| UNITED STATES DEPARTMENT OF AGRICULTURE<br>FOOD SAFETY AND INSPECTION SERVICE<br>WASHINGTON, DC<br><br>**CHANGE TRANSMITTAL SHEET** | Ξ DIRECTIVE<br>Γ REVISION<br>Γ AMENDMENT<br>Γ OTHER | |
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| **RECALL OF MEAT AND POULTRY PRODUCTS** | 8080.1, Rev. 4<br>Amend. 3 | 3/2/06 |

## I. PURPOSE

This change transmittal issues a revised Sections IX., *Public Notification* to FSIS Directive 8080.1, Revision 4. The revised section makes some changes to when FSIS issues press releases, and when it issues Recall Notification Reports. The changes are improvements to the way in which FSIS communicates information about recalls.

## II. CANCELLATION

This transmittal is cancelled when contents have been incorporated into FSIS Directive 8080.1 Rev. 4.

Assistant Administrator
Office of Policy, Program, and Employee Development

FILING INSTRUCTION

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**DISTRIBUTION: Inspection Offices, T/A Inspectors, Plant Mgt., T/A Plant Mgt., TRA, ABB, PRD, Import Offices**

**OPI: OPPED**

a. Does FSIS have reason to believe that the product in question is adulterated or misbranded?

b. Does any of the product in question remain in commerce and available to consumers? (All facts must be verified by a program employee before the recall committee can determine if product in commerce is not available to consumers.)

c. Is FSIS prepared to detain or move to seize the product in question?

5. If the answer to all of the above questions is "yes," a recall should be recommended. If the answer is "no" to any of the above questions, the committee should not recommend a recall. If the committee does not recommend a recall, RMS will document results of the preliminary inquiry and evaluation with a memo to the file. When a recall is recommended, RMS will submit a recall recommendation.

C. Recall Recommendation. When a recall is recommended by the Recall Committee, RMS will submit a recall recommendation in the form of a memo for approval by the AA/OFO.

1. The recommendation will contain:

a. whether the firm is voluntarily recalling the product

b. the reason for the recall, including why there is a reason to believe that the product is adulterated or misbranded;

c. the recall classification (i.e., Class I, Class II, or Class III);

d. the depth;

e. the scope;

f. the ability of distributors, consumers, or users of the product to identify it;

g. the estimated amount of product in distribution (amount of product that was distributed and is still within sell by/used by code at the time of the recall);

**NOTE:** The estimate of product in distribution is arrived at by the Recall Committee by taking into account the amount of product produced subject to the recall, and its sell by or use by dates or codes.

h. the area of distribution.

**NOTE**: Much of the above information is generally provided to the Recall Committee by the recalling firm through documents, or orally through telephone conference calls. The Recall Committee will allow the firm an opportunity to clarify any information it provided or to supply additional information that may be significant to a recall recommendation. Before deciding on a recommendation, RMS may request that FSIS inspection program personnel verify the information provided by the firm. The Agency strongly encourages firms to use electronic transfer of the information involved in the recall in order to facilitate the speed and accuracy of the information transfer.

2. If the AA/OFO approves the recall recommendation, RMS will contact the firm to make the formal request for a recall. RMS will follow-up by sending a letter to the firm confirming the evaluation of the hazard, scope of the recall, and the Agency's understanding of the firm's recall strategy. Congressional and Public Affairs (CPA) will also confirm the information for the press release if FSIS issues one. The DRO will begin to coordinate effectiveness checks (see Section X) and will be responsible for directing the activities of inspection program personnel.

## VIII. ACTION BY FIRM

A. FSIS outlines in "Product Recall Guidelines for Firms" (Attachment 1) the actions it expects a firm to take to ensure that the maximum amount of product is recovered in the shortest amount of time. The guidance includes model letters that a firm may use to communicate with its consignees (including providing instructions for product retrieval and extending the recall to additional consignees), model press releases, and recordkeeping requirements.

