RAW PRODUCT SAMPLING

Objectives

To demonstrate mastery of this module, you will

1. List the food safety sampling programs for raw products.
2. List the main pathogens of concern under MT03/MT04.
3. Select, from a list, those raw products subject to sampling under 05B02.
4. State where to find FSIS sampling instructions.
5. Explain the use of FSIS Form 10,210-3.
6. State how samples are collected.
7. List, in order, the steps of sampling.
8. Describe how to determine which product to sample.
9. State where and how sample results are received.
10. State when to mail samples.
11. List the actions associated with positive microbial results.

Introduction

Throughout the history of meat and poultry production, various pathogenic bacteria have caused foodborne illness. As an agency dedicated to protecting the public health, FSIS has used science to keep pace with, and to keep ahead of, these pathogens. Detecting the pathogen is the first step. From there, FSIS works with other governmental agencies, academia, industry, and consumer groups to set policy and establish guidelines and performance standards to reduce or eliminate the pathogen from meat and poultry products. Although *Escherichia coli* O157:H7 has been known to cause foodborne illness since 1982, it is only recently that large volumes of federally inspected meat and poultry have had to be recalled from commerce. 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 pathogens in raw product processing establishments.

Currently, raw ground beef products are subject to sampling per FSIS Directive 10,010.1, “Microbiological Testing Program for *Escherichia coli* O157:H7 in Raw Ground Beef” and FSIS Notice 11-03, “Update to FSIS Directive 10,010.1, Microbiological Testing Program for *Escherichia coli* O157:H7 in Raw Ground Beef”. Raw comminuted (chopped or formed) meat food products made from cattle carcasses (beef and/or veal) are sampled at the producing establishment performing the grinding operation. If the plant receives chubs of coarse ground beef and the product is used as is without further grinding, then the coarse

ground beef is not subject to sampling. Sample collection occurs at the originating establishment. However, if the plant receives coarse ground beef and processes it by further reducing the particle size, that product is subject to sampling after the grinding operation has occurred.

As FSIS is continuously improving its sampling protocol and techniques, updating sampling programs, and developing more rapid means of reporting results, the policy will change accordingly. For those reasons, it is not feasible to give sampling details in this module. **FSIS directives and notices contain policy details specific to sampling projects and programs** (see Attachment 2). 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 so that you are at least familiar with the fact that a notice or directive was recently issued that dealt with sampling. Because you are familiar with the information when you received it, you will know to read the issuance when you need to actually collect a sample that may be affected by the information in the issuance. FSIS Notice 11-03, dated 4/18/03, illustrates the importance of staying abreast of new Agency publications.

FSIS is responsible for maintaining effective inspection and enforcement programs to assure consumers that their supply of meat, poultry, and egg products is safe, wholesome, unadulterated, properly labeled and produced in a sanitary environment. Laboratory analyses play an integral role in verifying the plant's compliance with regulatory requirements.

Sampling activity is divided into food chemistry, microbiology, and residue samples. Inspection program employees select, prepare, and submit samples of meat, poultry, and egg products to laboratories for pathological[1], chemical[2] (includes residues), or microbiological analyses. They may even select, prepare, and submit samples of food additives to labs for chemical analyses.

Microbiological analyses include the various pathogenic bacteria or their toxins/metabolites that FSIS targets for sampling. Toxins are byproducts of the bacteria's normal metabolism. Preformed toxins (those produced before the bacteria or metabolites are ingested) are often quite stable to adverse environments, like heat treatment.

[1] Pathology samples are submitted from tissues collected from the slaughter operations or soon after (while the carcass is still basically intact). Lesions and other abnormalities are submitted to the labs. Advanced meat recovery (AMR) product samples are pathology samples that are taken from meat, instead of at the carcass.

[2] Chemical analyses include residue, fat, water, protein, additives, etc. Any component, whether intentional or not, of the product falls under the umbrella of "chemical" sampling.

Egg products aren't currently covered by HACCP regulations, so they are not covered in this module. This material is focused on in-plant sampling only. For that reason, import, compliance and retail sampling are not covered here.

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. Microbiological sampling programs are designed to verify that HACCP programs are effective in controlling harmful microorganisms in meat and/or poultry products.

Currently for raw products, FSIS emphasizes analyses of raw ground beef and/or veal product because of the public health implications. The sampling program is MT03/MT04.

The objective of this 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 ground beef.

Definitions

Affected
This is any product that represents the sampled lot, as well as product that was produced in the same time frame with the same process and equipment between complete clean-ups, or within a certain time period between complete clean ups if this can be supported by the establishment. *E. coli* O157:H7 contamination can occur at any point in the process. The contaminant can then be widely disseminated throughout the entire ground product by the grinding process itself. The potential for contaminating all subsequent handling, processing, and packaging equipment is significant. This potential to contaminate product exists until an effective, complete cleaning and sanitizing process has eliminated the source of the contamination and any subsequent cross-contamination.

If a sample analysis yields a positive result, then any product produced with the same process/equipment is suspect, unless an intervention occurred that would indicate a change in the status of the process/equipment. Generally, this intervention is a complete cleaning and sanitizing operation.

Aseptic
"Aseptic" means free from pathogenic organisms. 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. It is not necessary for you to sanitize the area and put on gloves. 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. From these baseline studies, FSIS may establish performance standards.

Raw ground beef products
Raw ground beef products covered under the *E. coli* O157:H7 sampling program (MT03/MT04) include any raw comminuted (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. Exceptions are Advanced Meat Recovery System[3] (AMR) beef, ground beef or veal for further processing into other products, and mixed ground species (other

[3] AMR product samples are pathology samples that are taken from the meat instead of the carcass.

than beef and veal). The Agency is in the process of evaluating an expanded program for raw beef products. **Refer to any new issuances on this topic for additional details.**

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 would involve at least the sampled lot, but is could be expanded depending upon a review by the Recall Management Division (RMD) of all factors in the situation. All recalls of meat and poultry products are voluntary. FSIS Directive 8080.1 gives additional details on recalls.

