Appendix R

FINAL REPORT

Fiscal Year 2023

Ohio April 2024

Federal-State Audit Staff
Office of Investigation, Enforcement and Audit
Food Safety and Inspection Service
U.S. Department of Agriculture

Executive Summary

This report describes the outcome of the annual review of the Ohio Department of Agriculture Department of Meat Inspection (ODA-DMI), conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), including an onsite audit conducted from April 24—May 5, 2023. The annual audit process consists of two parts: (1) annual review of the state self-assessment submissions and (2) triennial onsite audits, which are used to verify whether the State meat and poultry inspection (MPI) program enforces requirements "at least equal to" the Federal requirements. The purpose of the annual review was to: (1) verify the State of Ohio imposes laws, regulations, and related policies with authorities and requirements "at least equal to" those provided by the Federal Meat Inspection Act (21 U.S.C. 601, et seq.) and Poultry Products Inspection Act (21 U.S.C. 451, et seq.); (2) determine whether Ohio administers a State MPI program capable of ensuring meat and poultry products produced, distributed, and sold within the State are safe, wholesome, unadulterated, and properly labeled; and (3) confirm the State MPI program carries out its regulatory oversight activities effectively and efficiently.

The annual review focused on all nine "at least equal to" components: (1) Statutory Authority and Food Safety Regulations; (2) Inspection; (3) Sampling Programs; (4) Staffing, Training, and Supervision; (5) Humane Handling; (6) Compliance; (7) Laboratory Methods and Quality Assurance Program; (8) Civil Rights; and (9) Financial Accountability.

An analysis of the audit findings within each component did not identify systemic findings that may pose an immediate threat to public health.

On June 30, 2023, ODA-DMI submitted an action plan to correct the findings identified during the audit. The action plan identifies the underlying causes of the system-wide findings and the underlying causes of the specific findings at individual establishments. It includes a verification plan to ensure statewide correction of these findings. ODA-DMI Inspection personnel reviewed approximately 20 percent of the "equal to" licensed establishments in the state to verify compliance with:

- Hazard Analysis and Critical Control Point (HACCP) monitoring recordkeeping requirements,
- Sanitation Standard Operating Procedures (SSOP) recordkeeping requirements, and
- Critical Control Point (CCP) monitoring of an antimicrobial intervention mixing procedure.

If there were additional finding the checks would increase to 100% of establishments. There were no findings of public health concern that required recalls or enforcement actions. In addition, ODA-DMI provided evidentiary documents to demonstrate verification of establishment compliance with the regulatory requirements.

Based on thorough evaluations of the audit results and implemented corrective actions, FSIS determined that ODA-DMI is operating a meat and poultry inspection program "at least equal to" the Federal requirements.

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I. INTRODUCTION

This report communicates the results of an onsite verification audit conducted by the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) in Federal fiscal year (FY) 2023 to evaluate Ohio's administered meat and poultry inspection (MPI) program to determine if it is "at least equal to" FSIS' requirements and is capable of ensuring that the State's supply of meat and poultry products is safe, wholesome, unadulterated, and properly labeled and packaged. This report also summarizes information examined and analyzed as part of the annual review by FSIS to determine whether the Ohio MPI program is "at least equal to" the FSIS inspection system.

The "at least equal to" standard requires that State MPI programs operate in a manner that is at least as effective as FSIS' Federal inspection program in the protection of public health. Under the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA), FSIS may contribute up to 50 percent of the estimated total cost of the State's MPI program and provide administrative support if the State operates and maintains a program that is "at least equal to" the Federal inspection program (21 U.S.C. 661(a)(3) and 454(a)(3)).

II. OBJECTIVE, SCOPE, AND METHODOLOGY

The review focused on the nine "at least equal to" components: (1) Statutory Authority and Food Safety Regulations; (2) Inspection; (3) Sampling Programs; (4) Staffing, Training, and Supervision; (5) Humane Handling; (6) Compliance; (7) Laboratory Methods and Quality Assurance Program; (8) Civil Rights; and (9) Financial Accountability. For each identified component, the Ohio Department of Agriculture Department of Meat Inspection (ODA-DMI) submitted the self-assessment documents in the State Review and Communication Tool (SRCT) that included descriptions of current program operations and procedures, and other supporting documentation pertaining to the attainment of the component requirements. FSIS verifies the above components to ensure ODA-DMI is implementing food safety verification activities at State-inspected establishments that comply with applicable State laws, regulations, and policies to produce safe and wholesome products. FSIS examined the submitted documentation to verify ODA-DMI continues to maintain regulatory operations in accordance with FMIA (21 U.S.C. 601, et seq.) and PPIA (21 U.S.C. 451, et seq.) and to check for procedural nonconformities that may prevent operations from functioning as intended. In addition, FSIS evaluated the effectiveness of current internal control and risk assessment systems and determined if there were any findings. 1 FSIS also conducted an onsite audit to verify accuracy and implementation of the SRCT submissions for Components 1-9.

