Pathogen Reduction – *Salmonella* and *Campylobacter* Performance Standards Verification Testing

**Objectives**

To demonstrate mastery of Pathogen Reduction the trainee will:

1. Explain why *Salmonella* and *Campylobacter* testing is used.
2. State who will conduct *Salmonella* and *Campylobacter* testing.
3. List the species and types of product eligible for testing under the *Salmonella* performance standards.
4. List the species and types of product eligible for testing under the *Campylobacter* performance standards.
5. Describe how and when *Salmonella* and *Campylobacter* samples are taken.
6. Explain how to obtain completed *Salmonella* and *Campylobacter* results from LIMS-Direct and PHIS.

**References**

1. FSIS Regulations 310.25(b)
2. FSIS Directive 7355.1, “Use of Sample Seals for Laboratory Samples and Other Applications”.
4. FSIS Directive 10,200.1, “Accessing Laboratory Sample Information via LEARN (will be revised to reference LIMS-Direct)”.
8. FSIS Notice 22-15, “Changes to the *Salmonella* and *Campylobacter* Verification Testing Programs for Poultry Carcasses.”
9. FSIS Notice 16-15, “Raw Chicken Sampling Project”.
10. FSIS Notice 12-15, “Updating the PHIS Profile for Raw Chicken and Turkey Products”.
11. FSIS Notice 28-14, “Analysis for Salmonella of All Beef Sampled for Shiga Toxin-Producing Escherichia coli (STEC)”.
12. FSIS Notice 69-13, “Containers for Use When Collecting Raw Beef Samples for Shiga Toxin-Producing Escherichia coli (STEC) and Salmonella Testing”.
13. PHIS Directive 13,000.1, “Scheduling In-Plant Inspection Tasks in the Public Health Information System (PHIS)”.
14. PHIS Directive 13,000.2, “Performing Sampling Tasks In Official Establishment Using the Public Health Information System”.
15. PHIS Directive 5300.1, “Managing the Establishment Profile in the Public Health Information System (PHIS)”.
21. PHIS User Guide

Introduction

FSIS established the Salmonella verification program in 1996 as part of the Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems Final Rule. The PR/HACCP Final Rule established Salmonella performance standards that are used to verify process control in meat and
poultry slaughter and processing establishments that produced certain classes of product (9 CFR 310.25(b)(1) and 381.94(b)(1), respectively). The performance standards were developed using national baseline studies conducted before the rule’s implementation. Only the performance standards for livestock carcasses and certain raw ground meat products (9 CFR 310.25(b)) are still applicable.

Since then, FSIS has conducted additional prevalence and risk assessments for pathogens in FSIS regulated products, revised the performance standards to meet public health goals, and has published a number of Federal Register Notices (FRN).

- FSIS published new performance standards in 2010 and 2011 for *Salmonella* and *Campylobacter* for chilled carcasses in young chicken (broiler) and turkey slaughter establishments. The Agency has identified *Campylobacter* as part of FSIS’s pathogen reduction strategy and established *Campylobacter* performance standards for poultry carcasses.

- In December 2012, FSIS informed establishments that produce not ready-to-eat (NRTE) ground or otherwise comminuted chicken and turkey products that they were required to reassess their HACCP plans (FRN Docket No. 2012-0007; April 21, 2014) as a result of two multi-state outbreaks linked to ground turkey products. FSIS also expanded the *Salmonella* sampling beyond ground chicken and turkey to include all forms of non-breaded, non-battered comminuted Not-Ready-to-Eat (NRTE) poultry products to determine the prevalence of *Salmonella* and *Campylobacter* in NRTE comminuted poultry, and to develop pathogen reduction performance standards for these products.

- In 2014, FSIS published the Modernization of Poultry Slaughter Inspection; Final Rule (Federal Register Docket No. FSIS-2011-0012; August 21, 2014) to facilitate pathogen reduction in poultry products, improve the effectiveness of poultry slaughter inspection, make better use of Agency’s resources, and remove unnecessary regulatory obstacle to innovation. In this publication, FSIS informed industry that it was removing the codified *Salmonella* pathogen reduction performance standards for poultry (9 CFR 381.94(b)). Furthermore, in another publication (Federal Register Docket No. FSIS-2012-0038; June 5, 2014), FSIS announced that it will analyze for *Salmonella* all raw beef samples collected for shiga toxin-producing *E. coli* (STEC) analysis including the follow-up samples in response to STEC positive results. In addition, the raw ground beef samples portion for *Salmonella* analysis increased from 25 grams to 325 grams. FSIS will gather data necessary to determine the prevalence of *Salmonella* in ground beef and beef trim to propose new performance standards for ground beef.
In January 2015, the Agency identified new *Salmonella* and *Campylobacter* performance standards for raw chicken parts and NRTE comminuted poultry products. (FRN Docket No. FSIS-2014-0023; January 26, 2015). It also announced that it will use the results of routine sampling throughout the year, using a moving window approach, to assess whether the establishment’s processes are effectively addressing pathogens on poultry carcasses and other products derived from these carcasses. In this publication, FSIS is also implementing an exploratory sampling of raw pork products for pathogens of public health concern, as well as indicator organisms.

FSIS originally selected *Salmonella* as the target organism because it is a commonly reported cause of foodborne illness and is present in all major species. The *Salmonella* genus includes over 2,300 serotypes. There are several *Salmonella* serotypes commonly associated with human illness, including *Salmonella* Enteritidis and *Salmonella* Typhimurium. *Salmonella* bacteria are the most frequently reported cause of foodborne illness. According to the Centers for Disease Control and Prevention (CDC), salmonellosis causes an estimated 1.4 million cases of food borne illness and more than 400 deaths annually in the United States.

