Model Recall Plan

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This publication is designed to provide reasonably accurate and authoritative information in regard to the subject matter covered. The following content is intended to provide guidance regarding the development of a meat and poultry establishment recall plan.

Resources

- FSIS Directive 8080.1 Rev 6 Recall of Meat and Poultry Products
- How to Develop a Meat and Poultry Product Recall Plan
  http://www.fsis.usda.gov/PDF/RecallPlanBooklet_0513.pdf

Background and Objectives

A recall is an effective method of removing from commerce any product that may be adulterated or misbranded. Firms such as a manufacturer, distributor, or importer, take these actions as part of their responsibility to protect the public health and welfare.

A recall can be disruptive to a firm's operation and business; however, there are several steps that a firm can take to minimize this disruption. An operator of an inspected establishment should take measures that will ensure rapid and effective response if products that appear to be adulterated have entered commerce. The operator should prepare and maintain a detailed, written recall plan. This plan should describe, step by step, the procedures the firm will follow in case it becomes necessary to recall a product.

Recall Categories

According to USDA, recalls may be classified into one of the following three categories:

Class 1: Recall involves a health hazard where there is a reasonable probability that eating the food will cause health problems or death.
Examples:
- Pathogen in ready-to-eat product
- *E. coli* O157:H7 or Non O157 STECs in Raw ground Beef
- Undeclared class I allergen (*e.g.*, peanuts, shellfish, eggs, milk)

Class 2: Recall involves a potential health hazard where there is a remote probability of adverse health consequences from eating the product.
Examples:
- Undeclared Class II allergens such as wheat and soybean.
- Soft small pieces of plastic.

Class 3: Recall involves a situation when eating the product will not cause adverse health consequences.
Example:
- Undeclared, non-allergenic, G.R.A.S. ingredient such as excess added water.

Recall Plan

(Your Establishment's Name)

Establishment Information

Establishment Name: _____

Establishment Owner: _____

Establishment Address: _____

_____

City: _____

State: _____

Zip Code: _____

Phone: _____

Fax: _____

Email: _____

Website: _____

Establishment Number: _____

Establishment Inspection Structure: ☐ Federally Inspected ☐ State Inspected

(Check all that apply)

