VERIFYING COMPLIANCE WITH REQUIREMENTS FOR WRITTEN RECALL 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 have prepared and are maintaining required written recall procedures.

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). 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.

C. FSIS previously issued many of these instructions in FSIS Notices 67-12 and 34-13. FSIS Notice 67-12 has expired, and this Directive cancels FSIS Notice 34-13.

III. IPP RESPONSIBILITIES

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

B. At least once a year, IPP are to perform a directed Other Inspection Requirements task under the Public Health Information System (PHIS) to verify that establishments have written recall procedures.

1. If IPP determine that an establishment has written recall procedures, they are to document in PHIS that they performed the task, and that the establishment complies with 9 CFR 418.3.

2. If IPP determine that the establishment does not have written recall 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 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 procedures.

C. If EIAOs determine that the establishment did not specify in its written recall 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. QUESTIONS

Refer questions regarding this directive to the Policy Development Staff 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 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 Continue.

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