

Hazard Analysis Verification Task Documentation Workshop: Groveton Meats

Objective

To demonstrate being able to maneuver through the PHIS system, participants will perform the Hazard Analysis Verification task and independently document inspection results into PHIS.

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. Answer the four workshop questions.

The Inspection Method

PHIS may add directed tasks to the establishment task list, including a Hazard Analysis Verification task, HACCP verification task, and sanitation procedures, in response to certain events or results that indicate that the establishment may not be maintaining control of its food safety system, for example, in the case of positive pathogen test results. **Robert Barclay** recently submitted an FSIS sample of raw ground beef from Groveton Meats (MT43) and has received a confirmed positive result for *E. coli* O157:H7. Robert Barclay reviews his task list and considers the appropriate follow-up tasks, including a Directed HAV task, a HACCP verification task, a Sanitation SOP pre-op records review task, and/or a Sanitation SOP operational records review task. ***You, as Robert Barclay, decide to add the Directed HAV task to today's calendar and begin to perform the task.***

Description of the Establishment's Production Process

Groveton Meats is a small grinding establishment that produces ground beef, hamburger, and beef patties. It has one HACCP plan under the Raw Product Non-Intact HACCP category. The company produces about 5,000 lb of raw ground beef products a week. It operates a single 8-hour shift 5 days a week; the establishment has determined one day's production is a lot.

Incoming raw beef trimmings are from cattle less than 30 months of age that were raised in the U.S. The company purchases all beef trimmings from the slaughter establishment Open Beef, Inc., and receives 2 shipments a week.

The ground beef patties are 100% beef and produced using a two-step grinding method. The hamburger patties and beef patties have non-meat ingredients added at the blending step. The process of producing these patties involves a coarse grind, mixing and blending the meat and ingredients, and a final grind. Ingredients added to the hamburger patties include: salt, seasonings and corn syrup. Ingredients added to the beef patties include: breadcrumbs, salt, dried onions, seasonings and soy or milk protein. The company does not rework broken or misshaped patties and it does not accept returned products. The patties are distributed in one pound trays or bulk packed in 20 lb boxes.

Getting Started

Before continuing, consider:

- When performing the HAV task, what are the regulatory requirements you verify compliance with?
- What documents and records should you review?
- What specifically will you look for when reviewing these documents and records?
- How will you use the *FSIS Meat and Poultry Hazards and Controls Guide*?
- What findings would be evidence of noncompliance?
- If you are unclear about regulatory compliance, what should you do?

Note: Consult the HAV Task Summary Table and the HACCP regulations in your notebook for reference.

Review HACCP System Documentation

You proceed to the establishment's office and explain to Jeff Irvine, the Food Safety Manager that you will need to review the following documents for the raw non-intact (ground) process.

- Flow diagram
- Hazard analysis
- HACCP plan

- Prerequisite programs
- Supporting documentation
- Records demonstrating implementation of prerequisite programs and other supporting programs

Jeff Irvine provides one notebook binder labeled *HACCP Plan*, which includes the flow diagram and hazard analysis. He gives you another binder identified as *Supporting Programs*. The flow diagram, hazard analysis, HACCP plan, and some of Groveton Meat's prerequisite programs are on the following pages.

Note: Assume that all documents requiring a signature and date of implementation/modification meet regulatory requirements.

Note: Not all of the Groveton Meat's prerequisite programs could be provided for this training session. Workshop question # 1 asks you to make a list of all of the records and supporting documentation that you would need to review before completing the HAV task. For example, you would still need to review the allergen program and Sanitation SOP. Before you could document the HAV task as "completed" you would need to review all of the additional supporting documentation for decisions the establishment has made in the hazard analysis and the HACCP plan, records associated with the implementation of each of the prerequisite programs, and other documentation that would continue to support that a food safety hazard is not reasonably likely to occur in the process.

3. Are there findings or concerns that you believe need to be addressed through your supervisor?

4. What specific findings or concerns would you want to add to the meeting agenda and document in a MOI?

Groveton Meats

**Est. 44924
1200 Presley Drive
Los Angeles, CA 94852**

HAZARD ANALYSIS CRITICAL CONTROL POINT Raw Ground Process

April 27, 2008

PREPARED BY

Jeff Irvine, Food Safety Manager

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Groveton Meats - Reassessment Record

Date	Reason for Reassessment	Signature/Title
January 27, 2009	Annual reassessment	<i>Jeff Irvine, Food Safety Manager</i>
March 23, 2010	Annual reassessment	<i>Jeff Irvine, Food Safety Manager</i>
August 26, 2011	Annual reassessment	<i>Jeff Irvine, Food Safety Manager</i>
April 17, 2012	Annual reassessment	<i>Jeff Irvine, Food Safety Manager</i>
June 2, 2013	Undeclared Allergen	<i>Jeff Irvine, Food Safety Manager</i>
February 20, 2014	Annual reassessment	<i>Jeff Irvine, Food Safety Manager</i>
July 10, 2015	Annual reassessment	<i>Jeff Irvine, Food Safety Manager</i>
December 16, 2015	Metal in product	<i>Jeff Irvine, Food Safety Manager</i>

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Groveton Meats - Product Description

