Appendix T

Comprehensive Review and Determination Report

Fiscal Year 2021

South Dakota

Federal-State Audit Staff
Office of Investigation, Enforcement and Audit
Food Safety and Inspection Service
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# Table of Contents

Purpose.................................................................................................................................................. 1

Description of South Dakota’s MPI Program...................................................................................... 1

Annual Determination.............................................................................................................................. 1

Self-Assessment Review Methodology.................................................................................................. 1

Review of South Dakota’s Self-Assessment Submission............................................................................ 2

Self-Assessment Determination for South Dakota.................................................................................... 9
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 South 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 South Dakota’s MPI Program
The South Dakota Animal Industry Board (SDAIB) administers the South Dakota MPI program under authority of South Dakota Codified Law (Title 39, Chapter 5, sections 6-45). The program verifies compliance and enforces regulatory requirements at 32 inspected facilities and 54 custom exempt establishments.¹ South Dakota was recently (June 10, 2021) approved for inclusion in the Cooperative Interstate Shipment program, but currently has not nominated any establishments for inclusion.

Annual Determination
Based on the desk review of the submitted self-assessment documentation, FSAS determined that SDAIB is operating a meat and poultry inspection program “at least equal to” the Federal requirements. SDAIB has adopted laws, regulations, and programs, and implemented them in a manner that is “at least equal to” the Federal inspection program. As noted, SDAIB 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 in May 2019.

Self-Assessment Review Methodology
Annually, FSAS will conduct a desk review of documentation submitted by a representative agent of each non-designated² 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 official 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.

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

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 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.
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 South Dakota’s Self-Assessment Submission
FSAS evaluated the self-assessment documents for the applicable review components to determine whether SDAIB constitutes an inspection program “at least equal to” the Federal program. The determination and rationale for each review component are listed below.

FSAS received SDAIB’s complete self-assessment submission for components 1 through 6 on May 4, 2021. FSAS sent a notification to SDAIB requesting additional information. SDAIB 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 August 4, 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) and the Humane Methods of Slaughter Act, and the regulations promulgated under these laws. The supporting documentation included the South Dakota Codified Law (Title 39, Chapter 5, sections 6-45) and the Administrative Rules of South Dakota (Chapters 12:68:14 and 12:68:15). The South Dakota Codified Law provide authorities for mandatory ante-mortem (section 39-5-16) and post-mortem
In addition, the South Dakota Codified Law provides authorities that are “at least equal to” the FMIA about adulteration (section 39-5-14), misbranding (section 39-5-26), prohibited acts (section 39-5-39), access and examination (section 39-5-36), and product control actions (section 39-5-32). It also includes sufficient authorities for criminal, civil, and administrative sanctions to address violators.


In conclusion, SDAIB 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. SDAIB recently transitioned from using the FSIS Public Health Information System to schedule inspection tasks and to collect, consolidate, and analyze inspection data, to their own SharePoint tracking system, South Dakota Meat Inspection System (SDMIS) for non-CIS selected establishments. SDAIB administers inspection for any meat product intended for human consumption, wholly or in part, from the carcass or parts of any animal defined as “livestock” in the South Dakota Codified Law (section 39-5-6). The State inspection program impose regulations and perform inspection duties that ensure animals intended to be used in meat 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, SDAIB administers a food safety verification program that meets the intent of FSIS Directive 5000.1, Verifying an Establishment’s Food Safety System. Food safety verification activities are performed to ensure establishments’ compliance with applicable pathogen reduction, sanitation, and the Hazard Analysis and Critical Control Point (HACCP) regulations.

In addition to performing inspections and food safety verifications, SDAIB schedules and performs a comprehensive food safety assessment (FSA) at each inspected establishment at least once every four years in accordance with FSIS Directives 5100.1, Enforcement, Investigations and Analysis Officer (EIAO) Food Safety Assessment (FSA) Methodology, and 5100.4, Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology. These FSAs examine the design and validity of establishments’ food safety systems, which include hazard analyses, HACCP plans, Sanitation Standard Operational Procedures (Sanitation SOP), prerequisite programs, sampling programs, supporting documentation and records, and any other programs that constitute the establishments’ food
safety systems. SDAIB area veterinary supervisors (AVS) also conduct a biannual in-plant review in each area establishment. Both reviews examine the design and validity of establishments’ food safety systems, which includes hazard analyses, supporting documents, HACCP plans, Sanitation SOPs, prerequisite programs, sampling programs, and any other programs that constitute the establishments’ HACCP systems. The PHRE and FSA records support the conclusion that State inspection personnel recognize and document noncompliance and initiate appropriate regulatory actions.

