

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE

34-12

5/23/12

RESPONSIBILITIES RELATED TO RECEIVING NOTICE OF ADULTERATED OR MISBRANDED PRODUCT, AND VERIFYING WRITTEN RECALL PROCEDURES AND HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) REASSESSMENT DOCUMENTATION

I. PURPOSE

This notice informs inspection program personnel (IPP) of new requirements in the recently published [final rule](#): “Requirements for Official Establishments to Notify FSIS of Adulterated or Misbranded Product, Prepare and Maintain Written Recall Procedures, and Document Certain Hazard Analysis and Critical Control Points System Plan Reassessments” (77 FR 26929). The notice instructs IPP to make establishments aware of the requirements of the final rule and where to find information about the final rule. This notice instructs District Office (DO) personnel on how to respond when an official establishment notifies them that adulterated or misbranded product has entered commerce, as required under the final rule. It also provides instruction on how to verify that an official establishment is documenting its Hazard Analysis and Critical Control Point (HACCP) reassessments, as required by the final rule. Additional notices and instructions concerning the rule’s requirements concerning written recall procedures will be issued as necessary. The requirements concerning written recall procedures have delayed applicability dates based on establishment size.

II. BACKGROUND

A. On May 8, 2012, FSIS published the final rule “Requirements for Official Establishments to Notify FSIS of Adulterated or Misbranded Product, Prepare and Maintain Written Recall Procedures, and Document Certain Hazard Analysis and Critical Control Points System Plan Reassessments” (77 FR 26929). The rule requires official establishments to:

1. Notify the local FSIS District Office within 24 hours of learning or determining that an adulterated or misbranded meat or poultry product received by or originating from the official establishment has entered commerce (9 CFR 418.2);
2. Prepare and maintain written procedures for the recall of all meat and poultry products produced and shipped by the establishment (9 CFR 418.3);

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3. Prepare written recall procedures as required by 9 CFR 418.3 before being granted Federal inspection (9 CFR 304.3(a) and 381.22(a)); and

4. Document each reassessment of the establishment's HACCP plans (9 CFR 417.4 (a)(3)(ii)).

B. Beginning June 7, 2012, official establishments are to comply with the requirements for HACCP plan reassessment documentation and for notifying FSIS of shipment or receipt of adulterated or misbranded product. In addition, new applicants are to prepare their recall procedures before being granted Federal inspection.

C. In issuing the final rule (77 FR 26929 (May 8, 2012)), FSIS provided that existing official establishments have time to prepare written recall procedures to comply with 9 CFR 418.3.

1. Existing large establishments, defined as all establishments with 500 or more employees, are to prepare their written recall procedures by November 5, 2012.

2. Existing small establishments, defined as all establishments with 10 or more employees but fewer than 500, are to prepare their written recall procedures by May 8, 2013.

3. Existing very small establishments, defined as all establishments with fewer than 10 employees or annual sales of less than \$2.5 million, are to prepare their written recall procedures by May 8, 2013.

III. NOTIFICATION OF ADULTERATED OR MISBRANDED PRODUCT

A. Beginning June 7, 2012, official establishments are required to notify their local FSIS District Office (DO) within 24 hours of learning or determining that an adulterated or misbranded meat or poultry product received by or originating from the official establishment has entered commerce. Official establishments are to provide their DO with the type, amount, origin, and destination of the adulterated or misbranded product (9 CFR 418.2).

1. Product is in commerce if it is out of the producing establishment's direct control and is in distribution (e.g., in a warehouse, distribution center, retail facility, restaurant, or other institution).

2. The 24-hour period begins when an establishment has reason to believe that a product in commerce is adulterated or misbranded under the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA). For example, product would be adulterated if the final results of a laboratory analysis show that raw ground beef contains *E. coli* O157:H7, or if product contains an allergen that is not declared on the product label.

3. There may be situations in which laboratory results are not available, but based on epidemiological evidence, there may be a probability of harm from consuming the product. Under these circumstances, official establishments are to consider the strength of the epidemiological evidence to determine whether there is reason to believe that the product is adulterated or misbranded.

B. The DO is to notify the Recall Management Staff (RMS) as soon as possible after notification. If establishments contact other FSIS personnel, those employees are to

contact RMS promptly through supervisory channels.

IV. HACCP REASSESSMENT DOCUMENTATION

A. Official establishments are to make a record of each reassessment required by 9 CFR 417.4 (a)(3)(i). The regulations require them to document the reasons for any changes to the HACCP plan based on the reassessment or the reasons for not changing the HACCP plan based on the reassessment.

NOTE: For annual reassessments, if an official establishment determines that it does not need to make changes to its HACCP plan, it is not required to document the reasons for not changing the HACCP plan.

B. Beginning June 7, 2012, when CSIs perform a routine, HACCP Verification task in the Public Health Information System (PHIS), they may verify that the official establishment documents their HACCP reassessments. If applicable, CSIs are to check that the official establishment gives the reasons for any changes to the HACCP plan based on the reassessment or the reasons for not changing the HACCP plan based on the reassessment, unless during an annual reassessment the establishment determined that it did not need to make changes to its HACCP plan.

1. If CSIs identify that the establishment properly documented all reassessments, they are to document in PHIS that they performed the task, and that the establishment complies with the regulatory requirements.
2. If CSIs identify that the establishment reassessed the HACCP plan but did not document the reassessment, they are to document noncompliance with 9 CFR 417.4 (a)(3)(ii).

V. ADDITIONAL INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES

A. At the first weekly meeting following issuance of this notice, the inspector-in-charge is to:

1. Meet with representatives of establishment management and inform them of the requirements of the rule.
2. Tell the representatives that the following information is available on the FSIS website to help the establishment comply with the new regulatory requirements:
 - a. [Requirements for Official Establishments to Notify FSIS of Adulterated or Misbranded Product, Prepare and Maintain Written Recall Procedures, and Document Certain Hazard Analysis and Critical Control Points System Plan Reassessments](#) (77 FR 26929); and
 - b. [FSIS Directive 8080.1, Recall of Meat and Poultry Products, including Attachment 1, "Product Recall Guidelines for Firms."](#)
3. Advise the representatives that if they have any questions about the rule they can submit them through [askFSIS](#) or call 1-800-233-3935.

4. Document the meeting in PHIS in a memorandum of interview (MOI). At a minimum, the MOI is to include a list of participants in the meeting, materials provided, and items discussed with establishment management. Provide a copy of the MOI to establishment management.

VI. ASKFSIS QUESTIONS

Refer questions through [askFSIS](#). When submitting a question via askFSIS, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter **FSIS Notification, Recall Procedures, Grant of Inspection, or HACCP Reassessment Documentation**

Question Field: Enter your question with as much detail as possible.

Product Field: Select **General Inspection Policy** from the drop-down menu.

Category Field: Select **Regulations/Agency Issuances** from the drop-down menu.

Policy Arena: Select **Domestic (U.S.) Only** or **International (Import/Export)** from the drop-down menu.

When all fields are complete, press the **Submit** button.



Acting Assistant Administrator
Office of Policy and Program Development