Appendix Y

Comprehensive Review and Determination Report

FY 2012

West Virginia

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

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

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

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

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

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

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

Description of State MPI Program
The West Virginia Department of Agriculture, Meat and Poultry Inspection Division (WVDA/MPID) administers the West Virginia MPI program under authority of the West Virginia Code (Chapter 19, Articles 2B

and 2E). The program verifies and enforces regulatory requirements at 23 inspected facilities and 25 custom exempt establishments.[1]

Annual Determination
FSIS determined that WVDA/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 June 18 – 29, 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 Standards in raw classes of meat and poultry, comply with other consumer protection standards, and are accurately labeled (e.g., with nutrition information).

[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.

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[2] – This component evaluates whether the State MPI program conforms with 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 West Virginia's self-assessment submission.
- The self-assessment determination for West Virginia.

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

[2] 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.

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 West Virginia's Self-Assessment Submission

FSIS evaluated the self-assessment documents for the nine review components to determine whether WVDA/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 WVDA/MPID's self-assessment submission, for components 1 through 7, on November 29, 2011. On March 16, 2012, FSAB requested additional clarifying information from the WVDA/MPID staff, which was provided on March 23, 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 the HMSA, and the regulations promulgated under these laws. The supporting documentation includes the West Virginia Code, Chapter 19 (Articles 2B and 2E) and West Virginia Legislative Rule (Title 61, Series 16). The West Virginia Code provides statutory authorities for mandatory antemortem and postmortem inspection, and reinspection (§19-2B-6); and sanitation (§19-2B-6), record-keeping (§19-2B-5), and humane methods of slaughter requirements (§§19-2E-1 through 19-2E-7).

The West Virginia Code provides authorities that are "at least equal to" the FMIA and PPIA regarding adulteration (§19-2B-1a), misbranding (§19-2B-1a), prohibited acts (§19-2B-10), access and examination (§19-2B-5), and product control actions (§19-2B-6), as well as criminal, civil, and administrative sanctions to address violators.

The West Virginia Code grants the authority to promulgate regulations (§19-2B-3) and West Virginia adopted by reference Title 9, Code of Federal Regulations (9 CFR) Parts 301 *et seq*., 381, 416, 417, 424, 430, and 441 with exceptions, in the West Virginia Legislative Rule (Title 61, Series 16).

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

WVDA/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 ongoing verification procedures, WVDA/MPID performs a routine Food Safety Assessment (FSA) in each establishment at least once every four years. The assistant director, who completed the FSIS Enforcement, Investigation, and Analysis Officer (EIAO) training, performs FSAs to examine all food safety aspects that relate to establishments and their products, including the establishments' hazard analyses, HACCP plans, Sanitation SOPs, prerequisite programs, sampling programs, and any other programs that constitute the establishments' HACCP systems. The noncompliance and FSA records support the conclusion that WVDA/MPID personnel recognize and document noncompliance, and initiate appropriate regulatory actions.

WVDA/MPID enforces the West Virginia Code (Chapter 19, Article 213) when establishments do not comply with State authorities that are "at least equal to" the FMIA and PPIA. The West Virginia Code:

- Provides for due process.
- Requires all official meat and poultry establishments, meat and poultry distributors, and custom exempt facilities to acquire an annual license. This annual licensure is similar to a Federal grant of inspection.
- Authorizes the commissioner to refuse to issue, suspend, or revoke a license when it is determined that the applicant or licensee fails to comply with the West Virginia Code or relevant West Virginia Legislative Rules.

In addition, WVDA/MPID has procedures to document relevant facts for administrative actions to support that administrative actions are based on relevant facts and legal authority.

The submitted documents support the conclusion that WVDA/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 WVDA/MPID's sampling protocols, procedures, and results to the Federal policies and procedures.

WVDA/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. WVDA/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. WVDA/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 WVDA/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

WVDA/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. WVDA/MPID divides its jurisdiction into two circuits and assigns a veterinary supervisor to each circuit. WVDA/MPID employs retired inspectors to provide relief inspection, as needed. The veterinary supervisors, compliance officer, assistant director, and the director also provide relief inspection, when necessary. As of November 2011, WVDA/MPID employed a director, an assistant director, 13 full-time inspectors, a part-time inspector, 2 veterinary medical officers, 2 headquarters staff members, 3 laboratory staff members, and a compliance officer.

