March 17, 2008

RAW BEEF PRODUCT SAMPLING

Objectives

To demonstrate mastery of this module, you will

1. List the main pathogen of concern for raw beef products.
2. Select, from a list, those raw beef products subject to sampling under 05B02.
3. State where to find FSIS sampling instructions.
4. Explain the use of FSIS Form 10,210-3.
5. List, in order, the steps of sampling.
6. Describe how to determine which beef product to sample.
7. State how sample results are received.
8. State when to mail samples to the laboratory.
9. List the actions associated with positive microbial results.
10. List the requirements for transportation of product which has tested positive or presumptive positive for a pathogen.

Introduction

Throughout the history of meat and poultry production, various pathogenic bacteria have caused food borne illness. FSIS works with other governmental agencies, academia, industry, and consumer groups to set policy and establish guidelines and performance standards to reduce or eliminate pathogens from meat and poultry products. Each package of federally inspected product that is recalled bears the mark of inspection, which the public has come to trust as a sign that the product is safe. FSIS intends to maintain that public trust. To that purpose, FSIS samples products to detect the presence of pathogens in beef slaughter and raw beef product processes.

One way FSIS protects public health is by keeping pace with changes, such as emerging pathogens, new products and processes, and new laboratory analyses methods. You are responsible for properly selecting products and using appropriate sample collection techniques to ensure the integrity of samples received by the laboratories.

FSIS focuses its efforts based on ***risk***. Currently, FSIS is concerned with *E. coli* O157:H7 in raw beef operations because of its public health significance. Non-intact raw beef products contaminated with *E. coli* O157:H7 are adulterated. Intact raw beef products contaminated with *E. coli* O157:H7 that are intended to be processed into non-intact products are also adulterated.

All establishments producing non-intact raw beef products, including raw ground beef products, raw ground beef components, or raw beef patty components are subject to sampling per FSIS Directive 10,010.1, “Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7 in Raw Ground Beef Products and Raw Ground Beef Components and Beef Patty Components” and several FSIS Notices. However, at the present time, the primary focus of FSIS’s risk based sampling program

will remain on raw ground or chopped beef, hamburger, ground or chopped veal, veal or beef patties, and patty mix (per FSIS standard of identity in §319.15(a), (b) and (c). When an FSIS sample or another Federal or State entity's sample tests positive for *E. coli* O157:H7, inspection program personnel will collect and submit a follow-up sample from the originating slaughter establishment(s) and multiple follow-up samples from the establishment that produced the positive raw ground beef product, raw beef manufacturing trimmings, and other raw ground beef and raw beef patty component to the FSIS laboratory.

FSIS is continuously improving its sampling protocol and techniques, updating sampling programs, and developing more rapid means of reporting results. FSIS directives and notices contain policy details specific to sampling projects and programs (see Attachment 1). Policy changes rapidly and amendments and new issuances are developed to keep you informed. You must use the updated resources ***each*** time you take a sample. You should read issuances when they are published.

FSIS Directive 10,010.1 and several FSIS Notices contain key concepts regarding the testing of raw beef products for *E. coli* O157:H7. These include

- Expanded FSIS policy to include raw beef products (both intact and non-intact)
- No exemption from sampling
- Routine sampling of raw ground beef, and other non-intact beef products and intact beef products intended for use in raw ground beef products
- Verifying *E. coli* O157:H7 positive product disposition outside the plant
- Routine and multiple follow-up sampling after an FSIS positive sample
- FSIS verification at establishments that supplied non-intact beef products or intact beef products used to produce raw ground beef that tested positive for *E. coli* O157:H7
- Plant-generated *E. coli* O157:H7 samples
- Verifying instructional and disclaimer statements

Sampling is part of FSIS verification activities to ensure the protection of public health. HACCP programs integrate science-based controls into food production processes. These controls must be combined with some means of verifying that meat and poultry plants are achieving acceptable levels of food safety performance. FSIS microbiological sampling programs are designed to verify that HACCP programs are effective in controlling harmful microorganisms in meat and/or poultry products. Establishments may also include a microbiological sampling program into their HACCP system in order to verify that the system is performing as intended.

In raw beef operations, inspection program personnel routinely collect and submit samples of raw ground beef products under sampling project MT43, beef manufacturing trimmings intended for use in raw ground beef or beef patty product under sampling project MT50, and raw ground beef components (including raw beef patty components)

other than beef manufacturing trimmings under sampling project MT54 to laboratory for *E. coli* O157:H7 testing. The samples of beef manufacturing trimmings, and other raw ground beef and raw beef patty components are collected at the **slaughter establishment** that produced the trimmings or component.

The objective of FSIS's risk based verification sampling program is to test for *E. coli* O157:H7, and, as a result, stimulate industry actions to reduce the presence of that pathogen in raw beef products.

Definitions

Aseptic Techniques

An aseptic technique implies that you do not add any organisms to the sample when it is collected. It does **not** imply that the **sample** is aseptic. The purpose of aseptically collecting a sample is to prevent contaminating the sample ***or*** the surrounding product/product contact area. That is why it is important to aseptically collect a sample even when the sample is ***intact***. Wash and sanitize your hands before collecting an intact sample. Good personal hygiene is **essential** anytime a sample is collected, whether it is intact or not.

Baseline

These are sampling programs to determine the industry-wide prevalence of an organism in/on a certain type of product. FSIS may use data from baseline studies for establishing performance standards.

Beef Manufacturing Trimmings

These are beef trimmings from sub-primal cuts such as boneless chuck or other parts of boneless beef that are frequently used as components of raw ground beef. Beef manufacturing trimmings are routinely sampled under FSIS's risk based verification sampling program under project code MT50. Raw beef components such as head meat, cheek meat, weasand meat, organ meat, and advanced meat recovery (AMR) product **are not** sampled under the MT50 project code.

Trimmings that the establishment intends for use in further processing into ready-to-eat products **are not** sampled.

Non-intact beef products

Non-intact beef products include ground beef, beef that has been injected with solutions, beef that has been mechanically tenderized by needling, cubing, Frenching,

or pounding devices, and beef that has been reconstructed into formed entrees. Frenching is a method of preparing boneless chops by flattening with a cleaver.

Note: An **intact** *beef product is one in which nothing has penetrated into the muscle beyond the normal cut-up processes, such as primal cuts, subprimal cuts, steaks, roasts, boned out chucks, etc.*

Raw ground beef products

Raw ground beef products covered under the *E. coli* O157:H7 risk based sampling program include those manufactured with any raw (chopped or ground) beef or veal. Such products are ground beef, hamburger, veal patties, and beef patty mix (per §319.15(a), (b), and (c)) produced at and shipped from the establishment. Raw ground beef products are routinely sampled under FSIS's risk based verification sampling program under project code MT43.

Ground or chopped products made from both beef and other meat or poultry products and beef sausage products **are not** subject to FSIS sampling for *E. coli* O157:H7.

A raw ground beef product that contains any amount of beef product derived from advanced meat recovery (AMR) systems is considered a raw ground beef product.

Raw product comprised ***only*** of beef from AMR systems is ***not*** considered a raw ground beef ***product***.

Raw ground beef components other than beef manufacturing trimmings

These are intact or non-intact beef products intended for manufacturing into ground beef products identified in §319.15(a), (b), or (c). Such products include 2 piece chucks and other primal/sub-primal cuts, raw beef esophagus (weasand) meat, head meat, and cheek meat, beef from AMR systems, and lean finely textured beef (LFTB). Raw product comprised ***only*** of beef from AMR systems is considered a raw ground beef ***component*** or raw beef patty ***component***.
These products are routinely sampled under FSIS's risk based verification sampling program under project code MT54.

Raw beef patty components

These components include **all** raw ground beef components other then beef trim listed on the previous page, as well as partially defatted chopped beef (PDCB), finely textured PDCB, heart, and partially defatted beef fatty tissue (PDBFT). These products are routinely sampled under FSIS's risk based verification sampling program under project code MT54.

Recall

A recall is a plant's voluntary removal of distributed meat or poultry products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA). "Recall" does not include a market withdrawal or a stock recovery.

Product that is adulterated and has left the establishment's control may be subject to a recall. The Recall Management Staff (RMS) is notified immediately if product has left the establishment's control, and they coordinate any recall activities. The DO notifies the RMS (see FSIS Directive 8080.1, "Recall of Meat and Poultry Products"). RMS is notified so a press release can be issued and effectiveness checks can be performed. The press release has the product name, lot number and the supplier. The recall would involve at least the sampled lot, but it could be expanded depending upon a review by the RMS of all factors in the situation. All recalls of meat and poultry products are voluntary.

Raw beef products produced on the shift represented by the positive sample would be subject to voluntary recall. If the raw beef product was used as an ingredient in other raw products, those secondary products would also be subject to recall. If the positive product was used as an ingredient in cooked products or other further processed products, the FSIS Recall Committee evaluates the situation and proceeds on a case-by-case basis.

Sample

A sample for raw products is a collection of product that represents a larger group (the sampled lot).

