Appendix T

Comprehensive Review and Determination Report

FY 2012

South Dakota

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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Table of Contents

Introduction 1

Purpose 1

Background 1

Review Methodology 1

Description of State MPI Program 2

Annual Determination 2

Overview of Review Methodology 2

Self-Assessment Review Methodology 4

Review of South Dakota's Self-Assessment Submission 4

Self-Assessment Determination for South Dakota 9

Introduction

Purpose
This report presents the Food Safety and Inspection Service (FSIS) annual review results for the South Dakota meat inspection program and an overview of the review methodology. FSIS determined that the South Dakota meat inspection 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 South Dakota Animal Industry Board (SDAIB) administers the South Dakota meat inspection program under authority of South Dakota Codified Law (Title 39, Chapter 5, §§6 – 45). The program verifies and enforces regulatory requirements at 47 inspected facilities and 35 custom exempt establishments.[1]

Annual Determination (Based on Self-Assessment Review Only)
FSIS determined that SDAIB is operating a meat 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 for all review components. FSIS based its annual determination on review of the self-assessment documents only, since SDAIB 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

[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.

products, or drug residues at violative levels), comply with *Salmonella* Performance Standards in raw classes of meat and poultry, comply with other consumer protection standards, and are accurately labeled (e.g., with nutrition information).

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

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

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

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

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

9. Funding and Financial Accountability[2] – This component evaluates whether the State MPI program conforms to 7 CFR 3016, *Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments* and follows FSIS Directive 3300.1, Rev. 2, *Fiscal Guidelines for Cooperative Inspection Programs.*

FSIS determines whether the State's MPI program constitutes an inspection program "at least equal to" the Federal requirements based on the aforementioned criteria.

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

Self-Assessment Review

This section includes:

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

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 South Dakota's Self-Assessment Submission
FSIS evaluated the self-assessment documents for the nine 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.

FSAB received SDAIB's self-assessment submission, for components 1 through 7, on December 15, 2011. On April 5, 2012, FSAB requested additional clarifying information from the SDAIB staff, which was provided on April 30, 2012.

Component 1 – Statutory Authority and Food Safety Regulations

FSAB compared the submitted self-assessment and supporting documentation to the legal authority provided under the FMIA and HMSA, and the regulations promulgated under these laws. The supporting documentation included the South Dakota Codified Law (Title 39, Chapter 5, Sections 6 – 45) and South Dakota Administrative Rules (Chapters 12:68:14 and 12:68:15). The South Dakota Codified Law provides authorities for mandatory antemortem inspection (§39-5-16), postmortem inspection (§39-5-17), reinspection (§39-5-20), sanitation requirements (§39-5-24), record-keeping requirements (§39-5-36), and humane methods of slaughter requirements (§39-5-23.1and §39-5-23.2).

The South Dakota Codified Law provides authorities that are "at least equal to" the FMIA in regards to adulteration (§39-5-14), misbranding (§39-5-26), prohibited acts (§39-5-39), access and examination (§39-5-36), and product control actions (§39-5-32), as well as criminal, civil, and administrative sanctions to address violators.

The South Dakota Codified Law grants authority to promulgate rules and regulations (§39-5-8) and South Dakota adopts by reference Title 9, Code of Federal Regulations (9 CFR) parts 200 to end in South Dakota Administrative Rules (§12:68:14:01).

In conclusion, SDAIB provided evidence to show it operates under State laws and regulations that provide legal authority "at least equal to" that provided under the FMIA 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. SDAIB uses the Performance Based Inspection System (PBIS) to guide inspection program activities, collect establishment information, establish and maintain in-plant inspection procedure plans, and document establishment noncompliance. In addition, SDAIB reviews custom exempt operations in accordance with FSIS Directive 5930.1, *Custom Exempt Review Process.*

SDAIB 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 inspector's ongoing verification procedures, veterinary supervisors annually review the inspected establishments, in lieu of routine comprehensive food safety assessments (FSAs). These reviews follow FSIS' on-site establishment review methods and examine the establishments' sanitation and HACCP systems.

