Appendix N

Comprehensive Review and Determination Report

FY 2012

Montana

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

Background
The Federal Meat Inspection Act (FMIA) (21 U.S.C. 661) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 454) provide for FSIS to cooperate with State agencies in developing and administering State MPI programs. Individual State MPI programs need to operate in a manner and with authorities that are "at least equal to" the programs that FSIS has implemented under the antemortem and postmortem inspection, reinspection, sanitation, record-keeping, and enforcement provisions of the FMIA and PPIA. In addition, State MPI programs are expected to ensure that livestock are treated humanely by imposing humane handling requirements that are "at least equal to" those FSIS has established under the Humane Methods of Slaughter Act of 1978 (HMSA)(7 U.S.C. 1901 – 1906). The jurisdiction of a State MPI program is limited to product that is produced and sold within the State.

The FMIA and PPIA provide for FSIS to conduct at least annual reviews of State MPI programs and their requirements, including enforcement of those requirements, with respect to slaughter, preparation, processing, storage, handling, and distribution of livestock carcasses and parts, meat and meat food products of such animals, or poultry products (21 U.S.C. 661 (c) (4); 21 U.S.C. 454 (c) (4)). Cooperative agreements and annual certifications of State MPI programs are contingent upon FSIS determining that each State MPI program enforces requirements "at least equal to" those imposed under the Federal Acts. FSIS performs annual reviews to determine whether each State MPI program meets, and can maintain for a period of 12 months, the mandated "at least equal to" standard.

FSIS Directive 5720.3, *Methodology for Performing Scheduled and Targeted Reviews of State Meat and Poultry Inspection Programs,* and the *"At Least Equal To" Guidelines for State Meat and Poultry Cooperative Inspection Programs* describe the policies and procedures for FSIS comprehensive reviews. FSIS Directive 5720.3 provides FSIS personnel with the methodology to perform these reviews. The *"At Least Equal To" Guidelines for State Meat and Poultry Cooperative Inspection Programs* were developed to assist the State MPI programs establish and maintain inspection programs that are "at least equal to" the Federal inspection program.

Review Methodology
The comprehensive State MPI program review process consists of two parts: (1) an annual review of the State MPI program's self-assessment submission; and (2) a triennial verification on-site review to observe the State MPI program. Through the annual self-assessment and triennial verification on-site reviews, FSIS determines whether the State MPI program is "at least equal to" the Federal inspection program.

Each year, FSIS determines the "at least equal to" status of each State MPI program based on one or both parts of the comprehensive review. If the State MPI program is not scheduled for an on-site review during the fiscal year, FSIS makes an annual determination based on the results of the self-assessment review. If the State MPI program is scheduled for an on-site review during the fiscal year, FSIS makes an annual determination based on the results of both the self-assessment and the on-site review.

Description of State MPI Program
The Montana Department of Livestock's Meat and Poultry Inspection (MPI) Bureau administers the Montana MPI program under authority of the Montana Code Annotated (Title 81, Chapter 9). The program verifies and enforces regulatory requirements at 40 inspected facilities and 155 custom exempt establishments.[1]

Annual Determination
FSIS determined that the Montana MPI Bureau is operating a meat and poultry inspection program "at least equal to" the Federal requirements. The Montana MPI Bureau has adopted laws, regulations, and programs, and implemented them in a manner that is "at least equal to" the Federal inspection program for all reviews components. For the most part, FSIS based its annual determination on review of the self-assessment documents only, since the Montana MPI Bureau was not subject to an on-site review, for components 1 through 8, during Fiscal Year (FY) 2012. This determination is fully explained in the Self-Assessment Review section.

Overview of Review Methodology

The review methodology is published in two companion documents: FSIS Directive 5720.3, (March 14, 2011), *Methodology for Performing Scheduled and Targeted Reviews of State Meat and Poultry Inspection Programs,* and the *"At Least Equal To" Guidelines for State Meat and Poultry Cooperative Inspection Programs* (July 2008). These documents describe the methodology used by FSIS' reviewers and provide information to State MPI programs on the criteria that FSIS uses to make its annual determination of whether State MPI programs are "at least equal to" the Federal inspection program. This review process consists of an annual review of the State MPI program's self-assessment submission and a triennial on-site review.

