Appendix S

Comprehensive Review and Determination Report

FY 2012

South Carolina

Federal/State Audit Branch
Internal Control and Audit Division
Office of Program Evaluation, Enforcement and Review
Food Safety and Inspection Service
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Introduction

Purpose
This report presents the Food Safety and Inspection Service (FSIS) annual review results for the South Carolina Meat and Poultry Inspection (MPI) program and an overview of the review methodology. FSIS determined that the South Carolina MPI program met the "at least equal to" standard, based on its review of the self-assessment documents, on-site review, and follow-up information.

Background
The Federal Meat Inspection Act (FMIA) (21 U.S.C. 661) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 454) provide for FSIS to cooperate with State agencies in developing and administering State MPI programs. Individual State MPI programs need to operate in a manner and with authorities that are "at least equal to" the programs that FSIS has implemented under the antemortem and postmortem inspection, reinspection, sanitation, record-keeping, and enforcement provisions of the FMIA and PPIA. In addition, State MPI programs are expected to ensure that livestock are treated humanely by imposing humane handling requirements that are "at least equal to" those FSIS has established under the Humane Methods of Slaughter Act of 1978 (HMSA)(7 U.S.C. 1901 – 1906). The jurisdiction of a State MPI program is limited to product that is produced and sold within the State.

The FMIA and PPIA provide for FSIS to conduct at least annual reviews of State MPI programs and their requirements, including enforcement of those requirements, with respect to slaughter, preparation, processing, storage, handling, and distribution of livestock carcasses and parts, meat and meat food products of such animals, or poultry products (21 U.S.C. 661 (c) (4); 21 U.S.C. 454 (c) (4)). Cooperative agreements and annual certifications of State MPI programs are contingent upon FSIS determining that each State MPI program enforces requirements "at least equal to" those imposed under the Federal Acts. FSIS performs annual reviews to determine whether each State MPI program meets, and can maintain for a period of 12 months, the mandated "at least equal to" standard.

FSIS Directive 5720.3, *Methodology for Performing Scheduled and Targeted Reviews of State Meat and Poultry Inspection Programs,* and the *"At Least Equal To" Guidelines for State Meat and Poultry Cooperative Inspection Programs* describe the policies and procedures for FSIS comprehensive reviews. FSIS Directive 5720.3 provides FSIS personnel with the methodology to perform these reviews. The *"At Least Equal To" Guidelines for State Meat and Poultry Cooperative Inspection Programs* were developed to assist the State MPI programs establish and maintain inspection programs that are "at least equal to" the Federal inspection program.

Review Methodology
The comprehensive State MPI program review process consists of two parts: (1) an annual review of the State MPI program's self-assessment submission; and (2) a triennial verification on-site review to observe the State MPI program. Through the annual self-assessment and triennial verification on-site reviews, FSIS determines whether the State MPI program is "at least equal to" the Federal inspection program.

Each year, FSIS determines the "at least equal to" status of each State MPI program based on one or both parts of the comprehensive review. If the State MPI program is not scheduled for an on-site review during the fiscal year, FSIS makes an annual determination based on the results of the self-assessment review. If the State MPI program is scheduled for an on-site review during the fiscal year, FSIS makes an annual determination based on the results of both the self-assessment and the on-site review.

Description of State MPI Program
The South Carolina Livestock-Poultry Health Commission (SCLPHC) administers the South Carolina MPI program under authority of the South Carolina Code of Laws (Title 47, Chapters 17 and 19). The program

verifies and enforces regulatory requirements at 71 inspected facilities and 11 custom exempt establishments.[1] In addition, SCLPHC provides inspection at 11 facilities in the Federal State Cooperative Agreement Inspection Program.[2]

Annual Determination
FSIS determined that SCLPHC is operating a meat and poultry inspection program "at least equal to" the Federal requirements. This determination was based on: (1) FSIS' annual review of the self-assessment documents, and (2) FSIS' on-site review from March 5 – 15, 2012. This determination is fully explained in the Self-Assessment Review and On-Site Review sections.

Overview of Review Methodology

The review methodology is published in two companion documents: FSIS Directive 5720.3, (March 14, 2011), *Methodology for Performing Scheduled and Targeted Reviews of State Meat and Poultry Inspection Programs*, and the "*At Least Equal To" Guidelines for State Meat and Poultry Cooperative Inspection Programs* (July 2008). These documents describe the methodology used by FSIS' reviewers and provide information to State MPI programs on the criteria that FSIS uses to make its annual determination of whether State MPI programs are "at least equal to" the Federal inspection program. The review process consists of an annual review of the State MPI program's self-assessment submission and a triennial on-site review.

In addition to the annual reviews of each State MPI program, FSIS may perform a targeted review of a State MPI program in response to a condition or event that evidences program weaknesses, or as a reaction to a situation that could clearly result in a risk to public health. These targeted reviews may be conducted in addition to the scheduled reviews or may be performed at the same time. FSIS focuses the scope and activities of the targeted review on the conditions and evidence that triggered the need for the review and analyzes the review results to determine if the State MPI program is maintaining an "at least equal to" MPI program.

