Appendix K

Comprehensive Review and Determination Report

Fiscal Year 2021

Minnesota

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 Minnesota 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 Minnesota’s MPI Program
The Minnesota Meat and Poultry Inspection Program (MN MPIP) administers the Minnesota MPI program under authority of Minnesota Statutes (Chapters 31, 31A, and 34A). The program verifies compliances and enforces regulatory requirements at 57 inspected facilities and 236 custom exempt establishments.1

Annual Determination
FSIS determined that MN MPIP is operating a meat and poultry inspection program “at least equal to” the Federal requirements. MN MPIP 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. Since MN MPIP was not subject to an onsite review for Components 1 through 9 during fiscal year (FY) 2021, FSIS based its annual determination on review of the self-assessment documents only. This determination is fully explained in the Review of Minnesota’s Self-Assessment Submission section. The last onsite review of the MN MPIP was conducted by FSAS March 18 through 29, 2019.

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 FSAS, the Civil Rights Staff (CRS), Financial Reviews and Systems Branch (FRSB), Laboratory Quality Assurance Response and Coordination Staff, 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.

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).
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 Minnesota’s Self-Assessment Submission**

FSAS evaluated the self-assessment documents for the applicable review components to determine whether MN MPIP constitutes an inspection program “at least equal to” the Federal program. The determination and rationale for each review component are listed below.

FSAS received MN MPIP’s complete self-assessment submission for components 1 through 6 on January 8, 2021. FSAS sent a notification to MN MPIP requesting additional information. MN MPIP 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 February 10, 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 Minnesota Statutes (Chapters 31, 31A, and 34A) and Minnesota Administrative Rules (Chapters 1540 and 1545). The Minnesota Statutes provide authorities for mandatory ante-mortem and post-mortem inspection (Sections 31A.03 and 31A.04), reinspection (Section 31A.05), sanitation requirements

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\(^2\) 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 Humane Methods of Slaughter Act of 1978.
In addition, the Minnesota Statutes provide authorities that are “at least equal to” the FMIA and PPIA regarding adulteration (Section 34A.02), misbranding (Section 34A.03), prohibited acts (Sections 31.02, 31.602, 31A.10, and 31A.11), access and examination (Sections 31.04, 31A.18, 31A.25, and 34A.04), and product control actions (Sections 31A.23 and 34A.11). It also includes sufficient authorities for criminal, civil, and administrative sanctions to address violators.

The Minnesota Statutes grant the authority to promulgate rules and regulations (Section 31.101). Minnesota incorporates Title 9, Code of Federal Regulations (9 CFR), Parts 301 et seq., in the Minnesota Statutes (Section 31.101, Subdivision 10).

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

Component 2 – Inspection
FSAS compared the self-assessment submission and supporting documentation regarding inspection policies and procedures and regarding verification of establishments’ compliance, to the Federal requirements. MN MPIP uses the Minnesota Inspection System (MIS) to schedule inspection tasks and to collect, consolidate, and analyze inspection data. MIS also maintains data security and integrity “at least equal to” the Federal requirements.

MN MPIP developed the following directives to guide inspection activities:

- MN MPIP Directive 80.1, MIS (Minnesota Inspection System)
- MN MPIP Directive 80.2, The Establishment Profile in MIS
- MN MPIP Directive 80.3, Establishment HACCP Information
- MN MPIP Directive 80.4, Documentation of Procedure Results and Noncompliance Records
- MN MPIP Directive 80.6, The Hazard Analysis Verification Task

MN MPIP verifies that establishments develop, implement, and maintain Sanitation Standard Operating Procedures (SOP) and Hazard Analysis and Critical Control Point (HACCP) systems. In addition to the inspectors’ ongoing verification activities, MN MPIP routinely schedules and performs a comprehensive Food Safety Assessment (FSA) at each inspected establishment at least once every three years in accordance with MN MPIP Directive 50.1, Conducting Food Safety Assessments. These FSAs examine the design and validity of 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’ HACCP systems. The noncompliance records and FSA records support the conclusion that State inspection personnel recognize and document noncompliances, and initiate appropriate regulatory actions.
MN MPIP addressed new issuances published by FSIS as part of FSAS’ quarterly new issuance program and met “at least equal to” expectations in addressing how the new policies and instructions are incorporated into their inspection program.