Retain
When product is placed under a regulatory control action in an establishment under FSIS jurisdiction, it is considered retained. Retaining product is one form of a regulatory control action.

Sample
A sample for raw products is a collection of product that represents a larger group (the sampled lot) that has passed the plant's pre-shipment HACCP review. This is a verification of the plant's food safety system, and therefore the system must be allowed to function. This sample should be representative of the plant's ability to properly execute its HACCP plan. The collection of the sample should afford the plant an opportunity to take any corrective actions related to its food safety system prior to the sample being submitted to the laboratory.

Sampled lot
This is the amount of product represented by the sample. The plant defines the sampled lot. For microbial issues, the actual product represented by the sample may be from clean-up to clean-up. 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. It may take several sample units to make up one sample, depending upon the amount needed for the analysis. The amount of sample is detailed in various directives. Some samples are made up of more than one sample unit.

Sampling

The term “sampling” as used in this module implies FSIS 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 regarding sampling. The information entered on the form becomes part of a legal document.

There are three reasons for taking samples: inspector-generated, OPHS (Office of Public Health and Science) 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 and receiving an OPHS-generated form. You can no longer use any form but the FSIS Form 10,210-3 (Requested Sample Programs) that you obtain from OPHS.

OPHS directed samples are selected when sample requests are received in the mail. OPHS uses only the Requested Sample Programs form (10,210-3). For OPHS directed samples, the product history determines the sampling.

Special project samples are taken when FSIS is alerted to a foodborne illness outbreak by a state or local government, or when there is a special need.

Workshop I

1. What term means “product produced after the sampled lot”?
   a. like product
   b. affected product
   c. extended product
   d. subsequent product

2. 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.
   e. monitor in-plant activities.

Matching

Definitions

__ Sampling initiated by OPHS

__ A check to determine that a system is working as intended

__ Any raw comminuted beef or veal

__ Product representing a sampled lot, as well as product produced in the same time frame between complete clean-ups

__ Not adding pathogenic organisms

__ A collection of product that represents a larger group

__ The amount of product represented by a sample

__ Product is placed under official control in the plant

__ A plant’s voluntary removal of product from commerce

Answers

A. Affected
B. Aseptic
C. Directed
D. Raw ground beef products
E. Recall
F. Retain
G. Sample
H. Sampled Lot
I. Verification

Procedure 05B02

Procedure 05B02, although still under the "Economic Sampling" heading, entails microbial analyses with a direct bearing on food safety and public health. All the samples are requested from OPHS. The directed sample requests for microbial analyses are on the Requested Sample Programs form, 10,210-3. [Sometime in the near future, this form will be completed on-line.]

The 05B02 procedure is also used for directed samples that are not a food safety concern (hence, the "Economic Sampling" heading). These are Import samples for food chemistry analyses. Therefore, it is not a simple matter of stating that OCP (Other Consumer Protection) requirements are verified under 05B01 sampling and only health and safety requirements are verified under 05B02 sampling. Procedure 05B02 actually addresses both, depending upon the program area (domestic or imports).

The front line supervisor, district office, or Washington headquarters (not just OPHS) may also initiate the 05B02 samples. It is important that you recognize the difference between procedures 05B01 and 05B02, even though there is overlap between these two sampling procedures.

> ***Note**: The focus of the rest of this module is on the food safety aspects of sampling for verifying HACCP procedure code 03B for raw product.*

05B02 as it Relates to Food Safety

FSIS verifies the adequacy of an establishment's HACCP system by determining whether HACCP plans meet the requirements of §417 and all other applicable regulations, and whether the system is operating as intended. Verification activities include, but are not limited to, 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 may analyze raw ground beef for *E. coli* O157:H7, and raw chicken for *Campylobacter* in a baseline study.

For directed sample requests, the product/category is specified on the request form. Unless a specific product 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 Requested Sample Programs form) are sampled each time sample request forms are received.

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

Sampling Programs

Raw products that fall into 03B currently have a specific sampling program under directed food safety sampling (05B02).

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**
MT03/MT04	Raw Ground or Comminuted Beef or Veal (Beef or Veal Only) Federal Program

There is a similar sampling program at retail establishments, but since that is not an in-plant function, it is not addressed here.

Steps in Sampling

Step 1: Determine Product to Sample
You determine which product to sample by knowing the plant's processes and how product is labeled. Before collecting a sample, review the notices or 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 4).

Before collecting the sample, review pertinent FSIS directives and notices. The directive of concern, FSIS Directive 10,010.1, has recently been updated through FSIS Notice 11-03 that was issued on 4/18/03. FSIS Directive 10,010.1 was updated because the prevalence of *E. coli* O157:H7 has been shown to be seasonal and begins to rise in April and May. As a result, the Agency believes it is necessary to increase its verification efforts. Where inconsistencies exist, FSIS Notice 11-03 supercedes FSIS Directive 10,010.1.

Inspection personnel should disregard Section VI. B. of Directive 10,010.1(this section addressed various situations in the plant under which inspection personnel did not collect samples). Effective immediately, inspection personnel will collect a sample **whenever** they receive a directed sampling request (FSIS Form 10210-3) for this sampling project (MT03/04).

Additional changes addressed in FSIS Notice 11-03

- Collect the sample in final packaged form, whenever possible.
- Do not mail the sample until the pre-shipment review has been completed.
- **Recommend** that plant management hold the sampled lot of product.
- Freeze samples that must be held more than overnight.
- Provide the production volume information requested in block 28 of FSIS Form 10210-3.
- Verify the plant's corrective and preventive actions which **may** include collection of additional samples. These additional samples are directed by the District Office, which coordinates these sample requests with OPHS.

