

# FSIS Notice 74-13

**REVIEW OF RECORDS DURING PRESHIPMENT  
REVIEW IN ESTABLISHMENTS THAT HAVE A  
HACCP PLAN (9 CFR 417.2 (c))**

# History

- When HACCP was initiated in 1998, few establishments implemented prerequisite programs
  - *FSIS' original interpretation of 9 CFR 417.5(c) did not require review of prerequisite program records.*
- HACCP plans have evolved to include many types of support (i.e., prerequisite programs) for decisions that identified food safety hazards in the hazard analysis are not reasonable likely to occur .
  - *FSIS' current interpretation of 9 CFR 417.5(c) requires review of prerequisite program records, when they are production or lot specific, during preshipment review because those records are being used as support for food safety decisions.*

# Recalls

- FSIS is aware that several recalls associated with biological or chemical food safety hazards (e.g., *E. coli*O157:H7, allergens) occurred at establishments that did not fully implement their prerequisite programs, which were identified in their hazard analysis and designed to prevent the identified hazards from occurring.
- There were failures to effectively implement well designed programs, failure to reassess process changes that impact the design of the program , and lack of ongoing maintenance of these programs.

## 9 CFR 417.5 (c)

- Requires that records “*associated with the production of that product*” (i.e. a specific production, lot) be reviewed prior to shipment of the specific production
- Could include any or all of the following:
  - HACCP monitoring records
  - HACCP verification records (only in rare instances such as product testing CCP)
  - HACCP corrective action records
  - Prerequisite program implementation records

# 9 CFR 417.5 (c)

- Does not specify how preshipment review must be conducted
  - allows flexibility for each establishment to determine what works for them
  - Can be done on a continuous basis (e.g., at each CCP)
  - Can be done in stages
  - Can be done by multiple personnel
- It will be up to the establishment determine which records need to be reviewed for their specific product
- How the records are reviewed will depend on how the establishment has developed their preshipment review procedure

# FSIS PHIS Directive 5000.1

- The Notice reiterates previously provided instruction.
  - See Chapter III, Part II, Subpart B, III, (B)(8)(e) in FSIS PHIS Directive 5000.1.

*Occasionally, when verifying HACCP implementation, CSIs are to observe the establishment employee perform the preshipment review.*
- There should already have been discussion with the immediate supervisor of how IPP are to perform this task.

# FSIS PHIS Directive 5000.1

- If preshipment review has traditionally been conducted by the plant outside their official hours of operation, IPP should have informed plant management that;
  - IPP will periodically directly observe plant employees perform preshipment review; and
  - IPP will charge reimbursable services (OT) for the inspection verification.
- Establishments may elect to conduct preshipment review during their official hours of operation.

# Prerequisite Programs

- Establishments are required as per 9 CFR 417.2 (a)(1) to conduct a hazard analysis to identify hazards that are reasonably likely to occur (RLTO) in their production process.
- As a result, establishments may determine that identified potential hazards are not reasonably likely to occur (NRLTO) because of the implementation of programs such as:
  - Sanitation Standard Operating Procedures
  - Other prerequisite programs such as;
    - Product purchase specifications;
    - Water activity values;
    - Environmental storage temperatures; and
    - Good Manufacturing Practices (GMP).

# Additional Programs & activities

- A number of programs procedures are not traditionally associated with a specific production of product, for example;
  - SSOPs - addressed in 9 CFR 416.11 through 9 CFR 416.16
  - Pest control programs - addressed in 9 CFR 4176.2(a)
  - Calibration of process monitoring equipment - 9 CFR 417.4(a)
- Records associated with these types of programs would not typically be reviewed as part of the preshipment review procedure.

# Posted askFSIS Q & As (dated 12/3/2013)

- Multiple askFSIS Q&As are posted associated with:
- Implementation,
- Multiple Preshipment Reviews
- Review of Testing Results
- Sanitation SOP Records
- Extent of Records to be Reviewed
- Documenting Noncompliance
- 9 CFR 417.5(a)(1) and 9 CFR 417.5(c)

[http://askfsis.custhelp.com/app/answers/list/p/o/c/o/kw/FSIS Notice 74-13](http://askfsis.custhelp.com/app/answers/list/p/o/c/o/kw/FSIS%20Notice%2074-13)

# Using askFSIS

- Customers can submit additional questions through askFSIS by following the instructions in Section IV of the Notice:
  - Subject Field: Enter **Notice 74-13**
  - 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 **HACCP** from the drop-down menu.
  - Policy Arena: Select **Domestic (U.S. Only)** from the drop-down menu.

***NOTE: Following these instructions is very important in order for the questions go to the proper staff for a timely response and for future trend analysis***

# REMEMBER...

- IPP are to observe the establishment perform the preshipment review procedure . The is consistent with current policy.
- The focal point of the notice is review of records associated with a specific production.
- It is the establishments decision to determine the method to ensure, during the preshipment review, that all records associated with a specific production are available and have been reviewed.