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FINAL REPORT

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Oregon

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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 initial annual program review of the Oregon Department of Agriculture, Food Safety Animal Health, Oregon State Meat Inspection (Oregon SMI), conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), including an onsite audit conducted July 18-20, 2023. The annual audit process consists of two parts: (1) annual review of the State's self-assessment submissions and (2) triennial onsite audits, which are used to verify whether the State meat inspection (MI) program enforces requirements "at least equal to" the Federal requirements. The purpose of the onsite audit was to: (1) verify the State of Oregon 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.); (2) determine whether Oregon administers a State MI program capable of ensuring meat products produced, distributed, and sold within the State are safe, wholesome, unadulterated, and properly labeled; and (3) confirm the State MI program carries out its regulatory oversight activities effectively and efficiently.

The FSIS 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.

FSIS identified the following findings:

- Oregon has not published governing rules for Oregon Law Chapter 153 (formerly Senate Bill 479).
- Oregon SMI did not recognize instances of HACCP recordkeeping noncompliance when reviewing HACCP records of State-inspected establishments.
- Oregon SMI has not demonstrated its ability to conduct food safety assessments of State-inspected establishments' food safety systems.
- Oregon SMI has not fully demonstrated regulatory oversight procedures relating to establishment operational activities, such as antemortem, post-mortem, sanitation, sanitary dressing procedures, removal and disposal of specified risk materials, control of condemned or inedible materials and HACCP implementation.
- Oregon SMI had minimal sample collection occur since the MI program began operations. Oregon analysis and reaction to results was not demonstrated.
- Oregon SMI's had not fully implemented the staffing, training program, and State supervisory system.
- Oregon SMI had not demonstrated its ability to conducted procedures for verifying State-inspected establishments employ humane methods when slaughtering and handling of livestock.
- Oregon SMI official did not fully understand and demonstrate implementation of custom exempt product per the State requirements.

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

On August 15, 2023, Oregon SMI submitted an action plan to correct the findings identified during the audit. The action plan identifies the corrective actions taken by the State Officials for the in plant noncompliances. This is a newly established State Meat Inspection program. Establishments were granted inspection later in the year, employees were hired, training for inspectors was completed, and Oregon SMI provided evidentiary documents to demonstrate verification of establishment compliance with regulatory requirements. FSIS issued an “at least equal to” with provision determination ding further implementation of the new 153 law, FSAs, sampling methods and results, staffing, training, and supervision activities, humane handling, and custom exempt review process.

Failure to meet the terms of these provisions may result in the recommendation for the Assistant Administrator of OIEA to begin the process to designate the State of Oregon in accordance with the FMIA, and FSIS Directive 5710.1, Designation of States for Federal Meat or Poultry Inspection.

TABLE OF CONTENTS

I. INTRODUCTION	1
II. OBJECTIVE, SCOPE, AND METHODOLOGY	1
III. BACKGROUND.....	1
IV. COMPONENT 1: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS	3
V. COMPONENT 2: INSPECTION	5
VI. COMPONENT 3: SAMPLING PROGRAMS	7
VII. COMPONENT 4: STAFFING, TRAINING, AND SUPERVISION	8
VIII. COMPONENT 5: HUMANE HANDLING	9
IX. COMPONENT 6: COMPLIANCE.....	10
X. COMPONENT 7: LABORATORY METHODS AND QUALITY ASSURANCE PROGRAM	13
XI. COMPONENT 8: CIVIL RIGHTS	14
XII. COMPONENT 9: FINANCIAL ACCOUNTABILITY	14
XIII. DETERMINATION FOR OREGON.....	15

I. INTRODUCTION

This report communicates the results of an initial program review conducted by the U.S. Department of Agriculture’s Food Safety and Inspection Service (FSIS) in Federal fiscal year (FY) 2023 to evaluate Oregon’s administered meat inspection (MI) program to determine if it is “at least equal to” FSIS’ requirements and is capable of ensuring that the State’s supply of meat 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 Oregon SMI program is “at least equal to” the FSIS inspection system.

