UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC **CHANGE TRANSMITTAL SHEET**	☐ DIRECTIVE ☐ REVISION ☐ AMENDMENT ☐ OTHER	
Recall of Meat and Poultry Products	8080.1, Rev. 4 Amend. 2	7/26/05

I. PURPOSE

This change transmittal issues revised Sections X., *Effectiveness Checks* and XI. *Closure*, to FSIS Directive 8080.1, Revision 4. In the revised section X., new instructions are provided to the District Recall Officers (DROs) to ensure that effectiveness checks are conducted in a manner that adequately verifies that product that there is reason to believe is adulterated is removed from commerce during a recall. In the revised section XI., new instructions are provided to the Recall Management Staff (RMS) for that office to review certain information when an illness is associated with a recall. The change transmittal also issues a change on page 11 of Attachment 3, Recall Effectiveness Checks.

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

Remove Old Pages	Insert New Pages
10-13 Attachment 3, 11-12	10-15 Attachment 3, 11-12

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

OPI: OPPED

1. A RNR will be issued for every class of recall, even if FSIS does not issue a press release. RNRs will be posted on the FSIS Recall website.

2. RNRs provide consumers, industry, and the public health community with information related to the product in question. Along with the date and recall case number, RNRs should include the following:

a. The specific products recalled, along with any identifying codes or marks on the packages;

b. The name of the recalling firm, a contact at the firm, and the contact's phone number;

c. The quantity of product recalled;

d. The problem with the product or the reason for the recall and how/when it was discovered;

e. The areas in which the product has been distributed;

f. The classification of the recall and depth or level of the recall;

g. A link to the FSIS press release, if one has been issued;

h. Other agencies involved; and

i. A list of FSIS contacts with phone numbers.

C. FSIS will provide a draft copy of the press release or the RNR, in cases where no press release is issued, by fax or email 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.

Effectiveness checks are risk-based and dependent on the class of the recall (which is based on the hazard and any available epidemiological data) as well as the number of consignees. The DRO is responsible for coordinating recall activities.

If at any time during the effectiveness checks, inspection program personnel discover that a firm did not take prompt action to contact the consignees with recall instructions, or that the consignees are not acting with respect to the product in the manner requested by the firm, inspection program personnel will detain any product that they find in commerce as set out in FSIS Directive 8410.1, *Detentions and Seizures*. Inspection program personnel will immediately notify the DRO when the recalled product remains available to the consumer, and when the recalling firm's recall strategy has not been properly implemented.

A. DRO responsibilities upon notice of a recall

The DRO's responsibilities are to:

1. serve as the primary point of contact for the firm conducting the recall,

2. immediately request that the recalling firm provide information regarding product distribution including the names, addresses, and phone numbers of its consignees (Attachment 3),

3. review any notice of recall issued by the firm for accuracy of product information, risk, and clarity, e.g., the reason for the recall is not adequately disclosed because the firm fails to describe the product defect or adulterant; or a recall notice contains promotional or company information that obscures the risk of the product. If the recall notice is incomplete or inaccurate, the DRO is to immediately call the firm and explain the reasons why the notification or instructions are inadequate and follow the call with a letter to the firm and a courtesy copy to RMS,

4. inquire how the firm plans to control recovered product, and

5. inquire how the firm plans to handle product disposition.

NOTE: If the firm's recall strategy includes destroying product on site, the DRO must be notified. The DRO may assign FSIS inspection program personnel to witness destruction of the product in accordance with 9 CFR parts 329 and 381, Subpart U. Inspection program personnel are to document this on FSIS Form 8400-4 (b) as product disposition verification.

B. DRO responsibilities for coordinating inspection program personnel's activities in effectiveness and product disposition verification checks

The DRO's responsibilities are to:

1. coordinate effectiveness checks and direct the activities of inspection program personnel,

2. determine product distribution and request assistance from deputy district managers in districts where product was distributed. Assisting deputies are to determine whether additional consignees should be included on the initial distribution list, and

3. select a sample of consignees based on product distribution information using a statistical sampling plan (Attachment 3). In cases where the recalling firm does not have a recall plan (see Attachment 1), the DRO may instruct inspection program personnel to conduct more effectiveness checks than if the firm did have a recall plan.

