

HACCP Verification Task Documentation Workshop: Holland Point Foods

General Instructions

Work through this workshop as a group. Select a group leader. The leader should monitor the time and focus of the group, and ensure the discussion involves each member of the group. Keep notes on what the group decides should be recorded in PHIS.

The Inspection Method

Today you, Robert Barclay, have a routine Fully Cooked-Not Shelf Stable HACCP verification task scheduled at Holland Point Foods P44925 on the task calendar (**Note:** If a Fully Cooked, Not Shelf Stable task is not on the calendar, please add one to the task calendar). The establishment has one Deli Meat HACCP plan that covers the oven roasted/smoked fully cooked turkey breast production process. In addition, you know that this product is not post-lethality exposed to the processing environment because it is cooked in an impermeable bag, chilled in the bag, and shipped under refrigeration.

You decide to use the recordkeeping component to verify the monitoring, verification, and recordkeeping requirements at each CCP by reviewing the records from yesterday's production. You know from previous experience that this establishment defines specific production as shift's production. You proceed to the HACCP Coordinator's office, and request the HACCP plan and associated HACCP records from Mr. Mike Adams. Mr. Adams provides one notebook binder labeled *HACCP Plan*, which includes the flow chart, hazard analysis, HACCP plan, and supporting documentation for the HACCP plan. He also gives you another binder identified *HACCP Records*.

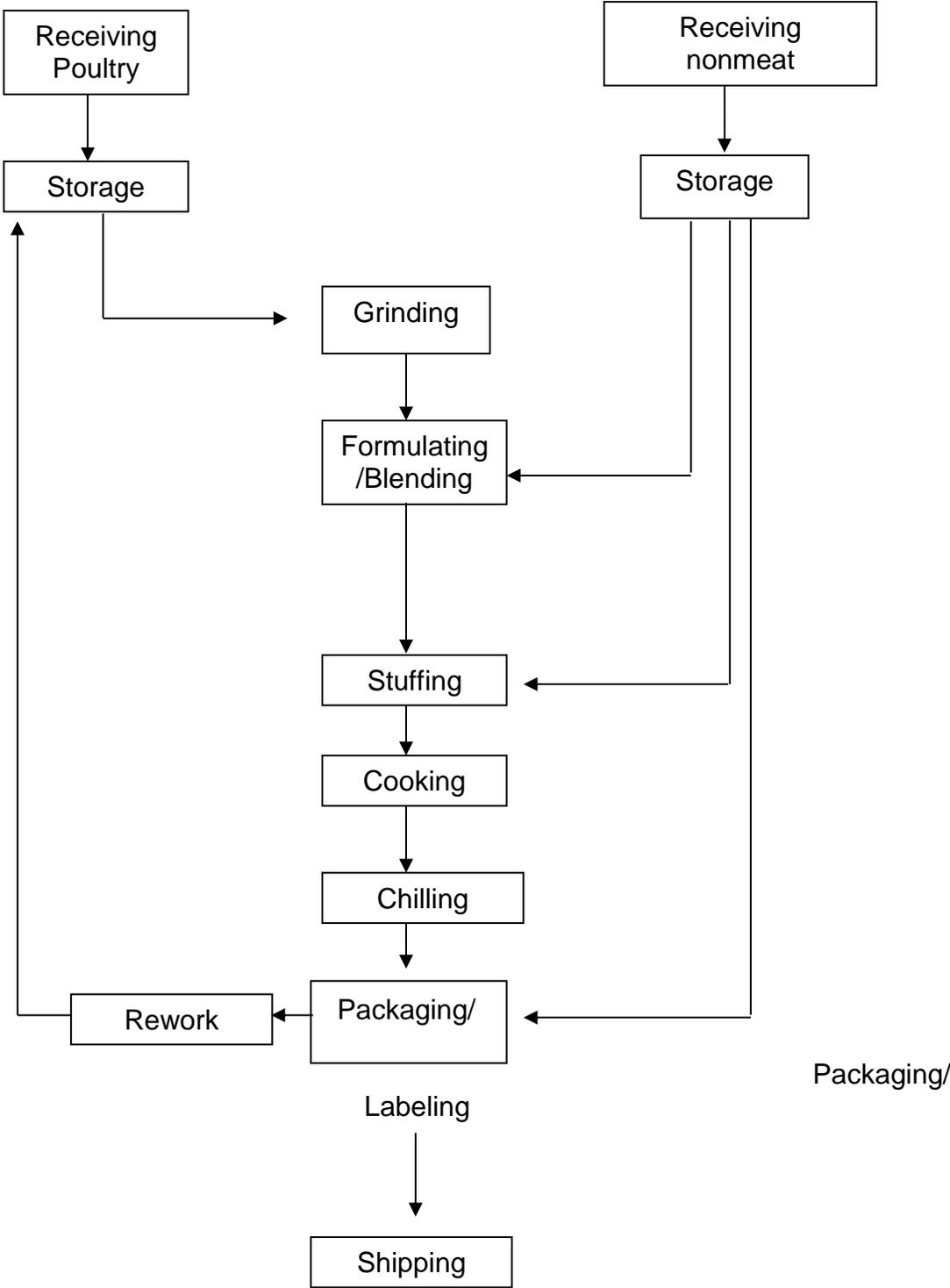
You also realize that before you can complete this task, you need to verify the implementation of the establishment's prerequisite programs and other documentation used to support the decision that **a particular hazard is not reasonably likely to occur (NRLTO)** in the specific production. Therefore, you tell Mr. Adams that you will need to review the written prerequisite programs and the records from implementing the program and any other records. He provides you with another binder labeled *Prerequisite Program & Implementation Records*. At 9:10 a.m., you sit down at a table in the adjoining office, and begin your review. The flow chart, hazard analysis, HACCP plan and HACCP records are on the following pages.