PROCESS CATEGORY: Raw, Not intact	PRODUCT: Ground Beef, Ground Round, Ground Sirloin, Ground Chuck
1. Common Name:	<ul style="list-style-type: none"> • Ground Beef Patties, Hamburger Patties, and Beef Patties
2. How Used	<ul style="list-style-type: none"> • Cooked and consumed
3. Formulation	<ul style="list-style-type: none"> • Ground Beef (75/25), Ground Round (85/15 & 90/10), Ground Chuck (85/15) • Meet standards of identity for ground beef, hamburger and beef patties. • Use fresh/frozen trim, boneless chucks, boneless sirloins, and boneless rounds from Open Beef; no other components used in our products • Non-meat food ingredients, flavorings, or spices are added to hamburger and beef patties
4. Type Of Package	<ul style="list-style-type: none"> • Consumer ready packages (frozen and fresh patties in one lb trays) • Bulk (frozen patties) in 20 lb box
5. Length Of Shelf Life:	<ul style="list-style-type: none"> • 3-6 months if frozen; 7 days at $\leq 40^{\circ}\text{F}$
6. Consumers & Intended Use	<ul style="list-style-type: none"> • Retail and HRI • General public • No distribution to schools or hospitals
7. Labeling Instructions	<ul style="list-style-type: none"> • Keep refrigerated/frozen • Safe food handling instructions
8. Distribution Control Needed	<ul style="list-style-type: none"> • Keep refrigerated/frozen

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Groveton Meats - Hazard Analysis

Raw Non-Intact Product Hazard Analysis (Ground Beef, Hamburger and Beef Patties)

Process Step	Food Safety Hazard	Reasonably Likely to Occur	Basis	Measures Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level	Critical Control Point
Receiving packaging materials	Biological –None				
	Chemical: (process contaminants and non-food grade materials)	No	May contain deleterious substances. FDA approved for intended use	Suppliers will provide a Letter of Guarantee that materials meet specifications for food grade packaging materials	
	Physical –None				
Storage of packaging materials	Biological –None				
	Chemical –None				
	Physical –None				
Receiving-Raw Beef Trimmings	Biological: Pathogens: <i>Salmonella</i> ; <i>E. coli</i> O157:H7	No	Raw meat is a known source for pathogens. <i>E. coli</i> O157:H7 is a known pathogen in raw beef products.	Purchase Specifications. Product temperature must be ≤ 40° F Suppliers have a HACCP program that meets all regulatory requirements and has validated CCP and/or validated process interventions in place that prevent, eliminate or reduce	

Process Step	Food Safety Hazard	Reasonably Likely to Occur	Basis	Measures Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level	Critical Control Point
	Biological: BSE/ SRMs	No	SRMs may be found in incoming product from beef animals	<p><i>Salmonella</i> and <i>E. coli</i> O157:H7 to undetectable levels. For each lot of product, the supplier provides a letter of guaranty for negative results for <i>E. coli</i> O157:H7. Groveton Meats will not comingle products from different suppliers. (Interventions for <i>E coli</i> should also reduce the levels of <i>Salmonella</i>)</p> <p>Supplier will provide a certificate that product will be derived from animals less than 30 months of age and the SRMs are removed</p>	
	Chemical: –None				
	Physical: Foreign Materials; metal, buckshot, bone needles, wood	Yes	Damaged containers can result in meat/poultry product exposure to foreign material and/or cross contamination.	<p>Visual inspection for damaged containers at receiving – (Receiving log)</p> <p>Grinder is equipped with a bone collection system, which collects hard materials. Grinder will not run without bone separator</p> <p>Metal detection program</p>	

Process Step	Food Safety Hazard	Reasonably Likely to Occur	Basis	Measures Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level	Critical Control Point
Receiving and Storage –Non-meat Ingredients	Biological: Pathogens	No	Incoming spices and seasonings may be contain pathogens, e.g., <i>Salmonella</i>	Supplier will provide a Letter of Guaranty	
	Chemical: Allergens	No	Some ingredients that are known allergens can cause allergic reaction or sensitivities	<p>Hamburger and beef patties will contain non-meat ingredients. In house SOP is used for the handling and storage of non-meat ingredients. All ingredients including specific allergens will be declared on labels. All non-meat ingredients will have labeling disclosing all ingredients in package</p> <p>At receiving, the company's Allergen Management Program will be implemented</p>	
	Deleterious substances	No	Ingredients may contain deleterious substances	Letters of Guarantee - Food grade (GRAS) or FDA approved for intended use	

Process Step	Food Safety Hazard	Reasonably Likely to Occur	Basis	Measures Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level	Critical Control Point
	Physical: Foreign materials	No	Damaged containers can result in product exposure to foreign material and/or cross contamination	Visual inspection for damaged containers at receiving Receiving log	
Storage of Beef Trimmings	Biological: Growth of pathogens	Yes	Raw meat is a known source for pathogens. An increase in product temperature will allow the growth of pathogens	Appropriate cold storage temperature	Yes CCP1-B
	Chemical –None				
	Physical –None				
Weigh Non-Meat Ingredients	Biological –None				
	Chemical: Allergens	No	Known allergens and certain ingredients such as MSG can cause allergic reaction or sensitivities in certain individuals	Allergen program addresses proper identification at receiving and storage, use of ingredients at weighing, blending, and labeling SSOP address separation and sanitation during production Non-meat Inventory and Formulation logs address amounts of ingredients on hand and used in formulation	
	Physical – None				