C. Inspection program personnel responsibilities for conducting effectiveness and product disposition checks

For a recall to be deemed effective, the number of consignees checked that are found to have the product available to the public must be equal to or less than the critical number in the sampling plan applied to the effectiveness check (Attachment 3). Using the sampling plan selected by the DRO, inspection program personnel are to:

1. contact or visit the consignees to determine whether they were notified of the recall and have removed the recalled product from commerce,

2. if recalled product is found in commerce, take appropriate action to detain it in accordance with FSIS Directive 8410.1 Rev 2, Detention and Seizure,

3. determine the amount of recalled product received by the consignee. In cases where the consignee cannot document how much of the recalled product it actually received, inspection personnel will explain this on FSIS Form 8400-4 (a),

4. verify that the consignees are handling the product in accordance with regulatory requirements and the instructions of the recalling firm by reviewing records and by observing product disposition. If product is to be destroyed at a federal establishment, in-plant inspection personnel may be asked to witness the destruction of product,

5. record the effectiveness checks on FSIS Form 8400-4 (a), and submit the completed forms to the DRO,

6. in cases where a product disposition verification cannot be made upon an initial check, conduct a follow-up check to verify that the product was handled in accordance with the instructions and regulatory requirements, and document this on

7. in cases where prohibited activities such as putting product that the Agency has reason to believe is adulterated in commerce are noted or suspected, document the occurrence and contact the DRO, who will contact OPEER to investigate and take any follow-up compliance or legal actions.

D. DRO responsibilities for reviewing effectiveness checks and confirming the firm's control and disposition of the product

1. The DRO is to compile the recall effectiveness reports from all assisting districts and state programs to make an overall assessment of recall effectiveness following the criteria and decision guidance in Attachment 3.

2. The DRO will analyze the information that is submitted by inspection program personnel on FSIS Forms 8400-4 (a & b) and review any findings of recalled product that was found in commerce. For example, the DRO should review the effectiveness checks findings to determine whether a pattern or trend exists that suggests certain consignees were not contacted.

3. The DRO is to contact the firm and verify whether the firm:

a. considers the recall closed,

b. controlled the recalled product as planned, and

c. disposed of the product as planned.

E. The DRO determination on the effectiveness of the recall

1. The DRO may determine that the recall was effective based on his or her review of the effectiveness and the product disposition verification checks, and that the establishment has gained proper control and made proper disposition of the product. If so, he or she will send a Final Recall Effectiveness Report (FRER) to the Director of RMS. The FRER is to:

a. summarize the findings of the recall effectiveness and product disposition verification check.

b. include any supporting documentation voluntarily provided by the firm, including information about the amount of recalled product recovered.

2. The DRO may determine that the recall action is ineffective based on the review of the effectiveness and product disposition verification checks and in consultation with RMS because of the firm's failure to control and dispose of the product. The DRO will

notify the recalling firm in writing and provide a courtesy copy to

the RMS Director, detailing the reasons why its recall action was deemed ineffective. The DRO will ask how the recalling firm intends to address the situation. If the recalling firm is unwilling or unable to correct its recall strategy, DRO will recommend that the Agency take further action to mitigate the risk to the public. The recommended actions may include public warnings, product detentions and seizures, or other appropriate actions.

NOTE: Inspection program personnel conducting checks would continue with all assigned checks even though a recall may appear ineffective. The recall activities should be classified as effective or ineffective, after considering both the number and the amount of product available in commerce.

3. If the DRO determines that the recalling firm or any of its consignees committed a prohibited act, the DRO will issue, when the facts indicate, a letter of prohibited activity to the firm.