MN MPIP verifies establishment compliance with the non-food safety (i.e., labeling) consumer protection regulatory requirements. MN MPIP uses applicable MN MPIP directives to instruct inspection personnel and MIS to schedule ongoing verifications and document noncompliance. A thorough review of the MIS data for a 12-month period supports the conclusion that MN MPIP inspectors correctly apply the inspection methodology and document noncompliance.

MN MPIP 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 MN MPIP approval.

MN MPIP enforces the Minnesota Statutes (Section 31.101, Subdivision 10), which adopt 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. MN MPIP follows MN MPIP Directive 90.1, Program Administrative Procedures, to document relevant facts of administrative actions and ensure that administrative actions are legally supportable and based on relevant facts.

MN MPIP reviews custom exempt operations in accordance with MN MPIP Directive 20.2, Custom Exempt Establishment Review, and MN MPIP Directive 20.3, Custom Exempt Enforcement, and documents the results on the Custom Exempt Inspection Form. Reviews are assigned to inspectors in the SharePoint system by the data coordinator, with frequencies reviewed and designated by supervisors. Custom exempt facilities are reviewed at least annually and facilities at which critical or major findings have been identified will be reinspected prior to the next routine inspection.

The submitted documents support the conclusion that MN MPIP:

- 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
FSAS compared MN MPIP’s sampling protocols, procedures, and results to Federal policies and procedures.

MN MPIP 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;

• *Salmonella* Performance Standards in raw classes of meat and poultry; *Campylobacter* Performance Standards in raw classes of poultry; and

• Other consumer protection standards.

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

In conclusion, a detailed review of the sampling protocols, procedures, and results confirmed that MN MPIP 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. MN MPIP has control measures in effect to confirm that its product sampling system functions as intended.

**Component 4 – Staffing, Training, and Supervision**

MN MPIP 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. Supervisors schedule slaughter and processing inspection assignments and post the assignment schedules in the MIS. This system also automatically notifies the inspectors of changes to the assignment schedules. The inspectors document daily activities and submit a bi-weekly report, along with timesheets, to supervisors. Supervisors compare daily MIS inspection tasks to the assignment schedules and bi-weekly reports to verify coverage of inspection assignments.

At the start of the FY 2021 review cycle, MN MPIP indicated they employ the following full-time employees: 1 program manager, 1 field staff supervisor, 1 veterinary medical officer, 1 compliance officer, and 15 meat inspectors. MN MPIP employs the following part-time employees: 1 veterinary medical officer, 1 food inspector, 17 laboratory personnel, 4 administrative/clerical employees, and 4 meat inspectors.

MN MPIP continues to implement a training program for new entry-level inspection personnel. New inspectors receive two to three months of classroom and in-plant training that covers basic slaughter techniques including ante-mortem and post-mortem inspection, Sanitation SOPs and HACCP procedures, sampling procedures, custom exempt review, and establishment sanitation standards. MN MPIP also trains new employees on computer operations and administrative
procedures such as time sheets, expense reports, daily and bi-weekly reports, civil rights, and occupational safety. MN MPIP provides on-going training, including food safety regulatory essentials, to the inspection staff, and maintains a record keeping system to track participation and completion of training.

Minnesota administers a mandated performance evaluation system for all State employees. MN MPIP 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. This system communicates to the 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 MN MPIP 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 MN MPIP’s inspection methodology, to document findings, and to initiate regulatory actions when necessary. Control measures are in effect to confirm that MN MPIP’s staffing and training systems function as intended.

Component 5 – Humane Handling
MN MPIP 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.

MN MPIP uses MN MPIP Directive 30.9, Humane Slaughter Verification Activities, to communicate instructions to inspection personnel. Inspectors perform humane handling (livestock) and good commercial practices (poultry) verification procedures daily when an establishment slaughters and records the results in MIS. The MN MPIP veterinarian conducts humane handling and good commercial practices reviews at slaughter facilities every 12-18 months in accordance with MN MPIP Directive 30.1, Humane Handling Verification, and documents the results on the Red Meat Humane Handling and Slaughter Evaluation or the Poultry Good Commercial Practices Evaluation forms. In addition, MN MPIP created a written Animal Handling Program guidance document for establishments to use to develop their own animal handling program.

In conclusion, the information supports the fact that MN MPIP 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
MN MPIP 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.

