Appendix N

Comprehensive Review and Determination Report

Fiscal Year 2021

Montana

Federal-State Audit Staff
Office of Investigation, Enforcement, and Audit
Food Safety and Inspection Service
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Purpose
This report communicates the United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS), Office of Investigation, Enforcement and Audit (OIEA), Federal-State Audit Staff’s (FSAS) annual review results and determination for the Montana 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 Montana’s MPI Program
The Montana Department of Livestock, Meat and Poultry Inspection Bureau (MDOL/MPIB) administers the Montana MPI program under authority of Montana Code Annotated (Title 81, Chapter 2, Part 1). The program verifies compliance and enforces regulatory requirements at 32 inspected facilities and 134 custom exempt establishments.¹

Annual Determination
FSIS determined that MDOL/MPIB 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 routine and targeted 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 Montana’s Self-Assessment Submission; and
- Self-Assessment Determination for Montana.

Self-Assessment Review Methodology
The annual self-assessment process is designed for each State to provide sufficient information to adequately demonstrate their administration of an “at least equal to” State MPI program. The review objective is to determine whether a State continues to administer an MPI program that meets Federal standards set for ensuring meat and poultry products are safe, wholesome, unadulterated, and correctly labeled and packaged. Each review cycle, State MPI program officials are to complete and submit self-assessment component surveys, supporting documentation and other self-assessment instruments to FSIS in accordance with the State Reporting and Communication Tool User Guide and FSIS’ “At Least Equal To” Guideline for State Meat and Poultry Inspection Programs.

FSIS begins the annual comprehensive review by assembling a review team comprised of subject matter experts from various FSIS program areas to review the nine components of the comprehensive review process. The review team, comprised of Agency representatives from

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).
FSAS, the 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. During the desk review process, the Office of Policy and Program Development and the Office of Field Operations are consulted, as needed, to gain context and perspective on current FSIS programs, policies, and procedures when determining whether a State MPI program meets Federal “at least equal to” standards.

If questions arise during the desk review or if additional documentation is needed to make a review determination regarding one or more components, FSIS will request clarifying information from the State MPI program. Upon completion of the desk review, FSIS makes one of the following three determinations for each component and for the non-designated\(^2\) 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 Montana’s Self-Assessment Submission**

FSIS evaluated the self-assessment documents for the nine review components to determine whether MDOL/MPIB implements an inspection program “at least equal to” the Federal program. The determination and rationale for each review component are listed below.

FSAS received MDOL/MPIB’s self-assessment submission for components 1 through 6 on March 30, 2021. FSAS sent a notification to MDOL/MPIB requesting additional information. MDOL/MPIB sent additional information clarifying their self-assessment submission and all supplementary information requested. FSAS reviewed the submitted clarification items, and accepted the requested information on September 24, 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 Montana Code Annotated (Title 81, Chapter 9) and Administrative Rules of Montana (Department 32, Chapter

\(^2\) Non-designated is a State that operates an MPI program under a cooperative agreement with FSIS. The State MPI program must administer inspection and food safety requirements “at least equal to” those imposed under the Federal Meat Inspection Act, Poultry Products Inspection Act and the Humane Methods of Slaughter Act of 1978.
6). The Montana Code Annotated provides authorities for mandatory ante-mortem and post-mortem inspection (Section 81-9-230), reinspection (Section 81-9-220), sanitation requirements (Section 81-9-220), record keeping requirements (Section 81-9-220), and humane methods of slaughter requirements (Section 81-9-219).

In addition, the Montana Code Annotated provides authorities that are “at least equal to” the FMIA and PPIA regarding adulteration and misbranding (Section 81-9-217), prohibited acts (Section 81-9-234), access and examination (Section 81-9-220), and product control actions (Section 81-9-116). It also includes sufficient authorities for criminal, civil, and administrative sanctions to address violators.

