Appendix U

Comprehensive Review and Determination Report

Fiscal Year 2021

Texas

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 Texas 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 Texas’ MPI Program
The Texas Department of State Health Services, Meat Safety Assurance Unit (TDSHS/MSAU) administers the Texas MPI program under authority of Texas Health and Safety Code (Title 6, Chapter 433). The program verifies compliance and enforces regulatory requirements at 217 inspected facilities and 137 custom exempt establishments.1 In addition, TDSHS/MSAU provides inspection at 13 facilities in the Federal-State Cooperative Agreement Inspection Program.2

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

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 Facilities operating under the Federal-State Cooperative Agreement Inspection Program (FSCIP), also known as Talmadge-Aiken establishments or cross-utilization facilities, are under Federal inspection, but operate with State inspection personnel. As a result, these facilities are not reviewed as part of the State MPI program review. However, since State inspection personnel staff these establishments, the number of these establishments is applicable to determinations on Component 4 – Staffing, Training, and Supervision.
comprehensive review process. The review team, comprised of Agency representatives from the FSAS; the Civil Rights Staff (CRS); Financial Reviews and Systems Branch (FRSB); Laboratory Quality Assurance Response and Coordination Staff (LQARCS); 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 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 Texas’ Self-Assessment Submission
FSAS evaluated the self-assessment documents for the applicable review components to determine whether TDSHS/MSAU constitutes an inspection program “at least equal to” the Federal program. The determination and rationale for each review component are listed below.

FSAS received TDSHS/MSAU’s self-assessment submission on February 21, 2021. FSAS sent a notification to TDSHS/MSAU requesting additional information. TDSHS/MSAU 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 September 7, 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 Texas Health and

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3 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 the Humane Methods of Slaughter Act of 1978.
Safety Code (Title 6, Chapter 433) and Texas Administrative Code (Title 25, Part 1, Chapter 221). The Texas Health and Safety Code provides the authorities for mandatory ante-mortem and post-mortem inspection, reinspection (Sections 433.021 and 433.022), sanitation requirements (Section 433.024), and record keeping requirements (Section 433.034). The Texas Administrative code provides authorities for humane methods of slaughter requirements (Sections 221.11(a)(11) and 221.14(a)(4)).

In addition, the Texas Health and Safety Code provides authorities that are “at least equal to” the FMIA and PPIA regarding adulteration (Section 433.004), misbranding (Section 433.005), prohibited acts (Sections 433.045, 433.051, 433.052, and 433.053), access and examination (Sections 433.025 and 433.034), and product control actions (Sections 433.030 and 433.031). It also includes sufficient authorities for criminal, civil, and administrative sanctions to address violators.

The Texas Health and Safety Code grants the authority to promulgate rules and regulations (Section 433.008). Texas adopts by reference Title 9 Code of Federal Regulations (9 CFR) parts 301, 303 (except 303.1(a) and (b)), 304-307, 309-322, 325, 327, 329, 331, 335, 350, 352, 354, 355, 362, 381 (except 381.10(a)(3)-381.10(c)), 416-418, 424, 430, 441, 442 and 500 in the Texas Administrative Code (Section 221.11(a)).

In conclusion, TDSHS/MSAU 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 with the Federal requirements. TDSHS/MSAU uses the FSIS Public Health Information System (PHIS) to schedule inspection tasks and to collect, consolidate, and analyze inspection data. TDSHS/MSAU 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 Texas Meat and Poultry Inspection Act 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, TDSHS/MSAU 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.

In addition to performing inspections and food safety verifications, TDSHS/MSAU schedules and performs a comprehensive food safety assessment (FSA) at each inspected establishment in accordance with FSIS Directive 5100.1, Enforcement, Investigations and Analysis Officer (EIAO) Food Safety Assessment (FSA) Methodology every four years. These FSAs examine the design and validity of establishments’ food safety systems, which include hazard analyses,
HACCP plans, Sanitation Standard Operating Procedures (Sanitation SOP), prerequisite programs, sampling programs, supporting documentation and records, and any other programs that constitute the establishments’ food safety systems. The FSA records support the conclusion that State inspection personnel recognize and document noncompliance and initiate appropriate regulatory actions.

