Appendix B

Comprehensive Review and Determination Report

Fiscal Year 2021

Arizona

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 Arizona 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 Arizona’s MPI Program
The Arizona Department of Agriculture (AZDA) administers the Arizona MPI program under authority of Arizona Revised Statutes (ARS), Title 3, Chapter 13, 3-2001 through 3-2169. The program verifies compliance and enforces regulatory requirements at 29 inspected facilities and 50 custom exempt establishments.1

Annual Determination
FSIS determined that AZDA is operating a meat and poultry inspection program “at least equal to” the Federal requirements. AZDA has adopted laws, regulations, and programs and has implemented them in a manner that is “at least equal to” the Federal inspection program for all review components. Since AZDA was not subject to an onsite review for Components 1 through 9 during fiscal year (FY) 2021, FSIS based its annual determination on review of the self-assessment documents only. This determination is fully explained in the Review of Arizona’s Self-Assessment Submission section. The last onsite review conducted of the AZDA by FSAS was in January of 2020.

Self-Assessment Review Methodology
The annual self-assessment process is designed for each State to provide sufficient information to adequately demonstrate their administration of an “at least equal to” State MPI program. The review objective is to determine whether a State continues to administer an MPI program that meets Federal standards set for ensuring meat and poultry products are safe, wholesome, unadulterated, and correctly labeled and packaged. Each review cycle, State MPI program officials are to complete and submit self-assessment component surveys, supporting documentation and other self-assessment instruments to FSIS in accordance with the State Reporting and Communication Tool User Guide and FSIS “At Least Equal To” Guideline for State Meat and Poultry Inspection Programs.

FSIS begins the annual comprehensive review by assembling a review team comprised of subject matter experts from various FSIS program areas to review the nine components of the comprehensive review process. The review team, comprised of Agency representatives from the Federal-State Audit Staff (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

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).
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-designated2 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 Arizona’s Self-Assessment Submission
FSIS evaluated the self-assessment documents for the applicable review components to determine whether AZDA constitutes an inspection program “at least equal to” the Federal program. The determination and rationale for each review component are listed below.

FSAS received AZDA’s complete self-assessment submission for components 1 through 6 on October 30, 2020. FSAS requested clarifying information from the AZDA staff, which they provided as requested. FSAS reviewed and accepted the requested information on June 28, 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 ARS (Title 3, Chapters 11 and 13) and the Arizona Administrative Code (Title 3, Chapter 2). The ARS provide authorities for mandatory ante-mortem and post-mortem inspection (Sections 3-2044 and 3-2153), reinspection (Sections 3-2056 and 3-2153), sanitation requirements (Sections 3-2051, 3-2054, 3-2058, and 3-2154), record keeping requirements (Sections 3-2005, 3-2081, and 3-2158), and humane methods of slaughter requirements (Section 3-2016).

In addition, the ARS provide authorities that are “at least equal to” the FMIA and PPIA regarding adulteration (Sections 3-2001 and 3-2151), misbranding (Sections 3-2001 and 3-2151),

2 Non-designated is a State that operates an MPI program under a cooperative agreement with FSIS. The State MPI program must administer inspection and food safety requirements “at least equal to” those imposed under the Federal Meat and Poultry Products Inspection Acts and the Humane Methods of Slaughter Act of 1978.
prohibited acts (Sections 3-2057 and 3-2156), access and examination (Sections 3-2005, 3-2054, and 3-2158), and product control actions (Sections 3-2083, 3-2084, 3-2085, 3-2165, and 3-2166). It also includes sufficient authorities for criminal, civil, and administrative sanctions to address violators.

The ARS (Title 3, Chapters 11 and 13) grants the authority to promulgate rules and regulations (3-2046 and 3-2161). Arizona incorporates by reference 9 CFR Chapter III, revised January 1, 2016, with minor exceptions in the Arizona Administrative Code (Title 3, Chapter 2, Article 2, Section R3-2-202).

In conclusion, AZDA 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. AZDA uses the FSIS Public Health Information System (PHIS) to schedule inspection tasks and to collect, consolidate, and analyze inspection data. AZDA 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 ARS 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, AZDA 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, AZDA schedules and performs a comprehensive food safety assessment (FSA) as routine (every four years) or for cause at each inspected establishment in accordance with FSIS Directive 5100.1, Enforcement, Investigations and Analysis Officer (EIAO) Comprehensive 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 Operating Procedures (Sanitation SOP), prerequisite programs, sampling programs, supporting documentation and records, and any other programs that constitute the establishments’ food safety systems. The PHRE and FSA records support the conclusion that State inspection personnel recognize and document noncompliance and initiate appropriate regulatory actions.