The Montana Code Annotated grants the authority to promulgate rules and regulations (Section 81-9-220). Montana adopts by reference 9 CFR Parts 301-321.3, 325-325.21, 329.1-329.9, 352-362.5, 381-381.103, 381.115-381.182, 381.190, 381.194, 381.210-381.218, 381.300-381.524, and 416.1-500.8 in the Administrative Rule of Montana 32.6.712.

The submitted documentation supporting MDOL/MPIB operates under State laws and regulations with legal authority “at least equal to” that provided under the FMIA, PPIA, HMSA, and applicable sections of 9 CFR.

During the desk review process, it was brought to FSIS’ attention that the State of Montana recently enacted the Montana Local Food Choice Act, formerly known as Senate Bill 199, which allows uninspected raw poultry products to be used in the processing of homemade food and food products for distribution and direct sale to the end consumers without any regulatory oversight. In May 2021, FSIS sent a letter to the State of Montana expressing the Agency’s concerns that the newly enacted State law may jeopardize the “at least equal to” status of the State MPI program. The letter outlined the following the Agency concerns:

- The Montana Local Food Choice Act contravened existing custom, poultry and retail exemption requirements of the Montana Code Annotated (Title 81, Chapter 9), and the Poultry Products Inspection Act (PPIA) (21 U.S.C. § 451, et seq.) by allowing only poultry carcasses and parts derived from poultry exempt operators to be used as an ingredient in homemade products and not subjecting the production of homemade products to any sanitation, labeling or recordkeeping requirements.
- As written, the new State law did not provide any apparent assurances to prevent misbranded or adulterated products from being distributed and sold in commerce.
- The Montana Local Food Choice Act included provisions prohibiting MDOL/MPIB or any other State agency from creating or adopting rules related to enforcement of sanitation, recordkeeping or labeling requirements for homemade foods.
- It was unclear if the authority granted by the Montana Code Annotated (Title 81, Chapter 9) would allow MDOL/MPIB to take enforcement actions against homemade products found in commerce that failed to meet the requirements of the Montana Local Food Choice Act.

In response, MDOL/MPIB answered the letter of concerns by arguing the Montana Local Food Choice Act does not restrict the MPI program’s authority to access to poultry exempt operators to verify compliance with sanitary, recordkeeping and labeling requirements of the Montana
Code Annotated (Title 81, Chapter 9), and the PPIA. Additionally, MDOL/MPIB emphasized their collaborative work with local health departments to remain vigilant of intrastate sale of homemade foods.

Thus, FSAS conducted a targeted onsite review in conjunction of the scheduled routine triennial onsite to verify MDOL/MPIB retained the ability to prevent the intrastate distribution and sale of adulterated or misbranded poultry products despite the enactment of the Montana Local Food Choice Act. The targeted onsite review focused on examining the sanitary practices of the eligible manufacturers (i.e., poultry exempt operators) of the source materials used to make homemade products and the labeling of homemade products offered for direct sale at farmers’ markets, the most common venue for the direct sale of homemade goods to the end consumer. The results of the targeted onsite review are summarized in the Part II – Onsite Review of this report.

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. MDOL/MPIB uses the FSIS Public Health Information System (PHIS) to schedule inspection tasks and to collect, consolidate, and analyze inspection data. MDOL/MPIB 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 Montana Code Annotated (Section 81-9-220). 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, MDOL/MPIB 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 to ensure establishments’ compliance with applicable pathogen reduction, sanitation, and the Hazard Analysis and Critical Control Point (HACCP) regulations.

In addition to performing inspections and food safety verifications, MDOL/MPIB schedules and performs a comprehensive Food Safety Assessment (FSA) at each inspected establishment in accordance with FSIS Directives 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. These FSAs examine the design and validity of establishments’ food safety systems, which include hazard analyses, HACCP plans, Sanitation Standard Operational Procedures (Sanitation SOPs), prerequisite programs, sampling programs, supporting documenting and records, and any other programs that constitute the establishments’ food safety systems. The PHRE and FSA records support the conclusion that State inspection personnel recognize and document noncompliance and initiate appropriate regulatory actions.