The “at least equal to” standard requires that State MI 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, FSIS may contribute up to 50 percent of the estimated total cost of the State’s MI 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)).

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, Oregon SMI 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 Oregon SMI 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 Oregon SMI 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.

III. BACKGROUND

The FMIA (21 U.S.C. 661) authorize FSIS to cooperate with State agencies in developing and administering State MI programs. An individual State MI program is limited to meat 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-

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.

mortem inspection, reinspection, sanitation, record keeping, and enforcement provisions of the FMIA (21 U.S.C. 601, et seq.). State MI 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 provides for FSIS to review, at least annually, each State MI program and its requirements and enforcement activities. If a State fails to administer a meat 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).

Annually, non-designated States are expected to assess and support determinations that their inspection programs operate in a manner “at least equal to” the Federal inspection program. FSIS requires State MI 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 MI program and demonstrate the program’s ability to meet the “at least equal to” Federal requirements for the next 12 months. State MI 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 MI 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 MI 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 MI programs at a minimum of every three years to verify the accuracy and implementation of the State MI programs’ self-assessment submissions. In years when a State MI 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.

Oregon SMI, a State organization with the overall authority to administer the State MI 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 the State’s self-assessment documentation and conducted an onsite verification audit of the State MI 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 MI programs through the SRCT. Oregon SMI provides inspection services to only two establishments at this time, FSIS chose to audit both.

Oregon administers the Oregon SMI program under authority of Oregon Revised Statutes (ORS) Chapter 603, ORS Chapter 616, and ORS Chapter 619. Oregon SMI is organized on three levels: State office, State inspection, and compliance program. The program verifies compliance and enforces regulatory requirements at inspected facilities and custom exempt operators.²

FSIS' Federal-State Audit Staff verified through interviews and record reviews that all Oregon SMI personnel are employed by the State of Oregon and are conducting verification activities as outlined in the self-assessment.

The table below details the number of State-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 State Inspected Establishments	Meat Only	1	1	0	2
	Total	1	1	0	2
Number of Custom Exempt Operators	Meat Only	0	65	15	80
	Total	0	65	15	80

IV. COMPONENT 1: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

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

FSIS reviewed the self-assessment documentation submitted as evidence showing that Oregon has enacted laws, administrative rules, and regulations that provide legal authority “at least equal to” that provided under the FMIA, HMSA, and applicable sections of 9 CFR.

The enacted State meat inspection laws, ORS Chapter 603, ORS Chapter 616, ORS Chapter 619, Oregon Administrative Rules (OAR) 603 –028 -0005 and OSR 603 –029 -0010 to end impose, at

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

a minimum, the following mandatory requirements that are “at least equal to” those under the FMIA:

- ante-mortem and post-mortem inspection (OAR 603 -029 -0300 and 603 -029- 0400);
- reinspection (OAR 603 -029 -1100);
- sanitation requirements (ORS 610.026 OAR 603 -029 -2100);
- record keeping requirements (OAR 603 -029 -1300 and 603 -029 -2170);
- humane methods of slaughter requirements (OAR 603 -029 -0700 and 603 -029 -0395);
- adulteration (ORS 616.235 and OAR 603-029-0010);
- misbranding (ORS 616.250);
- prohibited acts (ORS 619.051);
- access and examination (OAR 603 -029 -1300);
- product control actions (OAR 603 -029 -1500); and
- exemption from inspection (OAR 603 -029 -0020).

The ORS Chapter 603, ORS Chapter 616, and ORS Chapter 619 grant the authority to promulgate rules and regulations (OAR 603 -028 -0005 and OAR 603 -029 -0010 to 603 -029 -2505). Oregon Division 29 Rules, (603 -029 -0010 to 603 -029 -2505) are the regulatory rules in place that are consistent with federal regulations in 9 CFR 301.2 to 9 CFR 500 (rules of practice).

The FSIS auditor confirmed through onsite record reviews, interviews, and observations that Oregon SMI has statutory authority to enforce the provisions of ORS Chapter 603, ORS Chapter 616, and ORS Chapter 619 and the governing administrative rules and regulations, (OAR 603 -028 -0005 and OSR 603 -029 -0010 to 603 -029 -2505), respectively, at State inspected establishments and firms handling meat product within the State as outlined in the FY 2023 self-assessment submission.

