Appendix Q

Comprehensive Review and Determination Report

FY 2012

Ohio

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 Ohio Meat and Poultry Inspection (MPI) program and an overview of the review methodology. FSIS determined that the Ohio 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 Ohio Department of Agriculture, Division of Meat Inspection (ODA/DMI) administers the Ohio MPI program under authority of the Revised Codes for the State of Ohio. The program verifies and enforces regulatory requirements at 211 inspected facilities and 70 custom exempt establishments.[1]

Annual Determination
FSIS determined that ODA/DMI 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

[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.

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

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

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

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

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

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

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

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

Part I. Self-Assessment Review

This section includes:

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

[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.

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

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

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

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

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

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

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

FSAB received ODA/DMI's self-assessment submission, for components 1 through 7, on December 20, 2011. On March 13, 2012, FSAB requested additional clarifying information from the ODA/DMI staff, which was provided on April 8, 2012.

<u>Component 1 – Statutory Authority and Food Safety Regulations</u>
FSAB compared the submitted self-assessment and supporting documentation to the legal authority provided under the FMIA, PPIA, and HMSA, and the regulations promulgated under these laws. The supporting documentation includes the Ohio Revised Code (Chapters 119, 918, and 945) and the Ohio Administrative Code. The Ohio Revised Code provides statutory authorities for mandatory antemortem and postmortem inspection, and reinspection (§§901.2 and 918.22); sanitation requirements (§§918.02 and 918.23); record-keeping requirements (§§948.02 and 918.24); humane methods of slaughter requirements (Chapter 945); and authority to adopt and enforce rules (§§918.04 and 918.25).

The Ohio Revised Code and the Ohio Administrative Code include authorities that are "at least equal to" the FMIA and PPIA regarding adulteration (§918.01(H)), misbranding (§§918.01(O) and 3715.60), prohibited acts (§918.11), access and examination (§918.26 (B)), and product control actions (§918.01), and "at least equal to" criminal, civil, and administrative sanctions to address violators.

The Ohio Revised Code (§918.04) grants authority to promulgate regulations and Ohio adopted the 2011 version of Title 9, Code of Federal Regulations (9 CFR), Parts 300 to 500, with exceptions, in the Ohio Administrative Code (§901:2-1-01).

In conclusion, ODA/DMI 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 verification of establishments' compliance with the Federal requirements. ODA/DMI 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, ODA/DMI reviews custom exempt operations in accordance with FSIS Directive 5930.1, *Custom Exempt Review Process.*

ODA/DMI verifies that establishments develop, implement, and maintain Sanitation Standard Operating Procedures (SOPs) and Hazard Analysis and Critical Control Point (HACCP) systems. In addition to the inspectors' ongoing verification activities, ODA/DMI personnel, who are trained in Enforcement, Investigation, and Analysis Officer methodology, perform Food Safety Assessments (FSAs) to examine establishments' food safety systems. These FSAs examine 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, notices of intended enforcement, and verification plans support the conclusion that ODA/DMI personnel identify and document noncompliance, and initiate appropriate regulatory actions.

ODA/DMI enforces the Ohio Administrative Code (§901:2-1-01), 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. ODA/DMI has procedures to document relevant facts for administrative actions and to support that administrative actions are based on relevant facts and legal authority.

The submitted documents support the conclusion that ODA/DMI:

- 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 ODA/DMI's sampling protocols, procedures, and results to the Federal policies and procedures.

ODA/DMI 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. ODA/DMI 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. ODA/DMI 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 ODA/DMI 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

ODA/DMI 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. District supervisors assign inspectors' work schedules weekly, with instructions that outline daily visits to establishments, and arrange relief inspection during routine- and emergency-leave situations. As of November 1, 2011, ODA/DMI employed a program chief, an assistant chief, 77 food inspectors, 8 veterinary medical officers, 8 district supervisors, 2 inspection managers, and 3 compliance officers.