☐ Custom Exempt ☐ Retail Exempt

Identification of Recall Personnel

Establishment Owner

Name _____

Address _____

City _____ State _____ Zip _____

Phone (day) _____ Phone (night) _____

Cellular Phone _____ Email _____

Recall role/responsibility _____

Establishment Manager ☐ Same as the Owner of the Establishment

Name _____

Address _____

City _____ State _____ Zip _____

Phone (day) _____ Phone (night) _____

Cellular Phone _____ Email _____

Recall role/responsibility _____

Establishment Recall Coordinator ☐ Same as the Owner of the Establishment

Name _____

Address _____

City _____ State _____ Zip _____

Phone (day) _____ Phone (night) _____

Cellular Phone _____ Email _____

Recall role/responsibility _____

Other Recall Personnel

Name _____

Title/Position _____

Establishment Legal Counsel

Name _____

Address _____

City _____ State _____ Zip _____

Phone (day) _____ Phone (night) _____

Cellular Phone _____ Email _____

Establishment Insurance Contact

Name _____

Address _____

City _____ State _____ Zip _____

Phone (day) _____ Phone (night) _____

Cellular Phone _____ Email _____

Identification of Regulatory Contacts

FSIS District Office Recall Contact

Name _____

Address _____

City _____ State _____ Zip _____

Phone (day) _____ Phone (night) _____

Cellular Phone _____ Email _____

State Inspection Recall Contact

Name _____

Address _____

City _____ State _____ Zip _____

Phone (day) _____ Phone (night) _____

Cellular Phone _____ Email _____

Identification of Media Contacts

Local Newspaper Contact

Name _____

Address _____

City _____ State _____ Zip _____

Phone (day) _____ Phone (night) _____

Cellular Phone _____ Email _____

Local TV News Contacts

Name _____

Address _____

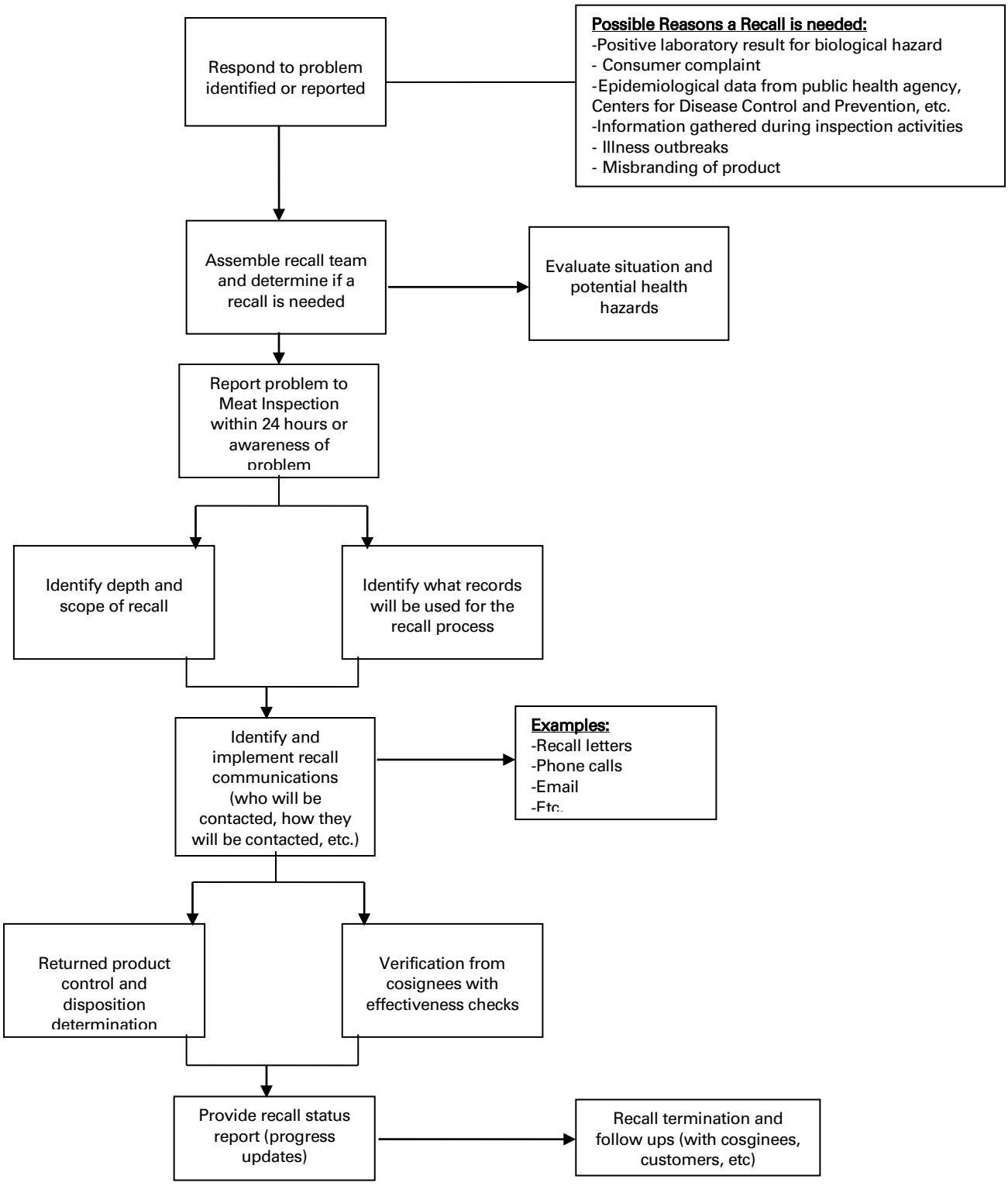
City _____ State _____ Zip _____

Phone (day) _____ Phone (night) _____

Cellular Phone _____ Email _____

Recall Procedures (Used for Possible Active Recall)

This establishment will take the following actions in deciding whether to recall a product and the steps that will be followed to complete a recall if the recall team should decide to do so.



Evaluation of Health Hazards (Used for Active Recall)

If a recall is needed, fill out the below to evaluate the associated health risks of the hazards identified associated with the product involved in the recall.

Recall Product _____ HACCP Plan_____

☐ Adulteration ☐ Misbranding ☐Other:_____

Hazard as identified in HACCP Plan _____

Has any disease or injuries already occurred from the use of this product?	
What segments of the population are expected to be exposed to this product?	☐ Children ☐ Elderly ☐ Immune-compromised ☐ Other: _____
To what relative degree is the seriousness of the health hazard to which the population at risk would be exposed?	
What is the likelihood of the occurrence of this hazard?	
What are the consequences (immediate or long-term) of the occurrence of the hazard?	

Scope of Recall (Used for Active Recall)

Below, outline how you will assess the amount of and what products (including those other than the actual product that caused the recall such as product that was made the same day or as part of a same lot). How big will your recall be and how do you choose this amount (clean-up to clean-up, an entire lot, etc.)?