Process Step	Food Safety Hazard	Reasonably Likely to Occur	Basis	Measures Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level	Critical Control Point
Weigh Raw Beef Trimmings	Biological: Growth of pathogens	No	Growth of pathogens could occur if product temperature were to rise	Processing area temperature control program is used to ensure that room temperature is less than 45°F	
	Chemical – None				
	Physical – None				
Coarse Grind (Short time frame)	Biological: Growth of pathogens	No	Friction from mechanical applications can increase product temperature and transfer microorganisms. Growth of pathogens could occur if product temperature were to rise Time and temperature relationships will not permit significant growth of pathogens	SOP used to ensure that grinding occurs within a specified timeframe and processing area temperature control program is used to ensure that room temperature is less than 45°F Historical data correlated room temperatures with product temperatures. (Supplier COA- indicates <i>E. coli</i> O157:H7 levels are undetectable)	
	Pathogen contamination	No	Possible cross contamination from one lot to another lot	Sanitation SOP addresses cleaning of equipment	
	Chemical – None				

Process Step	Food Safety Hazard	Reasonably Likely to Occur	Basis	Measures Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level	Critical Control Point
	Physical: Metal	Yes	Metal can be introduced by mechanical applications. Metal contaminants 7 mm or greater pose health risk.	Equipment maintenance procedure addresses the regular changing out of parts. Metal detection program	
Final grind	Biological: Growth of pathogens	No	Friction from mechanical applications can increase product temperature and transfer microorganisms Growth of pathogens could occur if product temperature were to rise Time and temperature relationships will not permit significant growth of pathogens	SOP used to ensure that grinding occurs within a specified timeframe and processing area temperature control program is used to ensure that room temperature is less than 45°F Historical data correlates room temperatures with product temperatures	
	Pathogen contamination	No	Possible cross contamination from one lot to another lot	SSOP addresses cleaning of equipment	
	Chemical: Allergens	No	Trace amounts of ingredients that are known allergens can cause allergic reaction or sensitivities	SSOP addresses cleaning of equipment when separation by time/space is not feasible. No product held for rework	

Process Step	Food Safety Hazard	Reasonably Likely to Occur	Basis	Measures Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level	Critical Control Point
	Physical: Metal	Yes	Metal can be introduced by mechanical applications. Metal contaminants 7 mm or greater pose health risk.	Equipment maintenance procedure addresses the regular changing out of parts. Metal detection program	
Patty Formation	Biological: Growth of pathogens	No	Growth of pathogens could occur if product temperature were to rise Time and temperature relationships will not permit significant growth of pathogens	Processing area temperature control program is used to ensure that room temperature is less than 45°F Historical data correlated room temperatures with product temperatures	
	Chemical– None				
	Physical– None				
Freezing	Biological: Growth of pathogens	No	Slow freezing process could allow the growth of pathogens	Product is maintained below 45°F and quick frozen once patties are formed	
	Chemical – None				
	Physical– None				
Packaging and Labeling	Biological– None				

Process Step	Food Safety Hazard	Reasonably Likely to Occur	Basis	Measures Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level	Critical Control Point
	Chemical: Allergens	No	Known allergens and certain ingredients such as MSG can cause allergic reaction or sensitivities in certain individuals	Allergen program addresses proper identification at receiving and storage, use of ingredients at weighing, blending and labeling	
	Physical: Metal	Yes	Product undergoes coarse grind, blending/mixing and final grind	Metal detection program addresses functioning metal detector set within manufacturer specifications for Fe/Non-Fe and non magnetic stainless steel	
Finished Product Storage-Refrigerated	Biological: Growth of pathogens	Yes	Raw meat is a known source for pathogens. Product must be maintained at or below a temperature sufficient to reduce the growth of pathogens	Appropriate storage temperature	Yes CCP1-B
	Chemical - None				
	Physical - None				
Finished Product Storage-Frozen	Biological-None				
	Chemical - None				
	Physical - None				

Process Step	Food Safety Hazard	Reasonably Likely to Occur	Basis	Measures Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level	Critical Control Point
Shipping and Distribution	Biological: Growth of microorganisms	No	Improper temperature control during shipping may allow the growth of pathogens	Trucks are refrigerated and maintained at a temperature sufficient to preclude outgrowth of microorganisms Bill of lading/Invoices	
	Chemical - None				
	Physical: Foreign material	No	Insanitary conditions of truck trailer can result in cross contamination of product	Trucks are routinely cleaned and inspected prior to shipping product Shipping log	

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Groveton Meats - HACCP Plan

Raw Non-intact (Ground) Process HACCP Plan

CCP Number	Critical Limit	Monitoring Procedures	HACCP Records	Verification Procedures	Corrective Actions
CCP-1B Refrigerated Storage of Beef Trimmings/ Finished Patties	Internal product temperature ≤ 45°F	<p>Room temperature of the cooler is monitored continuously with time/temperature recording chart; an alarm notifies cooler operator or designee if cooler temperature rises above 40°F; if alarm sounds, the cooler operator or designee will check internal product temps by inserting a long stem thermometer into the center of each combo bin and take action to ensure there is no critical limit deviation</p> <p>Twice a week the cooler operator or designee will check internal product temperatures in the cooler by inserting a long stem thermometer into the center of each combo bin and record the highest temperature</p>	<p>Time/Temperature Log Corrective Action Log Verification Log for product temps Thermometer calibration/Alarm record</p>	<p>At least biweekly the Production Supervisor or designee will check internal product temperatures in the cooler by inserting a long stem thermometer into the center of one combo bin or container Monthly calibration of room temperature/time recording chart probe and alarm check by maintenance personnel in accordance with manufacturer's directions Maintenance personnel will review the time/temperature recording chart when a new chart is installed. Production Supervisor or designee will observe the monitor and review HACCP records weekly Weekly calibration of the long stem and hand held product thermometer by Production Supervisor or designee in slush ice bath in accordance with manufacturer's directions</p>	<p>Per 417.3 QA personnel are responsible for assuring that corrective actions are taken</p>