In addition to the annual reviews of each State MPI program, FSIS may perform a targeted review of a State MPI program in response to a condition or event that evidences program weaknesses, or as a reaction to a situation that could clearly result in a risk to public health. These targeted reviews may be conducted in addition to the scheduled reviews or may be performed at the same time. FSIS focuses the scope and activities of the targeted review on the conditions and evidence that triggered the need for the review and analyzes the review results to determine if the State MPI program is maintaining an "at least equal to" MPI program.

The comprehensive review process evaluates the following nine components:

1. Statutory Authority and Food Safety Regulations – This component evaluates whether the State MPI program operates under laws and regulations that provide legal authorities "at least equal to" those provided under the FMIA, PPIA, and HMSA.

2. Inspection – This component evaluates whether State MPI program personnel perform inspection activities to verify whether establishments comply with applicable regulations and take appropriate enforcement actions when establishments are not in compliance with provisions that are "at least equal to" those of FSIS.

3. Product Sampling – This component evaluates whether State MPI program personnel sample meat or poultry products to verify whether they are free of adulterants (e.g., *E. coli* O157:H7 in non-intact, raw beef products and raw ground beef components, Shiga Toxin-producing *Escherichia coli* (STEC)

[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.

serotypes in beef manufacturing trimmings, *Listeria monocytogenes* and *Salmonella* in ready-to-eat products, or drug residues at violative levels), comply with *Salmonella* Performance Standards in raw classes of meat and poultry, comply with other consumer protection standards, and are accurately labeled (e.g., with nutrition information).

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

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

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

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

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

9. Funding and Financial Accountability[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.

[2] In light of the current economic conditions, some State governments are experiencing financial challenges, which may result in overall budget cuts that could effect their meat and poultry inspection programs. To ensure the safety of State-inspected meat and poultry products, FSIS has initiated more vigilant monitoring to track and analyze circumstances and conditions that adversely affect the State MPI program's financial resources. When FSIS identifies concerns with a State MPI program's financial resources, the Agency will further examine each situation to determine the impact on the State MPI program's inspection activities, product sampling programs, staffing, and compliance activities, and determine if the State MPI program is maintaining its "at least equal to" status.

Self-Assessment Review

This section includes:

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

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

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

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

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

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

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

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

FSAB received Montana MPI Bureau's self-assessment submission, for components 1 through 7, on November 16, 2011. On September 7, 2012, FSAB requested additional clarifying information from the Montana MPI Bureau staff, which was provided on September 24 and 26, 2012.

Component 1 – Statutory Authority and Food Safety Regulations

FSAB compared the submitted self-assessment and supporting documentation to the legal authority provided under the FMIA, PPIA, and HMSA, and the regulations promulgated under these laws. The supporting documentation includes the Montana Code Annotated (Title 81, Chapter 9) and Montana Administrative Rules (Title 32, Chapter 6). The Montana Code Annotated provides statutory authorities for mandatory antemortem and postmortem inspection (§81-9-230); sanitation, reinspection, and record-keeping requirements (§81-9-220); and humane methods of slaughter requirements (§81-9-219).

The Montana Code Annotated provides authorities that are "at least equal to" the FMIA and PPIA regarding adulteration (§81-9-217), misbranding and prohibited acts (§81-9-234), access and examination (§81-9-220), and product control actions (§81-9-234), as well as criminal, civil, and administrative sanctions to address violators.

The Montana Code Annotated (§81-9-220) grants the authority to adopt rules and Montana incorporates by reference Title 9, Code of Federal Regulations (9 CFR) Parts 301 – 320.7, 325 – 325.21, 329.1 – 329.9, 352 – 362.5, 381 – 381.37, 381.45 – 381.95, 381.115 – 381.182, 381.190, 381.194, 381.300 – 381.311, 416, 417, 424, 430.1, 430.4, 441.10, 442, and 500 in Montana Administrative Rule 32.6.712.