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¹ An issue identified by a Federal-State Audit Staff Auditor. There are two types of findings: 1. Noncompliance failure to meet a regulatory requirement. 2. Nonconformity, State Program, or any State Official fails to implement and/or follow a policy or procedure as proffered in their Self-Assessment.

III. BACKGROUND

The FMIA (21 U.S.C. 661) and the PPIA (21 U.S.C. 454) authorize FSIS to cooperate with State agencies in developing and administering State MPI programs. An individual State MPI program is limited to meat and poultry products that are produced and sold within the State and needs to operate in a manner and with authorities that are "at least equal to" the programs that FSIS implements under the ante-mortem and post-mortem inspection, reinspection, sanitation, record keeping, and enforcement provisions of the FMIA (21 U.S.C. 601, et seq.) and PPIA (21 U.S.C. 451, et seq.). State MPI programs are to ensure that livestock are treated humanely by imposing humane handling requirements that are "at least equal to" the requirements FSIS has established under the Humane Methods of Slaughter Act of 1978 (HMSA) (7 U.S.C. 1901–1906).

The FMIA and PPIA provide for FSIS to review, at least annually, each State MPI program and its requirements and enforcement activities. If a State fails to administer a meat and poultry inspection program that is "at least equal to" FSIS' Federal inspection program, FSIS will move to "designate" the State in accordance with 21 U.S.C. 661(c) and 454(c).

Annually, non-designated States are expected to assess and support determinations that their MPI programs operate in a manner "at least equal to" the Federal inspection program. FSIS requires State MPI programs to submit self-assessment documents through the SRCT each year and provides guidance for this process in FSIS' "At Least Equal To" Guideline for State Meat and Poultry Inspection Programs. At a minimum, the self-assessment documentation should be representative of the current operations of the State MPI program and demonstrate the program's ability to meet the "at least equal to" Federal requirements for the next 12 months. State MPI programs are to provide narratives in the submitted documentation for any identified administrative or operational changes made to their programs since the last FSIS review and "at least equal to" determination. As a part of the self-assessment process, State MPI programs are expected to consider the intent and assess the applicability of FSIS statutes, regulations, directives and notices in their inspection operations and compliance enforcement strategies. FSIS expects State MPI programs to submit for review copies of all applicable laws, administrative rules, regulations, and policies deemed necessary to carry out inspection programs "at least equal to" the Federal requirements.

In addition, FSIS conducts onsite audits of State MPI programs at a minimum of every three years to verify the accuracy and implementation of the State MPI programs' self-assessment submissions. In years when a State MPI program is subject to FSIS' onsite audits, the annual "at least equal to" determination will be based on analysis of results collected through FSIS' two-part review and audit process. Otherwise, the annual "at least equal to" determination will be based solely on review and analysis of the State's self-assessment submissions.

ODA-DMI, a State organization with the overall authority to administer the State MPI program, submitted the required program self-assessment documents to demonstrate administrative and program-wide compliance with all nine "at least equal to" components. FSIS evaluated State's self-assessment documentation and conducted an onsite verification audit of the State MPI program.

The establishment selection process for onsite audits employs a systematic approach that considers risk determinants such as sample results, recalls, production volume and other information obtained directly from the State MPI programs through the SRCT. For this audit, a sample of 14 establishments was selected from a total of 202 State-inspected establishments.

ODA-DMI administers the Ohio MPI program under authority of Ohio Revised Code (ORC) 918.01 et seq. ODA-DMI is organized on three levels: State office, State inspection, and compliance program. The program verifies compliance and enforces regulatory requirements at inspected establishments and custom exempt operators².

FSIS verified through interviews and record reviews that all ODA-DMI personnel are employed by the State of Ohio and are conducting verification activities as outlined in the self-assessment.

The table below details the number of inspected establishments and custom exempt operators.

Total Number of State-Inspected Establishments and Custom Exempt Operators

	Establishment Type	Slaughter Only	Processing Only	Combination Slaughter and Processing	Total
Number of	Meat Only	16	29	47	92
State-Inspected	Poultry Only	0	4	3	7
Establishments	Combination Meat and Poultry	0	79	24	103
	Total	16	112	74	202
Number of	Meat Only	1	9	50	60
Custom	Poultry Only	1	0	8	9
Exempt	Combination	0	5	5	10
Operators	Meat and Poultry				
	Total	2	14	63	79

IV. COMPONENT 1: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The State laws or administrative rules must grant the State MPI program legal authority to administer an inspection program. State MPI program is required to have meat and poultry inspection laws and governing regulations that impose mandatory ante-mortem and post-mortem inspection, reinspection, sanitation requirements, recordkeeping requirements, and enforcement authorities that are "at least equal to" those provided by the FMIA (21 U.S.C. 601, et seq.) or the PPIA (21 U.S.C. 451, et seq.).