Groveton Meats - Prerequisite Programs

SUPPLIER PURCHASE SPECIFICATIONS

Beef Manufacturing Trimmings, Non-Meat Ingredients, and Packaging Material

11/14/2008

All suppliers of boneless beef manufacturing trimmings must on a quarterly basis certify in writing (e.g., a Letter of Guarantee) that they are able to comply fully with the following incoming product/ingredient specifications:

1. All beef trimmings are produced under USDA inspection and are in containers bearing the mark of inspection.
2. The beef trimmings are derived from a slaughter process that:
 - achieves *Salmonella* set results that meet USDA's *Salmonella* Performance Standards keeping the establishment's *Salmonella* status in Category 1 (consistent process control),
 - has a HACCP plan which includes one or more validated antimicrobial intervention(s) at slaughter to eliminate or reduce *E. coli* O157:H7 below detectable levels, and
 - has procedures designed to control and remove all Specified Risk Materials (SRMs) and complies with the SRM regulatory requirements.
3. Each lot of beef trimmings is sampled for *E. coli* O157:H7. The sample must represent the lot, and the sampling method must be equivalent in sensitivity to FSIS N60 sampling and testing methods.
4. The temperature of all beef trimmings received must be $\leq 40^{\circ}\text{F}$.

Before any beef trimmings are used to produce ground beef products at Groveton Meats, each shipment of beef trimmings must be accompanied by or have on file:

1. A Letter of Guarantee or documentation stating intervention(s) was/were applied to the source materials of the beef trimmings in compliance with the supplier's HACCP program.

2. A letter of guaranty from the supplier stating that the lot of beef trimmings tested negative for *E. coli* O157:H7.
3. A Letter of Guarantee or documentation stating that the beef trimmings are derived from cattle that are less than 30 months of age and SRMs have been removed.

For non-meat ingredients and packaging materials, the manufacturer/supplier must provide a Letter of Guarantee identifying intended use of item with each shipment or have a continual Letter of Guarantee on file. All documents must include the conditions under which the ingredient or packaging material can be used safely.

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RECEIVING INSPECTION PROCEDURES

Beef Manufacturing Trimmings, Non-Meat Ingredients, and Packaging Material

11/14/2008

Required Documents for Beef Trimmings

Before unloading beef trimmings from a truck trailer, the receiving manager or designee will verify there is a letter or documentation accompanying the shipment stating that:

1. Intervention(s) was/were applied to the source materials of the beef trimmings in compliance with the supplier's HACCP program.
2. The beef trimmings are derived from cattle that are less than 30 months of age and SRMs have been removed.
3. Each lot of beef trimmings has been tested and found to be negative for E. coli O157H:7, e.g., each lot has an associated letter of guaranty.

Measuring Receiving Temperature

It is common knowledge that the surface temperature of previously chilled raw meat will rise faster than the internal temperature due to product equilibration which is affected by the ambient temperature under which product is held.

The surface temperature of the beef trimmings must be $\leq 40^{\circ}\text{F}$. Temperature is monitored in at least 2 containers per trailer by receiving foreman at the receiving dock for each delivery of beef trimmings.

Organoleptic Inspection of Containers

1. 100% visual inspection of product shipping container condition by the receiving foreman at the receiving/unloading dock. Containers are inspected for damage/integrity for each delivery of beef trimmings, non-meat ingredient products, and packaging materials.
2. 100% organoleptic inspection by the Production Supervisor when the beef trimmings, non-meat ingredients, or packaging material immediate container is damaged. The trimmings, non-meat ingredients, or packaging material is placed in designated "product reinspection" area in cold and/or

dry storage area for further examination for foreign material by the Production Supervisor.

Corrective Actions

If the required documentation does not accompany the shipment of beef trimmings, they are unloaded from the truck trailer, moved to the cooler, placed on “hold”, and remain on “hold” until the required documentation is received. The receiving manager or designee will immediately notify the supplier of the missing documentation. The supplier of our beef trimmings tests their beef trimming for the presence of *E. coli* O157:H7 while they are moving in transit. Therefore, the sample results are usually provided to Groveton Meats on the day the trimmings were placed on “hold” or the day after. The supplier will immediately notify us if the beef trimmings test presumptive positive for *E. coli* O157:H7 to arrange return of the beef trimmings. If we are notified that the beef trimmings are presumptive positive, we immediately inform the USDA inspector.

If the temperature of beef trimmings is above 40°F, the supplier may provide evidence, e. g., a temperature profile record, which demonstrates the temperature of the beef trimmings from time of shipping to receipt at Groveton Meats was above 40°F for no more than 2 hours but never above 50°F. When a temperature profile is not available from supplier, the receiving manager or designee places the beef trimmings on hold. The supplier is notified and the beef trimmings are returned to the supplier.

Beef trimmings, ingredients, or packaging materials with damaged containers are segregated and placed in “Product Reinspection” area by the receiving foreman or designee for further evaluation by the Production Supervisor who is responsible for performing organoleptic inspection and evaluation of the beef trimmings, ingredients, and/or packaging material.

