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

FSIS DIRECTIVE

10,250.1

9/20/13

SALMONELLA AND CAMPYLOBACTER VERIFICATION PROGRAM FOR RAW MEAT AND POULTRY PRODUCTS

CHAPTER I – GENERAL

I. PURPOSE

This directive incorporates into one document all instructions that FSIS has issued to inspection program personnel (IPP) regarding *Salmonella* and *Campylobacter* verification activities for raw meat and poultry products. This directive does not include sampling instructions for Steers or Heifers, Cows or Bulls, Ground Chicken (HC01), Ground Turkey (HC01), and Market Hog product classes at this time. FSIS is not currently sampling and testing for *Salmonella* in steers or heifers, cows or bulls, or market hogs. The sampling procedures for cattle and hog carcasses are included as attachments to this directive in case they are needed for special purposes. FSIS is sampling and testing ground or comminuted chicken and turkey products for *Salmonella* and *Campylobacter*. FSIS has included instructions for those products in notices. As it has announced in the *Federal Register*, FSIS intends to develop new performance standards (*Salmonella* and *Campylobacter*) for Not Ready-To-Eat (NRTE) ground or comminuted chicken and turkey products (see 77 FR 72686).

KEY POINTS:

- *Sampling raw product classes for FSIS verification testing for Salmonella and Campylobacter*
- *Sampling at low volume establishments*
- *Excluding an establishment from verification testing when all product produced is destined for Ready-to-Eat (RTE) product*
- *Reviewing data from any programs establishments use to control or monitor Salmonella in raw classes of product*
- *Requesting expedited scheduling of FSIS Salmonella verification sampling when an establishment has substantially altered its food safety system or temporarily changed its process without validation in the Hazard Analysis and Critical Control Point (HACCP) plan during or after FSIS sampling*
- *Reviewing establishment End of Set (EOS) letters to understand and evaluate test results*

DISTRIBUTION: Electronic

OPI: OPPD

II. CANCELLATION

FSIS Directive 10,230.5, Amendment 1, dated 2/4/98, Self-Instruction Guide for Collecting Raw Meat and Poultry Product Samples for *Salmonella* Analysis

FSIS Notice 19-13, dated 3/12/13, Sampling of Low Production Volume Raw Ground Beef Establishments for *Salmonella*

FSIS Notice 23-13, dated 3/22/13, Raw Product Destined for Ready-To-Eat Product Excluded from *Salmonella* Testing

FSIS Notice 54-12, dated 9/11/12, Performance Standards for *Salmonella* and *Campylobacter* in Chilled Carcasses at Young Chicken and Turkey Slaughter Establishments

FSIS Notice 57-12, dated 9/14/12, Young Chicken Carcass Sampling Eligibility

FSIS Notice 66-12, dated 10/24/12, Actions to Take When An Establishment Substantially Or Temporarily Alters Its *Salmonella* Control Process

III. SALMONELLA AND CATEGORIES

Salmonella Set: Certain number of samples taken on contiguous production days to evaluate an establishment's process control. This number varies by product class.

Category 1 – Consistent Process Control: Establishments with percent positive *Salmonella* results for samples collected and analyzed by FSIS at 50% or less of the performance standard in the two most recently completed sample sets.

Category 2T – Variable Process Control but Transitioning Towards Consistent Process Control: Establishments with percent positive *Salmonella* results for samples collected and analyzed by FSIS at 50% or less of the performance standard in the most recently completed sample set, but greater than 50% of the performance standard in the previously completed sample set.

Category 2 – Variable Process Control: Establishments with percent positive *Salmonella* results for samples collected and analyzed by FSIS above 50% but not exceeding the performance standard in the most recently completed sample set.

Category 3 – Highly Variable Process Control: Establishments with percent positive *Salmonella* results for samples collected and analyzed by FSIS exceeding the performance standard in the most recently completed sample set.

Salmonella Serotype: A group or sub-species of closely related *Salmonella* bacterial microorganisms distinguished by a characteristic set of cell structure antigens.

Salmonella Subtype: Includes a sample isolate's serotype, pulsed-field gel electrophoresis (PFGE) pattern, and antimicrobial resistance profile.

NOTE: After 90 percent of eligible young chicken establishments have been sampled for two full sets, the Agency will consider setting establishment categories 1, 2, and 3 for *Campylobacter* under the new performance standard (separate from *Salmonella*) and will consider publishing Category 2 and 3 establishments (see 75 FR 27291). FSIS announced that after 90 percent of young turkey establishments have been sampled for two full sets, the Agency will post names of establishments that do not meet the standard in the last set on the Agency Web site (see 75 FR 27292).

IV. BACKGROUND

A. The *Salmonella* Verification Program was established by FSIS in 1996 as part of the *Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems* Final Rule (61 FR 38806). Under this program, FSIS assesses industry performance and controls for reducing *Salmonella* contamination in raw meat and poultry products.

B. The PR/HACCP Final Rule established performance standards for *Salmonella* in certain product classes based on national baseline studies that were conducted before its implementation. FSIS has published a number of *Federal Register* notices since that time and has established revised performance standards for certain product classes. The Agency continues to actively work towards revising these performance standards to meet public health goals.

C. FSIS schedules approximately 75 *Salmonella* verification sample sets each month. The scheduling algorithm is used to allocate sampling resources by prioritizing the testing of Category 3 establishments, then testing of Category 2 establishments (including Category 2T establishments), and lastly testing of Category 1 establishments. The scheduling algorithm also takes into account which product class an establishment produces, prioritizing testing at young chicken establishments, and then at establishments producing other raw product classes in descending order of current Agency priority. Finally, the scheduling algorithm prioritizes testing at establishments with higher than the expected numbers of isolates with serotypes of *Salmonella* that commonly cause human illness (i.e., sets exceeding the 75th percentile for these serotypes, by product class). The Centers for Disease Control and Prevention (CDC) defines common human serotypes of public health concern as the top 20 *Salmonella* serotypes from human sources reported to the CDC, Public Health Laboratory Information System. This list is updated annually (last update is for 2011) and can be found at: <http://www.cdc.gov/ncezid/dfwed/PDFs/salmonella-annual-report-2011-508c.pdf>. A more detailed description of the FSIS scheduling criteria and algorithm are available at: *Salmonella* Scheduling Algorithm Functions.

D. The Agency has two Strategic Goals (Corporate Performance Measures) that are related to *Salmonella*:

1. The “All-Illness Measure”. This measure tracks and sets quarterly goals for reducing the total illnesses caused by three pathogens (*Salmonella*, *E. coli* O157:H7, and *Listeria monocytogenes*) attributed to FSIS regulated products. This measure is intended to help the Agency meet Healthy People 2020 goals; and
2. The percent of young chicken establishments meeting the new *Salmonella* performance standard. This measure is also tracked on a quarterly basis.

E. FSIS has issued a number of directives and notices outlining *Salmonella* and *Campylobacter* policies and instructions. This directive consolidates several of these issuances into one directive. In addition, FSIS performed a number of analyses on the implementation of existing instructions to the field. Based on this analysis, FSIS is clarifying several issues in this directive including:

1. Updated sampling instructions to clarify that:
 - a. IPP are to notify establishment management prior to taking a sample;
 - b. Not more than one *Salmonella* or *Campylobacter* sample is to be scheduled for collection per multi-shift production day;

- c. Religious exempt poultry product is not subject to sampling;
 - d. Mixed species ground product is not eligible for sampling under HC01; and
 - e. Any sample that is randomly selected across shifts, but is collected after FedEx is no longer available, can be held refrigerated overnight and shipped the next day and will not be discarded by the laboratory;
- 2. Information on current performance standards for young chickens and young turkeys; and
 - 3. Updated instructions on how to determine whether a class of product is exempt from sampling because the establishment is sending all such product to another Federal establishment to be made into RTE product.

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

I. GENERAL SAMPLING POLICIES

A. IPP are to routinely update product volumes in the Public Health Information System (PHIS) to ensure that all information is accurate (see **FSIS Directive 5300.1**, *Managing the Establishment Profile in the Public Health Information System*)

B. Prior to collecting samples, IPP are to be familiar with:

1. Random sampling, which may include the use of random number tables, drawing cards, or using computer generated random numbers;
2. Aseptic sampling techniques. In general, extraneous organisms from the environment, hands, clothing, sample containers, and sampling devices may lead to erroneous analytical results. Stringent requirements for microbiological analysis are necessary; therefore, use of aseptic sampling techniques and clean, sanitized equipment are of utmost importance; and
3. The sampling steps appropriate to the product class sampled. The Agency has a *Salmonella* verification program and associated performance standards for Young Chickens (YC; see Chapter III), Young Turkeys (YT; see Chapter IV), and Ground Beef (GB; see Chapter V). In addition, the Agency has established *Campylobacter* performance standards for YC and YT that are verified using the same sample as for *Salmonella*. Each of these product classes has a specific sampling methodology that IPP must be familiar with prior to sampling that class.

II. ORDERING SAMPLING SUPPLIES

IPP are to request sampling supplies at least 72 hours before sampling is to begin. Requests for sampling supplies for *Salmonella* and *Campylobacter* verification testing are to be sent through PHIS, which will automatically assign the supply order to an appropriate FSIS Laboratory.

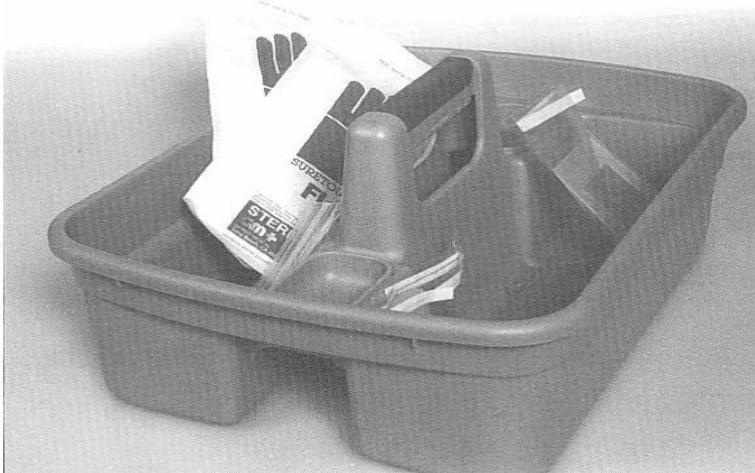
III. IPP RESPONSIBILITIES

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 could be used for transporting supplies and supporting sample bags to which IPP are adding sterile solutions;
2. Open a shipping container and check to ensure that all the supplies needed for sample collection are inside. Remove the supplies from the container. These can be stored in the government office;
3. Check the Buffered Peptone Water (BPW) container for particulate matter, cloudiness, or turbidity. Use only clear BPW. Pre-chill the BPW upon receipt by placing it in a secure refrigerator. Containers of defective BPW are to be clearly marked “bad” and returned to the supplying laboratory. (If comminuted product is being sampled, no BPW is required.);
4. Place gel packs in the freezer; and
5. Place the open shipping container in the cooler/refrigerator to prechill.

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

1. Gather the appropriate PHIS Sample Analysis Request Form for the product being sampled (Form 8000-18 or 8000-19); the general supplies for sample collection (e.g., sample collection bags, sterile gloves); and the specific materials for the type of sample to be collected (e.g., templates and specimen sponges for turkey carcass samples or sterile ring or Whirl-Pak™ bags for ground product);
2. Collect the sanitizing solution, if needed;
3. Retrieve the appropriate container of BPW from the refrigerator/cooler. Use only prechilled BPW when sampling;
4. Ensure that all sampling supplies are on hand and readily available before beginning sample collection;
5. Sanitize the cart, caddy¹, tote¹, or other designated work area surfaces by wiping with a clean disposable cloth or paper towel dipped in freshly prepared 500 parts per million (ppm) sodium hypochlorite solution (0.05% sodium hypochlorite) or other approved sanitizing solution that provides the equivalent available chlorine concentration. If IPP use a sodium hypochlorite solution, they are to make it just prior to use, since its strength diminishes upon standing. To make the solution, IPP are to add 2-4 oz of sodium hypochlorite (Purex® or its equivalent)¹ to one gallon (128 oz) of potable water. This will give a strength of 500-1000 ppm hypochlorite. The sample work area surfaces must be free of standing liquid before sampling supplies or product containers are placed on them.



¹IPP can purchase a plastic tote or caddy and Purex® bleach if necessary. Reimbursement of these expenses can be obtained either by submitting a travel voucher or a Standard Form 1164.

6. Wash and scrub hands to the mid-forearm before starting the actual sample collection procedure. Use antibacterial hand soap. Dry hands using disposable paper towels. The abrasive effect of the paper will aid in removing additional bacteria; and
7. Wear sterile gloves while collecting samples (see Attachment 1 – How to put on sterile gloves). The only items that should contact the external surface of the sterile glove on the sampling hand are the sample being collected, the sterile sampling utensil (e.g., the specimen sponge), and the template when used. Remember that the outside surfaces of the sample container are not sterile.

IV. SELECTING THE SAMPLE

A. IPP are to notify official establishment management just before collecting each sample that a routine *Salmonella* or *Campylobacter* sample is being collected as part of a set.

B. IPP are to use a method for randomly selecting the specific product for sampling. It is very important that all shifts, rails, chillers, coolers, and grinders have an equal chance of being selected for sampling (see Section I.B.1 of this Chapter).

C. IPP are to collect one sample each day the establishment produces the product indicated in the sampling task on the IPP's task bar in PHIS, unless otherwise instructed.

D. IPP are to collect representative samples from all production shifts as part of completing the full set. It is not necessary to ensure that equal proportions of samples are taken from each production shift. Not more than ONE sample is to be scheduled for collection per multiple-shift production day. The Inspector-in-Charge (IIC) is to coordinate the collecting and mailing of samples that occur during different shifts.

CHAPTER III – SALMONELLA AND CAMPYLOBACTER SAMPLING PROCEDURES FOR YOUNG CHICKENS (CARCASS; HC11)

I. PERFORMANCE STANDARDS

Product class	Pathogen	Performance standard	Number of samples tested	Sampling Method	Maximum number of positives to achieve standard	Revised Standard Implemented
Young Chickens (Carcass)	<i>Salmonella</i>	7.5%	51	100 ml BPW rinsate	5	7/1/11
	<i>Campylobacter</i>	10.4%			8	

II. 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.

B. FSIS does not collect samples of or analyze for *Salmonella* and *Campylobacter* chickens or chicken products produced under a religious exemption and not bearing the mark of inspection. Religious exempt poultry is considered a unique product that was not included in baseline studies from which *Salmonella* and *Campylobacter* performance standards were derived.

C. Products of any product class diverted for pet food manufacture without the mark of inspection are not subject to FSIS sampling for *Salmonella* or *Campylobacter*.

D. An establishment is excluded from sampling when the establishment either processes all product in a product class into RTE product or moves all product from a product class to another official federally-inspected establishment for further processing into an RTE product (see Chapter VII – Raw product destined for Ready-to-Eat product excluded from *Salmonella* testing).

