

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

FSIS DIRECTIVE

10,250.1
Revision 1

3/2/21

SAMPLING INSTRUCTIONS: *SALMONELLA* AND *CAMPYLOBACTER* VERIFICATION PROGRAM FOR RAW POULTRY PRODUCTS

CHAPTER I – GENERAL

I. PURPOSE

This directive revises the *Salmonella* and *Campylobacter* sampling instructions for raw poultry products that FSIS has issued to inspection program personnel (IPP). FSIS is revising and reissuing this directive to incorporate updated project codes and instructions from previously issued notices for the continuous verification sampling of poultry carcasses, chicken parts, and comminuted poultry products. FSIS has also moved non-sampling information related to these samples, including performance standards and categorization, to [FSIS Directive 10.250.2 Performance Standards: Salmonella Verification Program for Raw Poultry Products](#). FSIS removed all references to set-based sampling, including obsolete instructions for sampling meat products.

NOTE: FSIS intends to update the *Campylobacter* performance standards; therefore, although FSIS continues to test product for *Campylobacter*, it does not assess whether establishments meet the performance standards.

II. CANCELLATION

FSIS Directive 10,250.1, *Salmonella and Campylobacter Verification Program for Raw Meat and Poultry Products*, 9/20/13

III. REFERENCES

[FSIS Microbiology Laboratory Guidebook](#): *Isolation and Identification of Salmonella from Meat, Poultry, Pasteurized Egg, and Siluriformes (Fish) Products and Carcass and Environmental Sponges*; and *Isolation and Identification of Campylobacter jejuni/coli/lari from Poultry Rinse, Sponge and Raw Product Samples*

CHAPTER II – PREPARING TO SAMPLE RAW PRODUCT FOR *SALMONELLA* and *CAMPYLOBACTER* VERIFICATION TESTING

I. GENERAL SAMPLING POLICIES

A. Before collecting samples, IPP are to be familiar with:

1. Random sampling, which may include the use of random number tables or using the FSIS computer Random Number Generator;

DISTRIBUTION: Electronic

OPI: OPPD

2. Aseptic sampling technique. Resources for aseptic technique are available on [IPP Help](#) (IPP will be able to open the IPP Help button from the “FSIS Applications” start menu item on their FSIS Computer); and
3. Specific sampling methodology. The sampling steps appropriate to the product class sampled are defined in the product-specific chapters in this directive. Each of these product classes has a specific sampling methodology that IPP need to be familiar with before sampling that class.

B. When possible, IPP are to collect samples under each project code at a frequency of no more than once per week on a day the establishment produces the product indicated in the sampling task on the Public Health Information System (PHIS) Task Calendar - Establishment Task List. IPP are to document the sample collection as directed in [FSIS Directive 13,000.2](#), *Performing Sampling Tasks in Official Establishments Using the Public Health Information System*. IPP are to ensure that all requested information is entered completely and accurately into PHIS. In the case that there are more samples than weeks in the sampling window, IPP are to schedule sample collection evenly throughout the month. If necessary, more than one sample can be taken in a week.

C. IPP are to use a method for randomly selecting the specific product for sampling, as described in A.1 of this section. It is very important that applicable product from all shifts, lines chillers, coolers, and grinders have an equal chance of being selected for sampling. No more than one routine sample of a specific product class is to be scheduled for collection per multiple-shift production day, when possible.

D. IPP are not to share or split samples and supplies with the establishment. If the establishment is interested in doing its own analysis, IPP are to be aware it may use its own supplies to collect a different sample at approximately the same time and point of production the FSIS poultry sample is collected. Two samples from one site may give rise to different results, because contamination may not be evenly distributed within a sample.

E. IPP are to be aware that FSIS will assign the number of product samples for collection at each establishment based on information entered in the PHIS Establishment Profile, such as average production volume. Some establishments may not receive sampling tasks every month. It is possible that there will be a different number of samples assigned to an establishment each month. Establishments will not receive a sampling task in PHIS if the eligible finished product group in the PHIS profile has the intended use of ready-to-eat (RTE) as verified by IPP (See [Chapter VIII](#) of this directive) or if the average daily production volume is 1,000 lbs. or less. FSIS reviews eligibility before scheduling samples each month. IPP are to perform the PHIS Update Establishment Profile task monthly following the instructions in [FSIS Directive 5300.1](#), *Managing the Establishment Profile in the Public Health Information System*, to ensure the information is accurate. For more information, see the [PHIS Poultry Product Group Guidance](#) on IPP Help.

F. If sampling tasks remain in the task list at the end of the sampling window, IPP are to cancel them from the task list and provide the correct reason. If none of the listed reasons are appropriate, IPP are to select “Not collected for miscellaneous reasons” and provide additional details in the text box provided. IPP are not to allow sampling tasks to remain at the end of the sampling window.

Select Reason: Requested sample unavailable during sampling timef

Describe, If Other:

- Requested sample unavailable during sampling timeframe
- Requested sample/product never slaughtered/produced
- Not collected for miscellaneous reasons
- Plant closed/no kill
- FedEx did not pickup sample
- Inspection withdrawn
- Insufficient time to collect sample
- Inspection suspended officially
- Other

G. If an establishment does not produce eligible product, IPP are to cancel any remaining product verification sampling tasks. These tasks are to be canceled from both the “Establishment Task List” (Delete this task from the Task List) and, if scheduled, the “Task Calendar,” using the correct option (cancel this task and remove it and all other instances of this task from the Task List). In addition, the reason (i.e., Requested sample/product never slaughtered/produced) is to be provided.