1. The beef trimmings are evaluated and reconditioned as necessary and/or condemned and denatured as deemed appropriate.
2. Ingredients and packaging material are evaluated and repackaged/labeled if ingredients are not affected and/or condemned when the ingredient or packaging material is found to be contaminated.

Records

1. Letters of Guaranty
2. Bills of Lading
3. Receiving Log: Recorded information includes: Name of the supplier, product/item lot code(s), name of the product/item, and temperature of the beef trimmings. Organoleptic inspection is documented as acceptable or unacceptable. Corrective actions are documented as appropriate including the date, time, and initials of the responsible employee performing the inspection at receiving.

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PROCESSING ROOM TEMPERATURE MONITORING PROCEDURES

11/14/2008

Room temperature in all processing areas is maintained at $\leq 45^{\circ}\text{F}$. There are two processing areas-the grinding room (includes the trim weighing and blending) and the patty room (includes packaging). Two wall thermometers are installed in each room.

1. The Production Supervisor or designee observes the wall thermometers twice per shift during operating days and records the highest temperature reading on the Processing Room Temperature Log.
2. If the temperature reading is above 45°F , the time of the finding is documented on the record. Maintenance personnel immediately begin looking for the reason why the temperature is high and take corrective action.
3. The Production Supervisor will immediately measure the internal temperature of the beef trimmings or ground product as appropriate and continue measuring the internal temperature and room temperature at 15 minute intervals while the room temperature is above 45°F .
4. If the internal temperature of the product reaches 44°F or the room temperature is above 45°F for 2 hours, all production is stopped. All product is immediately placed in the cooler.
5. Production does not resume until the room temperature is $\leq 45^{\circ}\text{F}$.
6. If the room is above 45°F for 2 hours or more, a mid-shift clean-up of food contact surfaces is conducted before production is resumed.
7. The accuracy of the wall thermometers is checked once per month.

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!!! WORKSHOP NOTE !!!

Records Demonstrating Implementation of Prerequisite Programs

Note: On the following pages are the records demonstrating implementation of the purchase specifications/receiving procedure (letters of guaranty for *E. coli* O157:H7 testing, bills of lading, receiving log) and processing room temperature monitoring procedure (room temperature log). For these programs, these are **all of the available implementation records for two weeks of production** prior to the HAV task you are conducting.

STRAIGHT BILL OF LADING

Open Beef Co, Inc.
8305 Hawthorne
Way
Petaluma, CA 94954

Date	B/L #
1-24-16	25744

CONSIGNED TO:
Groveton Meats, Inc. 1200 Presley Drive Los Angeles, CA 94852

SPECIAL INSTRUCTIONS	
Trailer Temp:	34 degrees F

Pallets Used	S.O. Number	Seal Numbers	Ship Date	Delivery Date
	799	23012/931	1-24-16	1-25-16
Piece Count	Description		Weight	
5	Combos – Beef Trimmings 75/25 Lot 012416AC		2476 lbs.	
Total Pc Cnt:	5	Driver Initials: <i>JT</i>	Total Wt: 2476 lbs.	

Note: This shipment contains beef products derived only from animal determined to be less than 30 months of age and contains no SRM's such as tonsils or distal ileum.

THIS IS TO CERTIFY THAT THE ABOVE NAMED MATERIALS ARE PROPERLY CLASSIFIED, DESCRIBED, PACKAGED, MARKED & LABELED, RECEIVED, SUBJECT TO THE CLASSIFICATIONS AND TARIFFS IN EFFECT ON THE DATE OF THE ISSUE OF THIS BILL OF LADING, THE PROPERTY DESCRIBED ABOVE IN APPARENT GOOD ORDER, EXCEPT NOTED (CONTENTS AND CONDITION OF CONTENTS OF PACKAGES UNKNOWN), MARKED, CONSIGNED AND DESTINED AS INDICATED ABOVE WHICH SAID CARRIER AGREES TO CARRY TO ITS USUAL PLACE OF DELIVERY AT SAID DESTINATION, IT IS MUTUALLY AGREED AS TO EACH CARRIER OF ALL OR ANY OR, SAID PROPERTY OVER ALL OR ANY PORTION OF SAID ROUTE TO DESTINATION AND AS TO EACH PARTY AT ANY TIME INTERESTED IN ALL OR ANY OF SAID PROPERTY, THAT EVERY SERVICE TO BE PERFORMED HEREUNDER SHALL BE SUBJECT TO ALL THE BILL OF LADING TERMS AND CONDITIONS IN THE GOVERNING CLASSIFICATION OF THE DATED OF SHIPMENT.

SHIPPER HERBY CERTIFIES THAT HE IS FAMILIAR WITH ALL THE BILL OF LADING TERMS AND CONDITIONS IN THE GOVERNING CLASSIFICATION AND THE TERMS AND CONDITIONS ARE HERBY AGREED TO BY THE SHIPPER AND ACCEPTED BY HIMSELF AND HIS ASSIGNS

SHIPPER: Open Beef Co. PER: <u><i>JT</i></u>	CARRIER: Open Beef Co. PER: <u><i>JT</i></u> DATE: <u>1-25-16</u>
For Training Purposes Only	

STRAIGHT BILL OF LADING

Open Beef Co, Inc.
8305 Hawthorne
Way
Petaluma, CA 94954

Date	B/L #
1-27-16	25799

CONSIGNED TO:
Groveton Meats, Inc. 1200 Presley Drive Los Angeles, CA 94852

SPECIAL INSTRUCTIONS	
Trailer Temp:	33 degrees F

Pallets Used	S.O. Number	Seal Numbers	Ship Date	Delivery Date
	836	23054/55	1-27-16	1-28-16
Piece Count	Description		Weight	
5	Combos – Beef Trimmings 85/15 Lot 012716AJ		2513 lbs.	
Total Pc Cnt:	5	Driver Initials: <i>JT</i>	Total Wt: 2513 lbs.	