NOTE: While you were reviewing the HACCP records, you noticed that there were no corrective actions associated with this specific production so you cannot verify 9 CFR 417.3 because it is not applicable.

Each group is to:

- Review the flow chart, hazard analysis, HACCP plan and HACCP records provided
- Use the gather, access and determine (GAD) regulatory thought process demonstrated in the training, and the inspection tools on pages 18-20 (Tables 1–3) and the HACCP regulations (9 CFR 417) on pages 21–27 of this handout to verify compliance with the following regulatory requirements:
 - 417.2(c)(4)(5)(6)(7)
 - 417.4(a)(2)(i)(ii)(iii); 417.5(a)(1)(2)(3)
 - 417.5(b), and 417.5(c)
- Identify any prerequisite programs or supporting documentation that you would need to verify before completing the task.
- List the type of information and the concerns you are wanting addressed if more information is needed to verify compliance.

PROCESSING CATEGORY: Fully Cooked, Not Shelf Stable
Flow Diagram for Oven Roasted/Smoked Turkey Breast



HAZARD ANALYSIS – FULLY COOKED, NOT SHELF STABLE

Process step	Food safety hazard	Reasonably likely to occur?	Basis	If Yes in column 3, what measures could be applied to prevent, eliminate or reduce the hazard to an acceptable level?
Receiving – Poultry	Biological – <i>Salmonella</i> <i>L. monocytogenes</i> <i>Campylobacter</i> <i>C. perfringens</i> Chemical – None Physical – None	Yes	It is known that these pathogens are reasonably likely to occur in the poultry received.	Product will be stored at a temperature to preclude proliferation of these pathogens. These pathogens will be eliminated or reduced to an acceptable level during the cooking step.
Receiving – Nonmeat Ingredients	Biological – None Chemical – Not acceptable for intended use Physical – Foreign material	No	Letters of guaranty are received from all suppliers of nonmeat ingredients. Historical data demonstrates that no foreign material in nonmeat ingredients received.	

HAZARD ANALYSIS – FULLY COOKED, NOT SHELF STABLE

Process step	Food safety hazard	Reasonably likely to occur?	Basis	If Yes in column 3, what measures could be applied to prevent, eliminate or reduce the hazard to an acceptable level?
Storage – Poultry Storage - Nonmeat Grinding	Biological – Pathogens Chemical – none Physical – None Biological – None Chemical – None Physical – None Biological – None Chemical – None Physical – None	Yes	Pathogen proliferation is likely to occur in this product if temperature is not maintained at or below a level sufficient to preclude the proliferation.	Maintain product temperature at or below a level sufficient to preclude pathogen proliferation. Pathogens will be eliminated or reduced to an acceptable level at the cooking step.