III. 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 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 unit. For hot-boned carcasses, IPP are to randomly determine the line.

C. IPP are to use aseptic techniques and perform the following step-by-step procedures:

1. Wash and sanitize hands;

2. Sanitize work surfaces (surfaces that will contact supplies *while the supplies are being gathered*);
3. Gather the supplies;
4. Label the sample container;
5. Wash and sanitize hands again;
6. Take supplies to the sampling location;
7. Sanitize work surfaces (surfaces that will contact supplies *during sampling*);
8. Lay out supplies;
9. Open the large sterile bag; and
10. Put on the sterile gloves (see Attachment 1 – How to put on sterile gloves).

IV. COLLECTING THE SAMPLE (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 and after sufficient drip time to prevent dilution of the sample. 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. (Also see Chapter VIII, Section II. Actions to take when an establishment substantially or temporarily alters its *Salmonella* or *Campylobacter* control process).

C. IPP are to rinse the carcass with BPW (See Attachment 4 – How to rinse a Young Chicken carcass).

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

NOTE: In general, a drip time of 1 minute is sufficient. During this time, IPP are to be careful to avoid cross-contamination.

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. Open the BPW container and pour the BPW into the carcass cavity in the bag;
4. Manipulate the loose neck skin over the neck bones. (Do this through the bag.);
5. Expel the excess air from the bag, twist it closed, and fold the twist over;
6. Mix the BPW through the carcass cavity and outside of the carcass for one minute; and
7. Place the bag with the chicken on the sanitized flat surface with the top of the bag facing up.

E. IPP are to prepare the sample for shipping. It is acceptable to remove the gloves at this time; however, IPP are 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 sterile bag;
2. Open the large bag with the chicken, and pour 100 ml of the BPW liquid into the sterile sample container;
3. Take the screw-cap out of small resealable bag, and close the sample container. Ensure that the lid is correctly threaded, and do not over-tighten;
4. Place the sample container in the small resealable bag, expel excess air, and seal the bag;
5. Discard the remaining liquid; and
6. Return the chicken to the chill tank or to where the bird was collected.

F. The sample is now complete. Follow the storage and shipping instructions in Chapter VI – Submitting the collected sample.

CHAPTER IV – SALMONELLA AND CAMPYLOBACTER SAMPLING PROCEDURES FOR YOUNG TURKEYS (CARCASS; HC11)

I. PERFORMANCE STANDARDS

Product class	Pathogen	Performance standard	Number of samples tested	Sampling Method	Maximum number of positives to achieve standard	Revised Standard Implemented
Young Turkeys (Carcass)	<i>Salmonella</i>	1.7%	56	Back and thigh surface sampling- 50 cm ² for each using one cellulose sponge hydrated with BPW	4	7/1/11
	<i>Campylobacter</i>	0.79%			3	

II. PRODUCT ELIGIBILITY FOR SAMPLING

A. FSIS does not collect samples of or analyze for *Salmonella* and *Campylobacter* turkeys or turkey products produced under a religious exemption and not bearing the mark of inspection. Religious exempt poultry is considered a unique product that was not included in baseline studies from which *Salmonella* and *Campylobacter* performance standards were derived.

B. Products of any product class diverted for pet food manufacture without the mark of inspection are not subject to FSIS sampling.

C. An establishment is excluded from sampling when the establishment either processes all product in a product class into RTE product or moves all product from a product class to another official federally-inspected establishment for further processing into an RTE product (see Chapter VII– Raw product destined for Ready-to-Eat product excluded from *Salmonella* testing).

III. 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, or at the last readily accessible point before packaging or cut-up (or the equivalent in air-chill operations), 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 unit. For hot-boned carcasses, IPP are to randomly determine the line;

C. IPP are to use aseptic techniques and perform the following step-by-step procedures:

1. Wash and sanitize hands;
2. Sanitize work surfaces (surfaces that will contact supplies *while supplies are being gathered*);

3. Gather the supplies;
4. Make sure that one sponge bag is labeled with an “S” and the other one with a “C”;
5. Wash and sanitize hands again;
6. Take supplies to the sampling location;
7. Sanitize work surfaces (surfaces that will contact supplies *during sampling*);
8. Lay absorbent towels or sanitized rack on work surface to prevent the carcass from slipping;
9. Lay out supplies; and
10. Put on the sterile gloves (see Attachment 1 – How to put on sterile gloves).

IV. COLLECTING THE SAMPLE (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 sufficient drip time to prevent dilution of the sample. 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. (Also see Chapter VIII, Section 2. Actions to take when an establishment substantially or temporarily alters its *Salmonella* or *Campylobacter* control process);

C. IPP are to sponge the carcass and prepare the sample for shipping (follow the general sponging techniques as outlined in Attachment 2 – How to prepare the sponge and template for sample collection; Attachment 3 – How to sponge a carcass (General); and Attachment 5 – How to sponge a Young Turkey carcass).

D. 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.

NOTE: In general, a drip time of 1 minute is sufficient. During this time, IPP are to be careful to avoid cross-contamination.

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

1. Place the turkey breast-down on the towels or rack. Do not let sample sites (back and thigh; see Sample Sites for *Salmonella* Testing of Turkey Carcasses) touch any surfaces;

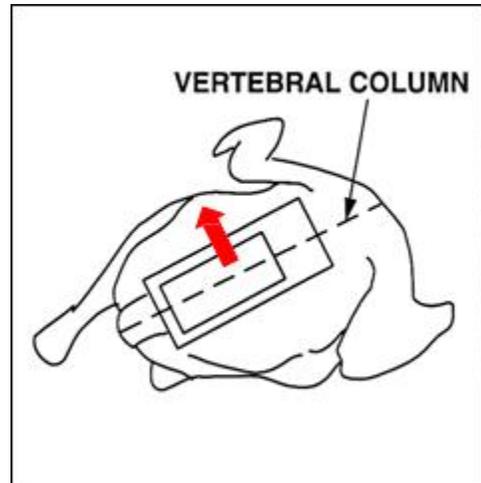
2. Remove and discard gloves;
3. Open sponge bag;
4. Pour smaller BPW container marked "S" into sponge bag marked "S";
5. Set empty BPW container aside;
6. Close bag and massage sponge;
7. Push sponge to top of bag and then open bag; set bag aside on a sanitized surface;
8. Open template bag and set 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* Testing of Turkey Carcasses). Do not touch the sampling area;
13. Hold template with one gloved hand and use other 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* Testing of Turkey Carcasses). Do not touch the sampling area;
16. Hold template with one gloved hand; use other hand to wipe area with sponge;
17. Turn sponge over to use its unused side for the thigh;
18. Do 10 vertical wipes over entire sample surface; then do 10 horizontal wipes 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 the procedure by pouring the larger BPW container marked "C" into sponge bag marked "C", then swab the RIGHT side of the same carcass using a new pair of gloves and a new template; and
22. Place the second sponge in the Whirl-Pak® bag (marked with a "C") and seal the bag.

E. The sample is now complete. Follow the storage and shipping instructions in Chapter VI – Submitting the collected sample.

Sample Sites for *Salmonella* Testing of Turkey Carcasses:

Back

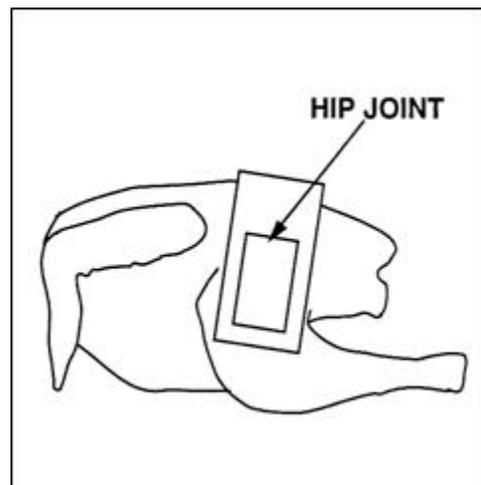
Locate the tail. The area to sample (5 cm x 10 cm) starts just anteriorly from the tail and extends forward along either side of the vertebral column. Two separate samples are taken individually, with one template and sponge used just to the left of the vertebral column, and the other template and sponge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



NOTE: Actual placement of each individual template used while sponging will be to the left or right of center and not directly on the vertebral column.

Thigh

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



CHAPTER V– SALMONELLA SAMPLING PROCEDURES FOR GROUND BEEF (HC01)

I. PERFORMANCE STANDARDS

Product class	Pathogen	Performance standard	Number of samples tested	Sampling Method	Maximum number of positives to achieve standard	Revised Standard Implemented
Ground Beef	<i>Salmonella</i>	7.5%	53	One sample per event	5	N/A

II. PRODUCT ELIGIBILITY FOR SAMPLING

- A. IPP are to sample ground and chopped raw meat from cattle carcasses (beef or veal) that meet the standards of identity for ground and chopped beef (9 CFR 319.15(a)) or hamburger (9 CFR 319.15(b)).
- B. IPP are not to sample beef patties as defined in 9 CFR 319.15(c), fabricated steaks, or similar products as defined in 9 CFR 319.15(d) under the HC01 ground beef code.
- C. Sampled products may contain meat derived from advanced meat recovery (AMR) systems, but IPP are not to sample AMR meat by itself.
- D. IPP are to make every effort to sample ground beef before other ingredients, such as spices and seasonings, have been added. However, in cases where such samples are not available, IPP are to sample ground beef to which other ingredients have been added.
- E. IPP are not to sample ground beef products that contain another species in addition to beef under the HC01 ground beef code.
- F. Establishments that produce **less than 1,000 pounds** of raw ground beef products in a typical day's production are sampled under sample code MT43S and are not to be sampled under the HC01 ground beef sampling program. Instructions for collecting MT43S are in notices on collecting ground beef for *E. coli* O157:H7 sampling.
- G. Products of any product class diverted for pet food manufacture without the mark of inspection are not subject to FSIS sampling.
- H. An establishment is excluded from sampling when the establishment either processes all product in a product class into RTE product or moves all product from a product class to another official federally-inspected establishment for further processing into an RTE product (see Chapter VII– Raw product destined for Ready-to-Eat product excluded from *Salmonella* testing).

III. PREPARING TO COLLECT A SAMPLE

- A. IPP are to select a time at which to collect the sample. Determine the times that raw ground product will be produced, then randomly select a time from within that time frame for collecting the sample.

B. IPP are to select a grinder from which to collect the sample. If more than one ground product line is in operation at the time of sample collection, IPP are to randomly select the ground product line from which to take the sample and use aseptic techniques and perform the following step-by-step procedures:

1. Wash and sanitize hands;
2. Sanitize work surfaces (surfaces that will contact supplies *while supplies are being gathered*);
3. Gather the supplies;
4. Label the sample bag;
5. Wash and sanitize hands again;
6. Take supplies to the sampling location;
7. Sanitize work surfaces (surfaces that will contact supplies *during sampling*);
8. Open the Whirl-Pak® bag;
9. Manipulate the ring to the top of the bag. Do this through the bag. Fold the bag bottom and set the bag upright on a sanitized surface;
10. Put on the sterile gloves (see Attachment 1 – How to put on sterile gloves);
11. Remove the ring; and
12. Unwrap the ring and lay it in the center of the sterile sheet of plastic.

IV. COLLECTING THE SAMPLE

A. IPP are to collect raw ground beef samples randomly (see Attachment 8 – How to collect a ground product sample (HC01)) after the final grinding process, before any addition of spices or seasonings (if possible), and prior to final packaging.

B. Where it is not possible or is unsafe to collect product prior to packaging, IPP are take samples aseptically after packaging but prior to chilling or freezing. IPP are to select several packages from which to collect a portion of the sample.

C. IPP are to:

1. Uniformly pack the collected ground beef into the ring;
2. Hold the ring over the open Whirl-Pak® bag and push the plug of ground product into the bag. Do not let the product touch the outside of the bag;
3. Shake the sample to the bottom of the bag, expel excess air, close the bag; and

4. Prepare the sample for shipping. It is acceptable to remove the gloves at this time. Continue to work in an aseptic manner.

D. The sample is now complete. Follow the storage and shipping instructions in Chapter VI– Submitting the collected sample.

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

I. PACKAGING THE SAMPLE

A. IPP are to place the frozen gel pack in the bottom of the refrigerated shipping container. During hot summer months, it may be necessary to include extra gel packs in the shipping container (these will be seasonally supplied by the labs).

B. IPP are to 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 freezing of portions of the sample which would have an effect on the sample results.

C. IPP are to ensure that the sample container (bags or jars) are correctly closed. Jar lids must be correctly threaded and not over-tightened to prevent leaking.

NOTE: The laboratory will discard samples in leaking containers.

D. IPP are to let the rinsate or sponge samples cool down prior to packaging by refrigerating for one hour if this does not delay shipment by FedEx.

E. IPP are to place the cooled sample (sponge, rinsate, or raw ground 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.

NOTE: The laboratory will discard the sample if sample containers other than those provided or extraneous packing materials are used to submit samples. Damage to the sample at the laboratory can occur during removal of extraneous tape.

F. IPP are to insert the foam plug and press it down to minimize space and to stabilize the sample during shipping. IPP are to firmly push the foam plug down onto the sample to prevent movement and leaking of the sample container.

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. However, multiple samples for that day (if needed) may be stored in the open shipping container that is placed in a cooler or 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 labs do not consider frozen samples (below 32°F (0°C)) or samples that are too warm (above 59°F (15°C)) to be valid and will not analyze them when they arrive at the labs. Some bacteria may be damaged by temperatures that are too cold, while temperatures that are too warm can allow bacteria to multiply. Maintaining samples at improper temperatures may contribute to inaccurate analytical results.

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. If IPP have entered a date on the form in PHIS, which is incorrect but cannot be changed in PHIS, they are to

write in the change manually using ink. The laboratory will accept changes (in ink) to dates at this time. IPP are to sign the completed sample form and place it in its plastic sleeve on top of the foam plug.

NOTE: Even though the information is being electronically submitted through PHIS, IPP must sign the paper PHIS form submitted with the sample. If the sample form is incomplete, i.e. not signed or dated, or omitted information, the lab will discard the sample.

I. 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](#). IPP are to close the box flaps so that the container closure system is secure. IPP are not to tape the box if there are tapeless closures.

II. SHIPPING THE SAMPLE

A. IPP are to select the correct pre-addressed FedEx Billable Stamp Receipt (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 8000-18 or 8000-19. A shipping label for all three labs is included in the empty shipping container, and IPP are to verify that the correct one is selected for the sample.

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

C. IPP are to attach the special "Saturday Delivery" label to the shipping container if the sample is collected on Friday. This label has special instructions to alert the FedEx driver that the laboratory will accept shipments on Saturday. IPP are to apply this label above the stamp receipt for Friday shipments only to ensure Saturday delivery.

D. IPP are to ensure sample security is maintained at all times (see [FSIS Directive 7355.1](#)).

E. IPP are to ship the refrigerated sample via overnight delivery to the designated FSIS laboratory. IPP are to call the overnight courier service (FedEx) 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, and after FedEx is no longer available for pickup the same calendar day. For example, samples collected from late production, second shifts, are to be held overnight under refrigeration and sent by overnight courier the next calendar day.