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

SDAIB 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 product, SDAIB requires establishments to submit completed label-approval applications that include label sketches and product formulation processing procedures to the AVS for approval. The AVS will then forward the label information to the SDAIB director in the Pierre office for final approval.

SDAIB enforces the Administrative Rules of South Dakota (section 12:68:14:01), 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. SDAIB maintains procedures to document relevant facts of administrative actions and ensure that administrative actions are legally supportable and based on relevant facts.

SDAIB has a system for reviewing custom exempt operations that is in accordance with FSIS Directive 8160.1, Custom Exempt Review Process. In-plant personnel perform the custom exempt task at a target rate of once monthly, and document their findings in SDMIS. The plants’ progress in correcting findings is documented on a 30-day progress report at the next visit (AIB Form MI-315). Necessary longer term plant improvements are documented on an Establishment Improvement Program form (AIB Form MI-312). SDMIS AVSs additionally review and document custom evaluations annually at custom exempt facilities that do not operate at official establishments, as well as perform three comprehensive reviews annually at those operating in official establishments.

The submitted documents support the conclusion that SDAIB:

- 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

4
• Monitors these activities through control measures to verify that the inspection system functions as intended.

Component 3 – Sampling Programs
FSAS compared SDAIB’s sampling protocols, procedures, and results to Federal policies and procedures.

SDAIB provided documentation to demonstrate that it maintains sampling programs, based on sound rationale and goals, for the following:

• *Escherichia coli* (*E. coli*) O157:H7 in raw non-intact beef products and raw ground beef components;
• Non-O157 Shiga toxin-producing *E. coli* (non-O157 STEC) in beef manufacturing trimmings;
• *Listeria monocytogenes* (*L. monocytogenes*) and *Salmonella* in ready-to-eat products;
• Other consumer protection standards.

The sampling plans include procedures for sample collection, sample integrity, and laboratory analysis. SDAIB developed policies to respond to positive results. These policies include actions to prevent adulterated product from entering commerce. SDAIB 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 SDAIB 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. SDAIB has control measures in effect to confirm that its product sampling system functions as intended.

Component 4 – Staffing, Training, and Supervision
SDAIB 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. Each AVS assigns inspectors’ work schedules monthly, with instructions for daily visits to operating establishments. The AVS documents any changes to these schedules, reviews these schedules to verify daily inspection coverage, and arranges relief inspection during routine and emergency leave situations.

SDAIB employs 1 director/State veterinarian, 1 assistant State veterinarian, 3 AVSs, 15 full time and 1 part time inspectors, 1 EIAO who is also an inspector and a compliance officer, 2 administrative /clerical employees, 1 compliance supervisor who is also a veterinary medical officer, and 2 compliance officers, as of September 30, 2020.
SDAIB continues to implement a training program for new entry-level inspection personnel. Inspectors first complete employee orientation within three days and then receive on-the-job training for six weeks. The supervisor and trainer provide instruction on basic livestock slaughter inspection, humane slaughter, control of specified risk materials for bovine spongiform encephalopathy, rules of practice, food defense, processing inspection, inspection methods training, HACCP, Sanitation SOPs, and sanitation performance standards. All inspectors and supervisors have access to USDA’s online training system (AgLearn) for additional trainings and continuing education. SDAIB maintains a record keeping system to track participation and completion of training.

SDAIB routinely evaluates job performance. The South Dakota mandated performance evaluation system communicates employees’ work responsibilities, performance goals and objectives, and annual performance evaluation results. The inspectors undergo annual job performance reviews by the SDAIB director. Additionally, the AVSs conduct annual slaughter critiques and evaluate inspectors’ performance each time he or she reviews an establishment. Each year, the AVSs document at least two performance reviews for each inspector on the In-Plant Review form. SDAIB maintains control measures to examine these performance reviews for quality, completeness, and accuracy.