In June 2023, after an initial onsite verification audit, the State of Oregon passed Senate Bill 479, which is now known as Oregon Law Chapter 153. This law permits the donation of meat to charitable organizations and other organizations that offer food for noncommercial purposes and directs the Oregon Department of Agriculture to imposed governing rules to oversee the meat donation program. The effective date was January 1, 2024. The proposed governing rules for this law required all animals and meat products used for this purpose to undergo State inspection. As of November 1, 2023, Oregon SMI still were developing governing rules for enforcing compliance with requirements of the law but committed to completing the rulemaking process before the enactment date.

FSIS issued Oregon SMI an “at least equal to” with provisions determination for this component until it can be verified that Oregon enacts governing rules for Oregon Law Chapter 153 (formerly Senate Bill 479). At a minimum, the law and governing rules require custom operators to use only Federal or State inspected and passed animals and parts in the production of meat products intended for donation. FSIS will conduct a targeted onsite verification audit in FY 2024 to verify the enactment of this law does not conflict applicable provisions of the FMIA or jeopardize Oregon SMI’s ability to operate a MI program in a manner at least equal to FSIS.

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).

FSIS reviewed the self-assessment documentation submitted as evidence showing that Oregon SMI 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 products;
- A risk-based methodology to analyze establishments’ food safety systems to verify that the establishments can produce safe and wholesome meat 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.

Oregon SMI uses a program called “Be Food Safe” that is analogous to the FSIS Public Health Information System (PHIS) to schedule inspection tasks and to collect, consolidate, and analyze inspection data. Oregon SMI administers inspection for any meat product intended for human consumption, wholly or in part, from the carcass or parts of any animal defined as “livestock” in the OAR (603 -028 -0010) and governing rules, regulations, and policies. The State inspection program maintains assurances that animals intended to be used in meat products sold commercially are slaughtered and processed in the presence of State inspection personnel, and the resulting products are inspected and passed for human consumption. Oregon SMI adopts and implements most relevant FSIS issuances its own policies for carrying out inspection and food safety verification activities.

Sanitation verification (in the form of either “review and observation” or “sanitation recordkeeping”) is conducted each production day. Sanitation verification is conducted according to OAR 603 -029 -2175, following the methodology outlined in Directive 5000.1, Verifying an Establishment’s Food Safety System. Additionally, Oregon SMI will not implement FSIS Directive 5100.4, Public Health Risk Evaluation Methodology, as every firm will receive a food safety assessment (FSA) upon completion of initial validation. Oregon will use the methodology in FSIS Directive 5100.1, Food Safety Assessment Methodology, to conduct FSAs on a 4-year cycle and “for cause” when necessary.

The submitted self-assessment documents provided evidence showing the development and maintenance of a labeling approval system. The Oregon SMI Meat Program Specialist reviews all labels prior to approval. Label information and formulation are evaluated based on OAR 603-029-1002 et seq, which is consistent with 9 CFR part 412. Oregon SMI has created a label review form that is consistent with the FSIS label approval form for identifying and documenting allergens listed in FSIS Directive 7230.1, revision 2. Generic approval of single ingredient labels will be allowed after initial validation of the HACCP system is conducted.

During the onsite audit, FSIS reviewed Sanitation SOP 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 and associated records; custom exempt records; noncompliance records; and enforcement letters. In addition, FSIS reviewed non-food safety consumer protection documents and procedures to determine whether Oregon SMI enforces non-food safety consumer protection regulatory standards “at least equal to” the Federal requirements. Documents reviewed included ongoing regulatory verification tasks, label approvals, labels, and product formulations.