HACCP PLAN

CCP DESCRIPTION, CRITICAL LIMITS, MONITORING PROCEDURES, CORRECTIVE ACTION(S)

PROCESSING CATEGORY: FULLY COOKED, NOT SHELF STABLE					
PRODUCT: Oven Roasted/Smoked Fabricated Turkey Breasts					
CCP # and Location	Critical Limits	Monitoring Procedures and Frequencies	HACCP Records	Verification Procedures and Frequencies	Corrective Action(s)
Cooking CCP # 1	Internal cooked product temperature will be $\geq 160^{\circ}\text{F}$	The smokehouse operator will measure the internal temperature of two pieces of product at the cold spots in each oven of product cooked using a hand held probe thermometer.	Cooking log Thermometer calibration log Corrective action log	Once per shift the smokehouse supervisor will measure the internal temperature of 2 pieces of product at the conclusion of the cooking process. Smokehouse supervisor will review Cooking logs daily. QA Manager will review the Thermometer calibration log once per week and Corrective Action log in each occurrence.	If a deviation from a critical limit occurs, the smokehouse supervisor will retain the product involved in the deviation and notify the QA Manager. The QA Manager will be responsible for the corrective actions meeting the requirements of 417.3(a).

Signature: Mike Adams

Date: 5-20-2011

Reassessed by: Mike Adams

Date: 1-25-2016

HACCP PLAN

CCP DESCRIPTION, CRITICAL LIMITS, MONITORING PROCEDURES, CORRECTIVE ACTION(S)

PROCESSING CATEGORY: FULLY COOKED, NOT SHELF STABLE					
PRODUCT: Oven Roasted/Smoked Fabricated Turkey Breasts					
CCP # and Location	Critical Limits	Monitoring Procedures and Frequencies	HACCP Records	Verification Procedures and Frequencies	Corrective Action(s)
Chilling CCP # 2	Product will be chilled from an internal temperature of 130°F to 80°F in 90 minutes and from 80°F to 40°F or less in 5 hours or less.	Oven operator will measure the internal temperature, using a hand-held thermometer, of 2 pieces of product at the time they are placed into the cooler and record the results on the chilling log. Hourly the QA technician will measure the internal temperature of 2 pieces of product from each oven of product in the cooler to ensure limit is met.	Chilling log Thermometer calibration log Corrective Action log	Daily, before operation, QA will check the hand-held thermometers used for measuring internal product temperatures and calibrate them within 2°F of an instrument of known accuracy. QA Manager will review chilling records daily, the Thermometer calibration log once per week, and Corrective Action log in each occurrence. Once per shift the packaging supervisor will observe the QA technician perform the monitoring activity.	If a deviation from a critical limit occurs, the QA technician will retain the product involved in the deviation and notify the QA Manager. The QA Manager will be responsible for the corrective actions meeting the requirements of 417.3(a).

Cooking Log

Date: 2-8-16

Critical limit: Product will be cooked to $\geq 160^\circ$ F

Product ID	Lot Number	Oven	Time	Temperature	Comments	Monitor's Initials	Verification Initials
ORBR	1-62	1	8:47 am	162°, 166°		JE	
ORBR	2-62	2	10:23 am	164°, 168°		JE	GG
		2-8-16	4:30 pm		Reviewed cooking log-record completed as per the HACCP plan.		MG

Chilling Log

Date: 2-8-16 Critical limit: Product will be chilled from 130° F to 80° F in ≤ 90 minutes and from 80° F to 40° F in ≤ 5 hours