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

The Montana MPI Bureau verifies that establishments develop, implement, and maintain Sanitation Standard Operating Procedures (SOPs) and Hazard Analysis and Critical Control Point (HACCP) systems. In addition to inspectors' ongoing verification activities, the Montana MPI Bureau training officer, who completed FSIS Enforcement, Investigations, and Analysis Officer (EIAO) methodology training, performs routine comprehensive food safety assessments (FSAs) as described in FSIS Directive 5100.1, *Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology.* These FSAs examine establishments' hazard analyses, HACCP plans, Sanitation SOPs, pre-requisite programs, testing programs, and any other programs that constitute establishments' HACCP systems. The Montana MPI Bureau follows the criteria and guidance in FSIS Directive 5100.4, *Prioritized Scheduling of Food Safety Assessments (FSA),* to schedule non-routine FSAs in response to food safety events.

The Montana MPI Bureau EIAO follows FSIS Directive 10,240.4, *Enforcement, Investigations, and Analysis Officer (EIAO) Assessment of Compliance with the Listeria monocytogenes* (*Lm*) *Regulation and Introduction of Phase 2 of the Lm Risk-based Verification Testing Program,* to perform intensified verification testing (IVT), as part of the FSAs. IVT is an environmental and product microbial testing protocol for *Listeria monocytogenes* to verify the adequacy of food safety systems in establishments that produce ready-to-eat products that are exposed to environmental conditions after the lethality step.

The Montana MPI Bureau enforces Montana Administrative Rule 32.6.712, which incorporates 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. The Montana MPI Bureau has procedures to document relevant facts for administrative actions and to ensure that administrative actions are based on relevant facts and legal authority. The Montana MPI Bureau follows the Montana Administrative Process Act to report administrative actions.

The submitted documents support the conclusion that the Montana MPI Bureau:

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

Component 3 – Product Sampling

FSAB compared Montana MPI Bureau's sampling protocols, procedures, and results to the Federal policies and procedures.

The Montana MPI Bureau provided documentation to show that it maintains sampling programs with sound rationale and goals for *E. coli* O157:H7 in raw non-intact beef products and raw ground beef components, *Listeria monocytogenes* and *Salmonella* in ready-to eat products, *Salmonella* Performance Standards in raw classes of meat and poultry, and other consumer protection standards. The Montana MPI Bureau participates in the National Residue Program, and collects and analyzes inspector-generated samples for violative drug residues. The sampling plans include procedures for sample collection, sample integrity, and laboratory analysis. The Montana MPI Bureau 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 the Montana MPI Bureau 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

The Montana MPI Bureau developed methods to determine 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. They have procedures in effect to document staffing in each establishment, identify failures to meet staffing requirements, and correct staffing deficiencies. The assistant manager assigns inspectors' work schedules two weeks in advance, with instructions for daily visits to operating establishments. The assistant manager reviews PBIS data and compares it to weekly schedules to verify daily inspection coverage; and arranges relief inspection during routine- and emergency-leave situations. As of October 1, 2011, the Montana MPI Bureau employed a bureau chief, a training officer/EIAO, a compliance officer/supervisor, an administrative assistant, a labeling specialist, 2 full-time supervisors, 13 full-time consumer safety inspectors, and a part-time relief consumer safety inspector.

The Montana MPI Bureau developed a training program for new entry-level inspection personnel. The training courses include the following topics: antemortem and postmortem inspection, pathogen reduction/HACCP, Sanitation SOPs, Sanitation Performance Standards, and food safety regulatory essentials. The Montana MPI

Bureau training officer follows a structured program that includes both classroom courses and on-the-job training. The Montana MPI Bureau documents employees' training histories on the State Training Report.

The Montana MPI Bureau provides ongoing computer-based trainings through AgLearn, the web-based USDA Learning System. In addition, the training officer develops training courses to communicate critical program policy changes. These courses are presented at quarterly training meetings. The Montana MPI Bureau assesses its training program's effectiveness through control measures.

Montana MPI Bureau supervisors use Montana Employee Performance Appraisal Forms and Establishment Review and Assessment Worksheets to develop performance plans, evaluate job performance, and record performance appraisal results. As part of the performance appraisals, supervisors observe consumer safety inspectors perform inspections and food safety verifications. Control measures are in effect to examine performance appraisal forms for quality, completeness, and accuracy.

