairy-plant-food-safety-plans/product-recall-plan-1/view
The Food Recall Manual (University of Florida Extension)
http://edis.ifas.ufl.edu/pdffiles/FS/FS10800.pdf

Introduction:

The primary goal of a food recall is to protect public health by removing from commerce product that has been determined to be unsafe. A recall plan can aid in the execution of a recall by distributing duties, centralizing current contact information and providing prewritten templates for communications. Key Individuals that will be participating in a company recall should review the recall plan and be familiar with the execution of the plan.

Definitions:

Consignee: Anyone who received purchased or used the product being recalled.
Depth of Recall: Defines the level of product distribution for the recall (consumer, retail, institutional, wholesale)
Distribution List: A product specific distribution list, which identifies accounts that received the recalled product. This list should include the name of customer, address, city, state, zip code, and customer contact, telephone number and email address.
Effectiveness Checks: Checks conducted by recalling firm to verify that all consignees have received notification about the recall and have taken appropriate action.
Market Withdrawal: A firm's removal or correction of a distributed product, which is not subject to legal action by a regulatory agency.
Recall: A firm's removal or correction of a marketed product that the regulatory agency considers to be in violation of the laws it administers and against which the agency would initiate legal action (i.e. embargo). Recall does not include a market withdrawal or stock recovery.
Recall Plan: A written contingency plan for use in initiating and implementing a recall in accordance with 21 CFR Sec. 7.40 through 7.49, 7.53, and 7.55.
Recall Strategy: A planned specific course of action to be taken in conducting a specific recall, which addresses the depth and scope of recall, and communication techniques.
Scope of Recall: Defines the amount and kind of product in question.
RFR: Reportable Food Registry: Established by section 1005 of the Food and Drug Amendments Act of 2007. Requires a responsible party to file a report through the RFR electronic portal (http://rfr.fda.gov) when there is reasonable probability that the use of or exposure to an article of food will cause serious adverse health consequences or death to humans or animals.
Responsible Party: The person who submits the registration information to FDA for a food facility that manufactures, processes, packs or holds food for human or animal consumption in the United States.
Scope of Recall: Defines the amount and kind of product in question.
Stock Recovery: A firm's removal or correction of a product that has not left the direct control of the firm.

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Other items to consider as part of Recall Plan: explanation of product coding, records maintenance and locations, complete list of customers, current copies of all labels that are in distribution, and a flow diagram of how the public will be notified in the event of a recall.

Roles and Responsibilities:

It is our company's responsibility to effectively organize and manage the recall of food that has been demonstrated to be unsafe or unsuitable.

Recall Committee (See contact information in Appendix A):

Recall Coordinator: The Recall Coordinator has been give authority by the management of OUR COMPANY to execute the activities of the recall. Responsibilities of the Recall Coordinator include, but are not limited to:

- Make recall decisions on behalf of OUR COMPANY
- Serve as a contact for FDA and/or WSDA Recall Coordinator
- Assure the documentation of all recall decision and action in a master recall file
- Initiate the formation of the recall committee
- Keep management informed of at all stages of the recall

Other committee members can include management, accounting, consumer affairs, distribution and supply, information technology, inventory/warehouse personnel, legal counsel, marketing, operations, production, purchasing, quality assurance, sales, maintenance, records management, regulatory affairs, support staff and sanitation.

Recall Discovery Phase

The first step in a recall situation is the discovery of a potential product problem. Discovery can happen in many ways: supplier notification, lab discovery, employee observation, consumer complaint or through regulator notification.

Recall Decision Phase:

OUR COMPANY will collect and analyze all information and data it has regarding product that may be recalled. OUR COMPANY will assess the scope of product that should be recalled (amount and type of product). OUR COMPANY will assess the depth of any recall. Levels of recall depth are:

- Wholesale level: Product has been distributed to a warehouse or distribution center and is not under the direct control of OUR COMPANY.
- Retail level: Product has been received by retailers for sale to household customers.
- HRI level: Product has been received by hotels, restaurants, and institutional customers.
- Consumer level: Product has been sold directly to consumers.

