Appendix Y

Comprehensive Review and Determination Report

Fiscal Year 2021

West Virginia

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 West Virginia 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 West Virginia’s MPI Program
The West Virginia Department of Agriculture/Meat and Poultry Inspection Bureau (WVDA/MPIB) administers the West Virginia MPI program under authority of West Virginia Code (Chapter 19, Articles 2B and 2E). The program verifies compliance and enforces regulatory requirements at 23 inspected facilities and 21 custom exempt establishments.1

Annual Determination
FSIS determined that WVDA/MPIB 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 West Virginia’s Self-Assessment Submission; and
• Self-Assessment Determination for West Virginia.

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 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

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).
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-designated\(^2\) 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 West Virginia’s Self-Assessment Submission**

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

FSAS received WVDA/MPIB’s self-assessment submission for components 1 through 6 on February 8, 2021. FSAS sent a notification to WVDA/MPIB affirming acceptance of their self-assessment submission and all requested supplementary information provided on April 5, 2021.

**Component 1 – Statutory Authority and Food Safety Regulations**

FSAS compared the submitted self-assessment and supporting documentation to the legal authority provided under the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Humane Methods of Slaughter Act (HMSA), and the regulations promulgated under these laws. The supporting documentation included the West Virginia Code (Chapter 19, Articles 2B and 2E) and West Virginia Legislative rule, Inspection of Meat and Poultry (Title 61, Series 16). The West Virginia Code provides authorities for mandatory ante-mortem and post-mortem inspection, reinspection (Section 19-2B-6), sanitation requirements

\(^2\) 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 Act and the Humane Methods of Slaughter Act of 1978.
(Section 19-2B-6), record keeping requirements (Section 19-2B-5), and humane methods of slaughter requirements (Sections 19-2E-1 through 19-2E-7).

In addition, the West Virginia Code provides authorities that are “at least equal to” the FMIA and PPIA regarding adulteration (Section 19-2B-2), misbranding (Section 19-2B-2), prohibited acts (Section 19-2B-10), access and examination (Section 19-2B-5), and product control actions (Section 19-2B-6). It also includes sufficient authorities for criminal, civil, and administrative sanctions to address violators.

The West Virginia Code grants the authority to promulgate rules and regulations (Section 19-2B-3). West Virginia adopts by reference Title 9, Code of Federal Regulations (9 CFR) Parts 301 et seq., 381, 412, 416, 417, 418, 424, 430, 441, 442, and 500 with exceptions, in the West Virginia Legislative Rule, Inspection of Meat and Poultry (Sections 61-16-2 and 61-16-3).

WVDA/MPIB provided evidence that supports the conclusion 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. WVDA/MPIB uses the FSIS Public Health Information System (PHIS) to schedule inspection tasks and to collect, consolidate, and analyze inspection data. WVDA/MPIB 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 West Virginia Code (Chapter 19, Article 2B) 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; the resulting meat food products are inspected and passed for human consumption. Furthermore, WVDA/MPIB administers a food safety verification program that meets the intent of FSIS Directives 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, WVDA/MPIB schedules and performs a comprehensive Food Safety Assessment (FSA) at least once every four years at each inspected establishment in accordance with FSIS Directives 5100.1, Enforcement, Investigations and Analysis Officer (EIAO) 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 Operational Procedures (Sanitation SOP), prerequisite programs, sampling programs, supporting documenting 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.
WVDA/MPIB verifies establishment compliance with the non-food safety (i.e., labeling) consumer protection regulatory requirements. WVDA/MPIB 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 WVDA/MPIB inspectors correctly apply the inspection methodology and document noncompliance.

WVDA/MPIB maintains a label approval policy and process to verify that labels are accurate and meet regulatory requirements. WVDA/MPIB follows FSIS guidance for generic label approvals and allows generic approval of labels for single cuts of meat, single ingredient products, and those without special claims. For labels not subject to generic approval, 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 WVDA/MPIB approval.

