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* and *Campylobacter* performance standards.
4. Describe how and when *Salmonella* and *Campylobacter* samples are taken.
5. Explain how FSIS uses the moving window approach when assessing process control.
6. Explain how to obtain completed *Salmonella* and *Campylobacter* results from LIMS-Direct and PHIS.
7. Recognize the description of the three process control categories.
8. Explain the Agency's actions when an establishment has failed a *Salmonella* performance standard for chicken and turkey carcasses, raw chicken parts, or not ready to eat comminuted poultry products.

References

1. FSIS Directive 7355.1, "Use of Sample Seals for Laboratory Samples and Other Applications".
2. FSIS Directive 10,210.5, "FSIS Sampling Data Reporting Through Laboratory Information Management System – Direct".
3. FSIS Directive10,250.1, "*Salmonella* and *Campylobacter* Verification Program for Raw Meat and Poultry Products", and the DVD titled, "Sampling Raw Meat and Poultry for *Salmonella*". There are a list of supplemental documents containing information and instructions about the agency's sampling programs.
4. PHIS Directive 13,000.1, "Scheduling In-Plant Inspection Tasks in the Public Health Information System (PHIS)".

5. PHIS Directive 13,000.2, “Performing Sampling Tasks In Official Establishment Using the Public Health Information System”.
6. PHIS Directive 5300.1, “Managing the Establishment Profile in the Public Health Information System (PHIS)”.
7. Federal Register Notice, Vol. 77, No. 235, December 6, 2012 (Docket No. FSIS 2012-0007), “HACCP Plan Reassessment for Not-Ready-to-Eat Comminuted Poultry Products and Related Agency Verification Procedures”.
8. Federal Register, Vol. 79, No. 108, June 5, 2014 (Docket No. FSIS-2012-0038), “Changes to *Salmonella* Verification Sampling Program: Analysis of Raw Beef for Shiga Toxin-Producing *Escherichia coli* and *Salmonella”*.
9. Federal Register Final Rule, Vol. 79, No. 162, August 21, 2014 (Docket No. FSIS-2011-0012), “Modernization of Poultry Slaughter”.
10. Federal Register Notice, Vol. 80, No. 16, January 26, 2015 (Docket No. FSIS-2014-0023), “Changes to the *Salmonella* and *Campylobacter* Verification Testing Program: Proposed Performance Standards for *Salmonella* and *Campylobacter* in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Related Agency Verification Procedures and Other Changes to Agency Sampling”.
11. Federal Register Notice, Vol. 81, No. 28, February 11, 2016 (Docket No. FSIS-2014-0023), “New Performance Standards for *Salmonella* and *Campylobacter* in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Changes to Related Agency Verification Procedures: Response to Comments and Announcements of Implementation Schedule”.
12. Federal Register Notice, Vol. 83, No. 218, November 9, 2018 (Docket No. FSIS-2018-0043), “Changes to *Salmonella* and *Campylobacter* Verification Testing Program: Revised Categorization and Follow-up Sampling Procedures”.
13. PHIS User Guide
14. “IPP Help” as a menu item under FSIS Applications; can access the following topics which contains all the pertinent information needed to collect samples under the different sampling project codes:
    - Raw Poultry Sampling Project Guidance
    - Follow-up Sampling *Salmonella*
    - Religious Exempt and Low Volume Poultry Carcass Sampling
    - Raw Pork Sampling Project Guidance
15. FSIS Notice 17-19, “Follow-up Sampling in Raw Poultry Establishments Not Meeting *Salmonella* Performance Standards”.
16. FSIS Notice 21-19, “Actions to Take in Raw Poultry Establishments Exceeding *Salmonella* Performance Standards”

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 (9 CFR 310.25(b)) are still applicable. Actually, the Agency tests all raw beef samples collected under the routine and follow-up sampling programs for *E. coli* O157:H7, non-O157 STECs, and *Salmonella* as per FSIS Directive 10,010.1, Revision 4.

The purpose of the microbiological performance standards, for the reduction of *Salmonella* in raw products, is to allow FSIS to verify whether establishments have effective process controls to address *Salmonella*.

Since the PR/HACCP Rule, FSIS has conducted additional prevalence and risk assessments for pathogens in FSIS regulated products, as well as revising the performance standards to meet public health goals. In addition, the agency has published a number of Federal Register Notices (FRN).