In addition to the veterinary supervisors' annual reviews, an SDAIB compliance officer, who is trained in Enforcement, Investigations, and Analysis Officer (EIAO) methodology, performs non -routine comprehensive food safety assessments (FSAs), as described in FSIS Directive 5100.1, *Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology*. These FSAs examine the establishments' hazard analyses, HACCP plans, Sanitation SOPs, pre-requisite programs, testing programs, and any other programs that constitute the establishments' HACCP systems. SDAIB follows the criteria and guidance in FSIS Directive 5100.4, *Prioritized Scheduling of Food Safety Assessments (FSA)*, to schedule non-routine FSAs in response to food safety events.

The SDAIB compliance officer follows FSIS Directive 10,240.5, *Enforcement, Investigations, and Analysis Officer (EIAO) Assessment of Compliance with the Listeria monocytogenes* (*Lm*) *Regulation and Introduction of Phase 2 of the Lm Risk-based Verification Testing Program* to perform intensified verification testing (IVT). IVT is an environmental and product microbial testing protocol for *Listeria monocytogenes* to verify the adequacy of food safety systems in establishments that produce ready-to-eat products that are exposed to environmental conditions after the lethality step.

The submitted records, which include Veterinary Supervisor In-plant Reviews, a non-routine FSA report, FSA records, and noncompliance records support the conclusion that SDAIB personnel identify and document regulatory noncompliance, and take appropriate regulatory actions.

SDAIB established a system to carry out enforcement actions when establishments do not comply with State authorities that are "at least equal to" the FMIA. South Dakota Administrative Rules (§12:68:14:01) adopts by reference 9 CFR Part 500, Rules of Practice, which includes regulations for due process, establishment notification, immediate withholding actions, suspensions, and grants of inspection withdrawal. SDAIB has procedures to document relevant facts of administrative actions, and to ensure that administrative actions are based on relevant facts and legal authority.

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.
- 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 SDAIB's sampling protocols, procedures, and results to the Federal policies and procedures.

SDAIB provided documentation to show that it maintains sampling programs with sound rationale and goals for *E. coli* O157:H7 in raw non-intact beef products and raw ground beef components, *Listeria monocytogenes* and *Salmonella* in ready-to eat products, *Salmonella* Performance Standards in raw classes of meat, and other consumer protection standards. SDAIB 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. SDAIB 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 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 and has control measures in effect to confirm that its product sampling system functions as intended.

Component 4 – Staffing and Training

SDAIB developed methods to determine staffing requirements, which consider 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. Procedures are in effect to document staffing in each establishment, identify failures to meet staffing requirements, and correct staffing deficiencies. Each Area Veterinary Supervisor (AVS) assigns the inspectors' work schedules monthly, with instructions for daily visits to operating establishments. Each 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. As of December 15, 2011, SDAIB employs a director, 21 inspectors, 4 AVSs, and 4 compliance officers. One compliance officer has completed enforcement, investigations, and analysis officer methodology training.

SDAIB developed a training program for new entry-level inspection personnel. Inspectors first complete employee orientation within 30 days and then receive on-the-job training for six weeks. The AVS 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, food safety regulatory essentials, HACCP/pathogen reduction, and sanitation performance standards. All inspectors and AVSs have access to the AgLearn system for additional trainings and continuing education. In addition, SDAIB holds an annual educational workshop for all personnel. SDAIB maintains a record-keeping system to track training completions.

SDAIB routinely evaluates job performance. This performance evaluation system communicates the employees' work responsibilities, performance goals and objectives, and annual performance evaluation results. The inspectors undergo annual job-performance reviews and annual slaughter critiques. Additionally, the AVS evaluates the inspectors' performance each time the AVS reviews an establishment. Each year, the AVS documents at least two performance reviews for each inspector. SDAIB maintains control measures to examine the documents for quality, completeness, and accuracy.