B. In a case where a firm decides not to accept the Agency's recommendation and chooses not to conduct a recall, FSIS will detain any product that would have been subject to a recall that it finds in commerce. FSIS, CPA will issue a press release informing the public that product that appears to be adulterated or misbranded has been shipped by the responsible firm, and that the firm has refused to recall it.

## IX. PUBLIC NOTIFICATION

A. Press Releases. A press release entitled Recall Release will inform consumers, industry, and the public health community with information related to the product in question. RMS coordinates with the Congressional and Public Affairs Office to develop a press release.

1. Generally, FSIS will issue a press release for Class I or Class II recalls. For Class III Recalls, RMS will develop and issue a Recall Notification Report (RNR) based on the information provided by the firm. FSIS generally will not issue a press release for Class III recalls except in situations of an egregious economic adulteration. In these cases, the agency may decide that there are overriding public welfare reasons that warrant issuing a press release. A press release is normally not necessary in cases where FSIS can verify that all products in question were removed from commerce and brought under the firm's control before FSIS requested a recall.

2. Federal, State, and local public health and food inspection agencies will receive the press release as notification recalls. An RNR will only be issued whenever a press release is not necessary such as for Class III recalls in general.

3. The press release will:

a. Clearly describe the product being recalled along with any identifying marks or codes, explain the reason for the recall, and describe the risk involved in consuming the product.

b. Provide instructions to the public on what to do with the product if people identify it and have it in their possession and the name and telephone number of a company contact for consumers to call with any questions.

c. Provide general information about the product's destination, for example, "The beef burritos were distributed to an airline caterer and restaurants in the States of….." or "Frankfurters were sold to grocery stores, delis, and convenience stores in the States of …."

d. When possible, and without slowing the public notification of the recall, provide an electronic picture of the product label(s) that can be posted on the FSIS Website and linked to the press release in order to provide the public with a clear description of the product.

4. When there are extenuating circumstances involving foodborne illnesses and contaminated products, but no legal identification of the source, the FSIS Administrator may decide to issue an immediate special "educational" press release. For example, if a foodborne illness outbreak is identified, and a common source is suspected but not confirmed, FSIS may issue an educational press release that provides guidance to consumers and health professionals about the risks of illness associated with the identified pathogen and symptoms.

5. When needed, FSIS will issue press releases announcing intrastate recalls and provide the appropriate factual information, including identification of the State that is overseeing the recall.

6. When informed by a foreign government's food inspection agency that it is overseeing a recall, and some of the product may have been distributed in the United States, FSIS will issue a press release announcing the recall to U.S. consumers. The press release will be issued in accordance with current FSIS policy regarding press releases. The press release will provide the appropriate factual information to consumers. This procedure will be followed in cases where FSIS does not have first-hand information that the product is adulterated or misbranded.

B. Recall Notification Report. An RNR will be used to notify the public whenever a press release will not be used. Generally, the Agency will issue an RNR when there is a class III recall (see Section A of this part). The RNR will be posted on the FSIS Recall website. It provides substantially the same information as the press release, however the format is different.

C. FSIS will provide a draft copy of the press release or the RNR, in cases where no press release is issued, by fax to the recalling firm 30 minutes prior to its release. The firm will be provided with this opportunity to review the release or the RNR for accuracy of the telephone numbers, contact names, code numbers, etc. If the firm does not respond within 30 minutes, FSIS will proceed with the planned release. If typographical or other inadvertent errors are noted by the firm, FSIS will correct them before releasing the documents.

## X. EFFECTIVENESS CHECKS

The recalling firm is responsible for developing and implementing an effective recall strategy to notify all consignees of the need to remove recalled product from commerce. Inspection program personnel will verify that the recall action is being conducted in an effective manner through effectiveness checks. Effectiveness checks constitute a process by which FSIS verifies whether the recalling firm has been diligent and successful in notifying and advising the consignees of the need to retrieve and control recalled product, and that the consignees have responded accordingly.