- 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)).

- 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). FSIS also announced that it would 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 February 2016, FSIS published new performance standards for *Salmonella* and *Campylobacter* in not ready-to-eat (NRTE) comminuted chicken and turkey products, in addition to raw chicken parts (FRN Docket

No. FSIS-2014-0023; February 11, 2016). The Agency also announced that it would begin assessing whether establishments meet the pathogen reduction performance standards for *Salmonella/Campylobacter* in raw chicken parts and NRTE comminuted chicken and turkey products. Furthermore, FSIS reassessed the minimum number of samples to assess process control for broiler carcass.

- In November 2018, FSIS is revising the categorization and follow-up sampling procedures in relation to the pathogen reduction performance standards. The establishment's category status will be based on FSIS results during the 52-week window and will no longer include follow-up sampling results as part of the moving window. In addition, the agency intends to use the revised categorization procedures for all establishments subject to a pathogen reduction performance standard for *Salmonella* or *Campylobacter*, including beef and pork establishments (in the future).

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. Besides reporting individual *Salmonella* and *Campylobacter* sample

results to establishments, FSIS posts nationwide *Salmonella* and *Campylobacter* data on its website on a quarterly basis.

In this module, we will focus our discussion on the *Salmonella* and *Campylobacter* testing program for poultry products.

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 ongoing scheduled sampling (routine sampling) employing a moving window approach to assess process control for all *Salmonella* and *Campylobacter* 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 Directive 5300.1, Revision 1 (2016). 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.

Poultry Products Eligible for Sampling

IPP will collect the following poultry samples, using a moving window sampling approach, to be **analyzed for both *Salmonella* and C*ampylobacter*** as described in Directive 10,250.1, and supplemental documents, as well as through the "IPP Help" menu under FSIS Application.

- 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 ground and other comminuted poultry sampling program

  NRTE comminuted poultry is any non-breaded, 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 Comminuted" product group (sausage, patties, meatloaf, and other non-breaded and non-battered comminuted products). 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).

Note: These products include final (consumer-ready) products or intermediary product for further processing as NRTE product that are destined for sale as NRTE product for consumers.

Note: The Agency began collecting samples of young chickens carcasses produced under a *religious exemption* and not bearing the mark of inspection. In addition, FSIS will be testing for *Salmonella* and *Campylobacter* on young chicken/turkey carcasses, as well as poultry products, from establishments that produce less than 1,000 pounds per day. These samples are being collected under different sampling project codes.

As explained in the January 2015 and February 2016 Federal Register Notices (Docket Number FSIS-2014-0023), FSIS began assessing whether establishments meet the pathogen reduction performance standards for *Salmonella* and *Campylobacter* in raw chicken parts. Furthermore, the Agency announced its plans to begin sampling additional raw chicken parts to gain additional information in the prevalence and the microbial characteristics of *Salmonella* and *Campylobacter* in those products (refer to the list of supplemental documents associated with Directive 10,250.1 and "IPP Help" menu under FSIS Applications).

- Raw Chicken Parts Sampling Program: instructs IPP to collect raw chicken parts (finished product) to be analyzed for *Salmonella* and *Campylobacter*. 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.

- Other Raw Chicken Parts Sampling Project (ORCPS): IPP will be collecting other raw chicken parts subject to sampling include hearts, whole or split gizzards, livers, necks, and quarter or half carcasses, together with both of those that are intact and those that are non-intact. These types of products will be analyzed for *Salmonella* and *Campylobacter*. 9 CFR 381.170(b) sets the requirements for specific cuts of poultry. This topic will not be discussed further in this module; refer to "IPP Help" menu under FSIS Applications – Raw Poultry Sampling Project Guidance for more information.

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 the entire 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 the establishment's 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, and NRTE comminuted poultry. *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. Subsequently, every week the 52-week period moves up one week adding a new week's testing result and

removing the oldest week's results (refer to the "Moving Window for Analysis of Testing Results" diagram).