The comprehensive review process evaluates the following nine components:

1. Statutory Authority and Food Safety Regulations – This component evaluates whether the State MPI program operates under laws and regulations that provide legal authorities "at least equal to" those provided under the FMIA, PPIA, and HMSA.

2. Inspection – This component evaluates whether State MPI program personnel perform inspection activities to verify whether establishments comply with applicable regulations and take appropriate enforcement actions when establishments are not in compliance with provisions that are "at least equal to" those of FSIS.

3. Product Sampling – This component evaluates whether State MPI program personnel sample meat or poultry products to verify whether they are free of adulterants (e.g., *E. coli* O157:H7 in raw, non-intact, beef products and raw ground beef components, Shiga Toxin-producing *Escherichia coli* (STEC) serotypes in beef manufacturing trimmings, *Listeria monocytogenes* and *Salmonella* in ready-to-eat products, or drug residues at violative levels), comply with *Salmonella* and *Campylobacter* Performance

[1] Custom exempt establishments are slaughter and processing establishments, which are not subject to the routine inspection requirements of the FMIA and PPIA, provided the specified operations meet the exemption requirements of Section 23 of the FMIA and Section 15 of the PPIA.

[2] Facilities operating under the Federal State Cooperative Agreement Inspection Program (FSCIP), also known as Talmadge-Aiken establishments or cross-utilization facilities, are under Federal inspection, but operate with State inspection personnel. As a result, these facilities are not reviewed as part of the State MPI program review. However, since State inspection personnel staff these establishments, the number of these establishments is applicable to determinations on Component 4 – Staffing and Training.

Standards in raw classes of meat and poultry, comply with other consumer protection standards, and are accurately labeled (e.g., with nutrition information).

4. Staffing and Training – This component evaluates whether the State MPI program provides competent inspection coverage in each establishment on days the establishment produces products that, if found to be safe, wholesome, unadulterated, and properly labeled, are to bear the State mark of inspection.

5. Humane Handling – This component evaluates whether State MPI program personnel perform regulatory verification procedures to assess whether establishment personnel humanely handle all livestock and take appropriate regulatory actions in response to noncompliance. State MPI program personnel are to also perform regulatory verification procedures to assess whether poultry carcasses showing evidence of having died from causes other than slaughter are considered adulterated and condemned, and to assess whether poultry is slaughtered in accordance with good commercial practices, in a manner that results in thorough bleeding of the poultry carcass and ensures that breathing has stopped before scalding so that the birds do not drown.

6. Non-Food Safety Consumer Protection – This component evaluates whether State MPI program personnel perform verification procedures to confirm that meat and poultry products are wholesome, not economically adulterated, truthfully labeled, and meets the non-food safety regulatory requirements; and take appropriate actions in response to noncompliance.

7. Compliance – This component evaluates whether State MPI program personnel perform surveillance activities with respect to meat or poultry products in intrastate commerce and take appropriate enforcement actions in the event that adulterated or misbranded products enter intrastate commerce.

8. Civil Rights – This component evaluates whether the State MPI program adheres to Federal civil rights laws and U.S. Department of Agriculture (USDA) civil rights regulations.

9. Funding and Financial Accountability[3] – This component evaluates whether the State MPI program conforms to 7 CFR 3016, *Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments* and follows FSIS Directive 3300.1, Rev. 2, *Fiscal Guidelines for Cooperative Inspection Programs.*

FSIS determines whether the State's MPI program constitutes an inspection program "at least equal to" the Federal requirements based on the aforementioned criteria.

Part I. Self-Assessment Review

This section includes:

- A description of the self-assessment review methodology followed for all State MPI programs.
- The review of South Carolina's self-assessment submission.
- The self-assessment determination for South Carolina.

[3] In light of the current economic conditions, some State governments are experiencing financial challenges, which may result in overall budget cuts that could affect their meat and poultry inspection programs. To ensure the safety of State-inspected meat and poultry products, FSIS has initiated more vigilant monitoring to track and analyze circumstances and conditions that adversely affect the State MPI program's financial resources. When FSIS identifies concerns with a State MPI program's financial resources, the Agency will further examine each situation to determine the impact on the State MPI Program's inspection activities, product sampling programs, staffing, and compliance activities and determine if the State MPI program is maintaining its "at least equal to" status.

Self-Assessment Review Methodology
The annual self-assessment is designed for each State MPI program to provide sufficient information to adequately demonstrate an "at least equal to" program. The self-assessment submission provides documentation regarding the State's laws, rules, policies, procedures, and programs to provide a basis for FSIS to determine whether the State MPI program meets the "at least equal to" Federal requirements standard. The self-assessment documents are to include evidence and documentation to support that the State MPI program's processes are in effect and current with FSIS policies. Following this submission, FSIS thoroughly reviews the self-assessment documentation.