Sampled lot

This is the amount of product represented by the sample. The plant defines the sampled lot. It is the establishment's responsibility to have the data to support that the raw ground beef, beef manufacturing trimmings, or raw ground beef or beef patty component from one portion of production is statistically distinguished, relative to contamination with *E. coli* O157:H7, from another portion of production. "Cleanup-to-cleanup" may be a part of the procedures that the establishment has in place to support statistically distinguishing one portion of production from another. "Cleanup-to-cleanup" may be an effective means of preventing cross contamination of one part of production to another with *E. coli* O157:H7. However, "cleanup-to-cleanup" without other supporting documentation may not be adequate to statistically distinguish one portion of production from another (i.e., "cleanup-to-cleanup" is not a stand-alone reason where E.

coli O157:H7 is concerned). If a sample analysis yields a positive result, any product produced in the same time frame with the same process or equipment is suspect, unless an intervention occurred that would indicate a change in the status of the process/equipment. Often, factors like the plant's coding system, the pathogen of concern, the processing and packaging, the equipment, the plant's sampling programs, the HACCP plan monitoring and verification activities, the SSOP records, etc., are considered when determining how much product is actually represented by the sample.

Sample unit

This is an individual package, or container, or portion of product. It may take several sample units to make up one sample, depending upon the amount needed for the analysis. The amount of sample to be collected is detailed in various FSIS directives and notices. Some samples (composite samples) are made up of more than one sample unit.

Sampling Types

The term "sampling" as used in this module implies FSIS verification sampling. FSIS sampling refers to you physically collecting product that represents a product type and submitting it to a lab for an actual analysis. Whenever plant sampling is discussed, it will be stated as such.

The lab is completely dependent on you to properly collect, prepare, and ship the sample. The forms that accompany each sample must be the correct ones for the sample request and must be accurate and completely filled out. Your role is vital. The information entered on the form becomes part of a legal document.

There are three types of sampling: inspector-generated, directed, and special projects.

Inspector-generated samples are based on suspicion, and the reason for the sampling determines the product/category. If you suspect adulterated product was produced, then you may submit a sample ***after*** getting approval to sample from your Frontline Supervisor (FLS) and receiving an original sample request form. You can no longer use any form but the FSIS Form 10,210-3 (Requested Sample Programs) that you obtain from OCIO-DSMD (Office of the Chief Information Officer – Data Systems Management Division). Inspector generated samples are usually just one-time events, depending on the reason.

Directed samples are selected when sample requests are received in the mail. The directed sample requests for microbial analyses are on the Requested Sample Programs form, 10,210-3. For directed samples, the product history determines the sampling. OCIO and OPHS (Office of Public Health Science) determine which plants to

sample based on risk, seasonality, product types, processing methods, plant histories, and randomness. Directed sampling involves on-going programs.

Special project samples are taken when FSIS is alerted to a food borne illness outbreak by a state or local government, or when there is a special need, like a baseline sampling program. Special project sampling has a definite start and stop date.

Workshop I

FSIS sampling is done to

a. verify that FSIS performance standards and regulations are met.
b. validate HACCP plans and compare results to plant analyses.
c. generate public support.
d. monitor in-plant activities.

Matching

	Definitions		Answers
	Sampling initiated by Headquarters	A	Raw ground beef components
	A check to determine that a HACCP system is working as intended	B	Aseptic
	Raw ground or chopped beef, hamburger, ground or chopped veal, veal, or beef patties, and patty mix	C	Directed
	Intact or non-intact beef products intended for manufacturing into ground beef product	D	Raw ground beef products
	Not adding pathogenic organisms	E	Recall
	A collection of product that represents a larger group	F	Retain
	The amount of product represented by a sample	G	Sample
	Product is placed under official control in the plant	H	Sampled Lot
	A plant's voluntary removal of product from commerce	I	Verification

Procedure Code 05B02

Procedure 05B02, although under the "Economic Sampling" heading, entails microbial analyses with a direct bearing on food safety and public health.

05B02 as it Relates to Food Safety

FSIS verification activities include collecting and testing raw products for microbial hazards. FSIS Directive 10,210.1, "Unified Sampling Form", lists the products and pathogens and toxins for which FSIS may collect and test samples. For example, FSIS conducts routine analyzes on raw ground beef products, beef manufacturing trimmings, and other raw ground beef components and beef patty components intended for use in raw ground beef products for *E. coli* O157:H7.

Since a directed sample request is ***not*** a scheduled procedure, 05B02 is recorded as **unscheduled** on the Procedure Schedule.

The raw beef products listed above fall into the 03B and 03C HACCP process categories and have a specific sampling program/project code under FSIS's risk-based verification sampling. For instance, the sampling program/project code for raw ground beef products (03B) is shown below.

Directed Microbial Sampling for Raw Product	
Products	**Microbial Analyses**
Raw ground or comminuted beef or veal products, including ground beef, hamburger, beef patties, beef patty mix, etc.	*E. coli* O157:H7
Project Number	**Project Name**
MT43/MT44	Raw Ground or Comminuted Beef or Veal (Beef or Veal Only) Federal Program

Steps in Sampling

Step 1: Determine the Product to Sample

For directed sample requests, the product/category is specified on the request form 10,210-3. The sampling project code such as MT43, MT50, or MT54 is indicated in block 14 of the request form, 10,210-3.

To assist you in determining which product to sample, you will need to know the plant's processes and how product is labeled. Before collecting a sample, review the FSIS

notices or FSIS directives covering that sample type or program. A directed sample request may have additional instructions printed in block 18 of the Requested Sample Programs form (see Attachment 3).

Beef Manufacturing Trimmings to Sample

You only collect samples of beef manufacturing trimmings that the establishment intends for use in raw ground beef or other raw ground beef products that were **produced from carcasses slaughtered at the establishment.**

To determine the intended use of the products, review establishment records and HACCP documents (flow charts, hazard analyses, etc.). In cases where the establishment records and HACCP documents are unclear about the intended use, the trimmings will be considered for use in raw ground beef products and other non-intact raw beef products.

If the establishment commingles the beef trimmings with beef product processed at other establishments, you collect the sample before the establishment commingles the product.

Do not collect samples of beef manufacturing trimmings from production lots that are going to be further processed into ready-to-eat products, or diverted to cooking, or from lots of commingled beef manufacturing trimmings produced at a **different** establishment.

Low-temperature rendered products, including partially defatted chopped beef (PDCB), lean finely textured beef (LFTB), and product known as boneless lean beef tissue (BLBT)) are produced from beef manufacturing trimmings and can be used as a component in raw ground beef and beef patty products. When these products are injected with gaseous ammonia, it rapidly raises the pH. Scientific studies support that this procedure serves as an antimicrobial intervention that reduces *E. coli* O157:H7 in beef manufacturing trimmings to an undetectable level.

If the establishment produces ammoniated low-temperature rendered product, **do not** sample this product or beef trimmings intended for use in ammoniated low-temperature rendered product under the routine sampling program for beef manufacturing trimmings (MT50) if the establishment:

- has one or more CCP for production of ammoniated low-temperature rendered product in its raw ground HACCP plan; and

- clearly segregates beef manufacturing trimmings destined for the ammoniated process from the beef manufacturing trimmings that will not

undergo the ammoniated process because other beef manufacturing trimmings do not receive an intervention are subject to FSIS sampling and testing for *E. coli* O157:H7.

Raw Ground Beef Components and Beef Patty Components other than Beef Manufacturing Trimmings to Sample

You only collect samples of raw ground beef **components** or raw beef patty **components** other than beef manufacturing trimmings that are intended for use in raw ground beef and other raw non-intact beef products **that were produced from carcasses slaughtered at the establishment**. The sample request will indicate if you are to sample such product.

To determine the intended use of the products, review establishment records and HACCP documents (flow charts, hazard analyses, etc.). In cases where such documents are unclear about the intended use or consumer, handle the product as if it were for use in raw non-intact product. Also, if the plant has not identified the intended use or consumers of the finished product, there is noncompliance with 417.2(a)(2).

Sample collection for these products is based on the priority list below. For example, if the establishment produces two piece chuck or other primal or sub-primal cut (#1 on the priority list) on the day of collection, you are to take a sample of it; if not, you are to collect product from advanced meat recovery (AMR) (#2 on the priority list) if it is available, and move down the list until there is an available product.

1. Two Piece Chuck or Other Primal/Sub-primal Cuts Intended for use in Raw Ground Beef
2. Product from AMR (Advanced Meat Recovery) Systems
3. Low Temperature Rendered LFTB (lean finely textured beef)
4. Partially Defatted Beef Fatty Tissue (PDBFT)
5. Partially Defatted Chopped Beef (PDCB)
6. Weasand Meat
7. Head Meat
8. Cheek Meat
9. Heart Meat

When you receive subsequent sample request forms with the project code MT54 in block 14, you should continue down through the list in the same manner, choosing the next item on the priority list that is produced by the establishment that day. You should select a different component than previously collected, when possible.

If the establishment commingles components with beef product processed at other establishments, you need to collect the sample before the establishment commingles the product.

Raw Ground Beef Products to Sample

The products that are included in "raw ground beef" are raw (chopped or ground) beef food products made from cattle carcasses (beef and/or veal), such as ground beef, hamburger, veal patties, and beef patty mix that are distributed to consumers as such. These are ground beef products identified in §319.15(a), (b), or (c).

Sampled products may ***contain*** raw ground beef and beef patty components such as beef derived from AMR systems, LFTB, or PDCB. Unless a specific product (e.g., beef patties) is requested, the IIC (Inspector-in-Charge) should oversee sample collection to ensure that different products (as long as it is the same type of product stated on the 10,210-3) are sampled each time sample request forms are received. You may be instructed to collect more than one sample per lot under certain circumstances.

Products that contain another species of livestock in addition to beef (e.g., beef and pork patty), or intended to be further processed into ready-to-eat products, or made with ground beef but subject to a different standard of identity than in 319.15, such as meatballs or meatloaf, **are not** sampled.