Recall Actions:

A. First 24 Hours:

OUR COMPANY has the responsibility to recall product in a clear and timely manner. We will make all reasonable efforts to remove affected products from commerce. Any products that are still in our control (inventory, in transit or in offsite distribution) will be detained and segregated. Identification codes and quantities will be documented by the <member of recall committee> to assist in the reconciliation or product amounts. OUR COMPANY'S Recall Committee is responsible for determining whether the recall is effective and will verify that all customers have been notified.

1. The Recall Coordinator will notify the appropriate regulatory agencies. See Appendix B for Regulatory Contact Information.
2. The <member of recall committee> will prepare a customer distribution list indicating where recalled product was shipped to. See Appendix I for Template. The Recall Coordinator will copy WSDA and/or FDA on the distribution list.
3. The <member of recall committee> will notify all customers that received recalled product(s). The method of notification of customers will be determined by the severity of the recall. The quickest way to reach customers is by telephone. A script should be prepared for the callers to use that provides clear information on the product, the problem and what we need customers to do. Written recall notice will be

provided to all customers who received recalled product(s). See Appendix C for Template. Confirm receipt of the Notice of Recall with all accounts. See Appendix D for Template. The recall coordinator will copy WSDA and/or FDA on any communications to customers.

4. If necessitated, the <member of recall committee> will notify consumers of the recall. This can include a press release (see Appendix E for Template) and a Food Safety Notice (see Appendix F for Template). Communication methods can include posting notification on social media sites, web sites and in stores in a location where product is sold. The Recall Coordinator will copy WSDA and/or FDA on any press releases sent to media outlets.
5. For situations where the recalled product may pose a significant health hazard, the recall coordinator will file Reportable Rood Registry (RFR) at **http://www.fda.gov/food/complianceenforcement/rfr/default.htm**

B. Product Recovery and Disposal:

1. The <member of recall committee> will control all affected product. Any returned product will be clearly marked not for sale or distribution and will be stored in an area that is separate from any other food products.
2. Any disposition or reconditioning of product may need to be documented and/or approved by WSDA or FDA.
3. The <member of recall committee> will also work with the appropriate local health jurisdictions (LJHs) agencies to determine a safe way to dispose of product.
4. All quantities and identification codes of disposed items will be recorded.
5. The Recall Coordinator will work with the <member of recall committee> to reconcile the volume of recalled product produced with the volume of recalled product on hand and returned.

C. Recall Effectiveness Checks:

OUR COMPANY is responsible for determining whether the recall is effective. We will verify that all customers have received notification and that they have taken appropriate action. We will confirm receipt of the Notice of Recall with all accounts. (See Appendix D for Template)

D. Recall Actions: Termination of Recall:

Termination of the recall is considered after all reasonable efforts have been made to remove the recalled product from commerce, including reconciliation, recall effectiveness and disposition. The Recall Coordinator will issue a report to the Recall

Committee as to the reason for the recall and the corrective action steps to prevent this from happening again.

Testing the Recall Plan:

A mock food recall is a method our company will use to test our recall plan on a <quarterly, biannual, annual> basis.

For the test, a product from our actual production records, with lot numbers and production dates, will be selected. The lot should be recently produced with some stock still on site or storage and some in the marketplace. This will allow OUR COMPANY to test internal and external ability to account for product.

The Recall Committee should convene and "work the plan". In all communication, however, be sure to stress the fact that this is a mock exercise designed strictly for emergency preparedness and that nothing is wrong with the actual product. The mock recall should involve a review of company records.

The goal of a mock recall is to prove that OUR COMPANY can effectively trace all raw materials through receiving, production, packaging, storage and determine the locations to which all product has been shipped.

A communication plan to make sure that recall/market removal notices are relayed to the responsible employees should also be part of the recall plan.

Testing the plan will quickly point out any shortcomings, which can then be revised to work better. The date and results of each mock recall should be documented in writing. (See Appendix K)

APENDIX A: Contact Information

Recall Committee and key personnel contact information: the contact information including phone number, email address and alternate 24/7 information of all committee members, their alternatives and "outside" key personnel.