Product ID	Lot Number	Time entered cooler	Temperature	Time	Comments	Monitor's Initials	Verification Initials
ORBR	1-62	10:05 am	98°, 99°			JE	
ORBR	1-62		77°, 78°	10:59 am		QA	
ORBR	1-62		67°, 65°	12:01 pm		QA	
ORBR	1-62		56°, 54°	12:56 pm		QA	
ORBR	1-62		44°, 46°	1:59 pm		QA	
ORBR	1-62		39°, 38°	2:50 pm	Observed monitoring activity	QA	PS
ORBR	2-62	11:28 am	100°, 98°			DF	
ORBR	2-62		80°, 78°	12:25 pm		SA	
ORBR	2-62		66°, 64°	1:23 pm		SA	
ORBR	2-62		54°, 52°	2:15 pm		SA	
ORBR	2-62		40°, 38°	3:18 pm	Observed monitoring activity	SA	SS
			2-8-16	3:45 pm	Reviewed chilling log-record completed as per the HACCP plan.		PG

Pre-shipment Review Log

Product ID: 1-62 and 2-62

Were monitoring records for CCP #1 complete? Yes

Were scheduled verification activities completed? Yes

Were there any deviations to the critical limit? No

If there were deviations, was appropriate corrective action taken? _____

Were monitoring records for CCP #2 complete? Yes

Were scheduled verification activities completed? Yes

Were there any deviations to the critical limit? No

If there were deviations, was appropriate corrective action taken? _____

Comments:

Reviewed by: Mike Adams

Date: 2-8-16

THERMOMETER CALIBRATION LOG								
Criteria Within $\pm 2^\circ$ F of Control Thermometer								
Date	Time	Department or Area	Thermometer ID#	Control Thermometer Reading	Personal Thermometer Reading	Adjustment Required (Yes or No)	Initials	Comments
2-8-16	6:00 am	Cooking	T-1	140°	140°	No	KM	
2-8-16	6:05 am	QA	T-2	40°	40°	No	KM	
2-8-16	6:07 am	Packaging	T-4	40°	39°	No	KM	
2-8-16	6:10 am	Formulation	T-3	40°	40°	No	KM	
2-8-16	6:15 am	Smokehouse Supervisor	T-5	140°	137°	Yes	KM	

If a thermometer is broken or taken out of service, document this in the comment column.

Reviewed by: _____

Date: _____

Supporting Data for Meeting Stabilization Performance Standard

Establishment P44925 normally showers the cooked product for an hour after the product has completed the cook cycle. The establishment gathered data by using data tracers in the product during the shower cycle in order to gather the information necessary to determine how they could meet the stabilization critical limit in their HACCP plan for fully cooked, not shelf stable products. The company has records showing that 45 minutes of showering will drop the internal temperature of the product to 130°F. The temperature recorded on the chilling record in the “time entered cooler” column represents the temperature of the product after the completion of the one-hour shower. Therefore, 15 minutes of the shower time must be included as part of the stabilization step in reducing the product temperature from 130 to 80°F.

Document Inspection Results in PHIS

Working independently, log back into the PHIS computer and document the inspection results you identified in the workshop questions into PHIS. You will:

- Document the results of the Fully Cooked, Not Shelf Stable HACCP verification task,
- If noncompliance was found, document the noncompliance on an NR, and
- Associate the NR if a noncompliance with the same cause has been documented

Use the following instructions as needed to get started in PHIS. If you need further instructions, consult the PHIS Quick Reference Guide.

Logging in to PHIS

1. Log-in as:

- User Name: ***FSIS_user***
- Password: ***FSIS***

2. If needed, start Internet Explorer using the Icon on upper left of the desktop:

- Double click the Internet explorer () icon
- PHIS comes up. Log In as:
 - User name: **Robert Barclay (your #)**
 - Do Not Click the “Create User Account” button

Add the HACCP Verification Task to the Task Calendar

Note: First, look at your task calendar for today. Do you have a routine Fully Cooked, Not Shelf Stable HACCP verification task scheduled? If not, follow these steps to add the task.

