

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

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# FSIS NOTICE

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67-12

11/5/12

## INSTRUCTIONS CONCERNING WRITTEN RECALL PROCEDURES AND FOOD DEFENSE PLANS

### I. PURPOSE

This notice provides instructions for inspection program personnel (IPP) to follow when verifying that large official establishments (with 500 or more employees) that produce meat and poultry products have prepared and are maintaining required written recall procedures. This notice also instructs IPP to remind large establishments of the availability of food defense plan guidance because food defense plans also facilitate the removal of adulterated products from commerce. Requirements for written recall procedures do not become effective for small and very small establishments until May 8, 2013. FSIS will issue additional instructions for IPP to verify that small and very small establishments have prepared and are maintaining written recall procedures before that future effective date.

### II. BACKGROUND

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 written procedures specify how the official establishment will decide whether to conduct a product recall and the procedures it will follow 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).

### III. WRITTEN RECALL PROCEDURES

A. The final rule established the following effective dates for requirements concerning written procedures for the recall of meat and poultry products:

1. Large establishments, defined as all establishments with 500 or more employees, are required to prepare their written recall procedures by November 5, 2012;
2. Small establishments, defined as all establishments with 10 or more employees but fewer than 500, are required to prepare their written recall procedures by May 8, 2013; and
3. Very small establishments, defined as all establishments with fewer than 10 employees or annual sales of less than \$2.5 million, are required to prepare their written recall procedures by May 8, 2013.

B. Guidelines for recall plans can be found in [Attachment 1 to FSIS Directive 8080.1](#). Establishments may use these guidelines to develop the required written procedures for recalls.

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**DISTRIBUTION:** Electronic

**NOTICE EXPIRES:** 11/1/13

**OPI:** OPPD

## **IV. FOOD DEFENSE PLANS**

A. FSIS considers food defense plans to be an important tool that can reduce the risk of intentional adulteration of food products. The Agency has developed guidelines on the food defense plans, which are available on the FSIS web site at:

[http://www.fsis.usda.gov/Food\\_Defense\\_&\\_Emergency\\_Response/Guidance\\_Materials/index.asp](http://www.fsis.usda.gov/Food_Defense_&_Emergency_Response/Guidance_Materials/index.asp).

B. Official establishments are not required to have food defense plans. The purpose of a voluntary functional food defense plan is to help establishments prepare and respond to intentional contamination of products that the establishment manufacturers. In such an event, swift removal of the adulterated materials from commerce is essential to protect the public health and welfare. One mechanism for doing this would be a recall. By having an integrated recall-food defense plan, a firm can implement either one, or both, of these measures at a moment's notice, as needed.

C. Model FSIS food defense plans are available at [http://www.fsis.usda.gov/PDF/General-Food-Defense-Plan-9-3-09%20\\_2\\_.pdf](http://www.fsis.usda.gov/PDF/General-Food-Defense-Plan-9-3-09%20_2_.pdf).

## **V. WEEKLY MEETING**

A. At large establishments (with 500 or more employees), IPP are to discuss, at the next weekly meeting, the following:

1. The requirement for large establishments to have written recall plans in place;
2. FSIS recommends that establishments have a voluntary, functional food defense plan, either independent of or integrated with written recall procedures. If IPP are aware that the establishment has a functional food defense plan, e.g., through information recorded in the PHIS establishment profile in response to the most recent Food Defense survey from summer 2013, they need not raise this recommendation at the weekly meeting; and
3. The availability of written recall procedure guidance and food defense plan guidance at the links above.

B. IPP are to document the meeting in a Public Health Information System (PHIS) Memorandum of Interview.

## **VI. VERIFYING WRITTEN RECALL PROCEDURES**

A. IPP are to verify that large establishments (with 500 or more employees) have prepared their written recall procedures.

B. To conduct this task at large establishments, IPP are to perform a directed Other Inspection Requirements task in PHIS. After initial verification of the written recall procedures, IPP are to verify, at least annually, the maintenance of the recall plans when performing a routine Other Inspection Requirement tasks.

1. If IPP determine that the establishment has prepared 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.
3. If IPP are unable to determine whether their findings represent regulatory noncompliance, they are

to discuss the issue with their supervisor before making a determination.

## VII. QUESTIONS

Refer questions regarding this notice through **askFSIS**. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter **Recall Procedures**  
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.



Assistant Administrator  
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