Recordkeeping Requirements

EIAO Training

Objectives

Upon completion of this module, you will be able to:

- Describe the purpose of HACCP records.
- List HACCP records that are required under 9 CFR 417.5.

Methodology

- To verify review these required records:
  - HACCP plan
  - HACCP records
  - Hazard analysis
  - Supporting documentation
  - Decision-making documents

Regulations

- 417.2(c)(6) Recordkeeping system
- 417.5(a)(1), 417.5(a)(2) Supporting documentation
- 417.5(a)(3) HACCP records
- 417.5(b) Record authenticity
- 417.5(d) Computerized records
- 417.5(e)(1)(2) Record retention/availability
- 417.5(c) Pre-shipment review

Recordkeeping System

Recordkeeping System

- 9 CFR 417.2(c)(6) Recordkeeping System
  - The HACCP plan shall, at a minimum provide for a recordkeeping system that documents the monitoring of the critical control points.
  - The records shall contain the actual values and observations obtained during monitoring.

Gather Information

- Does the HACCP plan set out a recordkeeping system that documents the monitoring of the CCP(s)?

- Do the records contain actual values or observations obtained during monitoring?

Supporting Documentation

Supporting Documentation

- 9 CFR 417.5(a)(1)(2)
- (a) The establishment shall maintain the following records documenting the establishment's HACCP plan:
- (1) The written hazard analysis prescribed in Sec. 417.2(a) of this part, including all supporting documentation
- (2) The written HACCP plan, including decision-making documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

Gather Information

- Does the establishment have supporting documentation for decisions made in the hazard analysis?

- Does the establishment have the decision making documents associated with selection of each CCP?

Gather Information

- Do documents explain why the establishment selected that location for the CCP?

- Is there a control at the identified point in the process to prevent, eliminate or reduce identified hazards?

Gather Information

- Does the establishment have scientific, technical, or regulatory support for a critical limit?
- Does the support appear credible?
- Does the establishment have documents supporting monitoring procedures & frequencies?

Gather Information

- Does the establishment have documents supporting the verification procedures and frequencies listed in the HACCP plan?

- If the establishment has supporting documents for these decisions, does the documentation support the decisions?

Supporting Documentation

- Scientific journal articles
- Regulations
- Pathogen modeling
- Processing authority
- Research
- Historical data

Pop Quiz

- What is the difference between the requirements in 417.5(a)(1) and 417.5(a)(2)?

Validation of the HACCP System

- Reminder!
- Validation of the HACCP system and support for decisions in the hazard analysis are closely related.
- Example
  - Failure to demonstrate the effectiveness of a prerequisite program may lead to lack of support for a decision in the hazard analysis.

Example - Regulatory Thought Process

- Noncompliance with validation requirements of 417.4(a)

May lead to the determination that:

No scientific or technical support for a decision in the hazard analysis or for a CCP and thus there is noncompliance with 417.5(a)(1)

417.5(a)(1) Noncompliance Regulatory Thought Process

417.5(a)(1) Noncompliance – Failure to support decisions in the hazard analysis

417.2(a)(1) Noncompliance – Failed to identify all hazards because of an inadequate hazard analysis

417.6(a) – Inadequate system Not meeting HACCP requirements

417.5(a)(1) Noncompliance Regulatory Thought Process

- A raw ground beef plant makes a decision that *E. coli* O157:H7 is not likely to occur and references a purchase spec. program which requires LOG's from each supplier and COA's for each incoming load of trimmings. Records show that one supplier's COA's only references APC results with no reference to *E. coli* O157:H7.

417.5(a)(1) Noncompliance Regulatory Thought Process

- If the plant cannot provide additional information related to measures taken to assure food safety and support the decisions in the HA it would lead to a determination of noncompliance with 417.5(a)(1) and thus noncompliance with 417.2 and leading to a determination of an inadequate HACCP system according to 417.6(a).

