FSIS Guideline: Modernization of Swine Slaughter Inspection

Developing Microbiological Sampling Programs in Swine Slaughter Establishments

September 2019

This guideline is designed to help swine slaughter establishments (especially small and very small) meet the sampling requirements under the final rule to modernize swine slaughter inspection.

This guideline is designed to assist all swine slaughter establishments, regardless of swine class to:

- Develop a microbiological sampling plan;
- Use microbial test results to assess their ability to maintain process control; and
- Make process control decisions throughout the swine slaughter process.

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This document follows the procedures for guidance documents in the Office of Management and Budget's (OMB) "Final Bulletin for Agency Good Guidance Practices." More information can be found on the Food Safety and Inspection Service (FSIS) webpage:

> https://www.fsis.usda.gov/wps/portal/footer/policies-and-links/significant-guidance-documents.

This is the revised version of the document titled *FSIS Guidance: Modernization of Swine Inspection System - Microbiological Sampling in Swine Slaughter Establishments* and reflects comments received during the comment period for the Modernization of Swine Slaughter Inspection Proposed Rule.

This guideline represents FSIS's current thinking on this topic. FSIS encourages establishments to use it to comply with requirements that apply to all establishments that slaughter swine.

The information in this guideline is provided to assist swine slaughter establishments (especially small and very small) and is not legally binding from a regulatory perspective.

Purpose of this Guideline

The purpose of this guideline is to assist all swine slaughter establishments, regardless of swine class, to comply with new microbiological sampling and analysis requirements that apply to all official swine slaughter establishments as published in the final rule "Modernization of Swine Slaughter Inspection."

Establishments may also find the information in this guideline helpful for developing their sampling plan programs prior to the implementation of the final rule. Note that this guideline includes a list of references as additional resources on technical concepts specific to the development of a microbiological sampling plan.

An establishment can always seek guidance from State HACCP contacts, coordinators and University extension specialists on developing and maintaining written sanitary dressing procedures, developing a written microbiological sampling plan, developing sample collection procedures, and using statistical process control to evaluate process control.

Changes from Previous Version

FSIS made changes throughout the guideline to clarify information and recommendations. In addition, FSIS made the following specific changes to the guideline to reflect changes in the final rule and comments received during the comment period for the proposed rule:

- Removed the word “compliance” from the document title and throughout the document to clarify that this document does not constitute regulatory requirements.
- Removed all references to pre-operational environmental sampling, consistent with changes to the final rule.
- Moved example control charts to Appendix 2 and clarified the recommendations for using such control charts without defining the specific format for displaying the data.
- Added Table 2 - Indicator Organism Optional Upper Control Limits for Market Hog Carcasses to replace the previous Table 4 - Indicator Organism Geometric Mean Values for Market Swine, providing better guidance for establishments that may want to use data from the 2011 FSIS Market Hog Baseline Survey to set their upper control limits.

Questions Regarding Topics in this Guideline

FSIS recommends that users who have questions regarding the information covered in this guideline search the publicly posted Questions & Answers (Q&As) in the askFSIS database or submit questions through askFSIS. Documenting these questions helps FSIS improve and refine present and future versions of the guideline and associated issuances.

When submitting a question, use the **Submit a Question** tab, and enter the following information in the fields provided:

Subject Field:	Enter **Swine Modernization Sampling Guideline.**
Question Field:	Enter question with as much detail as possible.
Product Field:	Select **General Inspection Policy** from the drop-down menu.
Category Field:	Select **Sampling** from the drop-down menu.
Policy Area:	Select **Domestic (U.S.) Only** from the drop-down menu.

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

FSIS Guideline: Modernization of Swine Slaughter Inspection

Developing Microbiological Sampling Programs in Swine Slaughter Establishments

Microbial Sampling Requirements Addressed by this Guideline

Livestock, including swine, have been identified as reservoirs for pathogens. The intestinal tract, mouth, skin, and hooves of swine can contain pathogens. Pathogens can be transferred to the carcass during the slaughter process and to pork parts throughout processing. Slaughter establishments typically employ a variety of controls to prevent, eliminate, or reduce pathogens during slaughter and processing.

In the food production environment, "control measures can be applied to prevent an unacceptable increase in a hazard, eliminate it, or reduce it to an acceptable level" (*Scientific Criteria to Ensure Safe Food*. IOM, 2003). Under Hazard Analysis and Critical Control Points (HACCP) regulations, an establishment is required to have controls in place to properly monitor and maintain its food safety system. Controls includes **process control procedures** supported by **science-based standards** that prevent, eliminate, or reduce biological, chemical, and physical hazards. An establishment can determine if the food safety system demonstrates either effective process control or loss of process control by analyzing the measurable attributes that are tailored to its system.

One means for establishments to verify whether they maintain process control is through **microbiological testing** for **indicator organisms**. Microbiological sampling and testing identify the presence of enteric pathogens in the context of the establishment's production process and processing steps, thus providing a microbiological measure of process control in addition to observation of carcasses and parts to detect visible contamination. Through statistical process control, an establishment defines what, in this context, are its control limits (i.e., upper and lower control limits) for indicator microorganisms.

Process Control Procedures and Measurable Science-Based Parameters

An establishment should design its operating conditions to meet defined food safety outcomes. This includes process control procedures and measurable science-based standards that affect establishment operating conditions.

An establishment's process control procedures may include:

- Sanitary dressing procedures effectively implemented to prevent carcass contamination and to minimize cross-contamination;
- Procedures for decontamination of carcasses that become contaminated;
- Procedures to prevent the creation of insanitary conditions;

- Antimicrobial intervention treatments; and
- Implementation of other best practices (e.g., those described in FSIS guidance documents).