Cancel Lab Sampling Task

Select an option

Cancel all remaining tasks

Reason:*

sample/product never slaughtered/produced

- Select
- Requested sample unavailable during sampling timeframe
- Requested sample/product never slaughtered/produced
- Not collected for miscellaneous reasons
- Plant closed/no kill
- FedEx did not pickup sample
- Inspection withdrawn
- Insufficient time to collect sample
- Inspection suspended officially

H. IPP are to be aware that ALL eligible products from various product classes produced at an establishment will be scheduled for sampling. For example, if an establishment produces young chicken carcasses, chicken parts, and not-ready-to-eat (NRTE) comminuted chicken, all three of these products may be scheduled for sampling during the month. IPP are to schedule sample collection of these different sampling projects independently of one another; more than one product class may be sampled within the same week.

II. SAMPLING SUPPLIES

A. Sampling supplies are automatically sent out to all eligible establishments each month.

B. If the sampling supplies have not arrived by the first day of the following calendar month and the sampling task has been assigned in PHIS, IPP are to request replacement sampling supplies. For example, if chicken parts sampling tasks are assigned in PHIS on June 24, IPP are to request replacement supplies only if they have not arrived by July 1. IPP are to request replacement supplies if

they are damaged, lost, or otherwise unavailable for use. IPP are to request these sampling supplies through PHIS. To do this, IPP are to right-click a scheduled lab sampling task (for example, "HC_CPT_LBW01") on the Task Calendar and then select "Request sampling supplies" from the drop-down menu. IPP are to request sampling supplies at least 72 hours (not including weekends and holidays) before they intend to collect the sample.

C. IPP are to return any unused sampling supplies that have been at establishments for 6 months or longer to the FSIS labs to ensure efficient use of Agency resources. Ground shipping labels to return sampling supplies can be requested from any of the FSIS laboratories. Laboratory personnel email instructions for completing and printing return labels to the requestor.

D. Should IPP have questions or concerns regarding the sampling supplies, they are to submit them to one of the FSIS laboratories via Outlook by selecting one of the email addresses below from the Global Address List.



E. IPP will receive the M16 box (shipping container) with sorting labels (project labels) plus one set of the following supplies:

1. 15" X 20" sterile plastic bag;
2. Pair of gloves;
3. 400 ml of sterile sampling buffer for rinse samples, OR 10, 25, or 50mL buffer for swab samples;
4. 120 ml specimen jar with lid for rinse samples, OR sterile sponges and templates for swab samples, OR Whirl-Pak® sample bags for comminuted samples;
5. Quart resealable zipper lock bag;
6. 6" X 12" plastic sleeve for the printed PHIS form (FSIS Form 8000-19);
7. Form 7355-2A/2B (sample seals);
8. Absorbent pad;
9. Cardboard separator;
10. Gel coolant pack; and
11. (3) Billable stamps (1 per FSIS Laboratory for submitting the sample).



F. IPP are to use only the supplies provided by FSIS for sampling. Additional cardboard separators and gel coolant packs may be included with the sample supplies depending upon the time of the year. Sample supplies that are not provided in the shipping container or that are not sent from any of the three FSIS laboratories for these projects are not to be used.

III. IPP RESPONSIBILITIES

A. One or more days prior to sample collection, IPP are to:

1. Designate an area for preparing and gathering sampling supplies. A stainless steel, wheeled cart is useful when carrying out the actual sample collection procedure. A small tote or caddy carried to the location of sampling can be used for transporting supplies and supporting sample bags to which IPP are adding sterile solutions;
2. Upon receipt of supplies, open the shipping container and check to ensure that all the supplies needed for sample collection are inside;
3. Check the sampling broth container for leaks and expiration information. If broth is expired, leaking, or has other condition issues upon arrival, it is to be discarded and IPP are to request a replacement broth from the laboratory, as described in II. B. of this chapter. IPP are not to discard sampling broth based solely on appearance (e.g., cloudiness). Pre-chill the broth upon receipt by placing it in a secure refrigerator (where the supplies will remain under FSIS control); and
4. Place gel packs in the freezer.

B. On the day of sampling, IPP are to:

1. Gather the appropriate PHIS Sample Analysis Request Form for the product being sampled (Form 8000-19); the general supplies for sample collection (e.g., sample collection bags, gloves); and the specific materials for the type of sample to be collected (e.g., templates and specimen sponges for turkey carcass samples or Whirl-Pak® bags for ground or comminuted product);
2. Collect the sanitizing solution for work surfaces used during sampling, if needed;
3. Retrieve the appropriate container of sampling broth from the refrigerator/cooler for rinsate or swab samples. Use only pre-chilled broth when sampling;

4. Ensure that all sampling supplies are on hand and readily available before beginning sample collection; and
5. Sanitize the cart, or other designated work area surfaces by wiping with a clean disposable cloth or paper towel dipped in sanitizer. This may be sanitizer supplied by the establishment or hypochlorite solution supplied by FSIS. The sample work area surfaces are to be free of standing liquid before sampling supplies or product containers are placed on them.

IV. SELECTING THE SAMPLE

- A. IPP are to notify official establishment management just before a routine, follow-up, or exploratory *Salmonella* or *Campylobacter* sample is being collected. IPP are to document any pertinent details (e.g., the location where the sample will be stored until the contract carrier picks it up for transport if there is not a fridge in the FSIS office) in a Memorandum of Interview (MOI).
- B. The Inspector-in-Charge (IIC) is to coordinate the collecting and mailing of samples that occur during different shifts.
- C. If an establishment produces a particular class of product (e.g., ground chicken) with both RTE and NRTE intended use, IPP are to sample product. In this situation, IPP are not to differentiate between the product going to establishments producing the RTE product versus the product going to establishments producing the NRTE product when taking a sample. [Chapter VIII](#) details verification activities when all of a particular class is going to RTE product.

