Appendix P

Comprehensive Review and Determination Report

Fiscal Year 2021

North Dakota

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 North Dakota 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 North Dakota’s MPI Program
The North Dakota Department of Agriculture (NDDA), North Dakota Meat and Poultry Inspection Program (NDMPIP) administers the North Dakota MPI program under authority of North Dakota Century Code. The program verifies compliance and enforces regulatory requirements at 11 inspected facilities and 74 custom exempt establishments. In addition, NDDA, NDMPIP also provides inspection at four facilities in the Cooperative Interstate Shipment Program.

Annual Determination
Based on the desk review of the submitted self-assessment documentation, FSIS determined that NDDA, NDMPIP is operating a meat and poultry inspection program “at least equal to” the Federal requirements. NDDA, NDMPIP has adopted laws, regulations, and programs, and implemented them in a manner that is “at least equal to” the Federal inspection program for components 1 through 9. As noted, NDDA, NDMPIP was not subject to an onsite review for components 1 through 9 during fiscal year (FY) 2021. The most recent onsite review performed by FSAS for components 1 through 6 occurred on April 8 through 18, 2019.

Self-Assessment Review Methodology
Annually, FSAS will conduct a desk review of documentation submitted by a representative agent of each non-designated State demonstrating its completion of an assessment of current State laws, rules, policies, and procedures that govern the MPI program’s inspection and operation activities with those administered by FSIS and supporting the State’s determination that their MPI program meets the “at least equal to” Federal standards. A State MPI program completes a self-assessment addressing all program inspection and operation activities using the self-assessment instruments provided by FSIS. The State agent is to submit the completed self-assessment instruments and any requested supporting documentation by November 1 of each review cycle.

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

2 The Cooperative Interstate Shipment program permits eligible small and very small State-inspected establishments to ship meat and poultry products in interstate commerce, provided the establishments selected for this program receive inspection services from designated State personnel that have been trained in the enforcement of the FMIA and PPIA, and conduct inspection in establishments, selected for this program, in a “same as” manner that complies with the FMIA and PPIA and implementing regulations (21 U.S.C. 683 and 472).

3 Non-designated State 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.
The submitted information should support the non-designated State’s self-determination that its MPI program is administered in a manner that is “at least equal to” the Federal inspection program. The self-assessment submission is to include narrative describing key MPI program inspection and operations activities and explanations supporting why the described activities meet the “at least equal to” Federal standards. Additionally, the self-assessment submission is to include evidence and documentation to support that the State MPI program’s policies and procedures for carrying out the activities currently are in effect.

At the start of each Federal fiscal year, FSIS assembles a review team comprised of subject matter experts from various FSIS program areas to review the nine components of the comprehensive review process. This FSIS review team includes staffs or personnel primarily from the following Agency program areas: OIEA, the Office of Management, the Office of Chief Financial Officer, and the Office of Public Health Science. During the review process, the Office of Policy and the 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 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 North Dakota’s Self-Assessment Submission
FSAS evaluated the self-assessment documents for the applicable review components to determine whether NDDA, NDMPIP constitutes an inspection program “at least equal to” the Federal program. The determination and rationale for each review component are listed below.

FSAS received NDDA, NDMPIP’s self-assessment submission for components 1 through 6 on December 30, 2020. FSAS sent a notification to NDDA, NDMPIP requesting additional information. NDDA, NDMPIP 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 June 23, 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 North Dakota Century Code and North Dakota Administrative Code. The North Dakota Century Code and North Dakota Administrative Code provide authorities for mandatory ante-mortem and post-mortem inspection (Sections 4.1-31-02 and 7-13-05-01 through 7-13-05-02); reinspection (Sections 4.1-31-02 through 4.1-31-03 and 7-13-07-01); sanitation requirements (Section 4.1-31-02); record keeping requirements (Sections 4.1-31-13 through 4.1-31-15); and humane methods of slaughter requirements (Sections 4.1-31-01.1 and 7-13-05-06).

In addition, the North Dakota Century Code provides authorities that are “at least equal to” the FMIA and PPIA regarding adulteration (Section 4.1-31-01), misbranding (Section 4.1-31-01.1), prohibited acts (Sections 4.1-31-06 through 4.1-31-07), access and examination (Sections 4.1-31-02 through 4.1-31-03), and product control actions (Sections 4.1-31-20 through 4.1-31-21). It also includes sufficient authorities for criminal, civil, and administrative sanctions to address violators.