An establishment's measurable science-based standards or parameters may include:

- Sanitary dressing monitoring;
- Zero tolerance for visible contamination checks;
- Microbiological testing results, for indicator organisms (e.g., Aerobic Plate Counts (APC), *Enterobacteriaceae* (EB), generic *E. coli*, total coliforms) and pathogens (e.g., *Salmonella*); and
- Critical operational parameters for antimicrobial interventions (e.g., concentration, pH, temperature).

These procedures and parameters should be incorporated into the establishment's HACCP plan, sanitation standard operating procedures (sanitation SOPs), or other prerequisite programs (collectively referred to as the establishment's HACCP system).

Requirements for Written Procedures and Microbiological Sampling

Under the final rule to modernize swine slaughter inspection, all swine slaughter establishments, regardless of swine class, are required to develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens, and visible fecal matter, ingesta, and milk throughout the entire slaughter process and dressing operation. FSIS recommends establishments consider potential contamination sources, such as incised lymph nodes, intestinal rupture, and stick wounds, when designing its sampling plan (Garrido 2014, Vieira-Pinto 2005, Bonardi 2013).

To demonstrate the effectiveness of such procedures in their food safety systems, all swine slaughter establishments are required to sample and test for microbial organisms at prescribed locations and frequencies, and to analyze the results obtained to assess the establishment's ability to maintain process control. Swine slaughter establishments are required to incorporate their written procedures, including their microbiological sampling plans, into their HACCP system.

The final rule modernizing swine slaughter requires all swine slaughter establishments to:

- Develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal material throughout the entire slaughter and dressing operation. To demonstrate effectiveness of such procedures using their HACCP system (i.e., HACCP plan, sanitation SOPs, or other prerequisite programs), establishments are required to sample for microbial organisms and analyze results at prescribed locations and frequencies to assess the establishment's ability to maintain process control.

- Incorporate their written procedures, including their microbiological sampling plans, into their HACCP system (i.e., HACCP plan, sanitation SOPs, or other prerequisite programs).
- Maintain records associated with these procedures.

Microbial Sampling Plan for Carcasses

The final rule removed the requirement that swine slaughter establishments sample and test carcasses for generic *Escherichia coli* (*E. coli* Biotype I) to monitor process control and removed the codified *Salmonella* pathogen reduction performance standards for hogs and replaced them with the new sampling and testing requirements. The new sampling and testing requirements allow an establishment to develop a sampling plan that is tailored to its process and, consequently, allows for more effective monitoring of process control than the current generic *E. coli* criteria.

Predominant Species:

Establishments that slaughter more than one type of livestock must test the type of livestock slaughtered in the greatest number.

An establishment that slaughters swine should determine which microbial organism(s) will be most effective in assessing its process control when developing its sampling plan. Each establishment has a configuration and process unique to the facility, the food safety system in place, and the hazards deemed reasonably likely to occur. Appendix 1 highlights the key elements that an establishment should address as part of its written microbiological sampling plan and can be used by an establishment as a self-assessment tool.

FSIS recommends that an establishment choose one or more indicator organism that will provide meaningful data in assessing process control. Potential indicator organisms include APC, EB, generic *E. coli*, and total coliforms. FSIS recommends an establishment use APC because it is less specific than generic *E. coli* and provides more quantifiable data. Enumeration allows an establishment to plot these data on a process control chart and monitor trends in its data and process over time. The more quantifiable microbiological data available to an establishment, the better it can assess and subsequently control variations in its process (Williams 2015). In contrast, generic *E. coli* is a smaller group (subset) of the *Enterobacteriaceae* family of bacteria; analysis of samples for generic *E. coli* often results in numerous non-detectable results ("zero values") which makes it difficult for an establishment to detect changes in microbial load at different points in establishment's process, and to identify trends in its data to make process control decisions.

Sampling Frequency

Under the final rule, swine slaughter establishments, except for very low volume (VLV) establishments, will be required to collect pre-evisceration and post-chill carcass samples at a frequency of one sample each per every 1,000 head slaughtered. As described in the preamble of the rule, VLV establishments are those which annually

slaughter no more than 20,000 swine, or a combination of swine and other livestock not exceeding 6,000 cattle and 20,000 total of all livestock. As is stated in the preamble to the final rule, establishments that slaughter more than one type of livestock must test the type of livestock slaughtered in the greatest number.

Establishments must analyze one carcass sample at pre-evisceration and one carcass sample at post-chill per sampling event; these samples do not need to be from the same carcass. Samples must be collected and analyzed at a frequency of once per 1,000 carcasses, with a minimum of one sampling event during each week of operation. VLV swine slaughter establishments, starting June 1 of every year, are required to take a minimum of one post-chill carcass sample per sampling event during each week of operation. If, after consecutively collecting and testing 13 weekly carcass samples, VLV establishments can demonstrate that they are not exceeding their upper control limit for microbial organisms and that they are effectively maintaining process control, they can modify their sampling plans to collect carcass samples less frequently.

VLV establishments that slaughter swine and are operating under traditional inspection may choose to continue conducting generic *E. coli* testing at post-chill to meet the sampling requirements in the final rule. FSIS considers the requirements under the former regulations for generic *E. coli* testing of swine to be a "safe harbor" for assessing process control. Former provisions that FSIS considers to be integral to that safe harbor include the following:

A. Testing for generic *E. coli*, FSIS requires an establishment to collect a series of 13 samples, at a minimum, to be able to assess process control.

