Appendix C

Comprehensive Review and Determination Report

FY 2012

Delaware

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 Delaware Meat and Poultry Inspection (MPI) program and an overview of the review methodology. FSIS determined that the Delaware MPI program met the "at least equal to" standard, based on its review of the self-assessment documents.

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 Delaware Department of Agriculture, Food Products Inspection Section (DDA/FPIS) administers the Delaware MPI program under authority of the Delaware Code (3 Del.C. §§8701 *et.seq.*). The program verifies

and enforces regulatory requirements at one inspected facility and seven custom exempt establishments.[1] In addition, DDA/FPIS provides inspection to seven facilities in the Federal State Cooperative Agreement Inspection Program.[2]

Annual Determination (Based on Self-Assessment Review Only)
FSIS determined that DDA/FPIS is operating a meat and poultry inspection program "at least equal to" the Federal requirements. DDA/FPIS 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. FSIS based its annual determination on review of the self-assessment documents only, since DDA/FPIS was not subject to an on-site review during Fiscal Year (FY) 2012. This determination is fully explained in the Self-Assessment Review section.

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. This 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 non-intact, raw

[1] Custom exempt establishments are slaughter and processing establishments, which are not subject to the routine inspection requirements of the FMIA and PPIA, provided the specified operations meet the exemption requirements of Section 23 of the FMIA and Section 15 of the PPIA.

[2] Facilities operating under the Federal State Cooperative Agreement Inspection Program (FSCIP), also known as Talmadge-Aiken plants or cross-utilization facilities, are under Federal inspection, but operate with State inspection personnel. As a result, these facilities are not reviewed as part of the State MPI program review. However, since State inspection personnel staff these establishments, the number of these establishments is applicable to determinations on Component 4 – Staffing and Training.

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* Performance 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 meet the non-food safety regulatory requirements; and take appropriate actions in response to noncompliance.

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

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

9. Funding and Financial Accountability[3] – This component evaluates whether the State MPI program conforms to 7 CFR 3016, *Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments* and follows FSIS Directive 3300.1, Rev. 2, *Fiscal Guidelines for Cooperative Inspection Programs.*

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

[3] In light of the current economic conditions, some State governments are experiencing financial challenges, which may result in overall budget cuts that could effect 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

This section includes:

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

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 the State's overall ability to maintain a 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 Delaware's Self-Assessment Submission

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

FSAB received DDA/FPIS' self-assessment submission, for components 1 through 7, on November 14, 2011. On five separate dates between March 23 and August 8, 2012, FSAB requested additional clarifying information from the DDA/FPIS staff, which was provided on seven separate dates between April 2 and August 8, 2012.

Component 1 – Statutory Authority and Food Safety Regulations

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 Delaware Code (3 Del.C. §§8701 *et.seq.*) and the Delaware Administrative Code (3 DE Admin. Code 301). The Delaware Code provides authorities for mandatory antemortem and postmortem inspection, reinspection, sanitation, and record-keeping requirements (3 Del.C. §8707); and humane methods of slaughter requirements (3 Del. C. §8706).

The Delaware Code provides authorities that are "at least equal to" the FMIA and PPIA regarding adulteration (3 Del.C. §8704), misbranding (3 Del.C. §8705), prohibited acts (3 Del.C. §§8710 and 8711), access and examination (3 Del.C. §8707), and product control actions (3 Del.C. §§8716 and 8717), as well as criminal, civil, and administrative sanctions to address violators.

The Delaware Code grants the authority to promulgate rules and regulations (3 Del. C. §8708(8)) and Delaware adopts by reference Title 9, Code of Federal Regulations (9 CFR), Parts 301 through 592, excluding Parts 390 and 391, as they currently appear, and as they may be amended from time to time, in the Delaware Administrative Code (3 DE Admin. Code 301).

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

DDA/FPIS 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, DDA/FPIS routinely schedules and performs a comprehensive Food Safety Assessment (FSA) at the inspected establishment at least once every four years. These FSAs examine the design and validity of establishments' food safety systems, which include hazard analyses, supporting documents, HACCP plans, Sanitation SOPs, prerequisite programs, sampling programs, and any other programs that constitute the establishments' HACCP systems. The submitted records, which include FSA and PBIS records, support the conclusion that DDA/FPIS personnel recognize and document noncompliance, and initiate appropriate regulatory actions.

DDA/FPIS established a system to carry out enforcement actions when establishments do not comply with State authorities that are "at least equal to" the FMIA and PPIA. DDA/FPIS enforces the Delaware Administrative Code (3 DE Admin. Code 301), which adopts by reference 9 CFR 500, Rules of Practice, and includes due process, establishment notification, immediate withholding actions, suspensions, and withdrawals of grants of inspection. DDA/FPIS has procedures to document relevant facts of administrative actions and ensure that such actions are legally supportable and based on relevant facts.

