Appendix J

Comprehensive Review and Determination Report

FY 2012

Maine

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 Maine Meat and Poultry Inspection (MPI) program and an overview of the review methodology. FSIS determined that the Maine 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 Maine Department of Agriculture, Food and Rural Resources, Division of Quality Assurance and Regulations, Meat and Poultry Inspection Program (MMPIP), administers the Maine MPI program under

authority of the Maine Revised Statutes **(**Title 22, Chapter 562-A). The program verifies and enforces regulatory requirements at 8 inspected establishments and 30 custom exempt establishments.[1]

Annual Determination
FSIS determined that MMPIP 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 11 – 15, 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 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 Maine's self-assessment submission.
- The self-assessment determination for Maine.

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 Maine's Self-Assessment Submission

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

FSAB received MMPIP's self-assessment submission, for components 1 through 7, on November 15, 2011. FSAB found the initial submission sufficient and did not need to request additional information.

<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 Maine Revised Statutes (Title 22, Chapter 562-A) and the Code of Maine Rules (01-001 Chapter 346). The Maine Revised Statutes provides authorities for mandatory antemortem inspection (22 §2517), postmortem inspection (22 §2517-A), reinspection (22 §2517-B); and sanitation (22 §2512), record-keeping (22 §2512), and humane methods of slaughter (22 §2521) requirements.

The Maine Revised Statutes provide authorities that are "at least equal to" the FMIA and PPIA regarding adulteration (22 §2511), misbranding (22 §2511), prohibited acts (22 §2523), access and examination (22 §2519-A), and product control actions (22 §2519 and 22 §2519-A), as well as criminal, civil, and administrative sanctions to address violators.

The Maine Revised Statutes grants the authority to promulgate regulations (22 §2513) and Maine adopted by reference Title 9, Code of Federal Regulations (9 CFR) in the Code of Maine Rules (01-001, Chapter 346, subsection 11).

In conclusion, MMPIP 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. MMPIP uses the Performance Based Inspection System (PBIS) to generate hard-copy documents to distribute to inspection personnel and guide inspection program activities, collect establishment information, establish and maintain in-plant inspection procedure plans, and document establishment noncompliance. In addition, MMPIP reviews custom exempt operations in accordance with FSIS Directive 5930.1, *Custom Exempt Review Process.*

MMPIP 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 Consumer Protection inspectors'(CPI) ongoing verification procedures, a Division of Quality Assurance and Regulations (QAR) employee, who completed Enforcement Investigation, and Analysis Officer methodology training, performs Food Safety Assessments (FSAs) to examine all food safety aspects that relate to establishments and their products. These FSAs assess the design and validity of the establishments' hazard analyses, HACCP plans, Sanitation SOPs, prerequisite programs, sampling programs, and any other programs that constitute the establishments' HACCP systems. The noncompliance records, FSA records, notices of intended enforcement, and verification plans support the conclusion that MMPIP personnel recognize and document noncompliance, and initiate appropriate regulatory actions.

MMPIP enforces the Code of Maine Rules, 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. MMPIP maintains a limited access secured database to document relevant facts for administrative actions and to fully support that administrative actions are based on relevant facts and legal authority.

The submitted documents support the conclusion that MMPIP performs inspection and regulatory verification procedures to confirm that State-inspected establishments comply with applicable regulations. MMPIP 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. The information made evident that MMPIP achieves inspection activities "at least equal to" the Federal requirements and has control measures in effect to monitor that the inspection system functions as intended.

Component 3 – Product Sampling

FSAB compared MMPIP's sampling protocols, procedures, and results to the Federal policies and procedures.

MMPIP 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, *Salmonella* Performance Standards in raw classes of meat and poultry, and other consumer protection standards. MMPIP participates in the National Residue Program, and collects and analyzes inspector-generated samples for violative drug residues. Although no MMPIP-inspected establishments currently produce ready-to-eat (RTE) products, MMPIP has prepared sampling protocols for *Listeria monocytogenes* and *Salmonella*, in case establishments start to produce RTE products. The sampling plans include procedures for sample collection, sample integrity, and laboratory analysis. MMPIP 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 MMPIP 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

MMPIP 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. Each establishment is assigned a specific day or days of the week, based on historical inspection needs, to slaughter or further process under MMPIP inspection. MMPIP assigns inspection personnel to each establishment, at least two weeks in advance, for the scheduled hours of operations and for additional establishment requests for inspection.