MDOL/MPIB verifies establishment compliance with the non-food safety (i.e., labeling) consumer protection regulatory requirements. MDOL/MPIB 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 12-month period supports the conclusion that MDOL/MPIB inspectors correctly apply the inspection methodology and document noncompliance.

MDOL/MPIB 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 MDOL/MPIB approval.

MDOL/MPIB enforces the Administrative Rule of Montana 32.6.712, 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. MDOL/MPIB maintains procedures to document relevant facts of administrative actions and ensure that administrative actions are legally supportable and based on relevant facts.

The submitted documents support the conclusion that MDOL/MPIB:

- 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 MDOL/MPIB’s sampling protocols, procedures, and results to Federal policies and procedures.

MDOL/MPIB 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;
- *Listeria monocytogenes (L. monocytogenes)* and *Salmonella* in ready-to-eat products;
- Other consumer protection standards.

The sampling plans include procedures for sample collection, sample integrity, and laboratory analysis. MDOL/MPIB developed policies to respond to positive results. These policies include actions to prevent adulterated product from entering commerce. MDOL/MPIB participates in the FSIS National Residue Program and collects and analyzes inspector-generated samples for violative drug residues.
A detailed review of the sampling protocols, procedures, and results confirmed that MDOL/MPIB 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, Training, and Supervision
MDOL/MPIB 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. Inspectors are assigned specific circuits, with Area Supervisors coordinating routine and emergency leave as needed. Inspectors complete and submit weekly activity reports. The field supervisors review the activity reports to verify daily inspection coverage and arrange relief inspection during routine and emergency leave situations.

As of August 2021, MDOL/MPIB indicated they employ 1 bureau chief, 1 administrative assistant, 1 EIAO, 1 label specialist, 3 Area Supervisors, 16 in-plant inspectors, and 2 compliance officers.

MDOL/MPIB continues to implement a training program for new entry-level inspection personnel. The training covers basic slaughter techniques and all inspection techniques required to perform slaughter duties, including basic Sanitation SOPs and HACCP procedures. The MDOL/MPIB has one designated trainer who also functions as the EIAO. The training subjects include livestock inspection, slaughter inspection, processing inspection, HACCP, Sanitation SOPs, and sanitation performance standards. With the transition to virtual delivery of FSIS Inspection Methods training, MDOL/MPIB has made a goal of sending every inspection program personnel (IPP) to Inspection Methods, and currently has several inspectors who have completed virtual Inspection Methods. MDOL/MPIB maintains a record keeping system to track participation and completion of training.

MDOL/MPIB 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 supervisors are to perform at least 2 IPPS assessments for each inspector annually. MDOL/MPIB maintains control measures to examine the IPPS assessments for quality, completeness, and accuracy. In addition, Montana mandates a performance plan and evaluation system for all State employees. This system communicates to its employees’ their work responsibilities, performance goals and objectives, and the results of their annual performance evaluations.

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

Component 5 – Humane Handling
MDOL/MPIB 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.

MDOL/MPIB uses FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock, to communicate instructions to inspection personnel. Inspectors document humane handling verifications in PHIS and on Weekly Activity Reports. During semi-annual visits, Area Supervisors evaluate establishments’ humane handling procedures and inspectors’ humane handling task performance. MDOL/MPIB Area Supervisors perform semi-annual humane handling reviews at slaughter facilities in accordance with FSIS Directive 6910.1, District Veterinary Medical Specialist (DVMS) - Work Methods.

The information supports the conclusion that MDOL/MPIB 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
MDOL/MPIB personnel conduct in-commerce surveillance of persons or firms that 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 are secure from threats or intentional acts of contamination.

MDOL/MPIB 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 Montana Code Annotated (Title 81, Chapter 9); and takes enforcement action, when needed, up to and including prosecution of individuals or firms that have violated the Montana Code Annotated. MDOL/MPIB 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 MDOL/MPIB Bureau Chief reviews all compliance reports for correctness, reviews all violations and relevant evidence, and then determines the appropriate case disposition and course of action.