V. SAMPLING ELIGIBILITY

A. General Exclusions That Apply to All Product Groups:

1. Product that is processed into RTE product onsite or moved to another official federally-inspected establishment for further processing into an RTE product (see Chapter VIII – Verification of Ineligible Raw Product Destined for Ready-to-Eat at an Official Establishment). IPP are to follow the instructions in Chapter VIII of this directive to determine whether the intended use of the product is for processing into RTE product and whether the establishment has controls to ensure that the product is processed into RTE product;
2. Any product group diverted for pet food manufacturing as inedible without the mark of inspection and labeled “Not for Human Food” is not subject to FSIS sampling for *Salmonella* or *Campylobacter*;
3. Product groups with an average daily production of 1,000 pounds or less are excluded from routine verification sampling; and
4. Poultry products which are breaded, battered, stuffed with a non-meat component, or wrapped in dough are currently excluded from routine verification sampling.

B. General Instructions for Sampling Projects with Multiple Eligible Product Types:

1. If an establishment produces raw product categorized in the PHIS Hazard Analysis and Critical Control Point (HACCP) processing category “Raw Product – Non-intact,” but the product will undergo further processing into a raw product at another establishment, then the product is eligible for sampling at the producing and the further processing establishments. For example, if an

establishment produces ground chicken and moves it to another establishment for further processing into raw chicken patties, then the ground chicken is eligible for sampling at the producing establishment, and the raw chicken patties are eligible for sampling at the further processing establishment;

2. Finished poultry products are to be sampled prior to freezing, unless the establishment applies a validated antimicrobial intervention that achieves a reduction in (and not only inhibits outgrowth of) *Salmonella* or *Campylobacter* at or after freezing. If establishments apply such an antimicrobial intervention at or after freezing, IPP are to collect product after such interventions have been applied. In this case, IPP are to randomly select product to be sampled, and the establishment would need to develop a tempering procedure for such product and apply it prior to IPP collecting the sample. The sample collection date entered in PHIS is the date that IPP collect the product, after it has been tempered;
3. If off-site interventions, such as high-pressure pasteurization (HPP) or irradiation, are applied to prevent or control *Salmonella* or *Campylobacter* in poultry products, IPP are to sample such products after they return to the producing establishment after such an off-site intervention is applied. If the eligible product does not return to the producing establishment, IPP are to contact their Office of Field Operations (OFO) Supervisor for instruction. The Frontline Supervisor will work with the District Office to ensure samples are collected;
4. When answering the "Product name" question in PHIS for each sample, IPP are to provide as much detail as possible. For example, if IPP collect a sample of ground turkey thigh made from deboned thigh meat, IPP would correctly indicate the product name as "ground turkey thigh (deboned)." It is not sufficient to respond "thigh trim" or "ground turkey" as the product name for this sample; and
5. IPP are to ensure sample security prior to shipping to the laboratory and are not to expose the sample box to excessive heat while at the establishment. The laboratory will discard rinse samples that arrive above 15°C (59°F) and will cancel *Campylobacter* testing if the sample is received below 0°C (32°F).

CHAPTER III – SALMONELLA AND CAMPYLOBACTER SAMPLING PROCEDURES FOR YOUNG CHICKENS (CARCASS; HC_CH_CARC01)

I. PRODUCT ELIGIBILITY FOR SAMPLING

A. Carcasses of "Rock Cornish game hens" (also called "Cornish game hen" or "poussin"), "broilers," "fryers," and "roasting chickens" (also called "roasters"), as described in 9 CFR 381.170(a), are in the "Young Chicken" product class and are to be sampled for *Salmonella* and *Campylobacter*. Other chicken product classes -- capon, hen, fowl, baking chicken or stewing chicken, and cock or rooster -- are not subject to FSIS verification testing at this time.

B. FSIS does not currently collect verification samples analyzed for *Salmonella* and *Campylobacter* from chicken carcasses produced under a religious exemption and not bearing the mark of inspection.

II. PREPARING TO COLLECT A SAMPLE

A. IPP are to select a time at which to collect the sample. IPP are to determine the times that chilled carcasses will be available at the end of the drip line, or at the last readily accessible point before packaging or cut-up (or the equivalent in air-chill or hot-bone operations), and then randomly select the time from within that time frame for collecting the sample.

B. IPP are to select a chiller or line from which to collect the sample. If more than one chiller system is in operation at the time of sample collection, IPP are to randomly select the chill tank from which to take the sample. IPP are to determine a safe, appropriate point from which to collect the sample.

C. IPP are to review the information in [Chapter II of this directive: Section I](#) “General Sampling Policies,” and [Section IV](#) “Selecting the Sample.”

III. COLLECTING THE SAMPLE (YOUNG CHICKEN CARCASS RINSE)

A. At the time selected, IPP are to randomly select a carcass from the post-chill area after all interventions have taken place. IPP are to select a carcass and then count back or ahead five carcasses and select the next carcass for sampling (to avoid any possible bias during selection). If the sixth carcass is not a whole bird (e.g., untrimmed, with or without neck), count back or ahead an additional five carcasses for sample selection. Repeat until a whole carcass is available.

B. In establishments where the end location of the drip line makes removing a carcass from a moving line unsafe for IPP, IPP are to pull the sample at the chiller exit, directly from the conveyor belt. If the establishment has temporarily altered the location of its normal final antimicrobial intervention because of an unforeseen event (e.g., equipment malfunction), IPP are to select a carcass after the new intervention step.

C. IPP are to take the randomly selected carcass and allow excess fluid to drain without contaminating any sterile items.