MMPIP employs a director, who is a veterinary medical officer, a CPI supervisor, and four full-time and one split-time CPIs, as of November 8, 2011. The Maine Department of Agriculture, Food and Rural Resources employs three additional veterinarians, who are trained in meat and poultry inspection, in the Divisions of Animal Health and Industry and Animal Welfare. These veterinarians provide relief for the MMPIP veterinary medical officer, and perform veterinary dispositions or investigations as necessary. One QAR employee, who completed Surveillance, Investigations, and Enforcement Methods (SIEM) training, performs compliance activities. This QAR employee serves as the recall coordinator and organizes the in-commerce compliance information that is gathered by CPIs, who perform in-commerce surveillance activities.

MMPIP developed a training program for new entry-level inspection personnel and a record-keeping system to track participation and completion of training. MMPIP uses the FSIS Center for Learning (CFL) training courses, CFL training materials, and a journeyman CPI to provide timely classroom and hands-on trainings to CPIs. The training program covers basic slaughter techniques and all inspection techniques required to perform slaughter duties. The training subjects include livestock inspection, slaughter inspection, processing inspection, HACCP, Sanitation SOPs, and sanitation performance standards. MMPIP also provides employees with food safety regulatory essentials training.

MMPIP maintains a performance appraisal system to evaluate job performance, and to establish work responsibilities, performance goals, and objectives. The MMPIP supervisor performs at least two in-plant performance reviews for each CPI annually and records the results on MMPIP In-Plant Performance Review Forms. Control measures are in effect to examine these performance reviews for quality, completeness, and accuracy. In addition, Maine mandates a performance plan and evaluation system for all State employees. Under this system, the MMPIP supervisor evaluates each CPI annually and records the results on the State of Maine Performance Management Form. During these performance evaluations, the supervisor discusses and establishes the CSIs' performance goals for the next 12 months.

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

Component 5 – Humane Handling

The PBIS records demonstrated that MMPIP 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.

MMPIP uses FSIS Directive 6900.1, *Humane Handling of Disabled Livestock*; and FSIS Directive 6900.2, *Humane Handling and Slaughter of Livestock*, as guidance to verify compliance with humane handling requirements. If the CPIs observe egregious inhumane handling, they are to take a regulatory control action immediately. MMPIP performs humane handling verification procedures each day the establishments conduct slaughter operations and documents the results of those procedures. In addition, Maine Department of Agriculture veterinarians conduct humane handling verification visits to assess establishments' compliance with humane handling and slaughter requirements.

In conclusion, the information made evident that MMPIP 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

MMPIP verifies establishment compliance with the non-food safety consumer protection regulatory requirements. MMPIP uses applicable FSIS Directives to instruct inspection personnel, and schedules ongoing verification procedures and documents noncompliance.

MMPIP maintains a label-approval policy and process to verify that labels are accurate and meet regulatory requirements. Designated MMPIP personnel must approve all labels prior to use. 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 MMPIP.

In conclusion, the submitted documents provided evidence to show that MMPIP 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

MMPIP developed a planned compliance review system based on the guidance in FSIS Directive 8010.1, *Methodology for Conducting In-Commerce Surveillance Activities*. MMPIP uses multiple levels of QAR personnel to conduct compliance surveillance reviews to verify that 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.

MMPIP personnel investigate apparent violations and food safety incidents; detain products when there is reason to believe that the products are adulterated, misbranded, or otherwise in violation of the Maine Revised Statues; and take enforcement action, when needed, up to and including prosecution of individuals or firms that have violated the Maine Revised Statutes. MMPIP has procedures to obtain and preserve 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 QAR food inspection supervisor or the MMPIP program manager review the surveillance and investigative records and decide whether to request further investigation or legal action. The SIEM officer follows MMPIP Directives 8010.1 through 8010.5, 8410.1, and 8080.3 to conduct investigations, assemble investigative records and case files, and enter these records in the MMPIP C-Net database. The SIEM officer forwards case files that

require further legal action to the Office of the Attorney General for prosecution. The submitted records support the conclusion that MMPIP documents investigations in a manner necessary to support enforcement action.

