SMALL AND VERY SMALL ESTABLISHMENT RECALL PLAN GUIDANCE

WHAT IS A FOOD RECALL?
A food recall is a voluntary action by a manufacturer or distributor to protect the public from products that may cause health problems or possible death. A recall is intended to remove food products from commerce when there is reason to believe the products may be adulterated or misbranded.

WHO DECIDES WHEN A RECALL IS NECESSARY?
Recalls are initiated by the manufacturer or distributor of the meat or poultry, sometimes at the request of FSIS. All recalls are voluntary. However, if a company refuses to recall its products, then FSIS has the legal authority to detain and seize those products in commerce.

RECALL PLAN REQUIREMENT
The U.S. Department of Agriculture’s Food Safety and Inspection Service (USDA/FSIS) is implementing provisions of the Food, Conservation, and Energy Act of 2008 by amending the Federal meat and poultry products inspection regulations by establishing a new 9 CFR part 418. Recalls, under which official establishments would be required to prepare and maintain procedures for the recall of all meat and poultry products produced and shipped by the establishment. This regulation was announced via the Federal in Docket No. FSIS-2008-0025, effective May 8, 2012.

The regulation requires new establishments to develop their written recall procedures at the same time as their HACCP plans in order to receive a Federal Grant of Inspection. Existing large establishments, defined as all establishments with 500 or more employees, will have six months from the date of publication of this final rule in the Federal Register to prepare their written recall procedures. Existing small establishments (those with 10 or more employees but fewer than 500) and very small establishments (those with fewer than 10 employees or annual sales of less than $2.5 million) will have one year from publication of this final rule in the Federal Register to prepare their written recall procedures.

Under this final rule, establishments are not required to submit their recall procedures to FSIS. They must, however, make the written recall procedures available for copying. FSIS will verify that all establishments maintain the required written recall procedures. FSIS will also protect establishments’ confidential business information from public disclosure to the extent authorized under the Freedom of Information Act (FOIA).
It is vitally important to be prepared to retrieve product that might pose a health risk to consumers through a food safety recall. Every processor should be able to trace back the raw materials involved in the production of a product (this is a good idea, but not required by USDA), follow the distribution of that product, and have in place a tested and proven means of securing the product. Although most processors probably have some idea of how this would be accomplished, many may not have a formalized written plan. Recalls, when warranted, are conducted by the processor in conjunction with USDA/FSIS. Although FSIS has no legal authority to mandate a recall, they may request a recall if the processor has not begun the process.

**ACTION STEPS FOR THE SMALL PROCESSOR**

1. Select a recall coordinator and assemble a recall team.

2. Determine the methods for traceability, both forward and backward, and write procedure necessary to locate product from either “avenue.”

3. Write all necessary forms for the media, customers, etc. in preparation for interaction with the public.

4. Contact a third party expert of process authority who can evaluate your recall plan for completeness and effectiveness.

5. Conduct periodic mock recalls and retrain based on areas requiring improvement.

**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

**ELEMENTS OF A RECALL PLAN**

**A. Identification of Recall Personnel** – All internal and external personnel to be involved in the recall actions, along with their respective telephone and fax numbers, email addresses, etc., as appropriate, should be identified. For each identified individual, an alternate to act in his or her absence should be specified. The roles and responsibilities of every person identified should be clearly specified.

**B. Recall Procedures** – The recall plan should specify, in detail, actions the firm will take in deciding whether to recall a product and in effecting the recall, should it decide to do so.
C. Evaluation of Health Hazards – Using the hazards identified in its HACCP plan, the firm should correlate and evaluate all known information on the nature and extent of the associated health risks. At a minimum, this evaluation should take into account the following factors:

- Whether any disease or injuries have already occurred from the use of the product.
- Assessment of the hazard to various segments of the population, e.g., children, the 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.
- Assessment of the relative degree of seriousness of the health hazard to which the population at risk would be exposed.
- Assessment of the likelihood of occurrence of the hazard.
- Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

D. Scope of Recall – This defines the amount and kind of product in question and depends on the establishment’s HACCP plan and processing operations. As a starting point, all products produced under a single HACCP plan between performance of complete cleaning and sanitation procedures (clean-up to clean-up) should be considered for recall. The scope of the recall may expand or contract from this point. The plan should specify how this is to be determined for various scenarios and contingencies. A system of product coding sufficient to permit positive identification and to facilitate effective recalls should be in use by all firms.