MDOL/MPIB maintains 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. These procedures include health hazard evaluation, recall classification, public notification, effectiveness checks, and closure. Firms are to notify
MDOL/MPIB within 24 hours of initiating a recall. MDOL/MPIB oversees the recall activities, coordinates actions to determine whether adulterated product was removed from commerce, and issues news releases as necessary to serve the interest of public health.

MDOL/MPIB established methods to record, triage, analyze, and track consumer complaints related to State-regulated meat or poultry products. Compliance personnel either investigate these complaints or refer them to the local health authority. The investigative methods include procedures to collect and safeguard evidence; conduct interviews; submit product samples to the laboratory; initiate recall procedures and/or regulatory and enforcement actions; and report potential food safety threats.

MDOL/MPIB has a system for reviewing custom exempt operations that is in accordance with FSIS Directive 8160.1, Custom Exempt Review Process. MDOL/MPIB IPP conduct custom exempt reviews at least twice annually at all exempt operators, and Meat Depots once annually. Meat Depots are defined in the Administrative Rules of Montana (ARM) 32.6.701 as a facility where meat or poultry food products, or meat or poultry by-products, capable for use as human food and intended for sale, are stored. MDOL/MPIB classifies findings from exempt establishment reviews as either critical, major, or minor. Critical findings are defined as conditions in which definite product adulteration has occurred and the facility will be reviewed again within five days and again the next quarter. Major findings are defined as those that are a likely cause of product adulteration and the facility will be reviewed again within 9- days (quarter). Minor findings are defined as those that may potentially cause product adulteration, and the facility will be reviewed again within 6 months.

The information supports the conclusion that MDOL/MPIB verifies that MDOL/MPIB has a system to investigate alleged violations of the FMIA, PPIA, HMSA and Montana Code Annotated and takes regulatory action “at least equal to” the Federal program. Control measures are in effect to confirm that the Compliance system functions as intended.

Component 7 – Laboratory Methods and Quality Assurance Program

LQARCS performed an off-site records review of Montana Department of Public Health (MDPH) during FY 2021 to evaluate laboratory quality assurance (QA) programs and method equivalence under the State MPI Program.

MDPH conducts microbiological testing for *Salmonella*, *L. monocytogenes*, *E. coli* O157:H7, and non-O157 STEC. On behalf of MDPH and MDOL/MPIB, FSIS Eastern Lab (EL) conducts food chemistry testing of State-inspected products for moisture, protein, fat, and salt.

FSIS compared the MDPH Laboratory Quality Assurance Program to the State Meat and Poultry Inspection (MPI) Program Laboratory Quality Management System Checklist and evidence of laboratory proficiency and analyst training was evaluated. Based on their self-assessment, MDPH met all laboratory QA requirements including analysts’ training and related proficiency testing.
EL has demonstrated adequate food chemistry capability for the measurement of moisture, protein, fat, and salt. MDPH has demonstrated adequate microbiological capabilities for detection of *Salmonella*, *L. monocytogenes*, *E. coli* O157:H7, and non-O157 STEC.

Based on the Component 7 methods and quality assurance program review, Montana may be eligible to perform inspection:

- At beef establishments producing raw ground beef and bench trim and at beef slaughter establishments producing manufactured trim, provided the State collects and submits the appropriate number of samples that are tested for *Salmonella*, *E. coli* O157:H7, and non-O157 STEC.

- At ready-to-eat meat and poultry establishments, provided the State collects and submits the appropriate number of samples that are tested for *Salmonella* and *L. monocytogenes*.

- At poultry slaughter establishments, provided 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 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 Montana is not currently inspecting MPI program poultry establishments slaughtering at least 20,000 chickens and/or turkeys per year.

Component 8 – Civil Rights
In January 2021, MDOL/MPIB 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. CRS concluded that MDOL/MPIB functions “at least equal to” the Federal civil rights requirements.