FSIS' review of the self-assessment submissions begins with the formation of a review team. The review team, comprised of representatives from the Federal State Audit Branch (FSAB), Civil Rights Division (CRD), Financial Review and Analysis Section (FRAS), and other program areas, as needed, evaluates each State MPI program's self-assessment submission to determine whether it meets the "at least equal to" criteria for all nine review components.

As questions arise during the self-assessment review or if more information or supporting documentation is needed, FSIS requests clarifying information from the State MPI program. The FSIS review team then makes a determination based on review of the entire self-assessment submission. For each State MPI program, FSIS makes one of the following three determinations for each component and for the State's overall ability to maintain an MPI program "at least equal to" the Federal requirements:

(1) "At least equal to": Means the State MPI program has adopted laws, regulations, and programs, and implemented them in a manner that is at least equivalent to the Federal inspection program for all review components.

(2) Not "at least equal to": Means the State MPI program has not adopted laws, regulations, or programs, or does not implement them in a manner that is at least equivalent to the Federal inspection program for one or more of the review components.

(3) Deferred: Means FSIS is unable to make a determination of the State MPI program's status because of the program's inability to immediately implement corrective actions resulting from the review findings.

Review of South Carolina's Self-Assessment Submission
FSIS evaluated the self-assessment documents for the nine review components to determine whether SCLPHC constitutes an inspection program "at least equal to" the Federal program. The determination and rationale for each review component are listed below.

FSAB received SCLPHC's self-assessment submission, for components 1 through 7, on November 11, 2011. FSAB found the initial submission sufficient and did not need to request additional information.

<u>Component 1 – Statutory Authority and Food Safety Regulations</u>
FSAB compared the submitted self-assessment and supporting documentation to the legal authority provided under the FMIA, PPIA, and HMSA, and the regulations promulgated under these laws. The supporting documentation includes the South Carolina Code of Laws (Title 47, Chapters 17 and 19) and the South Carolina Code of Regulations (Chapter 27, §§1022.B and 1023.C). The South Carolina Code of Laws provides authorities for mandatory antemortem and postmortem inspection, and reinspection (§§47-17-30 and 47-19-40), sanitation requirements (§§47-17-40 and 47-19-50), and record-keeping requirements (§§47-17-80 and 47-19-100). The South Carolina Code of Regulations (R.27-1023) provides the authority to enforce the humane methods of slaughter requirements.

The South Carolina Code of Laws provides authorities that are "at least equal to" the FMIA and PPIA regarding adulteration (§§ 47-17-20(j) and 47-19-20(j)), misbranding (§§47-17-50 and 47-19-20(k)), prohibited acts

(§§47-16-60 and 47-19-70), access and examination (§§47-17-60(g) and 47-19-120), and product control actions (§§47-17-320 and 47-19-40(c)), as well as criminal, civil, and administrative sanctions to address violators.

The South Carolina Code of Laws grants the authority to promulgate regulations (§§47-17-130 and 47-19-170). South Carolina adopted by reference Title 9, Code of Federal Regulations (CFR), Chapter III, Parts 300 – 320, 325, 329, 335, 352, 354, 416 – 417, 424, 430, 441, and 500 with minor exceptions in the South Carolina Code of Regulations (Chapter 27, §1032.C). South Carolina also adopted by reference 9 CFR, Chapter III, Parts 362 and 381, 416 – 417, 424, 430, 441, and 500 (§1022B). SCLPHC submitted a letter from a Clemson University regulatory attorney stating that Federal regulations that South Carolina adopted by reference are now a part of South Carolina Rules and Regulations, and may be the basis for regulatory enforcement action, including criminal prosecution.

In conclusion, SCLPHC provided evidence to show it operates under State laws and regulations that provide legal authority "at least equal to" that provided under the FMIA, PPIA, and HMSA, and the accompanying issuances.

Component 2 – Inspection

FSAB compared the self-assessment submission and supporting documentation regarding inspection policies and procedures, and verification of establishments' compliance to the Federal requirements. SCLPHC uses the Performance Based Inspection System (PBIS) to guide inspection program activities, collect establishment information, establish and maintain in-plant inspection procedure plans, and document establishment noncompliance. In addition, SCLPHC reviews custom exempt operations in accordance with FSIS Directive 5930.1, *Custom Exempt Review Process.*

SCLPHC verifies that establishments develop, implement, and maintain Sanitation Standard Operating Procedures (SOPs) and Hazard Analysis and Critical Control Point (HACCP) systems. SCLPHC's Operations Directive 104 communicates procedures and policies to monitor and verify establishments' food safety systems. Operations Directive 104 describes procedures to document establishment noncompliance, to track and verify resolution of establishment noncompliance, and to take immediate regulatory control actions, when appropriate. Operations Directive 104 also includes plant improvement program, special review, Food Safety Assessment (FSA) and In-Depth Review (IDR) procedures. Enforcement, Investigation, and Analysis Officers perform FSAs; and an area veterinarian, area supervisor, and food inspector work as teams to perform IDRs. Operations Directive 125 requires the area veterinarian to document corrective action verifications on Corrective Action Reports and to submit this report to the director. The submitted warning letters, FSA records, IDR records, Corrective Action Reports, and noncompliance records support the conclusion that SCLPHC personnel identify and document noncompliance, provide due process, and take enforcement actions when establishments fail to meet regulatory requirements.

