Appendix AA

Comprehensive Review and Determination Report

Fiscal Year 2021

Wyoming

Federal-State Audit Staff
Office of Investigation, Enforcement and Audit
Food Safety and Inspection Service
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Purpose
This report communicates the United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS), Office of Investigation, Enforcement and Audit (OIEA), Federal-State Audit Staff’s (FSAS) annual review results and determination for the Wyoming Meat and Poultry Inspection (MPI) program and presents an overview of the review methodology used for determining if the State MPI program is “at least equal to” FSIS’ MPI program.

Description of Wyoming’s MPI Program
The Wyoming Department of Agriculture, Consumer Health Service (WDA/CHS) administers the Wyoming MPI program under authority of the Wyoming Food, Drug and Cosmetic Safety Act (Section 35-7-123). The program verifies compliance and enforces regulatory requirements at 10 inspected facilities and 28 custom exempt establishments1.

Annual Determination
FSIS determined that WDA/CHS is operating a meat and poultry inspection program “at least equal to” the Federal requirements. This determination was based on: (1) FSIS’ annual desk review of the self-assessment documents, and (2) FSIS’ targeted onsite review. This determination is fully explained in the sections entitled “Part I – Self-Assessment Review” and “Part II – Targeted Onsite Review.”

Part I. Self-Assessment Review

Part I includes the following:
• Description of the Self-Assessment Review Methodology followed for all State MPI programs;
• Review of Wyoming’s Self-Assessment Submission; and
• Self-Assessment Determination for Wyoming.

Self-Assessment Review Methodology
The annual self-assessment is designed for each State MPI program to provide sufficient information to adequately demonstrate an “at least equal to” program. The self-assessment submission provides documentation regarding the State’s laws, rules, policies, procedures, and programs to provide a basis for FSIS to determine whether the State MPI program meets the “at least equal to” Federal requirements standard. The self-assessment documents are to include evidence and documentation to support that the State MPI program’s processes are in effect and current with FSIS policies. Following this submission, FSIS thoroughly reviews the self-assessment documentation.

FSIS’ review of the self-assessment submissions begins with the formation of a review team. The review team, comprised of Agency representatives from FSAS, Civil Rights Staff (CRS), Financial Reviews and Systems Branch (FRSB), Laboratory Quality Assurance Responses and Coordination Staff (LQARCS), and other program areas, as needed, evaluates each State MPI

1 Custom exempt establishments are slaughter and processing establishments that are not subject to the routine inspection requirements of the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), provided the specified operations meet the exemption requirements (21 U.S.C. 623 and 464).
program’s self-assessment submission to determine whether it meets the “at least equal to” criteria for all nine review components.

If questions arise during the self-assessment review, or if more information or supporting documentation is needed, FSIS will request the State MPI program to submit further clarifying information. Following reviews of the submitted information, a final determination will be made based on the self-assessment submission in its entirety. FSIS will make one of the following three determinations for each component and for the State’s overall ability to maintain an MPI program “at least equal to” the Federal requirements:

1. “At Least Equal To” means the State MPI program has adopted laws, regulations, and programs, and implemented them in a manner that is “at least equal to” FSIS’ Federal inspection program for all review components.

2. “At Least Equal To” with Provisions means FSIS makes a provisional determination of the State MPI program’s “at least equal to” status provided the program takes additional action to resolve review findings.

3. Not “At Least Equal To” means the State MPI program has not adopted laws, regulations, or programs, or does not implement them in a manner that is “at least equal to” FSIS’ Federal inspection program for one or more of the review components.

**Review of Wyoming’s Self-Assessment Submission**
FSIS evaluated the self-assessment documents for the nine review components to determine whether WDA/CHS implements an inspection program “at least equal to” the Federal program. The determination and rationale for each review component are listed below.

FSAS received WDA/CHS’s self-assessment submission for components 1 through 6 on October 30, 2020. FSAS sent a notification to WDA/CHS requesting additional information. WDA/CHS sent additional information clarifying their self-assessment submission and all supplementary information requested. FSAS reviewed the submitted clarification items, and accepted the requested information on January 15, 2021.

