

BACKGROUND AND QUESTIONS AND ANSWERS

The Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) final rule (July 1996) established pathogen reduction performance standards for *Salmonella* in raw meat and poultry products. Such standards are an essential component of FSIS's food safety strategy because they provide a direct measure of progress in controlling and reducing the most significant hazards associated with raw meat and poultry products. To verify that establishments are meeting the standards, FSIS collects raw meat and poultry product samples from establishments and tests the samples for *Salmonella*.

Performance Standards

The *Salmonella* performance standards are based on the nationwide prevalence of *Salmonella*, as determined by the FSIS Nationwide Microbiological Baseline Data Collection Programs and FSIS Ground Product Microbiological Surveys conducted over the past several years. From the performance standard for each specific raw product category, a sample set size was established, with a maximum number of positive samples allowed to meet the performance standard. For example, raw ground beef will be sampled each day the product is produced until 53 samples are collected and analyzed, with a maximum number of 5 positive samples allowed to meet the performance standard.

Pre-implementation Testing Phase

The Pathogen Reduction *Salmonella* Testing Program has two phases, pre-implementation testing and compliance testing. A pre-implementation sample set may be requested from any slaughter or grinding establishment that produces raw product covered by a standard prior to the establishment's coming under HACCP inspection. No enforcement action will be taken based on the results of pre-implementation testing; these results are for planning purposes only.

Compliance Testing Phase

Once an establishment is under HACCP inspection, pre-implementation testing stops and the eligibility for sampling under the compliance testing phase begins. There are two types of compliance testing.

1. Ongoing Random Testing – The purpose of the ongoing random testing is to assess the overall level of compliance with the *Salmonella* performance standards (310.25(b) and 381.94(b)) and to identify establishments that should be targeted.
2. **Targeted Testing** – Targeted testing consists of two types.
 - a. Product Specific – On a year-by-year basis the SCT will consider the sampling rates for types of products. Factors include overall industry compliance with the standards, public health concerns, and production volume. For example, this testing could target products that have a double digit *Salmonella* performance standard, i.e., broilers, ground chicken, and ground turkey.
 - b. Establishment Specific – This testing is conducted in establishments that fail to meet a performance standard.

Sample Collection

The collection of samples in establishments by inspection personnel is a significant Agency priority. The success of the sampling program is largely dependent on inspection personnel who accurately follow prescribed sampling techniques.

The self-instruction guidebook, *Salmonella* Analysis – Collecting Raw Meat and Poultry Samples, issued in FSIS Directive 10,230.5 and the video, Sampling Raw Meat and Poultry for *Salmonella*, provide all the information inspection personnel need to complete assigned sample collection and submission procedures. The guidebook and video have been provided to inspection personnel who are, or will be, responsible for collecting the samples. Inspection personnel should review these materials prior to collecting samples.

For compliance testing when an establishment is scheduled for *Salmonella* sampling, the Office of Public Health and Science sends inspection personnel the appropriate number of FSIS Form 10,210-7 to complete a sample set. The FSIS laboratory designated on the sample request forms send inspection personnel the sample collection supplies and shipping boxes. The inspector then collects one sample each day the establishment produces the product indicated on the sample collection form, as instructed in FSIS Directive 10,230.5.

When the laboratory analyzes a complete sample set, the DO will be notified of the set completion and results. The DO will notify the IIC of the results and instruct the IIC to stop sample collection. All unused supplies are returned to the appropriate FSIS laboratory and unused forms are discarded.

If there are questions regarding the Pathogen Reduction *Salmonella* Testing Program, contact the following:

Workload / scheduling – Your supervisor.

Sample Request Forms – Food Hazard Surveillance Division, **202- 501-7515**.

Supplies – FSIS Laboratory indicated on the FSIS Form 10,210-7; call the toll free sampling supply line, **1- 877-709-1982**.

General / technical – Technical Service Center, **1-800-233-3935**.