D. IPP are to allow a minimum of one minute drip time for poultry carcasses prior to rinsing or swabbing. During this time, IPP are to be careful to avoid cross-contamination.

E. IPP are to then perform the following step-by-step procedures:

1. Place the carcass in the bag (neck first);
2. Place the bag with the carcass on the flat sanitized surface;
3. Gently invert the sampling broth container three (3) times immediately prior to adding the sampling broth to the chicken carcass. Open the container and pour the sampling broth into the carcass cavity in the bag;
4. Expel the excess air from the bag, twist it closed, and fold the twist over;
5. Mix the broth through the carcass cavity and outside of the carcass for one minute;
6. Place the bag with the chicken on the sanitized flat surface with the top of the bag facing up;
7. Carefully open the plastic bag containing the bird without touching the inside of the bag or the inside corners;
8. Work the plastic bag down around the carcass and firmly grip one leg, without touching the inside of the plastic bag;

9. While holding the bag with one hand, carefully remove the bird from the bag with the other hand; and
10. Place the bird back on the conveyor or table.

NOTE: Rinsing the carcass with potable water is not necessary prior to placing the bird back on the conveyor or table.

F. IPP are to prepare the rinsate sample for shipping. It is acceptable to remove the gloves at this time; however, IPP are to continue to work in an aseptic manner and perform the following step-by-step procedures:

1. Remove the screw-cap from the sterile sample container and put the cap in the small resealable bag;
2. Open the large bag and aseptically pour 100 ml of rinsate into the sample container;
3. Take the screw-cap out of the small resealable bag and close the sample container. Avoid touching the inside of the lid so that it does not contaminate the sampling broth. Ensure that the lid is correctly threaded and tightened, but do not over-tighten. Tape or other material should not be applied to seal the jar;
4. Place the sample container in the small resealable bag, expel excess air, and seal the bag; and
5. Discard all remaining liquid from the carcass rinse bag; do not share remaining rinsate with establishment personnel.

G. The sample is now complete. Follow the storage and shipping instructions in Chapter VII – Submitting the Collected Sample (All Product Classes).

CHAPTER IV – SALMONELLA AND CAMPYLOBACTER SAMPLING PROCEDURES FOR YOUNG TURKEYS (CARCASS; HC_TU_CARC01)

I. PREPARING TO COLLECT A SAMPLE

A. IPP are to select a time at which to collect the sample. Determine the times that chilled carcasses will be available the end of the drip line, conveyor, or equivalent post-chill location after all interventions are completed and before processing. IPP are to randomly select the time from within that time frame for collecting the sample.

B. IPP are to determine a safe, appropriate point from which to collect the sample unit.

C. Review the information in [Chapter II, Section I](#) (General Sampling Policies), and [Section IV](#) (Selecting the Sample).

D. IPP are to use aseptic techniques as described in [IPP Help](#) and perform the following procedures:

1. Make sure that one sponge bag is labeled with an “S” and the other one with a “C,” and take supplies to the sampling location; and
2. Put on the gloves provided by FSIS as described in [IPP Help](#).

II. COLLECTING THE SAMPLE (YOUNG TURKEY CARCASS SPONGE SAMPLE)

A. At the time selected, IPP are to randomly select a carcass from the post-chill area after all interventions have taken place and after at least a one-minute drip time. IPP are to select a carcass and then count back or ahead 5 carcasses and select the next carcass for sampling (to avoid any possible bias during selection). If the sixth carcass is not a whole bird (e.g., untrimmed, with or without neck), count back or ahead an additional 5 carcasses for sample selection. Repeat until a whole carcass is available.

B. In establishments where the end location of the drip line makes removing a carcass from a moving line unsafe for IPP, IPP are to pull the sample at the chiller exit, directly from the conveyor belt. If the establishment has temporarily altered the location of its normal final antimicrobial intervention because of an unforeseen event (e.g., equipment malfunction), IPP are to select a carcass after the new intervention step.

C. IPP are to take the randomly selected carcass and allow excess fluid to drain without contaminating any sterile items. Do not touch the back or thigh areas.

D. IPP are to allow a minimum of one minute drip time for poultry carcasses prior to rinsing or swabbing. During this time, IPP are to be careful to avoid cross-contamination.

E. IPP are to then to perform the following step-by-step procedures:

1. Place the turkey breast-down on the work surface. Do not let sample sites (back and thigh; see Sample Sites for *Salmonella* Testing of Turkey Carcasses below) touch any surfaces;
2. Remove and discard gloves;
3. Open sponge bag;
4. Gently invert the smaller sampling broth container marked "S" three (3) times immediately prior to opening the container and pouring the sampling broth marked "S" into sponge bag marked "S;"
5. Set empty broth container aside;
6. Close bag and massage sponge;
7. Push sponge to top of bag and then open bag; set bag aside on a sanitized surface;
8. Open template bag and set aside on a sanitized surface;
9. Put on second pair of gloves;
10. Remove sponge;
11. Remove template;
12. Lay the template over the back sampling area and hold it to the left of the vertebral column (see Sample Sites for *Salmonella* and *Campylobacter* Testing of Turkey Carcasses below). Do not touch the sampling area;
13. Hold template with one gloved hand and use other gloved hand to wipe area with sponge;

14. Do 10 vertical wipes over entire sample surface; then do 10 horizontal wipes over entire sample surface;
15. Lay the template over the left thigh (see Sample Sites for *Salmonella* and *Campylobacter* Testing of Turkey Carcasses below). Do not touch the sampling area;
16. Hold template with one gloved hand; use other gloved hand to wipe area with sponge;
17. Turn sponge over to use its unused side for the thigh;
18. Wipe 10 times vertically over the entire sample surface; and 10 times horizontally over entire sample surface;
19. Place the sponge in the Whirl-Pak® bag (marked with an “S”) and seal the bag;
20. Discard the template;
21. Repeat steps 4-19 for the right side with the supplies marked “C;” and
22. Place the bird back on the conveyor or table.