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

Component 5 – Humane Handling
SDAIB 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.

SDAIB uses FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock, to communicate instructions to inspection personnel. Inspectors document humane handling verifications in SDMIS. At least three times in a 12-month period, AVSs evaluate establishments’ humane handling procedures and inspectors’ humane handling task performance. SDAIB uses FSIS Directive 6910.1, District Veterinary Medical Specialist (DVMS) -Work Method as guidance to perform human handling reviews at slaughter establishments.

In conclusion, the information supports the fact that SDAIB 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
SDAIB personnel conduct in-commodity 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. The SDAIB compliance officer, who completed Surveillance Investigations and Enforcement Methods training, trained the other three SDAIB compliance officers. The SDAIB compliance officers conduct surveillance activities in accordance with FSIS Directive 8010.1, Methodology for Conducting In-Commerce Surveillance Activities.

SDAIB 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 South Dakota Codified Law Title 39, Chapter 5; and takes enforcement action, when needed, up to and including prosecution of individuals or firms that have violated the South Dakota Codified Law Title 39, Chapter 5. SDAIB 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.

SDAIB management 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.

SDAIB 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 SDAIB within 24 hours of initiating a recall. SDAIB 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.

SDAIB established methods to record, triage, analyze, and track consumer complaints related to State-regulated meat or poultry products. Complaints are received through various methods, and compliance personnel either investigate these complaints or refer them to the local health authority and submit a Compliance Contact Report to the SDAIB meat compliance site’s document library. 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 SDAIB 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 the South Dakota State University-Animal Disease Research and Diagnostic Laboratory (South Dakota) was performed during FY21 to evaluate laboratory quality assurance (QA) programs and method equivalence under the State MPI Program.

As a participant in the Cooperative Interstate Shipment (CIS) “same as” program, South Dakota meets the requirements of the State Meat and Poultry Inspection (MPI) “at least equal to” Program Laboratory Quality Management System Checklist. South Dakota conducts microbiological testing for *Salmonella*, *L. monocytogenes*, *E. coli* O157:H7, and non-O157 STEC. Wisconsin Department of Agriculture, Trade, and Consumer Protection Bureau of Laboratory Services (Wisconsin) conducts chemistry testing on South Dakota’s behalf for the CIS program to include the measurement of moisture, protein, fat, and salt. The Louisiana Department of Agriculture and Forestry/Louisiana State University Agricultural Center Laboratory (Louisiana) conducts chemistry testing on South Dakota’s behalf for the MPI program to include moisture, protein, fat, and salt.

FSIS compared the South Dakota Laboratory Quality Assurance Program to the State Meat and Poultry Inspection (MPI) Program Laboratory Quality Management System Checklist and evidence of laboratory proficiency and analyst training was evaluated. Based on their self-assessment, South Dakota met all Laboratory QA requirements including analysts’ training and related proficiency testing. Wisconsin met all Laboratory QA requirements based on the self-assessment provided by the laboratory. Louisiana met all Laboratory QA requirements pending resolution of the corrective action submissions in response to the FY21 onsite audit.

Wisconsin has demonstrated adequate food chemistry capability for the measurement of moisture, protein, fat, and salt. Louisiana has adequate food chemistry capabilities for the measurement of moisture, protein, fat, and salt, pending resolution of the corrective action submissions in response to the FY21 onsite audit. South Dakota has demonstrated adequate microbiological capabilities for detection of *Salmonella*, *L. monocytogenes*, *E. coli* O157:H7, and non-O157 STEC.

Based on the Component 7 methods and quality assurance program review, South 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 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 that 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 South 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 December 2020, SDAIB 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. FSIS’ Civil Rights Staff concluded that SDAIB functions “at least equal to” the Federal civil rights requirements.

**Component 9 – Financial Accountability**
SDAIB 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 SDAIB is “at least equal to” Federal standards for financial accountability for FY 2021.

**Self-Assessment Determination for South Dakota**
Based on the submitted self-assessment documents and desk review results described above for FSIS determined that SDAIB provided adequate documentation to show it is operating a meat and poultry inspection program “at least equal to” the Federal requirements.