E. Depth of Recall – This is dependent upon the degree of hazard, extent of distribution, and the level to which the recalled product was distributed. The plan should specify how the depth of recall is to be determined for various scenarios and contingencies. Levels of recall depth may be:

- Consumer level, includes household consumers as well as all other levels of distribution to reach the household consumer; or
- Retail level, includes retail sellers and any intermediate wholesale level to reach the retail sellers; or
- User level, includes hotels, restaurants and other institutional type consignees and any intermediate wholesale level to reach these users; or
- Wholesale level, the distribution level between the manufacturer and retail or user level.

F. Recall Communications – A recalling firm is responsible for promptly notifying each of its affected consignees about the recall. The format, content, and extent of a recall communication should be commensurate with the hazard associated with the product being recalled, the strategy developed, and the recall plan. In general terms, the purpose of a recall communication is to convey:

- 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, the direct consignee should in turn notify its consignees that received the product about the recall;
- Instructions regarding what to do with the product.

G. Public Notification – The purpose of public notification is to alert the public that a product is being recalled. A recall plan should include contact information for all potential media outlets. A firm should consider the need for and means of public notification upon initiating a recall. The recall plan should specify what means of public notification will be used, if appropriate, for various scenarios and contingencies such as:

- General public notification by press release through the general news media, either national or local as appropriate, or
- Public notification through specialized media, e.g., professional, trade or ethnic press, store placards or to specific customers (if known), etc.
H. Effectiveness Checks – 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, fax transmission, or a combination thereof. The recalling firm is responsible for conducting effectiveness checks.

I. 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.

J. Recall Simulations – In order to evaluate its recall plan, the establishment should conduct periodic simulations. A 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, then the recall plan should be followed to establish a strategy for recalling the product. A recall simulation file should be maintained to record the details and results of all simulated recalls. If problems are identified during a recall simulation, the recall plan and procedures should be revised to correct the problems.
RECALL PLAN

(Your Establishment's Name)
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 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 ____________________

Local TV News Contacts

Name ________________________________
Address ________________________________
City ___________ State ___________ Zip ___________
Phone (day) ________________ Phone (night) ________________
Cellular Phone ________________ Email ____________________
**RECALL PROCEDURES**

This establishment will take the following actions in deciding whether to recall a product and in effecting a recall if the recall team should decide to do so.

**Procedures to determine if a recall is necessary:**
- Has adulterated or misbranded product been produced?
- Has adulterated or misbranded product been shipped?
- Where has the product been shipped?
- Is the product in commerce?
- Is the product available to consumers?

- Positive laboratory result for biological hazard
- Consumer complaint
- Epidemiological data from public health agency, Centers for Disease Control and Prevention, etc.
- Information gathered during inspection activities
- Illness outbreaks
- Misbranding of product

Assemble recall team and ask if a recall is recommended

Evaluate situation; Decide if, what, and how much to recall

Contact the District Office and initiate recall plan

Document why not and action taken
# Evaluation of Health Hazards

This establishment will utilize the chart below in to correlate and evaluate all known information on the nature and extent of the associated health risks of the hazards identified in the appropriate HACCP plan.

<table>
<thead>
<tr>
<th>Recall Product</th>
<th>HACCP Plan</th>
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<tbody>
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</tbody>
</table>

- □ Adulteration
- □ Misbranding
- □ Other: __________________________________________

Hazard as identified in HACCP Plan __________________________________________

<table>
<thead>
<tr>
<th>Has any disease or injuries already occurred from the use of this product?</th>
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</table>

- □ Children
- □ Elderly
- □ Immune-compromised
- □ Other: __________________________________________

<table>
<thead>
<tr>
<th>What segments of the population are expected to be exposed to this product?</th>
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<tr>
<th>To what relative degree is the seriousness of the health hazard to which the population at risk would be exposed?</th>
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<tr>
<th>What is the likelihood of the occurrence of this hazard?</th>
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<tr>
<th>What are the consequences (immediate or long-term) of the occurrence of the hazard?</th>
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</table>
**SCOPE OF RECALL**

*Explanation of the establishment’s Product Coding System and Record.*

It is to the benefit of the firm that the scope of the recall be identified correctly. If the recall needs to be expanded, additional FSIS Recall Releases may be issued resulting in further media postings.

- Microbial Pathogens
- Microbiological Independence
- Source materials used in other lots
- Cross contamination potential
- Foreign Material
- Type of foreign material
- How is it dispersed in product?
- Production practices that limit contamination?
- Undeclared Allergen
- Allergen control protocols in place?
- What caused the problem?
- Misbranding
- What caused the problem?