*Campylobacter* species, specifically *C. jejuni* and *C. coli*, are most often isolated from the intestinal tract of poultry as well as in poultry products. *Campylobacter* bacteria are the second most frequently reported cause of food borne illness, and *Campylobacter jejuni* is the most common strain causing illness.

*Salmonella* and *Campylobacter* contamination of raw poultry products occurs during slaughter operations, as well as during the live-animal rearing process (e.g., on-farm contamination can coat the exterior of the bird and remain attached to the skin). Contamination can be minimized with the use of proper sanitary dressing procedures and by the application of antimicrobial interventions during slaughter and fabrication of the carcasses into parts and comminuted product. In addition, if raw poultry is improperly handled during food preparation, *Salmonella* and *Campylobacter* can cross-contaminate other foods or food contact surfaces.

*Salmonella* and *Campylobacter* can be transmitted to humans by eating foods contaminated with animal feces. The goal of the newly revised *Salmonella* and *Campylobacter* testing program is to protect the consumer from contaminated products by verifying that each establishment meets the new performance standards.

The Agency has two Strategic Goals that are related to *Salmonella*:

- The “All-Illness Measure” – this measure tracks and sets quarterly goals for reducing the total illness 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 the Healthy People 2020 goals.

- The percent of young chicken establishments meeting the new *Salmonella* performance standard – FSIS identifies performance standards for *Salmonella* in up to eight classes of raw products. These standards are designed to cause industry to control for *Salmonella* and reduce the potential for human exposure. The best available projection is that 88 percent of establishments will have passed the new performance standard.

In addition to reporting individual *Salmonella* and *Campylobacter* sample results to establishments, FSIS posts nationwide *Salmonella* and *Campylobacter* data on its website on a quarterly basis.

**Salmonella and Campylobacter Verification Testing – The Role of the Inspector**

The *Salmonella* and *Campylobacter* verification sampling is conducted in establishments by FSIS inspection program personnel (IPP). IPP will collect samples using on-going scheduled sampling (routine sampling) using a moving window approach to assess process control for all *Salmonella* performance standards.

It is important for the IPP in establishments slaughtering or producing raw intact or raw non-intact chicken and turkey products to update the establishment’s Public Health Information System (PHIS) profile information as per FSIS Notice 12-15. The Agency has made changes to the product group options in the PHIS establishment profile to identify establishments that produce specific types of raw intact and non-intact chicken and turkey products.

**Products Eligible for Sampling**

Raw ground products, sampled and **analyzed for Salmonella** include:

- Ground and chopped raw meat from cattle carcasses (beef or veal which may or may not contain added ingredients, spices, or seasonings), that meet the standards of identity for ground and chopped beef (9 CFR 319.15(a)) and hamburger (9 CFR 319.15(b)). Sampled products may contain meat derived from advanced meat recovery (AMR) systems, but AMR meat by itself is not sampled.

  - Products that are **not** sampled in this program include beef patties as defined in 9 CFR 319.15(c), and fabricated steaks and similar products as defined in 9 CFR 319.15(d).
Note: Salmonella verification sample sets for raw ground beef products have been discontinued with the exception at establishments that recently exceeded the performance standard and are in 'Category 3' (FSIS Notice 28-14). FSIS also discontinued collecting MT43S samples in very low volume grinding establishments. In addition, raw beef samples collected for STEC analysis are also analyzed for Salmonella.

Note: FSIS is not currently sampling and testing for Salmonella in steers or heifers, cows or bulls, or market hogs per FSIS Directive 10,250.1.

IPP also collect the following poultry samples, using a moving window sampling approach, to be analyzed for both Salmonella and Campylobacter as described in Directive 10,250.1, Notice 22-15, and FSIS Notice 31-15.

- Poultry carcasses
  - young chicken carcasses including broilers, fryers, roasters, and Cornish game hens, as described in 9CFR 381.170(a), and
  - young turkey carcasses

- NRTE comminuted poultry

NRTE comminuted poultry is any non-breded, non-battered, raw NRTE chicken or turkey product that has been processed to reduce the particle size which may or may not contain added ingredients. NRTE comminuted poultry includes:

1. ground (Ground product group category) – ground chicken or turkey for any purpose (e.g., packed for consumer or for any type of further processing); or
2. mechanically separated (Mechanically Separated product group) – mechanically separated chicken or turkey, as defined in 9 CFR 381.173; or
3. hand or mechanically-deboned and further chopped, flaked, minced, or otherwise processed to reduce particle size. Chicken or turkey product, other than ground or mechanically separated falls under the Other Non-intact product group. These products include:

   - NRTE comminuted chicken product may be derived from any age chicken, including young chickens (broilers, fryers, and roasters), fowl, capons, and roosters, as defined in 9 CFR 381.170(a)(1); and
   - NRTE comminuted turkey product may be derived from any age turkey, including young turkeys, yearling turkeys, and old turkeys, as defined in 9 CFR 381.170(a)(2).
The Agency does not collect samples of chickens/turkeys or chicken/turkey products produced under a religious exemption and not bearing the mark of inspection. Products from any product class diverted for pet food manufacture without the mark of inspection are also not sampled. In addition, FSIS does not currently sample eligible product for Salmonella testing from poultry establishments that produces less than 1,000 pounds per day.