NOTE: Samples not received the day following the day of shipment will be discarded by the laboratory. All dates on the PHIS generated sampling form shipped with the sample must be accurate.

CHAPTER VII – RAW PRODUCT DESTINED FOR READY-TO-EAT PRODUCT EXCLUDED FROM *SALMONELLA* TESTING

I. CIRCUMSTANCES IN WHICH SAMPLING IS NOT WARRANTED

A. An establishment meets the criteria for exclusion when the establishment either processes all product in a product class (e.g., young chickens) into RTE product or moves all product in a product class to another official federally-inspected establishment for further processing into RTE product.

B. For example, an establishment slaughters young chickens and produces not ready-to-eat (NRTE) ground chicken as one of its products. The establishment ships all of its NRTE ground chicken product to another establishment that uses it to make an RTE product. In this situation, IPP are not to sample the NRTE ground chicken; however, if any raw products are not destined for RTE product in an official establishment, the young chicken carcasses would still be eligible for *Salmonella* sampling.

II. 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;

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)). If an establishment meets the criteria in Section II.A.1., above, all raw products in that product class would remain in the establishment to be further processed.

B. 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.

C. In establishments that claim to meet the criteria in Section II.A.2., above, 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.

D. 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 from a particular product class 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; and
3. The establishment has a contractual agreement with the receiving establishment so the producing establishment has knowledge of the receiving establishment's production process.

E. Some insufficient procedures would include:

1. The establishment only labels the raw product with a statement "for further processing"; and
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.

F. 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, then the establishment is still subject to the traditional sampling under the *Salmonella* verification testing program. IPP are to be aware that it is the responsibility of the establishment to maintain sufficient documentation to support the establishment's assertion that the product in question is further processed into RTE product.

NOTE: NRTE products destined to other than domestic, federally-inspected establishments for processing into RTE products do NOT meet the criteria in Section II.A.2. above. Examples of such establishments include foreign, state inspected, or food service establishments, including hotel, restaurant, institution (HRI) facilities.

G. If an establishment produces more than one lot of NRTE ground beef and ships the product to different establishments, and one of the establishments produces NRTE products, IPP are to sample product under the *Salmonella* verification testing program. Some of the product produced from the product class (e.g., NRTE ground beef) goes to at least one establishment that uses it for NRTE 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.

III. ADDITIONAL INSTRUCTIONS FOR IPP

A. Should an establishment NOT meet the criteria in Section II. A. above and produce both RTE and NRTE end products of a single product class, IPP are to make two entries for the product class in the 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.

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

B. Should an establishment meet the criteria in Section II.A. above 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;

NOTE: This establishment will NOT be scheduled for verification sampling through PHIS.

C. If IPP, while collecting samples for the *Salmonella* verification testing program in an establishment, determine that the establishment meets the criteria in Section II.A. above, they are to complete the set before proceeding with the instructions in this notice.

D. 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 a RTE product, then IPP are to update the entries in the establishment profile.

CHAPTER VIII – VERIFYING ESTABLISHMENT *SALMONELLA* AND *CAMPYLOBACTER* CONTROL PROGRAMS FOR RAW CLASSES OF MEAT OR POULTRY PRODUCT

I. REVIEWING ESTABLISHMENT *SALMONELLA* AND *CAMPYLOBACTER* CONTROL PROGRAMS FOR RAW CLASSES OF MEAT OR POULTRY PRODUCT

A. IPP are to determine whether an establishment has procedures in place designed to address the control or monitoring of *Salmonella* in any programs within its food safety system (e.g., HACCP, Sanitation Standard Operating Procedures, prerequisite programs, or other programs the establishment does not consider part of the HACCP system). These programs may include, but are not limited to:

1. *Salmonella* testing of live animals or animal raising facilities, testing of products, or testing of the production or lairage environment prior to slaughter;
2. Testing for other bacterial contamination when the establishment uses that data to support decisions about *Salmonella* or *Campylobacter*;
3. Interventions to reduce or eliminate *Salmonella* or *Campylobacter*, or
4. Other pre-harvest practices or purchase specification programs intended to reduce *Salmonella* in live animals or raw materials received at the establishment.

B. If the establishment has procedures in place designed to address the control of *Salmonella* or *Campylobacter*, or makes modifications to those procedures, IPP are to seek answers to such questions as:

1. What data are collected in support of the program?
2. How does the establishment view this data as a measure of its program? For example:
 - a. How does the establishment analyze the data and track the results of the program?
 - b. How does the establishment explain how the data will be used to support or verify the effectiveness of the program?
 - c. How does the establishment determine and explain the difference between normal fluctuations in the data and what represents that the program is not functioning as designed (i.e., is out of control)? and
 - d. Does the establishment consider the incoming *Salmonella* or *Campylobacter* load on the effectiveness of interventions used during processing (i.e., does it examine whether a high incoming *Salmonella* or *Campylobacter* load may overwhelm the interventions in place)?

C. In accordance with the instructions in [FSIS Directive 5000.2](#), *Review of Establishment Testing Data by Inspection Program Personnel*, on a weekly basis, IPP are to review the data from the program, unless another frequency is more appropriate based on when the establishment collects the data. For example, if the establishment collects *Salmonella* data or other data related to *Salmonella* on a monthly basis, then IPP are to review that specific data monthly.

D. IPP are to look for trends such as:

1. A significant portion of the program results exceed the established criteria over time;
2. A few instances of the program results exceed the established criteria by a large amount within a relatively short period of time; or
3. The program results show a consistent trend of worsening performance over a relatively long period of time.

E. In the example below, the results would not represent regulatory noncompliance in themselves. However, IPP are to discuss the findings with establishment management to find out how they interpreted and responded to the results.

Example: Establishment A analyzes a product sample for *Salmonella* once per shift and has set criteria (based on FSIS performance standards published in the Federal Register (76 FR 15282)) of no more than 5 positive results in a moving window of 51 samples. IPP would be expected to discuss these results with establishment management if they see any of the following trends:

1. IPP observe that, over the course of one month, the positive test results exceeded the establishment criteria of 5 positives in the 51-sample window 5 times out of 20 (25%);
2. IPP observe that over the course of one week, the positive test results reached 9 of the last 51 samples, significantly exceeding the establishment's control limit of 5 positives; or
3. IPP observe that over the course of 3 months, the positive test results exceeded the establishment's criteria 1 time during the first month, 3 times during the second month, and 7 times during the third month, demonstrating a trend of worsening performance.

F. If IPP have questions on the design of the program, the manner in which the establishment collects or analyzes the data, or developing trends, they are to address their concerns through supervisory channels.

NOTE: IPP are to follow instructions in FSIS Directive 5020.1, *Verification of Salmonella Initiative Program* to verify *Salmonella* sampling and testing in establishments participating in the SIP.

II. ACTIONS TO TAKE WHEN AN ESTABLISHMENT SUBSTANTIALLY OR TEMPORARILY ALTERS ITS SALMONELLA OR CAMPYLOBACTER CONTROL PROCESS

A. Following a *Salmonella* verification set, an establishment may make substantial changes to its food safety system, such as removing chlorine-based compounds from the process or substituting other antimicrobial chemicals. Such changes are acceptable if validated; however, in some cases, Agency testing might be warranted to verify that the food produced by the modified system is safe. Alternatively, an establishment may temporarily change its food safety process during FSIS *Salmonella* or *Campylobacter* verification sampling, then return to pre-sampling conditions once FSIS sampling is completed. For example, an establishment may increase chlorine levels in poultry chillers or on equipment to levels not supported in its hazard analysis, and then lower the levels again after set completion.

NOTE: These instructions are not restricted to poultry establishments.

B. IPP are to verify that changes to a food safety system are consistently accompanied by HACCP supporting documentation, including during and after FSIS *Salmonella* verification testing, based on requirements in 9 CFR 417.2(a) and 9 CFR 417.5(a)(1). In addition, IPP are to determine whether an establishment altered its food safety system to coincide with the FSIS *Salmonella* or *Campylobacter* verification sample set. The Public Health Veterinarian (PHV) is to file in the government office, or by means of PHIS, a Memorandum of Interview (MOI) detailing any changes or modifications that an establishment makes in its process when FSIS conducts a *Salmonella* or *Campylobacter* verification sample set. The PHV is to present the information to the establishment management for discussion at the next weekly meeting (see FSIS Directive 5010.1, *Food Safety Related Topics for Discussion During Weekly Meetings*, and [FSIS Directive 5000.1](#)).

C. Examples of changes typically covered by paragraph B. of this section include, but are not limited to:

1. Temporarily changing antimicrobials used in a poultry chiller only during a *Salmonella* or *Campylobacter* verification set, such as replacing chlorine with peroxyacetic acid (PAA);
2. Substantially increasing levels of antimicrobials above normal operating parameters only during a *Salmonella* or *Campylobacter* verification set. This type of change includes increasing to the upper bounds of levels within a validated system if the establishment routinely operates at the lower bounds. For example, if the establishment's validated range of chlorine in potable water measured at the chiller fresh water intake is 20-50 ppm, it routinely maintains a level of 20 ppm but increases the level to 50 ppm only during the set; and
3. Permanent replacement of systemic hyper-chlorinated water with non-chlorine- based antimicrobials since the last *Salmonella* or *Campylobacter* verification set without proper validation.

D. Examples of changes typically NOT covered by this policy include, but are not limited to:

1. Replacing equipment that will be operated in the same manner as old equipment. For example, replacing one poultry immersion chiller with another without changing antimicrobial or product temperature parameters; and
2. Permanently adding or removing antimicrobials at various steps in the process if the changes have been properly reflected in the establishment's food safety system with appropriate supporting documentation.

E. If IPP identify temporary changes, modifications, or inconsistencies in an establishment's production practices that coincide with the FSIS sample and confirmed through documentation and discussions that the changes are not supported in the HACCP system, the PHV is to inform the District Office (DO) through the supervisory chain. At the same time, the PHV is to submit the information through askFSIS directly to the *Salmonella* and *Campylobacter* Coordination Group (SCCG) and to request the scheduling of an additional *Salmonella* or *Campylobacter* verification set for the establishment.

F. The scheduling request is to be routed through the following [askFSIS](#) queue:

- Product (General Inspection Policy)

- Category (Sampling)
 - Sub-category (Request Expedited SALM Verif Set)

G. The PHV is to include the following information in the request:

1. Subject line: "Request Expedited *Salmonella* Verification Set";
2. Message text: the establishment name and number; and
3. A detailed summary of PHV and Frontline Supervisor (FLS) observations that might support the request for additional *Salmonella* or *Campylobacter* verification sampling.

NOTE: This queue is ONLY for requests for expedited sets covered by this chapter.

H. After review of the submitted information, the SCCG will send a reply, usually within 30 days through normal askFSIS incident response procedures, stating whether an additional *Salmonella* or *Campylobacter* verification set will be initiated for the establishment.

I. If the request for additional scheduling occurs when a *Salmonella* or *Campylobacter* verification set is still in progress, the current set will be carried to completion with the potential for another full set to follow. Higher priority for set scheduling will be given to establishments that do not collect daily *Salmonella* and other public health-related data, while lower priority will go to establishments demonstrating ongoing process control under the SIP (see FSIS Directive 5020.1).

J. If the establishment is not participating in SIP, IPP are to review the establishment's microbial testing data (see [FSIS Directive 5000.2](#)) and then to compare recent production period data to the results from the beginning of the *Salmonella* or *Campylobacter* verification set. Differing results may be related to variability in interventions being used by the establishment.

K. The PHV is to review the establishment's supporting documentation and issue an NR if the interventions are not implemented in a manner that is consistent with their supporting documentation or changes to the process are not supported in the hazard analysis. For example, the establishment's food safety system might ordinarily rely on the direct application of a particular pathogen reduction system, but the establishment varies the concentration without accompanying support in order to accommodate a specific purchase specification (e.g., export), or when FSIS verification sampling is conducted.

L. If IPP and the Frontline Supervisor (FLS) have evidence that the establishment changes to an unsupported alternative process, or continues to have noncompliances associated with unsupportable decisions, the DO is to consider scheduling a for-cause Food Safety Assessment (FSA). The FSA is to be used to determine whether the hazard analysis and supporting documentation associated with the alternative or modified process demonstrates that the process will prevent or control *Salmonella* or *Campylobacter* in a manner that is at least as protective as the process used during FSIS *Salmonella* or *Campylobacter* verification testing.

CHAPTER IX– REPORTING OF *SALMONELLA* AND *CAMPYLOBACTER* SAMPLING RESULTS

I. INDIVIDUAL SAMPLES

Laboratory results for individual samples will be available to IPP as soon as they are posted within LIMS Direct. Serotype data for *Salmonella* positive samples is added later once updated information becomes available.

NOTE: Calling the laboratory will not speed up reporting of results.

II. COMPLETED SET REPORTS

A. When sufficient samples to complete a set have been analyzed for pass or fail status, a completed Set Report summarizing all individual pass and fail sample results, as well as the pass or fail outcome of the entire verification set, will be e-mailed by the Data Analysis and Integration Group (DAIG) to the DO PR/HACCP e-mail distribution list for further distribution to IPP; an additional copy will be e-mailed to the establishment's Lab Sampling Contact listed in the PHIS plant profile.

B. IPP are not to issue a Noncompliance Record (NR) exclusively because of a failed *Salmonella* or *Campylobacter* verification set.

NOTE: Enforcement, Investigations, and Analysis Officers will review these sampling results in depth during any Food Safety Assessment conducted at the establishment per FSIS PHIS Directive 5100.4, Prioritized Scheduling of Food Safety Assessments Using the Public Health Information System. Also, establishments that fail a verification set move up in priority to be scheduled to receive an FSA. Should a verification set fail to meet the performance standard, there is no designated lag time prior to scheduling of an additional verification set. IPP are to advise establishments that they should NOT expect delays in initiating the follow-up set for purposes of allowing more time for equipment upgrades or changes to the establishment's food safety system. FSIS considers this a prudent public health protection measure, especially if the establishment is continuing to produce product for distribution into commerce. FSIS will continue to place any PFGE patterns found during the follow-up set into the CDC PulseNet database.

III. *SALMONELLA* AND *CAMPYLOBACTER* EOS LETTERS

A. Upon completion of the *Salmonella* verification set, the Agency provides detailed information about *Salmonella* serotypes that are associated with human illness in the *Salmonella* EOS letters that are sent to establishments. The EOS letter provides information about the results of the last two completed sample sets. This information includes positive and negative test results, as well as available information about the serotype, PFGE-based information, and public health ranking of the isolates. The letter specifically includes information on serotypes that are commonly associated with human illness, as well as other subtypes of potential public health concern. An EOS letter example is found in Attachment 9 - End of Set Letter Example.