MN MPIP 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 Minnesota Statutes; and takes enforcement action, when needed, up to and including prosecution of individuals or firms that have violated the Minnesota Statutes. MN MPIP 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.

MN MPIP management or compliance supervisor reviews all compliance reports for correctness, extracts pertinent information for reporting purposes, enters this information in a database, and files the hard copies. The program director or compliance personnel review all violations and relevant evidence and determine the appropriate case disposition and course of action.

MN MPIP developed the following directives to guide compliance activities:

- MN MPIP Directive 41.0, Meat Compliance Activity Data Program
- MN MPIP Directive 41.1, Planned Compliance Program
- MN MPIP Directive 41.2, Methodology for Conducting In-Commerce Surveillance Activities
- MN MPIP Directive 41.3, Investigative Methodology
- MN MPIP Directive 41.4, Procedures for Evidence Collection, Safeguarding, and Disposal
- MN MPIP Directive 41.5, Report of Investigation
- MN MPIP Directive 41.6, Field Compliance Actions
- MN MPIP Directive 42.1, Administrative Meeting
- MN MPIP Directive 42.2, Scheduling an Administrative Meeting
- MN MPIP Directive 42.3, Conducting an Administrative Meeting
- MN MPIP Directive 42.4, Followup for Administrative Meeting
- MN MPIP Directive 42.5, Assessing Administrative Penalties
- MN MPIP Directive 42.6, Assessing Civil Penalties

MN MPIP maintains procedures for the recall of meat and poultry products subject to its jurisdiction that are “at least equal to” the procedures described in MN MPIP Directive 45.1, Recalls. These procedures include health hazard evaluation, recall classification, public notification, effectiveness checks, and closure. Firms are required to notify MN MPIP within 24 hours of initiating a recall. MN MPIP 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.

MN MPIP established methods to record, triage, analyze, and track consumer complaints related to State-regulated meat or poultry products. Compliance personnel investigate these complaints and document the results on the MN MPIP Complaint Report. 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.

The submitted documents support the conclusion that MN MPIP maintains a system to verify compliance of meat and poultry products in intrastate commerce and takes appropriate enforcement actions in the event that adulterated or misbranded products enter intrastate commerce. Control measures are in effect to confirm that the compliance program functions as intended.

Component 7 – Laboratory Methods and Quality Assurance Program
An off-site records review of Minnesota Department of Agriculture, Laboratory Services Division (MDA) was performed during FY21 to evaluate laboratory quality assurance (QA) programs and method equivalence under the State MPI program.

MDA conducts microbiological testing for *Salmonella*, *L. monocytogenes*, *E. coli O157:H7*, non-O157 STEC and *Campylobacter*. Wisconsin Department of Agriculture, Trade and Consumer Protection Bureau of Laboratory Services (WDATCPBLS) conducts food chemistry testing on behalf of MDA to include moisture, protein, fat, and salt.

FSIS compared the MDA Laboratory Quality Assurance Program to the State MPI Program Laboratory Quality Management System Checklist and evidence of laboratory proficiency and analyst training was evaluated. Based on their self-assessment, MDA met all Laboratory QA requirements including analysts’ training and related proficiency testing. WDATCPBLS met all Laboratory QA requirements based on the self-assessment provided by the laboratory.

WDATCPBLS has demonstrated adequate food chemistry capability for the measurement of moisture, protein, fat, and salt. MDA has demonstrated adequate microbiological capabilities for detection of *Salmonella*, *L. monocytogenes*, *E. coli O157:H7*, non-O157 STEC and *Campylobacter*.

Based on the Component 7 methods and quality assurance program review, Minnesota 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 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.

Component 8 – Civil Rights
MN MPIP submitted the required FSIS Form 1520-1, Civil Rights Compliance of State Inspection Programs, to demonstrate adherence to Federal civil rights laws and USDA’s civil rights regulations. On April 19, 2021, CRS concluded that MN MPIP functions “at least equal to” the Federal civil rights requirements.

Component 9 – Financial Accountability
MN MPIP submitted quarterly and final Federal Financial Reports (SF-425), and an annual Indirect Cost Proposal to demonstrate it conforms to 7 CFR, Part 3016, Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments, and follows FSIS Directive 3300.1, Rev.2, Fiscal Guidelines for Cooperative Inspection Programs (March 2004). FRSB determined that MN MPIP is “at least equal to” Federal standards for financial accountability for FY 2021.

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