NOTE: If the plant irradiates its raw ground beef, then follow FSIS Directive 7700.1, "Irradiation of Meat and Poultry Products" (if the HACCP plan states that the product will be irradiated, even off-site, then no sample of that product is collected).

Step 2: Notify Plant Management

Plant management must be notified whenever a sample of its raw beef product is taken. It gives management the option of holding the product represented by the sample pending test results. Inform the plant of the reason why you are taking the sample (routine monitoring, follow-up sampling in response to an *E. coli* O157:H7 positive, a trace-back sample, or follow-up sampling in response to an *E. coli* O157:H7 outbreak). **Recommend** that plant management hold the sampled lot of product. Inform plant management that it is responsible for supporting its basis for defining what product is represented by the sample (i.e., the sampled lot). Since the plant may opt to hold the lot, it needs sufficient time to make the necessary arrangements to do so. The purpose of FSIS sampling is to verify the plant is producing unadulterated product.

Inspection program personnel need to be familiar enough with the process to realize that in some cases notifying the establishment one day prior to collecting the sample may not be adequate time to allow the establishment to hold all product represented by

the sample. If the establishment requests more than a couple days' notice prior to collection of the sample, you are to consider the request based on establishment product and process flow. The District Office or the Policy Development Division (formally known as the Technical Service Center) can be contacted for guidance. You should discuss the notification and time frames with plant management ***prior*** to any sample requests being received in order to have an agreed upon notification protocol in place when a sample must be collected.

In the case of raw ground beef product, you must give plant management a handout (included with sampling supplies from the lab) stating that you will take a sample and that the establishment may wish to voluntarily hold the product pending microbial analyses results. This handout can be discussed at a weekly plant meeting to address these issues with plant management so they are aware of the procedure and protocol you will follow. Inform the plant that if the product represented by the verification sample is not voluntarily held, it is subject to voluntary recall, retention, or seizure if the sample is positive for pathogens, including *E. coli* O157:H7.

Step 3: Collect the Sample

If possible, only collect a sample from the establishment current day's production of beef manufacturing trimmings, or other raw ground beef component or beef patty component, or raw ground beef product. The sample needs to be collected during normal production because the sample represents the ***process***.

4. COLLECT TISSUES/SAMPLES ON		
Day of:	Week of:	Within 30 days of:

In most cases, block 4 of FSIS Form 10,210-3 is pre-printed with a ***time frame***. Select the day to collect the sample during the time frame indicated. It has a pre-printed date that tells you when to collect a sample. Usually it has a date in the "within 30 days of" section. That means that by 30 days ***after*** (not before) the date printed in the block, you should have collected a sample. ***All*** samples not collected within the designated time frame on the sample request form (e.g., Day of, Week of, Within 30 days after the date printed in the box) are discarded at the labs. Do not send in a sample after the 30 days unless you are directed to do so. If the plant will not produce the targeted product in that time frame, you must send the form back to the lab with an explanation of why no sample was sent in block 33. FSIS needs to account for all sample request forms that were sent to the field.

33. IF THE REQUESTED SAMPLE(S) ARE NOT COLLECTED, CHECK OFF THE APPROPRIATE REASON & RETURN THIS FORM TO THE LAB INDICATED ABOVE

(72) ☐ REQUESTED PRODUCT(S) NOT PRODUCED DURING THE SAMPLING TIME FRAME. (If checked, plant will be subject to sampling at a later date.)

(60) ☐ PLANT DOES NOT SLAUGHTER SPECIES/CLASS OR PRODUCE THE REQUESTED PRODUCTS (If checked, plant will be removed from this sampling program.)

(57) ☐ NEEDED SUPPLIES OR APPROPRIATE SHIPPING CONTAINER NOT AVAILABLE

(53) ☐ OTHER (Explain)

All samples are selected ***randomly*** from the type of raw beef product requested. In order for the sample to be representative of a lot, every attempt must be made to avoid taking a sample that is biased (i.e., nonrandom). You don't necessarily have to randomly select the lot, but you do have to randomly select the sample from that lot. One of the best ways to ensure an unbiased sample is to randomly select a time to collect the sample. You can use a random number table or generator to determine that time.

Collect samples in a sanitary manner. You want to assure that the sample is not contaminated from outside sources. When it is not possible to collect the sample in final packaged form, follow instructions for aseptic sample collection. Put the sample (intact or not) in a sterile bag provided by the lab.

Put the sample in a secure location. If a sample must be held overnight, it must be refrigerated. If a sample must be held longer than overnight, it must be frozen.

Collecting Beef Manufacturing Trimmings

When collecting samples from beef manufacturing trimmings, you are to follow the instructions on the Trim and Sub-Primal Sample Collection Training CD and in FSIS Notices 17-07 and 18-07. Use the N60 sample collection method, i.e., collect 12 or more very thin slices of exterior surface tissue from the trim in each combo bin, box, or other container from one to 5 containers for a total of 60 pieces. Each slice should be approximately 1/8" thick, 4" in length, and 2" wide. The 60 pieces (a composite sample) should weigh 2 pounds.

Collecting Raw Ground Beef and Beef Patty Components other than Beef Manufacturing Trimmings

When collecting samples from raw ground beef and beef patty components other than beef manufacturing trimmings, you are to follow the instructions in FSIS Notice 17-07. For 2 piece chucks and other primals or sub-primal cuts, you follow the N60 sampling procedure. For AMR products, low temperature rendered products and comminuted

components, randomly select a sample consisting of 2-lb of product from a specific production lot. For heart, weasand, and other raw ground beef and beef patty components randomly collect one piece, or enough pieces, of the component to equal 2-lb. If the component is very large, follow the N60 sample collection method.

Collecting Raw Ground Beef Products

FSIS Directive 10,210.1 provides sampling instructions for raw ground beef and beef patty products (project codes MT43 and MT44). For these project codes, a 1-lb sample of ground beef product is needed, in final packaged form (whenever possible). The IIC should oversee sampling procedures to ensure that different products within the requested product type are sampled each time sample request forms are received.

If the lab receives an insufficient amount of product to perform the specified analyses, the sample is discarded (see Attachment 2 for discard reasons). If the plant has freezing as a CCP in its HACCP plan, additional guidance may be provided by OPHS on a case-by-case basis.

Collecting Samples in Establishments that Produce and Grind Beef Manufacturing Trimmings and/or Other Raw Ground Beef Components

Some establishments may produce raw beef products that are subject to different routine verification sampling programs, e.g., MT43, MT50, and MT54. Therefore, you may receive **multiple** routine sample requests (MT50 and MT43 or MT54) during the same 30-day sampling window. You are to complete **all** sample requests by selecting samples from independent production lots, unless you are only able to collect one sample (e.g., because the establishment produces 1,000 pounds or less of product on a daily basis, or only on an intermittent basis). In this situation, you should prioritize by sampling the beef manufacturing trimmings under the MT50 sampling program using the N60 collection method. If this establishment also routinely uses other raw ground beef components, you should also attempt to collect the MT54 sample if multiple routine sample requests are received during the same sampling window multiple times.

Step 4: Packing and Mailing the Sample

If the paperwork is not complete, or if it is missing, or for the wrong product, the sample ***will*** be discarded. Be sure the sample and the paperwork match, otherwise the sample is discarded.

All sample forms received ***without*** a collection date are discarded.

Microbiological pathogen samples submitted on FSIS Form 10,210-3 must have Part II, blocks 19, 20, 21, 22, and 28-32 completed. Otherwise the lab discards them.

19. DATE COLLECTED	20.DATE SENT TO LAB	21. PRODUCT TEMPERATURE	22. PRODUCT HELD ☐ YES ☐ NO

Note: *Block 21 doesn't apply to samples collected in the* ***final package form*** *such as raw ground beef and/or veal product samples.*

28. REMARKS

Note: *Block 28 has additional information and questions you need to answer. Check the box that best describes the raw beef component sampled. Provide the production volume information requested in block 28 of FSIS Form 10,210-3, along with any other requested information.*

29. COLLECTOR'S SIGNATURE	30. *NAME OF COLLECTOR (Print)*	31. BADGE NO.	32. TELEPHONE NO. AT EST.

Note: *The badge number is for the positive identification necessary for a traceable chain of custody. For example, if there are two Sam Smiths in FSIS, it is important to identify which Sam Smith sent the sample. Using your badge number does not violate your privacy, but it does supply the necessary positive identification for legal purposes.*

Only one sample should be in a shipping container to avoid confusion. The laboratory does not discard a sample just because two different samples are in the same shipper. If you do include more than one sample, write this information on the Container Seal. However, the labs will discard them if it is not clear which sample goes with which sample form.

Double-check and compare the address on the expanded billable stamp to make sure it is going to the lab indicated in block 9 of the sample form. The lab will discard the sample if you mail it to the wrong lab.

The shipping containers you receive should have the top and bottom sealed by the lab with tamper-evident tape. You will ***not*** receive any tamper-evident tape to use. If the

tape is cut or missing, ***do not*** open the container. Follow the instructions in FSIS Directive 7355.1 (seal it with the Container Seal, 7355-2A, and ship it back to the lab of origin for processing; complete the seal by writing "seal broken" in the "Form No." blank).

Pack the sample in this order.

