

Pathogen Reduction - *Salmonella*

OBJECTIVES

To demonstrate mastery of Pathogen Reduction the trainee will:

1. Explain why *Salmonella* testing is used.
2. State who will conduct *Salmonella* testing.
3. Describe how and when *Salmonella* samples are taken.
4. Obtain completed *Salmonella* results from LEARN.

Salmonella Testing - Background

The *Healthy People 2010* objectives relates to a food safety target reducing infections caused by key foodborne pathogens. One of the objectives is to reduce the number of salmonellosis cases to 6.8 per 100,000 by 2010 compared to the baseline of 13.7 per 100,000 in 1997. FSIS contributes to this objective by regulating the meat, poultry and egg products industries. FSIS has established performance standards for *Salmonella* in classes of raw meat and poultry products. Inspectors collect regulatory sample sets from raw products (carcasses of cows/bulls, steers/heifers, market hogs, broilers, ground beef, ground chicken, and ground turkey). The *Salmonella* serotypes commonly associated with human illness, primarily S. Typhimurium, S. Enteritidis, S. Hidelberg, and S. Newport, have been found in samples of raw meat and poultry collected by FSIS. Recent Agency data show the percent positive in *Salmonella* sets of broilers (young chickens) increased from 11.5% in 2002 to 12.8% in 2003, and to 13.5% in 2004. Although the overall percentage of positive samples in verification testing is still below the nationwide baseline prevalence figures, this persistent upward trend is cause for concern. Other product classes have not shown this persistent upward trend, and the percentage of positive verification samples has declined for all three beef product classes. In response to this disturbing increase in the percent positive in *Salmonella* sample sets, FSIS issued a Federal Register Notice and held a public meeting to gather input. At the public meeting, FSIS announced steps to increase public health protection by reducing exposure of humans to *Salmonella* from meat, poultry and egg products.

- FSIS reports individual *Salmonella* sample results to establishments.
- On a quarterly basis, FSIS posts nationwide *Salmonella* data by product class on the Agency web site.
- FSIS is collecting samples in establishments slaughtering young turkeys.
- FSIS records each completed sample set into one of three categories – (1) consistent process control for *Salmonella* reduction with 50% or less of the performance standard; (2) variable process control for *Salmonella* reduction with 51% or more of the performance standard or baseline guidance, but still meeting the standard or guidance; and (3) highly variable process control for *Salmonella* reduction with greater than the performance standard or baseline guidance. FSIS targets its *Salmonella* sampling according to these categories. FSIS makes serotype information available to establishments as soon as possible, and publishes annual aggregate results for serotypes.
- FSIS published a *Salmonella* compliance guideline for the broiler industry.
- FSIS conducts *Salmonella* sub-typing for its testing program.
- FSIS will conduct additional baseline studies to measure the national prevalence of *Salmonella* on raw products.

***Salmonella* Testing – The Role of the Inspector**

Testing is conducted in plants by FSIS personnel, who collect both carcass and ground product samples.

The Agency's *Salmonella* performance standards for raw meat and poultry and for raw ground products are in §310.25(b) and §381.94(b). The goal of the *Salmonella* testing program is to protect the consumer from contaminated products, especially from fecal contamination, by verifying that each establishment's performance meets the *Salmonella* standards.

The Agency searched for an organism that could be detected using modern microbiological techniques. *Salmonella* was selected as the target organism because it is a commonly reported cause of foodborne illness and is present to varying degrees in all major species. Also, current lab methods can recover *Salmonella* from a variety of meat and poultry products.

FSIS requires that beef, swine, and chicken carcasses be sampled for *Salmonella* testing. Currently, there are only guidelines for turkey carcasses. Ground products, including ground beef, ground chicken, and ground turkey, are also sampled. The *Salmonella* testing performance standards set for industry are regulatory requirements.

Salmonella samples are collected using the sponge technique from beef, swine, and turkey carcasses. Sponge sites are the same as those used for generic *E. coli* sampling.

- For beef, the sample sites are the flank, the brisket, and the rump.
- For swine, they are the belly, ham, and jowls.
- For turkey, the sites are back & thigh.

Chickens are sampled using whole bird rinses.