Depth of Recall (Used for Active Recall)

It is important to determine what the depth (levels of potentially affected consumers) might be from the recall of your product. If a recall occurs, you should identify how the product involved with this recall was distributed by circling the appropriate distribution terms:

Wholesale

The product has been distributed to a warehouse or distribution center where it is not under the direct control of the producing company. This is 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.)

Retail

The product has been received by retailers for sale to household consumers but has not yet been sold to consumers.

HRI

The product has been received by hotels, restaurants, and other institutional customers.

Consumer

The product has been sold to household consumers, although identifiable quantities may remain under the control of retailers.

Records (Used for Recall Planning and Active Recall)

List below what records you will use if a recall is needed. Examples of records include receiving logs, HACCP logs, shipping logs, etc.)

Name of Record	Location

Recall Communications (Used for Active Recall)

You are required to thoroughly communicate the recall situation with State or Federal regulatory agency within 24 hours of identifying the need for a recall. You are also required to communicate to your customers about the recall in a timely fashion.

Notifying FSIS

Once it is determined that recall action will be undertaken, the establishment will immediately notify FSIS or DATCP. For all FSIS contact, the establishment should notify the Emergency Response Division (ERD), Office of Public Health Science (OPHS), or the District Manager in the FSIS district where the firm is located. For all WI-DATCP contact, the establishment should notify the State of Wisconsin Meat Safety and Inspection Bureau. The basic information required includes, but is not limited to, the following:

- Complete and accurate product identity.
- The reason for the recall and details about when and how any defect or deficiency was discovered.
- An evaluation of the risk associated with consumption of the product, and how the evaluation was made (although FSIS will make its own determination of risk).
- How much of the product in question was produced and during what period of time.
- An estimate of how much of the product is in distribution and how long it has been in distribution.
- Area of the geographical distribution of the recalled product by state and, if exported, by country.
- Information about which distributors and customers received the product.
- Copies of any company correspondence with distributors, brokers or customers relating to the recall strategy or actions, and a copy of any proposed press release.
- The name, title, and telephone number of the recall coordinator for the company.

The following FSIS worksheet can be utilized to gather the required information on a recall to communicate with State and/or Federal Inspection for conveying to them:

EMERGENCY RESPONSE DIVISION RECALL WORKSHEET
(*Include attachments, additional pages, label copies, and label approvals as necessary*)

TO BE COMPLETED BY THE FIRM:

TODAY'S DATE: _____

ESTABLISHMENT NUMBERS: **EST.** _____ **P-**_____

HACCP PLANT: (YES) (NO)

ESTABLISHMENT NAME: _____

ADDRESS: _____

COMPANY RECALL COORDINATOR (NAME, TITLE, TELEPHONE)

COMPANY MEDIA CONTACT (NAME, TITLE, TELEPHONE)

REASON FOR RECALL:

IDENTIFY RECALL PRODUCTS SEPERATELY BY:

BRAND NAME			
PRODUCT NAME			
PACKAGE (TYPE & SIZE)			
PACKAGING DATE			
CASE CODE (IDENTIFYING)			
PRODUCTION DATE			
AMOUNT DISTRIBUTED (LBS./CASE)			
DISTRIBUTION LEVEL			
DISTRIBUTION AREA			
CHILD NUTRITION	**(YES) / (NO)**	**(YES) / (NO)**	**(YES) / (NO)**
DEPT. DEFENSE	**(YES) / (NO)**	**(YES) / (NO)**	**(YES) / (NO)**
INTERNET OR CATALOG SALES	**(YES) / (NO)**	**(YES) / (NO)**	**(YES) / (NO)**

Public Communication (Used for Active Recall)

If a recall is necessary, you are required to promptly notify each of the affected cosignees (parties you sold/distributed product to). A communication to each must include the following information:

- That the product in question is subject to a recall;
- That further distribution or use of any remaining product should cease immediately;
- 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;
- Instructions regarding what to do with the product; and
- Contact Information for questions (e.g. a name and toll free number).

The following letter can be used to send out to all cosigneees:

Model Recall Notification Letter
(On company letterhead)

CUSTOMER FIRM NAME AND ADDRESS *DATE*

Attn: *CONTACT PERSON AND TITLE*
Re: Recall *TYPE OF PRODUCT*

Dear Sir or Madam:

This letter is to confirm our telephone conservation that *ESTABLISHMENT NAME* is recalling the following product(s) 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(s). 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 the 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 ESTABLISHHMENT NAME in this action. If you have any questions, please do not hesitate to contact *ESTABLISHMENT RECALL COORDINATOR* at *PHONE NUMBER.*

Thank you for your cooperation.

