Changes to Reporting Requirements

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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

http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2008-0025F.pdf

Regulatory Impact

- 9 CFR 304.3 and 381.22 modified to add:
  - 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.

Regulatory Impact

- 9 CFR 417.4(a)(3)(ii) modified to add:

  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.

FAQs Reassessment

- Am I to document reassessment of the hazard analysis?
- Am I to document minor changes to the HACCP plan, such as a grammar change?
- Am I required to reassess now due to release of the Final Rule?
- Am I required to reassess every time I notify the DO that adulterated or misbranded product has been shipped?

Regulatory Impact

- 9 CFR 418 created to include:
  - 418.1 [Reserved]
  - 418.2 Notification.
  - 418.3 Preparation and maintenance of current, written recall procedures.
  - 418.4 Records.

FSIS Notice 34-12

- FSIS Notice 34-12 instructs:
  - Notify IPP to conduct awareness meeting with establishments announcing new requirements
    - Notification requirements are **effective now**
    - Reassessment requirements are **effective now**
    - Recall plans will be **staggered** implementation for existing establishments
      - Large plants: 6 months after Final Rule publishes
      - Vsmall/Small: 1 year after Final Rule publishes
    - Recall plans required immediately for new applicants for a grant of inspection

Regulatory Impact

- § 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.

FAQs about notification

- Am I to report receipt of plastic glove in combo of meat/poultry?
- Am I to report notification from one of my customers that they received meat/poultry from me that contained a piece of conveyor belt in it?
- Am I to report receipt even if I choose to recondition the product?
- Am I to report *E. coli* O157:H7 findings after receipt and further processing, e.g. during finished product verification testing of raw ground beef?

FAQs about notification

- Am I to report inaccurate net weight labeling?
- Are egg product establishments subject to the final rule?
- Are ID warehouses required to notify the DO upon receipt of adulterated/misbranded product?
- Are establishments in the same corporate structure required to notify the DO?

Regulatory Impact

- § 418.3 Preparation and maintenance of written recall procedures.
  - 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.

FAQs about recalls

- How much detail am I to include in the recall plan?
- Do I need to have a plan if I have a slaughter HACCP plan only and I sell all my products at my retail counter?
- What is meant by “effect” the recall?
- Are ID warehouses required to have recall plans?
- Where can a recall template be found?

Questions?