As explained in the January 26, 2015 Federal Register Notice (Docket Number FSIS-2014-0023), FSIS began exploratory sampling of chicken parts as well as of raw pork products for pathogens of public health concern as instructed in FSIS Notice 16-15 and FSIS Notice 23-15.

- Raw Chicken Parts Sampling Project: FSIS Notice 16-15 instructs IPP to collect raw chicken parts (finished product) to be analyzed for Salmonella and Campylobacter. Chicken parts that are subject to sampling include those that are non-intact (that have been needle injected with clear liquid or marinated in a clear solution, mechanically tenderized, vacuum tumbled, or similarly processed; refer to Attachment 1 of the notice). Definitions are found in 9 CFR 381.170(b), Standards for kinds and classes, and for cuts of raw poultry. Eligible chicken parts for sample collection include:
  - Legs: whole legs (no backbone attached), drumsticks, thighs, and cut up or portioned leg meat (3/4 inch larger in at least one dimension),
  - Breasts: whole and half breasts (with or without ribs), boneless and skinless breasts, tenderloins and tenders, and cut up portioned breast meat (3/4 inch larger in at least one dimension), and
  - Wings: whole wings (with or without the wing tip), mixed wing sections, drummettes, mid-sections (flats), wing tips, and boneless wings

  Note: Chicken half carcasses and quarter carcasses are not eligible for collection under this sampling program.

- Raw Pork Products Exploratory Sampling Project (RPPESP): As stated in FSIS Notice 23-15, IPP are to collect samples at establishments that produce raw pork products as part of the nationwide RPPESP. These samples are analyzed for Salmonella as well as for indicator organisms. The eligible raw pork products include:
  - Raw intact pork products – retail cuts, tray ready cuts, foodservice cuts, or portion cuts prepared for consumers that have not been tenderized, injected, pumped, or vacuum tumbled; and
— Raw non-intact pork products – retail cuts, tray ready cuts, foodservice cuts, or portion cuts prepared for consumers that have been tenderized, injected, pumped, or vacuum tumbled; ground pork, mechanically separated pork, AMR pork, pork sausage, patties or other formed products; and other comminuted pork.

**Circumstances in Which Sampling is not Warranted**

When an establishment processes all its products into ready-to-eat (RTE) product or diverts all of its raw products (including NRTE comminuted poultry) to another federally inspected establishment for further processing into a RTE product, FSIS will exclude the establishment from the *Salmonella* verification-testing program schedule, according to FSIS Directive 10,250.1 – Chapter VII.

For example, an establishment slaughters young chickens and produces NRTE ground chicken as one of its products. The establishment ships its entire ground chicken production to another establishment that uses it to make a RTE product. In this example, IPP would not sample the ground chicken. However, if other raw products were produced from the carcasses, then the chicken carcasses would still be eligible for *Salmonella* sampling.

If an establishment states that the intended use of all product produced is RTE product, then IPP are to verify the intended use while performing the appropriate HACCP task. IPP are to verify, either by observing or by reviewing records, that all the product is actually processed into RTE product in the establishment.

If an establishment claims to move all products from a particular product class to another federally inspected establishment for further processing into RTE products, IPP are to verify this by reviewing the establishment’s HACCP plan and hazard analysis for the intended use of the products. In addition, IPP are to verify that the establishment has procedures incorporated in its food safety system that effect the movement of all products from that product class to another federally-inspected establishment at which the product is further processed into RTE product.

If the establishment cannot produce sufficient documentation to demonstrate the assertion that the product is further processed into RTE product, then the product is still eligible for sampling under the verification testing program.

If IPP verify that the product in question meets one of the exclusion criteria above, then IPP are to follow the additional instructions in FSIS Directive 10,250.1 – Chapter VII.

When an establishment produces more than 1 lot of NRTE poultry product class (for example, ground chicken) and ships the product to different establishments that further process the poultry into RTE product, but one of the establishments
produces NRTE products, the IPP are to sample product under the Salmonella verification testing program. In this situation, the IPP is not to differentiate between the products going to the establishments producing the RTE products versus the products going to the establishments producing the NRTE product when taking the sample. In addition, IPP are to follow additional instructions described in FSIS Directive 10,250.1 – Chapter VII, Section III.

The Performance Standards

The Salmonella and Campylobacter performance standards apply to establishments overall process control, not to individual products. Products are not tested to determine their disposition, but rather to measure the effectiveness of the slaughter and grinding process in limiting contamination. Establishments do not have to hold product or recall product based on results of the Salmonella and Campylobacter samples.

FSIS replaced its existing Salmonella sampling set-approach with a routine sampling approach for ALL FSIS-regulated products subject for Salmonella and Campylobacter verification testing. This includes broiler and turkey carcasses, chicken parts, comminuted poultry, ground beef (tested for Salmonella only), and beef manufacturing trimmings (tested for Salmonella only). Salmonella and Campylobacter performance standard verification samples are taken as part of a moving window and the results are used to determine if an establishment is meeting the performance standard on a continuous basis. When assessing process control under a moving window approach, FSIS intends to evaluate, over a certain period of time, a number of sequential results from a single establishment. Thus, given the fixed timeframe of one year (52 weeks) for which an establishment has been sampled, FSIS would assess the first moving window by evaluating the number of samples taken within the 52-week period.

As an example, if an establishment has five Salmonella positives within 52 samples (one sample per week for a year), then the establishment passed the performance standard if the performance standard allows five positive samples among 52 samples. When the next sample is taken (week 53, in this example), the moving window would shift forward the fixed timeframe of one year (52 weeks); that is, the original week 1 (and the original first sample) is excluded, while the most recent week is included in the new 52-week moving window. This shifting is repeated with each new week and allows FSIS to continuously assess the process control of an establishment.