Currently, the only specific raw products sampled as on-going in directed sampling is ground beef or veal analyzed for *E. coli* O157:H7. The products that are included in "raw ground beef" are raw comminuted (chopped or ground) meat 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. (Sampled products may contain beef derived from advanced meat recovery systems and/or Mechanically Separated Beef, but these products are ***not*** to be sampled as such. Nor are products that contain another type of livestock product in addition to beef (for example, fresh beef and pork sausage)).

All raw, comminuted beef products, which bear the mark of inspection, are subject to sampling at federally inspected establishments. A sample should be collected when the product is reduced in particle size (ground) at the plant. If coarse ground product is produced for further processing, but shipped into commerce just as coarse ground beef, it is subject to sampling. If it goes to another plant that grinds it into smaller particles, it is subject to sampling at that plant. So the same product could actually be sampled twice (once each at each processing plant) depending upon how it is processed, labeled, and shipped.

In order for the sample to be truly representative of a lot, every attempt must be made to avoid taking a sample that is biased (i.e., nonrandom). One of the best ways to ensure an unbiased sample is to randomly select a time to collect the sample after grinding and ,whenever possible, in its final packaged form. You can use a random number table or generator to determine that time.

Step 2: Notify Plant Management

Plant management must be notified whenever a sample of its 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). (See Attachment 7.) Since the plant may opt to hold the lot, it needs sufficient time to make the necessary arrangements to do so. 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 stating that you will take a sample and that the establishment may wish to voluntarily hold the product pending microbial analyses results. (See Attachment 1.) 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. 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 microbial pathogens.

Provide the plant enough time to hold all product it determines is represented by the sample. Coordinate with plant management to determine at what time to provide the notification. Advanced notification should not be given to allow the plant to alter its processes prior to you collecting a sample.

Step 3: Collect the Sample

If possible, only collect samples from the current day's production that will have the pre-shipment review conducted on the same day as collection. It needs to be collected during normal production because the sample represents the process.

FSIS Directive 10,210.1 provides sampling instructions under project numbers MT03 and MT04. For these project numbers, a 1-lb sample of ground beef product is needed, in final packaged form, whenever possible. Samples are to be placed in the sterile sample bags provided by OPHS. In situations where a final package cannot be collected, an aseptically collected raw, unfrozen 1-lb sample is collected prior to packaging and freezing. 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. If the plant irradiates its raw ground beef, then FSIS Directive 7700.1 should be followed.

In most cases, block 4 is pre-printed with a time frame. 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*** the date printed in the block, you should have collected a sample. 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, then you must send the form back to the lab with an explanation.

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

Select the day to collect the sample during the time frame indicated.

All samples are selected randomly from the type of product requested. The IIC oversees sampling to ensure that different products within the requested product type are sampled each time sample request forms are received.

Collect samples in a sanitary manner. You want to assure that the sample is not contaminated from outside sources.

- Wash and scrub your hands thoroughly to the mid-forearm, using anti-bacterial hand soap (and sanitizer at 50 ppm chlorine equivalency if available).

- Open the "whirl-pack" type bag that is sent with the sample collection kit according to FSIS Directive 10,230.2, Part Two.

- Label the bag and package for shipping according to directions on the sample request form.

Put a bar code sticker from FSIS Form 7355-2 on the sample bag before putting the sample in a secure location. Samples are either kept refrigerated or frozen, depending on the instructions in the individual directives. The directives will specify if a product can be frozen or not before shipment. The Identification Label[4] must be attached to the zip-lock bag containing the sample and the 10,210-3 or immediate product container in such a way as to indicate that no tampering occurred with the sample. The 5-part sample seal explained in FSIS Directive 7355.1, Rev. 2, must be used on the sample, the paperwork, and the shipping container.

If the lab receives an insufficient amount of product to perform all of the specified analyses, the sample is discarded (see Attachment 3 for discard reasons). Access LEARN to track your sample receipt and results. LEARN means Laboratory Electronic Application for Results Notification. More information is contained in FSIS Directive 10,200.1. LEARN is a computer application that notifies FSIS personnel and establishment management of the receipt and status

[4] These (FSIS Form 7355-2) replace the green 7355-1 seals. These updated seals use bar codes for tracking and matching samples and forms.

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.

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.

All samples not collected within the designated time frame on the collection form (e.g., Day of, Week of, Within 30 days after the date printed in the box) are discarded at the labs.

If it is not possible to collect the sample on the same day that the pre-shipment review will be completed (e.g., product is held off-site prior to completion of the pre-shipment review, or the review is performed at a later date), samples collected from the current day's production must be refrigerated ***or*** frozen (based on instructions in the directives), kept secure, and the mailing postponed until the pre-shipment review is performed. After the plant completes the pre-shipment review, the sample is mailed on the next available day the contract carrier picks up.

The samples in these cases are collected prior to the completion of the pre-shipment review, but the sample cannot be mailed until either the pre-shipment review is completed or the product is shipped. If for whatever reason, the plant decides not to ship the product represented by the sample selected, but to rework it or dispose of it, then you must likewise discard the sample by returning it to the plant. Send in the 10,210-3 to the lab with an explanation of why no sample was sent in block 33 by marking "other" and a writing a short explanation.

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)

If you determine that the plant shipped the product without doing a pre-shipment review, immediately mail the sample to the lab (since the product is in commerce) and issue an NR for the pre-shipment noncompliance.

Step 4: Packing and Mailing the Sample
Samples should be shipped in FSIS-furnished containers, unless special arrangements are made with the lab. The ***proper*** paperwork (properly ***completed***) and labels must accompany **each** sample.