Component 9 – Financial Accountability
MDOL/MPIB submitted quarterly and final Financial Status Reports (SF-425), and an annual Indirect Cost Proposal to demonstrate it conforms to 7 CFR, Part 3016, Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments, and follows FSIS Directive 3300.1, Fiscal Guidelines for Cooperative Inspection Programs. FRSB determined that MDOL/MPIB is “at least equal to” Federal standards for financial accountability for FY 2021.

Self-Assessment Determination for Montana
Based on the submitted self-assessment documents and desk review results described above, FSIS determined that that MDOL/MPIB 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 Montana; and
- An onsite determination for Montana.

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 LQARCS, CRS, FRSB, 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 sends written notification to State MPI program officials at least 30 days prior to the start of the onsite review. LQARCS, CRS, and FRSB 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 Montana

FSIS analyzed all information gathered during the onsite review and MDOL/MPIB’s action plan, which addressed the findings identified during the review, to determine whether MDOL/MPIB has implemented and maintains its MPI program “at least equal to” the Federal requirements, and enforces 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 MDOL/MPIB, for components 1 through 6, July 20 to 29, 2021. Based on records and procedures reviewed, FSAS determined MDOL/MPIB was able to confirm the program is being implemented as described in self-assessment.

Component 1 – Statutory Authority and Food Safety Regulations
FSAS observed MDOL/MPIB’s enforcement of Montana Code Annotated (Title 81, Chapter 9) and Administrative Rules of Montana (Department 32, Chapter 6) and applicable 9 CFR adoption at seven State-inspected establishments and verified MDOL/MPIB enforced regulatory and statutory requirements in accordance with the submitted self-assessment documents.

FSAS conducted a targeted onsite review to verify how MDOL/MPIB was enforcing the requirements of the Montana Code Annotated (Title 81, Chapter 9) and the PPIA relative to any applicable transactions conducted under the Montana Local Food Choice Act. FSAS observed the surveillance activities, including sanitation reviews, conducted by MDOL/MPIB at three poultry exempt operations and ten farmers’ markets throughout the State. At the time of the targeted onsite review, MDOL/MPIB verified current poultry exempt operators were not producing source materials for homemade products or farmers’ market vendors offering for sale homemade products subject to the Montana Local Food Choice Act. FSAS also observed MDOL/MPIB conduct outreach activities throughout the State to educate vendors and producers regarding the requirements of the Montana Local Food Choice Act.

Although the production of homemade product were not detected at visited firms and venues, MDOL/MPIB and local health department expressed their commitment to monitoring intrastate commerce for the distribution and sale of homemade products subsequent to the enactment of the Montana Local Food Choice Act. As of September 2021, MDOL/MPIB still has not detected any poultry exempt facilities producing product (i.e., source material) under the provisions of the Montana Local Food Choice Act. FSIS has retained the right to conduct subsequent targeted reviews of the Montana MPI program as the production of homemade products increases throughout the Montana in future years.

Component 2 – Inspection
FSAS conducted reviews of seven State inspected establishments that included evaluations of food safety systems and sanitary conditions under which inspected products were produced, examinations of related establishment and MDOL/MPIB regulatory oversight records, and interviews of MDOL/MPIB personnel. 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 MDOL/MPIB enforces non-food safety consumer protection regulatory standards “at least equal to” the Federal requirements. FSAS verified MDOL/MPIB’s completion of ongoing regulatory verification tasks, label approvals, labels, and product formulations.