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

Component 5 – Humane Handling

The PBIS records demonstrate that the Montana MPI Bureau 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.

The Montana MPI Bureau uses FSIS Directive 6900.2, *Humane Handling and Slaughter of Livestock*, to instruct inspection personnel. The inspectors document humane handling verification results and submit reports to Montana MPI Bureau supervisors. As part of the management control system, the Montana MPI Bureau reviews these reports to verify that humane handling verification tasks are performed each day an establishment slaughters livestock. In addition, Montana MPI Bureau veterinarians review humane handling practices in each livestock slaughter establishment annually.

In conclusion, the information made evident that the Montana MPI Bureau 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

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

The Montana MPI Bureau maintains a label-approval policy and process to verify that labels are accurate and meet regulatory requirements. Designated Montana MPI Bureau personnel must approve 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 and a label sketch to obtain approval.

In conclusion, the submitted documents provided evidence to show that the Montana MPI Bureau 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

The Montana MPI Bureau maintains a planned compliance review system based on the guidance in FSIS Directive 8010.1, *Methodology for Conducting In-Commerce Surveillance Activities*. The compliance officer conducts surveillance activities to verify that persons or firms who prepare, transport, sell, or offer for sale meat and poultry products in intrastate commerce, comply with State statutory and regulatory requirements, and that meat and poultry products in intrastate commerce are wholesome, correctly packaged and labeled, and secure from threats or intentional acts of contamination.

The Montana MPI Bureau investigates apparent violations and food safety incidents; detains products when there is reason to believe that the products are adulterated, misbranded, or otherwise in violation of the Montana Code Annotated; and takes enforcement action when needed, up to and including prosecution of individuals or firms that have violated the Montana Code Annotated. The Montana MPI Bureau compliance officer follows the guidance in FSIS Directives 8010.2, *Investigative Methodology;* 8010.3, *Procedures for Evidence Collection, Safeguarding and Disposal;* and 8010.4, *Report of Investigation*, 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 Montana MPI Bureau chief reviews the reports of apparent violations and supporting case files for accuracy and relevancy, and determines appropriate actions. The Montana MPI Bureau chief reviews case files that may warrant criminal enforcement prior to forwarding these cases to the district attorney's office for prosecution.

The Montana MPI Bureau follows recall procedures for meat and poultry products subject to its jurisdiction that are equal to procedures described in FSIS Directive 8080.1, *Recall of Meat and Poultry Products*. The procedures include health hazard evaluation, recall classification, public notification, effectiveness checks, and closure. The Montana MPI Bureau 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.

The Montana MPI Bureau established methods to record, triage, analyze, and track consumer complaints related to State-regulated meat or poultry products. Enforcement personnel either investigate these complaints or refer them to the local health authority.

The submitted documents support the conclusion that the Montana MPI Bureau 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, the Montana MPI Bureau 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 the Montana MPI Bureau functions "at least equal to" the Federal civil rights requirements.

Component 9 – Financial Accountability

The Montana MPI Bureau submitted quarterly and final Financial Status Reports (SF-425), and an annual Indirect Cost Proposal to demonstrate it conforms to 7 CFR, Part 3016, *Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments,* and follows FSIS Directive 3300.1, *Fiscal Guidelines for Cooperative Inspection Programs.* On October 24, 2012, FRAS determined that the Montana MPI Bureau is "at least equal to" Federal standards for financial accountability for FY 2012.

During the week of September 17, 2012, FRAS conducted an on-site review fiscal review of the Montana MPI Bureau. This review encompassed Federal FYs 2009, 2010, and 2011. As a result of this review, FRAS determined that the Montana MPI Bureau is operating in compliance with the financial and administrative provisions of FSIS Directive 3300.1, Rev.2, and the criteria outlined in the FSIS "*At Least Equal To" Guidelines for State Meat and Poultry Cooperative Inspection Programs* (July 2008).

Self-Assessment Determination for Montana

Based on the evidence and review results described above, FSIS determined that the Montana MPI Bureau provided adequate documentation to show it is operating a meat and poultry inspection program "at least equal to" the Federal requirements.