1. Gel pack
2. Coolboard
3. Sample with paperwork (all in a zip-lock bag)
4. Foam plug
5. Close the shipper with seal (7355-2A – Container Seal)

To ensure the product is maintained at refrigeration temperature, place the sample in a pre-chilled shipping container with a frozen gel pack, even if the sample was previously refrigerated or frozen. The piece of cardboard called the coolboard goes on top of the gel pack to separate the gel pack from the sample. Put a small bar code sticker from Form 7355-2 at the top center of the sample form (i.e., paperwork) and put the form in a plastic bag or sleeve. Put another small bar code sticker on the bagged sample. Put the sample and paperwork into the larger zip-lock bag and affix the Identification Label (7355-2B) to the bag. Note that the 7355-2B is a ***label*** rather than a seal and must simply be affixed. There is no need to fold over and seal the bag with the label. The zip-lock bag, containing the bagged sample and the paperwork, is put into the shipper. Filler material is ***not allowed*** in the shipping container. This means that no newspaper, paper towels, etc., can be inside the shipping container to take up any empty space. The foam plug must be pushed down as far as possible to keep the sample from being tumbled inside the shipper. Put any extra unused bar codes into the box so that the lab can account for them, or put them on the Container Seal where they won't cover any written or printed information. Alternatively, if you keep a record of the sample, you can affix the extra bar code to your record. Close up the box and seal it.

For sample integrity, a Container Seal (FSIS Form 7355-2A) must be put on the shipping container in such a way that it cannot be opened without disturbing the seal.

Raw beef product samples are mailed to the laboratory on the first available day the contract carrier picks up after collecting the sample. **Do not wait** until the establishment completes pre-shipment review before submitting the samples to the laboratory for *E. coli* O157:H7 testing. If the establishment intends to test the product for *E. coli* O157:H7 before conducting the pre-shipment review, **do not wait** for the establishment to receive test results before submitting the sample to the laboratory. Make sure the correct date is in block 20 on the 10,210-3.

Samples are mailed so they arrive at the lab the next day. Samples should not be held over the weekend if it is avoidable (not more than three days). However, if a sample

must be held over the weekend (Friday to Monday), it must be frozen. The current contract carrier will ***deliver*** on Saturdays, but not ***pick-up***. With the newer expanded billable stamps, there is no need to designate Saturday delivery.

Cross-check that the lab address in block 9 of the FSIS Form 10,230-1 is the same as on the expanded billable stamp. If these are different, your sample will be discarded. If the lab listed in block 9 is different than the one on the expanded billable stamp, e-mail the lab listed in block 9 and request an expanded billable stamp from that lab. You should check this information when you **first** get your sample request, **not** when you are about to mail the sample.

Check the expiration date on the expanded billable stamp. Do not use it if it is expired.

On the expanded billable stamp, enter the establishment number, shipping date (day sample box picked up by carrier) and the establishment's phone number.

FSIS Laboratories

Samples are sent to the appropriate FSIS lab identified on the 10,210-3.

There are three FSIS Field Service Laboratories. The Eastern lab is in Athens, GA, the Midwest lab is in St. Louis, MO, and the Western lab is in Alameda, CA.

The FSIS labs are responsible for providing the sampling supplies.

Requesting Sampling Supplies

Whenever you receive a routine or follow-up sample request form from OCIO-DSMD, determine if you have the required sampling supplies on hand. If you need sampling supplies, send an e-mail request through Outlook following FSIS Notices 17-07 and 18-07. You need to order the supplies at least 72 hours before you intend to collect a sample. Email the FSIS laboratory which is identified in Block 9 of the sampling request form. Use one of the following email addresses:

Sampling Supplies-EasternLab@fsis.usda.gov
Sampling Supplies-MidwesternLab@fsis.usda.gov
Sampling Supplies-WesternLab@fsis.usda.gov

Include the following information:

- Proper sampling project code, e.g., MT43, MT50, or MT54
- Exact supplies needed
- Establishment's physical address (no P.O. Boxes)
- Establishment's phone number

Always cc your FLS on such e-mails.

With each shipment of supplies, there is a handout to give to plant management. Each time you take a regulatory sample you must give plant management that handout.

Example 1
You receive a sample request from OCIO-DSMD for project code MT43. You read the information on the 10,210-3 and the related directives. You note the time frame in block 4 of the form. On the appropriate date, you notify plant management that you will be collecting a sample today.

You ask what products are being produced that meet the product type requested. You are told by the production manager that today they are producing bulk raw ground beef in 20-lb twist-tie bags, raw hamburger in 2-lb tray packs, raw beef patties packed 12 to a vacuum sealed bag, and raw beef patty mix in 40-lb boxes.

In the recent past, you had sent in samples of the beef patties and the bulk ground beef, which were negative for *E. coli* O157:H7. To ensure you are sampling the various products, this time you select the hamburger. You inform the production manager that you'll sample the hamburger.

At the time you go out to collect the sample off the packaging line, you notify plant management. A QC person accompanies you out to the line. You wash your hands and then pick up a package off the line. The QC person asks why you selected that package. You tell her it was randomly based on time.

You realize that you won't be able to verify that until tomorrow morning, so you refrigerate the sample according to the directions in FSIS Directive 10,210.1. You put it in the retain cage in the cooler and secure it with a government lock. The following morning, you pack and send the sample to the FSIS lab listed on the 10,210-3 sample request form.

Workshop II

1. You suspect that a product may be out of compliance. Before taking a sample,
   a. make sure the plant is not aware of the sampling.
   b. contact an EIAO.
   c. get approval from your front line supervisor.
   d. first complete all scheduled procedures assigned for the day.

2. When would a ground beef sample be sent to the lab for an *E. coli* O157:H7 directed sample?
   a. the day before the “use by” date
   b. just prior to packaging
   c. the first day the contract carrier is available after the sample is collected
   d. as soon as the lot is assembled

3. Plant management is notified that you are taking a sample
   a. when you receive the analysis result (either from LEARN or the DO).
   b. if the plant has a good working relationship with FSIS.
   c. enough in advance to allow the plant to hold the product, but not soon enough to allow it to alter the process.
   d. because of the Freedom of Information Act (FOIA).

4. How many samples **should** be submitted per shipping container?
   a. 1
   b. 2
   c. 3
   d. 4

Scenario

You received FSIS Form 10,210-3 requesting a raw ground beef or veal sample under the MT43 project code. This is the first time you have received this type of sample request.

1. As a critical thinker, what do you do next?

The instructions tell you to randomly select and aseptically collect an unfrozen one pound sample prior to freezing. The plant receives beef trimmings and chubs of ground beef. The chubs may be added to the beef trimmings and ground, or they may be shipped without any further processing. The ground beef and beef trimmings are ground into ground beef, ground beef patties, raw beef and pork sausage, and cooked meatloaf. The plant has one grinder and does a complete cleaning and sanitizing of the equipment prior to the start of operations each day.

2. What product could you sample for the *E. coli* O157:H7 under this project?

3. When would you notify plant management that you will take a sample?

The plant manager asks you to tell him specifically the time when you will collect the sample so he can stop production after the sample is taken.

4. How do you respond?

5. What should you do after you collect and submit the sample?

Step 5: Results

Access LEARN (Laboratory Electronic Application for Results Notification) to track your sample receipt and results. LEARN is a computer application that notifies FSIS personnel and establishment management of the receipt and status of samples sent to FSIS analytical laboratories for testing. LEARN reports when a sample was received at the lab, if it was discarded and the reason for the discard, and the results of the analyses when they are completed. More information is contained in FSIS Directive 10,200.1.

If you click on the correct sample in LEARN, at the bottom of the screen there should be a discard reason/description. This is below the normal area on the screen where results are found. If the sample was discarded, notify the establishment. This is especially important when the plant is holding product. The product no longer needs to be held if the sample was discarded.

Microbial analyses results are reported as positive or negative. Some are listed as presumptive, which means that there is evidence to suggest the product is out of compliance, but additional analyses and/or samples are needed to confirm it. LEARN provides immediate notification of sample analyses.

OCIO e-mails sample results to plants that have an e-mail address in the PBIS plant profile. Even if the establishment receives sample results directly from OCIO, it is still your responsibility to notify the establishment when sample results are received.

Negative Results

The first lab analysis is accomplished within two days of sample receipt. It is a screening test that identifies the presence of *E. coli* O157:H7. If the screening test is negative, *E. coli* O157:H7 is not present (or below detectable levels) in the sample tested. The negative results are posted in the LEARN system. FSIS resumes normal sampling at that establishment.

Presumptive Positive Results

If the screening test is positive, the sample is potentially positive for *E. coli* O157:H7 and additional testing is necessary to confirm the result. This second step, called confirmatory testing, is usually accomplished within 5 days of the sample receipt, but can sometimes take longer.

The DO alerts the plant in cases where the lab notifies the DO (using BITES (Biological Information Transfer E-mail System) prior to posting the information in LEARN) due to a presumptive positive for *E. coli* O157:H7. This ensures that the plant receives that important message if you are not available. The District Office contact will also inform the plant that if the results are confirmed positive, FSIS will collect information regarding specific suppliers of the source materials used in the production of the product that tested positive (confirmed).

Supplier Information

- Name of the establishment
- Point of contact (name, title, e-mail address, and fax number)
- Phone number
- Supplier lot number
- Production date
- Name of supplied material and any additional information to clearly identify the material

If the source materials are imported from a foreign establishment, additional information will be needed by the establishment (country of origin, foreign establishment number, shipping mark, I-house, and bar-coding or other information to aid in identifying the product).

At the time the sample is presumptive positive, the plant should start to gather supplier information.

Positive Results

Positive results are also on the LEARN system. If positive results are obtained, notify the plant. A DO contact will also alert the establishment.