**Factors to consider:**

- When did the problem begin?
- When was it resolved?
- What product(s) were affected?
### RECORDS

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<tr>
<th>Name of Record</th>
<th>Type of Record</th>
<th>Location</th>
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**DEPTH OF RECALL**

The depth of recall will be determined for various scenarios and contingencies. The depth is dependent upon the degree of hazard, the extent of distribution and the level to which the recalled product was distributed. Levels of recall depth may be:

**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.
Once it is determined that recall action will be undertaken, the establishment will immediately notify FSIS. 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. 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 will be utilized to gather the required information on a recall:

**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:**

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IDENTIFY RECALL PRODUCTS SEPARATELY BY:

<table>
<thead>
<tr>
<th>BRAND NAME</th>
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</thead>
<tbody>
<tr>
<td>PRODUCT NAME</td>
<td></td>
<td></td>
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<tr>
<td>PACKAGE (TYPE &amp; SIZE)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PACKAGING DATE</td>
<td></td>
<td></td>
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<tr>
<td>CASE CODE (IDENTIFYING)</td>
<td></td>
<td></td>
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<tr>
<td>PRODUCTION DATE</td>
<td></td>
<td></td>
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<tr>
<td>AMOUNT DISTRIBUTED (LBS./CASE)</td>
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<td></td>
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<tr>
<td>DISTRIBUTION LEVEL</td>
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<td></td>
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<tr>
<td>DISTRIBUTION AREA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CHILD NUTRITION</td>
<td>(YES) / (NO)</td>
<td>(YES) / (NO)</td>
</tr>
<tr>
<td>DEPT. DEFENSE</td>
<td>(YES) / (NO)</td>
<td>(YES) / (NO)</td>
</tr>
<tr>
<td>INTERNET OR CATALOG SALES</td>
<td>(YES) / (NO)</td>
<td>(YES) / (NO)</td>
</tr>
</tbody>
</table>
PUBLIC COMMUNICATION

Recall communication can be accomplished by telephone, facsimile transmission, e-mail, or special delivery letters conspicuously marked, preferably in bold red type, on the letter and envelope "URGENT - FOOD RECALL." Telephone calls or other personal contacts will be documented and followed-up in some written form (e.g., letter, e-mail message, and/or fax). The following is the template the establishment will follow when contacting customers.

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 conversation 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 ESTABLISHMENT 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**

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, the firm will compile the following information:

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>How much product is implicated in the recall?</td>
<td></td>
</tr>
<tr>
<td>How is this product identified to a customer/retailer (i.e., lot markings)?</td>
<td></td>
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<tr>
<td>How much product is within a firm’s control?</td>
<td></td>
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<tr>
<td>How much product has left the firm’s control?</td>
<td></td>
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<tr>
<td>How many locations did the firm ship the product to, and where are those locations?</td>
<td></td>
</tr>
</tbody>
</table>
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

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. The establishment will check with the Agency before destroying product; FSIS may wish to witness the destruction. (Destroy means to render inedible for humans and animals, and all labeling is made unusable for trade).
**RECALL SIMULATIONS**

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 is 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**

<table>
<thead>
<tr>
<th>Recall Simulation Dates</th>
<th>Start Date:</th>
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<tbody>
<tr>
<td></td>
<td>End Date:</td>
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<tr>
<td>Client Contact Information</td>
<td></td>
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<tr>
<td>Production Records</td>
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<tr>
<td>Inventory</td>
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<td>Distribution</td>
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<tr>
<td>Notes</td>
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**RECALL ASSESSMENT**

The establishment will regularly, and in a timely manner, reports the results of effectiveness checks performed to FSIS in order to keep the Agency apprised of the status of recalls in progress. The reporting frequency will be agreed upon by the recalling firm and FSIS and will be expected to be more frequent as the degree of public health hazard presented increases. FSIS will conduct independent effectiveness checks as specified in FSIS Directive 8080.1, Rev. 3. In addition, the firm will notify FSIS 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

- 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: 

<table>
<thead>
<tr>
<th>Consignee</th>
<th>Date</th>
<th>Method of Notification</th>
<th>Response</th>
<th>Quantity on Hand</th>
<th>Quantity Returned</th>
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<td>Yes</td>
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**RECALL TERMINATION**

A recall will be terminated when FSIS 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 RMS will notify the firm in writing.

**RECALL FOLLOW UP**

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.

**RESOURCES**

- FSIS Directive 8080.1 Rev 6 Recall of Meat and Poultry Products