Appendix O

Comprehensive Review and Determination Report

FY 2012

North Carolina

Federal/State Audit Branch
Internal Control and Audit Division
Office of Program Evaluation, Enforcement and Review
Food Safety and Inspection Service
U.S. Department of Agriculture
December 2012

Table of Contents

Introduction.....1

Purpose 1

Background 1

Description of State MPI Program 1

Annual Determination.....2

Overview of Review Methodology 2

Part I. Self-Assessment Review.....3

Self-Assessment Review Methodology.....4

Review of North Carolina's Self-Assessment Submission 4

Self-Assessment Determination for North Carolina 9

Part II. On-Site Review.....9

On-Site Review Methodology.....9

On-Site Review of North Carolina.....11

On-Site Determination for North Carolina 14

Introduction

Purpose
This report presents the Food Safety and Inspection Service (FSIS) annual review results for the North Carolina Meat and Poultry Inspection (MPI) program and an overview of the review methodology. FSIS determined that the North 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.

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 North Carolina Department of Agriculture and Consumer Services, Meat and Poultry Inspection Division (NCDACS/MPID) administers the North Carolina MPI program under authority of the North Carolina General Statutes (Chapter 106, Articles 49B, 49C, and 49D). The program verifies and enforces regulatory

requirements at 68 inspected facilities and 78 custom exempt establishments.[1] In addition, NCDACS/MPID provides inspection at 94 facilities in the Federal State Cooperative Agreement Inspection Program.[2]

Annual Determination
FSIS determined that NCDACS/MPID 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 April 23 to May 4, 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 North Carolina's self-assessment submission.
- The self-assessment determination for North 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 North Carolina's Self-Assessment Submission
FSIS evaluated the self-assessment documents for the nine review components to determine whether NCDACS/MPID constitutes an inspection program "at least equal to" the Federal program. The determination and rationale for each review component are listed below.

FSAB received NCDACS/MPID's self-assessment submission, for components 1 through 7, on November 14, 2011. On February 2, 2012, FSAB requested additional clarifying information from the NCDACS/MPID staff, which was provided on February 21, 2012.

<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 North Carolina General Statutes (Chapter 106, Articles 49B, 49C, and 49D), and the North Carolina Administrative Code. The North Carolina General Statutes provide authorities for mandatory antemortem and postmortem inspection, and reinspection (§§106-549.17, 106-549.18, 106-549.19, and 106-549.53), sanitation requirements (§§106-549.22, 106-549.26 and 106-549.54), record-keeping requirements (§106-549.58), and humane methods of slaughter requirements (§106-549.17).

The North Carolina General Statutes provide authorities that are "at least equal to" the FMIA and PPIA regarding adulteration and misbranding (§§106-549.15 and 106-549.51), prohibited acts (§§106-549.23, 106-

549.24, and 106-549.56), access and examination (§§106-549.20, 106-549.36, 106-549.58, and 106-549.68), and product control actions (§§106-549.31, 106-549.32, 106-549.53, 106-549.65, and 106-549.66), as well as criminal, civil, and administrative sanctions to address violators.

The North Carolina General Statutes grant the authority to promulgate regulations (§§106-549.22, 106-549.28, and 106-549.61) and North Carolina adopted by reference Title 9, Code of Federal Regulations (9 CFR), Parts 300 through 500, including subsequent amendments and editions in the North Carolina Administrative Code (02 NCAC 52D .0101).

In conclusion, NCDACS/MPID 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. NCDACS/MPID 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, NCDACS/MPID reviews custom exempt operations in accordance with FSIS Directive 5930.1, *Custom Exempt Review Process.*

NCDACS/MPID verifies that establishments develop, implement, and maintain Sanitation Standard Operating Procedures (SOPs) and Hazard Analysis and Critical Control Point (HACCP) systems. In addition to the inspectors' ongoing verification activities, NCDACS/MPID routinely schedules and performs a comprehensive Food Safety Assessment (FSA) at each inspected establishment at least once every four years to examine the design and validity of the establishment's food safety system. These FSAs include establishments' HACCP plans and associated hazard analyses, supporting documents, prerequisite programs, verification sampling programs, Sanitation SOPs, and any other programs that make up the HACCP system. Regional Veterinary Medical Officers (RVMO), who are trained in Enforcement, Investigations, and Analysis Officers (EIAO) methodology, follow the procedures described in FSIS Directive 5100.1, *Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology,* to perform the FSAs and determine whether the establishments' food safety systems comply with regulatory requirements.