WVDA/MPID developed a training program for new entry-level inspection personnel and a record-keeping system to track completion of trainings. This program includes classroom courses for antemortem and postmortem inspection, pathogen reduction/HACCP, Sanitation SOPs, Sanitation Performance Standards (SPS), and processing inspection. Initially, the inspector-trainee works under the guidance of the veterinary supervisor, assistant director, and veteran inspectors to learn all aspects of slaughter inspection. Furthermore, the WVDA/MPID inspectors must complete classroom courses offered through the FSIS Center for Learning (e.g., Food Safety Regulatory Essentials (FSRE)) and on-line AgLearn trainings.

WVDA/MPID administers a performance-evaluation system that is mandated for all State agencies. This system requires supervisors to:

- Inform each employee of his or her work responsibilities and performance goals and objectives.
- Complete a performance evaluation for each employee at the end of each rating cycle or probationary period.
- Inform each employee of the results of the annual performance evaluations.

WVDA/MPID also follows the guidance in FSIS Directive 4430.3, *In-Plant Performance System (IPPS)*, to assess inspectors' job performance at least biannually. Control measures are in effect to verify the IPPS assessments are accurate and complete.

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

Component 5 – Humane Handling

The PBIS records demonstrated that WVDA/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.

WVDA/MPID uses FSIS Directive 6900.2, *Humane Handling and Slaughter of Livestock*, to communicate instructions to inspection personnel. The inspectors perform all categories of humane handling verification procedures during slaughter operations and document the results of these procedures in PBIS. During humane handling verification visits, veterinary supervisors observe the establishments' humane handling practices and the inspectors' verification procedures, and document the results.

In conclusion, the information made evident that WVDA/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

WVDA/MPID verifies establishment compliance with the non-food safety consumer protection regulatory requirements. WVDA/MPID uses applicable FSIS directives to communicate instruction to inspection personnel, and uses PBIS to schedule verification procedures and to document noncompliance.

WVDA/MPID maintains a label-approval policy and process to verify that labels are accurate and meet regulatory requirements. The *FSIS Foods Standards and Labeling Policy Book (August 2005)* and 9 CFR 319 are the compliance standards. This label-approval policy requires an establishment to submit a completed label-approval application, label sketch, the product's formulation, if applicable, or marking device to the Charleston office for approval prior to use. A thorough review of PBIS data, label-approval applications, label sketches, and noncompliance records supports the conclusion that WVDA/MPID inspectors perform regulatory verification procedures and apply the label-approval policy.

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

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

WVDA/MPID investigates alleged or actual statutory 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 violate the West Virginia Code. WVDA/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.

WVDA/MPID management reviews the compliance reports for correctness, extracts pertinent information for reporting purposes, enters the information in a database, and files the hard copies. The program director reviews all violations and relevant evidence, and determines the appropriate case dispositions and courses of action.

WVDA/MPID maintains procedures for the recall of 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*. The procedures include health hazard evaluation, recall classification, public notification, effectiveness checks, and closure. Firms are to notify WVDA/MPID when they initiate a recall. WVDA/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.

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

The submitted documents support the conclusion that WVDA/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 8 – Civil Rights

On November 8, 2011, WVDA/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 WVDA/MPID functions “at least equal to” the Federal civil rights requirement.

Component 9 – Financial Accountability

WVDA/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 WVDA/MPID is “at least equal to” Federal standards for financial accountability for Fiscal Year (FY) 2012.

Self-Assessment Determination for West Virginia

Based on the evidence and results discussed above, FSIS determined that WVDA/MPID provided adequate documentation to show it operates a meat and poultry inspection program “at least equal to” the Federal requirements. WVDA/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 West Virginia.
- The on-site determination for West Virginia.

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 West Virginia

The FSIS review team analyzed all information gathered during the on-site review and WVDA/MPID's action plan, which addressed the findings identified during the review, to determine whether WVDA/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 WVDA/MPID, for components 2 through 7, from June 18 – 29, 2012.

Component 2 – Inspection

FSAB reviewed the self-assessment documents and compared them to additional documents and conditions presented on-site. The 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 WVDA/MPID during six establishment reviews. During these reviews, WVDA/MPID personnel identified multiple noncompliances with the Sanitation SOPs, SPS, HACCP, and labeling regulatory requirements. FSAB identified noncompliance with the HACCP and Sanitation SOPs record-keeping requirements that WVDA/MPID officials did not identify. WVDA/MPID officials initiated regulatory control actions, when necessary, and issued noncompliance records.