QUESTIONS AND ANSWERS

1. **Question:** How do inspection personnel know when to begin *Salmonella* sampling?

Answer: The Food Hazard Surveillance Division of OPHS will schedule plants and products for *Salmonella* sampling. If a plant has been selected for sampling, headquarters sends inspection personnel FSIS Form 10,210-7 and the FSIS Laboratory sends the sample boxes and supplies. Upon receiving the supplies and forms, inspection personnel review the sampling guidebook provided with FSIS Directive 10,230.5 and begin sampling.

2. **Question:** Why are more sample request forms received than needed to complete a sample set?

Answer: Occasionally, samples must be discarded upon arrival at the laboratory. Reasons for discards include, but are not limited to, leaking and delays in transit by the courier. The extra forms will be used to submit samples to replace any discarded samples. If a sample set is completed before running out of forms, the inspector will be notified by the DO to stop sampling and discard any extra forms.

3. **Question:** What should the IIC do if they run out of sample request forms but have not been notified that the sample set is complete?

Answer: Contact the Food Hazard Surveillance Division, **202-501-7515**, for additional forms. Do not use forms designated for another establishment that may be on the same patrol.

4. **Question:** Is it permissible for the establishment to take a companion sample to the FSIS *Salmonella* sample each day?

Answer: Yes. For chicken whole bird rinses, it is permissible to give the establishment the remainder of the rinse fluid after the 30 ml has been poured onto the sample container. For sponge samples of cattle, swine, or turkey carcasses the **entire** sponge and BPW must be sent to the FSIS laboratory. The establishment may take its own sponge sample from the same carcass, or a 25g sample of ground product from the same lot. In any case, the FSIS laboratory result is the official result for regulatory purposes.

5. **Question:** Should samples be collected for pork sausage or turkeys even though there is no performance standard for these products?

Answer: Yes. If scheduled, these products are being tested under pre-implementation testing until the performance standards are established.

6. **Question:** What does an IIC do if instructed to sample for a specific product not produced at all by the establishment?

Answer: Send the forms to the laboratory, marking one form in the code 60 "Product not Produced" box. Indicate what products are produced in that establishment to assist in planning future sampling.

7. **Question:** What does an IIC do if instructed to sample product that is rarely produced by the plant?

Answer: If the plant **typically** produces this product less than 26 times per year, return the forms to the laboratory with a note indicating this. If the plant **typically** produces this product at least 26 days per year, sample every day the product is produced. If 30 days pass and the product has not been produced, return **ONE** FSIS Form 10,210-7 to the lab with the code 72 box checked. Continue this procedure every 30 days until the product is produced.

8. **Question:** If an establishment produces ground beef every day and ground pork one day per week, why do the sample request forms indicate to sample ground pork?

Answer: The product indicated on the sample request forms is either randomly selected by the computer system or is a product being targeted by FSIS for sampling in any establishment producing that product. As long as the establishment typically produces the indicated product at least 26 days per year, as explained in question 7, it should be sampled. Any other raw product produced by that establishment and covered by a performance standard may be selected for sampling at a later date.

9. **Question:** If an establishment only produces the requested product on the second shift, which is too late for Federal Express pickup, should a sample be collected?

Answer: Yes. It is very important that all shifts, rails, chiller, coolers, and grinders have an equal chance of being selected for sampling. The IIC should coordinate the collecting and mailing of samples that occur during different shifts. Late production can be sampled, provided the following guidelines are followed:

Carcasses – If a carcass sponge (cattle, swine, or turkey) or chicken rinse sample cannot be shipped the same calendar day it was collected, randomly select the carcass for sampling and hold it, refrigerated. The sponge sampling or chicken rinse procedure is to be completed the next business day that overnight shipping can occur. The collection date, as recorded on FSIS Form 10,210-7, is the date on which the carcass is sponged or rinsed. **Remember: the sponge or rinse sample must be shipped on the day it is collected.**

Ground Product – Ground product samples can be held refrigerated until overnight courier can ship the sample.