NCDACS/MPID performs Intensified Verification Testing (IVT), an environmental and product microbial testing protocol for *Listeria monocytogenes*, to verify the adequacy of food safety systems in establishments that produce ready-to-eat products that are exposed to environmental conditions after the lethality step. When applicable, current NCDACS/MPID policy requires that RVMOs perform an IVT, in conjunction with each FSA. A team of RVMOs performed 19 FSAs in FY 2011. The submitted records, which include FSA and noncompliance records, support the conclusion that NCDACS/MPID personnel identify regulatory noncompliance and appropriately apply regulatory control actions.

NCDACS/MPID established a system to carry out enforcement actions when establishments are not meeting provisions "at least equal to" the FMIA and PPIA. NCDACS/MPID enforces the North Carolina Administrative Code, which adopts by reference 9 CFR, Part 500, Rules of Practice, which includes provisions for due process, establishment notification, immediate withholding actions, suspensions, and withdrawal of grants of inspection. NCDACS/MPID has procedures to document relevant facts of administrative actions, and to ensure that administrative actions are justified and based on relevant facts.

The submitted documents support the conclusion that NCDACS/MPID:

- 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 NCDACS/MPID's sampling protocols, procedures, and results to the Federal policies and procedures.

NCDACS/MPID 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. NCDACS/MPID 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. NCDACS/MPID 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 NCDACS/MPID 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

NCDACS/MPID 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. NCDACS/MPID uses Establishment Workload and Assignment Computation forms to determine the workload for each inspector, and provides one relief inspector for every seven inspector assignments. NCDACS/MPID maintains controls to verify that each establishment has inspection coverage on each day that it produces inspected products. These controls require supervisors to review inspectors' Patrol/Headquarter Assignment Forms, PBIS data, and timesheets, each week, to confirm the hours that inspectors worked. As of September 18, 2011, NCDACS/MPID employed a director, an assistant director, 7 RVMOs, 9 administrative clerks, 9 area supervisors, 86 inspectors, 3 trainers, and 5 compliance officers.

NCDACS/MPID developed a training program and a system to track training completions. The formal courses include Occupational Safety and Health Administration (OSHA) Lockout/Tag-Out, Ethics and Conduct, Food Safety Regulatory Essentials, and Basic Slaughter Training. All new field inspection personnel complete a six-week on-the-job training (OJT) program, which includes performance evaluations. After completing the initial OJT program, field inspection personnel complete an additional three-month training program, which includes PBIS, Laboratory Electronic Application of Results Notification, Electronic Animal Disposition Reporting System, Humane Activities Tracking, and Homeland Security. After inspectors complete the initial training, trainers communicate any areas of concern to the inspector's area supervisor. The area supervisor evaluates progress and, depending on need, may request additional OJT for the employee. In addition, supervisory personnel attend equal employment opportunity and supervisory development courses taught by the North

Carolina Office of State Personnel. All veterinarians are Animal and Plant Health Inspection Service trained Foreign Animal Diseases Practitioners. Nine employees have completed the International HACCP Alliance EIAO course. NCDACS/MPID electronically tracks employee trainings on Employee Training Reports.

NCDACS/MPID administers a performance evaluation program that the North Carolina Office of State Personnel mandates, in addition to the In-Plant Performance System (IPPS) described in FSIS Directive 4430.1, *Performance Evaluation Plan*. This program defines performance standards and evaluates inspection staff members' performance. When area supervisors identify deficient areas, they contact the training staff to request additional trainings. Next, the training staff completes necessary follow-up trainings and submits a Training Summary Report. Following this, area supervisors evaluate employees' application of follow-up trainings through IPPS assessments. In addition to performance evaluations and IPPS assessments, area supervisors conduct quarterly meetings to update inspection personnel on current policies and address areas of concern.

After thorough review of the submitted documents, FSAB concluded that NCDACS/MPID 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 NCDACS/MPID's inspection methodology, document findings, and initiate regulatory actions, when necessary. Control measures are in effect to confirm that NCDACS/MPID's staffing and training systems function as intended.

Component 5 – Humane Handling

The PBIS records demonstrated that NCDACS/MPID 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.