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² Custom exempt operators are not subject to the routine inspection requirements of the FMIA and PPIA, provided the specified operations meet the exemption requirements (21 U.S.C. 623 and 464).

FSIS reviewed the submitted self-assessment documentation and confirmed Ohio administers ODA-DMI under the applicable State laws, rules, and regulations. The State Law, ORC Section 918 and Section 3715; and the Ohio Administrative Code (OAC) 901 includes legal requirements comparable to following mandatory requirements of the FMIA and the PPIA:

- ante-mortem and post-mortem inspection (ORC 918.02);
- reinspection (ORC 918.02);
- sanitation requirements (ORC 918.02);
- record keeping requirements (OAC 901:2-1-01 and ORC 918.24);
- humane methods of slaughter requirements (ORC 945.01);
- adulteration (ORC 918.01);
- misbranding (ORC 918.01);
- prohibited acts (ORC 918.11);
- access and examination (OAC 901:2-1-01);
- product control actions (ORC 918.01; 3715.55); and
- exemption from inspection (ORC 918.10).

The Ohio Administrative Code (OAC) grants the authority to promulgate rules and regulations. OAC Rule 901:2 -1 -01 adopts by reference 9 CFR 300 to 442 with exceptions listed in Rules 901:2 -1 -02(definitions); 901:2 -1 -03(sections not adopted). The following sections of the federal meat inspection regulations are deleted in their entirety and shall not become rules of the Ohio Department of Agriculture: From 9 CFR Part 300, the following paragraphs are hereby not adopted: 9 CFR 300.2(b)(3); 9 CFR 300.2(b)(5); 9 CFR 300.2(b)(7); 9 CFR 300.4(b); and 9 CFR 300.6(a)(2). From 9 CFR Part 301.2, the definition of the term "Territory" is not adopted. From 9 CFR Part 312, the following sections are hereby not adopted: 9 CFR 312.3; 9 CFR 312.8; 9 CFR 312.9; and 9 CFR 312.10. From 9 CFR Part 316, the following sections are hereby not adopted: 9 CFR. 316.12; and 9 CFR 316.13(c). From 9 CFR Part 317, the following sections are hereby not adopted: 9 CFR 317.7; and 9 CFR 317.9. 9 CFR Part 318.8, 9 CFR Part 321, 9 CFR Part 322, 9 CFR Part 325.3, 9 CFR Part 327, 9 CFR Part 331, 9 CFR Part 335.40, 9 CFR Part 350, and 9 CFR Part 351. From 9 CFR Part 352, the following sections are not adopted: 9 CFR Part 325.16; 9 CFR Part 325.18; and 9 CFR Part 325.19. From 9 CFR Part 354, the following paragraphs and sections are not adopted: 9 CFR Part 354.1(e); 9 CFR Part 354.1(p); 9 CFR Part 354.1(r); 9 CFR Part 354.1(u); 9 CFR Part 354.1(ff); 9 CFR Part 354.2(a); 9 CFR Part 354.2(b); 9 CFR Part 354.20(b) 9 CFR Part 354.64; 9 CFR Part 354.100(c); 9 CFR Part 354.101; 9 CFR Part 354.105; 9 CFR Part 354.106; 9 CFR Part 354.107; 9 CFR Part 354.110; 9 CFR Part 354.128; 9 CFR Part 354.140; 9 CFR Part 354.141; 9 CFR Part 354.142; 9 CFR Part 354.143; and 9 CFR Part 354.144. 9 CFR Part 355. 9 CFR Part 362, 9 CFR Part 381, Title 9 CFR Part 390, 9 CFR Part 391, 9 CFR 392, and 9 CFR 439; 901:2 -1 -04; and 901:2 -1 -05. OAC Rule 901:2 -2 -01 adopts by reference 9 CFR Part 500. The State program did not adopt regulations that do not apply to their processes, or they have their own written rule or law to address the item covered in the FSIS regulation.

FSIS confirmed through onsite record reviews, interviews, and observations that ODA-DMI has statutory authority to enforce the provisions of ORC 918.01 and Section 3715 and the governing administrative rules and regulations, OAC 901 and OAC Rule 901:2 -1 -01 which adopts by reference 9 CFR 300 to 442 with exceptions listed in Rules 901:2 -1 -02; 901:2 -1 -03; 901:2 -1 -04; and 901:2 -1 -05. OAC Rule 901:2 -2 -01 adopts by reference 9 CFR part 500, respectively,

at State-inspected establishments and firms handling meat and poultry products within the State as outlined in the FY2023 self-assessment submission. There were not any statutory or regulatory changes made this year that affect how ODA-DMI carries out its regulatory duties.