Only one sample should be in a shipping container to avoid confusion. But 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) The labs will discard them if it is not clear which sample goes with which sample form. They will also discard the sample if you mail it to the wrong lab. For this reason, you must double-check and compare the address on the FedEx Air-bill to make sure it is going to the lab indicated in block 9 of the sample form.

The shipping containers you use should have the top and bottom sealed by the lab with red and black striped tamper-evident tape. If you have shipping containers on hand that the lab has not recently sent to you, you may still use them, but you need to apply a second FSIS Form 7355-2A to the bottom with an explanation written on it. This is only to be done during a limited grace period to use the shippers that you had prior to the lab using the tape. You will ***not*** receive any tamper-evident tape to use.

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)

A frozen gel pack should be added for product that was stored 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. The zip-lock bag, containing the bagged sample (with a small bar code sticker) and the paperwork (with a small bar code sticker from Form 7355-2 on the top) in a plastic sleeve, 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 bar codes into the box so that the lab can account for them.

FSIS Form 7355-2B, Identification Label, is not durable and may tear if you are not careful when you apply it to the bag containing the sample and the sample form. 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. This further adds to the sample integrity. FSIS Form 7355-2A, Container Seal, is

stronger and does not tear easily. It was made specifically for the purpose of sealing the shipping container.

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). If the sample is collected and held pending the pre-shipment record review, make a note of this on the sample form for the lab. This will alert the lab as to why you waited to mail the sample. However, if a sample must be held over the weekend (Friday to Monday), it must be refrigerated or frozen, depending on the directive instructions. The current contract carrier will ***deliver*** on Saturdays, but not ***pick-up***. A "Saturday Delivery" label must be used. Put a checkmark (√) in the "Saturday Delivery" portion of the delivery airbill or stamp.

It is vital to include the ***completed*** paperwork. If the paperwork is not complete, or if it is missing or for the wrong product sample, the sample ***will*** be discarded. Be sure the sample and the paperwork match, otherwise the sample is rejected. The sample seal numbers all have to match, except if there are multiple samples, then the seal on the outside container only has to match one sample.

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, 22, and 28-32 completed. Otherwise the lab discards it.

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

Note: Block 21 doesn't apply to raw ground beef and/or veal.

28. REMARKS

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.

FSIS Laboratories

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

There are three FSIS Technical 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. Whenever supplies are needed, the program employee will e-mail a request through Outlook following FSIS Notice 54-02 (see Attachment 5).

Step 5: Results

Results are received through the LEARN system. Microbial analyses results are reported as positive or negative. Some are listed as presumptive.[5] LEARN provides immediate notification of presumptive positive *E. coli* O157:H7 sample analyses. Results are available as soon as the analysis is complete. OPHS e-mails sample results to plants who complete FSIS Form 10,230-2, FSIS Establishment E-mail (Internet) Address Collection Form, and submit it to OPHS.

The lab analysis has two distinct steps. The first step is accomplished in two days from collection of the sample (if it is mailed the same day it is collected). It is a screening test that identifies the presence of *E. coli* O157:H7, as well as other cross-reacting bacteria that are not *E. coli* O157:H7. If the screening test is negative, *E. coli* O157:H7 is not present in the sample tested.

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 collection (if it is mailed the same day it is collected), but can sometimes take longer.

Negative

Negative results from an FSIS lab are available on the LEARN system. You are responsible for providing results to the plant, even when OPHS e-mails results to the plant. Resume normal sampling at that establishment.

[5] Evidence is there to suggest the product is out of compliance, but additional analyses and/or samples are needed to confirm it.

Presumptive Positive

When there is a presumptive positive (posted in LEARN), notify the plant management that the sample was presumptive positive. Inform the plant that if the results are confirmed positive, you will collect specific supplier information regarding the product that tested positive (confirmed).

- Name of the establishment
- Point of contact
- Phone number
- Supplier lot number
- Production date

At the point of a presumptive positive, the plant should start to gather this information.

Positive

Positive results are also on the LEARN system. You are responsible for obtaining these results and notifying the plant. The DO only alerts the plant in cases where the lab notifies[6] the DO (prior to posting the information in LEARN) due to a presumptive positive for *E. coli* O157:H7. This contact ensures that the plant receives this important message if you are not available.

When a microbial test result is positive, you take action against the sampled lot and all affected products as well.

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. Copy your Frontline Supervisor.

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. The in-plant inspection personnel must take appropriate action if they find noncompliance.

[6] The lab uses BITES (Biological Information Transfer E-mail System) to notify the DO.

Issue an NR for all FSIS positive results. An FSIS test result of a positive for 05B02 sampling is a definite noncompliance. If product is still in the plant, determine whether or not the plant implements corrective actions that meet the requirements described in §417.3. If the plant does not control its product, then take regulatory control action (i.e., retain it). 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 later.)

Plant management must account for all affected products by identifying them and their location. The plant is expected to take the proper corrective and preventive measures (§417.3(a) or (b)). It may need to conduct a reassessment of its HACCP plan or reevaluate its SSOP or prerequisite programs.

Plants are expected to recall any affected product that has left the plant's immediate control (i.e., been distributed in commerce).

If the plant does not take control of its product, you take regulatory control action by retaining all affected product.

Plant-generated Sampling

Some plants may have their own sampling programs. Plants may sample for various reasons (checking suppliers, to satisfy contracts with customers, etc.), but most commonly they sample to verify their processes. These sampling programs may or may not be included in the plant's SSOP or HACCP plan[7]. If they are not included in these, then the plant is under no obligation to share analysis results with you. Again, the plant is not required to notify FSIS of a positive sample in this case, but the plant is required to take corrective actions that meet the requirements of §417.3 each time a positive result is received.

For example, a plant has its own testing program for E. coli O157:H7 in 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 take appropriate corrective actions per §417.3. You must verify that the plant took the necessary corrective actions to meet these requirements.