Ground samples consist of 25 grams of the ground product. A sterile ring is filled (only **level with the top of the ring, not domed or over-filled**). The ring is **not** sent to the lab, only the ground product. Discard the ring.

If the plant irradiates its raw ground product, then FSIS Directive 7700.1, "Irradiation of Meat and Poultry Products", should be followed (if the HACCP plan states that the product will be irradiated, even off-site, then no sample of that product is collected).

The Agency might require that either the carcass or the ground product derived from carcasses be sampled in a single establishment that produces both products. However, only one type of product is sampled at a time (no concurrent *Salmonella* sets conducted in the same plant).

Performance Standards and Baseline Guidance Results

The pathogen reduction performance standard applies to establishments, 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 *Salmonella* contamination. Establishments do not have to hold product or recall product based on results of the *Salmonella* samples.

Salmonella performance standards are regulatory requirements. Samples are taken in sets and the results of an entire set are used to determine if an establishment is meeting the performance standards. So failure to meet *Salmonella* performance standards is based on whether or not a set passes, not on individual samples. The chart below shows the number of samples required to complete a sample set for the different species, and the maximum number of positive results allowed before a set fails to meet the regulatory standards. A *Salmonella* test is positive when any *Salmonella* organisms are found.

SALMONELLA PERFORMANCE STANDARDS

Class of product	Performance Standard (% positive for <i>Salmonella</i>)	Number of samples tested (n)	Maximum number of positives [allowed] to achieve Standard (c)
Steers/heifers	1.0	82	1
Cows/bulls	2.7	58	2
Ground beef	7.5	53	5
Hogs	8.7	55	6
Fresh pork sausages	N/A	N/A	N/A
Broilers	20.0	51	12
Ground chicken	44.6	53	26
Ground turkey	49.9	53	29
Turkeys	N/A	N/A	N/A

The chart above, taken from the regulations, shows that the performance standards specify a maximum number of positive test results (c) permitted in a specified number of samples (n) for each species and category of raw product. Here's how to use this chart. Consider steers and heifers. The performance standard is set at 1%. To meet this standard an establishment can have no more than one positive sample result (c) out of every set of 82 carcasses (n) sampled.

Table B. – *Salmonella* Baseline Guidance Results for Young Turkeys

Product class/method	Baseline prevalence (percent positive for <i>Salmonella</i>)	Number of samples in set	Maximum number of positives
Young turkey carcasses/sponge	19.6	56	13

Table B is from the Federal Register Notice (Docket 04-026N).

The baseline guidance results are not the same as performance standards that are regulatory requirements. The guidance is what the establishments should strive for to demonstrate process control. FSIS will use the sampling data results to determine the level of sampling required for these products.

Workshop: *Salmonella*

1. Select from the list below the species and types of product that must be tested for *Salmonella* **performance standards**.

- | | |
|--------------------------------------------|-------------------------------------------|
| <input type="checkbox"/> Beef carcasses | <input type="checkbox"/> Ground chicken |
| <input type="checkbox"/> Chicken carcasses | <input type="checkbox"/> Ground pork |
| <input type="checkbox"/> Duck carcasses | <input type="checkbox"/> Ground turkey |
| <input type="checkbox"/> Equine carcasses | <input type="checkbox"/> Sheep carcasses |
| <input type="checkbox"/> Geese carcasses | <input type="checkbox"/> Swine carcasses |
| <input type="checkbox"/> Goat carcasses | <input type="checkbox"/> Turkey carcasses |
| <input type="checkbox"/> Ground beef | |

2. Why is *Salmonella* testing done by FSIS?

Procedure 05A03

The IIC receives sampling supplies and forms (FSIS Form 10,210-7). FSIS personnel conduct procedure 05A03 by collecting samples at an unannounced time each day the product is produced until enough samples have been taken and analyzed to constitute a set of samples. Carcasses and ground product must be randomly collected based on time and shift. Samples should be randomly selected across a shift's production. Samples should also be randomly selected across shifts if more than one shift exists. The purpose of this sampling program is to verify the establishment's process control for all applicable products and for all shifts. Attachment 1 in this module describes the procedure for collecting samples.

Note: Random refers to when the samples are selected, not to when the sponging or rinsing is initiated or completed. The time entered for collection is when the carcass is removed from the line and the "date" is the day the carcass is actually sponged or rinsed, which could be the day after the carcass was removed from the line.

