

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).

For directed sample requests, the product/category is specified on the request form 10,210-3. 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 Requested Sample Programs form) are sampled each time sample request forms are received.

FSIS Directive 10,010.1 was updated because the Agency believed it was necessary to increase its verification efforts. Inspection personnel will collect a sample **whenever** they receive a directed sampling request (FSIS Form 10,210-3) for this sampling project (MT03/04).

Products to Sample

Currently, the only specific raw **products** sampled as on-going in directed sampling are ground beef products analyzed for *E. coli* O157:H7. 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. (Sampled products may **contain** beef derived from advanced meat recovery systems, but advanced meat recovery system products are **not** sampled by themselves. Products that contain another type of livestock product in addition to beef (e.g., beef and pork patty) are also not sampled.)

Components to Sample

Additionally, raw ground beef components and beef patty **components** may be sampled.

You are only to collect samples of raw ground beef or raw beef patty components that are intended for use in raw non-intact product. The sample request will indicate if you are to sample such product. You may be instructed to collect more than one sample per lot. 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 user, 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).

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). **Recommend** that plant management hold the sampled lot of product. 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 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 should contact the District office or the Technical Service Center 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 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 pathogens, including *E. coli* O157:H7.

Step 3: Collect the Sample

If possible, only collect a sample from the current day's production. It needs to be collected during normal production because the sample represents the process. Collect the sample in final packaged form, whenever possible.

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). If the lab receives an insufficient amount of product to perform the specified analyses, the sample is discarded (see Attachment 3 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. If the plant irradiates its raw ground beef, then FSIS Directive 7700.1, "Irradiation of Meat and Poultry Products", should be followed.

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** 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.

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

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. 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). 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.

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 in Attachment 6 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.

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 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)

Step 4: Packing and Mailing the Sample

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.

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 them.

19. DATE COLLECTED	20. DATE SENT TO LAB	21. PRODUCT TEMPERATURE	22. PRODUCT HELD NO YES
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Note: Block 21 doesn't apply to raw ground beef and/or veal samples.

28. REMARKS

Note: Block 28 has additional information and questions you need to answer. 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.
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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 FedEx Air-bill 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 red and black striped tamper-evident 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. 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 bag or plastic sleeve. Put another small bar code sticker on the bagged sample. Put the sample and paperwork into the larger Ziploc 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.

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. 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 recordkeeping noncompliance.

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 frozen. 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 air bill or stamp.

Step 5: Results

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 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.

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.

OPHS e-mails sample results to plants that complete FSIS Form 10,230-2, “FSIS Establishment E-mail (Internet) Address Collection Form”, and submit it to OPHS. Even if the establishment receives sample results directly from OPHS, it is still your responsibility to notify the establishment when sample results are received.

Negative

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 in the sample tested. The negative results are posted in the LEARN system. FSIS resumes normal sampling at that establishment.

Presumptive Positive

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, using BITES (Biological Information Transfer E-mail System), notifies the DO (prior to posting the information in LEARN) due to a presumptive positive for *E. coli* O157:H7. This ensures that the plant receives this 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 supplier 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

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.

Issue an NR for all FSIS positive results under the appropriate ISP HACCP code using the "verification" trend indicator and 417.4 as the relevant regulation. An FSIS test result of a positive for 05B02 sampling is a noncompliance. 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, Rev. 4, 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 is expected to 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.

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

Off-site Product Disposition

Product 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, 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, Rev. 1.

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

When an FSIS sample for raw ground beef product is confirmed positive for *E. coli* O157:H7, 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 O2 procedure on the specific production that tested positive. You cannot complete the O2 procedure until the establishment has taken corrective actions and the product is properly dispositioned.

If you find no significant problems as a result of conducting the O2 procedure, contact OPHS via Outlook (send to "Sampling Forms – Headquarters") requesting a follow-up sample form (10,210-3). Copy your FLS (Frontline Supervisor) and DO (District contact) on this message. Be sure to include the

- Establishment number
- Number of forms needed (in this case 1)
- Type of sample to be collected (product sample)
- Purpose of the request (follow-up sampling in response to a confirmed positive in raw ground beef)
- Sample form number of the original positive sample triggering this request, and
- DO official approving the request.

You will be given guidance at the time you need to collect the follow-up sample. Specific instructions for the follow-up samples may be provided on the FSIS Form 10,210-3 you receive in answer to your e-mail request, in FSIS Directive 10,210.1, or through your District Office.

Collect the follow-up sample as soon as possible after the plant completes its corrective actions. If the plant delays disposition of the positive product, work with your FLS to determine when it would be appropriate to collect the follow-up sample. Your FLS should give you guidance on how to work with the plant to ensure proper and timely disposal of the product.

If you find regulatory noncompliance while performing the O2 procedure, document it on an NR (as per FSIS Directive 5000.1, Rev. 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. Collect one follow-up sample as soon as possible after the plant takes corrective actions (request the follow-up 10,210-3 from OPHS as indicated earlier).

You may uncover concerns regarding the adequacy of the HACCP system design when performing the O2 procedure. If so, do not collect a follow-up sample. Notify your FLS. The FLS will determine if it is necessary to have an Enforcement Investigations and Analysis Officer (EIAO) conduct a

comprehensive assessment of the plant's total food safety system. If the EIAO concludes that the corrective actions appear appropriate and effective, then the EIAO will contact OPHS for a sample form. You collect the follow-up sample as soon as possible after receiving the form. If the EIAO concludes the corrective actions are inappropriate or ineffective, or if the follow-up sample is also confirmed positive, the DO will give you further guidance on how to proceed.