Appendix J

Comprehensive Review and Determination Report

Fiscal Year 2021

Maine

Federal-State Audit Staff
Office of Investigation, Enforcement and Audit
Food Safety and Inspection Service
U.S. Department of Agriculture
April 2022

The USDA is an equal opportunity provider and employer.
# Table of Contents

Purpose .............................................................................................................................................1

Description of Maine’s MPI Program .................................................................................................1

Annual Determination ..........................................................................................................................1

Part I. Self-Assessment Review ........................................................................................................1

  Self-Assessment Review Methodology ..............................................................................................1

  Review of Maine’s Self-Assessment Submission ...............................................................................2

  Self-Assessment Determination for Maine .......................................................................................10

Part II. Onsite Review .......................................................................................................................10

  Onsite Review Methodology ...........................................................................................................10

  Onsite Review of Maine ..................................................................................................................11

  Onsite Determination for Maine .......................................................................................................13
Purpose
This report communicates the United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS), Office of Investigation, Enforcement and Audit, Federal-State Audit Staff’s (FSAS) annual review results and determination for the Maine Meat and Poultry Inspection (MPI) program, and presents an overview of the review methodology used for determining if the State MPI program is “at least equal to” FSIS’ MPI program.

Description of Maine’s MPI Program
The Department of Agriculture, Conservation and Forestry, Bureau of Agriculture, Food and Rural Resources, Division of Quality Assurance and Regulations (QA&R), Meat and Poultry Inspection Program (MMPIP) administers the Maine MPI program under authority of Maine Revised Statutes (Title 22, Chapter 562-A). The program verifies compliance and enforces regulatory requirements at 6 inspected facilities and 127 custom exempt establishments.¹ In addition, MMPIP provides inspection at three facilities in the Federal-State Cooperative Agreement Inspection Program.²

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 desk review of the self-assessment documents, and (2) FSIS’ onsite review. This determination is fully explained in the sections entitled “Part I – Self-Assessment Review” and “Part II – Onsite Review.”

Part I. Self-Assessment Review

Part I includes the following:
• Description of the Self-Assessment Review Methodology followed for all State MPI programs;
• Review of Maine’s Self-Assessment Submission; and
• 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 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

¹ Custom exempt establishments are slaughter and processing establishments that are not subject to the routine inspection requirements of the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), provided the specified operations meet the exemption requirements (21 U.S.C. 623 and 464).

² Facilities operating under the Federal-State Cooperative Agreement Inspection Program (FSCIP), also known as Talmadge-Aiken establishments 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.
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 Agency representatives from FSAS; Civil Rights Staff (CRS); Financial Reviews and Systems Branch (FRSB); Laboratory Quality Assurance, Response, and Coordination Staff (LQARCS); and other program areas, as needed, evaluates each State MPI program’s self-assessment submission to determine whether it meets the “at least equal to” criteria for all nine review components.

If questions arise during the self-assessment review, or if more information or supporting documentation is needed, FSIS will request the State MPI program to submit further clarifying information. Following reviews of the submitted information, a final determination will be made based on the self-assessment submission in its entirety. FSIS will make 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 equal to” FSIS’ Federal inspection program for all review components.

(2) “At Least Equal To” with Provisions means FSIS makes a provisional determination of the State MPI program’s “at least equal to” status provided the program takes additional action to resolve review findings.

(3) Not “At Least Equal To” means the State MPI program has not adopted laws, regulations, or programs, or does not implement them in a manner that is “at least equal to” FSIS’ Federal inspection program for one or more of the review components.

Review of 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.

FSAS received MMPIP’s self-assessment submission for components 1 through 6 on April 9, 2021. Subsequently, FSAS sent a notification to MMPIP affirming acceptance of the self-assessment submission and all requested supplementary information provided during the components 1 through 6 desk reviews on April 20, 2021.

Component 1 – Statutory Authority and Food Safety Regulations
FSAS compared the submitted self-assessment and supporting documentation to the legal authority provided under the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Humane Methods of Slaughter Act (HMSA), and the regulations promulgated under these laws. The supporting documentation included the Maine Revised Statutes (Title 22, Subtitle 2, Part 5, Chapter 562-A and Title 17-A, Part 2, Chapters 25 and 31) and the Maine Code of Regulations (Rule Chapters 01-001, Chapter 346, Section 1, Subsection 11). The Maine Revised Statutes provide authorities for mandatory ante-mortem inspection (22 Section 2517), post-mortem inspection and reinspection (22 Section 2517-A), sanitation
requirements (22 Section 2512), record-keeping requirements (22 Section 2512), and humane methods of slaughter requirements (22 Sections 2521 and 2521-A through C).