B. To collect the sample, the establishment must collect an excision or swab sample of the ham, belly, and jowl from the carcass at the end of the chilling process. FSIS Guideline: *Guidelines for Escherichia coli Testing for Process Control Verification in Cattle and Swine Slaughter Establishments* provides more detailed guidance on the sampling procedures.

Definitions

Pre-evisceration *refers to the location early in the slaughter process prior to evisceration of the hog.*

Post-chill *refers to a later point in the slaughter process after carcasses are chilled and all interventions have been applied prior to fabrication.*

C. Laboratories analyzing the samples should use a quantitative method for generic *E. coli* analysis that is approved and published: 1) as an official method of the Association of Official Analytical Chemists International (AOAC International) or 2) by a scientific body based on the results of a collaborative trial conducted in accordance with an internationally recognized protocol on collaborative trials and compared against the three-tube Most Probable Number

(MPN) method; this type of method must also agree with the 95 percent upper and lower confidence limits of the appropriate MPN index (9 CFR 310.25(a)(3).

Performance criteria are those that represent the highest expected microbial loads on carcasses when the slaughter process is under control. The generic *E. coli* baseline results, using the surface swab sampling technique, can serve as support to establishments that slaughter swine in assessing the effectiveness of their process, using their own test results (70 FR 8058).

An establishment may also choose to use the generic *E. coli* performance criteria defined in the Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule, also see Table 1 below, for samples collected using an excisional collection method. These generic *E. coli* performance criteria have been separated into three categories for process control verification: acceptable, marginal, and unacceptable. In the Pathogen Reduction/HACCP Regulation, "m and M" represent the 80th and 98th percentile of sample results, respectively, leaving 18 percent of the results in the marginal range based on the upper limits for the acceptable and marginal ranges.

An establishment is considered to be operating within the criteria when the most recent generic *E. coli* test result does not exceed the upper limit (M), and the number of samples, if any, testing positive at levels above (m) is three or fewer out of the most recent 13 samples (n) taken, as follows:

Table 1. Performance Criteria for Generic *E. coli* for Swine Carcasses Using Excisional Sampling

Lower limit of marginal range (m)	Upper limit of marginal range (M)	Number of Samples tested (n)	Maximum number permitted in the marginal range
10 CFU/cm^2	10,000 CFU/cm^2	13	3

Because each swine slaughter establishment will determine which microbial organism(s) will be most effective in assessing its process control when developing its sampling plan, additional indicator organism upper control limits are provided in Table 2. The upper control limits in Table 2, were determined from surface swab samples based on the FSIS Market Hog Baseline Study (MHBS) and may be used for all swine species; but establishments are not required to use this table. There may be some variability among swine classes. The information in Table 2 represents the 80th percentile limit for additional indicator organisms. Percentiles represent the percent of establishments that are below the associated number in the distribution of average bacteria indicators per establishment.

Table 2. Indicator Organism Optional Upper Control Limits for Market Hog Carcasses[d]

Indicator Organism	APCs		*Enterobacteriaceae*		Total Coliforms		*E. coli*	
Average CFU/cm²	Pre-evisceration	Post-chill	Pre-evisceration	Post-chill	Pre-evisceration	Post-chill	Pre-evisceration	Post-chill
	4200000	790	8,300	110	5,500	35	3,800	30
Distribution Percentile	80%		80%		80%		80%	

[d] FSIS MHBS, 2010 – 2011.

An establishment should aim for test results below those limits listed for its selected indicator organism at pre-evisceration and post-chill locations. Indicator organism results below the upper control limit shown in Table 2 indicate that the process is in control. FSIS recommends that the establishment plot its data on a control chart to evaluate its test results over time, and to evaluate process control and variability in its food safety system. Additionally, FSIS recommends that establishments monitor the log reduction between pre-evisceration and post-chill as an additional measure to evaluate process control.

Example: If an establishment has APC test results above 790 CFU/cm^2 at post-chill, its process is most likely out of control and the establishment should take corrective action to bring its process back under control. (*Compliance Guideline for Controlling Salmonella in Market Hogs, page 29*).

An establishment should evaluate its sampling data at a defined frequency and adjust its upper control limits to lower thresholds to reflect improved process control trends. It is not advisable that an establishment raise its upper control limits in response to upward trends in its sampling data since its upper control limits were initially calculated based on its process being in control.

Random Selection and Sampling of Carcasses

At a minimum, all swine slaughter establishments are required to collect carcass samples at the frequency specified in Table 3. Samples should be collected randomly at the frequency determined by the establishment as part of its sampling plan. If more than one shift is operating at the establishment, the samples can be taken on any shift. Variations have been found from samples collected on different shifts; therefore, it is important that the establishment ensure that all shifts have an equal opportunity to be selected for sampling.

An establishment should use a method for selecting a carcass for sampling that

includes the use of random numbers to ensure that sampling is not biased. Examples of methods include random number tables, calculator or computer-generated random numbers, or drawing cards.

The sampled carcass should be selected at random. If there are multiple lines, the establishment should randomly select the line for sample collection for that interval. Each line should have an equal chance of being selected at each sampling interval within the relevant time frame.

Carcasses should be selected at the identified points in the process. Official swine slaughter establishments, except for VLV establishments, must collect and analyze samples for microbial organisms at the pre-evisceration (i.e., the location early in the process prior to evisceration of the hog) and post-chill points in the process (i.e., the point in the slaughter process after all slaughter interventions are completed and the carcass has been chilled in the cooler). VLV establishments must collect and analyze samples for microbial organisms only at the post-chill point in the process.