Another example is that a plant has its own testing program for E. coli O157:H7 in its veal patty mix. The testing is part of the verification of the overall HACCP plan. The plant always holds product pending test results. The last test result was positive. The plant does not have to inform you of its positive result, even when the testing is part of the HACCP plan. However, the plant must take the proper corrective actions per §417.3. Again, you must verify that the plant meets all four requirements described in 417.3.

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

[7] Most commonly product-sampling programs are in the HACCP plan, because the programs are usually testing product and that has a direct bearing on food safety. If the plant chooses to put environmental testing into one of the regulatory required documents, it is more commonly found in the SSOP. If the program is mentioned in the hazard analysis as part of the supporting documentation, then records need to be provided as required in §417.5(a)(1) to continue to support why the hazard is not reasonably likely to occur.

The plant does not need to notify you of a positive plant test result. However, when you are aware that there was a positive result you must:

- 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)

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 a CSO.
   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 FedEx is available after the pre-shipment review is completed
   d. as soon as the lot is assembled

3. Plant management is notified of the 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

Recalls

All raw, comminuted beef products produced on the shift represented by the positive sample would be subject to voluntary recall. If the raw, comminuted 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.

The Recall Management Division (RMD) is notified immediately if product has left the establishment's control, and they coordinate any recall activities. You must determine the status of the products that were produced under the same HACCP plan in the same time frame as the sampled lot and report this back to the DO. The DO notifies the RMD (see FSIS Directive 8080.1, Rev. 3, Recall of Meat and Poultry Products). RMD 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.

Diverting Raw Product for Cooking

Ground beef containing *E. coli* O157:H7 is adulterated and must be condemned or rendered safe (e.g., cooking). The plant may divert products that tested positive for a pathogen to a cooking operation (with a lethality step). **Only** ground beef contaminated with *E. coli* O157:H7 is considered adulterated. Some plants may have testing programs that include trimmings. In the case where the plant has a positive test for a pathogen on its trimmings, FSIS expects the plant to take appropriate actions and to maintain records to support what actions it took regarding the product. If the plant cooks the product, the HACCP plan should specifically address the presence of the pathogen in the product, since the plan must address any hazards presented by the practice.

If the plant cooks product that tested positive, then critical limits and critical control points need to account for any potential added hazards. The plant may divert contaminated product to another plant for cooking. When raw ground beef product that tested positive is identified and sent to another federally inspected facility for cooking, it must be transported under FSIS control. The plant may use Form 7350-1, Request and Notice of Shipment of MPI Sealed Meat/Poultry. Follow District instructions on whether to seal the transport carrier. In contrast, if beef trimmings that tested positive for *E. coli* O157:H7 are sent to another federally inspected facility for cooking, they may be transported under company control. In these situations, the cooking establishment should have addressed receiving raw product with known pathogens in its HACCP plan.

If the practice is done occasionally, the plan may only need to address the procedures, critical limits, and critical control points to meet when lots containing known pathogens from product that tested positive are processed.

Note: Raw beef **trimmings** that tested presumptive positive for *E. coli* O157:H7 can be transported as long as controls are in place to safeguard the product and ensure its proper disposition (cooking or destruction). This includes marking the product shipping containers with such statements as “For Cooking Only” or “For Rendering”. The plant should document that it carried out the proper disposition for the product and those documents should be available to you.

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 ground beef/veal products, so FSIS is focusing on analyses for that organism in that product.

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. relabel product
    d. reduce product price

Scenario
You received FSIS Form 10,210-3 requesting a raw ground or comminuted beef or veal sample under the MT03 project code. This is the first time you have received this type of sample request.

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.

What product do you sample for the *E. coli* O157:H7 project?

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.

How do you respond?

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

ATTACHMENT 1

Notice to Give Plant Management When a Sample is Taken

To Establishment Manager:

X The inspector will be taking a sample of your Ready-to-Eat meat and/or poultry product or raw ground beef product to be tested for microbial hazards. Sampling is one component of verifying your HACCP system.

X To protect public health and to avoid the negative impact of a recall, FSIS strongly recommends that you hold all product represented by the sample until results are obtained.

X Most negative results are available within 3 days; confirmed positive results may take up to 8 days. Results will be provided to you be the inspector or the District Office. For results of future samples, you can receive results by e-mail (contact your District Office for a copy of FSIS Form 10,230-2).

X If a recall is needed, FSIS expects you to initiate the recall in a timely fashion—usually the same day. See FSIS Directive 8080.1 for further details.

X It is your responsibility to determine the amount of product represented by the sample. As a guide, FSIS considers all product produced under a single HACCP plan between performance of complete cleaning and sanitizing procedures (clean-up to clean-up, including start to finish under extended clean-ups) to be an appropriate definition of a sampled lot. See FSIS Directives 10,240.2 Rev. 1 and 10,010.1.

X If a test result is positive, and you have distributed the product, FSIS will request that you conduct a recall. FSIS may determine that more product or less product than that produced from clean-up to clean-up under the HACCP plan is represented by the sample. In making this determination, FSIS will consider such factors as the establishment's coding of product; the pathogen of concern; the processing and packaging; the equipment; the establishment's testing under its HACCP plan; the establishment's HACCP plan monitoring and verification activities performed in accordance with 417.2 and 417.4; Sanitation SOP records as required in 416.16; and whether some or all of the products controlled by the same or substantially similar HACCP plans have been affected.

ATTACHMENT 2

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 3/6/03. 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.