Once collected, samples are sent to the FSIS lab for testing. *Salmonella* test results only show the presence of the organism, not the number of organisms. If any *Salmonella* is found in the sample, the test result is positive. When the sample is positive, additional analyses are run to determine the *Salmonella* serotype. The Centers for Disease Control and Prevention annually publishes the 20 most common *Salmonella* serotypes that cause human illness (<http://www.cdc.gov/ncidod/dbmd/phlisdata/Salmonella.htm>). FSIS tests for these top 20.

FSIS inspection personnel should collect *Salmonella* samples in accordance with the step-by-step directions found in FSIS Directive 10,230.5. Samples are sent to the FSIS laboratories indicated on the form via Federal Express. The lab analyzes the samples and the Office of the Chief Information Officer (OCIO) tracks the data and results.

Salmonella sampling is a directed sampling procedure. Each time, it is documented as an unscheduled 05A03 on the Procedure Schedule and recorded as performed.

How to Get *Salmonella* Supplies and Sample Forms

When a sample set is scheduled but inadequate quantities of supplies or forms are received, the program employee should request additional materials. To obtain additional sampling supplies, e-mail the laboratory that sent the supplies. The employee should send an Outlook message using one of the following addresses.

Sampling Supplies – Eastern Laboratory
Sampling Supplies – Midwestern Laboratory

Sampling Supplies – Western Laboratory

For additional forms, program employees should request them in an Outlook message addressed to Sampling Forms - Headquarters. Forms are then sent from OCIO-DSMD (Office of Chief Information Officer – Data Systems Management Division).

In the e-mail, provide the establishment number, daytime phone number, project identification (if applicable) and the supplies or forms needed. Always cc the FLS.

How to Retrieve Sample Information from LEARN

Samples and the test results are tracked and posted in the Laboratory Electronic Application for Results Notification System (LEARN). Employees may access LEARN on FSIS computers. After logging onto the intranet, the employee can view *Salmonella* data by going to the following address:

<http://dchqintra/learn/welcome1.cfm>

Individual sample results will be posted on LEARN only after the analyses are complete. Information regarding individual sample results or individual establishment results can be accessed by following these instructions.

- Click on the web address listed above
- Enter the establishment number
- Click on Submit
- Click on Check for PR/HACCP Completed Set Results
- Click on Pass or Fail to see individual results

Samples for the set in LEARN are numbered based on the date the sponge, rinse or ground product is collected (i.e., collection date).

Negative samples normally take less time to analyze than positive samples. Therefore, samples posted in LEARN may not be listed in the same order in which they were collected. If sample 20 is positive and sample 21 is negative, sample 21 may be posted into LEARN before sample 20. Positive samples will also have serological testing, which adds to the time before posting.

Establishments may get the individual sample results via e-mail if their e-mail addresses are entered into PBIS. The IIC should enter the address if the establishment provides it. The IIC should still inform the establishment of the results he or she obtains from LEARN.

Additionally, FSIS posts quarterly summaries of plant set results on its website. In the past, the Agency posted this annually.

PREP Reports

The Pathogen Reduction Enforcement Program (PREP) is a database maintained by the OCIO. Numerous reports are generated and made available to the District Office regarding *Salmonella* sample set collection and results.

DESCRIPTION OF PATHOGEN REDUCTION ENFORCEMENT PROGRAM (PREP) REPORTS

- Schedule Report – This report notifies the District Manager (DM) and Frontline Supervisor (FLS) of establishments within their jurisdiction that have been mailed forms and supplies for *Salmonella* compliance testing. This report should be shared with the field inspection team to alert them to the scheduled sampling. Sample collection can be verified by the FLS through the Laboratory Electronic Application for Results Notification (LEARN) FSIS Intranet site.
- Set Full Report – This report notifies the DM, FLS, and inspection personnel that sufficient analyzable samples have been received in the lab to complete the sample set.
- Completed Set Report – This report notifies the DM, FLS, and establishment management that the set analysis is complete and whether the set passed or failed to meet the *Salmonella* performance standard for the tested product. This report is also accessible to the IIC at the establishment through LEARN. The IIC should share report results with establishment management.
- Non-Responders Report – This report periodically identifies the establishments under a DM's and FLS's jurisdiction that are scheduled for sampling but have not provided a sample or feedback in the previous 30 days. The DM should be able to account for each establishment on this list and be able to support the absence of sampling during this period.
- Current Testing Status Report - This report periodically identifies the establishments under a DM's and FLS's jurisdiction that are scheduled for sampling. It also provides the current set status, when sample collection began, how many samples have been analyzed to date, as well as when the most recent sample was submitted.