The charts below shows the maximum acceptable percent positive results or number of positives results allowed in the moving window before the establishment fails to meet the performance standard. A test is considered positive when any Salmonella or Campylobacter organisms are found.
Salmonella/Campylobacter Performance Standards for Poultry

<table>
<thead>
<tr>
<th>Product</th>
<th>Maximum Acceptable % Positive</th>
<th>Performance Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Salmonella</td>
<td>Campylobacter</td>
</tr>
<tr>
<td>Broiler Carcasses^</td>
<td>7.5</td>
<td>10.4</td>
</tr>
<tr>
<td>Turkey Carcasses^</td>
<td>1.7</td>
<td>0.79</td>
</tr>
<tr>
<td>Comminuted Chicken*</td>
<td>25.0</td>
<td>1.9</td>
</tr>
<tr>
<td>Comminuted Turkey*</td>
<td>13.5</td>
<td>1.9</td>
</tr>
<tr>
<td>Chicken Parts*</td>
<td>15.4</td>
<td>7.7</td>
</tr>
</tbody>
</table>

^ The maximum percent positive for Salmonella and Campylobacter under the performance standards for young chicken and turkey carcasses is listed in FSIS Directive 10,250.1
* Developed proposed performance standards published in the FRN Docket No. FSIS-2014-0023

**Note:** The new Salmonella performance standards are to be applied to sample results in place of the performance standards for young chickens (as broilers) and ground chicken and ground turkey codified in 9 CFR 381.94(b).

For highest-volume establishments, FSIS expects to collect 52 samples within the 52-week moving window. In this case, to assess process control (at establishments producing products with performance standards measured in 52 samples), one need only to count the number of positives test results within the 52-week moving window. For example, the proposed performance standard for Salmonella in raw chicken parts is eight positives out of 52 samples. Assuming that 52 samples were collected from the establishment within a 52-week moving window, if the establishment has eight or fewer Salmonella positives within that 52-week timeframe, then it would pass the performance standard. If, on the other hand, the establishment has nine or more Salmonella positives within that same 52-week timeframe, then it would fail the performance standard.

To assess process control in establishments that FSIS samples less often than weekly (i.e., lower volume establishments), FSIS will assess establishment performance (as percent positive) based on the (likely variable) number of samples collected and positive results within the 52-week moving window.
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illustrate this point, if a small establishment producing raw chicken parts is sampled fewer than 52 times in the 52-week moving window, only 26 times, for example, with three of those samples testing positive for *Salmonella*, 26 will be the denominator while three be the numerator. This gives the establishment a percent positive of 11.5 \((\frac{3}{26} \times 100 = 11.5\%)\). In this example, the resulting percent positive is less than 15.4, the acceptable percent positive for the proposed performance standards for *Salmonella* in raw chicken parts. As such, the establishment would pass the performance standard.

**Salmonella Performance Standards for Ground Beef**

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

1 As per Directive 10,250.1

For ground beef, an establishment can have no more than 5 positive sample results out of 53 samples in the moving window.

**Sampling Procedure**

The purpose of the *Salmonella* and *Campylobacter* verification sampling program is to verify the establishment’s process control for *all applicable products*. *All* eligible products produced at an establishment will be scheduled for sampling during the month under routine sampling. For example, if an establishment produces more than one product type (chicken carcasses, chicken parts, and NRTE comminuted chicken) that is eligible for sampling, then all of those products will be scheduled for sampling during the month.

If an establishment produces eligible product on more than one shift, IPP are to collect samples from different shifts for each sampling task so that all shifts are represented during routine sampling. IPP will collect a sample of product, using a random method, at an unannounced time for each sampling task, until enough samples have been taken and analyzed as part of the moving window. IPP are to collect samples in accordance with the step-by-step directions found in FSIS Directive 10,250.1 and FSIS notices for all product classes including young chicken and turkey carcasses. Attachment 1 in this module gives an overview of
the procedures for collecting samples as per FSIS Directive 10,250.1 (refer to the directive and FSIS notices for detail instruction on how to collect the samples).

**Note:** “Random” refers to the time the samples are selected, not to when the sponging or rinsing is initiated or completed. Random sampling may include the use of random number tables, drawing cards, or using computer generated random numbers. For example, the time entered for collection is when the carcass is removed from the line and the date is the day the carcass is sponged or rinsed.

*Salmonella* and *Campylobacter* verification sampling is a directed sampling task. Taking into account risk factors including production volume and past establishment testing performance (i.e., positive *Salmonella* and *Campylobacter* test results), FSIS will establish the sampling frequency accordingly for a particular establishment. The Public Health Information System (PHIS) displays sampling tasks on the establishment task list for the sampling programs that apply to the establishment. The following are sampling project codes for the *Salmonella* sampling programs.

- The **HC_CH_COM 01** (for chicken) and **HC_TU_COM01** (for turkey) sampling codes correspond to products in the “Ground Product” and “Other Comminuted” product groups by randomly selecting from available eligible raw ground and other comminuted (but not mechanically separated) products. As stated in FSIS Notice 31-15, FSIS has discontinued all ground chicken or turkey *Salmonella* verification sets. In addition, the **EXP_CH_MSK01** (for chicken) and **EXP_TU_MSK01** (for turkey) project codes described in this notice apply to those establishments that produce “Mechanically Separated Species” identified in PHIS.