SCLPHC enforces the South Carolina Code of Regulations, which adopts by reference 9 CFR Part 500, Rules of Practice, when establishments do not comply with State authorities that are "at least equal to" the FMIA and PPIA. SCLPHC has procedures to document relevant facts of administrative actions, and to ensure that administrative actions are factual and based on legal authority. The self-assessment includes narrative descriptions, policies, and supporting documents to show that SCLPHC's inspection system includes due process, assessing civil penalties, and withholding, suspension, and withdrawal of inspection.

The submitted documents support the conclusion that SCLPHC:

- Performs inspection and regulatory verification procedures to confirm that State-inspected establishments comply with applicable regulations.

- Maintains a system to carry out administrative enforcement actions when establishments do not comply with State authorities that are "at least equal to" the FMIA and PPIA.
- Achieves inspection activities "at least equal to" the Federal requirements.
- Monitors these activities through control measures to verify that the inspection system functions as intended.

Component 3 – Product Sampling

FSAB compared SCLPHC's sampling protocols, procedures, and results to the Federal policies and procedures.

SCLPHC provided documentation to show that it maintains sampling programs with sound rationale and goals for *E. coli* O157:H7 in raw non-intact beef products and raw ground beef components, *Listeria monocytogenes* and *Salmonella* in ready-to eat products, *Salmonella* Performance Standards in raw classes of meat and poultry, and other consumer protection standards. SCLPHC participates in the National Residue Program, and collects and analyzes inspector-generated samples for violative drug residues. The sampling plans include procedures for sample collection, sample integrity, and laboratory analysis. SCLPHC developed an action plan to respond to positive results. This plan includes actions to prevent adulterated product from entering commerce.

In conclusion, detailed review of the sampling protocols, procedures, and results confirmed that SCLPHC maintains verification testing to address adulterants, other measures of properly operating food safety systems, and other consumer protection standards "at least equal to" the Federal requirements and has control measures in effect to confirm that its product sampling system functions as intended.

Component 4 – Staffing and Training

SCLPHC developed methods to determine staffing requirements, which consider the inspectors' workloads and the number of inspectors required to provide daily inspection coverage in each establishment on days the establishment produces products bearing the State mark of inspection. Procedures are in effect to document staffing in each establishment, identify failures to meet staffing requirements, and correct staffing deficiencies. Each area supervisor assigns inspectors' work schedules weekly, with instructions outlining daily visits to the establishments, and arranges relief inspection during routine- and emergency-leave situations. When the area supervisors are absent, the area veterinarians perform these duties. To verify daily inspection coverage, the area veterinarian and area supervisor review PBIS data, at least weekly, contact inspectors in person or by telephone daily, and make weekly unannounced establishment visits. As of November 15, 2011, SCLPHC employed a director; 85 inspectors; 2 veterinary medical officers; 3 enforcement, investigations, and analysis officers; and 5 compliance officers.

SCLPHC developed a training program for new entry-level inspection personnel and a record-keeping system to document training completions. This training program covers basic slaughter techniques and all inspection techniques required to perform slaughter duties, including basic Sanitation SOPs and HACCP procedures. Administrative Directive 19, *New Employee Development Guide*, describes procedures for initial orientation, on-the-job and formal training, and performance evaluation. The training subjects include livestock inspection, slaughter inspection, processing inspection, HACCP, Sanitation SOPs, and Sanitation Performance Standards (SPS). SCLPHC also trains employees in Food Safety Regulatory Essentials (FSRE).

SCLPHC administers the South Carolina Employee Performance Management System to set performance standards, and perform and record annual performance evaluations. As part of this system, SCLPHC personnel receive ongoing interim evaluations at three- and six-month intervals. SCLPHC divides its jurisdiction into four geographical areas, and assigns an area supervisor and an area veterinarian to each area. Furthermore, area supervisors are evaluating officials and area veterinarians are rating officials for inspectors' performance evaluations. The completed performance evaluations are forwarded to the SCLPHC Director for final approval before submission to the South Carolina Personnel Management Department.

After thorough review of the submitted documents, FSAB concluded that SCLPHC has sufficient resources to provide the required inspection coverage at State-inspected establishments to ensure that only safe, wholesome, unadulterated, and properly labeled meat and poultry products receive the State mark of inspection. The information supports the conclusion that inspection personnel have the education and training needed to apply SCLPHC's inspection methodology, document findings, and initiate regulatory actions, when necessary. Control measures are in effect to confirm that SCLPHC's staffing and training systems function as intended.