ODA/DMI developed a training program for new entry-level inspection personnel and a record-keeping system to track training completions. This program covers basic slaughter techniques and all inspection techniques required to perform slaughter duties, including basic Sanitation SOPs and HACCP procedures. The training subjects include livestock inspection, slaughter inspection, processing inspection, HACCP, Sanitation SOPs, and Sanitation Performance Standards (SPS). ODA/DMI employees also complete food safety regulatory essentials trainings.

ODA/DMI incorporates the guidelines in FSIS Directive 4430.3, *In-Plant Performance System (IPPS)*, to set performance standards, and complete and record ongoing performance evaluations. District supervisors perform at least one IPPS assessment for each inspector annually. ODA/DMI has control measures in effect to examine the IPPS assessments for quality, completeness, and accuracy.

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

Component 5 – Humane Handling

The PBIS records demonstrated that ODA/DMI 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.

ODA/DMI uses FSIS Directive 6900.2, *Humane Handling and Slaughter of Livestock*, to communicate instructions to inspection personnel. Inspectors complete Ohio Department of Agriculture, Meat Inspection Field Logs to document humane handling verifications. Inspectors submit completed logs to the central office, where they are reviewed as part of the management-control system, to verify that humane handling verification tasks are performed each day an establishment slaughters livestock. During quarterly visits, District supervisors

perform IPPS assessments to specifically examine humane handling and humane methods of slaughter verification task performance, and examine establishments' humane handling procedures.

In conclusion, the information made evident that ODA/DMI 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 – Non-Food Safety Consumer Protection

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

ODA/DMI 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 approval from ODA/DMI.

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

ODA/DMI compliance 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.

ODA/DMI investigates apparent violations and food safety incidents; detains products when there is reason to believe that the products are adulterated, misbranded, or otherwise in violation of the Ohio Revised Code; and takes enforcement action when needed, up to and including prosecution of individuals or firms who have violated the Ohio Revised Code. ODA/DMI has procedures to obtain and preserve legal integrity of documentary and other evidence to support legal actions, and to report transportation accidents that involve State-inspected and passed meat and poultry products.

The ODA Enforcement Department, Chief of Enforcement or designee reviews the compliance reports for correctness, extracts pertinent information for reporting purposes, enters the information in a database, and files the hard copies. The Assistant Chief of Enforcement reviews the violations and relevant evidence, determines the appropriate case dispositions and courses of action, and provides copies to ODA/DMI.

ODA/DMI developed 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*. These procedures include health hazard evaluation, recall classification, public notification, effectiveness checks, and closure. ODA/DMI 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.

ODA/DMI 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 or regulatory enforcement actions, and report potential food safety threats.

The submitted documents support the conclusion that ODA/DMI 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 15, 2011, ODA/DMI 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 ODA/DMI functions "at least equal to" the Federal civil rights requirement.

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

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

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 Ohio

The FSIS review team analyzed all information gathered during the on-site review and ODA/DMI's action plan, which addressed the findings identified during the review, to determine whether ODA/DMI 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.

FSAB conducted an on-site review of ODA/DMI, 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 on-site documents reviewed included, but were not limited to, Sanitation SOPs and associated records; HACCP plans and associated records; generic *E. coli* sampling procedures and associated records; procedures for the removal, segregation, and disposition of specified risk materials and associated records; custom exempt records; noncompliance records; and enforcement letters.

FSAB evaluated ODA/DMI during eight establishment reviews. During these reviews, ODA/DMI personnel identified several noncompliances, with Sanitation SOPs and SPS requirements. FSAB identified several HACCP plan, HACCP record-keeping, and SPS noncompliances that ODA/DMI officials did not recognize. ODA/DMI officials initiated regulatory actions in the establishments, as necessary, and issued noncompliance records at the time the noncompliance were identified.