WVDA/MPIB enforces the West Virginia Legislative rule, Inspection of Meat and Poultry (Title 61, Series 16), 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. WVDA/MPIB 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 WVDA/MPIB:

- 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 WVDA/MPIB’s sampling protocols, procedures, and results to Federal policies and procedures.

WVDA/MPIB 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;
• *Salmonella* performance standards in raw classes of meat and poultry; and
• Other consumer protection standards.

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

A program nonconformity was identified where WVDA/MPIB was not requiring establishments to conduct ongoing verification testing to ensure that STEC was reduced to undetectable levels in product intended for non-intact use. In response to this program nonconformity, WVDA/MPIB developed a new guidance document, FY 2021 In-House Boxed Beef Verification Plan. This document provided the State-inspected establishments an outline of their responsibilities regarding ongoing verification testing for STEC, and a sampling plan that met the current compliance guidelines for this testing. As of September 2021, this verification plan has been implemented in all applicable WVDA establishments. This sufficiently demonstrated that WVDA/MPIB addressed this program nonconformity and has committed to verifying and enforcing compliance with 9 CFR 417.4(a)(2).

In conclusion, a detailed review of other sampling protocols, procedures, and results confirmed that WVDA/MPIB maintains program 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**

WVDA/MPIB 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. WVDA/MPIB divides the State into two geographic circuits and assigns a circuit supervisor to each circuit. Each circuit supervisor assigns inspectors’ work schedules and arranges relief inspection during routine and emergency leave situations. The circuits are sharing inspectors to provide relief inspection, as needed. The circuit supervisors, compliance officer, inspection manager, and the director/assistant director also provide relief inspection, when necessary. To verify daily inspection assignment coverage, the circuit supervisors monitor inspection task results and file seal security logs and conduct unannounced establishment visits. The inspection manager and director/assistant director randomly visit establishments to verify inspection coverage.

At the start of the FY 2021 review cycle, WVDA/MPIB employed 1 director/assistant director/compliance officer, 11 full-time inspectors, 3 part-time inspectors, 1 veterinary medical officer (VMO), 1 part-time VMO, 2 circuit supervisors, 1 full-time administrative assistant, 1
part-time administrative assistant, and 1 program manager/enforcement, investigations, and analysis officer, and 1 compliance personnel.

WVDA/MPIB continues to implement a training program for new entry-level inspection personnel. The training covers basic slaughter techniques and all inspection techniques required to perform slaughter duties, including basic Sanitation SOPs and HACCP procedures. Initially, the inspector-trainee works under the guidance of the veterinary supervisor, assistant director, and veteran inspectors to learn all aspects of slaughter inspection. The WVDA/MPIB inspectors must complete classroom courses offered through the FSIS Center for Learning (e.g., Inspection Methods Training) and online AgLearn trainings. Furthermore, the VMOs complete the FSIS public health veterinary training. Employees must pass testing before working without direct supervision, and each in-plant inspector is evaluated annually with a hands-on post-mortem inspection assessment by the public health veterinarian or circuit supervisor. WVDA/MPIB maintains a list of completed training in each employee’s file.

WVDA/MPIB incorporates the guidance in FSIS Directive 4430.3, In-Plant Performance System (IPPS), to set performance standards, and complete and record ongoing performance evaluations. The supervisors are to perform at least two IPPS assessments for each inspector annually. In addition, the supervisors assess new inspectors throughout training and evaluate written examination scores at the end of training. WVDA/MPIB maintains control measures to examine the IPPS assessments for quality, completeness, and accuracy.

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

Component 5 – Humane Handling
WVDA/MPIB 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.

WVDA/MPIB uses FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock, to communicate instructions to inspection personnel. Inspectors document humane handling verifications in PHIS and on WVDA/MPIB Report of Humane Handling Verification Visit forms. During quarterly visits, veterinary supervisors evaluate establishments’ humane handling procedures and inspectors’ humane handling task performance. WVDA/MPIB VMOs 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 WVDA/MPIB 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 – Compliance
WVDA/MPIB 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.