Component 5 – Humane Handling

The PBIS records demonstrated that SCLPHC schedules and performs regulatory verification procedures to assess whether establishment personnel humanely handle all livestock throughout the time they are on official establishment premises and takes appropriate regulatory action in response to noncompliance.

SCLPHC uses FSIS Directive 6900.2, *Humane Handling and Slaughter of Livestock,* to communicate instructions to inspection personnel. The inspectors complete the Humane Handling Activities Tracking System (HATS) spreadsheet and South Carolina Meat and Poultry Inspection Department (SCMPID) Form 1.5 daily, and submit these forms to area supervisors with the Monthly Slaughter and Processing Reports. SCLPHC management compares the HATS spreadsheets to the scheduled dates of slaughter for each establishment to determine whether inspectors submitted reports for each day the establishments performed slaughter operations. Area supervisors also review HATS spreadsheets to verify performance of humane handling verification tasks. A thorough review of the PBIS data for a 12-month period confirmed that SCLPHC inspectors correctly applied inspection methodology and documented noncompliance.

In conclusion, the information made evident that SCLPHC verifies compliance with the humane handling requirements and takes regulatory action "at least equal to" the Federal program. Control measures are in effect to confirm that the humane handling verification system functions as intended.

Component 6 – Non-Food Safety Consumer Protection

SCLPHC verifies establishment compliance with the non-food safety consumer protection regulatory requirements. SCLPHC uses applicable FSIS Directives to instruct inspection personnel, and uses PBIS to schedule ongoing verification procedures and to document noncompliance. A thorough review of PBIS data and noncompliance records supports the conclusion that SCLPHC inspectors correctly apply inspection methodology and document noncompliance.

Operations Directive 126, *Label Submission,* guides SCLPHC's label-approval policy and process to verify that labels are accurate and meet regulatory requirements. Prior to applying a label, mark, or device to an inspected meat or poultry product, an establishment representative must submit a completed application for label approval and a label sketch to obtain SCLPHC approval.

In conclusion, the submitted documents provided evidence to show that SCLPHC protects consumers from meat and poultry products that are unwholesome, economically adulterated, or not truthfully labeled, and is "at least equal to" the Federal program. Control measures are in effect to confirm that the non-food safety consumer protection verification system functions as intended.

Component 7 – Compliance

SCLPHC compliance personnel conduct in-commerce surveillance of persons or firms who prepare, transport, sell, or offer for sale meat and poultry products in intrastate commerce to verify compliance with State statutory and regulatory requirements, and to verify that meat and poultry products in intrastate commerce are wholesome, correctly packaged and labeled, and secure from threats or intentional acts of contamination.

SCLPHC investigates alleged or actual statutory or regulatory violations; controls products, when there is reason to believe that the products are adulterated, misbranded, or otherwise in violation of the South Carolina

Code of Laws; and takes enforcement action when needed, up to and including prosecution of individuals or firms that have violated the South Carolina Code of Laws. SCLPHC has procedures to maintain and preserve the legal integrity of documentary and other evidence to support legal action; and to report transportation accidents that involve State-inspected and passed meat and poultry products.

The SCLPHC director reviews the Compliance Activity Reports and Compliance Quarterly Reports for accuracy and completeness, and determines appropriate case dispositions and courses of action. The senior compliance officer reviews compliance records to verify that compliance officers perform follow-up reviews for previous violations.

SCLPHC maintains procedures for the recall of meat and poultry products subject to its jurisdiction equivalent to the procedures described in FSIS Directive 8080.1, *Recall of Meat and Poultry Products*. The procedures include health hazard evaluation, recall classification, public notification, effectiveness checks, and closure. SCLPHC oversees the recall activities, coordinates actions to determine whether adulterated product was removed from commerce, and issues press releases, as necessary, to serve the interest of public health.

SCLPHC established methods to record, triage, analyze, and track consumer complaints related to State-regulated meat or poultry products. SCLPHC either investigates these complaints or refers them to the local health authority. The investigative methods include procedures to collect and safeguard evidence, conduct interviews, submit product samples to the laboratory, initiate recall procedures or regulatory enforcement actions, and report potential food safety threats.

The submitted documents support the conclusion that SCLPHC maintains a system to verify compliance of meat and poultry products in intrastate commerce and take appropriate enforcement actions in the event that adulterated or misbranded products enter intrastate commerce. Control measures are in effect to confirm that the compliance program functions as intended.

Component 8 – Civil Rights

On August 17, 2011, SCLPHC submitted the required FSIS Form 1520-1, Civil Rights Compliance of State Inspection Programs, to demonstrate adherence to Federal civil rights laws and USDA civil rights regulations. CRD concluded that SCLPHC functions "at least equal to" the Federal civil rights requirement.