In addition, the Maine Revised Statutes provide authorities that are “at least equal to” the FMIA and PPIA regarding adulteration (22 Section 2511), misbranding (22 Section 2511), prohibited acts (22 Sections 2523 and 2525), access and examination (22 Sections 2517-B and 2519-B), and product control actions (22 Sections 2519 and 2519-A). It also includes sufficient authorities for criminal, civil, and administrative sanctions to address violators.

The Maine Revised Statutes grant the authority to promulgate rules and regulations (22 Section 2513). Maine adopts by reference Title 9, Code of Federal Regulations (9 CFR), Parts 300 to end, in the Maine Code of Regulations (01-001, Chapter 346, Subsection 11).

In conclusion, MMPIP provided evidence showing that it operates under State laws and regulations that provide legal authority “at least equal to” that provided under the FMIA, PPIA, and HMSA, and the accompanying regulations.

Component 2 – Inspection
FSAS compared the self-assessment submission and supporting documentation regarding inspection policies and procedures and regarding verification of establishments’ compliance, to the Federal requirements. MMPIP uses the FSIS Public Health Information System (PHIS) to schedule inspection tasks and to collect, consolidate, and analyze inspection data. MMPIP administers inspection for any meat or poultry product intended for human consumption, wholly or in part, from the carcass or parts of any animal defined as “livestock” or “poultry” in the Maine Revised Statutes and governing rules and regulations. The State inspection program impose regulations and perform inspection duties that ensure animals, intended to be used in meat and poultry products sold commercially, are slaughtered and processed in the presence of State inspection personnel, and the resulting meat food products are inspected and passed for human consumption. Furthermore, MMPIP administers a food safety verification program that meets the intent of FSIS Directive 5000.1, Verifying an Establishment’s Food Safety System. Food safety verification activities are performed by consumer protection inspectors (CPI) to ensure establishments’ compliance with applicable pathogen reduction, sanitation, and Hazard Analysis and Critical Control Point (HACCP) regulations.

In addition to performing inspections and food safety verifications, MMPIP schedules and performs a comprehensive Food Safety Assessment (FSA) at each inspected establishment in accordance with FSIS Directive 5100.1, Enforcement, Investigations and Analysis Officer (EIAO) Food Safety Assessment (FSA) Methodology, and 5100.4, Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology at least once every four years. These FSAs examine the design and validity of establishments’ food safety systems, which include hazard analyses, HACCP plans, Sanitation Standard Operating Procedures (Sanitation SOP), prerequisite programs, sampling programs, supporting documentation and records, and any other programs that constitute the establishments’ food safety systems. MMPIP currently is not using the PHRE in lieu of performing a full FSA at each of their establishments. Currently, the risk ranking is used to prioritize FSAs outside the demands of the four-year cycle, and the PHRE tool is used to familiarize the EIAO with the establishment
prior to completing the FSA. The PHRE and FSA records support the conclusion that State inspection personnel recognize and document noncompliance and initiate appropriate regulatory actions.

MMPIP verifies establishment compliance with the non-food safety (i.e., labeling) consumer protection regulatory requirements. MMPIP uses applicable FSIS directives to instruct inspection personnel and uses PHIS to schedule ongoing verifications and document noncompliance. A thorough review of the PHIS data for a 4-month period supports the conclusion that MMPIP inspectors correctly apply the inspection methodology and document noncompliance.

MMPIP maintains a label approval policy for generic and MMPIP headquarters approved labels as well as a Mandatory Label Requirements for Meat and Poultry Products procedure 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 must approve the label generically or an establishment representative must submit a completed application for label approval and a label sketch to obtain MMPIP approval.

MMPIP enforces the Maine Code of Regulations, 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 uses FSIS directives as guidance to document relevant facts of administrative actions and ensure that administrative actions are legally supportable and based on relevant facts. All documents are maintained in a limited access secured database.

The submitted documents support the conclusion that MMPIP:

- Performs inspection and regulatory verification procedures to confirm that State-inspected establishments comply with applicable regulations;
- Maintains a system to carry out administrative enforcement actions when establishments do not comply with State authorities that are “at least equal to” the FMIA and PPIA;
- Conducts inspection activities “at least equal to” the Federal requirements; and
- Monitors these activities through control measures to verify that the inspection system functions as intended.