- As stated in FSIS Notice 28-14, raw beef samples collected for STEC analysis are also analyzed for *Salmonella*. When IPP receive sampling tasks for FSIS’s routine and follow-up sampling for STEC, they are to collect ground beef and trim samples following the instructions of FSIS Directive 10,010.1.

- The **HC_CH_CARC01** and **HC_TU_CARC01** sampling code corresponds to young chicken and turkey carcasses, respectively, to reflect the moving window approach.

- The **HC_CPT_LBW01** sampling code is used to collect samples at establishments producing chicken parts. Follow instructions outlined in Notice 16-15.

- As stated in FSIS Notice 23-15, the raw pork products eligible for sampling will be collected based on the sampling project codes and product
description of PHIS product group in an establishment that produces raw intact and raw non-intact pork products. IPP follow the instructions delineated in the notice.

IPP document the completion of the sampling task in PHIS including completing the questionnaire. IPP schedule verification sampling tasks following the instructions in FSIS Directive 13,000.1 and perform the sampling tasks following the instructions in FSIS Directive 13,000.2.

**Sampling Method**

The specific sampling methodologies for the product classes to be sampled are explained in detail in FSIS Directive 10,250.1 and applicable FSIS notices.

IPP collect samples using a carcass sponge swab, a whole bird rinse, or taking a specific amount of ground/comminuted product using the sampling technique as described in FSIS Directive 10,250.1 and in published FSIS notices. Even though the Agency is not collecting livestock carcasses samples, the sampling procedures for cattle and hog carcasses are also included in the directive in case they are needed for special purposes.

Turkey carcasses are sampled using a sponge sample technique. Sponge sampling of turkey carcasses uses two sponges, one that is analyzed for *Salmonella* and the other for *Campylobacter*. Sponge sample sites are to the left and right of the back and thigh as per instructions delineated in the directive.

Chicken carcasses are sampled using whole bird rinses; IPP are to collect 100 ml rinsate.

**Note:** For poultry carcasses, at the post-chill sampling location, IPP are to determine a random time at which the carcass will reach the end of the drip line or the equivalent point in air-chill systems. IPP are to randomly select a poultry carcass from the post-chill area (after all interventions have taken place) and to allow drip time to prevent dilution of the sample.

Chicken parts are sampled by collecting approximately 120 ml of rinsate from 4 lbs. ± 10% of the eligible raw chicken parts.

The amount of ground product collected (final package or aseptically when not in final package) by the IPP will depend on the sampling project code as follows:

- Ground beef products, as well as raw beef trim samples collected for routine and follow-up projects for *E. coli* O157:H7 and other STECs are sampled as per instructions in FSIS Directive 10,010.1.
• NRTE comminuted poultry products are sampled by collecting sufficient product to fill the two provided Whirl-Pak bags up to the fill-line indicated on each bag, following the instructions as described in FSIS Notice 31-15. The total weight of the two bags of samples should be approximately two pounds. This larger sample size will provide consistency as the Agency moves toward analyzing each sample for both pathogens.

For the RPPESP, IPP will be collecting fresh, not frozen, raw pork samples in final packaging, whenever possible, corresponding to 2 lbs.

In establishments that produce more than one type of product subject to testing, all eligible products produced will be scheduled for sampling during the month under routine sampling.

Additional Sampling Directions

The Inspector-in-Charge (IIC) at establishments subject to Salmonella and Campylobacter verification testing should ensure that adequate sampling supplies are available prior to the start of each sampling task.

IPP are to notify official establishment management just before collecting a routine Salmonella or Campylobacter sample.

IPP are to schedule the directed sampling tasks on the task calendar (refer to Sample Management Module, section “Scheduling and Submitting a Directed Lab Sample”) and collect a sample the day the product class is produced.

Once the IPP has scheduled the sampling task, using the PHIS Laboratory Capacity Reservation System in the Task Calendar, then the IPP can proceed to collect the sample. The IPP may choose to print a draft copy of the “Sample Analysis Request” form to use as a reference during sample collection and to document product information (refer to Attachment 2 at the end of this module). Some information is already pre-printed in the Collection and Animal Information data fields of the sampling form, such as sample form ID, project code, and sample source.

Note: When entering information into PHIS for carcass-based Salmonella or Campylobacter sample collection (chicken whole bird rinses or turkey carcass swabs), IPP are to enter “N/A” (for Not Applicable) into all “Sample Management-Sample Collection” required data entry fields related to the producer name and address. Samples should not be frozen and should be kept secure at all times. Sample boxes should never be stored near heaters or areas exposed to excessive heat. Cool the shipping container the day before collecting the sample. The laboratory will discard rinse samples that arrive above 50°F or below 32°F. It is critical that refrigerated sample temperature is maintained during collection and shipment.
When a sample is collected, IPP are to enter the data requested in the data fields (as indicated above) on the sampling form, submit the sample form through PHIS, print and sign the form, pack and ship the sample as described in PHIS Directive 13,000.2 and the Sample Management module of this training. The lab analyzes the samples and the Data Analysis and Integration Staff (DAIS) tracks the data and results. IPP receive laboratory testing results when they are posted in LIMS-Direct and in the establishment’s home page in PHIS for both pathogens. IPP receive an alert on the PHIS Inspector home page when an FSIS sample result is positive.

**Workshop 1: Salmonella and Campylobacter Performance Standards**

1. Select from the list below the species and types of product eligible for testing under the Campylobacter performance standards.