Component 9 – Financial Accountability

SCLPHC submitted quarterly and final Financial Status Reports (SF-425), and an annual Indirect Cost Proposal to demonstrate it conforms to 7 CFR, Part 3016, *Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments*, and follows FSIS Directive 3300.1, *Fiscal Guidelines for Cooperative Inspection Programs.* On October 24, 2012, FRAS determined that SCLPHC is "at least equal to" Federal standards for financial accountability for Fiscal Year (FY) 2012.

Self-Assessment Determination for South Carolina

Based on the evidence and results discussed above, FSIS determined that SCLPHC provided adequate documentation to show it operates a meat and poultry inspection program "at least equal to" the Federal requirements. SCLPHC has adopted laws, regulations, and programs, and implemented them in a manner that is "at least equal to" the Federal inspection program for all review components.

Part II. On-Site Review

This section includes:

- A description of the on-site review methodology followed for all State MPI programs.
- The on-site review of South Carolina.
- The on-site determination for South Carolina.

On-Site Review Methodology

The on-site review determines whether the State implements its MPI program in a manner consistent with its self-assessment documents; and maintains and carries out its MPI program in a manner that is "at least equal to" the Federal inspection program. FSIS' on-site review team is comprised of representatives from FSAB, CRD, FRAS, and other program areas as needed.

The FSAB program auditor coordinates the on-site review and is the primary contact for State MPI program officials, FSIS officials, and team members. The FSAB program auditor schedules the on-site review, for components 2 through 7, with State MPI program officials. FSAB sends written notification to State MPI program officials at least 30 days prior to the start of the review. CRD and FRAS schedules the on-site reviews of components 8 and 9, respectively.

FSAB's on-site review begins with an entrance meeting teleconference with FSAB and State MPI program officials. During this meeting, FSAB explains the review process, answers any questions, and requests that State MPI program officials submit the following information within ten business days of the teleconference:

- Descriptions of any changes that have occurred in the MPI program since the most recent self-assessment submission
- A current list of establishments receiving inspection from the State MPI program
- A description of each State field supervisor's area of responsibility
- The HACCP processing categories for each State-inspected establishment and a ranking of the highest-volume producers for each HACCP processing category
- A list of all State-inspected establishments that the State MPI program has reviewed (e.g., through a review similar to an FSIS FSA or other State review) within the preceding 12-months
- A list of all State-inspected establishments that have a history of any of the following public health risks within the preceding 12-months:
  - Positive sample results for pathogens (e.g., Shiga Toxin-producing *Escherichia coli* (STEC) serotypes in beef manufacturing trimmings, *E. coli* O157:H7 in non-intact, raw beef products, or *Listeria monocytogenes* or *Salmonella* in ready-to-eat products)
  - *Salmonella* or *Campylobacter* verification sample set results that exceed the performance standard or guideline established by FSIS
  - Enforcement actions
  - Recalls
  - Structural damage to State-inspected establishments caused by a natural or other disaster

For each State MPI program, FSAB uses a statistically valid sampling method to determine the total number of establishments to review on-site, selects specific establishments to review based largely on the aforementioned public health risks, and includes establishments that the State MPI program reviewed during the preceding 12-

months. FSAB shares the list of establishments selected to review with State MPI program officials at least five business days before the on-site review.

At each establishment review, the FSAB program auditor:

- Reviews the State MPI program's verification of compliance with applicable State requirements on HACCP, Sanitation SOPs, SPS, non-food safety consumer protection, control of specified risk material, humane handling, and custom and retail exempt requirements.
- Observes State MPI program inspectors as they perform antemortem and postmortem inspection procedures.
- Documents, based on observation and records review, any establishment noncompliance that the State MPI program failed to identify or for which the State MPI program failed to take an appropriate regulatory action.
- Documents other findings that indicate that the State MPI program is not "at least equal to" the Federal program.
- Reports his or her findings to State MPI program officials at the conclusion of each establishment review.
- Discusses the review findings with State MPI Program officials, and then observes the State MPI Program officials as they lead the exit meeting with establishment management to discuss the findings of each establishment review.
- Ensures, before leaving an establishment, that State MPI program officials have taken appropriate actions with respect to all noncompliances observed during the establishment review.

In addition to the establishment reviews, the FSAB program auditor reviews product sampling, staffing, training, compliance, and management control documents at the State MPI program office. This review includes a representative sample of current State MPI program records and is necessary to determine whether the documents evidence that the State MPI program implements these programs in a manner consistent with the self-assessment documents, and whether the State MPI program maintains and carries out its program "at least equal to" the Federal inspection program.

After the establishment reviews and review of documents in the State MPI program office, FSAB analyzes all information gathered during the on-site review, as well as the results of the current year's self-assessment review, and identifies the findings. The findings are based on the reviewer's independent assessment during the on-site review and comparison of the on-site review findings with the State MPI program's operations and records, including the self-assessment submissions. The review team's findings focus on implementation of food safety policy and procedures and on whether the program meets the criteria for the nine review components. The FSAB program auditor presents the findings to State MPI program officials at the exit meeting teleconference.