Component 3 – Sampling Programs

FSIS compared MMPIP’s sampling protocols, procedures, and results to Federal policies and procedures.

MMPIP provided documentation to demonstrate that it maintains sampling programs, based on sound rationale and goals, for the following:

- *Escherichia coli* (*E. coli*) O157:H7 in raw non-intact beef products and raw ground beef components;
- Non-O157 Shiga toxin-producing *E. coli* (non-O157 STEC) in beef manufacturing trimmings;
• *Salmonella* performance standards in raw classes of meat and poultry; *Campylobacter* in raw classes of poultry; and

• Other consumer protection standards.

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

In conclusion, a 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. MMPIP has control measures in effect to confirm that its product sampling system functions as intended.

Component 4 – Staffing, Training, and Supervision

MMPIP developed methods to determine staffing requirements. The requirements consider each inspector’s workload and the number of inspectors required to provide daily inspection coverage in each establishment on days when the establishment produces products bearing the State mark of inspection. Procedures are in effect to document staffing in each establishment, identify failures to meet staffing requirements, and correct staffing deficiencies. 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 manager 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. Inspectors are to request leave from the QA&R inspection program manager and the MMPIP manager, who will alter the assignment schedule to meet the establishment inspection requests.

At the start of the FY 2021 review cycle, MMPIP indicated they employ one program manager, who is also the MMPIP public health veterinarian (MMPIP PHV), EIAO, and a part time compliance officer, and three full-time CPIs. The Maine Department of Agriculture, Conservation and Forestry, Division of Animal and Plant Health employs two additional veterinarians, who are trained in meat and poultry inspection. These veterinarians provide relief for the MMPIP public health veterinarian and perform veterinary dispositions and humane handling verification visits. A QA&R employee, who has completed EIAO Comprehensive Food Safety Assessment Methodology training and compliance enforcement training, serves as the MMPIP’s EIAO when the program manager cannot perform the assessments. The QA&R inspection program manager serves as the recall coordinator, who determines the actions taken in response to meat and poultry product recalls, leads recall effectiveness checks, and organizes trace back activities for adulterated or misbranded products implicated in recalls.

MMPIP continues to implement a training program for new entry-level inspection personnel. MMPIP uses the FSIS Center for Learning (CFL) training courses, CFL training materials, and a journeyman CPI to provide timely classroom and hands-on training 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 inspection methods training. MMPIP maintains a record keeping system to track participation and completion of training.

MMPIP maintains a performance appraisal system to evaluate job performance, and to establish work responsibilities, performance goals, and objectives. MMPIP incorporates the guidance in FSIS Directive 4430.3, In-Plant Performance System (IPPS), to set performance standards, and complete and record ongoing performance evaluations. The QA&R inspection program manager and the MMPIP manager perform at least two in-plant performance reviews (IPPS) for each CPI annually and record 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 QA&R inspection manager evaluates each CPI annually and records the results on the State of Maine Performance Management Form. During these performance evaluations, the QA&R inspection manager discusses and establishes the CPI’s performance goals for the next 12 months.

After thorough review of the submitted documents, FSAS 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, to document findings, and to 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

MMPIP schedules and performs regulatory verification procedures to assess whether establishment personnel humanely handle all livestock throughout the time the livestock are on official establishment premises, and it takes appropriate regulatory action in response to noncompliance.

MMPIP uses FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock, to communicate instructions to inspection personnel. MMPIP inspectors perform humane handling verification procedures each day the establishments conduct slaughter operations and documents the results of those procedures in PHIS. The MMPIP manager monitors compliance verification through Humane Handling Activity Tracking System (HATS) data and the results of completed humane handling verification tasks documented in PHIS. During IPPS visits, the QA&R inspection program manager and the MMPIP manager evaluate establishments’ humane handling procedures and inspectors’ humane handling task performance. Maine veterinary medical specialists (MVMS) perform annual humane handling verification visits at slaughter facilities in accordance with FSIS Directive 6910.1, District Veterinary Medical Specialist (DVMS) – Work Methods.

In conclusion, the information supports the fact 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 – 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 QA&R 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.

At the direction of the QA&R inspection program manager, 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 Statutes; 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.