TDSHS/MSAU verifies establishment compliance with the non-food safety consumer protection regulatory requirements. TDSHS/MSAU uses procedures analogous to FSIS directives to instruct inspection personnel, and PHIS to schedule ongoing verifications and document noncompliance. A thorough review of the PHIS data for a 12-month period supports the conclusion that TDSHS/MSAU inspectors correctly apply the inspection methodology and document noncompliance.

TDSHS/MSAU 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 TDSHS/MSAU approval. TDSHS/MSAU does not permit generic label approvals at the establishment level as outlined in FSIS Directive 7221.1, Prior Labeling Approval.

TDSHS/MSAU enforces Texas Health and Safety 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. TDSHS/MSAU maintains procedures to document relevant facts of administrative actions and ensure that administrative actions are legally supportable and based on relevant facts.

TDSHS/MSAU has a system for reviewing custom exempt operations that is in accordance with FSIS Directive 8160.1, Custom Exempt Review Process. TDSHS/MSAU reviews custom exempt operations quarterly using the Exempt Establishment Review and Assessment form to verify compliance with the Texas Administrative Code (Section 221.14) and 9 CFR 416 as sanitation reference.

The submitted documents support the conclusion that TDSHS/MSAU:

- 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 TDSHS/MSAU’s sampling protocols, procedures, and results to Federal policies and procedures.

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

Component 4 – Staffing, Training, and Supervision

TDSHS/MSAU 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. Circuit managers assign patrols and duty locations and arrange relief inspection during routine and emergency leave situations. To verify daily inspection coverage, circuit managers review PHIS data, including tasks performed, and corresponding employee work records. In addition, TDSHS/MSAU personnel utilize PHIS data to verify daily inspection.

At the start of the FY 2021 review cycle, TDSHS/MSAU indicated they employ 3 central office managers which include 2 public health veterinarians (PHV); 12 field supervisors which include 5 PHVs; 114 inspectors; 3 enforcement, investigations, and analysis officers which include 1 PHV; 9 compliance officers; 1 compliance manager; and 2 compliance administrative employees.

TDSHS/MSAU continues to implement a training program for new entry-level inspection personnel. TDSHS/MSAU provides employee orientation on policies and procedures,
administrative duties, and computer usage, and assigns an on-the-job trainer to each circuit (team lead). The training covers basic slaughter techniques and all inspection techniques required to perform slaughter duties, including basic Sanitation SOP and HACCP procedures. Each circuit has a designated on-the-job-trainer to provide new inspectors with administrative orientation followed by additional training on inspection duties. The training subjects include livestock inspection, slaughter inspection, processing inspection, HACCP, Sanitation SOP, and sanitation performance standards. TDSHS/MSAU also sends employees to FSIS’ Inspection Methods training. TDSHS/MSAU maintains a record keeping system to track participation and completion of training.

TDSHS/MSAU uses procedures analogous to FSIS Directive 4430.3 In-Plant Performance System (IPPS), to set performance standards, and to complete and record ongoing performance evaluations. The circuit managers are to perform at least two IPPS assessments for each inspector annually. In addition, the circuit managers are to perform an IPPS assessment at the end of the employees’ probationary employment periods. TDSHS/MSAU maintains control measures to examine the IPPS assessments for quality, completeness, and accuracy. In addition, Texas 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 TDSHS/MSAU 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 TDSHS/MSAU’s inspection methodology, to document findings, and to initiate regulatory actions when necessary. Control measures are in effect to confirm that TDSHS/MSAU’s staffing and training systems function as intended.

Component 5 – Humane Handling
TDSHS/MSAU 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.