FSIS also observed and evaluated inspection and food safety verification procedures conducted by Oregon SMI at the two State-inspected establishments during the onsite audit. Oregon SMI IIC identified and correctly documented instances of SPS noncompliance during the facility inspections. The FSIS program auditor identified instances of HACCP recordkeeping noncompliance that were overlooked by the Oregon SMI IIC during his records review. In response, Oregon SMI officials initiated regulatory actions at the establishments and issued noncompliance records. FSIS noted that Oregon SMI officials did not terminate the regulatory controls actions until the establishments provided satisfactory corrective measures for the

HACCP recordkeeping noncompliances. FSIS documented these noncompliances as isolated findings. The observed HACCP recordkeeping noncompliances did not affect the establishments' abilities to produce safe products under the applicable HACCP plans.

The FSIS auditor inquired about Oregon SMI's plans to perform FSAs following the establishments' completion of the initial validations of their HACCP systems as stated in the submitted self-assessment documents. In response, Oregon SMI director explained that one State-inspected establishment (slaughter only) had not operated enough days under their HACCP plan for slaughter to complete the 90-day initial validations and the other State-inspected establishment (processing only) was scheduled to undergo an FSA in April 2023. Oregon SMI agreed to submit in SRCT as a part of its FY 2024 self-assessment the completed FSA reports for both establishments. At this time, FSIS cannot verify Oregon SMI's implementation of FSIS Directive 5100.1 until FSIS reviews the FSA reports and interviews Oregon SMI officials who performed the FSAs.

Based on the results of the onsite audit, FSIS issued Oregon SMI an "at least equal to" with provisions determination for this component. The submitted self-assessment documents provided assurances that Oregon SMI developed regulatory inspection and food safety verification procedures that protect public health in manner "at least equal to" FSIS. FSIS could not fully evaluate Oregon SMI's performance of the procedures due to limited slaughter and processing activities conducted during the onsite audit. In 2023, the inaugural year of the Oregon SMI program, the two State-inspected establishments operated no more than two days each week. FSIS' review of Oregon SMI's inspection records confirm this fact. FSIS had limited opportunities to observe Oregon SMI conducting regulatory oversight procedures relating to establishment operational activities, such as antemortem, post-mortem, sanitation, sanitary dressing procedures, removal and disposal of specified risk materials, control of condemned or inedible materials and HACCP implementation. In addition, limited performance of these regulatory oversight procedures prevented FSIS from objectively assessing the effectiveness of Oregon SMI's Component 2 internal control system.

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.

Oregon SMI provided documentation to demonstrate that it 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.

FSIS examined Oregon SMI's product sampling documents, protocols, procedures, and results presented during the onsite audit. FSIS confirmed Oregon SMI implements most relevant FSIS issuances as their own policies for collecting samples, maintaining sample integrity, determining sampling frequencies, conducting sample analyses, responding to positive results, and preventing adulterated product from entering commerce. Additionally, Oregon SMI participates in the National Residue Program and collects and analyzes inspector-generated samples for violative drug residues.

FSIS noted that Oregon SMI's records show minimal sample collection has occurred since the MI program began operations in July 2022. Due to the very low production volume of the only State-inspected establishment producing RTE products, Oregon SMI collected one environmental and three food contact surface swabs quarterly under its modified *RLm* sampling program and two post-lethality exposed RTE products annually under the RTE-PROD sampling program. The second State-inspected establishment had not completed the slaughter HACCP plan's 90-day validation at the time of the onsite audit; therefore, the program's record documented no regulatory samples were collected under its raw beef sampling programs. The FSIS Auditor interviewed both the Oregon SMI director and IIC (former FSIS employees) to evaluate whether the actual sample collection procedures complied with the procedures described in the self-assessment documents. Oregon SMI did not collect any regulatory samples during the onsite audit.

Based on the results of the onsite audit, FSIS issued Oregon SMI an "at least equal to" with provisions determination for this component. The submitted self-assessment documents demonstrated that the Oregon SMI program developed sampling programs focused on adulterants and performance standards outlined in current FSIS regulations and policies. FSIS was unable to determine if the State MI program utilizes product sample collection procedures and safeguards described in the submitted self-assessment documents. Thus, FSIS notified Oregon SMI of its plan to conduct a targeted onsite audit in FY 2024 to observe and evaluate the program's sample collection procedures.