WVDA/MPIB 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 West Virginia Code; and takes enforcement action, when needed, up to and including prosecution of individuals or firms that have violated the West Virginia Code. WVDA/MPIB 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.

WVDA/MPIB 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 program director/assistant director reviews all violations and relevant evidence and determines the appropriate case disposition and course of action.

WVDA/MPIB 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 required to notify WVDA/MPIB within 24 hours of initiating a recall. WVDA/MPIB 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.

WVDA/MPIB 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 to collect and safeguard evidence, conduct interviews, submit product samples to the laboratory, initiate recall procedures and/or regulatory and enforcement actions, and report potential food safety threats.

WVDA/MPIB has a system for reviewing custom exempt operations that is in accordance with FSIS Directive 8160.1, Custom Exempt Review Process. In-plant personnel conduct custom exempt reviews with a target of quarterly. These exempt establishment reviews are scheduled by the circuit supervisor and documented on WVDA/MPIB form 11-F004. Follow-up reviews are recommended quarterly, monthly, or weekly based on the severity of findings. Completed 11-F004 forms are sent to a designated custom exempt coordinator in each circuit, who compiles a completed Custom Plant Quarterly Report and forwards them to WVDA/MPIB’s headquarters in Guthrie. Circuit supervisors review this Custom Plant Report as part of their duties, and in this
manner, control measures are in place to ensure that the custom exempt reviews are being completed at the intended frequency and as outlined in FSIS directives.

The information supports the conclusion that WVDA/MPIB 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 7 – Laboratory Methods and Quality Assurance Program
LQARCS conducted an onsite review of the West Virginia Department of Agriculture Agricultural Laboratory (WVDAAL) for microbiological pathogens and food chemistry testing. LQARCS evaluated the laboratory quality assurance (QA) program and methods for WVDAAL in conjunction with the onsite review, which is included in Part II of this document, Onsite Review.

Component 8 – Civil Rights
On October 29, 2020, WVDA/MPIB 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. CRS concluded that WVDA/MPIB functions “at least equal to” the Federal civil rights requirements and has fulfilled the self-assessment requirements for this component.

Component 9 – Financial Accountability
WVDA/MPIB 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. As of November 2021, FRSB determined that WVDA/MPIB is “at least equal to” Federal standards for financial accountability for FY 2021.

Self-Assessment Determination for West Virginia
Based on the submitted self-assessment documents and desk review results described above, FSIS determined that WVDA/MPIB 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 West Virginia; and
- An onsite determination for West Virginia.
**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 reviewer coordinates and tracks components 1 through 6 onsite review activities and monitors the status of components 7 through 9 reviews through communications with LQARCS, CRS, and FRSB. The FSAS reviewer schedules the onsite review, for components 1 through 6, with State MPI program officials. FSAS sends written notification to State MPI program officials at least 30 days prior to the start of the onsite review. If applicable, LQARCS, CRS, and FRSB 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 West Virginia**

FSIS analyzed all information gathered during the onsite review and WVDA/MPIB’s action plan, which addressed the findings identified during the review, to determine whether WVDA/MPIB 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 WVDA/MPIB, for components 1 through 6, May 17 to 27, 2021. Based on records and procedures reviewed, FSAS determined WVDA/MPIB 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 SOPs and associated records; HACCP plans and associated
records; generic $E. \text{ coli}$ 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 WVDA/MPIB 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 WVDA/MPIB during seven establishment reviews. WVDA/MPIB personnel identified several establishment noncompliances during the onsite review, with the Sanitation Performance Standards (SPS) at seven establishments, Sanitation SOPs at six establishments, and other inspection requirements at two establishments. At one establishment, the FSAS program reviewer identified noncompliance with the SPS requirements related to establishment grounds and facilities; construction; ventilation; equipment and utensils; sanitary operations and/or employee hygiene. At one establishment, FSAS identified the requirements related to Sanitation SOPs recordkeeping were not met. At two establishments, FSAS identified the requirements related to reassessments of the HACCP plan were not met. Additionally, at one establishment, FSAS identified the requirements related to the identification of custom products were not met. A program nonconformity was identified in one establishment with the location where the “Livestock Zero Tolerance Task” was being performed. WVDA/MPIB officials initiated regulatory actions in the establishments and issued noncompliance records at the time the noncompliances were identified. Evidence of closed out noncompliances was submitted with the program action plan to demonstrate the establishments bringing themselves back into compliance. Further, the WVDA/MPIB submitted evidence of circuit-wide employee retraining to address the program nonconformity identified.