Definitions

Hot-bone *refers to the process where carcasses (e.g., larger hogs and sows) are immediately deboned after slaughter prior to chilling.*

Establishments that bone their products before chilling (i.e., hot-boned products) must collect a pre-evisceration sample and a sample after the final wash instead of at post-chill, because these products are not chilled before further processing. All swine establishments must sponge or excise tissue from the ham, belly, and jowl areas. Following the application of an antimicrobial prior to the point of sample collection, a drip time of at least 60 seconds should be observed before sample collection to reduce antimicrobial carryover in the collected sample.

Table 3. Requirements for Microbial Sampling for Indicator Organisms in Swine Slaughter Establishments

Establishment Size Based on Volume	Microbial Sampling Requirement
Very low volume (VLV) **(Establishments that a**nnually slaughter no more than 20,000 swine, or a combination of swine and other livestock not exceeding 6,000 cattle and 20,000 total of all livestock.)	Starting June 1 of every year, establishments will collect a minimum of one post-chill sample during each week of operation. The sampling plan may be modified after 13 consecutive weekly samples demonstrate effective process control.
All other establishments	Establishments must analyze 1 sample collected at pre-evisceration and 1 sample collected at post-chill per sampling event. Samples must be collected at each location and analyzed at a frequency of one per every 1,000 carcasses, with a minimum of one sampling event pre-evisceration and post-chill during each week of operation. Note that the pre-evisceration and post-chill samples for each sampling event do not need to be taken from the same carcass.

As described in Table 3, under the final rule swine slaughter establishments, except for VLV establishments, are required to collect pre-evisceration and post-chill samples at a frequency of one sample each per every 1,000 carcasses. VLV establishments will be required to collect at least one post-chill sample during each week of operation, beginning June 1 each year. If, after collecting 13 consecutive weekly samples, VLV establishments can demonstrate that they are effectively maintaining process control, they can modify their sampling plans to collect samples less frequently.

Pre-Sampling Preparation and Aseptic Technique

Extraneous organisms from hands, clothing, sampling equipment, or the processing environment can contaminate samples and lead to erroneous analytical results. Aseptic sampling techniques should be followed to ensure accurate test results that are representative of the product and process.

Before beginning sample collection, it is important to assemble sampling supplies, such as sterile gloves, sterile sampling solutions, and sterile sampling sponges. Sterile sampling solutions, such as buffered peptone water (BPW) broth, should be stored according to the manufacturer's instructions; however, at least 1 day before sample collection, FSIS recommends that establishments check the solution's expiration date and other indicators of sterility based on the manufacturer's instructions.

An area should be designated as a staging site for preparing the sampling supplies. An easily sanitized surface, such as a stainless-steel table or wheeled cart, can be used. A small plastic tote may also be useful for transporting sampling supplies to sample collection sites.

Sterile gloves should be used when handling sterile sampling equipment (e.g., a sampling sponge) during the sample collection process. Care should be taken to prevent contamination of the external surface of the gloves prior to and during the sample collection process.

Sample Analysis

The establishment should ensure that the microbiological testing it conducts meets its food safety needs. An establishment needs to determine whether sample analysis will be performed by an outside laboratory or in its own microbiological testing laboratory on-site (if available).

Because of the costs and the logistics involved with maintaining an onsite microbiological testing laboratory, an establishment may choose to have its samples analyzed by an outside laboratory. FSIS has made available guidance to aid in the selection of a testing laboratory, *Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory*. This guidance document can assist an establishment when selecting a commercial or private laboratory to analyze its microbiological samples, the method used to analyze samples, and how the results are reported. The establishment should clearly communicate its needs to the testing laboratory and direct it to any necessary testing protocols or other guidance, including this document, that are available on the FSIS website. If an establishment selects a testing laboratory that does not apply appropriate testing methods or effective Quality Control/Quality Assurance (QC/QA) practices, it may not receive reliable or useful testing results to be able to support decisions made in its hazard analysis. The establishment is responsible for ensuring the appropriate analytical methods are used and should convey this information to the laboratory. FSIS has also made available a list of *Foodborne Pathogen Test Kits Validated by Independent Organizations* for the detection of relevant foodborne pathogens (i.e., *Salmonella*, *Campylobacter*, Shiga toxin-producing *E. coli*, including *E. coli* O157:H7, and *Listeria* spp., including *L. monocytogenes*). This list is updated periodically and is intended to be informational only. The list does not serve as an Agency endorsement or approval of any method or test kit.

FSIS recommends that an on-site microbiological testing laboratory be segregated from manufacturing areas and that access to the laboratory space be limited to prevent cross-contamination and assure the reliability of the test results. If the establishment tests for pathogens on-site, FSIS recommends that it have the following additional safeguards in place to ensure food safety and biosecurity:

- Follow requirements for Biosafety Level II laboratory operations as outlined in *Biosafety in Microbiological and Biomedical Laboratories* (BMBL);
- Restrict access to the laboratory to trained staff; and
- Ensure the laboratory is operating under the supervision of a qualified microbiologist or equivalent.

To obtain the most accurate results, samples should be analyzed as soon after collection as possible. If samples must be transported to an off-site laboratory, they should be shipped to the laboratory under refrigeration on the same day they are collected, via an overnight delivery or courier service. Multiple samples collected on the same day can be shipped together to the laboratory in the sample shipping container and should be analyzed individually and not composited into one sample.