FSIS did not identify any findings and determined that, ODA-DMI operates under State laws and regulations that provide legal authority "at least equal to" that provided under the FMIA, PPIA, HMSA, and governing regulations.

V. COMPONENT 2: INSPECTION

The State MPI program is required to administer a regulatory inspection program "at least equal to" that provided by FSIS. The inspection program is to include, at a minimum, inspection verification methods for verifying:

- Animals are suitable for slaughter, and carcasses and parts are eligible for human consumption;
- All meat and poultry products found in intrastate commerce are safe, unadulterated and truthfully labeled;
- All official establishments comply with sanitation performance standards (SPS), sanitation standard operating procedures (Sanitation SOP) and sanitary dressing regulatory requirements as articulated in 9 CFR 416, or equivalent governing State regulations;
- All official establishments develop, implement, and maintain written and Hazard Analysis and Critical Control Points (HACCP) systems as articulated in 9 CFR 417, or equivalent governing State regulations.

The inspection verification methods implemented by the State MPI program must include activities for evaluating compliance at official establishments with the applicable inspection and food safety verification requirements of 9 CFR 300 to End. These are to include observation of establishments' operations and employees' product handling practices, hands-on verification, and review of establishment records, with the results of verification being entered in the associated inspection records. The State MPI program also are to implement inspection verification methods for ensuring State-inspected meat and poultry products are wholesome, not economically adulterated, truthfully labeled, and meet regulatory requirements. The State MPI program must ensure inspection personnel interpret and apply relevant regulatory requirements uniformly when conducting inspection verification methods. The ultimate regulatory goal of the State MPI to protect consumers from meat or poultry products that are unwholesome, economically adulterated, or not truthfully labeled (21 U.S.C. 607 and 457).

FSIS reviewed the self-assessment documentation submitted as evidence showing that ODA-DMI has developed and implemented:

• An inspection system to ensure State-inspected establishments comply with applicable food safety and other consumer protection regulations (e.g., ante-mortem and post-mortem inspections, sanitation, HACCP system, and product standards and labeling);

- A label approval policy and process to verify labels, marks, or devices are accurate and comply with regulatory requirements prior to establishments applying them to inspected meat or poultry products;
- A risk-based methodology to analyze establishments' food safety systems to verify that the establishments can produce safe and wholesome meat or poultry products in accordance with applicable statutory and regulatory requirements;
- A system of administrative enforcement actions to bring establishments effectively under regulatory compliance in a manner that is not inferior to the comparable actions taken by FSIS; and
- An internal control system for evaluating the efficacy and effectiveness of the other systems.

ODA-DMI uses the FSIS Public Health Information System (PHIS) to schedule inspection tasks and to collect, consolidate, and analyze inspection data. ODA-DMI 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 Ohio Revised Code, Section 918.01 and governing rules, regulations and policies. The State inspection program maintains assurances that animals intended to be used in meat and poultry products sold commercially are slaughtered and processed in the presence of State inspection personnel. The resulting products are inspected and passed for human consumption. ODA-DMI adopts and implements most relevant FSIS issuances as its own policies for carrying out inspection and food safety verification activities.

ODA-DMI will in most cases utilize State specific forms in place of FSIS forms. ODA-DMI inspection personnel, instead of compliance personnel, perform custom exempt reviews per FSIS Directive 8160.1, Custom Exempt Review Process, approximately once every four weeks instead of annually. ODA-DMI perform Food Safety Assessments (FSA) for cause and at least every four years per FSIS Directive 5100.4, Public Health Risk Evaluation Methodology, instead of relying solely on the PHRE. ODA-DMI also performs administrative reviews between FSAs. Nonetheless, FSIS determined that the observed procedural differences did not impact ODA-DMI's capability to meet the intended purposes of the FSIS directives.

FSIS audited the conditions and documents onsite. The onsite documents audited included, but were not limited to, sanitation standard operating procedures and associated records; HACCP plans and associated records; generic *Escherichia coli (E. coli)* sampling procedures and associated records; procedures for the removal, segregation, and disposition of specified risk materials (SRM) and associated records; custom exempt records; noncompliance records; and enforcement letters. In addition, FSIS audited the non-food safety consumer protection documents and procedures to determine whether ODA-DMI enforces non-food safety consumer protection regulatory standards "at least equal to" the Federal requirements. This audit included, but was not limited to, ongoing regulatory verification tasks, label approvals, labels, and product formulations.