B. FSIS is working to establish mechanisms to routinely share and compare subtyping information. As a result, IPP are to be aware that FSIS includes information on serotypes found in the sampling when reporting sampling results, including whether the serotypes are on the CDC's list of the twenty serotypes most frequently associated with human illness, and plans to include additional subtype information (PFGE pattern-based information and antimicrobial resistance profile) when that subtype information becomes available. In addition, for Young Chicken and Young Turkey sets, the EOS letter includes *Campylobacter* results.

C. IPP are to be aware that in addition to assessing process control through analysis of set results, FSIS identifies *Salmonella* subtypes. FSIS considers that isolates with subtypes historically associated with human illness are more likely to cause human illness than those without such a history. The Agency has said that establishments that repeatedly produce product with *Salmonella* subtypes of public health concern are of high priority for a FSA (see FSIS Directive 5100.4). FSIS considers information on subtypes to be very important for protecting the public health. It provides information on subtypes to establishments through *Salmonella* EOS letters for them to use in their food safety decision-making processes.

NOTE: Since FSIS has not established a performance standard for *Salmonella* subtypes, this information is not used to determine whether the establishment has passed or failed the *Salmonella* verification set.

D. IPP are to be aware that the fact that isolates have subtypes historically associated with human illness does not automatically implicate the sampled product as the cause of any human illness or necessarily mean that the establishment's food safety system is ineffective. FSIS will determine these specific associations through an epidemiological investigation or an FSA.

E. IPP are to be aware that the EOS letters include the following sections: (See Attachment 9 - End of Set Letter Example)

1. **Process Control:** This section states whether an establishment has maintained consistent process control. The "*Summary Results from Last Two Sampling Sets*" table identifies the product tested, date set completed, number of samples analyzed, number of *Salmonella* and *Campylobacter* (where applicable) positives, and current *Salmonella* process control category;
2. **Public Health-Focused Evaluation of Isolates by Serotype:** This section provides detailed serotyping information from the establishment's last *Salmonella* verification set. This section includes the "*Serotype Results for the Most Recent Sampling Set*" table which provides the details of the serotype results for the current set as well as a brief explanation of the type of information provided in the table;
3. **Discussion of Compiled Set Results:** This section provides a brief explanation of the information provided in the letter, including information on future *Salmonella* and *Campylobacter* (where applicable) verification testing scheduled at the establishment and Agency expectations.

F. IPP are to be aware that it may take several weeks after completion of the set before an EOS letter is issued.

NOTE: Unless instructed by the DO, there is no follow-up verification for IPP to perform or enforcement action to take based on the information and results provided in the EOS letter. An Enforcement, Investigation, and Analysis Officer (EIAO) will verify the appropriateness of the establishment's response to the results in the next FSA performed at the establishment.

CHAPTER X– DISCUSSION OF INSPECTION FINDINGS WITH THE ESTABLISHMENT

- A. As set out in [FSIS Directive 5000.1](#), IPP are to conduct weekly meetings with the establishment to discuss topics that could affect food safety and the establishment's ability to meet regulatory requirements.
- B. When necessary at the weekly meeting, IPP are to discuss with establishment management any trends that IPP believe may indicate that the establishment's *Salmonella* or *Campylobacter* program is not in control. In addition, IPP are to ask what actions, if any, establishment management has taken to re-establish control.
- C IPP are to:
1. Provide the Completed Set Report to the establishment's management as soon as it is available;
 2. Inform the establishment that it will be receiving a detailed EOS letter by mail as soon as *Salmonella* serotype information is available for all positive samples, which can take several weeks; and
 3. Advise the establishment if it fails the *Salmonella* or *Campylobacter* set that it will most likely be immediately scheduled for an additional *Salmonella* or *Campylobacter* set.
- D. At the next weekly meeting after issuance and receipt of each EOS letter IPP are to:
1. Review the information in Sections A-F of [Chapter IX, Section III](#) and the results provided in the letter with establishment management;
 2. Discuss the subtyping information provided in the EOS letters with establishment management to emphasize the importance of the information;
 3. Advise establishment management that it should always consider process control and subtyping results in its decision-making process when evaluating its overall food safety system and make changes as appropriate;
 4. Inform establishment management that FSIS may determine that an establishment that does not adequately take the provided information into account in its decision-making process has an ineffective food safety system;
 5. Inform establishment management that technical and sampling questions can be directed through [askFSIS](#); and
- E. IPP are to document notes from the meeting on a MOI in accordance with [FSIS Directive 5000.1](#) and FSIS Directive 5010.1.

CHAPTER XI – DATA ANALYSIS

The Office of Data Integration and Food Protection (ODIFP) and the Office of Public Health and Science (OPHS) will analyze sample results from *Salmonella* and *Campylobacter* verification testing. Specifically, these offices will review available data on the serotyping and subtyping results for all positive samples, as well as review various data sources on a routine basis to evaluate the effectiveness of this directive. Results from these analyses will be shared with the Office of Field Operations (OFO) and the Office of Policy and Program Development (OPPD) to determine whether the findings suggest potential program improvements or guidance to IPP.

CHAPTER XII– QUESTIONS

Refer questions regarding this directive to the Policy Development Staff through askFSIS or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter **Directive 10,250.1**
Question Field: Enter question with as much detail as possible.
Product Field: Select **General Inspection Policy** from the drop-down menu.
Category Field: Select **Sampling/Salmonella** from the drop-down menu.
Policy Arena: Select **Domestic (U.S.) Only** or **International (Import Export)** from the drop-down menu.

When all fields are complete, press **Continue**.

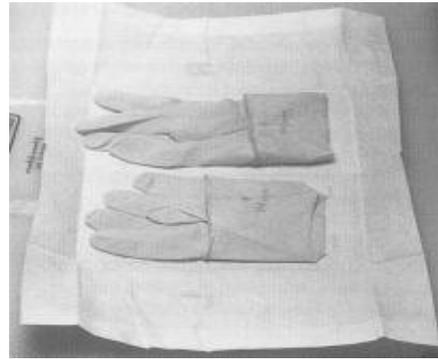


Assistant Administrator
Office of Policy and Program Development

ATTACHMENT 1 – HOW TO PUT ON STERILE GLOVES

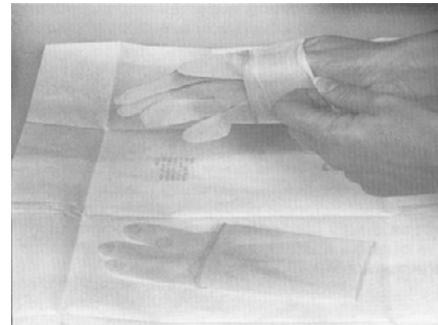
Step 1 First, wash and sanitize your hands to the mid-forearm. Dry your hands using disposable paper towels.

Position the glove package so that the letters L and R face you (L=left, R=right).



Step 2 When you first open the package, the gloves are folded, forming a cuff on the sleeve, and lying palm up. Leave the gloves in the package until you start to put them on.

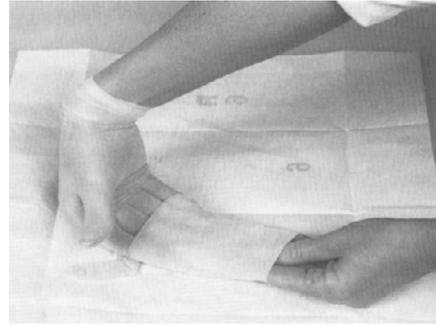
Step 3 Hold one glove open by the inside cuff area. Insert your hand into the glove, palm side up, and remove the glove from the package.



Step 4 Pull the glove completely on with the ungloved hand and pull the cuff up without touching the outside surface of the glove with your ungloved hand.

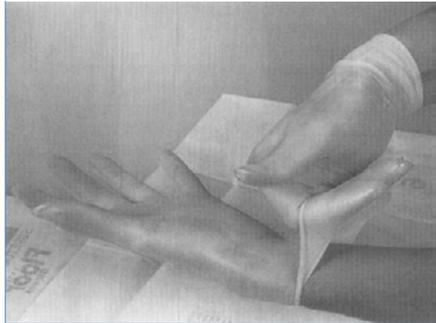
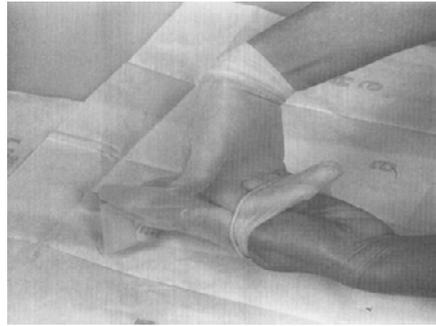


Step 5 Repeat the previous steps with the other glove, **with one key exception**: do not handle the second glove by the inside cuff. If you do, the outside of the first sterile glove may contact your hand and wrist as you pull the second glove on. Even though you washed and sanitized your hands, they are not sterile. The correct way is to place your ungloved hand, palm up, into the second glove.



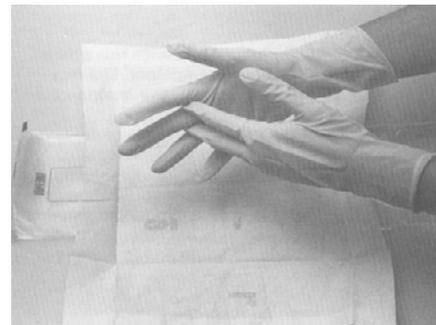
Insert the fingers of your gloved hand into the fold of the second cuff and ease the second glove on.

Step 6 Handle the second glove on the outside only and adjust the cuff on your wrist.



Step 7 Once both gloves are on, you can touch the outside of a glove with the other gloved hand to adjust the fit.

If at any time you are concerned that a glove may have become contaminated, discard it and repeat the procedure for putting on sterile gloves.



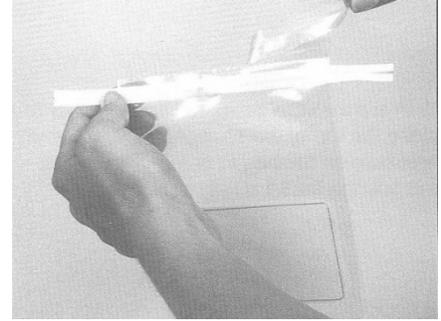
ATTACHMENT 2 – HOW TO PREPARE THE SPONGE AND TEMPLATE FOR SAMPLE COLLECTION

Step 1 These steps are to be performed immediately prior to performing the sponge sample collection.

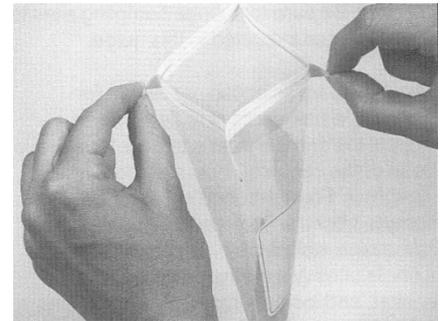
Wash and dry hands.

Retrieve the container of BPW from the refrigerator.

Open the sponge bag by holding it at one corner by the wire closure (usually colored white or yellow). Tear off the clear perforated strip at the top of the bag. Do not remove or tear off the wire closures.

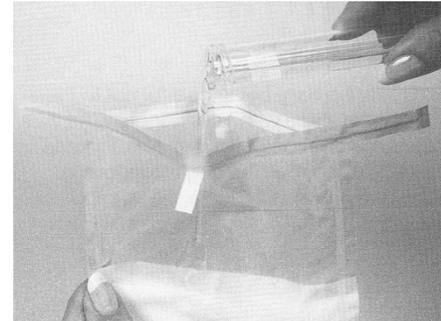


Step 2 Pull apart the two small white tabs on either side of the bag to open the mouth of the bag.



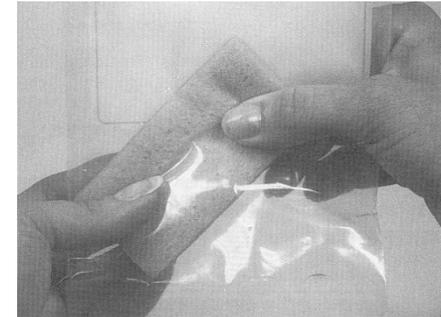
Step 3 Remove the cap from the pre-chilled sterile BPW container, being careful not to touch the container opening.

Carefully pour the entire contents of the BPW container (10 ml) into the sponge bag to moisten the sponge. Set the container aside.



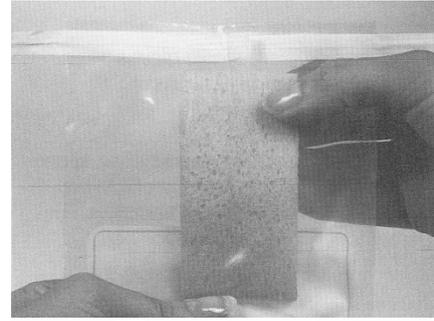
Step 4 Press the wire closures back together to close the top of the sponge bag.

Use hand pressure on the bag to carefully massage the sponge until it is fully moistened.



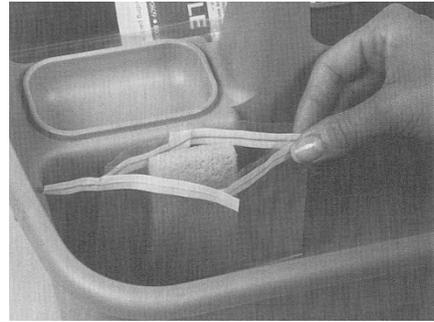
Step 5 With the bag still closed, carefully push the moistened sponge to the upper portion of the bag.

Position one width end of the sponge toward the opening.



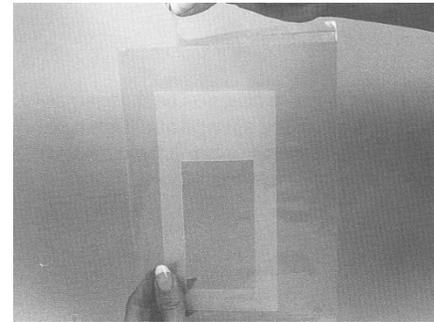
Step 6 Open the bag, being careful not to touch the inner surface with your fingers. The wire closure at the top of the bag should keep the bag open.

Set the bag aside, being careful not to contaminate the sponge.



Step 7 Open the template bag by holding the bag at one corner and tear off the clear, perforated strip at the top of the bag.

Set the bag aside, being careful not to contaminate the template.

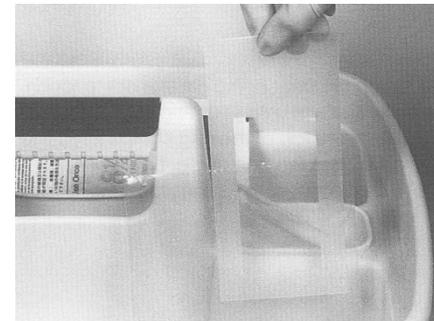


Step 8 Put on a pair of sterile gloves as described in Attachment 1 – How to put on sterile gloves.

Carefully remove the moistened sponge from the bag by grasping the end of the sampling sponge with your gloved sampling hand. Do not touch the outside of the bag.