To ensure sample integrity and an accurate bacterial count, a sample should arrive at the laboratory and the analysis initiated within 48 hours of collection. If the shipment and the initiation of the laboratory analysis cannot be accomplished within 48 hours of the sample collection, the carcass or product selected for sampling should be held under refrigeration and not sampled until the shipping and initiation of the sample analysis can be accomplished within 48 hours of sample collection. The same principle applies for samples that are analyzed in-plant: if the sample cannot be processed for testing within 48 hours of collection, the carcass selected for sampling should be held under refrigeration and sample collection delayed until the sample can be processed for testing within 48 hours of collection. FSIS recommends including the sample date and the date the laboratory started processing the sample to be included in the establishment records.

Sponge or excised tissue samples should not be held for an extended period prior to analysis. They should be analyzed in-plant within 48 hours or shipped on the day of collection for overnight delivery to the laboratory that will conduct the analysis shortly after the sample arrives. Sponge or excised tissue samples should be held at refrigerated temperatures, not frozen, and shipped cold to the laboratory in an insulated shipping container with frozen gel packs. Lastly, the identity and security of all microbiological samples should be maintained during shipping and analysis to ensure the integrity of the test results.

Recordkeeping

Under the final rule, swine slaughter establishments are required to maintain daily records sufficient to document the implementation and monitoring of the procedures to prevent fecal and microbiological contamination of product throughout the slaughter

process. Records may be maintained on computers if the establishment implements appropriate controls to ensure the integrity of the electronic data. Records must be maintained for at least 1 year and must be accessible to FSIS upon request.

To meet requirements, establishments need to maintain records sufficient to document the implementation and monitoring of sample collections; the testing procedures, including support for the adequacy of the testing frequency; and the test results. Records should include information, such as the:

- Time, date, and location of the sample collection;
- Sample collector's name;
- Name or description of the product or sample source; and
- Lot information and producer.

All entries should be dated and initialed by the sample collector immediately upon completion of the entry. If an outside laboratory is used for testing, then these records should also include sample shipment information, including sample identification information, shipment date and time, courier or other delivery service used, and shipment tracking information. The outside laboratory should maintain chain of custody and document the:

- Date the sample was received;
- Condition of the sample upon receipt, including sample temperature, if applicable;
- Date the analysis was started and completed; and the
- Test result.

Test results should also be recorded and linked to the sample collection records by a sample number, form number, or some other unique identifier. These records should be maintained in a way that ensures the integrity of the data. As noted above, these records can be maintained in an electronic format, provided there are measures in place to ensure the integrity of the information. These records should be readily accessible for review by the establishment and FSIS inspection program personnel upon request.

Using Statistical Process Control to Interpret Test Results from Carcass Sampling

Statistical process control provides a powerful mechanism for establishments to assess and interpret the data collected for ongoing HACCP verification. Statistical process control can provide an establishment with an early warning that its process may not be functioning as designed. This warning can allow an establishment to take corrective actions or make other process modifications to bring its process back into control. Statistical process control can also provide an establishment with reasonable assurance that its HACCP system is functioning as designed.

Establishments should consider available guidance and develop a statistically valid approach for interpreting sample results (Saini *et al.* 2011 and De Vries 2010). In cases where an establishment does not have the resources or capacity to develop its own statistical control limits or analytical procedures, establishments can utilize the results from the FSIS MHBS, provided in Table 2. The specific indicator organism limits for generic *E. coli*, APC, *Enterobacteriaceae*, and total coliforms correspond to the 80th percentile limit. FSIS compared the presence and levels of specific microbiological targets to determine whether significant differences existed between samples taken at pre-evisceration and post-chill. Percentiles represent the percent of establishments that are below the associated number in the distribution of average bacteria indicators per establishment. These indicator organism limits can be used by establishments to verify their process control. Given that samples collected per establishment in the FSIS MHBS were limited and the variation within individual establishments was high, the control limits in Table 2 are approximations.

Charting and Interpreting Test Results for Carcass Sampling

Specific techniques of statistical process control include the use of a control chart, which plots data over time but also displays an upper control limit for specific measurements and often a centerline, above and below which one would expect approximately an equal number of sample results, since the centerline is based on past sampling history. A sample result above the upper control limit would indicate the likely presence of a special cause of variation that should be addressed. Results within control limits indicate simply that the process is in control.

Control charts are used to:

A. Analyze and understand variables that affect the process;

B. Determine process capabilities; and

C. Assess effects of the variables on the difference between target and actual performance.

Test results should be plotted and evaluated in a series over time. The test result chart should be updated at a regular interval, ideally within the next business day following the reporting of test results by the testing laboratory. Every time a new test result is recorded, the oldest test in the series should be dropped from the moving window. For example, an establishment may choose to evaluate its test results in a moving window of 13 tests. The establishment would use this series of 13 tests to evaluate its process control over the period represented by the series of 13 tests. The control chart would be updated with each new test result reported, adding the new test result and removing the oldest test result on the chart. Refer to Appendix 2 below for hypothetical examples of process control charts.

Microbiological testing provides a measure of the extent of control at the step being evaluated and all preceding steps. By performing microbiological analyses at several points within a process it is relatively easy to identify the segment of the process where control has been lost. In addition, sanitary dressing verification and end-product testing (though not required) can provide an integrated measure of the performance of the entire process. Pre-evisceration and post-chill test results could be charted on the same graph with separate, corresponding upper control limits to better correlate the samples and calculate the log reduction between the two samples.

Actions in Response to Loss of Process Control

As part of its process control procedures, an establishment should define the actions it will take if the test results obtained exceed the limits it has set. The establishment should delineate what its actions will be, who will take each action, how the outcome of these actions will be documented, and how the actions will be verified.