The QA&R inspection program manager or MMPIP manager review the surveillance and investigative records and decide whether to request further investigation or legal action. The QA&R compliance coordinator follows MMPIP Directives 8010.1 through 8010.5, 8410.1, and 8080.3 to conduct investigations, write reports of investigations, assemble related investigative records and case files, and enter the documents in the MMPIP C-Net database. The QA&R compliance coordinator 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 “at least 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, QA&R 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. The QA&R compliance coordinator oversees the recall activities, coordinates actions to determine whether adulterated product was removed from commerce, and the QA&R inspection program manager or MMPIP manager 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 QA&R 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.
MMPIP has a system for reviewing custom exempt operations that is in accordance with FSIS Directive 8160.1, Custom Exempt Review Process. CPIs perform custom exempt reviews at least annually; follow-ups can occur at any frequency depending on the identified deficiencies. The MMPIP program manager will review each custom review and determine if the CPIs recommended follow-up frequency is appropriate based on the submitted report.

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 7 – Laboratory Methods and Quality Assurance Program
MMPIP utilizes three contract laboratories for microbiological pathogen testing and one contract laboratory for food chemistry testing. LQAS performed an off-site records review of Contract Laboratory A, Contract Laboratory B, and Contract Laboratory C during FY21 to evaluate laboratory quality assurance (QA) programs and method equivalence under the State MPI Program.

Wisconsin Department of Agriculture, Trade and Consumer Protection Bureau of Laboratory Services (Wisconsin) conducts MPI and Cooperative Interstate Shipment (CIS) food chemistry testing on Maine’s behalf to include moisture, protein, fat, and salt. Wisconsin also conducts CIS microbiological testing on Maine’s behalf to include Salmonella, E. coli O157:H7, non-O157 STEC, and Campylobacter. Contract Laboratory C conducts MPI microbiological testing for the analyses of Salmonella, and E. coli O157:H7. Contract Laboratory C sub-contracts with Contract Laboratory B for detection of Salmonella, E. coli O157:H7, and non-O157 STEC. Contract Laboratory C also has a sub-contract with Contract Laboratory A for confirmation of Salmonella, E. coli O157:H7 and non-O157 STEC. The State of Maine does not conduct analyses for Listeria monocytogenes and Campylobacter as part of the MPI program.

FSIS compared Contract Laboratory A, Contract Laboratory B, Contract Laboratory C, and Wisconsin Laboratory Quality Assurance Programs to the State Meat and Poultry Inspection (MPI) Program Laboratory Quality Management System Checklist and evidence of laboratory proficiency and analyst training was evaluated. Contract Laboratory A, Contract Laboratory B, Contract Laboratory C, and Wisconsin met all Laboratory QA requirements based on the self-assessment provided by each laboratory.

Contract Laboratory A has demonstrated adequate microbiological capabilities for the confirmation of Salmonella, E. coli O157:H7, and non-O157 STEC. Contract Laboratory C has demonstrated adequate microbiological capabilities for the detection of Salmonella, and E. coli O157:H7. Contract Laboratory B has demonstrated adequate microbiological capabilities for the detection of Salmonella, E. coli O157:H7, and non-O157 STEC. Wisconsin has demonstrated adequate food chemistry capabilities for the measurement of moisture, protein, fat and salt.

Based on the Component 7 methods and quality assurance program review, Maine may be eligible to perform inspection:
At beef establishments producing raw ground beef and bench trim, provided that the State collects and submits the appropriate number of samples that are tested for *Salmonella* and *E. coli* O157:H7 and at beef slaughter establishments producing manufactured trim, where the State is required to collect and submit the appropriate number of samples that are tested for *Salmonella*, *E. coli* O157:H7, and non-O157 STEC.

At poultry slaughter establishments, provided that the State collects and submits the appropriate number of samples that are tested for *Salmonella* and *Campylobacter*. MPI States with no participating facilities slaughtering at least 20,000 chickens and/or 20,000 turkeys per year are not required to test that raw product for *Salmonella* and *Campylobacter* since it is not required at similar Federally inspected plants. However, States should consider testing at a risk hierarchy that is commensurate with their establishment sizes and production volumes. Note: Analytical methods for *Salmonella* and *Campylobacter* in raw poultry products were not evaluated as Maine is not currently inspecting MPI program poultry establishments slaughtering at least 20,000 chickens and/or turkeys per year.

Component 8 – Civil Rights

In April 2021, CRS conducted a triennial civil rights compliance review of MMPIP. The review assessed the program’s compliance with applicable Federal laws, USDA regulations, and FSIS policies pertaining to civil rights in program delivery. The review also provided corrective actions and/or recommendations for improvement as necessary.