Contact Information:

- Recall Committee (24/7)
    - Recall Coordinator (phone number) (email)
    - Most Responsible Individual (phone number) (email)
    - Product Safety Manager (phone number) (email)
    - Customer Service Manager (phone number) (email)
    - Media Manager (phone number) (email)
    - Production Manager (phone number) (email)
    - Warehouse Supervisor (phone number) (email)
- Technical Consultants
    - Laboratory
    - Food Safety Consultant(s)
    - Sanitation Consultants
    - Information Technology
    - Legal Counsel
- Distribution Chain Contacts
- Media: Associated Press

APENDIX B-Regulatory Contact Information

WSDA: (Washington State Department of Agriculture) Responsible for protecting the public health by licensing, inspecting and assisting food manufacturers, warehouses, custom meat operations, animal feed manufacturers and dairies in Washington State.
WSDA Food Safety Program: 360-902-1876

FDA: Federal Food and Drug Administration. Responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

FDA Seattle District Recall Coordinator
Bothell, WA
Phone: 425-302-0467
Fax: 425-302-0403
orasearecalls@fda.hhs.gov

USDA/FSIS: United States Department of Agriculture, Food Safety and Inspection Service. Responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. FSIS recall of Meat & Poultry products found in Directive 8080.1 (http://www.fsis.usda.gov/wps/wcm/connect/77a99dc3-9784-4a1f-b694-ecf4eea455a6/8080.1.pdf?MOD=AJPERES)

Washington State DOH (Department of Health): They protect public health by tracking and publishing food recalls affecting Washington State on their website. They also track notifiable food borne illness complaints.

Washington State Local Health Jurisdictions (LHJ)/County Health: There are 35 LHJ in Washington State. They protect public health by inspecting and educating food retailers, restaurants and similar establishments.
http://www.doh.wa.gov/CommunityandEnvironment/Food/LocalFoodSafetyContacts.aspx

APENDIX C- Template for Customer Notification

COMPANY LETTERHEAD

< *Insert FOOD.*> RECALL

Date

Contact Name
Firm's Name
Address
City, State
Phone number

Dear < >:

This is to inform you of a product recall involving:

<*Insert:* **PRODUCT NAME, BRAND NAME, DESCRIPTION, UPC CODES, LOT NUMBERS>**

See enclosed product label **<**for ease in identifying the product at retail/user level**>.**

This recall has been initiated due to <problem>. Use of <or consumption of> this product may <include any potential health hazard>.

We began shipping this product on <date> (or). This product was shipped to you on <date>. (If possible, provide consignee with shipping dates and quantities shipped.)

Immediately examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

Customers are advised to (e.g. destroy, return, hold for pick up). If you re-label, re-pack, or use the recalled products to produce new products, please contact the FDA or State Recall Coordinator in your state.

This recall should be carried out to the <wholesale>, <retail>, <consumer> level.

Your assistance is appreciated and necessary to prevent <i.e. consumer illness or patient harm>. Please complete and return the enclosed response form as soon as possible. If you have any questions, call <name and telephone number>.

This recall is being made with the knowledge of the Washington State Department of Agriculture and <the Federal Food and Drug Administration (if applicable)>

APENDIX D- Template for Effectiveness Checks

Customer Name and Address

Recall Effectiveness
OUR COMPANY PRODUCT RECALL

PLEASE READ EACH QUESTION AND CHECK THE PROPER ANSWER YOU HAVE CHOSEN. PLEASE CHECK WITH ANYONE WHO MAY HAVE RECEIVED THE RECALL NOTIFICATION BEFORE ANSWERING.

DATE: _____

1. Did your firm receive notification that the (Our Company) is recalling its (Name) product(s)?

   YES NO

2. Did your firm receive shipments of the product being recalled? (If no, please sign and return).

   YES NO

3. Do you now have any of the recalled product on hand? (Please check inventories before answering).

   YES NO

4. If the answer to question 3 is YES, do you intend to return the product to (OUR COMPANY) as requested?
   YES NO

   If the answer to question 4 is NO, please explain your intentions:
   _____

4. Have you received any reports of illness or injury that might be related to this product?
   YES NO
   If yes, please provide details: _____