NCDACS/MPID schedules and performs regulatory verification procedures in accordance with FSIS Directives 6900.1, *Humane Handling of Disabled Livestock*; 6900.2, *Humane Handling and Slaughter of Livestock*; and 6910.1, *District Veterinary Medical Specialist (DVMS) – Work Methods*. The inspectors document verification procedure results on Humane Handling Reports, and submit these reports, each week, to the central office. RVMOs perform annual humane handling visits at all establishments that slaughter livestock to ensure that these establishments comply with regulatory requirements. NCDACS/MPID schedules and tracks humane handling visits on a spreadsheet, and the RVMOs document results on Humane Handling Visits Reports, which are filed in the central office.

In conclusion, the information made evident that NCDACS/MPID 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

NCDACS/MPID verifies establishment compliance with the non-food safety consumer protection regulatory requirements. NCDACS/MPID uses PBIS to schedule verification procedures and to document noncompliance, and distributes Meat and Poultry Inspection Division (MPID) Notice 7-08, *Label Approval Protocol for State Inspected Establishments* and FSIS Directive 7000.1, *Verification of Non-Food Safety Consumer Protection Regulatory Requirements*, to instruct inspection personnel.

NCDACS/MPID maintains a label-approval process, as described in MPID Notice 7-08, to verify that labels are accurate and meet regulatory requirements. This process requires an establishment to submit a label sketch and a product formulation, if applicable, with each application for a new label or marking device. NCDACS/MPID verifies that labels meet regulatory standards that are "at least equal to" 9 CFR, Parts 316 – 317, 319, 381, 441,

and 442, and the *FSIS Food Standards and Labeling Policy Book* before approving the label. NCDACS/MPID provides copies of MPID Notice **7**-08 and 9 CFR to inspected establishments and inspection personnel.

In conclusion, the submitted documents provided evidence to show that NCDACS/MPID 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

NCDACS/MPID carries out compliance procedures consistent with FSIS' Surveillance, Investigations, and Enforcement Methodology (SIEM). The five compliance officers, who are SIEM trained, conduct in-commerce surveillance activities in accordance with FSIS Directive 8010.1, *Methodology for Conducting In-Commerce Surveillance Activities.* These surveillance activities verify that persons or firms, who prepare, transport, sell, or offer for sale meat and poultry products in intrastate commerce comply with North Carolina's statutory and regulatory requirements; and verify that meat and poultry products in intrastate commerce are wholesome, correctly packaged and labeled, and secure from threats or intentional acts of contamination.

NCDACS/MPID investigates alleged or actual statutory violations, analogous to FSIS Directives 8010.2, *Investigative Methodology*; and follows the guidance in FSIS Directive 8010.4, *Report of Investigation*, to document investigations. During surveillance and investigations, NCDACS/MPID controls products when there is reason to believe that the products are adulterated, misbranded, or otherwise in violation of the North Carolina General Statutes, and follows established procedures to maintain and preserve the legal integrity of documentary and other evidence to support legal action, in accordance with FSIS Directive 8010.3, *Procedures for Evidence Collection, Safeguarding and Disposal*. In addition, NCDACS/MPID maintains procedures to investigate and report transportation accidents that involve State-inspected and passed meat and poultry products.

NCDACS/MPID takes enforcement actions, when necessary, up to and including civil penalties and prosecution of individuals or firms that have violated the North Carolina General Statutes. The submitted documents support that NCDACS/MPID took enforcement actions in 67 statute violation cases, and were directly involved in 4 prosecutions and court actions of statute violators in FY 2011.

As part of NCDACS/MPID's management controls, the compliance supervisor and director review compliance case file reports for accuracy and supportable legal dispositions.

NCDACS/MPID maintains recall procedures for meat and poultry products, subject to its jurisdiction, that are equal to procedures described in FSIS Directive 8080.1, *Recall of Meat and Poultry Products*. These procedures include health hazard evaluation, recall classification, public notification, effectiveness checks, and closure. Firms are to notify NCDACS/MPID within 24 hours of initiating a recall. NCDACS/MPID 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.

NCDACS/MPID established methods to record, triage, analyze, and track consumer complaints directly related to State-regulated meat or poultry products. 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. NCDACS/MPID documents and prioritizes consumer complaints on compliance referral forms and then assigns these complaints to compliance officers to investigate. NCDACS/MPID investigated 12 consumer complaints in FY 2011.