FSIS evaluated ODA-DMI inspection at 14 State-inspected establishments during the onsite audit. ODA-DMI personnel identified several establishment noncompliances with the Sanitation

SOP, Sanitation Performance Standards (SPS), HACCP design and validity, and non-food safety consumer protection requirements. State findings included:

- various SPS findings of residue on cooler door and equipment, debris on floor, condensation, and pest harborage,
- SSOP noncompliances found with pre-operational sanitation and carcass contamination,
- SRM removal was not documented, and
- unlabeled product was found.

ODA-DMI officials initiated regulatory actions in the establishments and issued noncompliance records at the time the noncompliances were identified. Items were cleaned, sanitized, and reinspected, contamination was removed, and products were labeled.

FSIS identified the following findings:

- Entry on Sanitation SOP operational sanitation monitoring record was not initialed by responsible employee as required by 9 CFR 416.16
- Entry on HACCP CCP monitoring record was not initialed or signed as required by 9 CFR 417.5(b), and
- Establishment was not mixing the 2 percent lactic acid CCP intervention correctly.

ODA-DMI officials issued noncompliance records at the time the noncompliances were identified. The Corrective Action plan submitted by the State showed that they verified that this finding was not found in 20 percent of other establishments not reviewed by the program auditor while onsite.

The FSIS determined that ODA-DMI maintains inspection and food safety verification systems that meet the "at least equal to" standards. Control measures are in effect to ensure that the inspection system functions as intended.

VI. COMPONENT 3: SAMPLING PROGRAMS

The State MPI program is required to assess establishments' control of microbial pathogens, violative levels of veterinary drugs, pesticides, contaminants, and other adulterants through product sampling. The State MPI program must have access to laboratory services to conduct chemical, microbiological, physical, and pathological testing. Laboratories conducting official analyses for State inspection programs must ensure test results are accurate, reliable, and reproducible.

FSIS reviewed ODA-DMI's product sampling documents, protocols, procedures, and results presented in the FY 2023 self-assessment submission. FSIS verified through interviews and record reviews that ODA-DMI maintains sampling programs, based on sound rationale and goals, for the following:

- 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 (RTE) products; and
- Other consumer protection standards.

ODA-DMI implements developed sampling procedures for collecting samples, maintaining sample integrity, determining sampling frequencies, conducting sample analyses, responding to positive results, and preventing adulterated product from entering commerce. Additionally, ODA-DMI participates in the National Residue Program and collects and analyzes inspectorgenerated samples for violative drug residues.

ODA-DMI adopts and implements most relevant FSIS issuances as its own policies for carrying out inspection and food safety verification activities.

FSIS Directive 10,240.5, ODA-DMI does sample for the RLm program at a different frequency than FSIS. ODA-DMI samples each RTE establishment twice per year, one product sample, three food contact surfaces, and two non-food contact surfaces. This results in more samples than FSIS would obtain during a four-year RLm schedule. Nonetheless, FSIS determined that the observed procedural differences did not impact ODA-DMI's capability to meet the intended purposes of the FSIS directives.

These included sampling plans and laboratory results for *E. coli* O157:H7 in raw non-intact beef products and raw ground beef components, non-O157 STEC in raw beef manufacturing trimmings, *L. monocytogenes* and *Salmonella* in ready-to-eat products, economic samples, violative drug residues, State laboratory activity reports, and sample seals.

FSIS did not identify any findings and determined that ODA-DMI 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. Control measures are in effect to ensure that the sampling programs function as intended.

VII. COMPONENT 4: STAFFING, TRAINING, AND SUPERVISION

The State MPI program must maintain enough staff to carry out its responsibilities. The State MPI program is to organize a sufficient number of trained veterinarians, inspectors, and enforcement staff to carry out the inspection and regulatory duties of the MPI program well. The State MPI program ensures its personnel receive the professional, technical, inspection, and managerial training necessary to maintain a competent and effective workforce. The State MPI program is to provide instructions to MPI personnel on performing daily inspection tasks and compliance enforcement activities.

FSIS reviewed ODA-DMI's submitted documents confirmed ODA-DMI implements administrative programs to ensure a competent workforce provides daily inspection coverage in each State-inspected meat and poultry establishment where the State inspection marks are applied to products. In addition, the documentation outlines a training program that includes both formal and informal job-related courses. The State's supervisory system aligns individual

workloads with Ohio's public health and regulatory goals and sets standards for assessing job performance that includes measures to correct unsatisfactory performance.