The submitted documents support the conclusion that DDA/FPIS:

- 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 DDA/FPIS' sampling protocols, procedures, and results to the Federal policies and procedures.

Although the sole DDA/FPIS-inspected establishment does not produce products that are eligible for verification product sampling, DDA/FPIS provided documentation to show that they developed 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, in case establishments come under State inspection and produce eligible products. The sampling plans include procedures for sample collection, sample integrity, and laboratory analysis. DDA/FPIS 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 confirmed that DDA/FPIS developed 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.

Component 4 – Staffing and Training

DDA/FPIS developed methods to determine staffing requirements, which consider the inspector's workloads and the number of inspectors required to provide daily inspection coverage in each establishment on days when the establishment produces products bearing the State mark of inspection. Procedures are in effect to document staffing in each establishment, identify failures to meet staffing requirements, and correct staffing deficiencies. The field supervisor regularly schedules inspection assignments in seven Federal establishments in the FSCIP, and in one State-inspected establishment. In addition, the field supervisor arranges relief inspection at all eight establishments during scheduled- and emergency-leave situations. The field supervisor reviews PBIS data and Weekly Activities Reports, and visits establishments periodically to assess daily staffing achievement. As of November 12, 2011, DDA/FPIS employed an administrator, a field supervisor, an administrative assistant, five inspectors, and two compliance officers. One compliance officer is a part-time employee. Both compliance officers perform surveillance, investigative, and enforcement activities, and the part-time compliance officer provides relief inspection, as needed.

DDA/FPIS developed a training program for new entry-level inspection personnel. The training program includes initial orientation, on-the-job and formal training, and performance evaluations. DDA/FPIS documents and monitors employees' training needs through a performance management system that tracks completion of training. DDA/FPIS personnel receive training exclusively through the FSIS Center for Learning and AgLearn, the web-based USDA learning system, since all DDA/FPIS inspectors routinely provide inspection services in Federal establishments in the FSCIP. The training curriculums include, but are not limited to, basic livestock and poultry inspection, slaughter inspection, HACCP systems, supervision, PBIS, and food safety regulatory essentials.

DDA/FPIS follows the guidance in FSIS Directive 4430.3, *In-Plant Performance System (IPPS)*, to set performance standards, and complete and record ongoing performance assessments of field inspectors. The field supervisor performs at least two IPPS assessments for each inspector annually and an IPPS assessment at the end of a new inspector's probationary employment period. DDA/FPIS management monitors the quality, completeness, and accuracy of completed IPPS assessments. The IPPS assessments are supporting evidence for the inspectors' annual performance evaluations. DDA/FPIS also complies with Delaware Code (29 Del. C. §§5901 *et. seq.*), Merit System of Personnel Administration, which sets forth provisions for Delaware State employees' annual job performance evaluations. This system follows the *State of Delaware Employee Performance Plan* and communicates the DDA/FPIS mission, employees' work responsibilities, performance goals and objectives, and the results of annual performance evaluations.

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

Component 5 – Humane Handling

Although no inspected establishments under DDA/FPIS' jurisdiction perform slaughter operations, the Delaware Administrative Code (3 DE Admin. Code 301) incorporates by reference 9 CFR, Part 313, Humane Slaughter of Livestock, and Part 500, Rules of Practice. DDA/FPIS reviews custom exempt slaughter operations in accordance with FSIS Directive 5930.1, *Custom Exempt Review Process*, which includes humane handling procedure reviews.

Component 6 – Non-Food Safety Consumer Protection

DDA/FPIS verifies establishment compliance with the non-food safety consumer protection regulatory requirements. DDA/FPIS uses applicable FSIS Directives to communicate instructions to inspection personnel, and PBIS to schedule ongoing verifications and to document noncompliance.

DDA/FPIS 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 DDA/FPIS approval.

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

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

DDA/FPIS investigates alleged or actual statutory or regulatory violations; controls products, when there is reason to believe that the products are adulterated, misbranded, or otherwise in violation of the State of Delaware Code; and takes enforcement action, when needed, up to and including prosecution of individuals or firms that have violated the Delaware Code. DDA/FPIS 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.

The DDA/FPIS administrator and field supervisor review relevant records and documents to verify that the compliance program operates as intended and that all actions are legally supportable.

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

DDA/FPIS 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 and enforcement actions, and report potential food safety threats.

The submitted documents support the conclusion that DDA/FPIS 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 12, 2011, DDA/FPIS 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 DDA/FPIS functions “at least equal to” the Federal civil rights requirements.

Component 9 – Financial Accountability

DDA/FPIS submitted quarterly and final Financial Status Reports (SF-425), and an annual Indirect Cost Proposal to demonstrate it conforms with 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 DDA/FPIS is “at least equal to” Federal standards for financial accountability for FY 2012.

Self-Assessment Determination for Delaware

Based on the evidence and review results described above, FSIS determined that DDA/FPIS provided adequate documentation to show it is operating a meat and poultry inspection program “at least equal to” the Federal requirements.