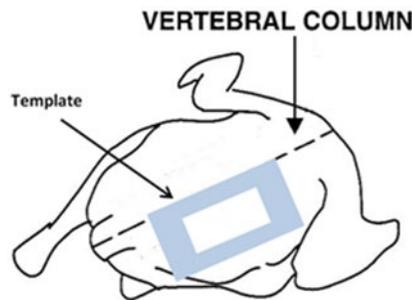
NOTE: Rinsing the carcass with potable water after sampling is not necessary.

F. The sample is now complete. Follow the storage and shipping instructions in Chapter VII – Submitting the Collected Sample.

Sample Sites for *Salmonella* and *Campylobacter* Testing of Turkey Carcasses:

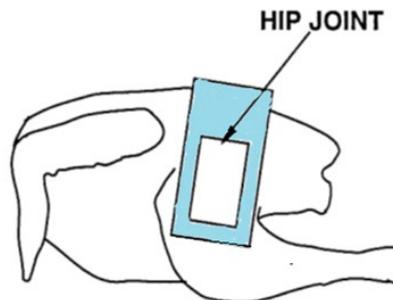
Back

Locate the tail. The area to sample (5 cm x 10 cm) starts just above the tail and extends forward along either side of the vertebral column. Two separate samples are taken individually, with one template and sponge used just to the left of the vertebral column, and the other template and sponge used just to the right of the vertebral column.



Thigh

Locate the hip joint. The area to sample (5 cm x 10 cm) starts at the hip joint and extends to cover the thigh area.



CHAPTER V – SALMONELLA AND CAMPYLOBACTER SAMPLING PROCEDURES FOR CHICKEN PARTS (LEGS, BREASTS, and WINGS ONLY); (HC_CPT_LBW01)

I. PRODUCT ELIGIBLE FOR SAMPLING

A. Products eligible for sample collection under the chicken parts sampling project include raw chicken legs, breasts, and wings that would typically be available for consumer purchase. These products can be skin-on or skinless and can be bone-in or boneless. Eligible parts can be mechanically tenderized, vacuum tumbled, or injected or otherwise marinated or coated in solutions or dry spice mixtures, but cannot be breaded, stuffed, or wrapped in dough, as noted in [Chapter II, Section V](#). Cut-up chicken parts are eligible for sampling provided they are equal to or larger than 3/4 inch in size in at least one dimension and are of a type that would typically be available for consumer purchase. Photographic images representative of typical chicken parts and subparts are available as a [List of Chicken Parts Eligible for Sample Collection](#) accessible through [IPP Help](#) (under [Sampling](#)). IPP are to review definitions below of the parts to ensure that the parts selected for sampling are accurately documented in PHIS:

1. For legs, whole legs (no backbone attached), drumsticks, thighs, thighs with backbone attached, and cut up or portioned leg meat (3/4 inch or larger in at least one dimension) are eligible for sampling;
2. For breasts, whole and half breasts (with or without ribs), boneless and skinless chicken breasts, tenderloins and tenders, and cut up or portioned breast meat (3/4 inch or larger in at least one dimension) are eligible for sampling; and
3. For wings, whole wings (with or without the wing tip), mixed wing sections, drumettes, mid-sections (flats), wing tips, and boneless wings are eligible for sampling.

B. Chicken half carcasses and chicken quarter carcasses are not currently eligible for collection under this sampling program. The following products are not eligible because they are chicken quarters:

1. Leg quarters which consist of a thigh and drumstick, with a portion of the back attached;
2. Breast quarters which consist of half a breast with the wing and a portion of the back attached;
3. Breast quarters without wing that consist of a half a breast with a portion of the back attached; and
4. The entire carcass that has been cut into four equal parts.

C. Only finished products are eligible for sampling. Finished products are the products that are shipped from the establishment. Eligible chicken parts are identified in PHIS in the finished product group as “Poultry Parts (legs, breasts, wings ONLY)” and “Injected, Tenderized, or Vacuum Tumbled Parts (legs, breasts, wings ONLY)”. IPP are not to sample source material or intermediate product and are not to request that an establishment cut up whole chickens for FSIS chicken parts sampling.

D. If a chicken part is of a type that would typically be available for consumers and is produced in an establishment, it is eligible for sampling even if it is not being packaged for consumer purchase by the establishment being sampled.

Example 1: An establishment produces boneless, skinless chicken breasts as a finished product, which is a product type typically available for consumers. The establishment packages and ships all the boneless, skinless chicken breasts for hotels, restaurants, or similar institutions (HRI). The product is eligible for parts sampling.

Example 2: An establishment produces raw bone-in chicken thighs as a finished product, which is a product type typically available for consumers. Some of the product is packaged in consumer-ready packaging while the rest is shipped for further processing into a not ready-to-eat (NRTE) product. All of the product is eligible for sampling regardless of where it is being shipped.

E. Parts that are portioned only (packed into smaller packages without any additional processing (examples of processing: cut-up, application of interventions) or repackaged only are not eligible for sampling.

F. Chicken parts produced at establishments that slaughter and further process or at establishments that further process (but do not slaughter) are eligible for sampling. For example, if source material received at a further processing establishment is deboned, marinated, or cut up into eligible chicken parts, IPP are to sample finished chicken parts at the further processing establishment.

