Appendix O

Comprehensive Review and Determination Report

Fiscal Year 2021

North Carolina

Federal-State Audit Staff
Office of Investigation, Enforcement and Audit
Food Safety and Inspection Service
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Purpose
This report communicates the United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS), Office of Investigation, Enforcement and Audit (OIEA), Federal-State Audit Staff’s (FSAS) annual review results and determination for the North Carolina Meat and Poultry Inspection (MPI) program, and presents an overview of the review methodology used for determining if the State MPI program is “at least equal to” FSIS’ MPI program.

Description of North Carolina’s MPI Program
The North Carolina Department of Agriculture and Consumer Service (NCDACS), Meat and Poultry Inspection Division (NCDACS/MPID) administers the North Carolina MPI program under authority of North Carolina General Statutes (Chapter 106, Articles 49B, 49C, and 49D). The program verifies compliance and enforces regulatory requirements at 51 inspected facilities and 222 custom exempt establishments. In addition, NCDACS/MPID provides inspection at 109 facilities in the Federal-State Cooperative Agreement Inspection Program.

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 desk review of the self-assessment documents, and (2) FSIS’ onsite review. This determination is fully explained in the sections entitled “Part I – Self-Assessment Review” and “Part II – Onsite Review.”

Part I. Self-Assessment Review
Part I includes the following:
- Description of the Self-Assessment Review Methodology followed for all State MPI programs;
- Review of North Carolina’s Self-Assessment Submission; and
- Self-Assessment Determination for North Carolina.

Self-Assessment Review Methodology
The annual self-assessment process is designed for each State to provide sufficient information to adequately demonstrate their administration of an “at least equal to” State MPI program. The review objective is to determine whether a State continues to administer an MPI program that meets Federal standards set for ensuring meat and poultry products are safe, wholesome, unadulterated, and correctly labeled and packaged. Each review cycle, State MPI program officials are to complete and submit self-assessment component surveys, supporting documentation and other self-assessment instruments to FSIS in accordance with the State

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1 Custom exempt establishments are slaughter and processing establishments that are not subject to the routine inspection requirements of the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), provided the specified operations meet the exemption requirements (21 U.S.C. 623 and 464).

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.
Reporting and Communication Tool User Guide and FSIS “At Least Equal To” Guideline for State Meat and Poultry Inspection Programs.

FSIS begins the annual comprehensive review by assembling a review team comprised of subject matter experts from various FSIS program areas to review the nine components of the comprehensive review process. The review team, comprised of Agency representatives from the Federal-State Audit Staff (FSAS); the Civil Rights Staff (CRS); Financial Reviews and Systems Branch (FRSB); Laboratory Quality Assurance Response and Coordination Staff (LQARCS); 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. During the desk review process, the Office of Policy and Program Development and the Office of Field Operations are consulted as needed to gain context and perspective on current FSIS programs, policies, and procedures when determining whether a State MPI program meets Federal “at least equal to” standards.

If questions arise during the desk review or if additional documentation is needed to make a review determination regarding one or more components, FSIS will request clarifying information from the State MPI program. Upon completion of the desk review, FSIS makes one of the following three determinations for each component and for the non-designated3 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 equal to” FSIS’ Federal inspection program for all review components.
2. “At Least Equal To” with Provisions means FSIS makes a provisional determination of the State MPI program’s “at least equal to” status provided the program takes additional action to resolve review findings.
3. 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” FSIS’ Federal inspection program for one or more of the review components.

**Review of North Carolina’s Self-Assessment Submission**

FSIS evaluated the self-assessment documents for the applicable review components to determine whether NCDACS/MPID implements an inspection program “at least equal to” the Federal program. The determination and rationale for each review component are listed below.

FSAS received NCDACS/MPID’s self-assessment submission for components 1 through 6 on March 30, 2021. FSAS reviewed the submitted clarification items, and accepted the requested information on July 22, 2021.