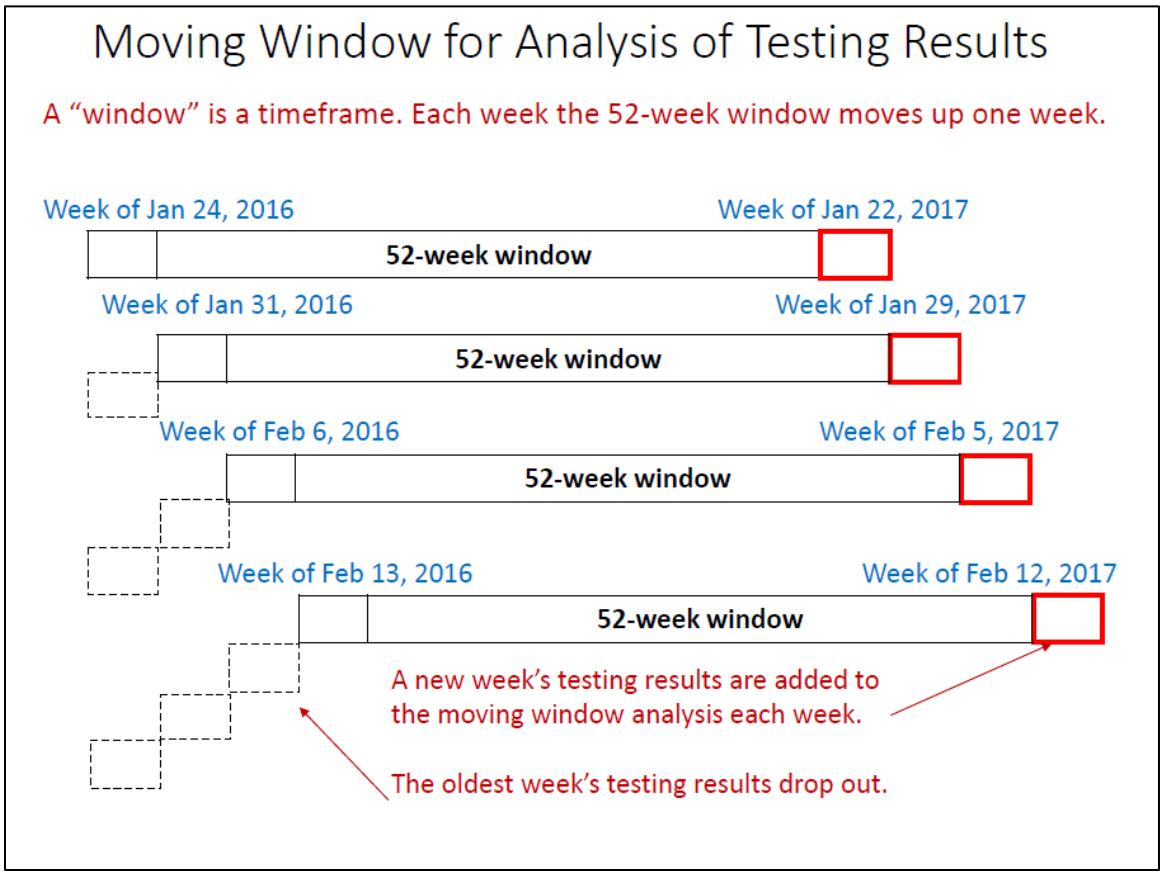

Diagram-shows how the moving window works

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 chart 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. In addition, FSIS will attempt to collect at least a minimum number of samples outlined in the chart below per year in order to assess process control in all establishments subject to

the performance standards. A test is considered positive when any *Salmonella* or *Campylobacter* organisms are found.

Salmonella/Campylobacter Performance Standards for Poultry

Product	Maximum Acceptable % Positive		Performance Standard		Minimum # of Samples to Assess Proc. Control	
	Salmonella	*Campylo-bacter*	*Salmonella*	*Campylo-bacter*	*Salmonella*	*Campylo-bacter*
Broiler Carcass[1]	9.8	15.7	5 of 51	8 of 51	11	10
Turkey Carcass[1]	7.1	5.4	4 of 56	3 of 56	14	19
Comminuted Chicken[2]	25.0	1.9	13 of 52	1 of 52	10	52
Comminuted Turkey[2]	13.5	1.9	7 of 52	1 of 52	10	52
Chicken Parts[3]	15.4	7.7	8 of 52	4 of 52	10	13

[1] The maximum acceptable percent positive for *Salmonella* and *Campylobacter* under the performance standards for young chicken and turkey carcasses is published in the FRN Docket No. FSIS 2014-0023 (2015).

