

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

[FDMS [Docket No. FSIS-2008-0025](#)] FR 77 Vol. 77, No. 89 /Tuesday, May 8, 2012 Pages 26929- 26937

Amendments to **§§ 304.3, 381.22, 417.4, 418.2, and 418.4** are applicable beginning **June 7, 2012**.

For the reasons discussed in the preamble, FSIS is amending **9 CFR Chapter III**, as follows:

PART 304—APPLICATION FOR INSPECTION; GRANT OF INSPECTION

In § 304.3, paragraph (a) is revised to read as follows:

§ 304.3 Conditions for receiving inspection.

(a) Before being granted Federal inspection, an establishment must have developed written sanitation Standard Operating Procedures, as required by part 416 of this chapter, **and written recall procedures as required by part 418 of this chapter.**

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

In § 381.22, paragraph (a) is revised to read as follows:

§ 381.22 Conditions for receiving inspection.

(a) Before being granted Federal inspection, an establishment must have developed written sanitation Standard Operating Procedures, as required by part 416 of this chapter, **and written recall procedures as required by part 418 of this chapter.**

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PART 417—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

In § 417.4, paragraph (a)(3) is *redesignated* as paragraph (a)(3)(i) and a new paragraph (a)(3)(ii) is added to read as follows:

§ 417.4 Validation, Verification, Reassessment.

* * * * *

(a) * * *

(3)

(i) *Reassessment of the HACCP plan.* Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with §417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of §417.2(c) of this part.

(ii) Each establishment must make a record of each reassessment required by paragraph (a)(3)(i) of this section and must 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. For annual reassessments, if the establishment determines that no changes are needed to its HACCP plan, it is not required to document the basis for this determination.

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A new part 418 is added to read as follows:

*Effective Dates for the regulations in **§ 418.3** are applicable as follows:

- In *large establishments*, defined as all establishments with 500 or more employees, **November 5, 2012**.
- In *small establishments*, defined as all establishments with 10 or more employees but fewer than 500, **May 8, 2013**.
- In *very small establishments*, defined as all establishments with fewer than 10 employees or annual sales of less than \$2.5 million, **May 8, 2013**.

PART 418—RECALLS

418.1 [Reserved]

418.2 Notification

418.3 Preparation and maintenance of written recall procedures.

418.4 Records.

Authority: 7 U.S.C. 450; 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

§ 418.1 [Reserved]

§ 418.2 Notification.

Each official establishment must promptly notify the local FSIS District Office within 24 hours of learning or determining that an adulterated or misbranded meat, meat food, poultry, or poultry product received by or originating from the official establishment has entered commerce, if the official establishment believes or has reason to believe that this has happened. The official establishment must inform the District Office of the type, amount, origin, and destination of the adulterated or misbranded product.

§ 418.3 Preparation and maintenance of written recall procedures.

* **[see above Effective Dates]**

Each official establishment must prepare and maintain written procedures for the recall of any meat, meat food, poultry, or poultry product produced and shipped by the official establishment. These written procedures must specify how the official establishment will decide whether to conduct a product recall, and how the establishment will effect the recall, should it decide that one is necessary.

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§ 418.4 Records.

All records, including records documenting procedures required by this part, must be available for official review and copying.