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3 Non-designated is a State that operates an MPI program under a cooperative agreement with FSIS. The State MPI program must administer inspection and food safety requirements “at least equal to” those imposed under the Federal Meat Inspection Act, Poultry Products Inspection Acts and Humane Methods of Slaughter Act of 1978.
Component 1 – Statutory Authority and Food Safety Regulations

FSAS compared the submitted self-assessment and supporting documentation to the legal authority provided under the FMIA, PPIA, and the Humane Methods of Slaughter Act (HMSA), and the regulations promulgated under these laws. The supporting documentation included the North Carolina General Statutes (Chapter 106, Articles 49B, 49C, and 49D and North Carolina Administrative Code (Title 02, Chapter 52, Subchapter 52D). The North Carolina General Statutes provide authorities for mandatory ante-mortem and post-mortem inspection, reinspection (Sections 106-549.17, 106-549.18, 106-549.53, and 106-549.53), sanitation requirements (Sections 106-549.22 and 106-549.54), record keeping requirements (Sections 106-549.36 and 106-549.58), and humane methods of slaughter requirements (Section 106-549.17).

In addition, the North Carolina General Statutes provides authorities that are “at least equal to” the FMIA and PPIA regarding adulteration (Section 106-549.15), misbranding (Section 106-549.56), prohibited acts (Section 106-549.23), access and examination (Sections 106-549.20, 106-549.36, and 106-549.58), and product control actions (Sections 106-549.31, 106-549.32, 106-549.65, and 106-549.66). It also includes sufficient authorities for criminal, civil, and administrative sanctions to address violators.

The North Carolina General Statutes grants the authority to promulgate rules and regulations (Sections 106-549.22, 106-549.26, and 106-549.61). North Carolina adopts 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 showing that 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 regulations.

Component 2 – Inspection

FSAS compared the self-assessment submission and supporting documentation regarding inspection policies and procedures and regarding verification of establishments’ compliance, to the Federal requirements. NCDACS/MPID uses the FSIS Public Health Information System (PHIS) to schedule inspection tasks and to collect, consolidate, and analyze inspection data. NCDACS/MPID administers inspection for any meat or poultry product intended for human consumption, wholly or in part, from the carcass or parts of any animal defined as “livestock” or “poultry” in the North Carolina General Statutes and governing rules and regulations. The State inspection program impose regulations and perform inspection duties that ensure animals intended to be used in meat and poultry products sold commercially, are slaughtered and processed in the presence of State inspection personnel, and the resulting meat food products are inspected and passed for human consumption. Furthermore, NCDACS/MPID administers a food safety verification program that meets the intent of FSIS Directive 5000.1., Verifying an Establishment’s Food Safety System. Food safety verification activities are performed to ensure establishments’ compliance with applicable pathogen reduction, sanitation, and the Hazard Analysis and Critical Control Point (HACCP) regulations.

In addition to performing inspections and food safety verifications, NCDACS/MPID schedules and performs a comprehensive food safety assessment (FSA) at each inspected establishment in
accordance with FSIS Directive 5100.1, Enforcement, Investigations and Analysis Officer (EIAO) Comprehensive Food Safety Assessment (FSA) Methodology, and 5100.4, Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology. These FSAs examine the design and validity of establishments’ food safety systems, which include hazard analyses, HACCP plans, Sanitation Standard Operating Procedures (Sanitation SOP), prerequisite programs, sampling programs, supporting documentation and records, and any other programs that constitute the establishments’ food safety systems. The PHRE and FSA records support the conclusion that State inspection personnel recognize and document noncompliance and initiate appropriate regulatory actions.

NCDACS/MPID verifies establishment compliance with the non-food safety (i.e., labeling) consumer protection regulatory requirements. NCDACS/MPID uses applicable FSIS directives to instruct inspection personnel and uses PHIS to schedule ongoing verifications and document noncompliance. A thorough review of the PHIS data for a 12-month period supports the conclusion that NCDACS/MPID inspectors correctly apply the inspection methodology and document noncompliance.