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 has reviewed the documentation submitted by Oregon SMI and confirmed that Oregon SMI has developed administrative programs for competent inspection coverage in State-inspected meat establishments. Oregon SMI's training program includes formal and informal job-related courses, and its State supervisory system ensures that strong performance is recognized, and unsatisfactory performance is corrected. With a limited workforce of three full-time employees, Oregon SMI can provide inspection services for two State-inspected establishments.

FSIS was unable to assess the effectiveness of Oregon SMI's Component 4 internal control system due to limited monitoring data. FSIS has issued Oregon SMI an "at least equal to" with provisions determination for this component and plans to conduct a targeted onsite audit to ensure its internal control system is effective. Overall, Oregon SMI is well-positioned to provide effective inspection services with its administrative programs, training program, and State supervisory system.

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.

Humane handling information was not submitted for review in FY 2022 as Oregon SMI did not have an operating State-inspected establishment that slaughtered livestock until March 2023. FSIS reviewed humane handling policies, ante-mortem inspection reports, noncompliance records, and periodic supervisory review records during the onsite audit in July 2023.

During the onsite audit, the FSIS auditor conducted a review of Oregon SMI's developed procedures and policies for verifying humane handling compliance and confirmed the program adopted with minor modifications FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock. The modified policy instructed Oregon SMI inspectors to document the results of humane handling verifications in the 'Be Food Safe' system and on Oregon SMI Meat Inspection Field Logs instead of PHIS. The reviewed documents also included noncompliance records and procedure schedules.

The FSIS auditor evaluated the humane handling of livestock, stunning methods, and the condition of antemortem facilities (such as livestock pens, driveways, and ramps) while performing an antemortem procedure review at the only State-inspected establishment that slaughters livestock. The observed antemortem procedures and humane handling practices were found to be satisfactory. The establishment's antemortem facilities, including the holding pen for

suspected animals, complied with the requirements of 9 CFR 309 and 416. At the time of the review, the only State-inspected establishment that slaughters livestock operated one or two days a week since it opened in March 2023. The establishment is still in the process of validating its food safety system.

Oregon SMI adopted FSIS Directive 6910.1, District Veterinary Medical Specialist (DVMS) - Work Methods, as the instructional policy for the Oregon SMI public health veterinarian (PHV) to follow when performing annual humane handling audits at slaughter establishments. The FSIS auditor was not able to evaluate the PHV's performance of a DVMS review because the slaughter facility operated infrequently. Therefore, the Oregon SMI's PHV needs to perform more DVMS reviews before FSIS can objectively verify compliance with FSIS Directive 6910.1. Once this is done, FSIS can review the outcome of that process during the targeted onsite audit scheduled to occur in FY 2024.

FSIS issued Oregon SMI an "at least equal to" with provisions determination for this component and plans to re-evaluate Oregon SMI's implementation of all humane handling verification procedures and related internal controls during the scheduled targeted onsite audit.

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);
- 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);
- Ensure establishments maintain written recall procedures for all meat and poultry products produced and shipped (21 U.S.C. 613);
- 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 withdrawal inspection services as warranted (21 U.S.C. 671). 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).

FSIS reviewed submitted self-assessment documents and confirmed Oregon SMI is still in the process of developing a compliance program and a system to enforce food safety, food defense, inspection exemption, and other consumer protection statutory requirements in intrastate commerce. The State MI program has adopted FSIS directives to:

- Conduct surveillance activities and investigations, as warranted, of firms producing meat 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 were limited to custom exempt facility review reports, surveillance activity reports and reports of investigations.

The audit of compliance documents and case files support the conclusion that Oregon SMI has adopted 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 products in intrastate commerce.

Oregon SMI has adopted the procedures and methods 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 ORS 603 -029 -0010. In addition, Oregon SMI has adopted procedures and methods in accordance with FSIS Directive 8010.4, Report of Investigation.

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

Oregon SMI established methods to record, triage, analyze, and track consumer complaints related to State regulated meat 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. Currently, all consumer complaints received have been related to FDA regulated products as no State inspected meat product has been produced.