Note: This shipment contains beef products derived only from animal determined to be less than 30 months of age and contains no SRM's such as tonsils or distal ileum.

THIS IS TO CERTIFY THAT THE ABOVE NAMED MATERIALS ARE PROPERLY CLASSIFIED, DESCRIBED, PACKAGED, MARKED & LABELED, RECEIVED, SUBJECT TO THE CLASSIFICATIONS AND TARIFFS IN EFFECT ON THE DATE OF THE ISSUE OF THIS BILL OF LADING, THE PROPERTY DESCRIBED ABOVE IN APPARENT GOOD ORDER, EXCEPT NOTED (CONTENTS AND CONDITION OF CONTENTS OF PACKAGES UNKNOWN), MARKED, CONSIGNED AND DESTINED AS INDICATED ABOVE WHICH SAID CARRIER AGREES TO CARRY TO ITS USUAL PLACE OF DELIVERY AT SAID DESTINATION, IT IS MUTUALLY AGREED AS TO EACH CARRIER OF ALL OR ANY OR, SAID PROPERTY OVER ALL OR ANY PORTION OF SAID ROUTE TO DESTINATION AND AS TO EACH PARTY AT ANY TIME INTERESTED IN ALL OR ANY OF SAID PROPERTY, THAT EVERY SERVICE TO BE PERFORMED HEREUNDER SHALL BE SUBJECT TO ALL THE BILL OF LADING TERMS AND CONDITIONS IN THE GOVERNING CLASSIFICATION OF THE DATED OF SHIPMENT.

SHIPPER HERBY CERTIFIES THAT HE IS FAMILIAR WITH ALL THE BILL OF LADING TERMS AND CONDITIONS IN THE GOVERNING CLASSIFICATION AND THE TERMS AND CONDITIONS ARE HERBY AGREED TO BY THE SHIPPER AND ACCEPTED BY HIMSELF AND HIS ASSIGNS

SHIPPER: Open Beef Co. PER: <u><i>JT</i></u>	CARRIER: Open Beef Co. PER: <u><i>JT</i></u> DATE: <u>1-28-16</u>
For Training Purposes Only	

STRAIGHT BILL OF LADING

Open Beef Co, Inc.
8305 Hawthorne
Way
Petaluma, CA 94954

Date	B/L #
1-31-16	258059

CONSIGNED TO:
Groveton Meats, Inc. 1200 Presley Drive Los Angeles, CA 94852

SPECIAL INSTRUCTIONS	
Trailer Temp:	34 degrees F

Pallets Used	S.O. Number	Seal Numbers	Ship Date	Delivery Date
	876	23124/25	1-31-16	2-1-16
Piece Count	Description		Weight	
5	Combos – Beef Trimmings 90/10 Lot 013116AF		2453 lbs.	
Total Pc Cnt: 5	Driver Initials: <i>JT</i>		Total Wt: 2453 lbs.	

Note: This shipment contains beef products derived only from animal determined to be less than 30 months of age and contains no SRM's such as tonsils or distal ileum.

THIS IS TO CERTIFY THAT THE ABOVE NAMED MATERIALS ARE PROPERLY CLASSIFIED, DESCRIBED, PACKAGED, MARKED & LABELED, RECEIVED, SUBJECT TO THE CLASSIFICATIONS AND TARIFFS IN EFFECT ON THE DATE OF THE ISSUE OF THIS BILL OF LADING, THE PROPERTY DESCRIBED ABOVE IN APPARENT GOOD ORDER, EXCEPT NOTED (CONTENTS AND CONDITION OF CONTENTS OF PACKAGES UNKNOWN), MARKED, CONSIGNED AND DESTINED AS INDICATED ABOVE WHICH SAID CARRIER AGREES TO CARRY TO ITS USUAL PLACE OF DELIVERY AT SAID DESTINATION, IT IS MUTUALLY AGREED AS TO EACH CARRIER OF ALL OR ANY OR, SAID PROPERTY OVER ALL OR ANY PORTION OF SAID ROUTE TO DESTINATION AND AS TO EACH PARTY AT ANY TIME INTERESTED IN ALL OR ANY OF SAID PROPERTY, THAT EVERY SERVICE TO BE PERFORMED HEREUNDER SHALL BE SUBJECT TO ALL THE BILL OF LADING TERMS AND CONDITIONS IN THE GOVERNING CLASSIFICATION OF THE DATED OF SHIPMENT.