When a presumptive positive sample is confirmed positive, collect the required supplier information from the plant and e-mail it to the DO contact designated to receive this message. Make a note of any information the plant is unable to provide. Copy your Frontline Supervisor.

Inspection program personnel need to determine if the establishment tests its raw beef products for *E. coli* O157:H7. If the plant has an *E. coli* O157:H7 testing program, you need to determine whether the plant tested the **same** production lot for *E. coli* O157:H7 that you sampled that was confirmed positive for *E. coli* O157:H7.

If the sample you submitted is positive and the plant tested the same product, check the plant's *E. coli* O157:H7 test results to determine whether it also found the sampled product positive for *E. coli* O157:H7. If the plant held the product or maintained control of the product (e.g., the plant moved the product off site but did not complete pre-shipment review or transfer ownership of the product to another entity) pending its own test results, and FSIS AND the establishment found the product positive for *E. coli* O157:H7, you **do not** issue an NR unless the plant fails to take the appropriate corrective actions.

When the sample you submitted is positive, or the plant finds the **same** production lot that you sampled positive for *E. coli* O157:H7, respond to questions in Attachment 1 of FSIS Notice 62-07 or Attachment 2 of FSIS Notice 68-07 depending on the raw beef product that was positive for *E. coli* O157:H7.

Issue an NR when FSIS finds product positive for *E. coli* O157:H7, but the plant does not, under the appropriate 03 ISP code using the "verification" noncompliance classification indicator and cite §417.4 and §301.2 as the relevant regulations. As soon as possible after the establishment has implemented its corrective action, perform the 02 procedure for the specific production that tested positive. Determine whether or not the plant implements corrective actions that meet the requirements described in §417.3.

Plants are expected to only ship wholesome unadulterated product. The establishment is responsible for determining what product it holds and what it determines to be "affected product". (FSIS Directive 8080.1 contains more information related to affected product or "scope".) If the plant does not control its product, then take a regulatory control action (retain product if it is available or take a withholding action per §500.3(a)(1) if the plant shipped the adulterated product into commerce). If any affected product has left the plant and it is no longer under the plant's control, notify the DO. A

recall may be recommended. (Documentation and enforcement will be covered in more detail in a later module.)

Plant management must account for all affected products by identifying them and their location. The plant must take **corrective actions** that meet one of the following requirements.

- 417.3(a) if *E. coli* O157:H7 is addressed in the HACCP plan, or
- 417.3(b) if *E. coli* O157:H7 is not addressed in the HACCP plan, or if it is addressed in prerequisite programs, or
- 417.3(b) and 416.15 if *E. coli* O157:H7 is addressed in the SSOP.

The establishment may need to conduct a reassessment of its HACCP plan or reevaluate its SSOP or prerequisite programs to meet these requirements. In addition, the plant should reassess (§417.4(a)(3)) because something in the process has changed.

If product disposition is to occur off-site, verify that the plant maintains appropriate control of the product.

Off-Site Product Disposition

Raw beef products confirmed positive for *E. coli* O157:H7 may be moved off-site for proper disposition, under appropriate controls. Product may be transferred to another official establishment for further processing to destroy the pathogen. Plants may opt to dispose of the product through rendering or disposal in a landfill. Plants may also divert product that is presumptive positive, rather than wait for a confirmation. Presumptive positive product must be controlled just like confirmed positive product. Plants may use their own controls (e.g., company seals) or move the product under FSIS control (e.g., USDA seals or FSIS Form 7350-1, “Request and Notice of Shipment of MPI Sealed Meat/Poultry”). When the product is destined for a landfill or rendering operation, it moves under company controls, because FSIS representatives are not at those locations to remove USDA seals or follow up with FSIS Form 7350-1.

When the establishment moves positive product off-site for disposition, verify the plant that produced the positive product maintains appropriate control of the product at all times, including while it is in transit to the off-site location where the product will either be reworked to destroy pathogens before entering commerce or be disposed of so it will not be used for human consumption.

Conduct the following additional verification activities when you perform your 02 procedure.

- Obtain the name of the receiving official establishment, renderer, or landfill. This includes the name and address for renderers or landfills.

- E-mail your District contact person with the receiving establishment number or the name and address of the landfill operation or renderer (where product will be further processed). Your DO will contact the DO with jurisdiction over the receiving locations.

- For product destined for a landfill operation or renderer, verify that the establishment will maintain control of the positive product while it is in transit (e.g., through company seals).

- For product being transferred to another official establishment for further processing, verify that either company or FSIS controls are in place.

- Verify that records are available demonstrating the positive product received proper disposition. This includes documentation evidencing proper disposal of the product at the official establishment, landfill operation, or renderer. You cannot complete your HACCP 02 procedure for this specific production until the plant conducts pre-shipment review. The plant cannot conduct the pre-shipment review until it receives documentation from the other official establishment, landfill operation, or renderer showing proper disposal. If you find noncompliance with this, contact the DO. The DO will investigate to determine if the plant committed the prohibited act of offering adulterated product for sale into commerce.

At the plant receiving positive product

If you are the inspection program employee at the plant that receives raw ground beef products, beef manufacturing trimmings, or other raw ground beef components, or raw beef patty components that tested positive for *E. coli* O157:H7, you have certain verification functions to perform.

When you perform the HACCP 01 or 02 procedures for such products, verify that the plant

- documents receipt of presumptive or confirmed positive product (as per §417.5),
- maintains control of the product, and
- addresses the presence of *E. coli* O157:H7 in its hazard analysis and HACCP plan (includes adequate lethality treatment to destroy the pathogen).

Document all noncompliance as per FSIS Directive 5000.1.

Follow-Up to an FSIS Positive Sample and Follow-Up Sampling

When an FSIS sample for a raw beef product is confirmed positive for *E. coli* O157:H7, and the plant has not found the same product to be positive, issue an NR for HACCP noncompliance, verify the plant's corrective actions, check appropriate decision-making documents, assist in any needed recall, collect supplier information, and conduct an 02 procedure on the specific production that tested positive. You cannot complete the 02 procedure until the establishment has taken corrective actions and the product has received proper disposition (including completing a pre-shipment review). If the establishment maintained control of the product and sampled it, and both the establishment's and FSIS's samples were found positive for *E. coli* 0157:H7, you are NOT to issue a Noncompliance Record. You must verify that the establishment's corrective actions meet the requirements in §417.3.

If you find regulatory noncompliance, **e.g., the plant fails to take corrective action in accordance with §417.3,** while performing the 02 procedure, document it on an NR (as per FSIS Directive 5000.1). If you find that the plant moved positive product without the necessary controls, or if you find that the plant does not have records documenting proper disposition of the positive product, contact your DO.

FSIS Verification at Establishments Producing Beef Manufacturing Trimmings and Other Raw Ground Beef and Beef Patty Components

When raw ground beef products are confirmed positive, FSIS will conduct verification activities at supplier establishments, including the originating supplying slaughter establishment, that produced the beef manufacturing trimmings, or raw ground beef or beef patty components that were used to produce the positive product. The DO will contact the IIC at the supplying plant. If you are at the ***supplying plant***, remind the plant that the notification is to ensure that the supplier knows that it ***could be*** the source of *E. coli* O157:H7 positive product. It is not a definitive determination that the supplier is the source of the pathogen contamination. The IIC at the supplying establishment will perform a HACCP 02 procedure to verify that the supplier met all regulatory requirements at all CCPs in the HACCP plan for production lots sent to the plant where the positive was found.

Follow-Up Sampling at Originating Supplying Slaughter Establishments

As outlined in FSIS notice 17-07, **each time** that an FSIS ground beef product verification sample or another Federal or State entity's ground beef product sample tests positive for *E. coli* O157:H7, inspection program personnel will collect **a follow-up sample** at the **originating supplying slaughter establishment(s)** that produced the beef manufacturing trimmings or other raw ground beef or raw beef patty components

used in the positive ground beef product sample. Sampling project code MT52 will be pre-printed in block 14 of the sample request form, 10,210-3.

The District Office (DO) will determine which suppliers is/are the originating supplying establishment(s) from the supplier information that the IIC forwards to the DO and generate a follow-up sample request for each of the originating supplying establishments. If the originating supplying slaughter establishment produced more than one type of component that the grinding establishment used, the DO will generate a sample request form for each type of component.

The DO will contact the IIC at the originating supplying slaughter establishments to ensure that the HACCP 02 procedure was performed and inform him/her of the type of beef component that the establishment supplied to the grinder so that inspection program personnel can sample that component from the establishment's current production for follow-up testing when the IIC receives a sample request form for project code MT52.

Upon receipt of the follow-up sample request form, 10,210-3, you randomly select the sample of beef manufacturing trimmings, or other raw ground beef components, or raw beef patty components from the establishment's current production following the sample collection instructions (e.g., the N60 procedure for beef trim and 2 piece chucks, and 2 lb of product needed for AMR product, low temperature rendered products, and comminuted components), and the instructions for notifying plant management before taking the sample in FSIS Notice 17-07 and previously covered in this handout. Document the follow-up sampling in the Performance Based Inspection System (PBIS) by recording an unscheduled procedure code O5B02.