After thorough review of the submitted documents, FSAB 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 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, document findings, and 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

The PBIS records demonstrate that SDAIB 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.

SDAIB uses FSIS Directive 6900.2, *Humane Handling and Slaughter of Livestock,* to instruct inspection personnel on humane handling verifications. Inspection personnel document the verification results on SDAIB Monthly Plant Activity Reports and in PBIS. SDAIB policy requires inspectors to immediately suspend inspection and contact the program director, if they observe egregious inhumane handling.

In addition, the SDAIB director and AVSs perform audits to evaluate the establishments' humane handling and slaughter practices and inspectors' performance of humane handling verification tasks.

In conclusion, the information made evident 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 – Non-Food Safety Consumer Protection

SDAIB verifies establishment compliance with the non-food safety consumer protection regulatory requirements. SDAIB maintains a label-approval policy and process to verify that labels are accurate and meet regulatory requirements, and routinely reviews meat product labels to verify regulatory compliance and accuracy. SDAIB requires establishments to submit completed label-approval applications that include label sketches and product formulation, when applicable, and to submit marking devices to the area AVS and the Pierre office for approval, prior to use.

A thorough review of PBIS data, label-approval applications, label sketches, and noncompliance records supports the conclusion that SDAIB inspectors carry out regulatory verification procedures and correctly apply the label-approval process.

In conclusion, the submitted documents provided evidence to show that SDAIB protects consumers from meat products that are unwholesome, economically adulterated, or not truthfully labeled, and is "at least equal to" the Federal program. Control measures are in effect to confirm that the non-food safety consumer protection verification system functions as intended.

Component 7 – Compliance

The SDAIB compliance review methods are consistent with FSIS' Surveillance, Investigations, and Enforcement Methodology (SIEM). The SDAIB compliance officer, who has completed SIEM training, conducts surveillance activities in accordance with FSIS Directive 8010.1, *Methodology for Conducting In-Commerce Surveillance Activities*, to verify that persons or firms who prepare, transport, sell, or offer for sale meat products in intrastate commerce comply with State statutory and regulatory requirements.

The SDAIB compliance officer investigates alleged or actual statutory or regulatory violations and controls products, when there is reason to believe that the products are adulterated, misbranded, or otherwise in violation of the South Dakota Codified Law. During these investigations, the SDAIB compliance officer follows the methods described in FSIS Directives 8010.2, *Investigative Methodology;* 8010.3, *Procedures for Evidence Collection, Safeguarding and Disposal;* and 8010.4, *Report of Investigation*, to collect and safeguard evidence, conduct interviews, submit product samples to the laboratory, initiate recall procedures and regulatory and enforcement actions, and report potential food safety threats.

SDAIB follows recall procedures for meat products subject to its jurisdiction that are equal to procedures described in FSIS Directive 8080.1, *Recall of Meat and Poultry Products*. The procedures include health hazard evaluation, recall classification, public notification, effectiveness checks, and closure. SDAIB 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. No SDAIB-inspected establishments recalled product in FY 2011.

SDAIB established methods to record, triage, analyze, and track consumer complaints related to State-regulated meat products. The SDAIB compliance officer investigates these complaints. The investigative methods include procedures to collect and safeguard evidence, conduct interviews, submit product samples to laboratory, and initiate recall procedures 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 products in intrastate commerce and takes appropriate enforcement actions in the event that adulterated or misbranded products enter intrastate commerce "at least equal to" the Federal program. Control measures are in effect to confirm that the compliance program functions as intended.

Component 8 – Civil Rights

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. CRD concluded that SDAIB functions "at least equal to" the Federal civil rights requirements.

Component 9 – Financial Accountability

SDAIB submitted quarterly and final Financial Status Reports (SF-425) 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 SDAIB is “at least equal to” Federal standards for financial accountability for FY 2012.

Self-Assessment Determination for South Dakota

Based on the evidence and review results described above, FSIS determined that SDAIB provided adequate documentation to show it is operating a meat inspection program “at least equal to” the Federal requirements.