SHIPPER HERBY CERTIFIES THAT HE IS FAMILIAR WITH ALL THE BILL OF LADING TERMS AND CONDITIONS IN THE GOVERNING CLASSIFICATION AND THE TERMS AND CONDITIONS ARE HERBY AGREED TO BY THE SHIPPER AND ACCEPTED BY HIMSELF AND HIS ASSIGNS

SHIPPER: Open Beef Co. PER: <u><i>JT</i></u>	CARRIER: Open Beef Co. PER: <u><i>JT</i></u> DATE: <u>2-1-16</u>
For Training Purposes Only	

STRAIGHT BILL OF LADING

Open Beef Co, Inc.
8305 Hawthorne
Way
Petaluma, CA 94954

Date	B/L #
2-3-16	258121

CONSIGNED TO:
Groveton Meats, Inc. 1200 Presley Drive Los Angeles, CA 94852

SPECIAL INSTRUCTIONS	
Trailer Temp:	33 degrees F

Pallets Used	S.O. Number	Seal Numbers	Ship Date	Delivery Date
	921	23198/99	2-3-16	2-4-16
Piece Count	Description		Weight	
5	Combos – Beef Trimmings 90/10 Lot 020316AB		2527 lbs.	
Total Pc Cnt:	5	Driver Initials: <i>JT</i>	Total Wt:	2527 lbs.

THIS IS TO CERTIFY THAT THE ABOVE NAMED MATERIALS ARE PROPERLY CLASSIFIED, DESCRIBED, PACKAGED, MARKED & LABELED, RECEIVED, SUBJECT TO THE CLASSIFICATIONS AND TARIFFS IN EFFECT ON THE DATE OF THE ISSUE OF THIS BILL OF LADING, THE PROPERTY DESCRIBED ABOVE IN APPARENT GOOD ORDER, EXCEPT NOTED (CONTENTS AND CONDITION OF CONTENTS OF PACKAGES UNKNOWN), MARKED, CONSIGNED AND DESTINED AS INDICATED ABOVE WHICH SAID CARRIER AGREES TO CARRY TO ITS USUAL PLACE OF DELIVERY AT SAID DESTINATION, IT IS MUTUALLY AGREED AS TO EACH CARRIER OF ALL OR ANY OR, SAID PROPERTY OVER ALL OR ANY PORTION OF SAID ROUTE TO DESTINATION AND AS TO EACH PARTY AT ANY TIME INTERESTED IN ALL OR ANY OF SAID PROPERTY, THAT EVERY SERVICE TO BE PERFORMED HEREUNDER SHALL BE SUBJECT TO ALL THE BILL OF LADING TERMS AND CONDITIONS IN THE GOVERNING CLASSIFICATION OF THE DATED OF SHIPMENT.

SHIPPER HERBY CERTIFIES THAT HE IS FAMILIAR WITH ALL THE BILL OF LADING TERMS AND CONDITIONS IN THE GOVERNING CLASSIFICATION AND THE TERMS AND CONDITIONS ARE HERBY AGREED TO BY THE SHIPPER AND ACCEPTED BY HIMSELF AND HIS ASSIGNS

SHIPPER: Open Beef Co. PER: <u><i>JT</i></u>	CARRIER: Open Beef Co. PER: <u><i>JT</i></u> DATE: <u>2-4-16</u>
For Training Purposes Only	

Receiving Log						
Date	Supplier	Product	Lot Codes	Temperature (trimmings)	Condition (Acc or UnAc)	Receiving Initials
1-25-2016	Open Beef	5 combos beef trim	Lot 012416AC	38, 40	Acc	<i>EP</i>
1-28-2016	Open Beef	5 combos beef trim	Lot 012716AJ	40, 40	Acc	<i>EP</i>
2-1-2016	Open Beef	5 combos beef trim	Lot 013116AF	38, 38	Acc	<i>EP</i>
2-4-2016	Open Beef	5 combos beef trim	Lot 020316AB	38, 40	Acc	<i>EP</i>
Corrective Actions:						

Open Beef Company, Inc.

**Petaluma, CA
700-777-7000**

"Where Good Beef Is Found"™

Dear Customer,

As part the Food Safety System at Open Beef, we apply a validated antimicrobial organic acid rinse to all of our carcasses and variety meats. This letter is to convey the results of Open Beef Co, Inc. *E. coli* O157:H7 "Verification" testing. We perform verification testing of trimmings that will be used as raw ground beef components to provide ongoing validation of our Food Safety system. We use the N-60 sampling method to collect our samples and the contract lab utilizes test methods which are equivalent in sensitivity to FSIS methods. Please note that a negative test is not a guarantee that the entire lot is free of *E. coli* O157:H7.

Current Results:

Lot Number – 012416AC

Production Date: 01/23/16

Sample Date: 01/23/16

Shipment Number – 25744

Trailer Number – T43

N60 Sample Result: NEGATIVE for *E. coli* O157:H7

Result Received: 01/26/16

Contract Lab: JDL Laboratories, Inc.

Please contact me if you have any further questions.

Bert Earnest

Bert Earnest

Director of Quality Assurance

For Training Purposes Only

Open Beef Company, Inc.
Petaluma, CA
700-777-7000

"Where Good Beef Is Found"™

Dear Customer,

As part the Food Safety System at Open Beef, we apply a validated antimicrobial organic acid rinse to all of our carcasses and variety meats. This letter is to convey the results of Open Beef Co, Inc. *E. coli* O157:H7 "Verification" testing. We perform verification testing of trimmings that will be used as raw ground beef components to provide ongoing validation of our Food Safety system. We use the N-60 sampling method to collect our samples and the contract lab utilizes test methods which are equivalent in sensitivity to FSIS methods. Please note that a negative test is not a guarantee that the entire lot is free of *E. coli* O157:H7.