On July 20, 2012, WVDA/MPID submitted an action plan to correct the findings identified during the review. This action plan identifies the underlying causes of both the system-wide findings and specific findings at individual establishments. It includes action items to ensure statewide correction of the review findings. In addition, WVDA/MPID provided evidentiary documents to show completion of each action item and statewide verification of establishments' compliance with the regulatory requirements.

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

WVDA/MPID's verification sampling program met FSIS' guidance to States for testing frequencies for pathogenic bacteria and *Salmonella* in raw and ready-to-eat products.

FSAB analyzed information from the WVDA/MPID office and establishment reviews, and concluded that WVDA/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 WVDA/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 WVDA/MPID office and establishment reviews, FSAB concluded that WVDA/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 WVDA/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 WVDA/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 WVDA/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 the information gathered and concluded that WVDA/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 compliance self-assessment documents and compared them to additional documents presented on site. These documents included, but were not limited to, Planned Compliance Review records,

Reports of Violation, Reports of Investigation, Seizure and Involuntary Destruction forms, Voluntary Destruction Statements, Personal Use Statements, Shipper and Receiver Certifications, Inquiry Statement Forms, consumer complaints logs, and photographic exhibits.

WVDA/MPID began using the FSIS In-Commerce System (ICS) in January 2012. The ICS includes functions to document:

- Firm information.
- Surveillance of in-commerce businesses.
- Product control actions.
- Investigations.
- Evidence collection.
- Reports of investigation.
- Enforcement actions.

At the time of the review, WVDA/MPID had documented at least 93 surveillance activities and investigations in ICS.

The review of compliance documents and case files supports the conclusion that WVDA/MPID conducts surveillance activities in accordance with FSIS Directive 8010.1, *Methodology for Conducting In-Commerce Surveillance Activities,* in firms that prepare, transport, sell, or offer for sale meat and poultry products in intrastate commerce to verify that these firms comply with West Virginia's statutory and regulatory requirements. The surveillance activities include food safety, food defense, non-food safety consumer protection, order verification, imported products, public health response, and product control actions. These activities also verify that meat and poultry products in intrastate commerce are wholesome, correctly packaged and labeled, and secure from threats or intentional acts of contamination.

WVDA/MPID investigates alleged or actual statutory or regulatory violations in accordance with 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 West Virginia Code. WVDA/MPID summarizes investigative findings and supporting evidence in its Reports of Investigation in accordance with FSIS Directive 8010.4, *Report of Investigation,* and maintains evidence integrity in accordance FSIS Directive 8010.3, *Procedures for Evidence Collection, Safeguarding and Disposal*. WVDA/MPID develops case files to organize investigative findings and evidence to support administrative, civil, or criminal legal actions.

WVDA/MPID follows the recall procedures in FSIS Directive 8080.1, *Recall of Meat and Poultry Products*, with minor modifications fitting its organizational structure. The procedures include health hazard evaluation, recall classification, public notification, effectiveness checks, and closure. WVDA/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.

WVDA/MPID maintains a system to record, analyze, and triage consumer complaints related to State-regulated meat or poultry products. These consumer complaints are reported to the Charleston office. The compliance officer examines the complaints, enters the information in ICS, and initiates investigations, when deemed necessary. FSAB reviewed the reports and supporting evidence for the two FY 2012 consumer complaint investigations and determined that WVDA/MPID carried out its consumer complaint investigations "at least equal to" the procedures described in FSIS Directive 5610.1, *Procedures to Implement the Consumer Complaint Monitoring Systems (CCMS).*

WVDA/MPID maintains procedures to report transportation accidents that involve livestock or State-inspected meat and poultry products; although, no such accidents occurred in West Virginia in FY 2012.

FSAB analyzed the information gathered during the review of WVDA/MPID office records and concluded that WVDA/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 10, 2012, CRD reviewed documents and conditions at the WVDA/MPID offices to determine whether WVDA/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 WVDA/MPID and concluded that WVDA/MPID is "at least equal to" Federal civil rights requirements.

Component 9 – Financial Accountability

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

On-Site Determination for West Virginia

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