10. **Question:** If an establishment only slaughters cattle (or swine) one day per week and the carcasses will not be in the cooler for at least 12 hours before the inspector's shift is over, does he/she have to return to the establishment the next day to perform the sample?

Answer: Yes, if at all possible, within the normal constraints of assignment and tour of duty. If this is not possible, collect and submit the sample on the same day as slaughter. These situations should be discussed with your supervisor. Additional guidance will be provided on a case-by-case basis by the TSC.

11. **Question:** Is mechanically separated product covered?

Answer: Not at this time. The definitions of the ground products covered under this testing program can be found in FSIS Notice 21-98, 6/9/98.

12. **Question:** How can the plant receive their sample set results by email?

Answer: Plant management can get an FSIS Form 10,230-2 from the DO and fax it to **202-501-0369**. Results will then be forwarded to the email address upon completion of a sample set.

13. **Question:** Page 3-2 of the *Salmonella* Guidebook specifies that partially skinned hogs can be sampled. Are fully skinned hogs eligible for sampling?

Answer: Yes. In the baseline study where swine carcasses were sponge sampled, any swine carcass was eligible for sampling.

14. **Question:** In addition to *Salmonella* compliance and pre-implementation testing, are other raw product samples being collected that may involve *Salmonella* testing?

Answer: Yes, the Microbiological Baseline Testing Programs. The following lists general information about these programs:

- The baseline programs are species-specific and generally last one year.
- Inspection personnel use FSIS Form 10,210-2.
- FSIS Form 10,210-2 indicates the week that the sample is to be collected.
- Inspection personnel follow sample collection procedures indicated on the form.
- The baseline programs are non-regulatory and no regulatory action will be taken.
- Results may be used to establish future *Salmonella* performance standards.
- The programs may include multiple samples and laboratory analyses.

Also, from time to time samples may be requested for *Salmonella* (or other organism) analyses for special projects/studies. Inspection personnel may use FSIS Form 10,210-2 or FSIS Form 10,210-3. Specific instructions for the study will be provided.

If sample request forms are received for both HACCP (compliance or pre-implementation) AND baseline samples, take samples according to the following priority, as time permits:

1. HACCP Compliance
2. Microbiological baseline
3. HACCP pre-implementation

15. **Question:** How do inspectors document the *Salmonella* sampling procedure?

Answer: *Salmonella* sampling is a directed sampling procedure. It is documented as an unscheduled 05A03 on the process schedule and recorded as performed. In the case of noncompliance (sample set fails to meet performance standard), recording the procedure code is sufficient. There is no Basic or Other box to check on the NR for *Salmonella*, and there is no trend indicator.

16. **Question:** If an establishment grinds a product covered by a performance standard but then uses it to make fully cooked product, is the raw ground product sampled?

Answer: No. Ground product is only sampled if it leaves the establishment in the raw state. If the raw ground product is processed into a ready-to-eat product prior to leaving the establishment it is not sampled. However, if the establishment further

processes some of its raw ground product but ships some in the raw state, the ground product shipped in the raw state is subject to sampling.

17. Question: Should the District Manager contact an establishment before a sample set is complete and, if so, when?

Answer: The District Managers are not required to contact an establishment before a sample set is complete. However, the Sample Coordinating Team (SCT) recommends that the DO contact an establishment whenever the number of positives exceeds 50 percent of "c," and a substantial number of samples are needed to complete the set. The SCT suggests 15 as a guideline for substantial number of samples because 15 represents a minimum of three weeks of testing and 15 is greater than 50 percent of "c" for all products in the testing program.

The purpose of the notification before the set is complete is to promote early corrective actions that will reduce pathogen levels. Therefore, a warning near the end of a set may serve no purpose. The District Managers should remember that the warning is not mandatory. They should use their judgment as to whether a substantial number of samples remain to complete the set, take into account the product being tested, and consider sampling frequency at the establishment.