Current Results:

Lot Number – 013116AF

Production Date: 01/30/16

Sample Date: 01/30/16

Shipment Number – 258059

Trailer Number – T43

N60 Sample Result: NEGATIVE for *E. coli* O157:H7

Result Received: 02/02/16

Contract Lab: JDL Laboratories, Inc.

Please contact me if you have any further questions.

Bert Earnest

Bert Earnest

Director of Quality Assurance

For Training Purposes Only

Groveton Meats
Processing Room Temperature Log

Room Temperature ≤ 45°F

Date	Grinding Room	Packaging Room	Initials	Comments and/or Corrective Actions
1-24-16	40°F 42°F	40°F 38°F	PS	
1-25 -16	39°F 40°F	40°F 40°F	PS	
1-26-16	40°F 41°F	40°F	PS	
1-27-16	40°F 41°F	40°F 38°F	DS	
1-28-16	38°F 39°F	40°F 39°F	PS	
1-31-16	39°F 41°F	40°F 40°F		
2-1-16	40°F 42°F	40°F 42°F	PS	
2-2-16	40°F	40°F 38°F	DS	
2-3-16	38F 41°F	39°F 40°F	PS	
2-4-16	39°F 40°F	40°F 41°F		

Reviewer: _____

Date: _____

For Training Purposes Only

Document Inspection Results in PHIS

Working independently, each person is to log into PHIS (User name: **Robert Barclay** (#)) and document the inspection results identified in the workshop questions. You will:

1. Schedule the HAV task, if necessary. First, determine whether you already have a directed HAV scheduled for today. If not, find the Directed HAV task in the task list and add it to your calendar.
2. Initiate/claim the HAV task
3. Enter the regulations verified
4. Document noncompliance findings on an NR
5. Create several inspection notes to document other findings
6. Create the agenda, using inspection notes. Include the items you want to discuss with establishment management, both non-compliance and other “non-regulatory” concerns

(Assume that you had the meeting and are ready to document the discussion.)

7. Create the MOI

Consult the PHIS Quick Reference Guide as needed.

HAV Task Summary Table

Refer to Directive 5000.6 for additional information about each step.

Step	Description	Verification Questions	Regs
1	Review flow chart and compare to production process.	<ul style="list-style-type: none"> Does the flow chart represent the actual production process? 	417.2(a)(2)
2	Review the hazard analysis and consider guidance in the FSIS Meat and Poultry Hazards and Controls Guide (HCG).	<ul style="list-style-type: none"> Does the flow chart or hazard analysis identify the intended use or consumers of the product? Does the hazard analysis appear to consider the relevant food safety hazards for the establishment's process, product, and intended use? For each hazard, does the establishment consider it RLTO or NRLTO? 	417.2(a)(2) 417.2(a)(1)
3	For each hazard the establishment considers RLTO, verify that the HACCP plan includes one or more CCPs to control it. <i>If no hazards are reasonably likely to occur, skip to step 4.</i>	<ul style="list-style-type: none"> Does the establishment have one or more CCPs to control the hazard in each product or process where it is reasonably likely to occur? Does the establishment have information to support the CCPs, CLs, monitoring and verification procedures? 	417.2(c)(2) 417.5(a)(2)
4	For each hazard the establishment considers NRLTO, determine what evidence the establishment uses to support the decision, including prerequisite programs and other supporting programs (e.g. written programs, records, and employee activities)	<ul style="list-style-type: none"> Does the establishment prevent the hazard by implementing a prerequisite or other supporting program (SSOP, GMP, SOP, etc.)? – <i>proceed to step 5.</i> Does the establishment support the decision with other documentation besides a prerequisite or other supporting program? – <i>proceed to step 6.</i> Does the written program appear to be designed to prevent the relevant hazard? Do the records and your observations indicate the program is consistently being implemented as written? Do the records and your observations indicate that the program continues to prevent the relevant hazard on an ongoing basis? 	417.5(a)(1)

HAV Task Summary Table (cont'd)

Refer to Directive 5000.6 for additional information about each step.

Step	Description	Verification Questions	Regs
5	Review other supporting documentation	<ul style="list-style-type: none"> • Does the establishment have copies of the documents referenced in the hazard analysis? • Do the documents appear to apply to the current establishment process? 	417.5(a)(1)
6	Review establishment validation documents, including scientific supporting documents and validation data.	<ul style="list-style-type: none"> • Does the establishment maintain documents to support the scientific or technical basis for the CCPs and prerequisite programs used to support decisions in the hazard analysis? • Does the establishment maintain in-plant validation data for the life of the plan? 	417.4(a)(1)
7	Verify reassessment requirements. Check most recent signature date for each HACCP plan.	<ul style="list-style-type: none"> • Has the establishment reassessed at least once in the most recent calendar year? • Has the establishment reassessed, if necessary, in response to any changes that could affect the hazard analysis? • Has the establishment reassessed, if necessary, in response to any unforeseen hazard? • Has the establishment documented the results of the reassessment? 	417.4(a)(3) 417.3(b) 417.4(a)(3)(ii)
8	Document your findings in PHIS	<ul style="list-style-type: none"> • No problems detected – document HAV task results in PHIS. • Clear case of noncompliance – document HAV task results and NR in PHIS and notify your supervisor. • Concerns about the establishment HACCP system – discuss situation with your supervisor for assistance in determining how to proceed. Document HAV task results in PHIS. 	

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

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 decisionmaking 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 include 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.