Selected FSIS Sampling References for Raw Product (03B)		
FSIS Directive/ Notice Number	**Directive Title**	**Directive Date**
5000.1	Enforcement of Regulatory Requirements in Establishments Subject to the HACCP System Regulations	11/21/97
7355.1, Rev 2	Use of Sample Seals for Laboratory Samples and Other Applications	12/3/02
8080.1, Rev 3	Recall of Meat and Poultry Products	1/19/00
10,010.1	Microbiological Testing Program for *Escherichia coli* O157:H7 in Raw Ground Beef	2/1/98
10,200.1	Accessing Laboratory Sample Information via LEARN	7/19/01
10,210.1, Amend 5	Unified Sampling Form	7/1/02
10,230.2, Amend 1	Procedures for Collecting and Submitting Domestic Samples for Microbiological Analyses	9/4/92
10,600.1	Sample Shipment Procedures	10/6/83
FSIS Notice 47-02	FSIS Actions Concerning Suppliers that may be Associated with *Escherichia coli* O157:H7 Positive Raw Ground Beef Product	11/20/02
FSIS Notice 11-03	Update to FSIS Directive 10,010.1, Microbiological Testing Program for *Escherichia coli* O157:H7 in Raw Ground Beef	4/18/03

The 10,230-3, Sampling Frame Update Form (FSIS Directive 10,230.3, Rev 1), is no longer necessary to fill out. The PBIS 5.0 captures the information that OPHS needs in order to send out appropriate sample requests to the appropriate establishments. The IIC should ensure that plant profile information is kept current and accurately reflects the products produced.

ATTACHMENT 3

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
Insufficient Tissue or Sample
Delayed Shipment
Shipped on Friday w/o Saturday Delivery label
Original Form Not Submitted w/Sample
Target Tissue Not Received
No Form Received with Sample
Original Form Altered by Sample Submitter
Plant Has It's Own Testing Program-Sample Submitted
Laboratory Problem*
No Gel Packs/Coolants in Sample Box
Sample Container Leaking
Collection Date Not Day Prior to Sample Receipt
E. coli Ground Product Held Too Long Before Shipping
Ground Prod Sample Held>3 Days Before Shipping
Sent to Wrong Lab
Sample ID # on Bag does not match ID # on Form
Security Seal Missing or Not Intact
Temperature Too Low
No Accredited Lab Tests Performed
Headquarters/ TSC/DO Discard
Sampling Instructions Not Followed

ATTACHMENT 4

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)

ATTACHMENT 5

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE	54-02	12/2/2002

Requesting Sample Collection Supplies

Effective February 1, 2003, the toll-free lab supply hotline (1-877-709-1982) will be replaced by the following Outlook email addresses:

Sampling Supplies – Eastern Laboratory
Sampling Supplies – Midwestern Laboratory
Sampling Supplies – Western Laboratory
Sampling Forms - Headquarters

If you need sample collection supplies, email the laboratory designated on your sample request form, or the lab to which you will be sending the sample (see FSIS Notice 18-02 and/or LEARN). In order for the lab to promptly respond, the message must contain:

- establishment number
- daytime phone number
- project identification (if applicable)
- supplies needed

If a daytime phone number is not available, the laboratory may need to reply by email. Supplies will be sent via FedEx to the Overnight Mail address in the PBIS database for this establishment.

If you need additional copies of FSIS Form 10,210-7 to complete a *Salmonella* sampling set, send an Outlook message to Sampling Forms – Headquarters. Directed sample requests on FSIS Form 10,210-3 cannot be regenerated if lost. All other FSIS sample forms (i.e., 10,600-1) should be ordered through the regular FSIS Field Supply system at Beltsville (1-800-714-8335).

The above Outlook addresses may be used immediately upon receipt of this notice. After February 1, 2003, the toll-free phone line will no longer be an active working number, so the Outlook addresses must be used.

DISTRIBUTION: Inspection Offices;T/A Inspectors;Plant Mgt;T/A Plant Mgt;TRA;TSC;Compliance officers;FSIS Laboratories;Import Offices	NOTICE EXPIRES: 12/1/2003	OPI: OPPD

What if I cannot access Outlook?

State inspectors without FAIM computers, should contact their state coordinators, who will email the following addresses from outside the FSIS Exchange server:

SamplingSupplies-EasternLab@fsis.usda.gov
SamplingSupplies-MidwesternLab@fsis.usda.gov
SamplingSupplies-WesternLab@fsis.usda.gov

The District Inspection Coordinator may also be contacted to assist inspection program personnel without FAIM computers to send emails to the appropriate Outlook mailbox.

Direct questions regarding these procedures to the Technical Service Center.

Philip S. Derfler **/s/**

Deputy Administrator
Office of Policy and Program Development

ATTACHMENT 6
This is a note accompanying sampling supplies.

FOOD SAFETY AND INSPECTION SERVICE SAMPLING PROGRAM
E. coli O157:H7 IN RAW GROUND BEEF
MT03 AND MT04

Recommendations For Collecting Samples Aseptically

Samples taken for microbiological analysis require the application of stringent techniques to assure that the sample is not contaminated from outside sources.

✓ Wash and scrub hands thoroughly to the mid-forearm, using anti-bacterial hand soap (and sanitizer at 50 ppm chlorine equivalency if available).

✓ Open "whirl-pack" type bag that was sent with this sample collection kit according to FSIS Directive 10230.2, Part. Two.

✓ Peel open package of sterile gloves from top without contaminating the exterior of the gloves.

✓ Remove the glove by holding it from the wrist side opening inner surface, avoid <u>any</u> contact with the outer surface of the glove.

✓ Insert hand without puncturing the glove.

✓ <u>Do not touch anything</u> with the exterior of the glove except the sample.

✓ If you have any concern that the glove may be contaminated, discard that glove and use another sterile glove.

✓ With the gloved hand, collect the sample. Place the sample into the opened bag.

✓ Remove and discard the glove and close the bag as described in FSIS Directive 10230.2. Label the bag and package for shipping according to directions on form 10,210-2.