Sincerely,
COMPANY OFFICIAL NAME AND TITLE

Firm's Effectiveness Checks (Used for Active Recall)

The purpose of effectiveness checks is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action. The methods for contacting consignees should be specified, for various scenarios and contingencies, and may be accomplished by personal visits, telephone calls, letters, facsimile transmission, or a combination thereof.

To assess the effectiveness of a recall, you will compile the following information:

How much product is implicated in the recall?
How is this product identified to a customer/retailer (i.e., lot markings)?
How much product is within a 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 it witnessed and documented with 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? (The firm produced this amount, shipped this amount, had this amount returned, destroyed or determined to be consumed or irretrievable.)

Returned Product Control and Disposition (Used for Planning & Active Recall)

You show list how you would control and/or dispose of any product involved in a recall that you still have in your possession or that has been shipped back to you. Returned Product Control and Disposition - The means of controlling and disposing of or correcting the defect in the stock returned during a recall should be specified in the recall plan. You must check with the regulatory agency (FSIS or WI-DATCP) before destroying any product; FSIS/WI-DATCP may wish to witness the destruction. (Destroy means to render inedible for humans and animals, and all labeling is made unusable for trade).

Recall Assessment/Status Report (Used for Active Recall)

The establishment will regularly, and in a timely manner, reports the results of effectiveness checks performed to FSIS/WI-DATCP in order to keep the regulatory agency apprised of the status of recalls in progress. The reporting frequency will be agreed upon by the recalling firm and FSIS/WI-DATCP and will be expected to be more frequent as the degree of public health hazard presented increases. FSIS/WI-DATCP will conduct independent effectiveness checks as specified in FSIS Directive 8080.1, Rev. 3. In addition, the firm will notify FSIS/WI-DATCP when it appears that the recall has been completed.

RECALL STATUS REPORT

- The number of consignees notified of the recall, the date and method of notification.
- The number of consignees responding to the recall communication.
- The quantity of product each consignee had on hand at the time the communication was received.
- The number and identity of consignees that did not respond.
- The quantity of product returned or held by each consignee.
- An estimated time for completion of the recall.

Recall Status Report (Used for Active Recall)

- **Estimated time for completion of the recall:** _____
- **Number of consignees notified of the recall, the date and method of notification:** _____
- **Number of consignees responding to the recall communication:** _____
- **Number and identity of consignees that did not respond:** _____

Consignee	Date	Method of Notification	Response		Quantity on Hand	Quantity Returned
			Yes	No		

Recall Termination (Used for Active Recall)

A recall will be terminated when FSIS/WI-DATCP has completed the recall effectiveness checks and determined that the recalling firm has made all reasonable efforts to recall the product, and that it has disposed of the recovered product, or the product is under FSIS control (retention or detention) or documented control by the firm. To effect a timely termination of the recall, the firm should provide all relevant information to the Agency once the firm has determined that it has retrieved all possible product. The firm will send a “closeout memo” to the relevant District Office or OIA IID, Headquarters containing the following:

- A list of customers,
- The amount of product retrieved
- The actions taken

Once the Agency determines that the firm has made all reasonable efforts to recall the product, the Recall Management Staff will notify the firm in writing.

Recall Follow up (Used for Active Recall)

Once a recall action has been completed, the establishment should notify its customers that the recall action has been completed, thank them for their assistance, and provide assurances that the problem has been corrected. The Recall Team should evaluate how the recall action was conducted to determine whether things should have been handled differently, and what, if any, changes should be made to the plan.

Recall Simulations (Used to Practice Recalls)

A recall simulation is used to determine whether the recall procedure is capable of identifying and quickly controlling a given lot of potentially affected product and reconciling the quantities produced, quantities in inventory, and quantities distributed. In addition, a recall simulation will identify potential problems and allow personnel to become familiar with recall procedures. If problems are identified during a recall simulation, the recall plan and procedures should be revised to correct the problems. Simulated recall should involve the selection, without prior notice to personnel involved in the simulated recall, of at least one lot of product that has been distributed in commerce. A hypothetical reason for recalling the product should be specified, and the recall plan should be followed to establish a strategy for recalling the product. Such scenarios may be simple (e.g. one contaminated lot of product) or very complex (e.g. contaminated ingredient used in multiple products and involving rework). A recall simulation file should be maintained to record the details and results of all simulated recalls. The recall simulation file includes the name, address, and telephone number of clients for the test lot, production records, the inventory, and distribution of the test lot.

RECALL SIMULATION LOG

Recall Simulation Dates	Start Date: End Date:
Client Contact Information	
Production Records	
Inventory	
Distribution	
Notes	