You should only collect follow-up samples of beef manufacturing trimmings or raw ground beef components or beef patty components that the establishment intends for use in raw ground beef or other raw ground beef products. If the originating supplying slaughter establishment commingles beef manufacturing trimmings or other raw ground beef or raw beef patty components with beef product from **other establishments**, collect the follow-up sample before the establishment commingles the product. **Do not** collect follow-up samples of commingled beef manufacturing trimmings or other raw ground beef or beef patty components produced at a **different establishment.**

If the originating establishment is not currently producing the type of component requested, you are to collect a follow-up sample of another component that is available. Collect a sample of beef manufacturing trimmings if the establishment is producing them. If the originating establishment is also not producing beef manufacturing trimmings, then collect a sample of another type of raw ground beef or beef patty component (e.g., head meat, heart meat, or product from AMR systems).

Pack the sample and complete sample request form as outlined in this handout. Send the sample to the laboratory on the first available day the contract carrier picks up after collecting the sample.

Follow-Up Sampling at the Originating Supplying Slaughter Establishments For Intact Raw Beef Components <u>not</u> Intended For Use in Raw Ground Beef Products

When an FSIS raw ground beef product sample tests positive for *E. coli* O157:H7, inspection program personnel are to **select a carcass** at the originating supplying slaughter establishment for follow-up sampling under project code MT52 rather than the component of the carcass if the originating slaughter plant can demonstrate

- Through HACCP production records and purchase specifications the intact beef product used as a ground beef component was not intended for grinding or non intact product, and the plant had informed purchasers of this intent, and

- That the intact product was derived from beef carcasses in a manner to avoid cross contamination with other product, e.g., product was packaged separately and not commingled with other beef prior to packaging. Inspection program personnel must be able to verify that the product was handled as stated above through records review or direct observation.

If both of these conditions are met, you collect a sample from the carcass while the carcass is hanging in the cooler prior to fabrication using the N60 sample collection method described in FSIS notice 17-07, i.e., collect very thin slices of exterior surface tissue from the **same part of the carcass** that was used in the positive FSIS raw ground beef product for a total of 60 pieces. Each slice should be approximately 1/8" thick, 4" in length, and 2" wide. The 60 pieces (a composite sample) should weigh 2 pounds. Document the follow-up sampling in the Performance Based Inspection System (PBIS) by recording an unscheduled procedure code O5B02.

If the follow-up sample result for the carcass is positive for *E. coli* O157:H7, then only that carcass will be associated with the positive sample result. The plant will need to take corrective actions for that carcass. Head and cheek meat from that carcass which was removed during the slaughter process will not be implicated by the positive result.

Pack the sample and complete sample request form as outlined in this handout. Send the sample to the laboratory on the first available day the contract carrier picks up after collecting the sample.

Multiple Follow-Up Sampling After an FSIS Positive Sample Result

Analysis of *E. coli* O157:H7 sample data collected by FSIS indicates that a plant that has had a positive sample is likely to receive a second positive within 120 days of receiving the first positive result. In response to this finding, FSIS has implemented a multiple follow-up sample testing protocol.

As outlined in FSIS notice 66-07, **each time** that FSIS or another Federal or State entity finds raw ground beef product, beef manufacturing trimmings, or other ground beef or raw beef patty components OR follow-up samples of beef trimmings or other ground beef or raw beef patty components, to be positive for *E. coli* O157:H7, inspection program personnel will receive 16 follow-up sample request forms, 10,210-3, to sample product from the establishment that produced the positive product or the originating slaughter establishment. The sample request forms are automatically generated and sent to the establishment. For low volume establishments, (establishments which produce less than 1000 pounds of the product to sample daily), eight samples need to be collected. The remaining sample request forms need to be returned to the laboratory in the shipping container with the last follow-up sample submission. The type of sample requested will be based on the type of raw beef product implicated in the positive test result. The sampling project code pre-printed in Block 14 of form 10,210-3 identifies the type of raw beef product to sample.

- Sample raw ground beef product under the MT44 project code after a routine MT43 project code (ground beef product) positive result
- Sample beef manufactured trimmings OR other raw ground beef or raw beef patty components under the MT53 project code after a routine MT50 project code (beef trim) positive result OR a routine MT54 project code (raw ground beef/beef patty component) positive result
- Sample beef manufactured trimmings or ground beef/beef patty components under the MT53 project code after a follow-up MT52 project code (beef trim or component from the originating slaughter plant) positive result
- Sample beef manufactured trimmings or ground beef/beef patty components under the MT52 project code when the originating slaughter plant has been identified in System Tracking *E. coli* Positive Suppliers (STEPS) as a supplier of source materials for product FSIS found positive 120 days prior to the date of the current ground beef positive result

Sampling from production lots produced after the positive result starts as soon as possible following receipt of the 16 follow-up sample request forms. You **DO NOT** wait for the establishment to complete the corrective actions taken in response to the positive result before conducting follow-up sampling. As soon as the plant resumes normal production of the product(s) to be sampled, start your sample collection at the following daily and weekly frequencies.

- Sample a maximum of two follow-up samples per shift per day from different lots. This should be followed unless the establishment can not continue to operate under that sampling frequency or your workload will not accommodate that sampling frequency. If either of these concerns arise, discuss it immediately with FSIS supervision.
- At a minimum collect three samples per week unless the establishment can not to continue to operate under that sampling frequency or your workload will not accommodate that sampling frequency. If either of these concerns arise, discuss it immediately with FSIS supervision.

You only collect follow-up samples of beef manufacturing trimmings or raw ground beef components or beef patty components that the establishment intends for use in raw ground beef or other raw ground beef products. Randomly select the sample of raw ground beef product, beef manufacturing trimmings, or raw ground beef or beef patty component from the establishment's current production following the sample collection instructions (e.g., 1 lb of raw ground beef product, the N60 procedure for beef trim and 2 piece chucks, and 2 lb of product needed for AMR product, low temperature rendered products, and comminuted components), and the instructions for notifying plant management before taking the sample in FSIS Directive 10,010.1, FSIS notice 17-07 and previously covered in this handout. Document each follow-up sample collected in the Performance Based Inspection System (PBIS) by recording an unscheduled procedure code O5B02.

Pack the sample and complete sample request form as outlined in this handout. You may submit more than one sample per shipping container if each sample is individually identified and the shipping container is large enough to hold more than one sample. Send the sample to the laboratory on the first available day the contract carrier picks up after collecting the sample.

While you are collecting follow-up samples for *E. coli* O157:H7 testing, you may receive a routine verification sample request form for raw beef product to be tested for *E. coli* O157:H7. In this situation, continue to collect follow-up samples and make follow-up sampling the priority, rather than routine sampling. If your workload and the establishment's production practices allow it, collect the sample for routine testing within the allotted 30 days. Do not collect a follow-up sample and a routine verification sample from the same product lot.

The District Office (DO) will schedule a Food Safety Assessment (FSA) at an establishment within 30 days after being notified that FSIS or another Federal Agency or State entity has found raw beef product positive for *E. coli* O157:H7. The follow-up sampling results will provide objective data that an EIAO will use in formulating an Agency position when conducting the FSA. The DO will consider the results of follow-

up sampling and take the appropriate enforcement actions (e.g., NOIE, withhold or suspend inspection, reinstate a suspension), if warranted.

E. coli O157:H7 Positive Follow-Up Sample Result

Access LEARN to track your follow-up sample receipt and results. Respond to discarded samples, negative results, presumptive positive results, and confirmed positive results as previously described in your handout. The actions FSIS takes in response to *E. coli* O157:H7 positive FSIS follow-up sample are same actions FSIS takes for an *E. coli* O157:H7 positive FSIS routine verification sample.

When an FSIS generated follow-up sample is found positive for *E. coli* O157:H7 and establishment's sample for the same lot is also positive, you should not issue an NR provided that the plant held the product represented by sample (or maintained control of the product) pending its own test results. You need to verify that the plants takes corrective actions that meet the requirements in §417.3.

When an FSIS generated follow-up sample is found positive and the plant either did not test the product lot or did not find the pathogen, you will issue an NR under the appropriate 03 ISP code using the "verification" noncompliance classification indicator and citing §417.4 and §301.2 as the relevant regulations. As soon as possible after the establishment has implemented its corrective action, perform the HACCP 02 procedure for the specific production that tested positive. Determine whether or not the plant implements corrective actions that meet the requirements described in §417.3.

As outlined in FSIS Notice 62-07, whenever FSIS finds its sample positive or the establishment finds the same production lot that FSIS sampled positive for *E. coli* O157:H7, you need to prepare an e-mail message which is described in FSIS Notice 62-07 or 68-07. The message should be addressed to O157:H7establishmentPractices@fsis.usda.gov. The subject line should read "Establishment Testing Follow-up". The text body of the message should address the questions in Attachment 1 of FSIS Notice 62-07 or Attachment 2 of FSIS Notice 68-07 depending on the raw beef product that was positive for *E. coli* O157:H7. You need to respond to all questions that apply to the positive product in the attachment.

If the plant decides to change the intended use of the product after you collect a sample such as diverting all the product represented by the sample to cooking, you will issue an NR under the appropriate 03 ISP code using the verification noncompliance trend indicator when the sample tests positive *E. coli* O157:H7 unless the plant's decision to divert the product was based on its own positive test result.

If disposition of the positive product is to occur off-site, verify that the plant has met all corrective action requirements, e.g., maintained control of product during transportation,

has records identifying who received the product and showing proper disposition/disposal, and conducted a pre-shipment after receiving the disposition/disposal records, as described in Notices 17-07, 18-07, 62-07, and 66-07, and in the **Off-Site Product Disposition section** of this handout. If you find noncompliance, document it in accordance with Directive 5000.1. Notify the DO through supervisory channels when the plant has not properly moved the positive product off-site.