LW-A-0030.00
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ATTACHMENT 7

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

# FSIS NOTICE	47-02	11/20/02

FSIS Actions Concerning Suppliers that may be Associated with *Escherichia coli (E. coli)* O157:H7 Positive Raw Ground Beef Product

I. What kind of notice do program personnel provide before collecting raw ground beef samples for *E. coli* O157:H7 testing?

A. At federally inspected establishments (excluding import establishments):

1. Before collecting routine samples of raw ground beef for *E. coli* O157:H7 testing, inspection program personnel notify official establishment management and provide enough time for the establishment to hold the entire sampled lot.

2. Inspection program personnel inform the establishment of the reason they are taking the sample (e.g., routine monitoring, follow-up sampling in response to an *E. coli* O157:H7 positive, a traceback sample, or follow-up sampling in response to an *E. coli* O157:H7 outbreak).

B. At retail facilities:

1. Compliance Officers are to make an effort to notify the retail facility the day before they plan to collect the sample so the retail facility can prepare to hold the expected sampled lot. However, in cases when this is not possible, Compliance Officers should try to get to the retail facility as close to the beginning of the grinding operation as possible. Compliance Officers do not collect product from retail cases.

DISTRIBUTION: Inspection Offices; T/A Inspectors; Plant Mgt.; TRA; ABB; TSC; Import Offices; FSIS Laboratories	NOTICE EXPIRES: 12/1/03	OPI: OPPD

2. At this time, Compliance Officers obtain from the retail facility the names and establishment numbers of the establishments supplying the source materials for the lot of ground beef being sampled. In the event the source material utilized is store generated trim, the Compliance Officer obtains and records the names and establishment numbers of the establishments from which the store generated trim was derived. This information is recorded on the retail worksheet. In addition, the Compliance Officer records the supplier lot number, production date, and other identifying information that would be useful to the supplier if it is later notified of an *E. coli* O157:H7 positive. This information is posted to the OUTLOOK folder established for this purpose.

C. At import establishments:

Import inspectors notify the import establishment when a shipment is to be sampled for *E. coli* O157:H7 so that the establishment has an opportunity to voluntarily hold the product until the results are reported. FSIS holds the product to be sampled when intensified sampling for *E. coli* O157:H7 is being performed.

II. What happens if there is a presumptive positive at a Federal grinding establishment?

The Inspector in Charge (IIC) uses Laboratory Electronic Application Results Notification (LEARN) to check for sample results. If the results are presumptive positive, the IIC notifies establishment management that the sample was presumptive positive. The IIC also informs the establishment that if the results are confirmed positive, he or she will be collecting (under the authority of 9 CFR 320.1) the following information regarding the suppliers of the presumptive positive product:

1. Name of establishment, Point of Contact,, and Phone number
2. Supplier lot number
3. Production date

The IIC advises the establishment that it should begin to gather the information above.

Note: On weekends and holidays, if the establishment is not operating, the District Office carries out the above process.

III. What will FSIS do if the sample is confirmed positive for *E. coli* O157:H7?

A. At federally inspected establishments (excluding import establishments):

1. The IIC collects from the establishment the information in paragraph II above.
The IIC makes note of any information that the establishment is unable to provide.

2. The IIC forwards the information, via email, to the designated District Office contact for this procedure, with a "cc" to the Circuit Supervisor.

3. The District Office contact person notifies all of the supplying establishments in his or her own District, by telephone, of the positive finding and provides the suppliers the production date for the product that the supplier provided to the grinder, the lot number of the supplied product, and other information that would be useful to the supplier to help identify the *E. coli* O157:H7 positive lot.

4. District contact persons document the date and time of the oral notification and send this information along with the supplier information to the Director, Recall Management Division, via electronic mail.

5. If any of the suppliers are located in other Districts, the District Office contact provides the supplier information to his or her counterparts in the appropriate Districts so that notification to the suppliers is carried out by the District Office within which the supplier is located.

6. The Recall Management Division issues a written notification to each supplier, with a "cc" to the applicable District Office.

NOTE: If the confirmed positive sample includes imported product, then the District Office contact person provides the supplier information to the Office of International Affairs (OIA) contact person. The OIA contact person in turn forwards this information to the head of the inspection service in the country where the supplier establishment is located.

B. At retail facilities:

1. The District Office is notified of a retail positive through the Biological Information Transfer and E-mail System (BITES).

2. The District Office contact accesses the OUTLOOK folder with the list of suppliers for the sampled product that tested positive.

3. The District Office contact person notifies all of the supplying establishments in his or her own District, by telephone, of the positive finding and provides the suppliers the production date for the product the supplier provided to the grinder, the lot number of the supplied product, and other information that would be useful to the supplier to help identify the *E. coli* O157:H7 positive lot.

4. District contact persons document the date and time of the oral notification and send this information along with the supplier information to the Director, Recall Management Division, via electronic mail.

5. If any of the suppliers are located in other Districts, the District Office contact provides the supplier information to his or her counterparts in the appropriate Districts so that notification to the suppliers is carried out by the District Office within which the supplier is located.

6. The Recall Management Division issues a written notification to each supplier, with a "cc" to the applicable District Office.

NOTE: If the confirmed positive sample includes imported product, then the District Office contact person provides the supplier information to the OIA contact person. The OIA contact person in turn forwards this information to the head of the inspection service in the country where the supplier establishment is located.

C. At the supplying establishment:

1. The District Office informs the Circuit Supervisor and IIC of each supplier establishment notified. This notification includes identifying information about the production lot that the establishment supplied. **It is important to note that this notification is to ensure that the establishment knows that it could be the source of the *E. coli* O157:H7. It is not a definitive determination that the supplier establishment is the actual source of the pathogen.**

2. The IICs at the supplying establishments ensure that inspection program personnel perform a HACCP 02 procedure to verify that the establishment met all regulatory requirements at all CCPs in the HACCP plan (monitoring, verification, recordkeeping, corrective actions, and reassessment) for the production lots sent to the establishment at which the positive was found. If inspection program personnel find noncompliance, they take appropriate action as described in FSIS Directive 5000.1.