On July 9, 2021, WVDA/MPIB submitted an action plan to correct the findings identified during the review. The action plan identifies the underlying causes of the system-wide findings and the underlying causes of the specific findings at individual establishments, and includes a verification plan involving circuit supervisor review of all establishments not visited to ensure statewide correction of these findings. In addition, WVDA/MPIB provided evidentiary documents to demonstrate verification of establishment compliance with the regulatory requirements on August 17, 2021. Based on records and procedures reviewed, FSAS determined WVDA/MPIB was able to confirm the program is being implemented as described in self-assessment.

**Component 3 – Sampling Programs**

FSAS reviewed WVDA/MPIB’s product sampling documents, protocols, procedures, and results presented onsite. These included sampling plans and laboratory results for $E. \text{ coli} \ O157:H7$ in raw non-intact beef products and raw ground beef components, non-$O157$ STEC in raw beef manufacturing trimmings, $L. \text{ monocytogenes}$ and $Salmonella$ in ready-to-eat products, $Salmonella$ performance standards in raw classes of meat and poultry, $Campylobacter$ performance standards in raw classes of poultry, economic samples, violative drug residues, State laboratory activity reports, and sample seals.
A program nonconformity was identified where WVDA/MPIB was not requiring establishments to conduct ongoing verification testing to ensure that STEC was reduced to undetectable levels in product intended for non-intact use. In response to this program nonconformity, WVDA/MPIB developed a new guidance document, FY 2021 In-House Boxed Beef Verification Plan. This document outlined to WVDA/MPIB establishments their responsibilities regarding ongoing verification testing for STEC, and a sampling plan that met the current compliance guidelines for this testing. As of September 2021, this verification plan has been implemented in all applicable WVDA establishments. This sufficiently demonstrated that WVDA/MPIB addressed this program nonconformity and has committed to verifying and enforcing compliance with 9 CFR 417.4(a)(2). A detailed review of other sampling protocols, procedures, and results during the State Office visit confirmed that WVDA/MPIB maintains program 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. Based on records and procedures reviewed, FSAS determined WVDA/MPIB 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 WVDA/MPIB 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 WVDA/MPIB office and establishment reviews, FSAS concluded that WVDA/MPIB 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 WVDA/MPIB’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 ante-mortem and post-mortem inspection, humane handling, processed products, HACCP, Sanitation SOPs, rules of practice, IPPS guidelines, compliance, and Inspection Methods training. FSAS concluded that WVDA/MPIB personnel had sufficient training, knowledge, and staffing levels to properly execute their regulatory tasks.

Component 5 – Humane Handling
FSAS reviewed the humane handling program and documents presented onsite to determine whether WVDA/MPIB 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. FSAS reviewed humane handling of livestock, stunning methods, and the condition of livestock pens, driveways, and ramps.

At one establishment, WVDA/MPIB officials identified the requirements related to livestock pens, driveways, and ramp maintenance were not met, and at one establishment, FSAS identified the requirements related to livestock pens, driveways, and ramp maintenance were not met.
Component 6 – Compliance
FSAS conducted an onsite review of the compliance program activities and all specified documents to determine whether WVDA/MPIB 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, 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 WVDA/MPIB 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.