Plant-Generated Sampling

Some plants may have their own sampling programs for *E. coli* O157:H7. Plants may sample for various reasons (checking suppliers, to satisfy contracts with customers, etc.), but most commonly they sample to verify their processes produce safe, wholesome unadulterated product. These sampling programs may or may not be included in the plants' SSOP or HACCP plans. Even though these programs may not be included as part of the SSOP or HACCP system, plants are still required to share records and analyses results with you.

Based on the regulatory requirements of 9 CFR 417.2(a)(2) and 9 CFR 417.5(a)(1), FSIS believes that the results of such testing and monitoring activities related to the production of product are subject to FSIS review and must be available to FSIS personnel upon request, including records from prerequisite programs. FSIS Directive 5000.2 states that, ***on at least a weekly basis***, inspection program personnel must review the results of any testing and of any monitoring activities the plant performed that may have an impact on the hazard analysis. Based on review of establishment records, if you have concerns about the design of testing, monitoring, or verification activities outside of a HACCP plan, or concerns about results from such activities, procedures, or prerequisite programs, contact the Technical Service Center or raise the concern through supervisory channels. It may be determined that an EIAO needs to conduct a food safety assessment to assess such factors as what the test results reveal about food safety and whether the design of testing, procedures, or prerequisite programs are adequately supported by the decisions made in the hazard analysis.

Note: *You can collect a sample, with supervisory approval, anytime you suspect noncompliance or have reason to believe that a sample is warranted (inspector-generated sample).*

The plant is not obligated to notify FSIS when it receives a positive sample, but it must take corrective actions that meet the requirements of §417.3 each time a positive result is obtained. The plant must also maintain appropriate control for any product that is presumptive positive or confirmed positive for *E. coli* O157:H7 that is shipped to another establishment, or to a landfill or renderer for appropriate disposition.

Example 2
A plant has its own testing program for *E. coli* O157:H7 for its raw hamburger patties. The plant has not included it as a verification activity in its HACCP plan. In the last test, the result was positive. The plant always holds product pending results. The plant does not need to inform you of its positive result. But, the plant must implement corrective actions that meet the requirements of 9 CFR 417.3. You must verify that the plant took the necessary corrective actions to meet these requirements. You should become aware of the positive from your regular review (at least weekly) of the plant's sampling results or from reviewing corrective action records or observing corrective actions the plant takes.

Example 3
A plant has its own testing program for *E. coli* O157:H7 in its beef trim. The testing is part of the verification of the overall HACCP plan. The plant analyzes the samples while the product is in transit, but still under the plant's control. When the result is received, the plant completes the pre-shipment review. The product is ***not*** in commerce, but in transit. The last test result was positive. The plant must implement corrective actions that meet the requirements of 9 CFR 417.3. Again, you must verify that the plant meets ***all*** four requirements described in 417.3.

Whether the plant brings the product back to the establishment for disposition, or it diverts it for further processing at another official establishment or to a landfill or renderer, the plant must demonstrate control of the adulterated product until that product receives proper disposition. The establishment must provide documents evidencing proper disposition.

When you are aware that there was a positive result you must

- Conduct a HACCP 01 or 02 procedure to verify the plant's corrective actions (§417.3(a) or (b)), and
- Issue an NR **only** if the plant fails to implement the corrective actions that meet the requirements of §417.3(a) or (b).

Note*: The HACCP 02 procedure cannot be completed until pre-shipment review is completed, which includes review of disposition documentation.*

Some plants may opt to divert the product to another official establishment for cooking when they receive a ***presumptive positive*** in their testing program, or to a landfill or renderer. However, the plant is still obligated to meet ***all*** parts of 417.3. It is still required to have proper control of the product while it is in transit for disposition. It also must maintain documentation of appropriate disposition.

When product that is ***presumptive positive or confirmed positive*** for *E. coli* O157:H7 is transported to another official establishment for appropriate disposition, the plant sending the product must

- maintain records identifying the official establishment, renderer, or landfill operation that receives the presumptive positive or positive product,
  NOTE*: If the product is analyzed while in transit, the plant must maintain records identifying the official establishment to which the product is being sent.*
- maintain control of product (company controls or FSIS controls),
- maintain records that indicate product received proper disposition, and
- complete pre-shipment review only after it has all disposition records for that particular product.

If you are aware that presumptive positive or positive product is in transit, verify the controls. In addition, e-mail the DO information about the intended product disposition location (establishment number, or name and address of renderer or landfill).

If inspection personnel find noncompliance with the plant's handling of presumptive or confirmed positive product, contact the District Office. The DO will investigate to determine if the plant sold or transported adulterated product.

Example 4
The establishment has a finished product sampling program as part of its verification of the HACCP plan for raw ground beef product. Its last sample was presumptive positive.

The plant diverted the product to cooking at its own in-plant cooking operation. It identified all affected product and cooked it separately from its other products. The company used a HACCP plan that had been designed specifically for product known to contain *E. coli* O157:H7 and which contains a CCP for lethality that was validated to eliminate *E. coli* O157:H7. Records demonstrating the positive product received proper disposition are available.

The plant identified the source of the presumptive positive *E. coli* O157:H7 contamination as coming from a new supplier. Plant management required the supplier to demonstrate that validated antimicrobial interventions are implemented in its process before purchasing any other products from that supplier.

The plant includes this certification as a HACCP verification.

Alternative Lot Definitions

Inspection program personnel may permit an establishment that samples beef manufacturing trimmings, other raw ground beef components, or raw beef products

under its own testing program to reduce its lot size to one combo bin or other unit (e.g., box) on the day that FSIS conducts sampling if the establishment

- Has an intervention for *E. coli* O157:H7 at a CCP in the HACCP plan that covers the product or requires an intervention for *E. coli* O157:H7 at a CCP for that product's source materials, and

- Samples and tests ***every*** production lot for *E. coli* O157:H7 and generally collects its samples of beef manufacturing trimmings, other raw ground beef components, or raw ground beef products across multiple combo or other sample units

If these criteria are met and the plant reduces its lot size to a single combo bin or sample unit when you collect the sample of the product, you are to collect the sample from that the single combo bin or sample unit following the instructions in FSIS Notices 17-07, 18-07, or Directive 10,010.1.

Instructional or Disclaimer Statements

Although instructional and disclaimer statements do not affect the samples you collect, you may encounter them while performing your verification duties.

Establishment that Labels the Product

An ***instructional statement*** concerning *E. coli* O157:H7 is a statement that addresses how the product should be prepared or handled to ensure the pathogen is eliminated or reduced to undetectable levels. Examples of such statements are "for full lethality treatment" (any process that eliminates or reduces *E. coli* O157:H7 to undetectable levels) or "for cooking only" (application of sufficient heat to eliminate or reduce the pathogen to undetectable levels).

A ***disclaimer statement*** concerning *E. coli* O157:H7 is a statement regarding the type of verification activities addressing the pathogen that were **NOT** used in producing the product. An example of such a statement is "product has not been tested for *E. coli* O157:H7". A disclaimer that the product has not been tested for *E. coli* O157:H7 implies that *E. coli* O157:H7 may be a food safety hazard reasonably likely to occur in the product in the absence of controls. Therefore, the information contained in the disclaimer statement would be inconsistent with a determination in the hazard analysis that it is unnecessary to address this hazard in the HACCP plan, and the HACCP plan may be determined inadequate (§417.6). In other words, *E. coli* O157:H7 must be addressed in the HACCP plan if disclaimer statements are used.

Instructional and disclaimer statements are not required. They can only be used on product for use at other official establishments (not for use on retail product). The Labeling and Consumer Protection Staff (LCPS) must approve the use of such statements. When LCPS grants sketch approval for instructional statements, LCPS specifies that such statements can only be used on products destined for official establishments that ensure the product receives adequate lethality treatment. When LCPS grants sketch approval for disclaimer statements, LCPS specifies that such statements can only be used on products destined for official establishments that address *E. coli* O157:H7 in their HACCP plans. Establishments' use of instructional or disclaimer statements is entirely optional.

When you conduct an 04B04 procedure, verify the plant has received sketch approval from LCPS for any instructional or disclaimer statements. The plant is required to maintain these approvals in its labeling records. Issue an NR (reference §317.4(a)) if the plant did not receive sketch approval or does not maintain that sketch approval in its labeling records.

When you conduct a HACCP 01 or 02 procedure, verify that if the plant has instructional or disclaimer statement,

- it is not serving as a control or CCP to address *E. coli* O157:H7,
- it is not justifying the plants determination that *E. coli* O157:H7 is NOT a hazard reasonably likely to occur,
- its use is reflected in the plant's decision-making documentation or hazard analysis, and
- the plant's HACCP plan for products bearing disclaimer statements includes validated intervention for *E. coli* O157:H7 (in a CCP).

Document noncompliance as per FSIS Directive 5000.1.

Establishment Receiving Product with Instructional or Disclaimer Statements

If you are assigned to a plant that receives product with instructional or disclaimer statements, when you perform a HACCP 01 or 02 procedure, verify that the plant's HACCP plan addresses the use of product with disclaimer statements as if it may be contaminated with *E. coli* O157:H7, and the plant follows any instructional statements on the incoming product. Document noncompliance as per FSIS Directive 5000.1.

Retain products processed with incoming product that bear instructional or disclaimer statements if the plant didn't follow the instructional statement, or if its hazard analysis or decision-making documents don't address the use of product with disclaimer statements as if it were contaminated with *E. coli* O157:H7. Retain product if the process is not adequate to eliminate or reduce *E. coli* O157:H7 to undetectable levels, or if the product is not intended for further processing that would destroy the pathogen.