During the onsite review MDOL/MPIB personnel identified several establishment noncompliances with the Sanitation Performance Standards (SPS), Sanitation SOPs, HACCP
design and validity, and non-food safety consumer protection requirements. The FSAS program reviewer identified several establishment noncompliances with the SPS, HACCP design and validity, slaughter and processing operations and other inspection requirements. The FSIS review team members identified the trend that several establishments throughout the State had not clearly identified which products in process or storage are produced under custom exemption, retail exemption, or State inspection. Further, FSIS and MDOL/MPIB review team members identified the trend that several establishments throughout the State were not meeting the requirements related to their *L. monocytogenes* sampling programs. FSAS review team members also identified the trend that several establishments throughout the State were not appropriately conducting ongoing verification testing to ensure that their HACCP plans reduced Shiga Toxin-producing *E. coli* (STEC) to undetectable levels in product intended for non-intact use. MDOL/MPIB officials initiated regulatory actions in the establishments and issued noncompliance records at the time the noncompliances were identified.

In response the MDOL/MPIB submitted a corrective action plan on Sept 9, 2021, that included the following items.

- Documentation showing the closure of all noncompliance records related to State noncompliance or FSAS findings identified at reviewed establishments along with evidence demonstrating the identified findings and noncompliances were corrected or did not exist at establishments not visited during the review;
- Evidence confirming MDOL/MPIB has held proposed circuit-wide training that, at a minimum, instructs in-plant personnel on how to perform livestock zero tolerance tasks in accordance with FSIS Directive 6420.2, Verification Procedures for Controlling Fecal Material, Ingesta, and Milk in Livestock Slaughter Operations, and how to verify establishments’ compliance with regulatory requirements related to HACCP systems and pertinent sampling protocols in accordance with FSIS Directive 5000.2, Review of Establishment Data by Inspection Personnel;
- Documentation showing the enforcement of product verification testing for the presence of STEC as one of the required ongoing verification activities performed by establishments that produce beef raw non-intact products under inspection; and
- Evidence showing the development and implementation of a program based in-commerce compliance activity data system that is readily accessible by all MDOL/MPIB compliance personnel, maintains a registry of facilities eligible for risk-based surveillance activities at a minimum, and creates an archive for MDOL/MPIB surveillance activity or investigation reports.

On September 30, 2021, FSAS issued the FY21 Interim Annual Comprehensive Audit and Determination Report which concluded MDOL/MPIB adopted laws, regulations, and policies necessary to meet the “at least equal to” Federal standards. However, nonconformities pertaining to implantation noted in the items listed above prevented the MPI program from achieving the desired regulatory outcomes for all Component 2 food safety and inspection activities. Thus, FSIS granted MDOL/MPIB an “at least equal to” with provisions determination for FY21 until the MPI program has implemented effectively corrective measures necessary to mitigate the identified nonconformities. This “at least equal to” with provisions determination
remained in place until FSAS verified the adequacy of the documentation submitted by MDOL/MPIB to address provisions outlined in the interim report.

Between September 26, 2021, and January 31, 2022, MDOL/MPIB submitted intermittently documentation necessary to demonstrate the program’s completion of all proffered corrective actions. On February 5, 2022, FSAS determined the submitted documentation demonstrated the effective implementation of measures to correct all findings identified during the FY21 review.

Component 3 – Sampling Programs
FSAS reviewed MDOL/MPIB’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, L. monocytogenes and Salmonella in ready-to-eat products, economic samples, violative drug residues, State laboratory activity reports, and sample seals.

A program nonconformity related to sampling programs was noted whereby several establishments were not conducting ongoing verification testing to support that their HACCP plans reduce STEC in beef intended for raw non-intact use. MDOL/MPIB should submit corrective actions to address this program nonconformity to satisfy a provisional “at least equal to” determination.

On September 9, 2021 MDOL/MPIB proposed circuit-wide training to address this program nonconformity but had not yet provided FSAS with a training agenda, training materials or proof of training completion. MDOL/MPIB submitted a tentative training schedule on September 30, 2021 but needed to provide further evidence of training completion and materials reviewed.

On January 31, 2022, MDOL/MPIB submitted the documentation showing the successful completion of all inspection personnel successfully completed the proffered training regarding ongoing verification testing for STEC. On February 5, 2022, FSAS determined the submitted documentation demonstrated the effective implementation of measures to correct all findings identified during the FY21 review.