On August 10, 2012, ODA/DMI submitted an action plan to correct the findings identified during the review. This action plan identifies the underlying causes of both system-wide findings and specific findings at individual establishments. It includes a verification plan to ensure statewide correction of these findings. To correct the review findings, ODA/DMI held supervisory meetings to discuss specific action plan items. Afterwards, each supervisor held district work unit meetings to share the action plan strategy with inspectors. ODA/DMI personnel subsequently reviewed each establishment to look for the same or similar noncompliances identified during the FSIS on-site review; take regulatory actions, as appropriate; and verify establishments' corrective actions. Noncompliances identified during the FSIS on-site review and ODA/DMI's follow-up establishment reviews did not warrant the recall of any meat or poultry products. ODA/DMI submitted evidentiary documents to demonstrate verification of establishment compliance with the regulatory requirements.

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

ODA/DMI's verification-testing program met FSIS' guidance to States on frequency of testing for pathogenic bacteria and *Salmonella* in raw and ready-to-eat products, and discovered positive *Listeria monocytogenes* results in ready-to-eat product and positive *E. coli* O157:H7 results in raw beef product. ODA/DMI followed its defined procedures and appropriately responded to both positive test results.

FSAB analyzed information from the ODA/DMI office and establishment reviews, and concluded that ODA/DMI 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 ODA/DMI 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 ODA/DMI office and establishment reviews, FSAB concluded that ODA/DMI 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 ODA/DMI's inspection methodology, make decisions based upon the correct application of inspection methodology, document findings, and initiate regulatory action. The training program includes measures to ensure that inspection personnel receive training in the areas of meat and poultry antemortem and postmortem inspection, humane handling, processed products, HACCP, Sanitation SOPs, rules of practice, IPPS guidelines, compliance, and food safety regulatory essentials.

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 ODA/DMI 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 ODA/DMI enforces non-food safety consumer protection regulatory standards "at least equal to" the Federal requirements. This review included, but was not limited to, procedure schedules, label approvals, labels, and product formulations.

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

Component 7 – Compliance

FSAB reviewed the self-assessment documents and compared them to additional documents presented on-site. These included, but were not limited to Reports of Investigation, Daily Activity Reports, Programmed Compliance Plans, Incident Reports, Case Reports, Reports of Apparent Violations, Notices of Warning, court records, and consumer complaint investigations.

The review of compliance documents and case files supports the conclusion that ODA/DMI 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. ODA/DMI 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 Ohio Revised Code. The Reports of Investigation were completed in accordance with FSIS Directive 8010.4, *Report of Investigation*. ODA/DMI uses the investigative findings and evidence to pursue enforcement actions for administrative, civil, or criminal sanctions.

ODA/DMI follows the recall procedures in FSIS Directive 8080.1, *Recall of Meat and Poultry Products*, with minor modifications fitting its organizational structure. ODA/DMI reported that, during the review period, State-inspected establishments initiated seven separate product recalls in response to *Listeria monocytogenes*

and *E. coli* O157:H7 positive sample results, foreign material contamination, and product produced without the benefit of inspection.

ODA/DMI maintains a system to review, analyze, and triage consumer complaints. ODA/DMI gathers information pertinent to these complaints, directs the compliance division to investigate these complaints, and files completed investigation documents in the State office. FSAB reviewed the consumer complaint tracking sheet and a sample of investigative records and determined that ODA/DMI reacts to consumer complaints appropriately. ODA/DMI followed up with the complainant and took appropriate actions to include product recall, as necessary.

FSAB analyzed information gathered during the review of ODA/DMI office records and concluded that ODA/DMI 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

CRD did not conduct an on-site civil rights review of ODA/DMI in FY 2012. Therefore, the annual determination was based on the self-assessment review results only.

Component 9 – Financial Accountability

During the week of July 29, 2012, FRAS conducted an on-site review fiscal review of ODA/DMI. This review encompassed Federal fiscal years 2009, 2010, and 2011. As a result of this review, FRAS determined that ODA/DMI is operating in compliance with the financial and administrative provisions of FSIS Directive 3300.1, Rev.2, and the criteria outlined in the FSIS "*At Least Equal To" Guidelines for State Meat and Poultry Cooperative Inspection Programs* (July 2008).

On-Site Determination for Ohio

Based on the evidence and results discussed above, FSAB determined that ODA/DMI 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.