WVDA/MPIB 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 Section 19-2B et seq. The Reports of Investigation were completed in accordance with FSIS Directive 8010.4, Report of Investigation. WVDA/MPIB uses the investigative findings and evidence to pursue enforcement actions for administrative, civil, or criminal sanctions.


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

WVDA/MPIB has a system for reviewing custom exempt operations that is in accordance with FSIS Directive 8160.1, Custom Exempt Review Process. In-Plant personnel conduct custom exempt reviews with a target of quarterly. These exempt establishment reviews are scheduled by the circuit supervisor and documented on WVDA/MPIB form 11-F004. Follow-up reviews are recommended quarterly, monthly, or weekly based on the severity of findings. Completed 11-F004 forms are sent to a designated custom exempt coordinator in each circuit, who compiles a completed Custom Plant Quarterly Report and forwards them to the Guthrie office. Circuit supervisors review this Custom Plant Report as part of their duties, and in this manner, control measures are in place to ensure that the custom exempt reviews are being completed at the intended frequency and as outlined in FSIS Directives.

Based on records and procedures reviewed, FSAS determined WVDA/MPIB was able to confirm the program is being implemented as described in self-assessment.

Component 7 – Laboratory Methods and Quality Assurance Program
LQARCS performed an onsite review of the West Virginia Department of Agriculture, Regulatory and Environmental Affairs Division (WVDA) during FY21 to evaluate laboratory quality assurance programs and method equivalence under the State MPI Program.
WVDA conducts microbiological testing for *Salmonella*, *L. monocytogenes*, *Campylobacter*, *E. coli* O157:H7, and non-O157 STEC. WVDA conducts food chemistry testing for moisture, protein, fat, and salt.

FSIS compared the WVDA Laboratory Quality Assurance Program to the State Meat and Poultry Inspection (MPI) Program Laboratory Quality Management System Checklist and evidence of laboratory proficiency and analyst training was evaluated. WVDA met all Laboratory QA requirements.

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

Based on the Component 7 methods and quality assurance program review, West Virginia can 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 that 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.

Component 8 – Civil Rights
In April 2021, CRS conducted a civil rights compliance review of WVDA/MPIB. The review was conducted to determine the State’s compliance with applicable civil rights laws, USDA regulations, and FSIS policies, and where necessary, provide recommendations for improvement. The review focused on State compliance in eight areas: (1) Civil Rights Assurances; (2) State Infrastructure and Program Accountability; (3) Public Notification; (4) Civil Rights Complaints of Discrimination; (5) Civil Rights Training; (6) Disability Compliance; (7) Program Accessibility to Individuals with Limited English Proficiency; and (8) Compliance with the Age Discrimination Act of 1975.

The review was conducted through a document and telephonic facility assessment, telephonic interviews, and review of documents. The last review was performed in March 2018.
The FY 21 review of component 8 found the State of West Virginia to be in compliance with “at least equal to” standards for applicable civil rights laws, USDA regulations, and FSIS policies. CRS concluded that WVDA/MPIB is operating “at least equal to” Federal civil rights requirements.

**Component 9 – Financial Accountability**

In FY 2021, a Component 9 fiscal review was not scheduled, however, FRSB issued a final determination report for a fiscal review conducted the week of August 17, 2020, which covered federal FYs 2017-2019. The report documented the results and corrective actions taken for the findings identified. In summary, FRSB determined the financial systems, records, reports, and procedures employed by WVDA/MPIB in the accounting for the MPI program were sufficient. Ultimately, FRSB determined that WVDA/MPIB is operating in full compliance with the financial and administrative provisions of FSIS Directive 3300.1, Rev.2, Fiscal Guidelines for Cooperative Inspection Programs (March 2004) and the criteria outlined in the FSIS “At Least Equal To” Guideline for State Meat and Poultry Inspection (MPI) Programs (November 2016).

**Onsite Determination for West Virginia**

Based on the evidence and results discussed above, FSIS determined that WVDA/MPIB 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.