After further analysis of data from ODA-DMI office and establishment audits, FSIS concluded that ODA-DMI has an adequate number of trained persons to provide the required inspection coverage in the establishments, perform compliance verification activities, and provide supervisory oversight, and has implemented procedures to ensure daily inspection coverage in operating establishments. Inspection personnel apply ODA-DMI's inspection methodology and make decisions based upon the correct application of inspection methodology, document findings, and initiate regulatory action if needed. The training program includes measures to ensure that inspection personnel receive training in the areas of basics of red meat slaughter, humane handling, sanitation, and processing. This training consists of assigning the meat inspector trainee with a trainer for approximately 3-4 months. During that time, the trainee is expected to study and gain knowledge from the issued workbook, training modules, FSIS directives, and onsite observations on the slaughter floor and throughout the plant for sanitary conditions. The ODA-DMI utilizes the resources of FSIS via AgLearn and in-class instruction for employee training. All ODA-DMI inspectors and supervisors have been trained in PHIS basics as well as through classroom trainings, either on the State level or via FSIS. All new inspectors attend the Inspection Methods course offered by FSIS to gain knowledge in PHIS and inspection activities. All ODA-DMI veterinarians are sent through the FSIS Public Health Veterinarian training, as well as enforcement, investigations and analysis officer (EIAO) training early in their career. The ODA-DMI is also continuing to send meat inspection supervisors to the FSIS EIAO training. A training folder is maintained for each employee that includes documentation of all training completed.

FSIS did not identify any findings and determined ODA-DMI maintains 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 determination that inspection personnel have the education and training to consistently apply ODA-DMI's inspection methodology, document findings, and initiate regulatory actions when necessary. Control measures are in effect to ensure that the staffing, training, and supervision systems function as intended.

VIII. COMPONENT 5: HUMANE HANDLING

The State MPI program is required to ensure the slaughter and handling of livestock is done humanely in accordance with the HMSA 1978 (7 U.S.C. 1901–1906) and FMIA 21 U.S.C. 603 (b) and 610 (b)). The State MPI program is expected to impose laws "at least equal to" the HMSA and the requirements outlined in FSIS Directives 6900.1 and 6900.2. When livestock are slaughtered humanely, they are to be rendered insensible to pain by means that are rapid and effective before being shackled, hoisted, thrown, cast, or cut. The HMSA requires establishments to comply with a prescribed method of slaughter in which the animal loses consciousness by severing its carotid arteries simultaneously and instantly with a sharp instrument when slaughtered livestock in accordance the ritual requirements of with Jewish faith and any other religious faiths.

The State MPI Program is required to ensure poultry operators comply with Good Commercial Practices (GCP). The Poultry Products Inspection Act (PPIA) (21 U.S.C. 453(g)(5)) and the regulations (9 CFR 381.90) provide that poultry carcasses showing evidence of having died from causes other than slaughter are considered adulterated and must be condemned. The regulations (9 CFR 381.65(b)) also require that poultry be slaughtered in accordance with GCP. Poultry are to be slaughtered in a manner that ensures that breathing has stopped before scalding, so that the birds do not drown, and that slaughter results in thorough bleeding of the poultry carcass. Compliance with these practices helps ensure that poultry are treated humanely.

FSIS reviewed submitted humane handling policies, ante-mortem inspection reports, noncompliance records, and periodic supervisory review records. The results of the reviews revealed ODA-DMI 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 takes appropriate regulatory action in response to noncompliance.

FSIS audited the humane handling program and documents presented onsite to determine whether ODA-DMI adequately enforces the humane slaughter of livestock regulatory standards to ensure that animals presented for slaughter are humanely handled throughout the time they are on official establishment premises. These documents included, but were not limited to, noncompliance records and procedure schedules. When conducting establishment audits, FSIS observed humane handling of livestock, stunning methods and the condition of livestock pens, driveways, and ramps.

ODA-DMI has adopted 9 CFR parts 313 and 381, they follow FSIS Directives 6900.2 and 6910.1 with no noted differences. ODA-DMI have humane handling policies and procedures "at least equal to" FSIS.

ODA-DMI 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 ODA-DMI, Meat Inspection Field Logs. During annual humane handling verification visits, public health veterinarians evaluate establishments' humane handling procedures and inspectors' humane handling task performance.

ODA-DMI employs public health veterinarians who perform annual humane handling audits at slaughter facilities in accordance with FSIS Directive 6910.1, District Veterinary Medical Specialist (DVMS) - Work Methods.

FSIS did not identify any findings and determined that ODA-DMI operates under State laws and regulations that provide legal authority "at least equal to" that provided under the FMIA, PPIA, HMSA, and governing regulations.