NCDACS/MPID maintains a 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 NCDACS/MPID approval.

NCDACS/MPID enforces the North Carolina Administrative Code (02 NCAC 52D.0101), 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. NCDACS/MPID maintains procedures to document relevant facts of administrative actions and ensure that administrative actions are legally supportable 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;
- Conducts inspection activities “at least equal to” the Federal requirements; and
- Monitors these activities through control measures to verify that the inspection system functions as intended.

Component 3 – Sampling Programs

FSIS compared NCDACS/MPID’s sampling protocols, procedures, and results to Federal policies and procedures.

NCDACS/MPID provided documentation to demonstrate that it maintains sampling programs, based on sound rationale and goals, for the following:
- *Escherichia coli (E. coli)* O157:H7 in raw non-intact beef products and raw ground beef components;
- Non-O157 Shiga toxin-producing *E. coli* (non-O157 STEC) in beef manufacturing trimmings;
- *Listeria monocytogenes* (L. monocytogenes) and *Salmonella* in ready-to-eat products; and
- Other consumer protection standards.

The sampling plans include procedures for sample collection, sample integrity, and laboratory analysis. NCDACS/MPID developed policies to respond to positive results. These policies include actions to prevent adulterated product from entering commerce. NCDACS/MPID participates in the FSIS National Residue Program and collects and analyzes inspector-generated samples for violative drug residues.

In conclusion, a 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, Training, and Supervision**

NCDACS/MPID developed methods to determine staffing requirements. The requirements consider each inspector’s workload and the number of inspectors required to provide daily inspection coverage in each establishment on days when 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 the Establishment Workload and Assignment Computation form to determine the workload for each inspector assignment and maintains a level of personnel sufficient to provide routine inspection at establishments producing inspected products; NCDACS/MPID maintains one relief inspector for each area with one additional relief inspector in the east and one in the west to be shared, as needed.

At the start of the FY 2021 review cycle, NCDACS/MPID indicated they employ 4 headquarters (HQ) managers, 6 administrative personnel, 3 trainers, 10 field supervisors, 6 veterinary medical officers (VMO), 84 inspectors, 1 compliance program manager, and 4 compliance officers. NCDACS/MPID also indicated that five of their personnel (two HQ managers, one trainer, and two VMOs) are additionally cross trained as enforcement, investigations and analysis officers.

NCDACS/MPID continues to implement a training program for new entry-level inspection personnel. The formal courses include “Occupational Safety and Health Administration (OSHA) Safety Training”; “Lockout/Tag-Out”; “Ethics and Conduct”; “Inspection Methods”; and “Basic Slaughter Training”. All new field inspection personnel complete a six-week on-the-job training (OJT) program, which includes performance evaluations. 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 coach the employee or request
additional OJT for the employee. NCDACS/MPID electronically tracks employee training on Employee Training Reports.

NCDACS/MPID administers a performance evaluation program that the North Carolina Office of State Human Resources mandates; NCDACS/MPID also evaluates personnel using the methods described in FSIS Directive 4430.3, In-Plant Performance System (IPPS). This program defines the 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 the necessary followup trainings, and submits a Training Summary Report. In addition to performance evaluations and IPPS assessments, area supervisors conduct routine meetings to update inspection personnel on current policies and address areas of concern. NCDACS/MPID maintains control measures to examine the IPPS assessments for quality, completeness, and accuracy. This system communicates to its employees their work responsibilities, performance goals and objectives, and the results of their annual performance evaluations.

After thorough review of the submitted documents, FSAS 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, to document findings, and to 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
NCDACS/MPID schedules and performs regulatory verification procedures to assess whether establishment personnel humanely handle all livestock throughout the time the livestock are on official establishment premises, and it takes appropriate regulatory action in response to noncompliance.