***Salmonella* Sets and Categories**

The set is the required number of samples to be tested for a product class (for example, for steers/heifers it is 82 and for ground beef it is 53). If the sample set meets the *Salmonella* performance standards or baseline guidance results, it passes. Sets that exceed the standards or guidance fail.

FSIS laboratories keep records of *Salmonella* test set results. To better use limited resources, FSIS stops sampling the *third* consecutive set if the maximum number of positives is exceeded, regardless of whether or not the set is complete. The plant will be scheduled for a new sample set (same product class) as soon as possible.

At the completion of each set, the DO sends an “end of set letter” to the establishment explaining the establishment’s status based on the overall set results. Each letter lists specific set factors: the number of *Salmonella* serotypes associated with human illness (high, average or low for the product class tested) and the timeframe for when the next sample set will begin at that establishment. These factors determine into which category the establishment is placed. There are 3 categories. The plant’s last 2 consecutive sample sets define the plant’s category.

Category 1 (Consistent Process Control) indicates process control which is 50% or less of the performance standard or baseline guidance. In order for FSIS to have confidence that the establishment does have control, the category is based on the last 2 consecutive sets. For example, the broiler standard is 12. If a broiler set had a total of 5 positive samples, this is less than half (6) of the maximum number of positives allowed to still meet the standard (12).

Category 2 (Variable Process Control) indicates that the plant had 51% or higher of the performance standard or baseline guidance, but did not exceed the maximum number of positives. In order for FSIS to have confidence that the establishment does have some control, although variable, the category is based on the last 2 consecutive sets. Establishments in this category demonstrate intermediate process control.

Category 3 (Highly Variable Process Control) shows that the set failed and the establishment’s controls are questionable.

Establishments in Category 3 will be sampled at a higher frequency than those in Categories 1 or 2.

The end of set letter tells the establishment when it can expect the next sample set for the same product to begin (Category 1 – 12 to 24 months, Category 2 – within 6 months, Category 3 – within 30 days). In addition, FSIS will randomly sample plants in Category 1 on a monthly basis to ensure process control is maintained.

Salmonella Set Failures

FSIS adopted pathogen reduction performance standards for *Salmonella* to verify that plant HACCP systems are effectively reducing contamination with this pathogenic microorganism. FSIS believes that the production of raw meat and poultry with *Salmonella* prevalence below the current national level is readily achievable with available technology and production methods.

When a set fails and the establishment is in Category 3, the District Manager may determine that an Enforcement, Analysis and Investigation Officer needs to conduct a Food Safety Assessment (FSA) at that establishment since its controls are questionable.

Pathogen Reduction – Salmonella Examples

Example 1

You are a CSI assigned to a large, two-shift broiler slaughter operation. Today, you receive shipping containers and sampling supplies from the Eastern Laboratory for *Salmonella* Performance Standard sampling set for broilers. Yesterday you received a set of FSIS 10,210-7 forms. As the IIC's designee for sample collection, you are aware that *Salmonella* sampling is a directed sampling procedure. You perform the procedure by selecting samples at random, unannounced times each day the product is produced.

Several months have elapsed since you were directed to collect samples. Throughout the sampling process, you have tracked the progress through daily monitoring of LEARN for sample receipt and individual sample results. You have submitted 53 samples to date. The 53rd sample was sent yesterday. LEARN indicates that two have been discarded.

Is it time to stop sampling?

Answer:

No. Do not stop sampling until the District notifies you (Set Full Report) that the sample set is complete.

Example 2

You are an IIC/CSI at Est. 00038M, a mature cattle slaughter plant. The plant is currently in the process of being sampled for cows/bulls *Salmonella* performance standard testing. Plant management tells you that they received an e-mail of the last sample test result, which was another positive. That gives the plant a total of 2 positives for the set so far. This puts the plant one over the 50% of the maximum number of positives allowed for meeting the standard. If there is another positive in the set, the plant will fail the standard.