With your other gloved hand, retrieve the template by its outer edge, taking care not to contaminate the inner edges that define the template's sampling areas.

Perform the sponge sample collection for the specified species.

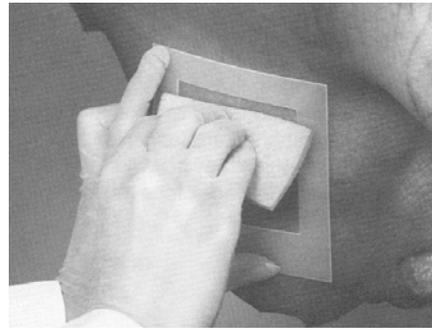


ATTACHMENT 3 – HOW TO SPONGE A CARCASS (GENERAL)

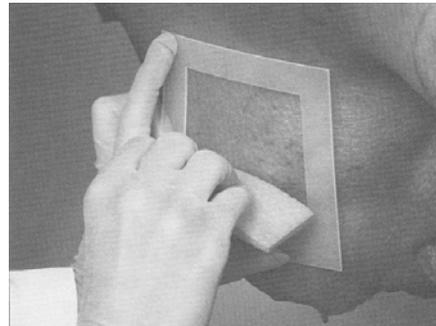
There are two methods to move the sponge across the sample surface for each direction:

Sponging Method One:

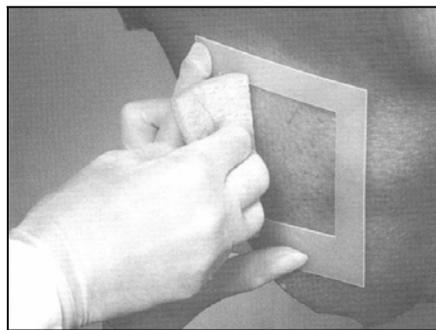
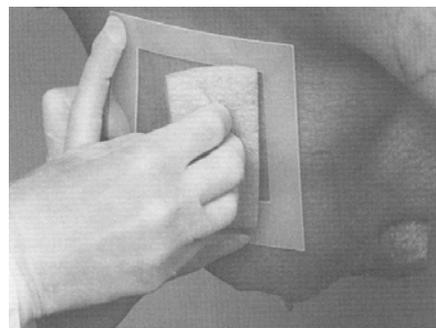
Firmly hold the sponge and wipe it across the surface in one direction. For vertical, wipe the sponge down. For horizontal, wipe it from left to right.



Lift the sponge and place it in the same beginning position and repeat wiping in the same direction across the sample site. Repeat this until it has been done 10 times.

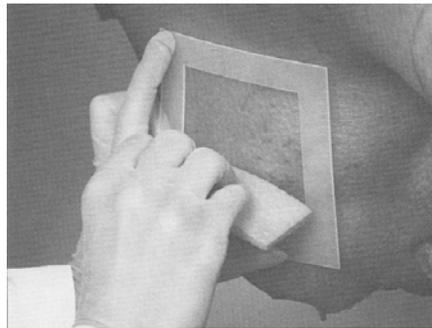
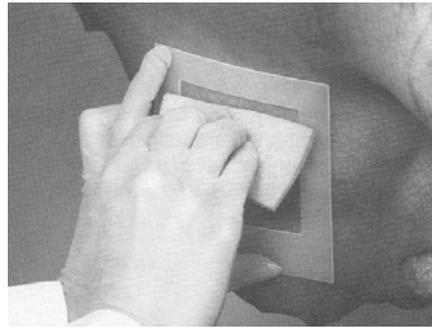


Then change to the other direction (horizontal or vertical) and follow the same steps using the same side of the sponge.

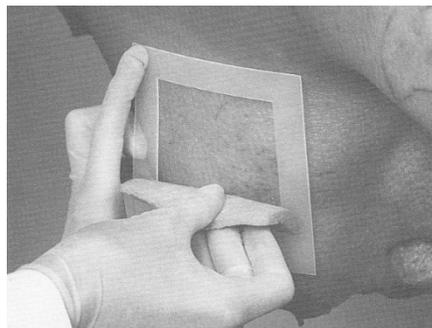


Sponging Method Two:

Firmly hold the sponge and wipe it across the surface in one direction. For vertical, wipe the sponge down. For horizontal, wipe it from left to right.

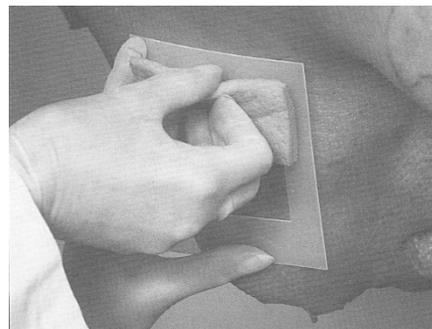


When you reach the end of the wipe, lift the sponge and turn your wrist so that your hand and the sponge are facing back in the direction that was just wiped. This allows the same surface of the sponge to contact the sample site.

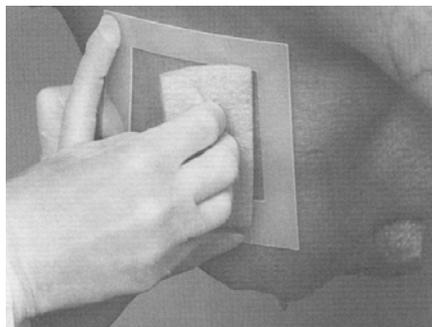


Now wipe the sponge across the surface going the other way.

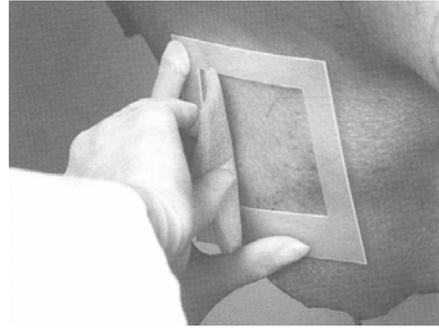
Repeat this until the surface has been wiped with 10 passes of the sponge (i.e., for horizontal, wiping left-to-right and right-to-left for 5 cycles; and for vertical, wiping from top-to-bottom and bottom-to-top for 5 cycles).



Then change to the other direction (horizontal or vertical) and follow the same steps using the same side of the sponge.



Do not switch sponging methods while at the same sample site. Remember that it is extremely important to conduct this and all sampling in a uniform manner to ensure valid sample results.



ATTACHMENT 4 – HOW TO RINSE A YOUNG CHICKEN CARCASS

Step 1 Sampling supplies included in shipping container:

- 1– pair Sterile gloves
- 1 – 15” x 20” large sterile plastic bag
- 1– 400 ml sterile pre-chilled Buffered Peptone Water (BPW)
- 1– 120 ml sterile specimen jar with lid
- 1 – quart resealable ziplock-type bag (secondary container)
- 1 – 6” x 12” plastic sleeve for completed sample form
- 1 – FSIS Form 7355-2A/2B Laboratory sample security seal set
- 3 – FedEx preprinted billable stamps (one for each FSIS laboratory)
- 1 – Absorbent pad
- 1 – Foam plug per shipping container
- Cardboard separators
- Gel coolant packs



Ensure that all sample supplies are on hand. Use a small tote or caddy for carrying supplies to the sampling location. Sanitize the work surface.

Wash and dry hands.

Carefully open the large sterile bag. Do not contaminate the interior of the bag. The bag may lie on its side, opened, while you select the chicken carcass for sampling.

Put on a pair of sterile gloves as described in Attachment 1 – How to put on sterile gloves.

Step 2 Using one gloved hand, pick up the selected chicken carcass by the legs and allow any excess fluid to drain.

NOTE: For safety purposes, do not remove the chicken carcass from the shackle but collect it after it has dropped from the line.

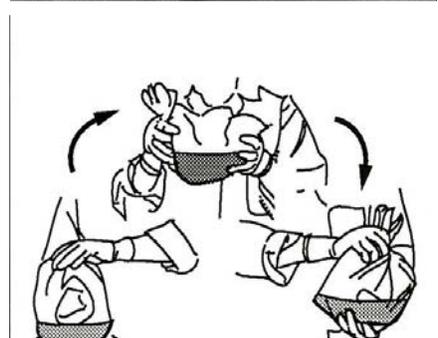
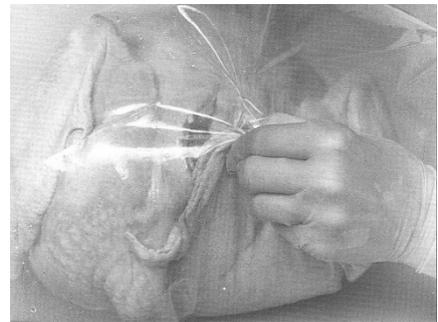
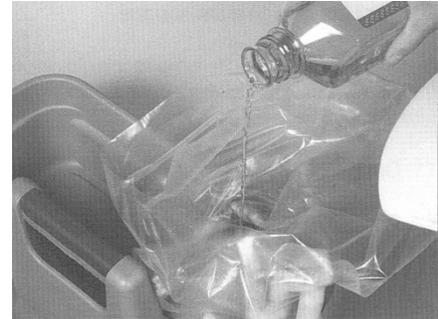
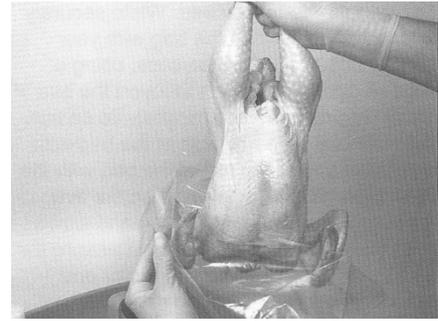
With the other hand, pick up the open sample bag. Place the bird in the sample bag with the legs and vent toward the bag opening. Do not touch the inside of the bag with either hand.

Step 3 Rest the bottom of the bag on a flat surface. Holding the top of the bag slightly open, uncap the pre-chilled BPW container and pour its entire contents into the carcass cavity.

Step 4 Pick up the bag by the top and, through the bag, manipulate the loose neck skin on the carcass to position it over the neck bone to act as a cushion and prevent punctures to the bag.

Step 5 Expel most of the air from the bag, twist the top of the bag and fold the twist over. Firmly hold the bag closed. While securely supporting the bird in the bag with your hands, rinse the entire carcass, using a repeated rocking motion to invert the bird 30 times (approximately 1 minute). To do this, hold the bird at the bottom of the bag with one hand and at the top of the bag with the other.

Keeping a secure grip on the bird, repeatedly invert your bottom hand slowly over the top. This procedure will ensure that all surfaces of the carcass, interior and exterior, are rinsed. As the bird is rinsed, a fluid “sloshing” sound should be heard.



Step 6 Before collecting the 100 mL rinsate, aseptically remove the chicken from the sample bag by the following steps:

1. Rest the bag on a flat surface;
2. Carefully open the plastic bag containing the bird without touching the inside of the bag or the inside corners;
3. Work the plastic bag down around the carcass so that you can firmly grip one leg, without touching the inside of the plastic bag;
4. While holding the bag with the one hand, carefully remove the bird from the bag with the other hand; and
5. Place the bird back on the conveyor or table.



NOTE: It is not necessary to rinse the carcass with potable water prior to returning it to the line.

Collect the 100 mL rinsate sample from the sample bag immediately by:

1. Removing the lid from the empty 120 mL sterile specimen jar, being careful not to contaminate the inside of the specimen jar or the lid, and by not allowing the bag to contact the interior surfaces of the jar;
2. Using the “V” formed by the bag at the lower corner as a pouring spout, carefully pour the rinsate into the open jar, collecting as much of the BPW rinsate as possible, but at least 100 mL, and
3. Placing the cap back on the jar and checking to be sure that the lid is securely in place.

Step 7 Place the collected and labeled sample container in a ziplock-type bag, expel any excess air, and seal the bag.

Collected samples are to be refrigerated within five (5) minutes of collection and held under refrigeration and FSIS control until shipment to the laboratory.

Repeat these steps above for each *Salmonella* sample request. Use a different carcass for each sample.



ATTACHMENT 5 – HOW TO SPONGE A YOUNG TURKEY CARCASS

Step 1 There will be TWO carcass swabs per post-chill sample with 10 mL of BPW diluent used to moisten the sponge for the *Salmonella* sample and 25 mL of BPW diluent used to moisten the sponge for the *Campylobacter* sample. IPP are to collect one turkey carcass for sampling. The first sponge is to be used to swab the left side of the carcass for *Salmonella*, while the second sponge is to be used to swab the right side of the carcass for *Campylobacter*.



Also, refer to Attachment 3 - How to sponge a carcass (General).

Sampling supplies included in the shipping container for each young turkey sampling event:

- 3- pairs of Sterile gloves
- 1- 10 mL tube of BPW marked "S"
- 1- 25 mL tube of BPW marked "C"
- 2- sterile specimen sponges in marked Whirl-Pak® bags (one sponge labeled "C", one sponge labeled "S")
- 2- sterile templates 5" x 10" cm in bag
- 2- quart resealable ziplock-type bags (secondary container)
- 1- 6" X 12" plastic bag for completed sample form
- 3- FedEx preprinted billable stamps (one for each FSIS laboratory)
- 1- FSIS Form 7355-2A/2B (Laboratory sample security seals)
- 1- Absorbent pad
- 1- Foam plug per shipping container
- Cardboard separators
- Gel coolant packs

Ensure that all sample supplies are on hand. Use a small tote or caddy for carrying supplies to the sampling location. Sanitize the work surface. Wash and dry hands.

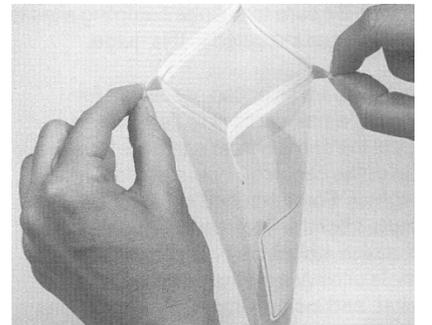
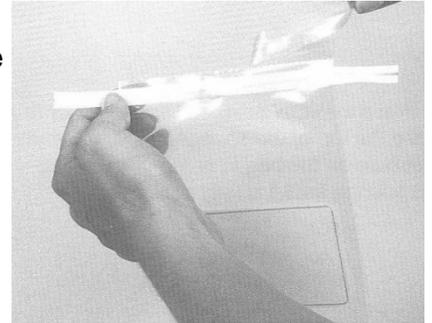
Place clean paper towels, tray-pack absorbent pads, a sanitized wire rack, or equivalent on the sanitized work surface. These will prevent the turkey carcass from slipping during sponge sampling.

Put on a pair of sterile gloves as described in Attachment 1 – How to put on sterile gloves.