HACCP Records Requirement

HACCP Records Requirement

- 417.5(a)(3) HACCP Records – The establishment shall maintain –
  - Records documenting the monitoring of CCP's and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan;
  - The calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation
  - Verification procedures and results;
  - Product code(s), product name or identity, or slaughter production lot.
  - Each of these records shall include the date the record was made.

Gather Information

- Do the records document monitoring of CCPs and CLs?

- Do the records include actual times, temperatures, or other quantifiable values described in the HACCP plan?

Gather Information

- Do monitoring, verification, and corrective action records include product codes, product name or identity, or slaughter production lot, and the date the record was made?

- Are verification procedures and the results documented?

Gather Information

- Is the time recorded when the verification activity was performed?
- Do the records contain the date the record was made?
- Are the process-monitoring calibration procedures and results being recorded?

Pop Quiz – Is this record in compliance?

Date	Lot No.	Time	Solution Conc.	Pressure	Corrective Actions	Monitored by	Verified by *
2-1-2003	**1**	**0730**	**OK**	**30psi**	**-**	**TDM**	**PP**

***direct observation verification-results as per HACCP plan**

Pop Quiz – Is this record in compliance?

Thermometer Calibration Log
Calibrate to 32 degrees F. in slush ice water

Date	Time	Area	Therm.ID	Personal Therm. Reading	Adjustment Required	Initials	Comment
3-1-2003		Carcass Chilling	2A	32	No	TDM	

Pop Quiz – Is this record in compliance?

Chicken Carcass Fecal Reprocessing Log 4-12-2003					
Time	Product ID	Results	Monitor Initials	Verifier Initials	Corrective Actions or Comments
0645	Lot 1	0	TDM		
0750	Lot 1	0	TDM	GW*	
0840	Lot 4	0	PP		
* Direct Observation verification-results per HACCP plan					

Record Authenticity

Records Authenticity

- 417.5(b) Records Authenticity
  - Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.

Gather Information

- Was each entry on the record made at the time the event occurred?
- Does each entry include the time?
- Was each entry on the record signed or initialed by the establishment employee making the entry?
- Does each record include the date?

Pop Quiz

- You observe a monitoring person perform a zero tolerance check and go about other duties without writing down the results. You come back 1 hour later and find the check documented. Is there any noncompliance here?

Pop Quiz

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Yes, the result was not recorded at the time performed.

Computerized Records

Computerized Records

- 417.5(d) Computerized Records
  - Records maintained on computers. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

Gather Information

- Are appropriate controls provided to ensure the integrity of electronic data and signatures?

Record Retention and Availability

Record Retention/Availability

- 417.5(e)(1) and (2)
  - 1 year for slaughter or refrigerated
  - 2 years for frozen
  - Off-site storage after 6 months
  - Presented within 24 hours after the 6 months

Gather Information

- Are the records being maintained for the required amount of time?
- Are the records kept on site for 6 months?
- If the records are stored off-site after 6 months, can they be retrieved in 24 hours?

Pre-shipment Review

Pre-shipment Review

- 417.5(c)
- Product considered “produced and shipped” once this occurs
- Perform review and observation occasionally

Other Locations

- The pre-shipment review can be accomplished if the product is at a location other than the producing establishment
  - Review must occur before the product leaves the control of the producing establishment

Gather Information

- Has the establishment reviewed the records associated with the production of the product prior to shipment?

- Has the pre-shipment review been signed and dated by an establishment employee?

Pop Quiz

- If you are unable to determine if the plant performed a pre-shipment review how should you proceed?

Records Misrepresentation

- Do not discuss with plant
- Document on a memo to file
- Call DO on secure phone

QUESTIONS?

Recordkeeping Workshop

- A livestock slaughter establishment has a CCP for a hot water rinse to control pathogens but has no supporting documentation for the critical limit.
- What would be your regulatory-statutory thought process for a possible enforcement action if the safety of the product is in question?