Plant management recognizes the serious nature of this information. The plant establishes additional anti-microbial intervention measures after a reassessment of its 03J HACCP plan. The plant requests a suspension of the current *Salmonella* sampling program to allow them a "reasonable period of time to validate the efficacy of the newly established measures". They respectfully request that FSIS stops sampling for a month.

After consideration of the rationale provided by plant management, what actions should you take?

Answer:

You consider the rationale provided by plant management. You inform plant management that reassessment and modification are appropriate, but the collection of the sample set continues until completion. The individual results are provided so that the plant can make modifications if it chooses to do so.

Workshop: *Salmonella*

3. How do inspectors document the *Salmonella* sampling procedure?

4. Match the correct Category with its description.

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

_____ Failed last set

_____ Passed last 2 consecutive sets with less than half of the maximum positives allowed

_____ Passed the last 2 consecutive sets with more than half of the maximum positives allowed

Attachment 1

***Salmonella* Ground Sampling (05A03)**

It is important to have good aseptic sampling techniques and follow the step-by-step procedure when sampling. The procedure FSIS personnel use to collect samples for *Salmonella* testing is the same aseptic procedure used by plant personnel to collect carcass sponge samples. Information regarding sampling is available in FSIS Directive 10,230.5, Amendment 1.

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 up prior to entering the chill tank, any 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.

Open the Whirl-Pak® filter bag identified with a pink fluorescent label and set it aside. Open the sterile bag containing the 25 gram sample ring by pushing the plastic-wrapped ring up to the top of the bag without touching the plastic wrap or the inner surface of the bag. Then the bag and its contents are set aside on a sterile surface.

The sampler puts on the sterile gloves. The sampler then removes the sterile plastic-wrapped ring template from the bag, without touching the outside of the bag or any other nonsterile surface.

The sterile tape or seal on the plastic wrap is opened. The ring is unwrapped. The sterile sheet is placed on the sanitized work surface. The ring is placed in the center of the wrap.

Without touching anything but the sample and the ring, the sampler collects enough raw ground product to fill the ring. Ground product is selected from various portions of the batch to ensure that the sample is representative of the product. On a sterile surface the sample is firmly packed into the ring (**do not over-fill the ring, just make product level with the top**), eliminating air pockets. The sample is packed until it is even with the top of the ring. The rings are designed to collect 25 grams of product, the required sample size for the laboratory analysis.

The filled ring is lifted from the sheet and held over the open Whirl-Pak bag. With a gloved finger the sampler pushes the ground product out of the ring into the bag. Do not include the ring with the sample or the sample will be discarded.

Excess air is expelled and the top of bag is folded over 3 to 4 times. It is sealed.

Attachment 2

Salmonella Regulations, Livestock, 310.25(b) and Poultry, 381.94(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 2--*Salmonella* Performance Standards

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

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\

 \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.

Sec. 381.94 Contamination with Microorganisms; process control verification criteria and testing; pathogen reduction standards.

(b) Pathogen reduction performance standards; Salmonella.

(1) Raw poultry product performance standards for Salmonella. (i) An establishment's raw poultry 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 2.--Salmonella Performance Standards

Class of product	Performance Standard (per cent positive for Salmonella) ^a	Number of samples tested (n)	Maximum number of positives to achieve Standard (c)
Broilers.....	20.0%	51	12
Ground chicken.....	44.6	53	26
Ground turkey.....	49.9	53	29
Turkeys.....	^b N.A.	N.A.	N.A.
Squabs.....	^b N.A.	N.A.	N.A.
Ratites.....	^b N.A.	N.A.	N.A.

^a Performance Standards are FSIS's calculation of the national prevalence of Salmonella on the indicated raw products based on data developed by FSIS in its nationwide microbiological baseline 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; baseline targets for turkeys, squabs, or ratites will be added upon completion of the data collection programs for that product.

(2) Enforcement. FSIS will sample and test raw poultry 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\

\3\ A copy of FSIS's "Sample Collection Guidelines and Procedure for Isolation and Identification of Salmonella from Raw 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.

(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.