1. Left click on “**Task Calendar**” from the Navigation menu on the Home page, then left click the “**down arrow**” in the box next to “select establishment” and select “**Holland Point Foods**”
2. Left click and hold on the slider bar to the right of the “**Establishment Task List**” panel, scroll through the list until you find a routine **Fully Cooked, Not Shelf Stable HACCP verification task** with the appropriate start and end dates

3. Find the “**Routine**” column for the task, and then left click on the “**Add**” link for the Fully Cooked, Not Shelf Stable HACCP verification task
4. In the pop-up box, **Type Today’s Date** in the Start Date box or use the calendar icon to select today’s date and left click on the “**Save**” button

Initiate/Claim the HACCP Verification Task

1. Scroll down to the “**Task Calendar**” panel, left click the “**down arrow**” in the box next to “Establishment” that has the word “all” and select “**Holland Point Foods**”
2. Find today’s date and the “**Fully Cooked, Not Shelf Stable HACCP verification task**” that you just added
3. Right click on the “**Fully Cooked, Not Shelf Stable HACCP verification task**” on the calendar
4. Highlight and left click “**Document**”
5. Left click on the “**Activity tab**”, and left click the “**radio button**” in front of the word “**Recordkeeping**” for the verification activity
6. Left click on the “**Regulations tab**” to determine the mandatory regulations that must be verified
7. Scroll down and left click on the “**save**” button
8. Left click on the “**close** button”

Documenting the HACCP Verification Task Results

1. Scroll down to the “**Task Calendar**” panel, left click the “**down arrow**” in the box next to “Establishment” that has the word “all” and select “**Holland Point Foods**”
2. Right click on the “**Fully Cooked, Not Shelf Stable HACCP verification task**” on the calendar
3. Highlight and left click “**Document**”
4. After the inspection results page opens, enter your inspection results
 - Enter the mandatory regulations and any other regulations you verified,
 - If noncompliance was found, document the noncompliance on an NR, and
 - Finalize the noncompliance after checking for recent NRs with same cause.

Summary – Verifying the HACCP Regulatory Requirements

Table 1 below summarizes the Steps that IPP perform during the HACCP verification task. **Table 2** and **Table 3** on the following pages provide a quick reference for the questions that IPP should seek answers to when verifying each of the HACCP Implementation regulatory requirements.

**Table 1
 HACCP Verification Task Summary**

Step 1: Select Product Type and Specific Production	Select product type within the process category	Ensure all product types within process category are verified over time.
	Select specific production.	Select product type that the est. is currently producing.
	Verify all HACCP regulatory requirements at each CCP by following Steps 3-9	
Step 2: Review the HACCP Plan for the Selected Product Type	Understand the monitoring and verification procedures and frequencies	
	Note the most recent signature date (must be entered into PHIS)	417.2(d)
	Note changes to the HACCP plan and update the establishment profile	
Step 3: Verify Monitoring	Per Directive 5000.1	417.2(c)(4)
Step 4: Verify Verification	Per Directive 5000.1	417.2(c)(7), 417.4(a)(2)(i)(ii)(iii)
Step 5: Verify Recordkeeping	Per Directive 5000.1	417.2(c)(6), 417.5(a)(3), 417.5(b), 417.5(d), 417.5(e)(1), 417.5(e)(2), 417.5(f)-Note: contact supervisor if records are not made available
Step 6: Verify Implementation of Prerequisite program (PRP)/Other Control Measures Used to Support Hazards Not Reasonably Likely to Occur (NRLTO)	Per Directive 5000.1	417.5(a)(1)
	Review PRP records for the specific production, Observe program implementation, Verify implemented as written, and Verify records continue to support decision that hazard is NRLTO	Contact supervisor if records are not made available per 417.5(f)
	Consider whether implemented in a manner that supports the Hazard Analysis decisions	
	Contact supervisor if uncertain whether implementation or records support the decision in the Hazard Analysis	
Step 7: Verify Corrective Action (CA)	Per Directive 5000.1 Initiate a directed HACCP verification task to verify CA when no routine HACCP verification task is available	417.5(c), 417.3(a), 417.3(b)
Step 8: Verify Pre-shipment Review	Per Directive 5000.1	417.5(c)
Step 9: Consider the Implications of any noncompliance	Document findings of compliance and noncompliance. Associate any previous noncompliances. Use systems based thinking per Directive 5000.1	417.6

If IPP find that adulterated product may have entered commerce, they are to notify the DO personnel through supervisory channels immediately.