Oregon SMI has a system that includes procedures for reviewing custom exempt operations that differs slightly from the procedures outlined in FSIS Directive 8160.1, Custom Exempt Review Process. Custom exempt reviews are conducted annually by the Oregon Department of Agriculture (ODA), Food Safety Program's Retail Food Safety Specialists at firms licensed to operate only as custom exempt facilities. Oregon SMI conducts custom exempt facility reviews at State-inspected establishments that also provide custom-exempt services.

ORS 603.045 to 603.065, and ORS 619.021 to 619.066 grant the Oregon Department of Agriculture, Food Safety Program's Retail Food Safety Specialists oversight authority of Oregon meat handlers licensed to operate only as custom exempt facilities. Since OAR 603 -029 - authorizes Oregon SMI to regulate custom exempt activities at State-inspected establishments, the two State agencies collaborate to ensure all custom exempt operators comply with labeling and sanitation requirements of OAR 603-029-1002 et seq. In March 2023, Oregon SMI began conducting custom exempt reviews of State-inspected establishments in accordance with FSIS Directive 8160.1, Custom Exempt Review Process. The results of the custom exempt reviews were shared with the Food Safety Program. Oregon SMI conducted follow-up reviews for any noncompliance observed during the initial custom exempt review. The Oregon SMI Program

Manager sets the timeline for conducting a follow-up review based on the severity of the noncompliance observed during the initial review. FSIS determined that this procedural difference presented in the self-assessment documents did not impact Oregon SMI's ability to meet the intent of the FSIS policies.

During the onsite audit, the FSIS auditor observed an Oregon SMI official detain a tub of product labeled "pool" in accordance with FSIS Directive 8410.1, Detention and Seizure, while performing a custom exempt facility review. Further inspection and a brief interview with the custom exempt operator revealed that the pooled product was collected from the trimmings of single-owner animals slaughtered and processed under the custom exemption. The custom-exempt operator intended to use the pooled product as a source material for making a raw sausage to be shared with the individual owners of the animals. The custom operator stated that the reason for pooling the product was that each owner's animal did not yield enough source material during processing to make a sausage batch specifically for the owner. Instead, the operator chose to make a sausage batch from the pooled trimmings collected from all animals and share equal portions of the batch with the owners. The Oregon SMI official responded by informing the custom exempt operator that the practice violated OAR regulations and planned to release the pooled product to the custom operator for use. FSIS intervened and explained that releasing the commingled custom exempt product violated section 623 (a) of FMIA and regulatory procedures outlined in FSIS Directive 8410.1. The FMIA requires custom operators to return to each owner custom prepared meat products from animals of their own raising, exclusively for use in the household of such owner, household members, and nonpaying guests and employees. After a discussion, the Oregon SMI official decided to maintain the detention of the pooled product and ensure that it was destroyed by the custom operator. FSIS documented the events of this situation as a systemic finding, which highlights the need for increased awareness and adherence to regulations to prevent such practices in the future.

Following the onsite audit, Oregon SMI submitted an action plan on August 15, 2023, addressing this systemic finding and other findings identified during the onsite audit. The action plan identifies the underlying causes of the specific findings and provide assurances for correcting all findings statewide. FSIS raised concerns about Oregon SMI's handling of the pooled custom exempt product, especially knowing that the enactment of Oregon Law Chapter 153 (formerly Senate Bill 467) permits livestock owners to use the services of custom exempt operators to slaughter livestock and process meat products for donation to charitable organizations. Oregon Law Chapter 153 tasked the Oregon Department of Agriculture with developing and implementing administrative rules for governing the meat donation program outlined within the requirements of this law.

FSIS issued Oregon SMI an "at least equal to" with provisions determination for this component. Based on FSIS' finding and observations, Oregon SMI is developing with assistance from OIEA's Compliance Investigation Division. This decision will stand until FSIS conducts a targeted audit in FY 2024 to assess the competency of Oregon SMI compliance officers and Oregon SMI's implementation of governing rules for Oregon Law Chapter 153.