FSIS has made available the Compliance Guideline for Controlling *Salmonella* in Market Hogs. The guideline summarizes potential control points for *Salmonella* in the pre- and post-harvest production process. Establishments should use this guide to improve management practices, to ensure effective sanitary dressing procedures and to assist in investigating events of apparent loss of process control. When an establishment makes changes at the appropriate locations in its process, process control should improve and result in the production of raw pork products that are within acceptable parameters, including indicator organisms and *Salmonella*.

If an establishment determines that the trends in its test results indicate a loss of process control, the establishment should act to investigate the root cause(s). As discussed in the previous section on process control, an establishment should consider how the different parts of its food safety system work together and how they affect the entire food safety system. To do this, establishments should evaluate its process control procedures, sanitary dressing practices, and sanitation procedures to determine whether the root cause(s) can be identified, and subsequently, take steps to correct the problem. This evaluation should include a review of an establishment's process monitoring records and its processes during normal operations. The establishment should consider any implementation problems it has encountered or changes in procedures or practices, such as sanitary dressing procedures, including but not limited to:

- Procedures for routine cleaning and sanitizing of equipment, including hand tools used to remove contamination or to make cuts into the carcass;

- The design, configuration, and calibration of equipment to ensure proper function within operational parameters to prevent contact between carcasses and parts, and prevent contamination of carcasses;

- Employee hygiene practices, such as ensuring employees frequently wash hands, equipment, utensils, and aprons that come in contact with carcasses, and that employees are properly trained when there are new or substitute employees on the line; and

- The implementation of antimicrobial or mechanical intervention treatments, such as carcass washes, sprays, or brushes, in accordance with the limits selected and supported by the establishment, including effective application to ensure coverage of the entire carcass.

Following its investigation, the establishment should respond to its findings by deploying appropriate decontamination procedures and antimicrobial intervention treatments, as necessary, to address contamination that may have occurred on carcasses or parts. The establishment should also take steps to initiate any necessary equipment repair or recalibration and employee training, when identified as a root cause for loss of process control.

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Congressional Review Act

Pursuant to the Congressional Review Act at 5 U.S.C. 801 et seq., the Office of Information and Regulatory Affairs has determined that this guideline is not a “major rule,” as defined by 5 U.S.C. 804(2).

Appendix 1: Microbiological Sampling Plan Self-Assessment Tool

The self-assessment tool below is designed to assist establishments in designing a sampling plan and selecting a testing laboratory. A regulated establishment should ensure that microbiological testing meets its food safety needs. Establishments should clearly communicate their needs to the testing laboratory and direct them to any necessary testing protocols or other guidance.

1. Written Microbiological Sampling Plan

a. Sample Collection

- ❑ Procedure for random selection of carcasses for sampling
- ❑ Location within process where samples are collected
  - ❑ Pre-evisceration
    - ❑ Bleed Out
    - ❑ Other
  - ❑ Post-chill
- ❑ Frequency of sample collection
- ❑ Aseptic technique for gloving and sample collection
  - ❑ Description of sample collection procedure
- ❑ Designated, trained employee to collect the sample
- ❑ Date and time collected

b. Sample Handling and Shipping

- ❑ Proper sample handling and packaging to ensure sample integrity
  - ❑ Sample identification
  - ❑ Held under refrigeration/not frozen
  - ❑ Packed in an insulated shipping container with cold packs
  - ❑ Shipped to the testing laboratory on same day as collected
- ❑ Name of person or service (e.g., FedEx or courier service) transporting the sample
  - ❑ Chain-of-custody documentation when samples transported from the establishment to an off-site laboratory (e.g., tracking number used by a delivery service such as FedEx or courier)
- ❑ Validated holding time met (time from collection to analysis)

c. Testing Method and Test Results Reporting

- ❑ Description of the testing method used by laboratory
- ❑ Microbiological test results report received from testing laboratory
  - ❑ Results reported in appropriate units of measure
- ❑ Test results recorded on a control chart (moving window format)
- ❑ Interpretation of results based on defined process control criteria
  - ❑ Acceptable
  - ❑ Unacceptable
- ❑ Actions taken in response to test results and trends in results over time

2. Testing Laboratory

a. Selecting a Microbiological Testing Laboratory

Establishments should refer to the FSIS *Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory* for guidance on selecting a microbiological testing laboratory. The checklist provided in the guidance is intended to assist establishments to determine whether a microbiological laboratory can produce accurate and reliable results.

Some general criteria to consider in selecting a testing laboratory include:

- ❑ Personnel (i.e., training, expertise)
- ❑ Facilities
- ❑ Equipment
- ❑ Operations
- ❑ Analytical methods

a. Laboratory Testing Method

FSIS has made available a list of *Foodborne Pathogen Test Kits Validated by Independent Organizations* for the detection of relevant foodborne pathogens (*i.e.*, *Salmonella*, *Campylobacter*, Shiga toxin-producing *E. coli*, including *E. coli* O157:H7, and *Listeria* spp., including *L. monocytogenes*). This list is intended to be informational and is not an endorsement or approval of any particular method, regardless of its inclusion in the list. Some general criteria to consider when selecting a method include:

- ❑ Sample size analyzed
- ❑ Microorganism tested for (e.g., *Salmonella*, APC, generic *E. coli*)
- ❑ Analytical method used (e.g., AOAC, NordVal)
- ❑ Date test was received at the laboratory
- ❑ Date analysis was started
- ❑ Date analysis was completed
- ❑ Analytical results recorded and reported to establishment
- ❑ Corrective actions related to test results, such as laboratory error, unacceptable sample temperature upon arrival

Appendix 2: Process Control Chart Examples

Charts 1-5 below are hypothetical control charts. Establishments are not required by regulation to display data in the represented chart format. FSIS does not require a specific format for data analysis; however, this type of display is commonly used. The data shown in these charts are for example purposes only and not intended to be a measure of comparison for raw, establishment data. These data plots show hypothetical examples of using microbiological test results, collected over time, to verify the effectiveness of a food safety system (Buchanan 2000). Chart 1 depicts microbiological results in a well-controlled system. Charts 2 through 4 depict microbiological results when there is loss of process control with the following different patterns: excessive variability (Chart 2); gradual process failure (Chart 3); abrupt failure (Chart 4); and recurring transitory failure (Chart 5).

