

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

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# FSIS DIRECTIVE

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5000.8  
Rev.1

6/17/20

## VERIFYING COMPLIANCE WITH REQUIREMENTS FOR WRITTEN RECALL PLAN PROCEDURES

### I. PURPOSE

This directive provides instructions for inspection program personnel (IPP) to follow when verifying that official establishments that produce meat or poultry products establish and actively maintain the required written recall plan procedures. FSIS is reissuing this directive to include additional information on how IPP are to verify an establishment's recall plan procedures. It also provides instructions for the use of FSIS's Public Health Information System (PHIS) in the recall plan procedures verification activity and instructs IPP to verify that establishments maintain recall plan procedures while they operate under a conditional grant of inspection.

### II. CANCELLATION

FSIS Directive 5000.8, *Verifying Compliance with Requirements for Written Recall Procedures*, 12/18/2003

### III. 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](#)). Among other things, the rule requires official establishments to prepare and maintain written procedures for the recall of meat and poultry products produced and shipped by the establishment. The regulations require that the written procedures specify how the official establishment will decide whether to conduct a product recall and what the establishment will do should it decide that one is necessary ([9 CFR 418.3](#)). Official establishments are not required to submit their recall procedures to FSIS. However, they are required to make the written recall procedures available to IPP for review and copying if necessary ([9 CFR 418.4](#)).

B. Guidelines for recall plans can be found in Attachment 1 to [FSIS Directive 8080.1, Recall of Meat and Poultry Products](#), and in the [How to Develop a Meat and Poultry Product Recall Plan](#) guidebook. Establishments may use these guidelines to develop the required written procedures for recalls.

### IV. IPP RESPONSIBILITIES

A. IPP are to verify that official establishments that produce meat and poultry products have written recall procedures.

**NOTE:** In accordance with [FSIS Directive 5220.1, Granting or Refusing Inspection; Voluntary Suspending or Withdrawing Inspection; and Reinstating Inspection under the Public Health Information System](#), the FLS is to determine whether a prospective establishment has developed written recall plan procedures in

accordance with [9 CFR 418.3](#) Under this directive, the FLS will ensure that all noncompliant observations are corrected before returning required forms to the Grant Curator for the establishment to receive a conditional grant.

B. After an establishment receives a conditional grant of inspection and during the conditional period, IPP are to perform a directed Recall Plan Verification under the Other Inspection Requirements task in the PHIS to verify and document that the establishment is maintaining and is prepared to implement its written recall plan procedures.

**NOTE:** For instructions on how to schedule directed tasks in PHIS, see section X in [FSIS PHIS Directive 13000.1](#).

C. If IPP determine that an establishment has written recall plan procedures, they are to document in PHIS that they performed the task and that the establishment complies with [9 CFR 418.3](#). IPP are to update the establishment profile to indicate that the establishment has a written recall plan. IPP are to access the Other tab in the General profile section, place a check mark in the appropriate box as shown below, and click save to update the profile.

The screenshot shows the 'Other' tab selected in a navigation bar with tabs for 'Establishment', 'Ownership', 'Jurisdiction', 'Exemptions', and 'Other'. Below the navigation bar is a section titled 'Plans:' containing two questions: 'Does the establishment have a written Recall Plan?' and 'Does the establishment have a written Food Defense Plan?'. Both questions have a checked checkbox. Below this is a section titled 'Miscellaneous:' containing a dropdown menu for 'HACCP Establishment Size' set to 'Large', two text input fields for 'Latitude' and 'Longitude', and a checkbox for 'Is the establishment Outside City Corporate Limits?' which is unchecked.

D. If IPP determine that the establishment does not have written recall plan procedures, they are to document the noncompliance in PHIS on a noncompliance record, citing [9 CFR 418.3](#).

#### IV. ENFORCEMENT, INVESTIGATIONS AND ANALYSIS OFFICER (EIAO) RESPONSIBILITIES

A. When conducting food safety assessments (FSAs), EIAOs are to assess whether the establishment has written recall plan procedures that specify:

1. How the official establishment will decide whether to conduct a product recall, and
2. The procedures the official establishment will follow should it decide that one is necessary.

B. EIAOs are to follow the methodology in [FSIS Directive 5100.1](#), *Enforcement, Investigations and Analysis Officer (EIAO) Food Safety Assessment Methodology*, when assessing the establishment's written recall plan procedures.

C. If EIAOs determine that the establishment did not specify in its written recall plan procedures how it will decide whether to conduct a recall, or how it will effect a recall, they are to recommend to the in-plant

IPP's supervisor that the in-plant IPP perform a directed Other Inspection Requirements task in PHIS and document a noncompliance with [9 CFR 418.3](#)

## V. DISTRICT OFFICE RESPONSIBILITIES

District Managers are to verify establishments that have applied for grants to produce meat and poultry products have written recall plan procedures notated in their PHIS profile prior to providing final Grants of Inspection.

## VI. QUESTIONS

Refer questions regarding this directive to the Office of Policy and Program Development through [askFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter **Directive 5000.8**.  
Question Field: Enter question with as much detail as possible.  
Product Field: Select **General Inspection Policy** from the drop-down menu.  
Category Field: Select **Public Health Information System (PHIS)** from the drop-down menu.  
Policy Arena: Select **Domestic** from the drop-down menu.

When all fields are complete, press **Continue**.

**NOTE:** Refer to [FSIS Directive 5620.1](#), *Using askFSIS*, for additional information on submitting questions.



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