Table 2—Monitoring, Verification, and Recordkeeping Requirements

Step 3 Monitoring	Step 4 Verification	Step 5 Recordkeeping
<p><u>9 CFR 417.2(c)(4)</u></p> <p>1. Does the HACCP plan list the monitoring procedures and frequencies that are used to monitor each of the CCP to ensure compliance with the critical limits?</p> <p>2. Are the monitoring procedures being performed as described in the HACCP plan?</p> <p>3. Are the monitoring procedures being performed at the frequencies for the CCP listed in the HACCP plan?</p> <p>4. Are the CL met?</p>	<p><u>9 CFR 417.2(c)(7) 417.4(a)(2)(i)(ii)(iii)</u></p> <p>1. Does the HACCP plan contain procedures and frequencies for the calibration of the process-monitoring instruments?</p> <p>2. Does the HACCP plan contain procedures and frequencies for direct observations of monitoring activities & corrective actions?</p> <p>3. Does the HACCP plan list procedures and frequencies for the review of records generated and maintained in accordance with 9 CFR 417.5(a)(3)?</p> <p>4. Does the HACCP plan list product sampling as a verification activity?</p> <p>5. Are process-monitoring instrument calibration activities conducted as per the HACCP plan?</p> <p>6. Are direct observation verification activities conducted as per the HACCP plan?</p> <p>7. Are records generated in accordance with 9 CFR 417.5(a)(3) being reviewed by the establishment?</p>	<p><u>Recordkeeping Requirement – 9 CFR 417.2(c)(6)</u></p> <p>1. Does the HACCP plan set out a recordkeeping system that documents the monitoring of the CCP?</p> <p>2. Do the records contain actual values & observations obtained during monitoring?</p> <p><u>HACCP Records Requirement – 9 CFR 417.5(a)(3)</u></p> <p>1. Do the records document the monitoring of CCP and critical limits?</p> <p>2. Do the records include actual times, temperatures, or other quantifiable values, as prescribed in the establishment’s HACCP plan?</p> <p>3. Do the monitoring, verification, and corrective action records include product codes, product name or identity, or slaughter production lot, and the date each record was made?</p> <p>4. Are verification procedures and results documented?</p> <p>5. Is the time recorded when the verification activity was performed?</p> <p>6. Does the record contain the date the record was made?</p> <p>7. Are process-monitoring calibration procedures & results recorded?</p> <p><u>Records Authenticity Requirement – 9 CFR 417.5(b)</u></p> <p>1. Was each entry on the record made at the time the event occurred?</p> <p>2. Does each entry include the time?</p> <p>3. Was each entry on the record signed or initialed by the establishment employee making the entry?</p> <p>4. Does each record include the date?</p> <p><u>Computerized Records Requirement – 9 CFR 417.5(d)</u></p> <p>Are appropriate controls provided to ensure integrity of electronic data and signatures?</p> <p><u>Record Retention and Availability Requirement – 9 CFR 417.5(e)(1) and (2)</u></p> <p>1. Are the records being maintained for the required amount of time, i.e., one year for slaughter and refrigerated products and two years for frozen, preserved, or shelf-stable products?</p> <p>2. Are the records kept on-site for 6 months?</p> <p>3. If the records are stored off-site, can they be retrieved in 24 hours?</p> <p><u>Official Review of Records – 9 CFR 417.5(f)</u></p> <p>Are all records, plans, and procedures required by Part 417 available for official review?</p>

Table 3- Prerequisite Program Implementation, Corrective Action and Pre-shipment Review Requirements