II. COLLECTING THE SAMPLE (PARTS RINSE)

A. Additional details and guidance concerning sample collection are accessible through [IPP Help](#).

B. IPP are to collect a rinsate from 4 lbs. \pm 10% (3 pounds, 10 ounces to 4 pounds, 6 ounces) of the specified raw chicken parts. Collect the rinsate from the eligible chicken parts immediately after collection of the parts. IPP are not to hold the chicken parts under refrigeration overnight prior to collecting the rinsate.

C. To choose and collect the parts to be sampled, IPP are to:

1. Randomly select which available eligible chicken parts (legs, breasts, and wings) to sample. If an establishment produces more than one type or subtype of eligible chicken part, then IPP are to alternate sampling of the parts each sampling task to ensure that all products are collected during the sampling project. If an establishment produces both eligible intact and eligible non-intact chicken parts, IPP are to alternate sampling of intact and non-intact parts;

NOTE: Randomization of parts selection is critical to achieve sample variety.

2. Collect only one chicken part subtype per sampling event. For example, if IPP are collecting chicken breast tenderloins, they are to collect only chicken breast tenderloins and not a mixture of other breast pieces or other parts such as legs;
3. Collect and place into the sampling bag a sufficient number of eligible chicken parts to total 4 lbs. \pm 10% (3 pounds, 10 ounces to 4 pounds, 6 ounces) in weight. Avoid transferring excess processing liquid when placing the chicken parts in the sampling bag;
4. Place the bag with the parts on the flat sanitized surface;
5. Gently invert the sampling broth container three (3) times immediately prior to adding the sampling broth to the chicken parts. Open the container and pour the sampling broth onto parts in the bag;

6. Expel the excess air from the bag, twist it closed, and fold the twist over;
7. Mix the broth with the parts for one minute;
8. Place the bag with the chicken parts on the sanitized flat surface with the top of the bag facing up;
9. Carefully open the plastic bag containing the parts without touching the inside of the bag or the inside corners;
10. Carefully pour approximately 120 ml of the sampling broth into the specimen jar.
Important: Do not allow the bag to touch the sterile specimen jar. Securely close the specimen jar with the screw-top lid. Avoid touching the inside of the lid so that it does not contaminate the sampling broth;
11. Discard any remaining rinse fluid into a drain. Do not discard the chicken parts. Rinsing the parts with potable water is not necessary. Return the parts to where you initially collected them unless the establishment requests otherwise; and
12. Refrigerate the sample promptly after collection. IPP are to hold the rinsate in a refrigerator set at 40° F or lower and under FSIS control until the samples are shipped. IPP are not to freeze samples.

CHAPTER VI – SALMONELLA AND CAMPYLOBACTER SAMPLING PROCEDURES FOR NRTE COMMINUTED POULTRY; (HC_CH_COM01, HC_TU_COM01)

I. PRODUCT ELIGIBLE FOR SAMPLING

A. IPP are to collect products in the “Ground Product” and “Other Comminuted” product groups (for example, fresh raw sausage and fresh raw patties) under only the HC_CH_COM01 and HC_TU_COM01 sampling codes, randomly selecting from available eligible raw ground and other comminuted (but not mechanically separated) products. Comminuted products containing added ingredients such as spices, seasonings, rosemary extract, or vegetables (but not other raw meat or poultry) are eligible for sampling.

EXAMPLE: If an establishment produces ground chicken with an average daily production volume of greater than 1,000 pounds but produces other raw comminuted chicken products such as raw chicken sausage with an average daily production volume of less than 1,000 pounds, then IPP are to schedule only ground chicken (and not the other raw comminuted products) for collection.

B. The following products are not eligible for sampling under this project:

1. Injected, needle- or blade-tenderized, or vacuum tumbled raw poultry parts or carcasses, because they are not considered to be NRTE comminuted poultry;

NOTE: If the injected, needle-tenderized, or vacuum tumbled product is subsequently processed in the same establishment to reduce particle size, such as by grinding or other process, then the raw comminuted products manufactured from these non-intact source materials would be eligible for sampling. For example, if injected chicken breast trimmings are source materials used in raw ground poultry, then the raw ground poultry itself (but not the trimmings) is eligible for sampling.

2. Mixed-species NRTE comminuted poultry products (for example, raw sausage containing both raw ground turkey and raw ground pork or containing both raw ground chicken and raw ground turkey);
3. Diced, chunked, or sectioned poultry that is not in small pieces or that is otherwise not comminuted. In general, this would refer to pieces 3/4 inch or greater in any dimension;
4. Hand- or mechanically-deboned products that are not further chopped, flaked, minced, or otherwise processed to reduce particle size;
5. Whole muscle parts because they are not comminuted;
6. Poultry trimmings because they are not comminuted;
7. Comminuted poultry that is portioned (product from a larger package broken down into smaller packages but not cut-up or otherwise processed) only or repackaged only;
8. Any NRTE finished product containing comminuted poultry that has been cooked or heat-treated (for example, in the HACCP processing category "Heat-treated but not Fully Cooked – Not Shelf Stable"); and
9. Dumplings, wontons, potstickers, eggrolls, pelmeni, or other comminuted chicken or turkey products wrapped in dough or other similar covering (nor their source material when these are the final products in the establishment).

II. SAMPLE COLLECTION (COMMINUTED PRODUCT)

- A. IPP are to randomly collect eligible raw comminuted poultry samples by product group.
- B. IPP are to collect finished product in its final package whenever possible. IPP are to collect the appropriate number of packages so that the sample equals two pounds or may collect a slack-filled package for larger products. IPP are to place the product collected in its final packaging in the larger, non-sterile bag provided with the sampling supplies.