In conclusion, NDDA, NDMP/IP 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. NDDA, NDMP/IP uses the FSIS Public Health Information System (PHIS) to schedule inspection tasks and to collect, consolidate, and analyze inspection data. NDDA, NDMP/IP 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 North Dakota Century Code and North Dakota Administrative Code and governing rules and regulations. The State inspection program impose regulations and perform inspection duties that ensure animals intended to be used in meat and poultry products sold commercially, are slaughtered and processed in the presence of State inspection personnel, and the resulting meat food products are inspected and passed for human consumption. Furthermore, NDDA, NDMP/IP 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 Hazard Analysis and Critical Control Point (HACCP) regulations.
NDDA, NDMPIP verifies that establishments develop, implement, and maintain Sanitation Standard Operating Procedures (SOP) and HACCP systems. In addition to the inspectors’ ongoing verification activities, NDDA, NDMPIP routinely schedules and performs a comprehensive Food Safety Assessment (FSA) at each inspected establishment at least once every four years. These FSAs examine the design and validity of establishments’ food safety systems, which include hazard analyses, supporting documentation, HACCP plans, Sanitation SOPs, prerequisite programs, sampling programs, and any other programs that constitute the establishments’ food safety systems. The noncompliance records; FSA records; and notices of intended enforcement support the conclusion that State inspection personnel recognize and document noncompliance and initiate appropriate regulatory actions.

NDDA, NDMPIP verifies establishment compliance with the non-food safety (i.e., labeling) consumer protection regulatory requirements. NDDA, NDMPIP 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 NDDA, NDMPIP inspectors correctly apply the inspection methodology and document noncompliance.

NDDA, NDMPIP maintains a label approval policy and process to verify that labels are accurate and meet regulatory requirements. NDDA, NDMPIP allows generic labeling approval by establishments, and inspection personnel review the labels for accuracy and conformance with the general labeling requirements. When deemed necessary, inspection personnel are to provide labeling information to the Bismarck office or the NDDA, NDMPIP labeling officer for review. Establishment officials submit the labels that do not meet the generic label approval process to the Bismarck office for review and approval.

NDDA, NDMPIP enforces the North Dakota Administrative Code, 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. NDDA, NDMPIP maintains procedures to document relevant facts of administrative actions and ensure that administrative actions are legally supportable and based on relevant facts.

NDDA, NDMPIP has a system for reviewing custom exempt operations that is in accordance with FSIS Directive 8160.1, Custom Exempt Review Process. A field inspector is assigned to custom exempt plants within their region and is responsible for scheduling and tracking reviews. Reviews are conducted on a risk-based frequency as outlined in the NDDA, NDMPIP protocols, Custom Exempt Reviews Guideline. The frequency of reviews and enforcement actions taken at custom exempt establishments will be based on its assigned risk category as listed below. Categories are differentiated from one another based on risk to public health and/or failure or unwillingness on the part of custom exempt establishments to comply with requirements.

The submitted documents support the conclusion that NDDA, NDMPIP:

- 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 NDDA, NDMPIP’s sampling protocols, procedures, and results to Federal policies and procedures.

NDDA, NDMPIP 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. NDDA, NDMPIP developed policies to respond to positive results. These policies include actions to prevent adulterated product from entering commerce. NDDA, NDMPIP 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 NDDA, NDMPIP 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. NDDA, NDMPIP has control measures in effect to confirm that its product sampling system functions as intended.

Component 4 – Staffing, Training, and Supervision
NDDA, NDMPIP 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. Senior inspectors arrange relief inspection for routine and emergency leave situations, monitor inspection data, review inspectors’ weekly activity reports and visit establishments to ensure daily inspection coverage is provided.
At the start of the FY 2021 review cycle, NDDA, NDMPIP indicated they employ one director, two supervisors/CID Enforcement, Investigations and Analysis Officers, six inspectors, one part-time PHV, one part-time outreach assistant, one relief inspector, one part-time administrative assistant, and one compliance officer, as of October 1, 2020.

NDDA, NDMPIP 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 self-assessment documents describe procedures for initial orientation, on-the-job and formal training, and performance evaluation. The training subjects include livestock inspection, slaughter inspection, processing inspection, HACCP, Sanitation SOPs, and sanitation performance standards. NDDA, NDMPIP inspectors also receive Inspection Methods training. NDDA, NDMPIP maintains a record keeping system to track participation and completion of training.