<p>Step 6 Prerequisite Program Implementation</p>	<p>Step 7 Corrective Actions</p>	<p>Step 8 Pre-shipment Review</p>
<p><u>Supporting Documentation Requirement – 9 CFR 417.5(a)1</u></p> <p>1. Is the establishment implementing the procedures in the program as written?</p> <p>2. Does the establishment maintain records to support the implementation of the program, including verification records and results from outside auditors?</p> <p>3. Do the records show that the prerequisite program continues to support the decision that the relevant hazard is not reasonably likely to occur on an ongoing basis</p>	<p><u>Corrective actions in response to a deviation from a critical limit – 9 CFR 417.3(a)</u></p> <p>1. Did the establishment identify and eliminate the cause of the deviation?</p> <p>2. Did the corrective actions ensure that the CCP is brought under control?</p> <p>3. Were measures implemented to prevent recurrence of the deviation?</p> <p>4. Did the actions ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce?</p> <p><u>Corrective Actions in Response to a Deviation Not Covered by a Specific Corrective Action or an Unforeseen Hazard – 9CFR 417.3(b)</u></p> <p>1. Did the establishment segregate and hold all affected product?</p> <p>2. Did the establishment perform a review to determine the acceptability of the affected product for distribution?</p> <p>3. Did the establishment take necessary action with respect to the affected product to ensure that no product that is injurious to health, or otherwise adulterated as a result of the deviation, enters commerce?</p> <p>4. Was a reassessment conducted to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan?</p>	<p><u>Pre-shipment Review Requirement – 9 CFR 417.5(c)</u></p> <p>1. Has the establishment reviewed the records associated with the production of the product, prior to shipment?</p> <p>2. Has the pre-shipment review been signed and dated by an establishment employee?</p> <hr/> <p>Step 9 Consider the Implications of any noncompliance and Document</p> <p>1. Is there a pattern of repeated failure to implement the HACCP procedures as written?</p> <p>2. Is there reason to believe that the establishment’s food safety system is not effectively preventing or controlling the applicable food safety hazards?</p> <p>3. Has product been prepared, packed, or held under insanitary conditions where it may have become contaminated with filth or rendered injurious to health?</p> <p>4. Has the establishment produced adulterated products or shipped adulterated products in commerce?</p>

Note: The Corrective Action requirement is verified at **each occurrence**. For example, when the IPP is performing the HACCP verification task and the IPP notices that the establishment had a deviation from a critical limit, the IPP would verify that the corrective action requirements had been met.

9 CFR Part 417--Hazard Analysis and Critical Control Point (HACCP) Systems

Sections:

- 417.1 Definitions.
- 417.2 Hazard Analysis and HACCP plan.
- 417.3 Corrective actions.
- 417.4 Validation, Verification, Reassessment.
- 417.5 Records.
- 417.6 Inadequate HACCP Systems.
- 417.7 Training.
- 417.8 Agency verification.

Authority: 7 U.S.C. 450; 21 U.S.C. 451-470, 601-695; 7 U.S.C. 1901-1906; 7 CFR 2.18, 2.53. Source: 61 FR 38868, July 25, 1996, unless otherwise noted.

Sec. 417.1 Definitions.

For purposes of this part, the following definitions shall apply:

Corrective action - Procedures to be followed when a deviation occurs.

Critical control point - A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical limit- The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Food safety hazard- Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

HACCP System- The HACCP plan in operation, including the HACCP plan itself.

Hazard - SEE Food Safety Hazard.

Preventive measure - Physical, chemical, or other means that can be used to control an identified food safety hazard.

Process-monitoring instrument - An instrument or device used to indicate conditions during processing at a critical control point.

Responsible establishment official-The individual with overall authority on-site or a higher level official of the establishment.

Sec. 417.2 Hazard Analysis and HACCP Plan.

(a) *Hazard analysis.* (1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would

establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.

(2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.

(3) Food safety hazards might be expected to arise from the following:

- (i) Natural toxins;
- (ii) Microbiological contamination;
- (iii) Chemical contamination;
- (iv) Pesticides;
- (v) Drug residues;
- (vi) Zoonotic diseases;
- (vii) Decomposition;
- (viii) Parasites;
- (ix) Unapproved use of direct or indirect food or color additives; and
- (x) Physical hazards.

(b) *The HACCP plan.* (1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:

- (i) Slaughter--all species.
- (ii) Raw product--ground.
- (iii) Raw product--not ground.
- (iv) Thermally processed--commercially sterile.
- (v) Not heat treated--shelf-stable.
- (vi) Heat treated--shelf-stable.
- (vii) Fully cooked--not shelf-stable.
- (viii) Heat treated but not fully cooked--not shelf-stable.
- (ix) Product with secondary inhibitors--not shelf-stable.