X. COMPONENT 7: LABORATORY METHODS AND QUALITY ASSURANCE PROGRAM

State MI programs must use product sampling and laboratory methods with capabilities and safeguards “at least equal to” FSIS’ Federal inspection program’s product sampling and laboratory methods. State MPI programs are required to update and maintain their laboratory microbiological and chemical detection methods so they are “at least equal to” FSIS’ Federal inspection program methods, as detailed in the FSIS Microbiology Laboratory Guidebook and USDA FSIS Chemistry Laboratory Guidebook.

An onsite audit of the Oregon Department of Agriculture Laboratory Services (ODALS) was performed during FY 2023 to evaluate laboratory quality assurance programs and method equivalence under the State MI Program.

The ODALS conducts microbiological testing for *Salmonella*, top seven Shiga Toxin producing *E. coli* (STEC), and *L. monocytogenes*. The Wisconsin Department of Agriculture, Trade and Consumer Protection Bureau of Laboratory Services (Wisconsin) conducts food chemistry testing on ODALS’ behalf to include moisture, protein, fat, and salt.

FSIS compared the ODALS 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. ODALS met all Laboratory Quality Assurance (QA) requirements. Wisconsin met all Laboratory QA requirements based on the self-assessment provided by the laboratory.

Wisconsin has demonstrated adequate food chemistry capability for the measurement of moisture, protein, fat, and salt. ODALS has demonstrated adequate microbiology capabilities for the detection of *Salmonella*, STEC, and *L. monocytogenes*.

Based on the Component 7 methods and quality assurance program review, Oregon 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 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. Note:

Analytical methods for *Salmonella* and *Campylobacter* in raw poultry products were not evaluated as Oregon is not currently inspecting poultry establishments slaughtering at least 20,000 chickens and/or turkeys per year.

XI. COMPONENT 8: CIVIL RIGHTS

The State MI program adheres 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 April and May 2023, Oregon SMI 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 Oregon SMI. 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 September 11, 2023, FSIS determined the Oregon'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 appropriates 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 ensures that there is appropriate use of Federal funds, adequate accounting support for the State inspection program, and timely and accurate submission of expense reports.

Oregon Department of Agriculture 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 (March 2004). The FSIS determined that Oregon Department of Agriculture is "at least equal to" Federal standards for financial accountability for FY 2023.

Following the State of Oregon Department of Agriculture's recent integration into the FSIS' Meat Inspection Program (MI), FSIS conducted an evaluation to ensure compliance and alignment with Federal standards for financial accountability. This evaluation comprised a virtual desk review within the initial 90 days and an in-person onsite financial accountability verification review. FSIS' assessment affirms that the State of Oregon Department of Agriculture is operating "at least equal to" the Federal standards during FY 2023.

XIII. DETERMINATION FOR OREGON

Based on the evidence and results discussed above, FSIS determined that Oregon SMI conditionally operates its MPI program "at least equal to" the Federal requirements for Components 1-6. This determination is contingent upon the program's completion and submission of the next FY self-assessment including target onsite:

- Oregon publishing and implementing governing rules for Oregon Law Chapter 153 (formerly Senate Bill 479).
- Oregon SMI completed FSA reports that follow FSIS Directive 5100.1 and enforcement actions if necessary.
- Demonstration of antemortem, post-mortem, sanitation, sanitary dressing procedures, removal and disposal of specified risk materials, control of condemned or inedible materials and State official evaluations of establishment HACCP implementation.
- Implementation of the sampling program and analysis and reaction to the results for all required HACCP categories.
- Evidence of the regular staffing, training program, and State supervisory system.
- Written procedures and evidence of humane handling activities, including DVMS reviews and related internal controls.
- Demonstration of the State properly implementing the custom exempt requirements as identified in the State procedures.

FSIS issued Oregon SMI an "at least equal to" with provisions determination. This decision will stand until FSIS conducts a targeted audit in FY 2024.

Failure to meet the terms of these provisions may result in the recommendation for the Assistant Administrator of OIEA to begin the process to designate the State of Oregon in accordance with the FMIA, and FSIS Directive 5710.1, Designation of States for Federal Meat or Poultry Inspection.