MMPIP developed 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*. The procedures include health hazard evaluation, recall classification, public notification, effectiveness checks, and closure. Firms are to notify MMPIP when they initiate a recall. If a recall is necessary, MMPIP personnel visit the facilities that received the products to verify that the recalling firm notified its customers and that necessary steps were taken to make certain that the product is no longer available to consumers. MMPIP 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.

MMPIP established methods to record, triage, analyze, and track consumer complaints related to State-regulated meat or poultry products. MMPIP personnel or other QAR personnel investigate these complaints. 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 MMPIP 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, MMPIP 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 MMPIP functions "at least equal to" the Federal civil rights requirement.

Component 9 – Financial Accountability

MMPIP 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 MMPIP is "at least equal to" Federal standards for financial accountability for Fiscal Year (FY) 2012.

Self-Assessment Determination for Maine

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

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 Maine

The FSIS review team analyzed all information gathered during the on-site review and MMPIP's action plan, which addressed the findings identified during the review, to determine whether MMPIP 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 MMPIP, for components 2 through 7, from June 11 – 15, 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 MMPIP during three establishment reviews. During these reviews, MMPIP personnel identified several establishment noncompliances with SPS (non-product contact surfaces) and HACCP (inadequate prerequisite programs) requirements. In one of the three establishments, FSAB identified HACCP noncompliance (inadequate supporting documents for the hazard analysis decisions), which MMPIP personnel did not recognize. MMPIP officials initiated regulatory actions in the establishments and issued noncompliance records at the time the noncompliances were identified.

On July 6, 2012, MMPIP submitted an action plan to correct the findings identified during the review. The 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. MMPIP reviewed the other establishments that were not included in the on-site review to determine whether these establishments were in compliance with the regulatory requirements associated with the review findings and take necessary regulatory actions, if necessary. In addition, MMPIP provided evidentiary documents to demonstrate verification of establishment compliance with the regulatory requirements.

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

MMPIP's verification testing program met FSIS' guidance to States on frequency of testing for pathogenic bacteria and *Salmonella* in raw products, and discovered positive *E. coli* O157:H7 results in raw ground beef at

one establishment that both slaughters cattle and produces non-intact beef products. MMPIP appropriately responded to the positive test results and determined that the establishment held the product represented by the positive sample and verified that the product was properly disposed. MMPIP examined the establishment's test results and sanitary dressing and process control procedures for evidence of a systemic problem, issued a noncompliance record, and verified that the establishment implemented appropriate corrective actions. MMPIP collected additional follow-up samples to verify the effectiveness of the establishment's corrective actions.

FSAB analyzed information from the MMPIP office and establishment reviews, and concluded that MMPIP 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 MMPIP 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 MMPIP office and establishment reviews, FSAB concluded that MMPIP has an adequate number of trained staff to provide the required inspection coverage in the establishments, perform compliance activities, and provide supervisory oversight; and has implemented procedures to ensure daily inspection coverage in operating establishments.

The review results support the conclusion that inspection personnel have the education and training needed to apply MMPIP'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 MMPIP 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 MMPIP 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 MMPIP 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, General Inspection Reports, Reports of Investigation, Review and

Compliance Records, Embargo Notices, Photographic Records, Notices of Findings, Food Processing Inspection Reports, Retail Food Inspection Reports, Investigation Reports, and Notices of Warning.

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

In response to an *E. coli* O157:H7 positive test result from raw ground beef, which was produced in an MMPIP-inspected establishment, MMPIP reviewed its recall procedures. As part of these procedures, MMPIP verified that the establishment had not released affected product in commerce and had properly disposed of the product represented by the positive result. Therefore, MMPIP determined that a recall was not necessary.

MMPIP maintains a system to review, analyze, and triage consumer complaints. Consumer complaints are received from other Federal and State agencies as well as from the public. MMPIP gathers information pertinent to these complaints, directs the compliance division to investigate these complaints, and files completed investigation documents in the State office.

FSAB analyzed the information gathered during the review of MMPIP office records and concluded that MMPIP 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 October 8, 2012, CRD reviewed documents and conditions at the MMPIP offices to determine whether MMPIP 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 MMPIP and concluded that MMPIP 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 MMPIP in FY 2012. Therefore, the annual determination was based on the self-assessment review results only.

On-Site Determination for Maine

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