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

AZDA 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 the assigned inspector at the establishment. Any ingredients, formulations, and claims with documentation must be submitted with the sketch label. The inspector in charge will sign and submit the sketch label to the area supervisor and to the program manager for final approval. Once a label is approved, the program manager will return two copies of the approved label through the area manager to the inspector. One copy goes in the inspector’s file and one to the establishment.

AZDA enforces the Arizona Administrative Code R3-2-202, 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. AZDA maintains procedures to document relevant facts of administrative actions and ensure that administrative actions are legally supportable and based on relevant facts.

AZDA has a system for reviewing custom exempt operations that is in accordance with FSIS Directive 8160.1, Custom Exempt Review Process. AZDA inspection personnel perform custom exempt reviews that are geographically located in their inspection assignment. The supervisor maintains a tracking log and informs inspectors when they need to perform reviews and followup visits. Custom exempt reviews are scheduled approximately once per year.

The submitted documents support the conclusion that AZDA:

- 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 management controls to verify that the inspection system functions as intended; and
- Monitors these activities through control measures to verify that the inspection system functions as intended.

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

AZDA 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

• Other consumer protection standards.

The sampling plans include procedures for sample collection, sample integrity, and laboratory analysis. AZDA developed policies to respond to positive results. These policies include actions to prevent adulterated product from entering commerce. AZDA 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 methods, protocols, procedures, and results confirmed that AZDA 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, Training, and Supervision**

AZDA developed methods to determine staffing requirements. The requirements consider each inspector’s workload and the number of inspectors required to provide daily inspection coverage in each establishment on days when the establishment produces products bearing the State mark of inspection. Procedures are in effect to document staffing in each establishment, identify failures to meet staffing requirements, and correct staffing deficiencies. Supervisors provide the inspector a work assignment or schedule with instructions for daily visits to operating establishments and arrange relief inspection during routine and emergency leave situations. To verify daily inspection assignment coverage, supervisors review weekly travel and activity reports, establishment sign-in logs, and PHIS inspection data.

At the start of the FY 2021 review cycle, AZDA indicated they employ 1 program manager, 1 area supervisor, 1 compliance officer, 11 food inspectors, 1 part-time veterinary medical officer, and 2 part-time administrative staff members.

AZDA continues to implement a training program for new entry-level inspection personnel. New employees receive administrative training as well as slaughter and processing training. The training covers ante-mortem and post-mortem inspection, humane handling, HACCP, Sanitation SOPs, and sanitation performance standards. Inspection personnel also receive the FSIS Inspection Methods training. AZDA maintains a record keeping system to track participation and completion of training for each employee.

AZDA administers the Managing Accountability and Performance system to set performance standards and evaluate job performance. This system communicates to the employees their work responsibilities, performances goals and objectives, and the results of their performance evaluations. AZDA evaluates each employee annually.
After thorough review of the submitted documents, FSAS concluded that AZDA has sufficient resources to provide the required inspection coverage at AZDA 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 AZDA’s inspection methodology, to document findings, and to initiate regulatory actions, when necessary. Control measures are in effect to confirm that AZDA’s staffing and training systems function as intended.

Component 5 – Humane Handling
AZDA 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.

AZDA uses FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock, to communicate instructions to inspection personnel. Inspectors document humane handling verifications in PHIS and on AZDA’s Humane Activity Tracking System logs. The AZDA program manager or area supervisor verify compliance with the humane handling regulatory requirements at applicable establishments during the annual in-depth review and document the verification results on the Establishment Review and Evaluation Report and on the Humane Handling Verification Assessment form.

The information supports the conclusion that AZDA verifies compliance with 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
AZDA 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.

AZDA 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 ARS; and takes enforcement action, when needed, up to and including prosecution of individuals or firms that have violated the ARS. AZDA 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.

AZDA 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 manager reviews all violations and relevant evidence and determines the appropriate case disposition and course of action in conjunction with the department legal counsel.
AZDA 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 AZDA immediately when initiating a recall. AZDA 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.

AZDA 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 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 AZDA 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 Arizona Department of Agriculture State Laboratory (ADA) was performed during FY21 to evaluate laboratory quality assurance (QA) programs and method equivalence under the State MPI program.

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

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

The EL has demonstrated adequate food chemistry capability for the measurement of moisture, protein, fat, and salt. ADA 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, Arizona 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 Arizona is not currently inspecting MPI program poultry establishments slaughtering at least 20,000 chickens and/or turkeys per year.

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

**Component 9 – Financial Accountability**
In November 2020, AZDA submitted quarterly and final Financial Status Reports (SF-425), and the 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 AZDA is “at least equal to” Federal standards for financial accountability for FY 2021.

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