XI. CLOSURE

A. RMS is responsible for submitting a recommendation for the termination of a recall to the AA, OFO.

B. Before submitting the recommendation, RMS is to review the recall termination report from the DRO, and if a recall is associated with a reported illness:

1. ask the Office of Public Health Science (OPHS) Human Health Sciences Division (HHSD) whether any current illnesses are associated with the recalled product.

a. If data indicate that illnesses continue to occur because product remains in commerce, the recall case will remain open. RMS may request that the firm expand the recall if evidence indicates that additional products are causing illness. <

b. If data indicate that no additional illness associated with the recalled product is being reported, and there are no signs that recalled product remains in commerce, RMS may proceed to recommend closing the recall.

C. RMS's recommendation to close the recall should summarize the recall efforts by the firm and the findings of the effectiveness checks.

D. After receiving concurrence from the AA, OFO, RMS is to notify the recalling firm in writing that the recall is closed.

NOTE: FDA oversees egg product recalls in accordance with the Egg Products Inspection Act and two Memoranda of Understanding between the Department of Health and Human Services and United States Department of Agriculture (dated June 7, 1983 and February 23, 1999).

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b. Nine consignees checked have not received the Notice of Recall from the recalling firm, or its subsequent consignees, but were notified of the recall through the media. Six of the nine consignees have removed the product from sale. The remaining three consignees have identified and segregated the product awaiting shipment to the recalling firm. No product is available to the consumer.

1) Action: recall is deemed effective. No product is available to consumers.

c. Inspection program personnel find that four consignees have not received the recall notice and are still offering the product for sale. Five more consignees received the notice but have not taken the requested product action. Therefore, the product remains available to the consumer at a total of 9 locations, exceeding the critical number.

1) Action: Recall is deemed ineffective.

2) Whenever recalled product is found in commerce during an on-site verification at a consignee (or sub-consignee), the EIAO will detain any of the products on hand.

3) The EIAO will ascertain whether the business received a recall notification and instructions from the recalling firm or one of its consignees.

4) The EIAO will notify the DRO of his/her findings at the business regarding the detained product, and whether or not adequate recall instructions were received.

a. If a recall notification and product instructions were not received, the DRO will proceed as discussed below in section iv.

b. If a recall notification was received, but the consignees did not respond appropriately to the instructions of the recalling firm, the consignee may have committed an act prohibited by the FMIA or PPIA. In such cases, the DRO will immediately notify the Compliance and Investigations Division, OPEER, and the OPEER Regional Office to investigate and for follow-up legal actions in accordance with the Acts.

5) The DRO will also notify any state or local food or health authority with jurisdiction over the business involved for its appropriate follow-up action in conjunction with the FSIS, OPEER.

iv. Responding to an ineffective recall

a. If at any time during the verification of the recall, the DRO determines that the recall effort is ineffective, the DRO will notify the Director of RMS.

b. The DRO will write a letter to the recalling firm detailing the reasons why the recall has been found to be ineffective. The DRO should ask whether the recalling firm intends to act to address the situation.

c. If, after having been formally notified by FSIS of the ineffectiveness of their recall, the recalling firm is unwilling or unable to extend or modify its recall strategy, FSIS will act to mitigate the risk to the public including issuing public warnings, product seizures, or other appropriate legal and/or compliance actions in accordance with the FMIA and PPIA.

G. Verification result summaries

i. The DRO will prepare a summary of recall activities and provide it to the RMS. The focus of the summary should be to:

a. Declare the amount of product recovered, relative to the amount of product recalled, both in absolute (pounds) and relative (%) terms.

b. State, in specific terms, how the defect in the product was corrected or how the product was disposed of.

c. State the total number of effectiveness checks and disposition verification checks performed and the numbers conducted both on-site and by telephone.

d. Assign an overall effectiveness rating to the recalling firm's recall activities (effective or ineffective).

e. Determine how many consignees may still have product on sale.

f. Identify reasons for continued sale.

g. Identify other deficiencies in the firms recall process (if applicable).

h. Summarize actions taken by FSIS in the case.

ii. The summary should include a description of the corrective actions taken to correct each identified deficiency, i.e. the product removed and segregated in shipping area, re-notification was issued for all convenience stores including names of affected distributors, as applicable. The DRO will send the memo to the Director of the Recall Management Staff.