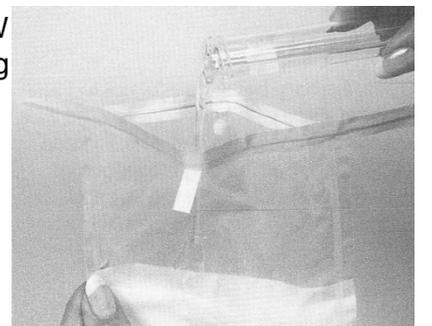
Step 2 While wearing the first pair of sterile gloves, remove the turkey in a safe manner. Holding the turkey by the legs and avoiding contact with the back or thigh areas, place the turkey breast down on a sanitized work surface covered with clean paper towels or absorbent pads to prevent the carcass from slipping during sponge sampling. Remove and discard the gloves. If heavy birds require assistance for lifting, have helpers wear sterile gloves and ensure that they do not touch the sampling areas.

NOTE: For safety purposes, do not remove the turkey carcass from the shackles but collect it after it has dropped from the line.

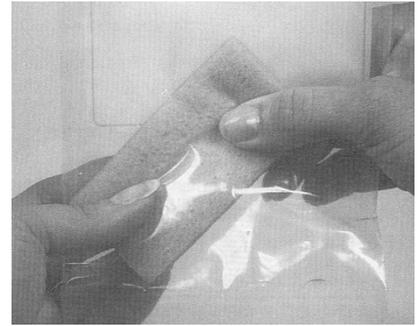
Step 3 Open the sponge bag by tearing off the top perforated strip. Do not remove the wire closures from the bag. Pull apart the two small white tabs on either side to open the mouth of the bag.



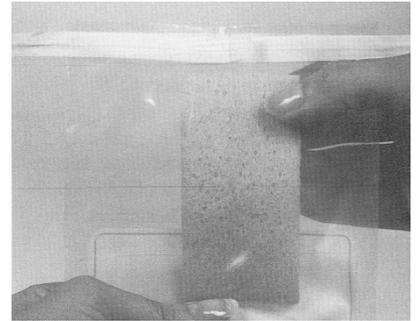
Step 4 Remove the cap from the smaller, 10-mL pre-chilled sterile BPW container marked "S" designated for *Salmonella* sampling, being careful not to touch the container opening. Carefully pour the entire contents of the BPW container into the sponge bag marked "S". Do not contaminate the top inside of the Whirl-Pak® bag. Set the empty BPW container aside.



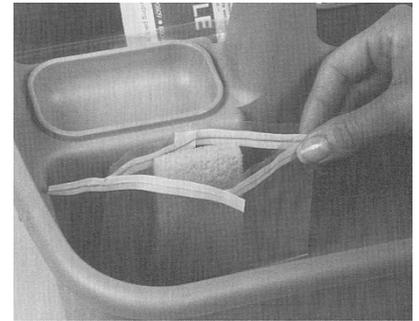
Step 5 Press the wire closures back together to close the top of the sponge bag. Use hand pressure on the outside of the bag to carefully massage the sponge until it is fully moistened.



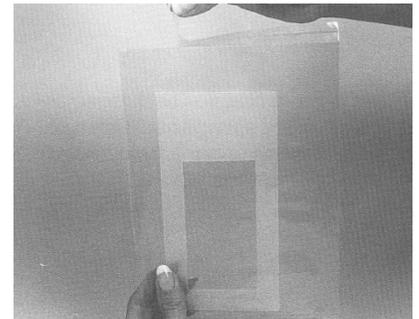
With the bag still closed, squeeze any excess diluent out of the sponge while carefully pushing the moistened sponge to the uppermost portion of the bag.



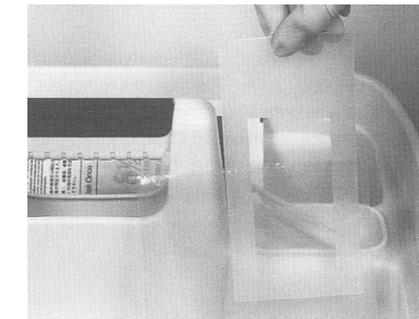
Step 6 Open the sponge sample bag, being careful not to touch its inner surface. The wire closure should keep the bag open. Set the bag aside, being careful not to contaminate the sponge and careful not to spill the remaining BPW fluid.



Step 7 Open the sterile template bag by tearing off the top perforated strip. Set the template bag aside, being careful not to contaminate the template.



Step 8 Put on the second pair of sterile gloves. Carefully remove the moistened sponge from the bag by grasping the end of the sampling sponge with your gloved sampling hand. Do not touch the outside of the Whirl-Pak® bag.



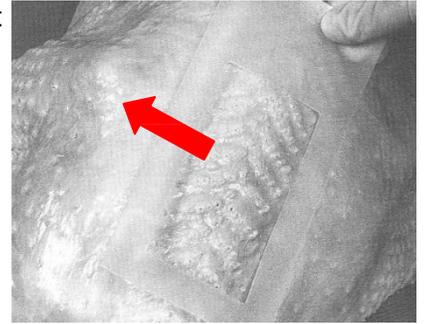
With your other gloved hand, retrieve the template by its outer edge, taking care not to contaminate the inner edges that define the template's sampling area.

Step 9 It is important to sponge the sampling areas in the order of “least to most” contaminated to avoid spreading contamination on the carcass. Be sure to sponge sampling sites in the sequence indicated.

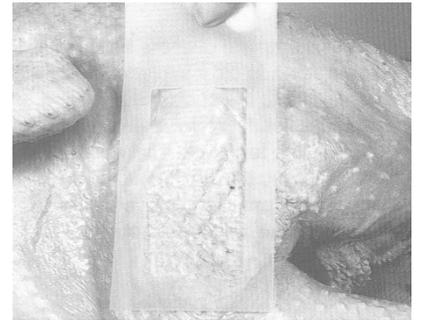
Place the template over the back sampling area and hold it in place to the LEFT of the vertebral column. Using your sampling hand, wipe the sponge over the entire enclosed area approximately 10 times vertically and 10 times horizontally. Use only one side of the sponge.

NOTE: The template may need to be “rolled” from side to side as the sponging is performed since the surface of the carcass is not flat. This will ensure that the full 50 cm² area is sampled during the sponging.

Repeat the sponging procedure using the same sponge but with the template placed over the LEFT thigh sampling area. Turn the sponge over so that the unused side of the sponge contacts the thigh surface, wiping the entire area enclosed by the template with approximately 10 vertical and 10 horizontal passes of the sponge. Lay aside the template to discard later.

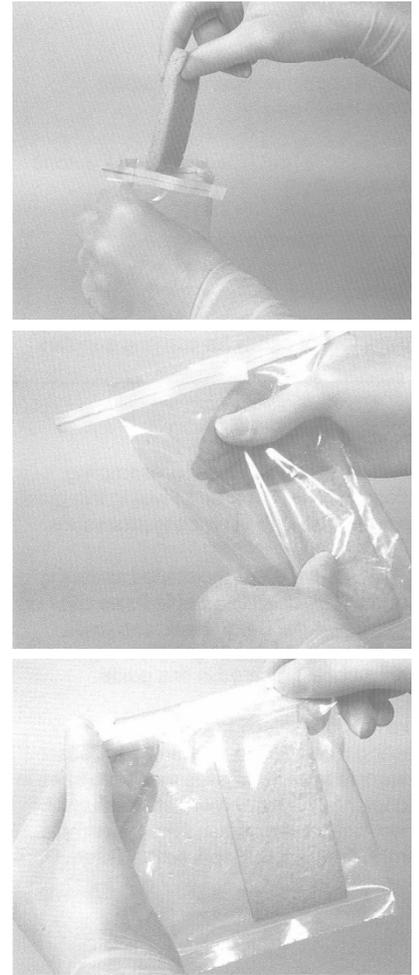


NOTE: Actual placement of each individual template used while sponging will be to the left or right of center and not directly on the vertebral column.



Step 10 Carefully replace the sponge into the Whirl-Pak® sample bag (marked with an “S”) with any remaining portion of BPW without touching the outside of the bag with the sponge. Expel any excess air from the sample bag and fold over the top edge of the bag 3 or 4 times to close the top. Secure the top by folding the wire attachments back against the bag.

Discard the template.



Step 11 REPEAT steps 1- 10 using the other, larger, 25-mL pre-chilled sterile BPW container marked “C” designated for *Campylobacter* sampling and the Whirl- Pak® sponge bag marked “C”. Swab the RIGHT side of the same turkey carcass using a new pair of gloves and a new template. Upon completion of the second swabbing, and securing the swab in its marked sample bag, return the turkey carcass to the point where you collected the bird.

Step 12 Each sample sponge should be carefully secured in its own separate Whirl-Pak® sample bag (previously marked appropriately with either an “S” or a “C”). Place the Whirl-Pak® sample bags into the appropriately labeled zipperlock bags. Collected samples are to be refrigerated within five (5) minutes of collection and held under refrigeration and FSIS control until shipment to the laboratory.

Repeat these steps above for each sample request. Use a different carcass for each sample.

ATTACHMENT 6 – HOW TO SPONGE A BEEF CARCASS

I. PURPOSE OF THIS ATTACHMENT

Routine *Salmonella* verification of beef (Steers/Heifers and Cows/Bulls) carcasses has been suspended. The methodology is provided here for use in special projects or other instances where it may be required.

II. PREPARING TO COLLECT A SAMPLE

- A. Select a time at which to collect the sample. Determine the times that carcasses chilled for 12 hours or more will be on hand. Then randomly select a time from within that time frame for collecting the samples.
- B. Select the cooler site from which to collect the sample. Select a safe and accessible site in the cooler for collecting samples from a beef half-carcass. This site may be located at the transfer chain, grading chain, a rail, or other safe, uncrowded location in the cooler.
- C. Use aseptic techniques as outlined in Chapter II, Section I.A.2.
 1. Wash and sanitize hands.
 2. Sanitize work surfaces (surfaces that will contact supplies while they are being gathered).
 3. Gather the supplies.
 4. Label the sponge bag.
 5. Wash and sanitize hands.
 6. Take supplies to the sampling location.
 7. Sanitize work surfaces (surfaces that will contact supplies during sampling).
 8. Lay absorbent towels or sanitized rack on work surface to prevent the carcass from slipping.

III. COLLECTING THE SAMPLE (SPONGE SAMPLE)

- A. At the random time selected, go to the sampling location. Do not choose the carcass that is at the predetermined location. Instead, count back or ahead 5 sample units and choose the sixth unit to sample. (The reason for counting back or ahead 5 half-carcasses is to avoid any possible bias during selection.) Normally it should not be necessary to have the establishment move many half-carcasses to access a random one to sample.
- B. Sponge the carcass and prepare the sample for shipping (follow the general sponging techniques as outlined in Attachment 2 – How to prepare the sponge and template for sample collection; and Attachment 3 – How to sponge a carcass (General)):
 1. Position equipment (keep safety in mind).
 2. Locate the areas of the carcass for sampling (see Sample Sites for *Salmonella* Testing of Beef Carcasses).
 3. Layout supplies.
 4. Open the sponge bag.
 5. Pour BPW into the sponge bag.
 6. Close the bag and massage the sponge.
 7. Push the sponge to the top of the bag, open it, and set it aside on a sanitized surface.
 8. Open the template bag and set it aside on a sanitized surface.
 9. Put on the sterile gloves (see Attachment 1 – How to put on sterile gloves).

10. Remove the sponge.
11. Remove the template.
12. Lay the template over the flank (see Sample Sites for *Salmonella* Testing of Beef Carcasses). Do not touch the sampling area.
13. Hold the template with one gloved hand and use the other hand to wipe the area with the sponge.
14. Do 10 vertical wipes over the entire sample surface; then do 10 horizontal wipes over the entire sample surface.
15. Lay the template over the brisket (see Sample Sites for *Salmonella* Testing of Beef Carcasses). Do not touch the sampling area.
16. Hold the template with one gloved hand and use the other hand to wipe the area with the sponge.
17. Do 10 vertical wipes over the entire sample surface; then do 10 horizontal wipes over the entire sample surface.
18. Carefully climb to sample the rump without touching the template or sponge to any area not being sampled.
19. Lay the template over the rump (see Sample Sites for *Salmonella* Testing of Beef Carcasses). Do not touch the sampling area.
20. Hold the template with one gloved hand and use the other hand to wipe the area with the sponge.
21. Do 10 vertical wipes over the entire sample surface; then do 10 horizontal wipes over the entire sample surface.
22. Place the sponge in the Whirl-Pak® bag and seal the bag.
23. The sample is now complete. Follow the storage and shipping instructions in Chapter VI – Submitting the collected sample.

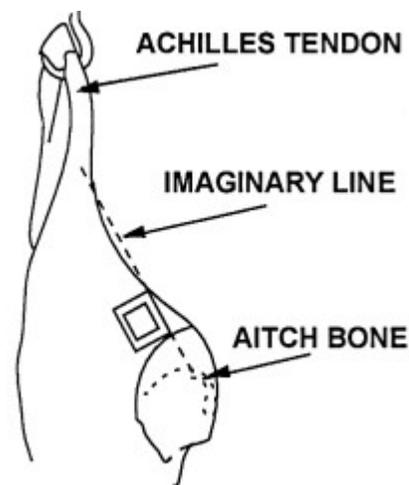
Sample Sites for *Salmonella* Testing of Beef Carcasses

Rump

Locate the posterior aspect of the ischium or aitch bone. Draw an imaginary line toward the Achilles tendon. At the point where the line intersects the cut surface of the round is the starting point for the rump sample.

Place the template over this area of the rump.

NOTE: This illustration has been purposely altered: a true lateral view of the carcass would not show the aitch bone. From a medial view, the whole 10 cm x 10 cm sample area could not be seen. Therefore, a lateral view with a portion of the round removed is shown to illustrate the location of the aitch bone.



Flank

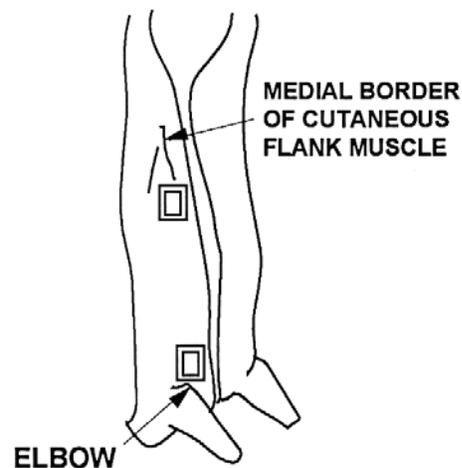
Locate the cutaneous flank muscle (external abdominal oblique) and follow the medial border of the muscle anteriorly until it comes within approximately 3" of the midline.

This will be where to place the template.

Brisket

Locate the elbow of the carcass. Draw an imaginary line straight across (medially) to the midline cut.

This will be where to place the template.



IV. BEEF CARCASS SPONGE SAMPLING TECHNIQUE

Step 1 Sampling supplies included in shipping container:

- 1 - Sterile specimen sponge in Whirl-Pak® bag
- 1 - 10 ml sterile pre-chilled Buffered Peptone Water (BPW)
- 1 - Sterile template in bag
- 1 - pair Sterile gloves
- 1 - 6" x 12" plastic sleeve for completed sample form
- 1 - FSIS Form 7355-2A/2B Laboratory sample security seal set
- 3 - FedEx preprinted billable stamps (one for each FSIS laboratory)
- 1 - Absorbent pad
- 1 - Foam plug per shipping container
- Cardboard separators
- Gel coolant packs



Ensure that all sample supplies are on hand. Use a small tote or caddy for carrying supplies to the sampling location. Sanitize the work surface. Wash and dry hands.