   _____

   Name of person completing questionnaire: _____

   Title: _____

   Return this form to: _____

   Questions? Please contact (OUR COMPANY) at: _____

APENDIX E- Template for Press Release

<COMPANY NAME>
<COMPANY ADDRESS>
<COMPANY CITY, STATE, ZIP>

FOR IMMEDIATE RELEASE <**TODAY'S DATE**>

<**COMPANY OFFICIAL NAME, TITLE, PHONE**>

<**DESCRIPTIVE TITLE OF RECALL**>

<DATE><CITY> <COMPANY NAME, ADDRESS>, is recalling its <SPECIFIC PRODUCT(S)> because they<SPECIFIC REASON FOR RECALL>.INSERT PATHOGEN OR OTHER REASON FOR RECALL DESCRIPTION

The recalled <PRODUCT> was distributed <DISTRIBUTION DESCRIPTION>. <SPECIFIC PRODUCT DESCRIPTION>

Illnesses <HAVE/HAVE NOT> been reported to date in connection with this problem.

The contamination was noted after testing by <STATE/FEDERAL AGENCY NAME or OTHER> revealed the presence of <PATHOGEN NAME> in some <DESCRIPTION OF PRODUCT>.

Production of the product has been suspended while <THE COMPANY, STATE AND FEDERAL OFFICIALS> continue their investigation as to the source of the problem.

Consumers who have purchased <DESCRIPTION OF PRODUCT> are urged to return them to the place of purchase for a full refund. Consumers with questions may contact <THE COMPANY and COMPANY CONTACT NUMBER> <TIME PERIOD>

Model press releases can be found on FDA website at:
http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm

This format, with product names, lot codes, best by dates and distribution information communicates risk to the public in a clear manner. Our company will work with FDA and/or WSDA to make sure communication is clear to the public.

APENDIX F- Template for Food Safety Notice

Date issued:

FOOD SAFETY NOTICE

OUR COMPANY

<Descriptive Title of Recall>

<**CITY**> <COMPANY NAME, ADDRESS>, is recalling its <SPECIFIC PRODUCT(S)> because they<SPECIFIC REASON FOR RECALL>.INSERT PATHOGEN OR OTHER REASON FOR RECALL DESCRIPTION

The recalled <PRODUCT> was distributed <DISTRIBUTION DESCRIPTION>. <SPECIFIC PRODUCT DESCRIPTION>

Illnesses <HAVE/HAVE NOT> been reported to date in connection with this problem.

The contamination was noted after testing by <STATE/FEDERAL AGENCY NAME or OTHER> revealed the presence of <PATHOGEN NAME> in some <DESCRIPTION OF PRODUCT>.

Production of the product has been suspended while <THE COMPANY, STATE AND FEDERAL OFFICIALS> continue their investigation as to the source of the problem.

Consumers who have purchased <DESCRIPTION OF PRODUCT> are urged to return them to the place of purchase for a full refund. Consumers with questions may contact <THE COMPANY and COMPANY CONTACT NUMBER>.

<INSERT PICTURE/LABEL of RECALLED PRODUCT>

Date Expires:

Our Company will ask retailers to post Food Safety Notice in the area of the store in which product is held. We will also post this notice on our website and social media accounts.

APENDIX G: Record of Mock Recalls

Date Begin & End	Product	Success Rate/Comments

APPENDIX H: Useful References

21 CFR Part 7 (Recalls (Including Product Corrections)--Guidance on Policy, Procedures, and Industry Responsibilities):
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=7&showFR=1&subpartNode=21:1.0.1.1.6.3

Industry Guidance: Information on Recalls of FDA Regulated Products:
http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm

FDA Recall Coordinators nationwide:
http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm

FDA Recalls, Market Withdrawals and Safety Alerts:
http://www.fda.gov/Safety/Recalls/default.htm

Enforcement Report:
http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm

Reportable Food Registry (RFR):
http://www.fda.gov/food/complianceenforcement/rfr/default.htm

Food Allergen Labeling and Consumer Protection Act (FALCPA):
http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/allergens/ucm059116.htm

FSIS Directive 8080.1 Recall of Meat & Poultry products:
http://www.fsis.usda.gov/wps/wcm/connect/77a99dc3-9784-4a1f-b694-ecf4eea455a6/8080.1.pdf?MOD=AJPERES

USDA/FSIS Small Plan News Guidebook: Introduction to the Microbiology of Food Processing
http://www.fsis.usda.gov/shared/PDF/SPN_Guidebook_Microbiology.pdf