D. At import establishments:

1. If the product is on hold at the import establishment, whether on FSIS hold or voluntary hold, the IIC refuses entry of the lot.

2. If the lot has moved into commerce from the import establishment:

a. The IIC sends, via e-mail, to the designated District Office contact for this procedure, the country of origin, foreign country establishment number, health certificate number, shipping mark, and the name and address of the consignee from the health certificate. Additionally, if the Importer of Record from block 6a of FSIS Form 9540-1, Import Inspection Application and Report, is different from the Consignee on the health certificate, the IIC provides this information.

b. A “cc” is sent to the Circuit Supervisor.

c. The IIC faxes a copy of the health certificate, FSIS Form 9540-1, and FSIS Form 10,210-3, Requested Sample Programs Form, to the TSC at (402) 221-7479.

d. The District Office contact person notifies the Consignee or the Importer of Record in his or her own District by telephone of the positive finding, and provides the country of origin, foreign country establishment number, health certificate number, and the shipping mark.

e. The TSC faxes the information to the OIA, which in turn notifies the head of the inspection service in the foreign country of the positive sample and requests that appropriate action be taken.

f. If the Consignee or Importer of Record is located in another District, the District Office contact provides the information to his or her counterpart in the appropriate District so that notification can be carried out by the District Office within which the Consignee or Importer of Record is located.

g. The District Office contact person documents the time and date of the verbal notification and sends this information along with the information to the Director, Recall Management Division, via electronic mail.

h. The Recall Management Division issues written notification to the Consignee or Importer of Record.

IV. What FSIS office maintains the supplier information collected?

The Office of Field Operations will develop and maintain a database of the information gathered regarding suppliers. The information will be kept in an Outlook folder.

Philip S. Derfler /s/

Deputy Administrator
Office of Policy and Program Development

ATTACHMENT 8

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

# FSIS NOTICE	11-03	4/18/2003

UPDATE TO FSIS DIRECTIVE 10,010.1, MICROBIOLOGICAL TESTING PROGRAM FOR *ESCHERICHIA COLI* O157:H7 IN RAW GROUND BEEF

I. PURPOSE

This notice provides updated instructions to inspection program personnel on some of the issues covered by FSIS Directive 10,010.1, *Microbiological Testing Program for Escherichia coli O157:H7 in Raw Ground Beef.* FSIS will revise FSIS Directive 10,010.1 shortly with more comprehensive procedures. In the meantime, FSIS is issuing this Notice because, based on our data, the prevalence of *E. coli O157:*H7 begins to rise in April and May, and the Agency needs to increase verification efforts at this time. To the extent that FSIS Directive 10,010.1 is inconsistent with this Notice, it is superceded and revoked.

II. BACKGROUND

On October 7, 2002, the Agency issued a Federal Register notice, *E. coli* O157:H7 Contamination of Beef Products, (issued to inspection program personnel as attachment 1 in FSIS Notice 44-02) that advised establishments of their obligation to reassess their HACCP plans for raw beef products. The Federal Register notice also announced the availability of guidance materials for industry and discussed revisions to be made to FSIS Directive, 10,010.1.

III. UPDATED PROCEDURES TO REPLACE PORTIONS OF FSIS DIRECTIVE 10,010.1

A. What are the updated procedures that are effective immediately?

1. Inspection program personnel are to collect a raw ground beef sample **whenever** they receive an FSIS Form 10,210-3 for microbiological sampling

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project MT03, regardless of whether the establishment meets criteria set forth in FSIS Directive 10,010.1, VI.B. All raw ground beef; hamburger; ground veal; veal or beef patties; or other products meeting the standard of identity in 9 CFR 319.15 (a-c), are eligible for verification sampling by FSIS.

2. Inspection program personnel are to collect samples from the current day's production, and the samples should be, whenever possible, in their final packaged form. Samples should not be shipped until the establishment has performed the pre-shipment review for that lot.

3. Inspection program personnel are to provide the establishment management sufficient notification of the sample collection and provide them enough time to hold the sampled lot (See FSIS Notice 47-02). Inspection program personnel are to recommend to the establishment management that it hold the sampled lot pending the laboratory results.

4. If a sample must be held overnight, it should be refrigerated. If a sample must be held longer than overnight, it should be frozen, as instructed in FSIS Directive 10,210.1, amendment 3, page 25, instruction 3. Samples can be frozen regardless of day of collection, i.e., product sampled on Monday that will not have pre-shipment review completed until Wednesday morning should be frozen on Monday and shipped on Wednesday.

5. Samples should be shipped as soon as Federal Express service is available after pre-shipment review.

6. Should a sample test positive, the establishment will be expected to take appropriate corrective and preventive action in accordance with 9 CFR 417.3. Verification of the establishment's corrective and preventive action may include the pulling of one or more samples from one or more lots, as determined by supervisory and inspection program personnel in the establishment. Office of Field Operations will coordinate sampling activities with the Office of Public Health and Science. Section VI. E. 2. of FSIS Directive 10,010.1 is revoked.

7. Beginning with MT03 samples scheduled for collection in May 2003, information regarding production volumes of these products will be requested in Block 28 of the FSIS Form 10,210-3 for each MT03 sample. Inspection program personnel are to provide this information based on pre-shipment clearance records maintained by the establishment as required by section 9 CFR 417.5. Volume data are vital to the development and implementation of risk-based verification programs.

Direct questions to the Technical Service Center.

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