[2] New performance standards published in the FRN Docket No. FSIS-2014-0023 (2016) using the larger 325 g analytical portion.

[3] New performance standards published in the FRN Docket No. FSIS-2014-0023 (2016) using the 4 lb. sample.

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 number of samples collected and positive results within the 52-week moving window. To 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 ((3 ÷ 26) X 100 = 11.5%). In this example, the resulting percent positive is less than 15.4, the acceptable percent positive for the performance standard for *Salmonella* in raw chicken parts. As such, the establishment would pass the performance standard.

In conclusion, establishments fail to meet the standards when verification samples are found to exceed the maximum allowed percent positive during a 52-week analysis period (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 supplemental documents, including applicable 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 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. Follow instructions outlined in the directive, supplemental documentations and guidelines.

- 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.

- 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.

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, supplemental documents 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, supplemental documents and guidelines, including published FSIS notices.

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 of 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 under the appropriate sampling project code is as follows:

- 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 the “IPP Help” menu (FSIS Applications) - Raw Poultry Sampling Project Guidance. The total weight of the two bags of samples should be approximately <u>two pounds</u>. This larger sample size will provide consistency as the Agency moves toward analyzing each sample for both pathogens.

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 with the laboratory assignment, 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. **Be careful** to send the sample to the appropriate laboratory as identified on the sample form; otherwise, it will be discarded. The lab analyzes the samples and the Office of Planning, Analysis and Risk Management (OPARM) 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	____	Ground chicken
____	Chicken carcasses	____	Ground pork
____	Duck carcasses	____	Ground turkey
____	Equine carcasses	____	Sheep carcasses
____	Geese carcasses	____	Swine carcasses
____	Goat 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 C*ampylobacter.*

_____ 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 uses a moving window to assess process control or to assess whether the establishment is meeting the *Salmonella* and/or *Campylobacter* performance standards.

_____ 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 recently modified its process control category classification system as follows:

Category 1 – Consistent Process Control: Establishments that have achieved 50 percent or less of the maximum allowable percent positive during the most recent completed 52-week moving window.

Category 2 – Variable Process Control: Establishments that meet the maximum allowable percent positive but have results greater than 50 percent of the maximum allowable percent positive during the most recent completed 52-week moving window.

Category 3 – Highly Variable Process Control: Establishments that have exceeded the maximum allowable percent positive during the most recent completed 52-week moving window.

Note: FSIS is not currently assessing the *Campylobacter* performance standards because is in the process of revising the performance standards in raw poultry products. The agency will not be taking any further action concerning to the sampling results until the new *Campylobacter* performance standards are in place.

Note: OPARM handles the data analysis and reporting; it also determines the official establishment category.

FSIS will be posting and updating category status on the FSIS website using the revised categorization procedures on a monthly basis.

http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/salmonella-verification-testing-program/.

The Agency also post aggregate reports showing the categories 1/2/3 distribution for each relevant product class subject to FSIS *Salmonella* testing, as applicable. FSIS has temporarily discontinue posting *Campylobacter* aggregate category results on the FSIS website until further notice.

- FSIS continue to post individual establishment reports for chicken and turkey slaughter establishments showing category distribution for current performance standards for poultry products produced.
- FSIS will also continue providing aggregate sampling results (not individual establishments) relative to process control for establishments producing young chicken or turkey carcasses, raw chicken parts, or NRTE comminuted chicken and turkey products.

Agency's Actions

As per recently published instructions (FSIS Notices 18-18 and 32-18), when an establishment is assigned to Category 2 or 3, IPP are to do the following:

- For Category 2 – IPP and supervisors will receive an alert entitled, "Warning: Product Exceed One Half of Performance Standard", through the PHIS dashboard. During the next weekly meeting, IPP will discuss with plant management that the results indicate variable control of *Salmonella,* as well as advise the establishment to make changes to avoid failing the performance standard; document the discussion in an MOI following instructions, as per published policy (Notice 18-18).