Component 4 – Staffing, Training, and Supervision
FSAS reviewed the staffing and training program onsite to assess whether MDOL/MPIB 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 MDOL/MPIB and establishment reviews, FSAS concluded that MDOL/MPIB 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 MDOL/MPIB’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 ante-mortem and post-mortem inspection, humane handling, processed products, HACCP, Sanitation SOPs, rules of practice, IPPS guidelines, and compliance. With the
transition to virtually delivered FSIS Inspection Methods training, MDOL/MPIB has recently begun sending all field inspection personnel to FSIS Inspection Methods training.

On September 9, 2021 MDOL/MPIB proposed circuit-wide training to address this program nonconformity but had not yet provided FSAS with a training agenda, training materials or proof of training completion. MDOL/MPIB submitted a tentative training schedule on September 30, 2021 but needed to provide further evidence of training completion and materials reviewed.

On January 31, 2022, MDOL/MPIB submitted the documentation showing the successful completion of all inspection personnel successfully completed the proffered training regarding ongoing verification testing for STEC. On February 5, 2022, FSAS determined the submitted documentation demonstrated the effective implementation of measures to correct all findings identified during the FY21 review.

Component 5 – Humane Handling
FSAS reviewed the humane handling program and documents presented onsite to determine whether MDOL/MPIB 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 FSAS findings related to humane handling were noted during the onsite review.

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

While reviewing documents at the State Office, the program auditor identified the following nonconformity with MDOL/MPIB’s compliance surveillance tracking systems. The MDOL/MPIB was not maintaining a complete list of facilities that would be eligible for targeted risk-based surveillance activities. In their self-assessment clarification answer, MDOL/MPIB stated that they were working on transitioning to a new system utilizing USA Herds, an animal health database, for tracking surveillance activities which should be implemented in the next 1-2 months. MDOL/MPIB also stated that a complete list of eligible surveillance targets would be developed by October 1, 2021; MDOL/MPIB delivered the list on time. Therefore, given the pending implementation of a surveillance tracking system, the development of a surveillance record, and a complete list of facilities eligible for risk-based surveillance activities, a provisional determination was made for the “at least equal to” status of the MDOL/MPIB program.

On January 31, 2022, MDOL/MPIB submitted documentation necessary to close out the proffered corrective actions regarding the compliance surveillance tracking systems. On
February 5, 2022, FSAS determined the submitted documentation demonstrated the effective implementation of measures to correct all findings identified during the FY21 review.

This onsite verification review confirmed MDOL/MPIB investigates apparent statutory violations, as set out in FSIS Directive 8010.2, Investigative Methodology and Directive 8010.4, Report of Investigation, and controls products when there is reason to believe that the products are adulterated, misbranded, or otherwise in violation of the Montana Code Annotated.


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

MDOL/MPIB has a system for reviewing custom exempt operations that is in accordance with FSIS Directive 8160.1, Custom Exempt Review Process. MDOL/MPIB IPP conduct custom exempt reviews at least twice annually at all exempt operators, and once annually at meat depots. MDOL/MPIB classifies findings from exempt establishment reviews as either critical, major, or minor. Critical findings are defined as conditions in which definite product adulteration has occurred and the facility will be reviewed again within five days and again the next quarter. Major findings are defined as those that are a likely cause of product adulteration and the facility will be reviewed again within 9 days and again the next quarter. Minor findings are defined as those that may potentially cause product adulteration, and the facility will be reviewed again within 6 months.

Component 7 – Laboratory Methods and Quality Assurance Program

MDOL/MPIB received an onsite review in FY 2018 and is scheduled for an onsite lab method review of their laboratories in FY 2022. This year’s annual determination is based on the QA self-assessment checklist and related records only.

Component 8 – Civil Rights
CRS did not conduct an onsite review of MDOL/MPIB in FY 2021. Therefore, the annual determination will be based on the self-assessment review results only.

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

Onsite Determination for Montana
Based on the evidence and results discussed above, FSIS determined that MDOL/MPIB 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.