Also, refer to Attachment 3 - How to sponge a carcass (General).

Put on a pair of sterile gloves as described in Attachment 1 – How to put on sterile gloves.

Step 2 Carefully remove the moistened sponge from the bag by grasping the end of the sampling sponge with your gloved sampling hand. Do not touch the outside of the bag.

With your other gloved hand, retrieve the template by its outer edge, taking care not to contaminate the inner edges that define the template's sampling areas.

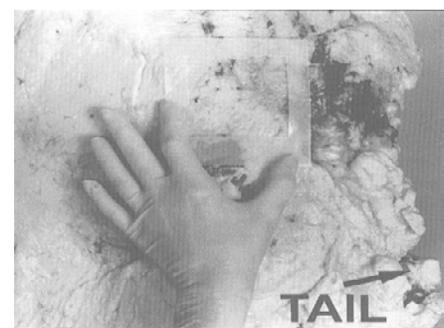
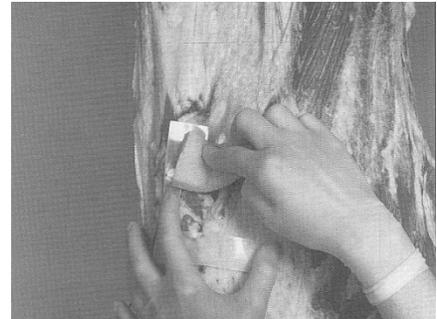
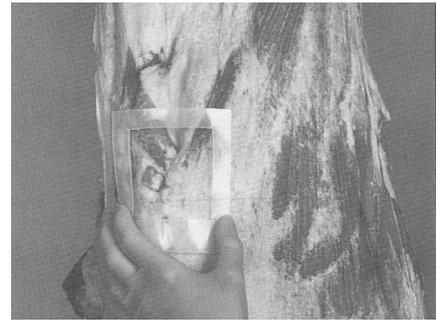
Place the template over the **flank** sampling area and hold it in place. Be careful not to contaminate the enclosed sampling area with your hands.

Step 3 With the sampling hand, wipe the sponge over the entire enclosed area (5 cm x 10 cm) approximately 10 times vertically and 10 times horizontally. Use only one side of the sponge.

NOTE: the template may need to be "rolled" from side to side as the sponging is performed since the surface of the carcass is not flat. This will ensure that the full 100 cm² area is sampled during the sponging.

Step 4 Repeat steps 2 and 3 for the **brisket** area, using the same surface of the sponge that you used to wipe the **flank** sampling area.

Step 5 Repeat steps 2 and 3 for the **rump** area, this time using the "clean" side of the sponge (the side that was not used to wipe the flank and brisket areas). After sponging the **rump** area, transfer the template back to the sampling hand. Be careful not to contaminate the sponge. Climb down from the ladder while holding the handrail with your "climbing" hand. Lay the template aside to discard later.



ATTACHMENT 7 – HOW TO SPONGE A SWINE CARCASS

I. PURPOSE OF THIS ATTACHMENT

Routine *Salmonella* verification of swine (Market Hogs) carcasses has been suspended. The methodology is provided here for use in special projects or other instances where it may be required.

II. PREPARING TO COLLECT A SAMPLE

- A. Select a time at which to collect the sample. Determine the times that carcasses chilled for 12 hours or more will be on hand. Then randomly select a time from within that time frame for collecting the samples.
- B. Select the cooler site from which to collect the sample. Select a safe and accessible site in the cooler for collecting samples from a swine carcass. This site may be located at the transfer chain, grading chain, a rail, or other safe, uncrowded location in the cooler.
- C. Use aseptic techniques as outlined in Chapter II, Section I.A.2.
 1. Wash and sanitize hands.
 2. Sanitize work surfaces (surfaces that will contact supplies while they are being gathered).
 3. Gather the supplies.
 4. Label the sponge bag.
 5. Wash and sanitize hands.
 6. Take supplies to the sampling location.
 7. Sanitize work surfaces (surfaces that will contact supplies during sampling).

III. COLLECTING THE SAMPLE (SPONGE SAMPLE)

- A. At the random time selected, go to the sampling location. Do not choose the carcass that is at the predetermined location. Instead, count back or ahead 5 sample units and choose the sixth unit to sample. Counting back or ahead 5 carcasses avoids any possible bias during selection. Normally it should not be necessary to have the establishment move many carcasses to access a random one to sample.

Swine carcasses that are routinely partially skinned may be used.

- C. Sponge the carcass and prepare the sample for shipping (follow the general sponging techniques as outlined in Attachment 2 – How to prepare the sponge and template for sample collection; and Attachment 3 – How to sponge a carcass (General)):
 1. Position equipment (keep safety in mind).
 2. Locate the areas of the carcass for sampling (see Sample Sites for *Salmonella* Testing of Swine Carcasses).
 3. Layout supplies.
 4. Open the sponge bag.
 5. Pour BPW into the sponge bag.
 6. Close the bag and massage the sponge.
 7. Push the sponge to the top of the bag, open it, and set it aside on a sanitized surface.
 8. Open the template bag and set it aside on a sanitized surface.

9. Put on the sterile gloves (see Attachment 1 – How to put on sterile gloves).
10. Remove the sponge.
11. Remove the template.
12. Lay the template over the belly (see Sample Sites for *Salmonella* Testing of Swine Carcasses). Do not touch the sampling area.
13. Hold the template with one gloved hand and use the other hand to wipe the area with the sponge.
14. Do 10 vertical wipes over the entire sample surface; then do 10 horizontal wipes over the entire sample surface.
15. Carefully climb to sample the ham without touching the template or sponge to any area not being sampled.
16. Lay the template over the ham (see Sample Sites for *Salmonella* Testing of Swine Carcasses). Do not touch the sampling area.
17. Hold the template with one gloved hand and use the other hand to wipe the area with the sponge.
18. Do 10 vertical wipes over the entire sample surface; then do 10 horizontal wipes over the entire sample surface.
19. Carefully climb down to sample the jowl without touching the template or sponge to any area not being sampled.
20. Lay the template over the jowl (see Sample Sites for *Salmonella* Testing of Swine Carcasses). Do not touch the sampling area.
21. Hold the template with one gloved hand and use the other hand to wipe the area with the sponge.
22. Do 10 vertical wipes over the entire sample surface; then do 10 horizontal wipes over the entire sample surface.
23. Place the sponge in the Whirl-Pak® bag and seal the bag.
24. The sample is now complete. Follow the storage and shipping instructions in Chapter VI – Submitting the collected sample.

Sample Sites for *Salmonella* Testing of Swine Carcasses

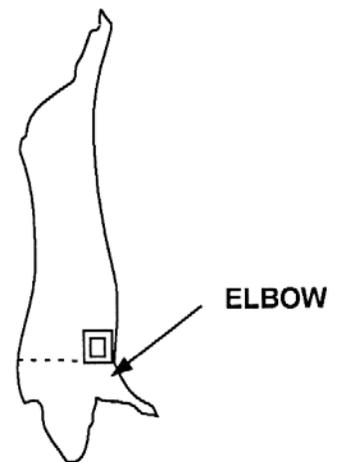
Belly

Locate the elbow of the carcass.

Place the template over this area (armpit) of the belly.

Jowl

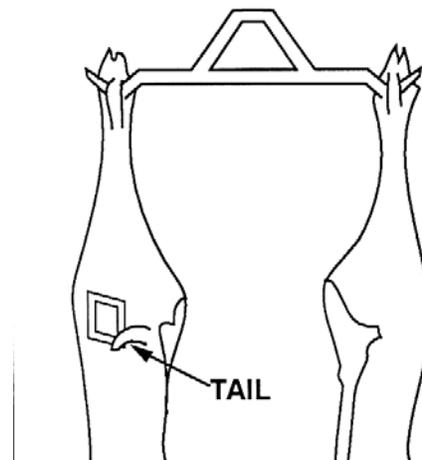
Draw an imaginary line from the atlas/axis joint to the ventral midline; all skin below that point will be considered the jowl.



Ham

From the dorsal position, locate the lateral surface of the base of the tail.

Place the template over this area of the ham. Do not include the base of the tail.



IV. SWINE CARCASS SPONGE SAMPLING TECHNIQUE

Step 1 Materials:

- 1 - Sterile specimen sponge in Whirl-Pak® bag
- 1 - 10 ml sterile pre-chilled Buffered Peptone Water (BPW)
- 1 - Sterile template in bag
- 1 - pair Sterile gloves
- 1 - 6" x 12" plastic sleeve for completed sample form
- 1 - FSIS Form 7355-2A/2B Laboratory sample security seal set
- 3 - FedEx preprinted billable stamps (one for each FSIS laboratory)
- 1 - Absorbent pad
- 1 - Foam plug per shipping container
- Cardboard separators
- Gel coolant packs

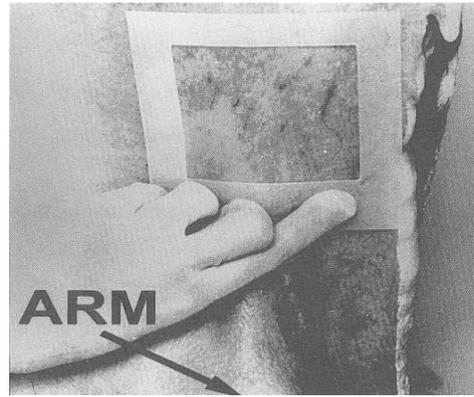


Ensure that all sample supplies are on hand. Use a small tote or caddy for carrying supplies to the sampling location. Sanitize the work surface. Wash and dry hands.

Also, refer to Attachment 3 - How to sponge a carcass (General).

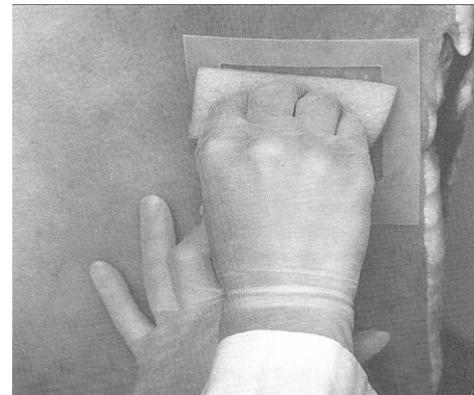
Put on a pair of sterile gloves as described in Attachment 1 – How to put on sterile gloves.

Step 2 Place the template over the **belly** sampling area and hold it in place. Be careful not to contaminate the enclosed sampling area with your hands.



Step 3 With the sampling hand, wipe the sponge over the entire enclosed area (5 cm x 10 cm) approximately 10 times vertically and 10 times horizontally. Use only one side of the sponge.

NOTE: The template may need to be “rolled” from side to side as the sponging is performed since the surface of the carcass is not flat. This will ensure that the full 100 cm² area is sampled during the sponging.



After sponging the **belly** area, transfer the template to your sampling hand. Be careful not to contaminate the inner edges of the template’s sampling area. Climb the ladder or platform, holding on to the handrail with the hand not used to perform sponging. This glove is now contaminated and must be treated as such, so do not handle any sterile surfaces with it.

Step 4 Once you are at a convenient and safe height for sampling the **ham**, transfer the template back to your “climbing” hand, taking care not to contaminate the inner edges of the template’s sampling area or your sampling hand.

Repeat steps 2 and 3 for the **ham** area, using the same surface of the sponge that you used to wipe the belly area.

After sponging the **ham** area, carefully transfer the template back to the hand holding the sponge (sampling hand). Do not contaminate the inner edges of the templates sampling area. Be careful not to contaminate the sponge.

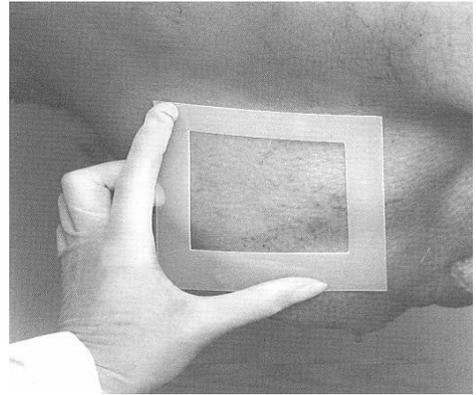


Climb down from the ladder while holding the handrail with your “climbing” hand.

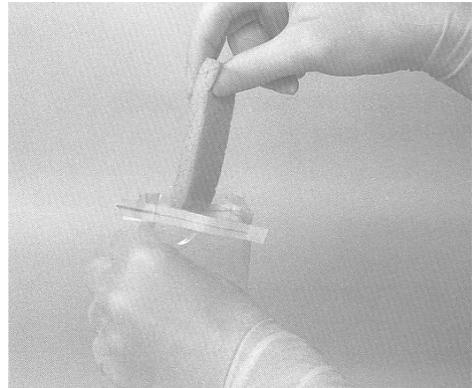
Step 5 Transfer the template from your sampling hand back to your other hand, taking care not to contaminate the template's inner edges.

Repeat steps 2 and 3 for the **jowl** area, this time using the "clean" side of the sponge (the side that was not used to wipe the belly and ham areas).

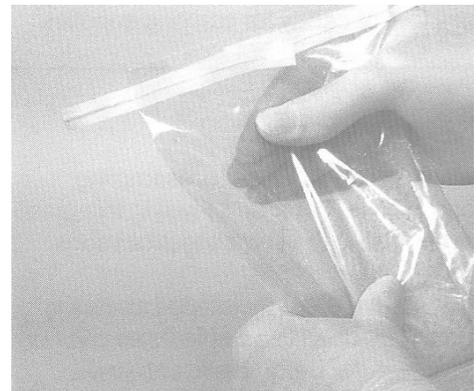
Lay the template aside to discard later.



Step 6 Place the sponge in the sample bag. Be careful not to touch the outside of the bag with the sponge.



Step 7 Expel any excess air from the sample bag and fold over the top edge of the bag 3 or 4 times to close it.