NOTE: IPP are not to use the Whirl-Pak® bags when collecting product in its final packaging.

- C. For finished product not available in final packaging or when the package is too large, IPP are to collect the sample aseptically, as close to the finished process as possible, after all antimicrobial interventions have been applied. IPP are to collect the samples as close to packaging as possible (e.g., grab the sample from a combo bin or grab from a 40-pound box) and use the sterile Whirl-Pak® bags as instructed below in II.E.
- D. IPP are to use only the sampling and shipping materials provided by the FSIS laboratory specific to the NRTE comminuted poultry sampling project; IPP are not to use spoons or other implements to collect a sample other than what is included in FSIS-provided sampling supplies.
- E. When using the Whirl-Pak® bags, IPP are to:
 1. Randomly select product to sample;
 2. Collect sufficient product to fill the two provided Whirl-Pak® bags up to the fill-line indicated on each bag. When the bag is closed, product should meet the line indicated on the bag, as

illustrated in the photo-led instructions in [IPP Help](#). IPP are not to overfill the bag. The total weight of the two bags of samples should be approximately two pounds; and

3. Ensure that each Whirl-Pak® bag is properly closed. To do this, IPP are to carefully squeeze out the air remaining in the bag and tightly fold over the top at least four times as trapped air and loose closures may lead to leakage. When folding over the tops of each bag, IPP are to ensure that they do not touch the bag near its opening. Next, IPP are to fold over the side tabs to secure the folds in place and to not tie the ends. This process is to be repeated for the second bag.

F. IPP are to place both Whirl-Pak® bags in the same secondary containment bag (zipper-lock type bag), expel excess air from the bag, and close the containment bag using the zipper lock closure.

CHAPTER VII – SUBMITTING THE COLLECTED SAMPLE (ALL PRODUCT CLASSES)

I. PACKAGING THE SAMPLE

A. IPP are to follow the instructions provided in [FSIS Directive 7355.1 Use of Sample Seals for Laboratory Samples and Other Applications](#), on the use of sample seals (FSIS Form 7355-2A/2B) on specimens and containment bags to maintain sample security and identification.

B. IPP are to allow the samples to cool down by refrigerating for one hour prior to packing, if this does not delay shipment by the carrier.

C. IPP are to place the frozen gel pack in the bottom of the refrigerated shipping container, then place the corrugated cardboard pad on top of the gel pack to prevent the sample from coming in direct contact with the frozen gel pack. This barrier prevents portions of the sample from freezing, which would have an impact on the sample results.

D. IPP are to place the cooled sample (sponge, rinsate, or raw ground or comminuted product) on top of the cardboard pad. IPP are to use only the sampling and packing supplies provided by the labs. IPP are not to tape or wrap the sample, or to fill the sample box with newspaper or similar packing materials and are not to use staples in any element of the package.

E. IPP are to ensure that the sample container (bag or jar) is correctly closed. Jar lids are to be correctly threaded and not over-tightened to prevent leaking.

NOTE: The laboratory will discard samples if the containers are leaking.



Example of a cross-threaded rinse container that leaked during shipment.

F. During certain months, the FSIS laboratories will include additional gel packs in the sampling supplies to assist in maintaining proper sample temperature. IPP are to pack the sample in one of the ways described and illustrated below:

1. Gel packs on top and bottom: Place the absorbent pad in the bottom of the box, followed by gel coolant pack(s), one cardboard separator, sample(s) inside the containment bag, one cardboard separator, gel coolant pack(s), and then the foam plug on top; or
2. Gel packs on opposite sides: Within the box, place the absorbent pad in the bottom of the box. On top of this, place gel coolant pack(s) standing upright (against the side of the box), one cardboard separator, samples(s) inside the plastic containment bag, one cardboard separator, and gel coolant pack(s) standing upright (against the opposite side of the box).

PACKING THE SHIPPING CONTAINER:

When multiple gel packs are supplied, package the sample as shown in the images.



G. IPP are to pack the sample in the shipping container as close to the expected courier pickup time as possible. The shipping container itself should not be used as a refrigerator. IPP are never to store packed and prepared sample boxes near areas exposed to excessive heat or allow them to go below 32°F (0° C).

NOTE: The laboratory will discard samples that arrive above 15°C (69°C) or *Campylobacter* testing will be cancelled if below 0°C (32°F). Some target bacteria may be damaged by temperatures that are too cold, while temperatures that are too warm can allow competing bacteria to outgrow the targets. Maintaining samples at improper temperatures may contribute to loss of viable target bacteria.

H. IPP are to accurately fill in the “Time Collected” and “Mail/Ship Date” sections of the PHIS generated sampling form. If the collection or ship date printed on the form is inaccurate, and IPP are unable to correct it, IPP are to cancel the sampling task from the PHIS task calendar by right clicking on the task. IPP are to reschedule the sampling task with the correct collect or ship date. This action will result in a new form being generated and may also result in a different assigned lab. IPP are to sign the completed sample form and place it in its plastic sleeve. This sleeve should then be placed with the sample, securely under the foam plug.

I. IPP are to remove any old stamp receipts and carrier shipping bar codes from the container and affix the billable stamp addressed to the FSIS laboratory printed on PHIS Form 8000-19 on the shipping container.

J. IPP are to apply the FSIS Laboratory Sample Container Seal (FSIS Form 7355-2A) to the inner flap of the shipping container as described in [FSIS Directive 7355.1 Use of Sample Seals for Laboratory Program Samples and Other Applications](#).