(2) A single HACCP plan may encompass multiple products within a single processing category identified in this paragraph, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and are observed in practice.

(3) HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of part 318, subpart G, or part 381, subpart X, of this chapter.

(c) *The contents of the HACCP plan.* The HACCP plan shall, at a minimum:

(1) List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.

(2) List the critical control points for each of the identified food safety hazards, including, as appropriate:

- (i) Critical control points designed to control food safety hazards that could be introduced in the establishment, and
 - (ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;
 - (3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;
 - (4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;
 - (5) Include all corrective actions that have been developed in accordance with Sec. 417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point; and
 - (6) 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.
 - (7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with Sec. 417.4 of this part.
- (d) *Signing and dating the HACCP plan.* (1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.
- (2) The HACCP plan shall be dated and signed:
 - (i) Upon initial acceptance;
 - (ii) Upon any modification; and
 - (iii) At least annually, upon reassessment, as required under Sec. 417.4(a)(3) of this part.
- (e) Pursuant to 21 U.S.C. 456, 463, 608, and 621, the failure of an establishment to develop and implement a HACCP plan that complies with this section, or to operate in accordance with the requirements of this part, may render the products produced under those conditions adulterated.

Sec. 417.3 Corrective actions.

- (a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:
- (1) The cause of the deviation is identified and eliminated;
 - (2) The CCP will be under control after the corrective action is taken;
 - (3) Measures to prevent recurrence are established; and
 - (4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

(b) If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;

(2) Perform a review to determine the acceptability of the affected product for distribution;

(3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;

(4) Perform or obtain reassessment by an individual trained in accordance with Sec. 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

(c) All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with Sec. 417.4(a)(2)(iii) and the recordkeeping requirements of Sec. 417.5 of this part.

Sec. 417.4 Validation, Verification, Reassessment.

(a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.

(1) *Initial validation.* Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCPs, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

(2) *Ongoing verification activities.* Ongoing verification activities include, but are not limited to:

(i) The calibration of process-monitoring instruments;

(ii) Direct observations of monitoring activities and corrective actions; and

(iii) The review of records generated and maintained in accordance with Sec. 417.5(a)(3) of this part.

(3) *Reassessment of the HACCP plan.* (i) 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 Sec. 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 Sec. 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.

(b) *Reassessment of the hazard analysis.* Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. 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; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

Sec. 417.5 Records.

(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 CCPs and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

(3) Records documenting the monitoring of CCPs 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.

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

(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with Sec. 417.7 of this part, or the responsible establishment official.

(d) *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.

(e) *Record retention.* (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.

(2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.

(f) *Official review.* All records required by this part and all plans and procedures required by this part shall be available for official review and copying.

Sec. 417.6 Inadequate HACCP Systems.

A HACCP system may be found to be inadequate if:

- (a) The HACCP plan in operation does not meet the requirements set forth in this part;
- (b) Establishment personnel are not performing tasks specified in the HACCP plan;
- (c) The establishment fails to take corrective actions, as required by Sec. 417.3 of this part;
- (d) HACCP records are not being maintained as required in Sec. 417.5 of this part; or
- (e) Adulterated product is produced or shipped.

Sec. 417.7 Training.

(a) Only an individual who has met the requirements of paragraph (b) of this section, but who need not be an employee of the establishment, shall be permitted to perform the following functions:

(1) Development of the HACCP plan, in accordance with Sec. 417.2(b) of this part, which could include adapting a generic model that is appropriate for the specific product; and

(2) Reassessment and modification of the HACCP plan, in accordance with Sec. 417.3 of this part.

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.

Sec. 417.8 Agency verification.

FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:

- (a) Reviewing the HACCP plan;
- (b) Reviewing the CCP records;
- (c) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;
- (d) Reviewing the critical limits;
- (e) Reviewing other records pertaining to the HACCP plan or system;
- (f) Direct observation or measurement at a CCP;
- (g) Sample collection and analysis to determine the product meets all safety standards; and
- (h) On-site observations and record review.

9 CFR PART 418—RECALLS

Sections:

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.

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.

§ 418.4 Records.

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