NCDACS/MPID uses FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock, to communicate instructions to inspection personnel. Inspectors document humane handling verifications in PHIS. NCDACS/MPID regional veterinary medical officers (RVMO) perform annual humane handling reviews at slaughter facilities in accordance with FSIS Directive 6910.1, District Veterinary Medical Specialist (DVMS) - Work Methods.

The information supports the conclusion that NCDACS/MPID verifies compliance with 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 – Compliance
NCDACS/MPID personnel conduct in-commerce surveillance of persons or firms that 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 are secure from threats or intentional acts of contamination.

NCDACS/MPID 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 North Carolina General Statutes; and takes enforcement action, when needed, up to and including prosecution of individuals or firms that have violated the North Carolina General Statutes. NCDACS/MPID 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.

NCDACS/MPID management reviews all compliance reports for correctness, extracts pertinent information for reporting purposes, enters this information in a database, and files the hard copies. The supervisory compliance officer reviews all violations and relevant evidence, and then determines the appropriate case disposition and course of action.

NCDACS/MPID maintains procedures for the recall of meat and poultry products subject to its jurisdiction that are “at least equal to” the 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 news releases as necessary to serve the interest of public health.

NCDACS/MPID established methods to record, triage, analyze, and track consumer complaints related to State-regulated meat or poultry products. Compliance personnel either investigate these complaints or refer them to the local health authority. The investigative methods include procedures for collecting and safeguarding evidence; conducting interviews; submitting product samples to the laboratory; initiating recall procedures and/or regulatory and enforcement actions; and reporting potential food safety threats.

NCDACS/MPID has a system for reviewing custom exempt operations that is in accordance with FSIS Directive 8160.1, Custom Exempt Review Process. RVMOs perform the review at custom and retail exempt establishments every 3 months, and at custom exempt only establishments every 12 months. RVMOs recommend increasing frequency of visits when identifying any unacceptable findings. An Area supervisor perform the review at State inspected establishment annually.

The submitted documents support the conclusion that NCDACS/MPID maintains a system to verify compliance of meat and poultry products in intrastate commerce and takes 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 7 – Laboratory Methods and Quality Assurance Program
OPHS conducted an onsite review of the North Carolina Department of Agriculture & Consumer Services Food & Drug Protection (NCDACS/FDP) for microbiological pathogens. USDA/FSIS/Eastern Laboratory (EL) conducts food chemistry testing on NCDACS/FDP’s behalf. OPHS evaluated the laboratory quality assurance (QA) and methods for NCDACS/FDP in conjunction with the onsite review, which is included in Part II of this document, Onsite Review.

Component 8 – Civil Rights
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. On August 10, 2021, CRS concluded that NCDACS/MPID functions “at least equal to” the Federal civil rights requirements.

Component 9 – Financial Accountability
NCDACS/MPID submitted quarterly and final Financial Status Reports (SF-425), and the 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. FRSB determined that NCDACS/MPID is “at least equal to” Federal standards for financial accountability for FY 2021.

Self-Assessment Determination for North Carolina
Based on the evidence and review results described above, FSIS determined that NCDACS/MPID provided adequate documentation to show it is operating a meat and poultry inspection program “at least equal to” the Federal requirements.

Part II. Onsite Review

Part II includes:

- A description of the onsite review methodology followed for all State MPI programs;
- An onsite review of North Carolina; and
- An onsite determination for North Carolina.

Onsite Review Methodology
The onsite review determines whether the State implements its MPI program in a manner that is “at least equal to” the Federal inspection program and maintains program policies and procedures in accordance with those submitted in the annual self-assessment documents. The FSIS onsite review team is comprised of representatives from FSAS, CRS, FRSB, LQARCS, and other program areas as needed. FSIS Directive 5720.3, Methodology for Performing Scheduled and Targeted Reviews of State Meat and Poultry Inspection Programs, outlines the comprehensive State MPI program review process.
As the primary contact for State MPI program officials and FSIS review team members, the lead FSAS program auditor is to coordinate and track components 1 through 6 onsite review activities and to monitor the status of components 7 through 9 reviews through communications with LQARCS, CRS, and FRSB. The FSAS auditor schedules the onsite review, for components 1 through 6, with State MPI program officials. FSAS will send written notification to State MPI program officials at least 30 days prior to the start of the onsite review. LQARCS, CRS, and FRSB are to schedule onsite reviews of components 7 (laboratory methods and quality assurance program), 8 (civil rights), and 9 (financial accountability), respectively.

