Appendix K

Comprehensive Review and Determination Report

FY 2012

Minnesota

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 Minnesota Meat and Poultry Inspection (MPI) program and an overview of the review methodology. FSIS determined that the Minnesota 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 Minnesota Department of Agriculture, Dairy and Food Inspection Division (MDA/DFID) administers the Minnesota MPI program under authority of the Minnesota Statutes (Chapters 31 and 31A). The program verifies and enforces regulatory requirements at 59 inspected facilities and 228 custom exempt establishments.[1]

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

Overview of Review Methodology

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

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

The comprehensive review process evaluates the following nine components:

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

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

3. Product Sampling – This component evaluates whether State MPI program personnel sample meat or poultry products to verify whether they are free of adulterants (e.g., *E. coli* O157:H7 in non-intact, raw beef products and raw ground beef components, Shiga Toxin-producing *Escherichia coli* (STEC) serotypes in beef manufacturing trimmings, *Listeria monocytogenes* and *Salmonella* in ready-to-eat products, or drug residues at violative levels), comply with *Salmonella* Performance Standards in raw

[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.

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.

Self-Assessment Review

This section includes:

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

[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 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 Minnesota's Self-Assessment Submission
FSIS evaluated the self-assessment documents for the nine review components to determine whether MDA/DFID constitutes an inspection program "at least equal to" the Federal program. The determination and rationale for each review component are listed below.

FSAB received MDA/DFID's self-assessment submission, for components 1 through 7, on November 15, 2011. On August 1, 2012, FSAB requested additional clarifying information from the MDA/DFID staff, which was provided on August 10 and 14, 2012.

<u>Component 1 – Statutory Authority and Food Safety Regulations</u>
FSAB compared the submitted self-assessment and supporting documentation to the legal authority provided under the FMIA, PPIA, and HMSA, and the regulations promulgated under these laws. The supporting documentation includes the Minnesota Statutes (Chapters 31 and 31A) and Minnesota Administrative Rules (Chapters 1540 and 1545). The Minnesota Statutes provide authorities for mandatory antemortem and postmortem inspection, and reinspection (§§31A.03 and 31A.04); sanitation requirements (§31A.08); record-keeping requirements (§31A.18); and humane methods of slaughter requirements (§31.59).

The Minnesota Statutes provide authorities that are "at least equal to" the FMIA and PPIA regarding adulteration (§31A.02, Subdivision 13), misbranding (§31A.02, Subdivision 14), prohibited acts (§§31A.10 and

31A.11), access and examination (§§31A.18 and 31A.25), and product control actions (§§31.05, 31A. 23, and 31A.24), as well as criminal, civil, and administrative sanctions to address violators.

The Minnesota Statutes grant authority to promulgate regulations (§31.101) and Minnesota incorporated Title 9, Code of Federal Regulations (9 CFR), Parts 301 *et seq*., as part of its meat and poultry rules (§31.101, Subdivision 10).

In conclusion, MDA/DFID 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. MDA/DFID uses the Minnesota Inspection System (MIS) to guide inspection program activities, collect establishment information, establish and maintain in-plant inspection procedure plans, and document establishment noncompliance. MIS is analogous to FSIS' Performance Based Inspection System. In addition, MIS generates Inspection Benchmarking Reports, which detail establishment and inspection verification data. MDA/DFID management reviews these reports to assess establishment compliance and inspector performance, and to schedule inspection. MDA/DFID reviews all custom exempt operations in accordance with a Minnesota Directive that schedules the review frequencies based on risk and performance history. This directive meets the intent of FSIS Directive 5930.1, *Custom Exempt Review Process.*

MDA/DFID verifies that establishments develop, implement, and maintain Sanitation Standard Operating Procedures (SOPs) and Hazard Analysis and Critical Control Point (HACCP) systems. In addition to the inspectors' ongoing verification activities, Enforcement, Investigation, and Analysis Officers (EIAOs) perform comprehensive Food Safety Assessments (FSAs) to examine all food safety aspects that relate to the establishments and their products in accordance with the instructions provided in a Minnesota Directive. These assessments examine the design and validity of the establishments' food safety systems, which include hazard analyses, supporting documents, HACCP plans, Sanitation SOPs, prerequisite programs, sampling programs, and any other programs that constitute the establishments' food safety systems. MDA/DFID policy is to perform a routine FSA in each establishment at least once every three years. The self-assessment documents include noncompliance records, FSA records, notices of intended enforcement, and verification plans that support the conclusion that MDA/DFID personnel identify and document noncompliance, and initiate appropriate regulatory actions.

MDA/DFID enforces the Minnesota Statutes (§31.101, Subdivision 10), which adopt 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. MDA/DFID follows Minnesota Directive 90.1 to document relevant facts for administrative actions and ensure that administrative actions are based on relevant facts and legal authority.

The submitted documents support the conclusion that MDA/DFID:

- 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 MDA/DFID's sampling protocols, procedures, and results to the Federal policies and procedures.