In addition to issuing an NR, notify the DO of the conditions observed concerning the use of instructional or disclaimer statements. The DO may dispatch an EIAO to conduct a comprehensive food safety assessment or invoke an enforcement action.

Summary

Procedure 05B02 is devoted to directed sampling for food safety concerns. Currently, the microbiological hazard of *E. coli* O157:H7 is of most concern in raw beef/veal products, so FSIS is focusing on analyses for that organism in these products.

As new technologies and methods of producing products are developed, and as new pathogens emerge that affect meat and poultry food safety, FSIS will adjust its efforts to continue being a public health agency. New or different microorganisms may be added to the list of those for which the Agency currently tests. It will continue to be the responsibility of the in-plant inspection force to verify that establishments meet their food safety obligations.

Workshop III

1. What options does the plant have regarding disposition of product that tested positive for a pathogen but did not leave the plant's control? (Choose ***all*** that apply.)

    a. destroy product
    b. divert product for cooking
    c. re label product
    d. send the product to a landfill or renderer

2. When will you collect samples of raw ground beef and beef patty components other than beef manufacturing trimmings? (Select all that apply.)

    a. Upon receiving 16 follow-up sample request forms, 10,210-3, after a positive of a raw ground beef product sample taken by FSIS
    b. When receiving a sample request form, 10,210-3 with project code MT54 in block 14.
    c. Only when the establishment does not take the appropriate corrective actions for a raw ground beef product *E. coli* O157:H7 positive
    d. Only after the establishment has completed the appropriate corrective actions for a raw beef product *E. coli* O157:H7 positive

3, Select which products you could sample when directed to collect a sample of raw ground beef product (MT43/MT44).

a. Hamburger
b. Ground beef
c. Beef patties
d. Ground beef patties
e. Beef breakfast sausage
f. Ground beef and pork mix for meatloaf

4. Select which raw ground beef or beef patty components may be sampled for *E. coli* O157:H7 testing by FSIS under project code MT54.

a. Weasand meat
b. Beef cheek meat
c. Beef hearts
d. Beef head meat
e. Beef from AMR systems
f. Lean finely textured beef (LFTB)
g. Partially defatted beef fatty tissue

5. If the plant sends presumptive positive product for *E. coli* O157:H7 to a landfill, what are the requirements to do so?

6. If the plant sends presumptive positive product for *E. coli* O157:H7 to a landfill, what does the CSI do?

7. Which products, when confirmed positive for *E. coli* O157:H7 are considered adulterated?

   a. Mechanically tenderized beef steak
   b. PDBFT for use in raw beef patties
   c. Beef trimmings for use in grinding
   d. Beef subprimals boned for use in raw ground beef
   e. Raw ground veal patties

Scenarios

1. The establishment where you are assigned slaughters and fabricates beef. It samples its own trimmings as a prerequisite program. On Thursday afternoon, you remembered that, according to FSIS Directive 5000.2, you are to review such records on at least a weekly basis. You go to the office where the records for the prerequisite program are kept and review the sampling results. You notice that on Monday morning, the beef trim tested from the previous Wednesday was confirmed positive for *E. coli* O157:H7. What are your responsibilities in this scenario?

2. Last week, you submitted a sample of the plant's raw ground beef patties to the FSIS lab. Three days ago you notified the plant that the sample was presumptive positive. Today, when you arrived at the plant, the plant manager told you that he'd been informed by the District Office that the sample was confirmed positive. What are your responsibilities in this scenario?

ATTACHMENT 1

Resources

Currently, there are several directives associated with microbial sampling of raw products that fall into the 03B, 03C, and 03J process categories. This list is current as of 6/17/04. You should review the pertinent directives prior to obtaining a sample. The review should consist of checking to see if the directive is the current version. The FSIS website lists those directives that have been published most recently. The Outlook Folder (Public Folders ⇒ All Public Folders ⇒ Agency Issuances ⇒ Directives or Indexes and Checklists) has a listing of the current directives (and any revisions, etc.). The actual directives are posted under the Directives Folder. New listings may also be posted in LEARN on the "What's New" page.

FSIS Directive Number	Directive Title
5000.1	Enforcement of Regulatory Requirements in Establishments Subject to the HACCP System Regulations
5000.2	Review of Establishment Data by Inspection Program Personnel
7355.1	Use of Sample Seals for Laboratory Samples and Other Applications
7700.1	Irradiation of Meat and Poultry Products
8080.1	Recall of Meat and Poultry Products
10,010.1	Microbiological Testing Program for *Escherichia coli* O157:H7 in Raw Ground Beef
10,200.1	Accessing Laboratory Sample Information via LEARN
10,210.1	Unified Sampling Form
10,230.2	Procedures for Collecting and Submitting Domestic Samples for Microbiological Analyses
10,600.1	Sample Shipment Procedures

"Compliance Guidelines for Establishments on the FSIS Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7" are at http://www.fsis.usda.gov/Regulations_&_Policies/Compliance_Guides_Index/index.asp

ATTACHMENT 2

Discard Reasons

Only those reasons that may apply to raw samples are listed here. The codes are not given in this table since they are used for tracking purposes. Your frontline supervisor has access to this information and monitors the number of discarded samples. You should review the sample and paperwork before submitting them to the lab to ensure these mistakes are not made.

No Sample Received with Form
Collected Outside Scheduled Time Frame
Temperature Too High
Tissue/Sample Spoiled/Rancid
Container Damaged
Wrong Tissue/Sample for Requested Analysis *(Residue samples)*
Insufficient Tissue or Sample
Delayed Shipment *(FedEx doesn't' get sample to the lab in 24 hour time frame)*
Shipped on Friday w/o Saturday Delivery label
Original Form Not Submitted w/Sample
Target Tissue Not Received *(Residue samples)*
No Form Received with Sample
Original Form Altered by Sample Submitter
Laboratory Problem*
No Gel Packs/Coolants in Sample Box
Sample Container Leaking
Collection Date Not Day Prior to Sample Receipt
Sent to Wrong Lab
Sample ID # on Bag does not match ID # on Form
Security Seal Missing or Not Intact
No Accredited Lab Tests Performed
Headquarters/ TSC/DO Discard
Sampling Instructions Not Followed

ATTACHMENT 3

Internal lab code here	U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE **REQUESTED SAMPLE PROGRAMS** ☐ FOOD CEMISTRY ☐ MICROBIOLOGY ☐ RESIDUE	*Barcode here* 1. SAMPLE FORM NO.

PART 1. SAMPLE COLLECTION AND MAILING INSTRUCTIONS

2. SAMPLE TYPE CODE	3. EST. NO.	4. COLLECT TISSUES/SAMPLES ON			5. REGION/ DISTRICT	6 STATE	7. CIRCUIT/IFO
		Day of:	Week of:	Wthin 30 days of:			

8. ESTABLISHMENT ADDRESS/SAMPLE COLLECTION ADDRESS (i.e., Est.,Retail Store)	9. NAME & ADDRESS OF RECEIVING LABOATORY

10. SLAUGHTER CLASS CODE	11. SPECIES TO COLLECT	12. TISSUE	13. ANALYSIS REQUESTED

14. PROJECT NO.	15. COUNTRY OF ORIGIN	16. COUNTRY COPY	17. FOREIGN EST. NO.

18. ADDITIONAL INSTRUCTIONS

PART II. COLLECT SAMPLE INFORMATION (To be compluted by sample collector)

19. DATE COLLECTED	20. DATE SENT TO LAB	21. PRODUCT TEMPERATURE	22. PRODUCT HELD ☐ YES ☐ NO

23. FSIS N9540-1 NO.	24. LOT NO.	25. IMPORTS ☐ NORMAL (06) ☐ INCREASED (07) ☐ SPECIAL (53) ☐ HOLD (24)

26. PRODUCER/DEALER/OWNER-NAME/ADDRESS/STATE/ZIP CODE	*27. ANIMAL ID (Tag No.)*

28. REMARKS

29. COLLECTOR'S SIGNATURE	*30. NAME OF COLLECTOR (Print)*	31. BADGE NO.	32. TELEPHONE NO. AT EST.

33. IF THE REQUESTED SAMPLE(S) ARE NOT COLLECTED, CHECK OFF THE APPROPRIATE REASON & RETURN THIS FORM TO THE LAB INDICATED ABOVE

(72) ☐ *REQUESTED PRODUCT(S) NOT PRODUCED DURING THE SAMPLING TIME FRAME. (If checked, plant will be subject to sampling at a later date)*

(60) ☐ PLANT DOES NOT SLAUGHTER SPECIED/CLASS OR PRODUCE THE REQUESTED PRODUCTS *(If checked, plant will be removed from this sampling program)*

(57) ☐ NEEDED SUPPLIES OR APPROPRIATE SHIPPING CONTAINER NOT AVAILABLE

(53) ☐ *OTHER (Explain)*

PART III, LABORATORY RECEIPT INFORMATION

34. SAMPLE PACKAGING ☐ 3034 Intact Package ☐ 3035 Non-intact Package	35. SAMPLE RECEIPT DATE

36. PRODUCT CODE	37. NO. SAMPLES IN COMPOSITE	38. SAMPLE RECEIPT TEMPERTURE

39. SAMPLE RECEIPT CONDITION CODE	40. SEAL CONDITION CODE	41. DISCARD CONDITION CODE

FSIS FORM 10,210-3(3/97)