   - Beef carcasses
   - Chicken carcasses
   - Duck carcasses
   - Equine carcasses
   - Geese carcasses
   - Goat carcasses
   - Ground chicken
   - Ground pork
   - Ground turkey
   - Sheep carcasses
   - Swine carcasses
   - Turkey carcasses
   - Ground beef
   - Chicken parts

2. True or False:

   - Each sample collected in a young chicken or turkey slaughter establishment under the moving window approach will be analyzed for both Salmonella and Campylobacter.
   - When an establishment processes all of its raw product into RTE products, FSIS will collect samples from the raw product that the establishment produces to be analyzed for the Salmonella.
   - FSIS has replaced its existing Salmonella sampling set-approach with a routine sampling approach for all FSIS-regulated products subject to Salmonella and Campylobacter verification testing.
   - An establishment that produces young chicken carcasses can have no more than 5 positive results for Salmonella in a 51 sample moving window to meet the performance standard.
Defining Categories

If the sample under the routine *Salmonella* verification sampling meets the *Salmonella* and *Campylobacter* performance standards (i.e., the maximum acceptable percent positive allowed under the moving window approach), it passes. If the sample results in the moving window exceed the maximum percent positive allowed, the establishment has not met the performance standard.

FSIS uses categories in evaluating an establishment’s level of process control and for scheduling *Salmonella* and *Campylobacter* performance standard verification testing. For all products sampled under routine *Salmonella* verification sampling, FSIS has modified the time component of the categories definitions as follows:

**Category 1 – Consistent Process Control:** Establishments that have achieved 50 percent or less of the performance standard during all completed 52-week moving windows over the last six months. This performance demonstrates the best process control for this pathogen.

**Category 2 – Variable Process Control:** Establishments that meet the standard for all completed 52-week moving windows but have results greater than 50 percent of the standard during any completed 52-week moving window over the last six months. This performance demonstrates intermediate process control for this pathogen.

**Category 3 – Highly Variable Process Control:** Establishments that have exceeded the performance standard during any completed 52-week moving window over the last six months. This performance demonstrates the least process control for this pathogen and means the establishment has failed the *Salmonella* performance standard.

The Agency will also post the following information on the FSIS Web site:


- Beginning July 1, 2015, FSIS will begin web-posting individual establishment category information for chicken and turkey carcasses.
- Until July 2015, FSIS will continue to web-post existing Category 3 poultry carcass establishments.
- The Agency will post aggregate reports quarterly showing the categories 1/2/3 distribution for each relevant product class subject to FSIS *Salmonella* and *Campylobacter* testing, as applicable.
  - FSIS will continue to post aggregate reports for chicken and turkey slaughter establishments showing category distribution for current performance standards for carcasses.
– Starting in March 2015, FSIS will begin posting aggregate reports showing the category 1/2/3 distribution for chicken parts as data becomes available, and comminuted chicken and turkey using historical data and new results beginning in March based on the proposed performance standards.

**Agency Actions**

Under the new performance standards and under the new moving window approach, when an establishment does not meet a performance standard (i.e., the number of positive samples within a specified timeframe exceeds the maximum acceptable for that product class), FSIS will immediately conduct follow-up samples that will be analyzed for both *Salmonella* and *Campylobacter*, where applicable. Specifically, either 16 or eight follow-up samples will be collected depending on the size and production volume of the establishment. The Agency will analyze the follow-up sampling data independent of the moving window approach to assess whether the establishment is making or has made changes to its food safety system to improve its process control.

In addition, when the establishments do not meet the performance standards, FSIS will conduct a for-cause Food Safety Assessment (FSA) at the establishment that produced the product.

Even when establishments meet the performance standards, if FSIS *Salmonella* or *Campylobacter* verification testing data from an establishment show a high number of positives or serotypes of human health significance, FSIS may perform Incident Investigation Team testing or conduct a for-cause FSA that includes collection of samples or take other appropriate actions (additional sanitary dressing verification procedures) at the establishment that produce the product.

**Workshop 2: *Salmonella* and *Campylobacter* Performance Standards**

1. How do IPP document the *Salmonella* and *Campylobacter* performance standard verification sampling task?
2. Match the correct Category with its description.

a. Category 1
b. Category 2
c. Category 3

_____ has exceeded the performance standards during any completed 52-week moving window

_____ has achieved 50 percent or less of the performance standard during all completed 52-week moving windows

_____ met the standard for all completed 52-week moving windows but has results greater than 50 percent of the standard during any completed 52-week moving window
Hands-on Exercise: PHIS Instructions

Working independently, log into PHIS. You will:

- Add the (HC_CH_CARC01) - HACCP Verification for Young Chicken Carcasses sampling verification task to the calendar, and
- Complete the task.

Use the following instructions as needed. If you need further instructions, consult the PHIS Quick Reference Guide.

Logging in to PHIS

- When PHIS comes up, log in as:
  ➢ User name: Cindy Soundly

Add the Sampling (HC_CH_CARC01) - HACCP Verification for Young Chicken Carcasses Sampling Verification Task to the Task Calendar

1. Left click on “Task Calendar” from the Navigation menu on the Home page, then left click the “down arrow” in the box next to “Select Establishment” and select “Novosibar”; in the box next to “Filter Task by” select “Lab Sampling”

2. In the “Task Name” column, scroll through the list until you find a directed (HC_CH_CARC01) - HACCP Verification for Young Chicken Carcasses sampling task with the appropriate start and end dates

3. Find the “Assign” column for the task, and then left click on the “Add” link for the (HC_CH_CARC01) - HACCP Verification for Young Chicken Carcasses sampling task

4. In the Lab capacity pop-up window use the calendar icon to select today’s date in the Collection Date and Parcel Pickup Date boxes and left click on the “Save” button.