MDA/DFID 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* and *Campylobacter* Performance Standards in raw classes of meat and poultry, and other consumer protection standards. MDA/DFID 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. MDA/DFID 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 MDA/DFID 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

MDA/DFID follows Minnesota Meat and Poultry Inspection Program Directive 90.4 to determine the inspectors' workloads and the number of inspectors required to provide daily inspection coverage in each establishment on days when the establishment produces products bearing the State mark of inspection, and document staffing in each establishment. Procedures are in effect to identify failures to meet staffing requirements and correct staffing deficiencies. Supervisors schedule slaughter and processing inspection assignments, and post the assignment schedules where inspectors can easily access them. This system also automatically notifies the inspectors of changes to assignment schedules. To record daily activities, inspectors complete and submit bi-weekly reports, along with time sheets, to supervisors. Supervisors compare daily MIS inspection tasks performed results to the assignment schedules and bi-weekly reports to verify coverage of inspection assignments. MDA/DFID also uses the bi-weekly report data to calculate the time spent in various program activities, such as slaughter and processing inspection, custom exempt review, and travel. As of October 24, 2011, MDA/DFID employed a program manager, 2 supervisors, 13 full-time and 6 part-time inspectors, 1 full-time and 2 part-time veterinary medical officers, 2 EIAOs, and 1 full-time and 1 part-time compliance officer.

MDA/DFID developed a training program for new entry-level inspection personnel. New inspectors receive 2 to 3 months of classroom and in-plant training that covers basic slaughter techniques, and all inspection techniques required to perform slaughter duties, including basic Sanitation SOPs and HACCP procedures, computer operations, sampling procedures, custom exempt review, and establishment sanitation standards. MDA/DFID also trains new employees on administrative procedures, such as time sheets, expense reports, weekly reports, civil rights, and occupational safety. MDA/DFID provides ongoing training, including food safety regulatory essentials, to the inspection staff and documents all trainings on Training Reporting Forms, which are stored in MDA/DFID's training database. As of October 2011, MDA/DFID employed new software to assign and record employee trainings more efficiently, and to add internet training to its delivery methods.

Minnesota administers a mandated performance-evaluation system for all State employees. The Performance Review form communicates the employees' work responsibilities, performance goals and objectives, and annual performance evaluation results. MDA/DFID performs employee performance evaluations on all employees annually, and evaluates all new employees twice during a 6-month probationary period. These evaluations consider all job performance elements. Additionally, inspectors receive feedback from the EIAOs during the FSAs.

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

Component 5 – Humane Handling

The MIS records demonstrate that MDA/DFID 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.

To instruct inspection personnel, MDA/DFID developed the *Humane Handling and Slaughter of Livestock* training document. MIS/DFID personnel perform humane handling verification procedures, which are scheduled through MIS, each day that an establishment performs slaughter operations. MIS also tracks and reports these verification procedures. MDA/DFID personnel document humane slaughter and handling deficiencies in the same manner as other establishment noncompliances. The MDA/DFID field veterinarian conducts humane handling audits at all slaughter establishments and documents the results on the Red Meat Humane Handling and Slaughter Evaluation or the Poultry Good Commercial Practices Evaluation reports.

In conclusion, the information made evident that MDA/DFID 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

MDA/DFID verifies establishment compliance with the non-food safety consumer protection regulatory requirements. MDA/DFID uses MIS to schedule and record ongoing verification procedures, and to document noncompliance; and uses applicable directives to instruct inspection personnel. A thorough review of the MIS data supports the conclusion that MDA/DFID personnel correctly apply inspection methodology and document noncompliance.

MDA/DFID 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 obtain approval from designated MDA/DFID personnel. MDA/DFID generates reports to track all label approvals. Each facility maintains an electronic label-inventory file.

In conclusion, the submitted documents provided evidence to show that MDA/DFID 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

MDA/DFID developed a planned compliance review system based on the guidance in FSIS Directive 8010.1, *Methodology for Conducting In-Commerce Surveillance Activities*. MDA/DFID's compliance review procedures are consistent with FSIS Surveillance, Investigations, and Enforcement Methods (SIEM) training. MDA/DFID hired an additional part-time compliance officer, who aids the full-time compliance officer with surveillance activities to verify that products in intrastate commerce are wholesome, correctly labeled and packaged, and secure from threats or intentional acts of contamination.

MDA/DFID investigates apparent violations and food safety incidents; detains or embargos product when there is reason to believe that the products are adulterated, misbranded, or otherwise in violation of the Minnesota Statutes; and takes enforcement action, when needed, up to and including prosecution of individuals or firms that have violated the Minnesota Statutes. MDA/DFID has procedures to obtain 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 program manager reviews all MDA/DFID compliance documents and the database-generated quarterly reports for correctness, and determines whether the compliance program operates effectively. The program manager also ensures that all compliance correspondence includes applicable statutory requirements for appeal dates and statutory references, and accurately summarizes the facts.

MDA/DFID developed procedures for the recall of meat and poultry products subject to its jurisdiction that are equivalent 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 MDA/DFID within 24 hours of initiating a recall. MDA/DFID 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.

MDA/DFID maintains a system to record, triage, analyze, and track consumer complaints related to State-regulated meat or poultry products. The compliance officer follows MDA/DFID consumer compliant procedures, which are based on the guidance in FSIS Directive 5610.1, *Procedures to Implement the Consumer Complaint Monitoring System (CCMS*). All complaints are documented on the MDA/DFID Complaint Report. The investigative methods include procedures to collect and safeguard evidence, conduct interviews, submit product samples to the laboratory, initiate recall procedures and regulatory enforcement actions, and report potential food safety threats.

The submitted documents support the conclusion that MDA/DFID 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.

<u>Component 8 – Civil Rights</u>
On November 10, 2011, MDA/DFID 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 MDA/DFID functions “at least equal to” the Federal civil rights requirements.

<u>Component 9 – Financial Accountability</u>
MDA/DFID 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 MDA/DFID is “at least equal to” Federal standards for financial accountability for FY 2012.

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