NDDA, NDMPIP 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 two to four IPPS assessments for each inspector annually. In addition, senior inspectors are to perform an IPPS assessment at the end of the employees’ probationary employment periods. NDDA, NDMPIP maintains control measures to examine the IPPS assessments for quality, completeness, and accuracy. In addition, North Dakota 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, FSIS concluded that NDDA, NDMPIP 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 NDDA, NDMPIP’s inspection methodology, to document findings, and to initiate regulatory actions when necessary. Control measures are in effect to confirm that NDDA, NDMPIP’s staffing and training systems function as intended.

Component 5 – Humane Handling
NDDA, NDMPIP 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.

NDDA, NDMPIP uses FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock, to communicate instructions to inspection personnel. NDDA, NDMPIP policy requires inspectors to immediately suspend inspection and contact the program director if the inspectors observe egregious inhumane handling. In accordance with FSIS Directive 6910.1, District Veterinary Medical Specialist (DVMS) – Work Methods, the NDDA, NDMPIP director and supervisory inspectors perform reviews to evaluate establishments’ humane handling and slaughter practices, and inspectors’ performance of humane handling verifications.
In conclusion, the information supports the fact that NDDA, NDMPIC 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
NDDA, NDMPIC 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.

NDDA, NDMPIC 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 North Dakota Century Code; and takes enforcement action, when needed, up to and including prosecution of individuals or firms that have violated the North Dakota Century Code. NDDA, NDMPIC 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 NDDA, NDMPIC director 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 reviews all violations and relevant evidence and determines the appropriate case disposition and course of action.

NDDA, NDMPIC 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 required to notify NDDA, NDMPIC within 24 hours of initiating a recall. NDDA, NDMPIC 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.

NDDA, NDMPIC established methods to record, triage, analyze, and track consumer complaints related to State-regulated meat or poultry products. NDDA, NDMPIC documents consumer complaints on the State form, Consumer Complaint Information Sheet, and assigns the complaints to the compliance officer for investigation. 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.

The submitted documents support the conclusion that NDDA, NDMPIC 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.
commerce. Control measures are in effect to confirm that the compliance program functions as intended.

Component 7 – Laboratory Methods and Quality Assurance Program
NDDA, NDMPIP contracts all laboratory work to other states that meet the Laboratory quality assurance (QA) requirements of the State MPI Program Laboratory Quality Management System and the Cooperative Interstate Shipment (CIS) “same as” program.

NDDA, NDMPIP also has an agreement with South Dakota State University Animal Disease Research and Diagnostic Laboratory (SDSU-ADRDL) for the CIS “same as” program and the State MPI “at least equal to” program to perform FSIS Microbiology Laboratory Guidebook methods for the microbiological analysis of *Salmonella*, *L. monocytogenes*, *E. coli* O157:H7 and non-O157 STEC on its behalf. South Dakota has demonstrated adequate microbiology capabilities for the detection of *Salmonella*, *L. monocytogenes*, *E. coli* O157:H7 and non-O157 STEC.

SDSU-ADRDL met all Laboratory QA requirements based on the self-assessment provided by the laboratory.

NDDA, NDMPIP has an agreement with USDA/FSIS /Eastern Laboratory to perform food chemistry testing for the CIS and MPI programs on its behalf. USDA/FSIS Eastern Laboratory has demonstrated adequate food chemistry capability for the measurement of moisture, protein, fat, and salt.

Based on the Component 7 methods and quality assurance program review, North Dakota 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 North Dakota is not currently inspecting MPI program poultry establishments slaughtering at least 20,000 chickens and/or turkeys per year.
Component 8 – Civil Rights
In November 2020, NDDA, NDMPIP 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 NDDA, NDMPIP functions “at least equal to” the Federal civil rights requirements.

Component 9 – Financial Accountability
NDDA, NDMPIP 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 MMPIP is “at least equal to” Federal standards for financial accountability for FY 2021.

Self-Assessment Determination for North Dakota
Based on the submitted self-assessment documents and desk review results described above, FSIS determined that North Dakota Department of Agriculture, North Dakota Meat and Poultry Inspection Program provided adequate documentation to show it is operating a meat and poultry inspection program “at least equal to” the Federal requirements.