The State MPI program must submit within ten business days of the date of the exit conference a written action plan to correct all findings. The action plan needs to:

- Identify the underlying causes of any findings that may be system-wide and ensure statewide correction of such findings.
- Identify the underlying causes of specific findings at individual establishments and ensure that the State MPI program verifies that the establishments address such findings.
- Identify the verification plan or management controls that the State MPI program will implement throughout the year to verify adequate implementation of the corrective actions.

FSIS reviews the information gathered during the on-site review, including the State MPI program's action plan to determine whether the State MPI program is functioning "at least equal to" the Federal requirements. FSIS makes one of the following three determinations for each component and the State's overall ability to maintain its MPI program "at least equal to" the Federal requirements:

(1) "At least equal to": Means the State MPI program has adopted laws, regulations, and programs, and implemented them in a manner that is "at least equal to" the Federal inspection program for all review components.

(2) Not "at least equal to": Means the State MPI program has not adopted laws, regulations, or programs, or does not implement them in a manner that is "at least equal to" the Federal inspection program for one or more of the review components.

(3) Deferred: Means FSIS is unable to make a determination of the State MPI program's status because of the program's inability to immediately implement corrective actions resulting from the review findings.

On-Site Review of South Carolina

The FSIS review team analyzed all information gathered during the on-site review and SCLPHC's action plan, which addressed the findings identified during the review, to determine whether SCLPHC has implemented and maintains its MPI program "at least equal to" the Federal requirements; and was enforcing requirements "at least equal to" those imposed under the Federal Acts. The rationale for each determination is listed below for each component.

FSAB conducted an on-site review of SCLPHC, for components 2 through 7, from March 5 – 15, 2012.

<u>Component 2 – Inspection</u>

FSAB reviewed the self-assessment documents and compared them to additional documents and conditions presented on-site. The on-site documents reviewed included, but were not limited to, Sanitation SOPs and associated records; HACCP plans and associated records; generic *E. coli* sampling procedures and associated records; procedures for the removal, segregation, and disposition of specified risk materials and associated records; custom exempt records; noncompliance records; and enforcement letters.

FSAB evaluated SCLPHC during seven establishment reviews. During these reviews, SCLPHC personnel identified several SPS noncompliances, and FSAB identified additional SPS noncompliances and HACCP record-keeping noncompliances that SCLPHC personnel did not recognize. SCLPHC officials initiated regulatory actions in the establishments and issued noncompliance records at the time the noncompliances were identified.

On April 6, 2012, SCLPHC submitted an action plan to correct the findings identified during the review. The action plan identifies the underlying causes of both system-wide findings and specific findings at individual establishments. It includes a verification plan to ensure statewide correction of these findings. On July 23, 2012, SCLPHC submitted evidentiary documentation to demonstrate full implementation of the action plan and to demonstrate SCLPHC's verifications to confirm establishment compliance with regulatory requirements. As part of this action plan, SCLPHC conducted work unit meetings, in each district, to provide additional trainings on sanitation requirements to all inspection personnel. Afterward, SCLPHC performed performance evaluations to verify that this training was effective.

FSAB analyzed the information from the establishment reviews and SCLPHC's action plan, and concluded that SCLPHC personnel identify and document noncompliance with regulatory requirements, take appropriate regulatory actions, and verify that establishments correct noncompliance. SCLPHC verifies that inspected establishments have developed, implemented, and maintain Sanitation SOPs and HACCP systems, which

evaluate and address hazards, and routinely verify that products are safe, wholesome, unadulterated, and properly labeled.

Component 3 – Product Sampling
FSAB reviewed the product sampling self-assessment documents and compared them to additional documents presented on-site to include sampling plans and laboratory results.

SCLPHC's verification sampling program met FSIS' guidance to States on frequency of testing for pathogenic bacteria and *Salmonella* in raw products, and discovered positive *Salmonella* results from a fully cooked ham at one establishment that slaughters, and produces raw and fully cooked products. SCLPHC appropriately responded to the positive test result and determined that the establishment held the product represented by the positive sample and verified that the product was properly disposed. SCLPHC inspection personnel examined the establishment's test results, and sanitary dressing and process control procedures for evidence of a systemic problem, issued a noncompliance record, and verified that the establishment implemented appropriate corrective actions. SCLPHC collected additional follow-up samples to verify the effectiveness of the establishment's corrective actions.

FSAB analyzed the information from the SCLPHC office and establishment reviews, and concluded that SCLPHC maintains sampling plans for *E. coli* O157:H7, *Salmonella* Performance Standards, *Listeria monocytogenes* and *Salmonella*, violative drug residues, and economic sampling for targeted products.

Component 4 – Staffing and Training
FSAB reviewed the staffing and training self-assessment documents, and compared them to additional documents and conditions on-site to assess whether SCLPHC carries out its staffing and training systems consistent with the self-assessment documents and "at least equal to" the Federal requirements. After further analysis of data from the SCLPHC office and establishment reviews, FSAB concluded that SCLPHC has an adequate number of trained staff to provide the required inspection coverage in establishments, perform compliance activities, and provide supervisory oversight; and has implemented procedures to ensure daily inspection coverage in operating establishments.