Upon completion of an onsite review, FSIS is to make 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” FSIS’ Federal inspection program for all review components.
2. “At Least Equal To” with Provisions means FSIS makes a provisional determination of the State MPI program’s “at least equal to” status provided the program takes additional action to resolve review findings.
3. 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” FSIS’ Federal inspection program for one or more of the review components.

**Onsite Review of North Carolina**

FSIS analyzed all information gathered during the onsite 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 determination and rationale for each review component are listed below.

FSAS conducted an onsite review of NCDACS/MPID, for components 1 through 6, April 19 to April 30, 2021. Based on records and procedures reviewed, FSAS determined NCDACS/MPID was able to confirm the program is being implemented as described in self-assessment.

**Component 2 – Inspection**

FSAS reviewed the conditions and documents onsite. The onsite documents reviewed included, but were not limited to, Sanitation SOP 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. In addition, FSAS reviewed the non-food safety consumer protection documents and procedures 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, ongoing regulatory verification tasks, label approvals, labels, and product formulations.
FSAS evaluated NCDACS/MPID during 10 establishment reviews. NCDACS/MPID personnel identified several establishment noncompliances during the onsite review, with the Sanitation SOP, Sanitation Performance Standards, HACCP implementation and validation, and sampling program. The FSAS program auditor identified several establishment noncompliances that State MPI program officials did not recognize. NCDACS/MPID officials initiated regulatory actions in the establishments and issued noncompliance records at the time the noncompliances were identified.

On June 1, 2021, NCDACS/MPID submitted an action plan to correct the findings identified during the review. The action plan identifies the underlying causes of both the system-wide findings and the specific findings at individual establishments, and includes a verification plan to ensure statewide correction of these findings. In addition, NCDACS/MPID provided evidentiary documents to demonstrate verification of establishment compliance with the regulatory requirements.

Component 3 – Sampling Programs
FSAS reviewed NCDACS/MPID’s product sampling documents, protocols, procedures, and results presented onsite. These included sampling plans and laboratory results for E. coli O157:H7 in raw non-intact beef products and raw ground beef components, non-O157 STEC in raw beef manufacturing trimmings, L. monocytogenes and Salmonella in ready-to-eat products, violative drug residues, State laboratory activity reports, and sample seals. FSAS determined NCDACS/MPID was able to confirm the program is being implemented as described in self-assessment.

Component 4 – Staffing, Training, and Supervision
FSAS reviewed the staffing and training program onsite to assess whether NCDACS/MPID carries out its staffing, training, and supervisory 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, FSAS concluded that NCDACS/MPID has an adequate number of trained persons to provide the required inspection coverage in the establishments, perform compliance activities, and provide supervisory oversight, and has implemented procedures to ensure daily inspection coverage in operating establishments. Inspection personnel apply NCDACS/MPID’s inspection methodology, and 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 ante-mortem and post-mortem inspection, humane handling, shelf stable products, HACCP, Sanitation SOP, labeling, and Inspection Methods training. No issues were identified with the staffing, training and supervision component at the State Office.

Component 5 – Humane Handling
FSAS reviewed the humane handling program and documents presented onsite to determine whether 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. These documents included, but were not limited to, noncompliance records and procedure schedules. FSIS reviewed humane handling of
livestock, stunning methods, and the condition of livestock pens, driveways, and ramps. No issues were identified with humane handling during the onsite review.