II. SHIPPING THE SAMPLE

A. IPP are to select the correct pre-addressed billable stamp (shipping label) for the designated laboratory performing the analysis. The designated lab for the sample can be found in item 5 of the collection information block on PHIS Form 8000-19. A billable stamp for all three laboratories is included in the empty shipping container. IPP are to select the billable stamp that matches the FSIS laboratory printed on PHIS Form 8000-19 and enter the return address information on that billable stamp.

B. IPP are to fill in the plant number, ship date, and plant phone number. IPP are to sign the billable stamp and remove the top copy for the IPP's records. IPP are to place the remaining copies on the box so that it covers any old billable stamps still adhered to the box.

C. IPP are to ensure sample security is maintained at all times (see [FSIS Directive 7355.1](#)) and ensure that the sample remains under FSIS control until pickup by the carrier.

D. IPP are to ship the refrigerated sample via overnight delivery to the designated FSIS laboratory. IPP are to call the carrier by phone and schedule a pickup of the sample. Samples collected on first shift are to be scheduled for pick up and are to be shipped on the *same calendar day* the sample is collected, when possible. IPP are to hold any sample overnight that they randomly select too late in the first shift or across the shifts, when the carrier is no longer available for pick up the same calendar day. For example, samples collected from late production or second shifts are to be held overnight under refrigeration and sent by overnight courier the next calendar day. IPP are not to ship samples on a Sunday or the day before a Federal holiday.

CHAPTER VIII – VERIFICATION OF INELIGIBLE RAW PRODUCT DESTINED FOR READY-TO-EAT AT AN OFFICIAL ESTABLISHMENT

I. IPP VERIFICATION RESPONSIBILITIES

A. If the establishment:

1. Processes all product or all product from a particular product class into RTE product; or
2. Moves all product or all product from a particular product class to another official federally inspected establishment for further processing into RTE product.

B. IPP are to verify during the performance of the associated HACCP procedure that the intended use of all the product the establishment produces is for processing into RTE product (9 CFR 417.2(a)(2)).

C. IPP are to verify by:

1. Observing that all the product moves to be further processed into RTE product in the establishment;
or
2. Reviewing records to ensure that all products are further processed into RTE products in the establishment. Records may include those containing production codes or production lot codes.

D. In establishments that claim to meet the criteria for exclusion from sampling due to product all going to RTE, IPP are to review the establishment's HACCP plan and hazard analysis for the intended use of the products and are to verify that the establishment has procedures incorporated in its food safety system that effect the movement of all product from that product class to another federally-inspected establishment at which the product is further processed into RTE product.

E. Some acceptable ways that IPP could verify that the establishment has necessary procedures incorporated into its food safety system include:

1. The establishment maintains records showing that the official establishment receiving the raw product processes all of the product into RTE product, such as a copy of HACCP records showing the product meets a lethality Critical Control Point (CCP) matched with bills of lading with corresponding production codes;
2. The establishment receives letters of guarantee showing that all product of a certain type is further processed into RTE product and maintains on-going communication with the receiving establishment to verify that all its product is being processed as RTE; or
3. The establishment has a contractual agreement with the receiving establishment so the producing establishment has knowledge of the receiving establishment's production process.

F. Some insufficient procedures would include:

1. The establishment only labels the raw product with a statement, such as "for further processing"; or
2. The establishment only maintains a letter from the receiving establishment that says it only produces RTE, without the receiving establishment gathering additional information to verify that all product is processed into RTE product in an official establishment.

G. If an establishment does not have procedures incorporated into its food safety system that effect the movement of all product to another federally-inspected establishment at which the product is further processed into RTE product, the establishment is subject to sampling under the *Salmonella* and *Campylobacter* verification testing program. The establishment is required to maintain sufficient documentation in its decision making documents ([9 CFR 417.2](#)) to support the establishment's assertion that the product in question is further processed into RTE product.

NOTE: NRTE products destined for other than domestic, federally-inspected establishments for processing into RTE products do not meet the criteria for exclusion from sampling. Examples of such establishments include foreign, state inspected, food service establishments, or HRI facilities. For example, if an establishment moves NRTE product such as raw comminuted poultry to a foreign, state-inspected, or food service establishment for further processing into RTE product, that product is eligible for sampling under the NRTE comminuted poultry sampling project at the producing establishment.

H. If an establishment produces more than one lot of NRTE comminuted chicken and ships the product to different establishments, and one of the establishments produces NRTE products, IPP are to sample product under the *Salmonella* and *Campylobacter* verification testing program.

III. ADDITIONAL INSTRUCTIONS FOR IPP

A. Should an establishment not meet the criteria for exclusion from sampling and produces both RTE and NRTE end products of a single product class, IPP are to make two entries for the product class in the PHIS Establishment Profile; and

1. Check the “RTE” intended use box in the Establishment Profile on one of the entries; and
2. Not check the “RTE” intended use box in the Establishment Profile on the other entry.

B. This establishment will be scheduled for verification sampling through PHIS if it meets the product volume and other scheduling eligibility requirements.

C. Should an establishment meet the criteria for exclusion from sampling and produce only RTE end products of a single product class, IPP are to:

1. Make a single entry for the product class in the Establishment Profile; and
2. Check the “RTE” intended use box in the Establishment Profile for that product;

D. This establishment will not be scheduled for verification sampling through PHIS.

E. If IPP determine that an establishment no longer processes all raw product from a particular class into RTE product, or no longer moves all raw product from a particular class to another official federally-inspected establishment for further processing into an RTE product, then IPP are to update the entries in the Establishment Profile.

CHAPTER IX – QUESTIONS

Refer questions regarding this directive to the Office of Policy and Program Development through [askFSIS](#) by telephone at 1-800-233-3935.



Assistant Administrator
Office of Policy and Program Development