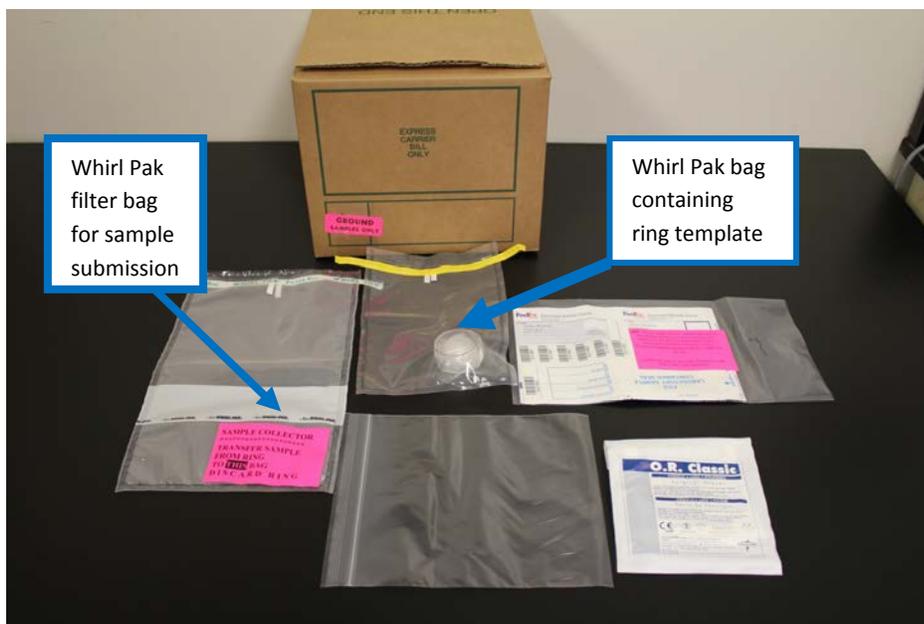


Step 8 Do not double-bag the sample. Discard the template. Collected samples are to be refrigerated within five (5) minutes of collection and held under refrigeration and FSIS control until shipment to the laboratory. Repeat these steps above for each Salmonella sample request. Use a different carcass for each sample.



ATTACHMENT 8 – HOW TO COLLECT A GROUND PRODUCT (BEEF, CHICKEN OR TURKEY) SAMPLE (HC01)

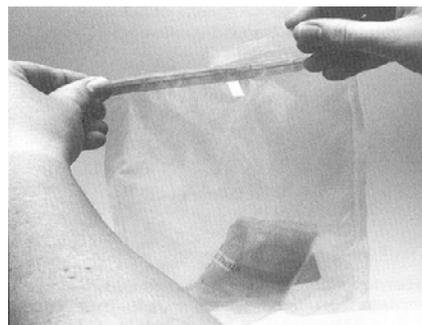
Step 1 Ensure that all sample supplies are on hand. Use a small tote or caddy for carrying supplies to the sampling location. Sanitize the work surface. Wash and dry hands.



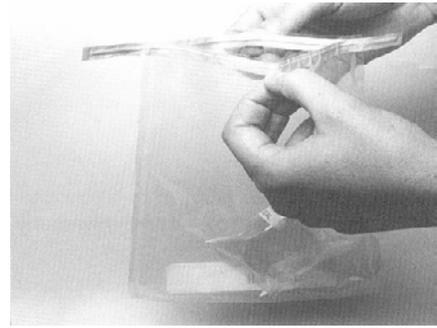
Materials for sampling contained in shipping container:

- 1 - Sterile Whirl-Pak® bag with a sterile, clear, rigid plastic ring template overwrapped in a sealed sheet of sterile plastic.
- 1 – Sterile Whirlpak® filter bag (labeled with a pink label)
- 1 – pair Sterile gloves
- 1 – 6” x 12” plastic sleeve for completed sample form
- 1 – FSIS Form 7355-2A/2B Laboratory sample security seal set
- 3 – FedEx preprinted billable stamps (one for each FSIS laboratory)
- 1 – Absorbent pad
- 1 – Foam plug per shipping container
- Cardboard separators
- Gel coolant packs

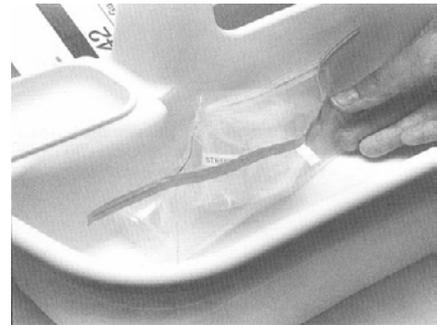
Step 2 Open the Whirl-Pak® bag containing the ring template by holding it at one corner by the wire closure (usually colored white or yellow). Tear off the clear perforated strip at the top of the bag. Do not remove or tear off the wire closures.



Step 3 Pull apart the two small white tabs on either side of the bag to open the mouth of the bag.

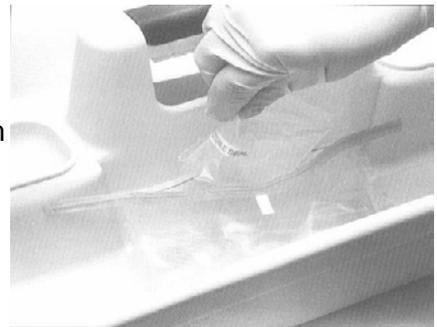


Step 4 While touching only the outside of the bag, manipulate the sterile plastic wrapped ring up to the top of the bag. Fold the bottom of the bag to keep the ring positioned at the top and set the bag upright on a sterile surface. Be careful not to contaminate the ring or the inside of the bag.



Step 5 Put on a pair of sterile gloves as described in Attachment 1 – How to put on sterile gloves.

Remove the sterile plastic wrapped ring template from the bag. Be careful that you do not touch the outside of the bag or any other non-sterile surface.

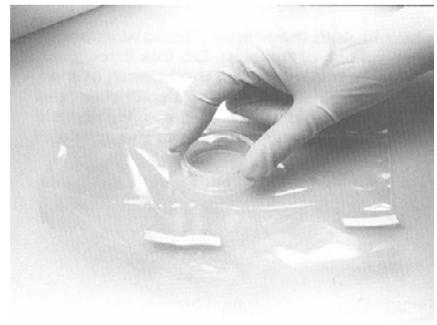


Step 6 Open the Whirl-Pak® filter bag by holding it at one corner by the wire closure. Tear off the clear perforated strip at the top of the bag. Do not remove or tear off the wire closures. Pull apart the two small white tabs on either side of the bag to open the mouth of the bag.

The interior of the bag is sterile so be careful not to touch the inside. Set the bag upright in the caddy.

Step 7 Open the sterile tape seal and unwrap the sterile plastic ring template.

Place the sterile sheet of plastic on a flat sanitized work surface. Place the sterile rigid plastic ring in the center of the plastic sheet.



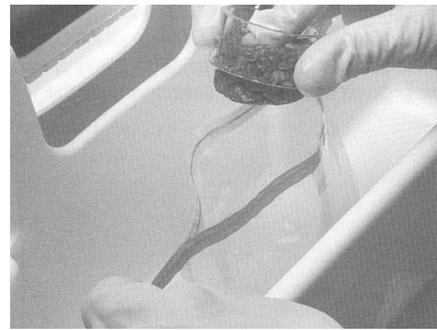
Step 8 Collect enough raw ground product to fill the sterile ring. Select various portions of the product to ensure that the sample is representative of the batch of product. Do not touch any surface except for the ring and the raw ground product selected for sampling.



Step 9 Pack the sample into the ring. Do this firmly to eliminate any air pockets. Fill the ring level to the top. It is critical that the ring be filled in this manner to ensure that a 25-gram sample is uniformly collected.

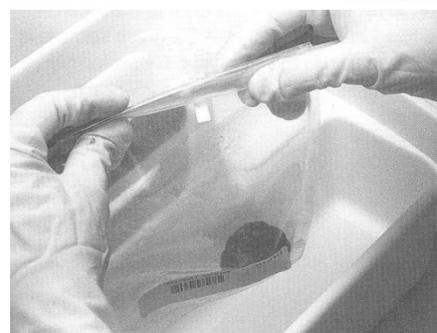


Step 10 Lift the filled ring from the plastic sheet. Hold the ring over the open end of the sterile Whirl-Pak® filter bag. Push the sample out of the ring and into the bag. Do not let the sample touch anything other than the inside of the bag.



NOTE: do not place the sample in the Whirl Pak bag that contained the ring template. Use the Whirl Pak filter bag only (the one with the pink label applied)

Step 11 Lift the bag. Shake the sample to the bottom. Expel any excess air from the sample bag and fold over the top edge of the bag 3 or 4 times to close it. Secure the bag by folding the attached wire back against the bag.



Do not double-bag the sample. Discard the sample ring and the plastic sheet. Collected samples are to be refrigerated within five (5) minutes of collection and held under refrigeration and FSIS control until shipment to the laboratory.

Repeat these steps above for each sample request.

ATTACHMENT 9 – END OF SET LETTER EXAMPLE

This is an example of an EOS letter with fictitious data to illustrate the sections and flow of the letter. Depending on the results, the letter will have additional or deleted information:

Establishment 99999 P

Sunshine Farms

Sunshine City, FL 00000

Dear Establishment 99999 P:

This letter is sent to provide compiled *Salmonella* serotype and *Campylobacter* set results¹ and inform you of where your establishment stands with respect to this risk-based *Salmonella* and *Campylobacter* testing program and strategy. The Food Safety and Inspection Service (FSIS) bases its *Salmonella* and *Campylobacter* verification testing program and strategy on the combination of an establishment's overall process control, individual *Salmonella* subtype (serotype, pulsed-field gel electrophoresis (PFGE) pattern, and antimicrobial susceptibility profile) results. FSIS focuses more intently on establishments that have had a high percentage of *Salmonella* or *Campylobacter* positive test results, with emphasis on *Salmonella* serotypes that are commonly associated with human illness, as well as other *Salmonella* subtypes and *Salmonella* antimicrobial resistance patterns of potential public health concern. You have been provided individual sample results as they have become available.

Process Control

With the completion of a Young Chicken carcass *Salmonella* and *Campylobacter* verification sample set on September 23, 2011, Establishment 99999 P has tested at or below half the acceptable number of positives for *Salmonella* and at or below the acceptable number of positives for *Campylobacter* verification testing for this product class. These results are an indication that the establishment maintained consistent process control for the incidence of generic *Salmonella* during the period of sampling. Together with the results from the previous set, this places Establishment 99999 P in Category 1. In addition these results show that your establishment has passed the *Campylobacter* Performance Standard for the last set and this product class. Several compliance guidelines can be accessed on the FSIS webpage² and provide detailed information on controlling *Salmonella* and *Campylobacter*. A more detailed explanation of FSIS *Salmonella* process control categories can also be found on the FSIS webpage³.

Summary Results from Last Two Sampling Sets:

Product class	Performance Standard*	Date set completed	Number of samples	Number of samples	Number of samples	Current <i>Salmonella</i>
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¹ The lag-time between reporting individual results and this compiled letter is a result of the time required to complete all laboratory and reporting procedures. PFGE and antimicrobial susceptibility pattern information will be provided in a separate mailing when the information becomes available.

² http://www.fsis.usda.gov/Regulations_&_Policies/Compliance_Guides_Index/index.asp#Salmonella

³ *Salmonella* Scheduling Algorithm Functions

	Number of samples taken	Maximum <i>Salmonella</i> positives allowed	Maximum <i>Campylobacter</i> positives allowed		analyzed	positive for <i>Salmonella</i>	positive for <i>Campylobacter</i>	process control category
Young Chickens	51	5	8	09/23/11	51	1	2	Cat 1
		12	NA	06/05/09	51	5	NA	

*New Performance Standard in effect as of July 1, 2011

Public Health-focused Evaluation of Isolates by Serotype

FSIS has evaluated the serotype4 of the *Salmonella* isolates from the most recent verification sample set referenced above and is providing public health-focused information on these recent isolates. Serotyping, PFGE pattern identification, and antimicrobial susceptibility profiling5 of bacterial isolates provide added distinction to *Salmonella* isolates from food and environmental samples and from human specimens. This information can be used to better focus food safety efforts to protect public health. Compiled serotypes are provided in this letter to facilitate the establishment’s efforts to identify interventions (e.g., pre-harvest interventions) it may use to address these serotypes. PFGE and antimicrobial susceptibility pattern information will be provided in a separate mailing once it becomes available.

Salmonella Serotype Results for the Most Recent Sampling Set:

Form ID	Collection Date	Serotype	Serotype commonly associated with human illness6
00000000	08/03/11	ENTERITIDIS	Yes***

*** There was one sample that had a serotype commonly associated with human illness in this set, which is a medium number for this product class7.

Serotype commonly associated with human illness: These *Salmonella* isolates have a serotype that is commonly associated with human illness. A list of the serotypes that are more commonly associated with human illness can be found on the CDC Web site at:

<http://www.cdc.gov/ncezid/dfwed/PDFs/salmonella-annual-report-2011-508c.pdf>

4 Serotypes of positive samples are provided by the National Veterinary Services Laboratory of USDA.

5 PFGE and antimicrobial susceptibility patterns of positive samples are provided by the Agricultural Research Service

6 Based on the CDC’s most recent published list of 20 most frequently reported *Salmonella* serotypes from humans (<http://www.cdc.gov/ncezid/dfwed/PDFs/salmonella-annual-report-2011-508c.pdf>). FSIS will inform establishments through this letter if serotypes are otherwise of heightened interest, as determined through additional analysis of available data.

7 Based on the distribution of serotypes commonly associated with human illness in this product class found in FSIS verification testing over the past two calendar years, where results lower than the 25th percentile equals “low”, results above the 75th percentile equals “high”, and all other results equal “medium”.

Isolates with a serotype not included on this list have a serotype that is less frequently associated with human illness. Please note that all *Salmonella* serotypes are considered to be capable of causing illness in humans.

Discussion of Compiled Set Results

The following results related to your operation are being provided for you to use in the evaluation of your operation:

The verification results are an indication that your establishment maintained consistent process control for the incidence of generic *Salmonella* during the period of sampling and passed the *Campylobacter* Performance Standard. In addition one *Salmonella* isolate had a serotype commonly associated with human illness, which is a medium number for this product class. In the event additional follow-up searches alter the establishment's serotyping results, a revised letter will be issued to the establishment.

FSIS will use *Salmonella* process control and serotype as well as *Campylobacter* set results to further determine scheduling for *Salmonella* and *Campylobacter* testing. Based on the present *Salmonella* serotypes commonly associated with human illness, Establishment 99999 P is likely to be scheduled for another sample set sooner than an establishment that did not have the individual serotype results that your establishment has had.

FSIS expects establishments to consider these testing results in the decision-making process when evaluating the effectiveness of its overall food safety system. This could be accomplished by establishments identifying and implementing relevant pre-harvest or post-harvest strategies. More information on such strategies can be found in available Agency Compliance Guidelines for controlling *Salmonella* and *Campylobacter* which can be accessed on the FSIS webpage⁸.

Please be advised that an establishment that does not adequately take the provided information into account in the decision-making process when evaluating the effectiveness of its overall food safety system may be determined to have an ineffective food safety system. In addition, if FSIS determines that a product produced by an establishment is associated with human illness because *Salmonella* is present in that product, FSIS may consider the product adulterated and take appropriate regulatory action.

Please direct questions to askFSIS (<http://askfsis.custhelp.com>).

Sincerely,

[DM]

Office of Field Operations

cc: Inspector-in-Charge (via electronic copy)
Front-Line Supervisor (via electronic copy)
Washington, DC FSIS HQ Personnel (via electronic copy)

⁸ http://www.fsis.usda.gov/Regulations_&_Policies/Compliance_Guides_Index/index.asp#Salmonella