TDSHS/MSAU uses procedures analogous to FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock, to communicate instructions to inspection personnel. Inspectors document humane handling verifications in PHIS. Circuit veterinarians evaluate establishments’ humane handling procedures and inspectors’ humane handling task performance as part of their supervisory duties. Additionally, TDSHS/MSAU has updated the Humane Handling Directive to reflect/formalize the expectation that MSAU circuit managers evaluate humane handling at a minimum frequency of once every 18 months, and the EIAO will review humane handling during ongoing in-plant reviews and in-depth FSAs.

In conclusion, the information supports the fact that TDSHS/MSAU 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**

TDSHS/Policy Standards Quality Assurance Unit (PSQAU) 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.

TDSHS/PSQAU 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 Texas Health and Safety Code or Texas Administrative Code; and takes enforcement action, when needed, up to and including prosecution of individuals or firms that have violated the Texas Health and Safety Code or Texas Administrative Code. TDSHS/PSQAU 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.

TDSHS/PSQAU 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 to notify TDSHS/PSQAU within 24 hours of initiating a recall. TDSHS/PSQAU 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. In September 2019, a class III recall for a recordkeeping failure was identified. TDSHS/PSQAU followed the procedures identified in FSIS Directive 8080.1, Recall of Meat and Poultry Products.

TDSHS/PSQAU established methods to record, triage, analyze, and track consumer complaints related to State-regulated meat or poultry products. Compliance personnel either investigate these complaints or refer them to the local health authority. The investigative methods include procedures for collecting and safeguarding evidence; conducting interviews; submitting product samples to the laboratory; initiating recall procedures and/or regulatory and enforcement actions; and reporting potential food safety threats.
The submitted documents support the conclusion that TDSHS/PSQAU 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 Testing**

A desk audit of the Texas Department of State Health Services Laboratory (TDSHS) was performed during FY21 to evaluate laboratory quality assurance (QA) programs and method equivalence under the State MPI Program.

TDSHS conducts microbiological testing for *Salmonella*, *L. monocytogenes*, *E. coli* O157:H7, and non-O157 STEC. USDA/FSIS/Eastern Laboratory (EL) conducts food chemistry testing on TDSHS’ behalf for the measurement of moisture, protein, fat, and salt.

FSIS compared the TDSHS 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. TDSHS met all Laboratory QA requirements.

EL has demonstrated adequate food chemistry capability for the measurement of moisture, protein, fat, and salt. TDSHS 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, Texas 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. Note: Analytical methods for *Salmonella* and *Campylobacter* in raw poultry products were not evaluated as Texas is not currently inspecting MPI program poultry establishments slaughtering at least 20,000 chickens and/or turkeys per year.
Component 8 – Civil Rights
On March 17, 2021, CRS conducted a civil rights compliance review of the TDSHS/MSAU program.

The review was conducted to determine compliance with applicable civil rights statutes, U.S. Department of Agriculture (USDA) regulations, and FSIS policies, and where necessary to provide recommendations for program improvement. The review focused on State compliance in eight areas: (1) Civil Rights Assurances; (2) State Infrastructure and Program Accountability; (3) Public Notification; (4) Civil Rights Complaints of Discrimination; (5) Civil Rights Training; (6) Disability Compliance; (7) Program Accessibility to Individuals with Limited English Proficiency; and (8) Compliance with the Age Discrimination Act of 1975.

The review consisted of telephonic interviews with the TDSHS Director and a representative from Texas Health and Human Services (HHS); telephonic interviews with ten State inspected establishments; and a review of documents and the HHS website. A previous review was conducted in March 2018, and while there were several areas that required corrective action, the review overall found the program to be in compliance.

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

Self-Assessment Determination for Texas
Based on the submitted self-assessment documents and desk review results, FSIS determined that TDSHS/MSAU provided adequate documentation to show it is operating a meat and poultry inspection program “at least equal to” the Federal requirements.