5. After scheduling the sample, collect the sample.

Documenting the (HC_CH_CARC01) Task Results

1. Scroll down to the “Task Calendar” panel, left click the “down arrow” in the box next to “Establishment” that has the word “all” and select “Novosibar”
2. Right click on the “(HC_CH_CAR01) task” you added to your task calendar

3. Highlight and left click “Document”

4. After the Sample Management-Sample Collection page opens
   - Enter all the appropriate information in each tab
   - In the Sample Collection Data Tab:
     - Select the “Passed and Shipped (by establishment)” in the Animal Status entry field
     - Type “N/A” in the Herd/Flock Owner and Address entry fields
   - Verify that the pertinent information is accurate, click Submit to Lab button to transmit the information
   - Click Print Form at the top right of the page. Affix the sample ID seal in the designated space at the top center of the form and follow the steps to ship the sample to the appropriate lab.
Attachment 1

FSIS Directive 10,250.1 describes the sampling steps appropriate to the product class sampled. For NRTE comminuted poultry products and raw chicken parts, IPP are to follow instructions as stated in FSIS Notice 31-15 and Notice 16-15, respectively. Following is a brief narrative for the procedures described in Directive 10, 250.1 that the IPP will be carrying out when collecting the samples.

General Sampling Procedures

It is important to use good aseptic sampling techniques and follow the step-by-step procedure when sampling. Information regarding the sampling procedure IPP use to collect samples for Salmonella testing is available in FSIS Directive 10,250.1, Chapter II, Section III.

If an establishment has an antimicrobial spray as a CCP in their HACCP plan, carcass samples are taken after the spray and prior to packaging or cut-up. If poultry carcasses are cut into major portions (e.g., front and rear halves) prior to entering the chill tank, equivalent pieces that make a whole bird can be selected and sampled for Salmonella testing. Ground product samples are collected after grinding and before final packaging. When possible, samples should be collected before spices or seasonings are added.

The sample location and time for the product identified for sampling (beef, chicken, or turkey) are randomly selected. The sampling area is sanitized. The FSIS sampler must wash and sanitize hands and arms to the mid-forearm, and then dry them.

Procedure for Collecting Young Chicken Rinsate

IPP are to take all necessary precautions not to contaminate any of the sampling supplies and are to discontinue the sampling procedure if a contamination event occurs that would compromise the integrity of the submitted sample. IPP are to review and follow the instructions in FSIS Directive 10,250.1, Attachment 1, How to Put On Sterile Gloves; and Attachment 4, How to Rinse a Young Chicken Carcass, for placing the chicken carcass in the large sterile plastic sample bag, adding pre-chilled Buffered Peptone Water (BPW), and thoroughly rinsing the bird.

IPP are to remove the chicken aseptically from the sample bag before collecting the 100 ml rinsate. To do this, carefully open the bag containing the bird. Work the plastic bag down around the carcass and firmly grip one leg, without touching the inside of the plastic bag while holding the bag with the one hand, carefully remove the bird from the bag with the other hand; and place the bird back on the conveyor or table.
IPP are to collect the 100 ml rinsate sample from the sample bag immediately. Remove the lid from the empty 120 ml sterile specimen jar container. Be careful not to contaminate the inside of the specimen jar or the lid, and do not allow the bag to contact the interior surfaces of the jar. Using the “V” formed by the bag at the lower corner as a pouring spout, carefully pour the rinsate into the open jar. Collect as much of the BPW rinsate as possible, but at least 100 ml. Place the cap back on the jar and check to be sure that the lid is securely in place. Place the collected and labeled sample container in a Ziploc-type bag. Hold the sample under refrigeration and FSIS control until shipment to the laboratory.

**Sampling Procedures for Turkeys**

The following sampling procedure instructions are for young turkey slaughter establishments only. IPP that are assigned to such establishments are to use the sample collection methods described in FSIS Directive 10,250.1. IPP are to take all necessary precautions not to contaminate any of the sampling supplies and are to discontinue the sampling procedure if a contamination event occurs which would compromise the integrity of the submitted samples.

IPP are to review and follow the instructions in FSIS Directive 10,250.1, Attachment 1, *How to Put On Sterile Gloves*; 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*, for general turkey sponging technique, but with the following additional instructions. Note that the turkey sample kit will contain two tubes of Buffered Peptone Water (BPW): one 10-ml tube marked “S” designated for *Salmonella* sampling and another 25-ml tube marked “C” designated for *Campylobacter* sampling.

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. 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.

Remove the cap from the smaller, 10-ml pre-chilled sterile BPW container marked “S”, 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. Press the wire closures back together to close the top of the sponge bag. Use hand pressure on the outside of the bag to massage the sponge until it is fully moistened. With the bag still closed push the moistened sponge to the top of
the bag. 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.

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

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. 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. You may need to “roll” the template from side to side as you sponge since the carcass surface is not flat.

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. Discard the template.

Carefully replace the sponge into the Whirl-Pak® sample bag 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.

Repeat the above steps using the other, larger, 25-ml pre-chilled sterile BPW container marked “C” 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.

Each sponge should be carefully secured in its own separate Whirl-Pak® sample bag (previously marked appropriately with either an “S” or a “C”).