IX. COMPONENT 6: COMPLIANCE

The State MPI program is required to enforce compliance with all applicable laws and regulations and to take appropriate action in the event of noncompliance. The State MPI program must have the ability to:

- Detain adulterated or misbranded product (21 U.S.C. 672 and 467 (a));
- Take appropriate control in intrastate commerce of adulterated or misbranded product and to ensure proper disposition of such product, including seizure, condemnation, and destruction where appropriate (21 U.S.C. 673 and 467 (b));
- Ensure establishments maintain written recall procedures for all meat and poultry products produced and shipped (21 U.S.C. 613 and 459(c)(1));
- Conduct surveillance activities to ensure animal carcasses, and carcass parts that are not intended for use as human food are not diverted to such uses; and
- Refuse or withdraw inspection services as warranted (21 U.S.C. 671, 467, and 457 (b)). The State must maintain a statutory process to prosecute anyone who forcibly assaults, resists, opposes, impedes, intimidates, or interferes with officials in the performance of their official duties (21 U.S.C. 675 and 461 (c)).

FSIS reviewed submitted self-assessment documents and confirmed ODA-DMI maintains a compliance system to enforce food safety, food defense, inspection exemption, and other consumer protection statutory requirements in intrastate commerce. ODA-DMI follows State compliance policies or adopted FSIS directives to:

- Conduct surveillance activities and investigations, as warranted, of firms producing meat and poultry products in intrastate commerce;
- Control unsafe or violative products through detentions, seizures, and voluntary recalls;
- Take appropriate enforcement actions when adulterated or misbranded products are found in intrastate commerce; and
- Develop case files to ensure all enforcement actions imposed are legally supported by applicable State laws.

FSIS audited the documents presented onsite. These included, but were not limited to, Reports of Investigation, Daily Activity Reports, Programmed Compliance Plans, Incident Reports, Case Reports, Recalls, Consumer Complaints, Reports of Apparent Violations, and Notices of Warning, etc.

The audit of compliance documents and case files support the conclusion that ODA-DMI follows the procedures and methods in FSIS Directive 8010.1, Methodology for Conducting In-Commerce Surveillance Activities, to assess food safety, food defense, non-food safety consumer protection, and compliance with administrative and judicial court orders in firms that prepare, transport, sell, or offer for sale meat and poultry products in intrastate commerce.

ODA-DMI investigates alleged or actual statutory or regulatory violations, as set out in FSIS Directive 8010.2, Investigative Methodology, and controls products when there is reason to believe the products are adulterated, misbranded, or otherwise in violation of the Ohio Revised Code. The Reports of Investigation were completed in accordance with FSIS Directive 8010.4,

Report of Investigation. ODA-DMI uses the investigative findings and evidence to pursue enforcement actions for administrative, civil, or criminal sanctions.

ODA-DMI follows the recall procedures in FSIS Directive 8080.1, Recall of Meat and Poultry Products, with minor modifications fitting its organizational structure. No State-inspected establishments or retail firms recalled product during FY 2023.

ODA-DMI maintains a system to audit, analyze, and triage consumer complaints. ODA-DMI gathers information pertinent to these complaints, directs the compliance division to investigate the complaints, and files completed investigation documents in the State office. 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.

ODA-DMI has a system for reviewing custom exempt operations that is in accordance with FSIS Directive 8160.1, Custom Exempt Review Process. ODA-DMI inspection personnel will continue to perform all custom exempt reviews. Reviews will be scheduled every four weeks with follow-ups as necessary.

FSIS did not identify any findings and determined ODA-DMI maintains sufficient resources to conduct surveillance reviews at registered firms, which may lead to investigations and enforcement actions. The information supports individuals, firms, and corporations in complying with applicable State statutes when producing, transporting, storing, and distributing meat and poultry products in intrastate commerce. The information supports the conclusion that inspection personnel have the education and training needed to apply ODA-DMI's inspection methodology, to document findings, and to initiate regulatory actions when necessary. Control measures are in effect to ensure that the compliance systems function as intended.

X. COMPONENT 7: LABORATORY METHODS AND QUALITY ASSURANCE PROGRAM

State MPI programs must use product sampling and laboratory methods with capabilities and safeguards "at least equal to" the FSIS' product sampling and laboratory methods. State MPI program is to update and maintain as necessary its laboratory microbiological and chemical detection methods to keep pace with the applicable FSIS methods detailed in the FSIS Microbiology Laboratory Guidebook and USDA FSIS Chemistry Laboratory Guidebook.

An onsite audit of the Ohio Department of Agriculture Consumer Protection Laboratory (ODACPL) was performed during FY 2023 to evaluate laboratory quality assurance programs and method equivalence under the State MPI Program.

As a participant in the Cooperative Interstate Shipment (CIS) "same as" program, Ohio meets the requirements of the State Meat and Poultry Inspection (MPI) "at least equal to" Program

Laboratory Quality Management System Checklist. The ODACPL performs FSIS MLG methods on CIS program samples for *Campylobacter*, *L. monocytogenes*, *Salmonella*, *E. coli* O157:H7 and non-O157 Shiga toxin-producing *E. coli* (nonO157 STEC) analyses. USDA/FSIS/Eastern Laboratory conducts food chemistry testing on ODACPL's behalf to include the measurement of moisture, protein, fat, and salt.