The review focused on compliance in eight areas: (1) Civil Rights Assurances; (2) State Infrastructure and Program Accountability; (3) Public Notification; (4) Civil Rights Complaints of Discrimination in Program Delivery; (5) Civil Rights Training; (6) Disability Compliance; (7) Program Accessibility for Individuals with Limited English Proficiency, and (8) Compliance with the Age Discrimination Act of 1975.

The review was conducted by desk review and telephonic interviews with QA&R personnel and State-inspected meat and poultry plant owner/operators during the week of April 12, 2021. The last compliance review of the program was conducted by CRS in March 2018.

The overall assessment found the State of Maine adequately followed “at least equal to” standards for applicable civil rights laws, USDA regulations, and FSIS policies.

Notwithstanding this determination, the recommendations under Area 4 should be completed and proof of compliance submitted with the State’s next annual self-assessment submission on FSIS Form 1520-1, Civil Rights Compliance State of State Inspection Programs, due to FSIS on November 1, 2021.

Component 9 – Financial Accountability

MMPIP submitted quarterly and final Federal Financial 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

**Self-Assessment Determination for Maine**
Based on the evidence and review results described above, FSIS determined that MMPIP provided adequate documentation to show it is operating a meat and poultry inspection program “at least equal to” the Federal requirements.

### Part II. Onsite Review

Part II includes:

- A description of the onsite review methodology followed for all State MPI programs;
- An onsite review of Maine; and
- An onsite determination for Maine.

**Onsite Review Methodology**
The onsite review determines whether the State implements its MPI program in a manner that is “at least equal to” the Federal inspection program and maintains program policies and procedures in accordance with those submitted in the annual self-assessment documents. The FSIS onsite review team is comprised of representatives from FSAS, CRS, FRSB, LQARCS, and other program areas as needed. FSIS Directive 5720.3, Methodology for Performing Scheduled and Targeted Reviews of State Meat and Poultry Inspection Programs, outlines the comprehensive State MPI program review process.

As the primary contact for State MPI program officials and FSIS review team members, the lead FSAS program auditor is to coordinate and track components 1 through 6 onsite review activities and to monitor the status of components 7 through 9 reviews through communications with LQARCS, CRS, and FRSB. The FSAS auditor schedules the onsite review, for components 1 through 6, with State MPI program officials. FSAS will send written notification to State MPI program officials at least 30 days prior to the start of the onsite review. LQARCS, CRS, and FRSB are to schedule onsite reviews of components 7 (laboratory methods and quality assurance program), 8 (civil rights), and 9 (financial accountability), respectively.

Upon completion of an onsite review, FSIS is to make one of the following three determinations for each component and the State’s overall ability to maintain its MPI program “at least equal to” the Federal requirements:

1. **“At Least Equal To”** means the State MPI program has adopted laws, regulations, and programs, and implemented them in a manner that is “at least equal to” FSIS’ Federal inspection program for all review components.
2. **“At Least Equal To” with Provisions** means FSIS makes a provisional determination of the State MPI program’s “at least equal to” status provided the program takes additional action to resolve review findings.
(3) Not “At Least Equal To” means the State MPI program has not adopted laws, regulations, or programs, or does not implement them in a manner that is “at least equal to” FSIS’ Federal inspection program for one or more of the review components.

**Onsite Review of Maine**

FSIS analyzed all information gathered during the onsite 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 determination and rationale for each review component are listed below.

FSAS conducted an onsite review of MMPIP, for components 1 through 6, June 21 to 25, 2021. Based on records and procedures reviewed, FSAS determined MMPIP was able to confirm the program is being implemented as described in self-assessment.

**Component 2 – Inspection**

FSAS reviewed the conditions and documents onsite. The onsite documents reviewed included, but were not limited to, Sanitation SOPs and associated records; HACCP plans and associated records; generic *E. coli* sampling procedures and associated records; procedures for the removal, segregation, and disposition of specified risk materials and associated records; custom exempt records; noncompliance records; and enforcement letters. In addition, FSAS reviewed the non-food safety consumer protection documents and procedures to determine whether MMPIP enforces non-food safety consumer protection regulatory standards “at least equal to” the Federal requirements. This review included, but was not limited to, ongoing regulatory verification tasks, label approvals, labels, and product formulations.