Place bagged carcass sponges under refrigeration within five (5) minutes of collection. Place the collected and labeled sample bags in their own separate zip-lock type bag, which is provided, and hold under refrigeration and FSIS control until shipped.
## Attachment 2

### FSIS Form 8000-19: Sample Analysis Request Form

**U.S. DEPARTMENT OF AGRICULTURE**  
**FOOD SAFETY AND INSPECTION SERVICE**  
**SAMPLE ANALYSIS REQUEST FORM**

<table>
<thead>
<tr>
<th>COLLECTION INFORMATION</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. SAMPLE FORM ID:</td>
<td>100028969</td>
</tr>
<tr>
<td>2. PROJECT CODE:</td>
<td>HC11_BR</td>
</tr>
<tr>
<td>3. SAMPLE SOURCE:</td>
<td>Animal-Chicken-Broiler / Young Chicken Carcass Rinse</td>
</tr>
<tr>
<td>4. ANALYSIS:</td>
<td>Salmonella &amp; Campylobacter</td>
</tr>
<tr>
<td>5. ASSIGNED LAB:</td>
<td>Eastern Laboratory (Athens, GA)</td>
</tr>
<tr>
<td>6. SAMPLE SEAL LABEL#:</td>
<td></td>
</tr>
</tbody>
</table>

**ANIMAL INFORMATION**

| 13. SLAUGHTER DATE: | 10/31/2011 |
| 14. TAG NO:         |           |
| 15. ANIMAL STATUS:  | Passed and Shipped (by establishment) |
| 16. RVIS CASE NO:   |           |
| 17. TISSUE:         |           |
| 18. IN-PLANT TEST:  | N/A |
| 19. IN-PLANT TEST#: | N/A |
| 20. IN-PLANT TEST RESULT: | N/A |

**COLLECTION REMARKS:**

**QUESTIONNAIRE (IF Applicable)**

**SIGNATURE:**

**TITLE:**

**DATE:**

**TIME:**

**FOR LABORATORY USE ONLY**

<table>
<thead>
<tr>
<th>Date Received</th>
<th>Analyst Code</th>
<th>Receipt Temperature</th>
<th>Not-Analyzed Code</th>
<th>Not-Analyzed Explain</th>
</tr>
</thead>
</table>

PAGE 1 OF 1  
FSIS FORM 8000 - 19 (07/24/11)
Attachment 3

Salmonella Regulations, Livestock, 310.25(b)

Sec. 310.25 Contamination with microorganisms; process control verification criteria and testing; pathogen reduction standards.

(b) Pathogen reduction performance standard; Salmonella. (1) Raw meat product performance standards for Salmonella. An establishment’s raw meat products, when sampled and tested by FSIS for Salmonella, as set forth in this section, may not test positive for Salmonella at a rate exceeding the applicable national pathogen reduction performance standard, as provided in Table 2:

<table>
<thead>
<tr>
<th>Class of product</th>
<th>Performance Standard (percent positive for Salmonella)</th>
<th>Number of samples tested (n)</th>
<th>Maximum number of positives to achieve Standard (c)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steers/heifers</td>
<td>1.0%</td>
<td>82</td>
<td>1</td>
</tr>
<tr>
<td>Cows/bulls</td>
<td>2.7%</td>
<td>58</td>
<td>2</td>
</tr>
<tr>
<td>Ground beef</td>
<td>7.5%</td>
<td>53</td>
<td>5</td>
</tr>
<tr>
<td>Hogs</td>
<td>8.7%</td>
<td>55</td>
<td>6</td>
</tr>
<tr>
<td>Fresh pork sausages</td>
<td>N.A.</td>
<td>N.A.</td>
<td>N.A.</td>
</tr>
</tbody>
</table>

a Performance Standards are FSIS’s calculation of the national prevalence of Salmonella on the indicated raw product based on data developed by FSIS in its nationwide microbiological data collection programs and surveys. Copies of Reports on FSIS’s Nationwide Microbiological Data Collection Programs and Nationwide Microbiological Surveys used in determining the prevalence of Salmonella on raw products are available in the FSIS Docket Room.

b Not available; values for fresh pork sausage will be added upon completion data collection programs for those products.

(2) Enforcement. FSIS will sample and test raw meat products in an individual establishment on an unannounced basis to determine prevalence of Salmonella in such products to determine compliance with the standard. The frequency and timing of such testing will be based on the establishment’s previous test results and other information concerning the establishment’s performance. In an establishment producing more than one class of product subject to the pathogen reduction standard, FSIS may sample any or all such classes of products.

3 A copy of FSIS’s “Sample Collection Guidelines and Procedure for Isolation and Identification of Salmonella from Meat and Poultry Products” is available for inspection in the FSIS Docket Room.
(3) Noncompliance and establishment response. When FSIS determines that an establishment has not met the performance standard:

(i) The establishment shall take immediate action to meet the standard.

(ii) If the establishment fails to meet the standard on the next series of compliance tests for that product, the establishment shall reassess its HACCP plan for that product and take appropriate corrective actions.

(iii) Failure by the establishment to act in accordance with paragraph (b)(3)(ii) of this section, or failure to meet the standard on the third consecutive series of FSIS-conducted tests for that product, constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan, in accordance with part 417 of this chapter, for that product, and will cause FSIS to suspend inspection services. Such suspension will remain in effect until the establishment submits to the FSIS Administrator or his/her designee satisfactory written assurances detailing the action taken to correct the HACCP system and, as appropriate, other measures taken by the establishment to reduce the prevalence of pathogens.