**Component 1 – Statutory Authority and Food Safety Regulations**
FSAS compared the submitted self-assessment and supporting documentation to the legal authority provided under the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Humane Methods of Slaughter Act (HMSA), and the regulations promulgated under these laws. The supporting documentation included the Wyoming Food, Drug and Cosmetic Safety Act (Title 35, Chapter 7, Article 1) and the Wyoming Food Safety Rule (Chapter 14, Section 1). The Wyoming Food Safety Rule adopts the FMIA, PPIA, and HMSA (Chapter 14, Section l(a)(ii)) and Title 9, Code of Federal Regulations (9 CFR) Parts 301-307, 309-321, 325, 329, 352, 354, 362, 381, 412, 416-418, 424, 430, 441, 442, 500, and 590 (Chapter 14, Section 1(a)(i)). Therefore, Wyoming Statutes provide the required statutory and regulatory authorities for mandatory ante-mortem and post-mortem inspection, reinspection, sanitation requirements, record keeping requirements, and humane methods of slaughter requirements.
In addition, the Wyoming Food, Drug and Cosmetic Safety Act provides authorities that are “at least equal to” the FMIA and PPIA regarding adulteration and misbranding (Section 35-7-116), prohibited acts (Section 35-7-111), access and examination (Section 35-7-121), and product control actions (Section 35-7-114). It also includes sufficient authorities for criminal, civil, and administrative sanctions to address violators.

The Wyoming Food, Drug and Cosmetic Safety Act grants the authority to promulgate rules and regulations (Section 35-7-120). WDA/CHS adopts by reference 9 CFR Parts 301-307, 309-321, 325, 329, 352, 354, 362, 381, 412, 416-418, 424, 430, 441, 442, 500, and 590 in the Wyoming Food Safety Rule (Chapter 14, Section 1(a)(i)).

On February 20, 2020, FSAS was made aware of proposed legislation, House Bill 0155 (WY HB0155), to amend the Wyoming Food Freedom Act (WFFA), Wyoming Statute (W.S.) 11-49-101, et seq. The new legislation, W.S. 11-49-104 (“Animal Shares”), appeared to create an exemption from inspection based on shared animal-ownership that could allow for the distribution of uninspected meat products pursuant to this ownership. FSIS expressed concerns because the proposed legislation could potentially conflict with provisions of the FMIA (21 U.S.C. Section 601, et seq.). WY HB0155 was passed by the Wyoming legislature on March 17, 2020 and was enacted on July 1, 2020. At the time of enactment, it was unclear whether the WDA/CHS had authority to impose sanitation, labeling, and recordkeeping requirements outlined for custom exempt operations in the Wyoming Food, Drug and Cosmetic Safety Act (Title 35, Chapter 7, Article 1) and the Wyoming Food Safety Rule (Chapter 14, Section 1) on slaughter and processing activities covered by W.S. 11-49-104. Consequently, FSIS identified the enactment of W.S. 11-49-104 as potentially jeopardizing the State of Wyoming’s “at least equal to” status.

In response to the expressed concerns, WDA/CHS explained that the Wyoming Food, Drug and Cosmetic Safety Act still grants the MPI program the authority to impose all applicable statutory and regulatory requirements at custom exempt operations, despite the enactment of W.S. 11-49-104. WDA/CHS noted that Section 35-7-124 of the Wyoming Food, Drug and Cosmetic Safety Act requires all meat and poultry handlers to be licensed by the State of Wyoming’s regulatory authority, WDA/CHS, before doing business. This provision requires WDA/CHS to impose the applicable requirements of 9 CFR 300 to end, at the facilities of custom operators, despite the WFFA’s omission of language prescribing the regulatory oversight of the animal share program. The MPI program imposes the Wyoming Food, Drug and Cosmetic Safety Act (Section 35-7-123) and applicable sections of the Wyoming Food Safety Rule at custom exempt operations and can withdraw licenses of custom exempt operators that fail to comply. State livestock brand inspection is required by the Wyoming Livestock Board (Chapter 17 Brand Inspection and Recording Permits of the Wyoming Administrative Rules, and the Food Freedom Act Section 11-49-109(h)). This requires livestock sold and slaughtered in the same county to have a bill of sale and livestock sold in a different county to have a brand inspection. Both documents have specific requirements pertaining to the ownership of the livestock, (ie. Name, address, and contact information).

From January 25, 2021 to February 5, 2021, FSAS conducted a targeted onsite review of the Wyoming MPI program’s enforcement of the Wyoming Food, Drug and Cosmetic Safety Act, as
well as all applicable requirements of 9 CFR Part 300 to end, as related to transactions conducted under W.S. Section 11-49-104 before making a final “at least equal to” determination for FY 2021. The results of the review are documented in Part II of this report.

Component 2 – Inspection
FSAS compared the self-assessment submission and supporting documentation regarding inspection policies and procedures and regarding verification of establishments’ compliance, to the Federal requirements. WDA/CHS uses the USA Food Safety system to schedule inspection tasks and to collect, consolidate, and analyze inspection data. The USA Food Safety system also maintains data security and integrity “at least equal to” the Federal requirements.

Inspectors complete USA Food Safety system inspection records for each day of inspection to include:
- Operational processing categories and inspected areas;
- Inspection results;
- Noncompliance findings identified with regulatory references; and
- Establishments’ corrective actions and dates of completion.