FSAS evaluated MMPIP during four establishment reviews. MMPIP personnel identified several establishment noncompliances during the onsite review, with the Sanitation SOPs, Sanitation Performance Standards, and non-food safety consumer protection requirements. The FSAS program auditor identified establishment noncompliances with HACCP Plan design. None of the noncompliances identified by MMPIP officials or FSAS program auditors indicated the presence of a food safety issue. MMPIP officials initiated regulatory actions in the establishments and issued noncompliance records at the time the noncompliances were identified.

On July 16, 2021, MMPIP submitted an action plan to correct the findings identified during the review. The action plan identifies the underlying causes of both the system-wide findings and the specific findings at individual establishments, and includes a verification plan to ensure statewide correction of these findings. In addition, MMPIP provided evidentiary documents to demonstrate verification of establishment compliance with the regulatory requirements.

**Component 3 – Sampling Programs**

FSAS reviewed MMPIP’s product sampling documents, protocols, procedures, and results presented onsite. These included sampling plans and laboratory results for *E. coli* O157:H7 in raw non-intact beef products and raw ground beef components; non-O157 STEC in raw beef manufacturing trimmings; *Salmonella* performance standards in raw classes of meat and poultry; *Campylobacter* in raw classes of poultry; economic samples; violative drug residues; State
laboratory activity reports; and sample seals. Based on records and procedures reviewed, FSAS determined MMPIP was able to confirm the program is being implemented as described in self-assessment.

Component 4 – Staffing, Training, and Supervision
FSAS reviewed the staffing and training program onsite to assess whether MMPIP carries out its staffing, training and supervisory systems consistent with the self-assessment documents and “at least equal to” the Federal requirements. After further analysis of data from the MMPIP office and establishment reviews, FSAS concluded that MMPIP has an adequate number of trained persons to provide the required inspection coverage in the establishments, perform compliance activities, and provide supervisory oversight, and has implemented procedures to ensure daily inspection coverage in operating establishments. Inspection personnel apply MMPIP’s inspection methodology, and make decisions based upon the correct application of inspection methodology, document findings, and initiate regulatory action. The training program includes measures to ensure that inspection personnel receive training in the areas of meat and poultry ante-mortem and post-mortem inspection, humane handling, processed products, HACCP, Sanitation SOPs, rules of practice, IPPS guidelines, compliance, and Inspection Methods training. No issues were identified with the staffing, training and supervision component at the State Office.

Component 5 – Humane Handling
FSAS reviewed the humane handling program and documents presented onsite to determine whether 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. These documents included, but were not limited to, noncompliance records and procedure schedules. FSIS reviewed humane handling of livestock, stunning methods, and the condition of livestock pens, driveways, and ramps. No issues were identified with the humane handling practices.

Component 6 – Compliance
FSAS conducted an onsite review of the compliance program activities and all specified documents to determine whether MMPIP implements a compliance program in accordance with the submitted self-assessment documentation. These included, but were not limited to, Reports of Investigation, Daily Activity Reports, Programmed Compliance Plans, Incident Reports, Case Reports, Reports of Apparent Violations, and Notices of Warning.

The review of compliance documents and case files support the conclusion that 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.


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

MMPIP has a system for reviewing custom exempt operations that is in accordance with FSIS Directive 8160.1, Custom Exempt Review Process. CPIs perform custom exempt reviews at least annually; follow-ups can occur at any frequency depending on the identified deficiencies. MMPIP’s program manager will review each custom review and determine if the CPIs recommended follow-up frequency is appropriate based on the submitted report. Custom exempt operations visited during the onsite review were found to have minimal deficiencies from regulatory requirements. No issues were identified with the compliance program.

Component 7 – Laboratory Methods and Quality Assurance Program
LQARCS did not conduct an onsite review of Contract Laboratory A, B, C and Wisconsin analytical methods in FY 2021. Therefore, the annual determination will be based on the self-assessment review results only.

Component 8 – Civil Rights
While CRS did not conduct an onsite review of documents and conditions at the MMPIP offices, CRS did interview telephonically and reviewed documents to determine whether MMPIP complies with Federal civil rights laws and USDA civil rights regulations, and achieves the intended outcome of the Federal requirements in FY 2021.

Component 9 – Financial Accountability
FRSB did not conduct an onsite fiscal financial review and compliance review of MMPIP in FY 2021. Therefore, the annual determination will be based on the self-assessment review results only.

Onsite 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.