***NOTE:** *The maximum acceptable level is not an accurate number; refer to Table 2 above for the upper control limit for different indicator organisms or to the establishment's support on file.*

Chart 1: System Under Control

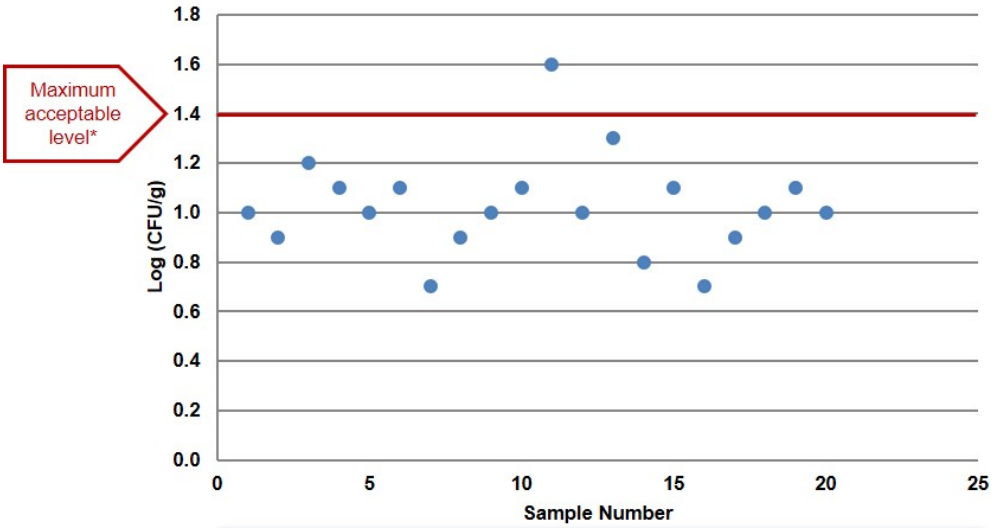

Chart 1 depicts a pattern of microbiological sampling results that would be seen in a well-controlled system with a process under control. In a well-controlled system, the majority of test results will be clustered around a central value. It is important to note that even in a well-controlled system; there is some frequency of isolated results above the acceptable level.

Chart 2: Lack of Process Control Due to Excessive Variability

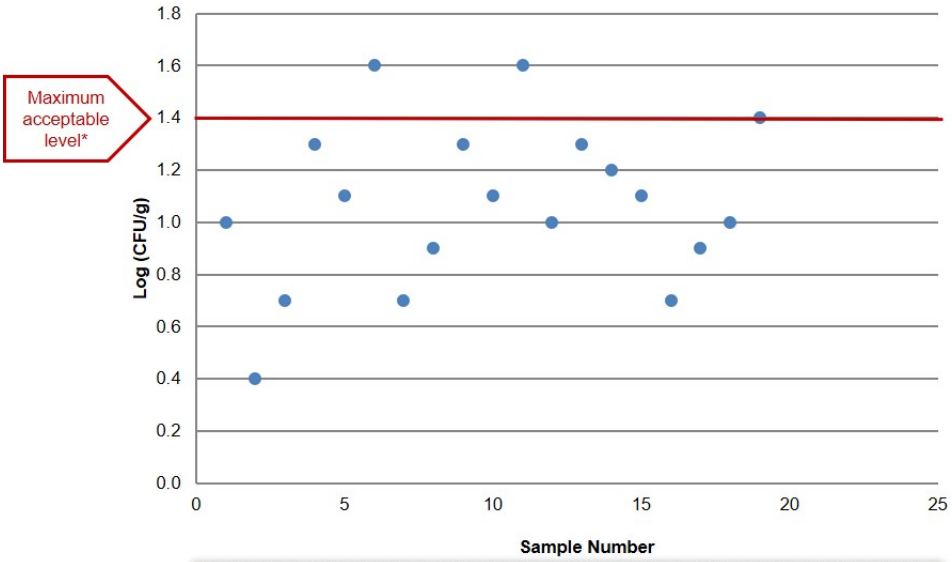

Chart 2 depicts a loss of process control due to excessive variability. This is reflected in both an increased number of results above the maximum acceptable level and an increase in the scatter of points below the maximum acceptable level. This chart suggests either a loss of control at a critical control point or the existence of another critical control point that had not been identified and controlled.