The review results support the conclusion that inspection personnel have the education and training needed to apply SCLPHC's inspection methodology, make decisions based upon the correct application of inspection methodology, document findings, and initiate regulatory action. The training program includes measures to ensure that inspection personnel receive training in the areas of meat and poultry antemortem and postmortem inspection, humane handling, processed products, HACCP, Sanitation SOPs, rules of practice, performance guidelines, compliance, and FSRE.

Component 5 – Humane Handling
FSAB reviewed the humane handling self-assessment documents and compared them to additional documents and conditions presented on-site. These documents included, but were not limited to, noncompliance records and procedure schedules. FSAB reviewed humane handling of livestock and stunning methods.

FSAB analyzed information gathered during the establishment reviews and concluded that SCLPHC adequately enforces the humane slaughter of livestock regulatory standards to ensure that animals presented for slaughter are humanely handled throughout the time they are on official establishment premises. Livestock pens, driveways, and ramps were maintained in a manner that would not cause injury to animals and the establishments were using acceptable driving and stunning methods.

Component 6 – Non-Food Safety Consumer Protection
FSAB reviewed the non-food safety consumer protection self-assessment documents and compared them to additional documents and conditions presented on-site to determine whether SCLPHC enforces non-food safety

consumer protection regulatory standards "at least equal to" the Federal requirements. This review included, but was not limited to, procedure schedules, label approvals, labels, and product formulations.

FSAB analyzed information gathered and concluded that SCLPHC adequately performs ongoing regulatory verification procedures to confirm establishment compliance with labeling, product standards, and other non-food safety consumer protection requirements applicable to products being produced.

Component 7 – Compliance

FSAB reviewed the self-assessment documents and compared them to additional documents presented on-site. These included, but were not limited to, Reports of Investigation, State Compliance Activity Reports, Review and Compliance Records, Warning Notices, Arrest Warrant with Magistrate Disposition, Consent Agreement and Order, Meat Handlers Review, and Food Defense Surveillance Findings.

The review of compliance documents and case files supports the conclusion that SCLPHC follows the procedures and methods in FSIS Directive 8010.1, *Methodology for Conducting In-Commerce Surveillance Activities*, to assess food safety, food defense, non-food safety consumer protection, and compliance with administrative and judicial court orders in firms that prepare, transport, sell, or offer for sale meat and poultry products in intrastate commerce. SCLPHC investigates alleged or actual statutory or regulatory violations, as set out in FSIS Directive 8010.2, *Investigative Methodology*, and controls products when there is reason to believe that the products are adulterated, misbranded, or otherwise in violation of the South Carolina Code of Laws. The Reports of Investigation were completed in accordance with FSIS Directive 8010.4, *Report of Investigation*. SCLPHC uses the investigative findings and evidence to pursue enforcement actions for administrative, civil, or criminal sanctions.

SCLPHC follows the recall procedures in FSIS Directive 8080.1, *Recall of Meat and Poultry Products*, with minor modifications to suit its organizational structure. No State-inspected establishments or retail firms recalled product during FY 2012.

SCLPHC maintains systems to investigate transportation accidents and to review, analyze, and triage consumer complaints. SCLPHC gathers information pertinent to these complaints, directs the compliance division to investigate, and files completed investigation documents in the State office.

FSAB analyzed the information gathered during the review of SCLPHC office records and concluded that SCLPHC conducts surveillance, investigations, enforcement, and other activities to ensure that meat and poultry products distributed in intrastate commerce for use as human food are safe, wholesome, correctly labeled and packaged, and secure from threats or intentional acts of contamination.

Component 8 – Civil Rights

On August 28, 2012, CRD reviewed documents and conditions at the SCLPHC offices to determine whether SCLPHC complies with Federal civil rights laws and USDA civil rights regulations, and achieves the intended outcome of the Federal requirements. The review considered the following four areas: Public Notification, Civil Rights Training, Discrimination Complaints, and Program Accessibility.

CRD analyzed the information gathered during the on-site review of SCLPHC and concluded that SCLPHC is "at least equal to" Federal civil rights requirements.

Component 9 – Financial Accountability

On May 21 – 25, 2012, FRAS conducted an on-site review fiscal review of SCLPHC. This review encompassed Federal fiscal years 2009, 2010, and 2011. As a result of this review, FRAS determined that SCLPHC is operating in compliance with the financial and administrative provisions of FSIS Directive 3300.1,

Rev.2, and the criteria outlined in the FSIS "*At Least Equal To" Guidelines for State Meat and Poultry Cooperative Inspection Programs* (July 2008).

On-Site Determination for South Carolina

Based on the evidence and results discussed above, FSIS determined that SCLPHC operates its MPI program "at least equal to" the Federal requirements for all review components, and enforces requirements "at least equal to" those imposed under the Federal Acts.