- For Category 3 – IPP and supervisors will receive an alert entitled, "Failure to Meet a *Salmonella* Performance Standard", through the PHIS dashboard. During the next weekly meeting, IPP will discuss with plant management the failure to meet the *Salmonella* performance standard and that FSIS will be collecting follow-up samples; document in an MOI (Notice 32-18). In addition, IPP are to determine if:

    - corrective actions have been identified and implemented as written, as per 9 CFR 417.3
    - establishment has reassessed its HACCP system and modified its HACCP plan, including supporting documentation (417.3(b) and 381.65(g))

FSIS will conduct follow-up samples and will only be scheduled for those raw poultry products subject to *Salmonella* performance standards (i.e., the number of positive samples within a specified timeframe exceeds the maximum acceptable for that product class); these aforementioned samples will be analyzed for both *Salmonella* and *Campylobacter*, where applicable (Notice 11-18).

IPP will receive a "New Follow-up Sampling Task" alert through the PHIS dashboard approximately 30 days after the Category 3 alert.

The follow-up samples will be assigned for raw poultry carcasses, chicken parts, and NRTE comminuted poultry products under the project codes below.

F_CH_CARC01 (for young chicken carcasses)
F_TU_CARC01 (for young turkey carcasses)
F_CPT_LBW01 (for raw chicken parts)
F_CH_COM01 (for NRTE comminuted chicken product)
F_TU_COM01 (for NRTE comminuted turkey product)

Note: At this time, FSIS will not implement follow-up sampling in establishments that do not meet the *Campylobacte*r performance standard in raw chicken parts or NRTE comminuted poultry products.

Specifically, either 16 or eight follow-up samples will be collected depending on the size and production volume of the establishment. IPP are to collect one follow-up sample per shift (when possible) as instructed in Notice 11-18. The Agency will analyze the follow-up sampling; FSIS will no longer include follow-up sampling results as part of the moving window when determining establishment category status.

IPP are to consider whether the overall pattern of inspection findings indicate a systemic problem with the establishment's HACCP system, or whether the establishment is slaughtering and/or processing poultry under insanitary conditions. IPP are to bring such concerns to their FLS to evaluate the need to take further enforcement action.

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

_____ have exceeded the maximum allowable percent positive during the most recent completed 52-week moving window

_____ have achieved 50 percent or less of the maximum allowable percent positive during recent completed 52-week moving window

_____ meets the maximum allowable percent positive but have results greater than 50 percent of the maximum allowable percent positive during the most recent 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_CAR01) 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:

     o Select the "Passed and Shipped (by establishment)" in the Animal Status entry field
     o 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 the "IPP Help" menu under FSIS Applications. 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 0n 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; including Attachment 1: *How to Put 0n 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

Form ID:100028969

SAMPLE ANALYSIS REQUEST FORM

– For Lab Use Only–

Place Sample Seal Label Here

100028969

COLLECTION INFORMATION

1. SAMPLE FORM ID:	100028969	7. ESTABLISHMENT ID:	P42
2. PROJECT CODE:	HC_CH_CARC01	8. ESTABLISHMENT NAME:	Safest and Best Poultry
3. SAMPLE SOURCE:	Animal-Chicken-Broiler / Young Chicken Carcass Rinse	9. COLLECTION DATE:	10/31/2011
4. ANALYSIS:	Salmonella & Campylobacter	10. SHIPMENT DATE:	10/31/2011
		11. COLLECTOR NAME:	Jane Doe
		12. COLLECTOR PHONE:	–
5. ASSIGNED LAB:	Eastern Laboratory	(Athens,GA)	
6. SAMPLE SEAL LABEL#:			

ANIMAL INFORMATION

13. SLAUGHTER DATE:	10/31/2011	21. HERD/FLOCK OWNER:	John Doe
14. TAG NO:		22A. ADDRESS LINE 1:	
15. ANIMAL STATUS:	Passed and Shipped (by establishment)	22B. ADDRESS LINE 2:	
		23. CITY:	Anywhere
		24. STATE:	TX
16. RVIS CASE NO:		25. ZIP CODE:	00000
17. TISSUE:			
18. IN-PLANT TEST:	N/A		
19. IN-PLANT TEST#:	N/A		
20. IN-PLANT TEST RESULT:	N/A		

26. COLLECTION REMARKS:

27. QUESTIONNAIRE ***(If Applicable)***

SIGNATURE: _____ **TITLE:** _____ **DATE:** _____ **TIME:** _____

FOR LABORATORY USE ONLY

Date Received	Analyst Code	Receipt Temperature	Not-Analyzed Code	Not-Analyzed Explain

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