FSIS compared the ODACPL Laboratory Quality Assurance (QA) 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. ODACPL met all laboratory QA requirements.

USDA/FSIS/Eastern Laboratory has demonstrated adequate food chemistry capability for the measurement of moisture, protein, fat, and salt. ODACPL has demonstrated adequate microbiological capabilities for detection of *Salmonella*, *L. monocytogenes*, *E. coli* O157:H7, non-O157 STEC and *Campylobacter*.

Based on the Component 7 methods and quality assurance program review, Ohio may be eligible to perform inspection:

- At beef establishments producing raw ground beef and bench trim, provided that the State collects and submits the appropriate number of samples that are tested for *Salmonella* and *E. coli* O157:H7 and at beef slaughter establishments producing manufactured trim, where the State is required to collect and submit the appropriate number of samples that are tested for *Salmonella*, *E. coli* O157:H7, and non-O157 STEC.
- At RTE meat and poultry establishments, provided that the State collects and submits the appropriate number of samples that are tested for *Salmonella* and *L. monocytogenes*.
- At poultry slaughter establishments, provided that the State collects and submits the appropriate number of samples that are tested for Salmonella and Campylobacter. MPI states with no participating facilities slaughtering at least 20,000 chickens and/or 20,000 turkeys per year are not required to test that raw product for *Salmonella* and *Campylobacter* since it is not required at similar federally inspected plants.

On August 22, 2023, FSIS determined the analytical methods used for microbiological and chemical analyses are "at least equal to" the FSIS methods.

XI. COMPONENT 8: CIVIL RIGHTS

The State MPI program is to adhere to Federal Civil Rights laws: Title VI of the Civil Rights Act of 1964 (42 U.S.C. 200(d)), Section 504 of the Rehabilitation Act of 1973, as Amended (29 U.S.C. 794), Age Discrimination Act of 1990 (42 U.S.C. 12101, et seq.) and applicable USDA Civil Rights regulations.

In November 2022, ODA-DMI 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 conducted a Civil Rights compliance review of ODA-DMI The review was conducted to determine compliance with applicable Civil Rights statutes, USDA regulations, and FSIS policies and, where necessary, provide recommendations for program improvement. The review focused on the State's compliance in eight components: (1) Civil Rights Assurances; (2) State Infrastructure and Program Accountability; (3) Public Notification; (4) Complaints of Discrimination; (5) Civil Rights Training; (6) Civil Rights Compliance, (7) Program Accessibility to Individuals with Limited English Proficiency; and (8) Compliance with the Age Discrimination Act of 1975.

On August 15, 2023, FSIS determined Ohio's Civil Rights program to be in compliance with "at least equal to" standards for applicable civil rights laws, USDA regulations, and FSIS policies.

XII. COMPONENT 9: FINANCIAL ACCOUNTABILITY

The State is to appropriate funds commensurate with those provided by FSIS as specified in the Cooperative Agreement. Funding is sufficient to ensure the operation of an inspection program consistent with the criteria of the Cooperative Agreement and the satisfactory and uninterrupted operation of State inspection program activities. The State is to ensure that there is appropriate use of Federal funds, adequate accounting support for the State inspection program, and timely and accurate submission of expense reports.

ODA-DMI submitted quarterly and final Federal Financial Reports (SF-425), and an annual Indirect Cost Proposal to demonstrate it conforms to 2 CFR Part 400 Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, and follows FSIS Directive 3300.1, Fiscal Guidelines for Cooperative Inspection Programs.

FSIS determined that ODA-DMI is "at least equal to" Federal standards for financial accountability for FY 2023.

XIII. DETERMINATION FOR OHIO

On June 30, 2023, ODA-DMI submitted an action plan to correct the findings identified during the onsite audit. The action plan identifies the underlying causes of the specific findings at individual establishments and includes a verification plan to ensure statewide correction of these findings. ODA-DMI Inspection personnel reviewed approximately 20 percent of the "equal to" licensed establishments in the State to verify compliance with: HACCP monitoring recordkeeping requirements, Sanitation SOP recordkeeping requirements, and CCP monitoring of an antimicrobial intervention mixing procedure. If there were additional findings the checks would increase to 100 percent of establishments. There were no findings of public health concern that required recalls or enforcement actions. In addition, ODA-DMI provided evidentiary

documents to demonstrate verification of establishment compliance with the regulatory requirements.

Based on the evidence and results described above, FSIS determined that ODA-DMI operates its MPI program "at least equal to" the Federal requirements for all audit components and enforces requirements "at least equal to" those imposed under the Federal Acts.