**Component 6 – Compliance**

FSAS conducted an onsite review of the compliance program activities and all specified documents to determine whether NCDACS/MPID implements a compliance program in accordance with the submitted self-assessment documentation. These included, but were not limited to, Reports of Investigation, Daily Activity Reports, Consumer Complaint tracking log, Case Files, Compliance Review Database, 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 North Carolina MPID Notice 1-21, Standard Operating Procedure for Completing Compliance Referral Form 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 Database.

NCDACS/MPID has a system for reviewing custom exempt operations that is in accordance with FSIS Directive 8160.1, Custom Exempt Review Process. The inspector in charge performs custom exempt review in State inspected establishments per the frequency scheduled by PHIS. RVMOs schedule, track, and perform custom exempt review at custom only facilities once per year and at custom/retail facilities once per quarter. The need for followup reviews is determined by findings. No issues were identified with the compliance program.

**Component 7 – Laboratory Methods and Quality Assurance Program**

An onsite review of the NCDACS/FDP was performed during FY21 to evaluate laboratory quality assurance programs and method equivalence under the State MPI Program.
NCDACS/FDP conducts microbiological testing for *Salmonella, E. coli* O157:H7, non-O157 STEC, and *L. monocytogenes*. USDA/FSIS/Eastern Laboratory (EL) conducts chemistry testing on NCDACS/FDP’s behalf for the measurement of moisture, protein, fat and salt.

FSIS compared the NCDACS/FDP Laboratory Quality Assurance Program to the State Meat and Poultry Inspection Program Laboratory Quality Management System Checklist and evaluated evidence of laboratory proficiency and analyst training. NCDACS/FDP met all Laboratory QA requirements.

The EL has demonstrated adequate food chemistry capability for the measurement of moisture, protein, fat and salt. NCDACS/FDP has demonstrated adequate microbiological capabilities for detection of *Salmonella, E. coli* O157:H7, non-O157 STEC, and *L. monocytogenes*.

Based on the Component 7 methods and quality assurance program review, North Carolina may be eligible to perform inspection:

- At beef establishments producing raw ground beef and bench trim, and at beef slaughter establishments producing manufactured trim, provided the State collects and submits the appropriate number of samples that are tested for *Salmonella, E. coli* O157:H7, and non-O157 STEC.

- At “ready-to-eat” meat and poultry establishments, provided the State collects and submits the appropriate number of samples that are tested for *Salmonella* and *L. monocytogenes*.

- At poultry slaughter establishments, provided the State collects and submits the appropriate number of samples are tested for *Salmonella* and *Campylobacter*. MPI States with no participating facilities slaughtering at least 20,000 chickens and/or 20,000 turkeys per year are not required to test raw product for *Salmonella* and *Campylobacter* since it is not required at similar federally inspected plants. However, States should consider testing at a risk hierarchy that is commensurate with their establishment sizes and production volumes. Note: Analytical methods for *Salmonella* and *Campylobacter* in raw poultry products were not evaluated as North Carolina is not currently inspecting MPI program poultry establishments slaughtering at least 20,000 chickens and/or turkeys per year.

**Component 8 – Civil Rights**

In March 2021, CRS conducted a civil rights compliance review of NCDACS/MPID. The review assessed the State’s compliance with applicable Federal civil rights laws, USDA regulations, and FSIS policies; where necessary, recommendations were provided. Compliance was assessed in eight areas: (1) Civil Rights Assurances; (2) State Infrastructure and Program Accountability; (3) Public Notification; (4) Complaints of Discrimination; (5) Civil Rights Training; (6) Disability Compliance; (7) Program Accessibility for Individuals with Limited English Proficiency; and (8) Compliance with the Age Discrimination Act of 1975. The review was conducted using telephonic interviews, a facility assessment, and review of documents. The last review of the State was conducted in 2018.
Because of this review, CRS concluded that NCDACS/MPID is “at least equal to” Federal civil rights requirements.

Component 9 – Financial Accountability
FRAS did not conduct an onsite financial review and compliance review of NCDACS/MPID in FY 2021. Therefore, the annual determination will be based on the self-assessment review results only.

Onsite 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.