Chart 3: Loss of Process Control Due to Gradual Process Failure

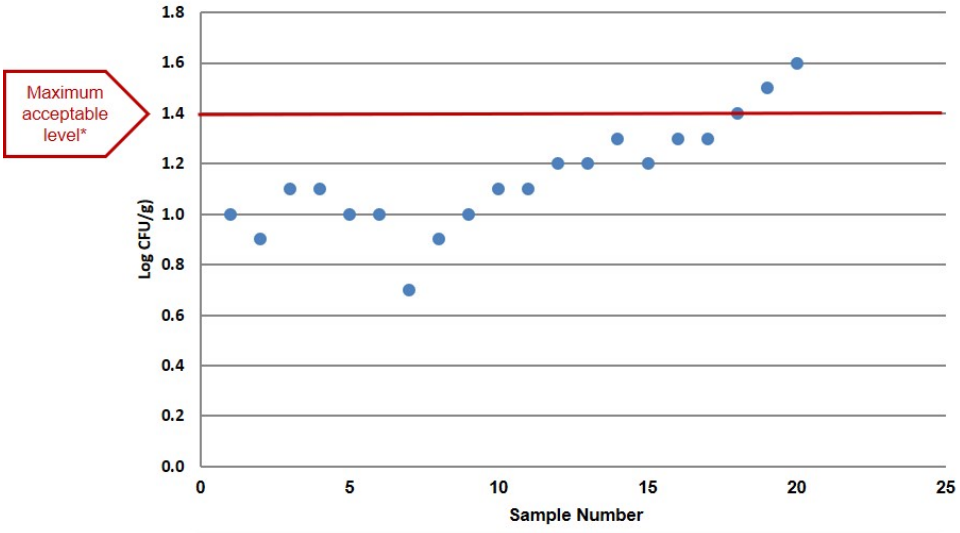

Chart 3 depicts a situation where a component of the process is losing its effectiveness over time. This loss of process control is apparent by the upward trend in the data points toward the maximum acceptable level.

Chart 4: Loss of Process Control Due to Abrupt Failure

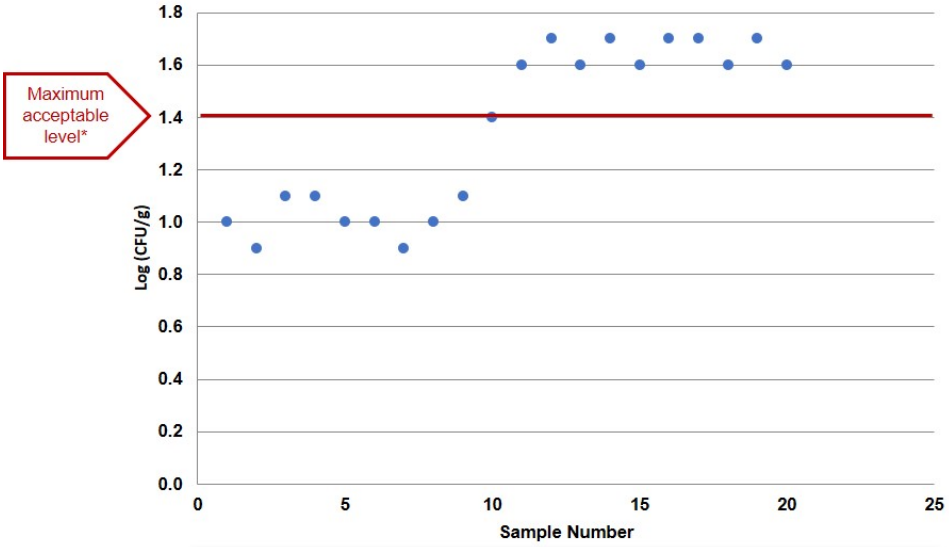

Chart 4 depicts a catastrophic loss of process control. This pattern of test results would be encountered in a situation such as an abrupt failure of a key piece of equipment, such as an antimicrobial wash cabinet.

Chart 5: Loss of Process Control Due to Recurring Transitory Failure

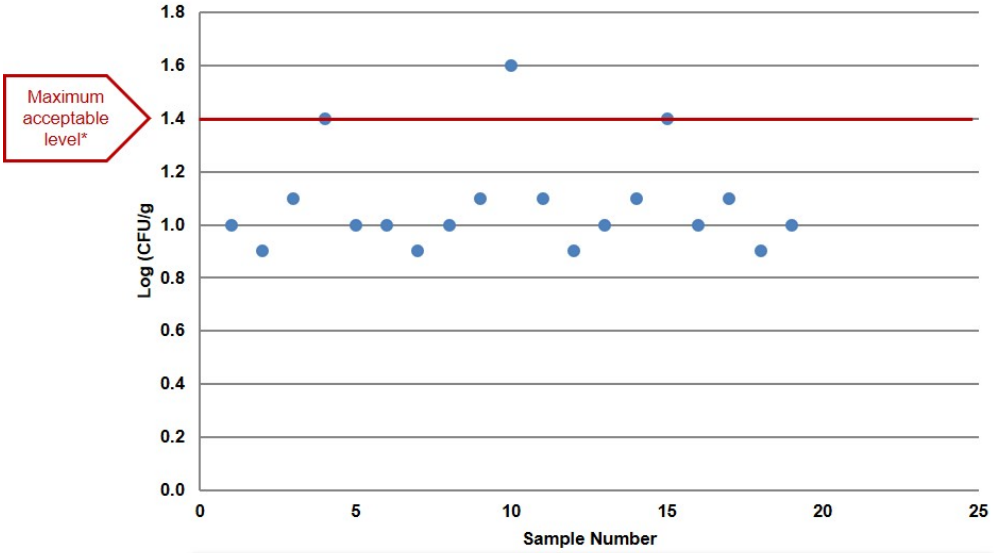

Chart 5 depicts conditions where there is an intermittent but recurring problem within the process. Note the distinct periodicity of the test results over time. An example of a situation where this pattern may be observed is the dripping of condensation onto product as it travels down a conveyor belt.