The submitted documents support the conclusion that NCDACS/MPID 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 October 30, 2011, NCDACS/MPID 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 NCDACS/MPID functions "at least equal to" the Federal civil rights requirement.

Component 9 – Financial Accountability
NCDACS/MPID 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 NCDACS/MPID is "at least equal to" Federal standards for financial accountability for Fiscal Year (FY) 2012.

Self-Assessment Determination for North Carolina
Based on the evidence and results discussed above, FSIS determined that NCDACS/MPID provided adequate documentation to show it operates a meat and poultry inspection program "at least equal to" the Federal requirements. NCDACS/MPID 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 North Carolina.
- The on-site determination for North 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 North Carolina

The FSIS review team analyzed all information gathered during the on-site review and NCDACS/MPID's action plan, which addressed the findings identified during the review, to determine whether NCDACS/MPID 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 individual determination is listed below for each component.

FSAB conducted an on-site review of NCDACS/MPID, for components 2 through 7, from April 23 to May 4, 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 NCDACS/MPID during six establishment reviews. During these reviews, NCDACS/MPID personnel identified multiple noncompliances with HACCP monitoring, Sanitation SOPs, SPS, and labeling requirements. FSAB identified noncompliances with Sanitation SOPs, SPS, custom exemptions, and generic *E. coli* requirements that NCDACS/MPID personnel did not recognize. NCDACS/MPID officials initiated regulatory actions in the establishments and issued noncompliance records at the time the noncompliances were identified.

On May 24, 2012, NCDACS/MPID submitted an action plan to correct the findings identified during the review. This plan identifies actions to correct specific findings at individual establishments and includes evidentiary documents to demonstrate verification of establishment compliance with regulatory requirements.

FSAB analyzed information from the establishment reviews and NCDACS/MPID's action plan, and concluded that NCDACS/MPID personnel identify and document noncompliance with regulatory requirements, take appropriate regulatory actions, and verify that establishments correct noncompliance. NCDACS/MPID 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.

NCDACS/MPID met FSIS' guidance to States on frequency of testing for pathogenic bacteria and *Salmonella* in raw products.

FSAB analyzed information from the NCDACS/MPID office and establishment reviews, and concluded that NCDACS/MPID 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 NCDACS/MPID 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 NCDACS/MPID office and establishment reviews, FSAB concluded that NCDACS/MPID 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 NCDACS/MPID'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 antemortem and postmortem inspection, humane handling, processed products, HACCP, Sanitation SOPs, rules of practice, IPPS 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 NCDACS/MPID 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 presented on-site to determine whether NCDACS/MPID 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 NCDACS/MPID 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, Daily Activity Reports, Programmed Compliance Plans, Incident Reports, Case Reports, Reports of Apparent Violations, and Notices of Warning.

The review of compliance documents and case files support the conclusion that NCDACS/MPID 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.

NCDACS/MPID 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 North Carolina General Statutes. The Reports of Investigation were completed in accordance with FSIS Directive 8010.4, *Report of Investigation.* NCDACS/MPID uses the investigative findings and evidence to pursue enforcement actions for administrative, civil, or criminal sanctions.

NCDACS/MPID follows the recall procedures in FSIS Directive 8080.1, *Recall of Meat and Poultry Products*, with minor modifications fitting its organizational structure. No State-inspected establishments or retail firms recalled product during FY 2011 and up until May 3, 2012.

NCDACS/MPID maintains a system to review, analyze, and triage consumer complaints. NCDACS/MPID gathers information pertinent to these complaints, directs the compliance division to investigate these complaints, and files completed investigation documents in the State office.

FSAB analyzed the information gathered during the review of NCDACS/MPID office records and concluded that NCDACS/MPID 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 July 23, 2012, CRD reviewed documents and conditions at the NCDACS/MPID offices to determine whether NCDACS/MPID 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 NCDACS/MPID and concluded NCDACS/MPID is "at least equal to" Federal civil rights requirements.

Component 9 – Financial Accountability

FSAS did not conduct an on-site financial audit and compliance review of NCDACS/MPID in FY 2012. Therefore, the annual determination was based on the self-assessment review results only.

On-Site Determination for North Carolina

Based on the evidence and results discussed above, FSIS determined that NCDACS/MPID 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.