WDA/CHS management reviews inspected establishments quarterly. These quarterly reviews examine establishment conditions, Good Manufacturing Practices, Sanitation Standard Operating Procedures (Sanitation SOP), Sanitation Performance Standards (SPS), Hazard Analysis and Critical Control Point (HACCP) systems, sampling reports, USA Food Safety system inspection reports, and enforcement records.

WDA/CHS verifies that establishments develop, implement, and maintain Sanitation SOPs and HACCP systems. In addition to the inspectors’ ongoing verification activities, WDA/CHS routinely schedules and performs a comprehensive Food Safety Assessment (FSA) at each inspected establishment. These FSAs examine the design and validity of the establishment’s food safety systems, which include hazard analyses, supporting documents, HACCP plans, Sanitation SOPs, prerequisite programs, sampling programs, and any other programs that constitute the establishment’s HACCP systems. The noncompliance records, FSA records, notices of intended enforcement, and verification plans included with WDA/CHS’s self-assessment submission support the conclusion that State inspection personnel recognize and document noncompliance, and that they initiate appropriate regulatory actions.

WDA/CHS addressed new FSIS issuances distributed through FSAS’ quarterly new issuance program and met “at least equal to” expectations for incorporating the new policies and instructions into their inspection program.

WDA/CHS verifies establishment compliance with the non-food safety (i.e., labeling) consumer protection regulatory requirements. WDA/CHS uses applicable FSIS directives to instruct inspection personnel and it uses the USDA Food Safety system and database to schedule ongoing verifications and document noncompliance. A thorough review of the USA Food Safety system data for a 12-month period supports the conclusion that WDA/CHS inspectors correctly apply the inspection methodology and document noncompliance.
WDA/CHS maintains a label approval policy and process to verify that labels are accurate and meet regulatory requirements. Prior to applying a label, mark, or device to an inspected meat or poultry product, an establishment representative must submit a completed application for label approval and a label sketch to obtain WDA/CHS approval.

WDA/CHS enforces the Wyoming Food Safety Rule (Chapter 14, Section 1 (a)(i)), which adopts by reference 9 CFR Part 500, Rules of Practice, when establishments do not comply with State authorities that are “at least equal to” the FMIA and PPIA. WDA/CHS maintains procedures to document relevant facts of administrative actions and ensure that administrative actions are legally supportable and based on relevant facts.

The submitted documents support the conclusion that WDA/CHS:

- Performs inspection and regulatory verification procedures to confirm that State-inspected establishments comply with applicable regulations;
- Maintains a system to carry out administrative enforcement actions when establishments do not comply with State authorities that are “at least equal to” the FMIA and PPIA;
- Conducts inspection activities “at least equal to” the Federal requirements; and
- Monitors these activities through control measures to verify that the inspection system functions as intended.

**Component 3 – Sampling Programs**

FSIS compared WDA/CHS’ sampling protocols, procedures, and results to Federal policies and procedures.

WDA/CHS provided documentation to demonstrate that it maintains sampling programs, based on sound rationale and goals, for the following:

- *Escherichia coli* (*E. coli*) O157:H7 in raw non-intact beef products and raw ground beef components;
- Non-O157 Shiga toxin-producing *E. coli* (non-O157 STEC) in beef manufacturing trimmings;
- *Listeria monocytogenes* (*L. monocytogenes*) and *Salmonella* in ready-to-eat products;
- *Salmonella* performance standards in raw classes of meat; and
- Other consumer protection standards.

The sampling plans include procedures for sample collection, sample integrity, and laboratory analysis. WDA/CHS developed policies to respond to positive results. These policies include actions to prevent adulterated product from entering commerce. WDA/CHS participates in the FSIS National Residue Program and collects and analyzes inspector-generated samples for violative drug residues.

In conclusion, a detailed review of the sampling protocols, procedures, and results confirmed that WDA/CHS 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. WDA/CHS has control measures in effect to confirm that its product sampling system functions as intended.

Component 4 – Staffing, Training, and Supervision

WDA/CHS developed methods to determine staffing requirements. The requirements consider each inspector’s workload and the number of inspectors required to provide daily inspection coverage in each establishment on days when the establishment produces products bearing the State mark of inspection. Procedures are in effect to document staffing in each establishment, identify failures to meet staffing requirements, and correct staffing deficiencies. Inspectors submit their weekly schedule to the State Office and follow State policies to arrange relief inspection. Supervisors may also use the Meat Plant Coverage Form to arrange relief inspection during routine leave situations. Additionally, WDA/CHS personnel complete a USA Food Safety system inspection record in each establishment on each day they perform inspection activities.

At the start of the FY 2021 review cycle, WDA/CHS indicated they employ 2 managers, 1 administrative staff member, 3 field supervisors, 9 inspectors, and 12 relief inspectors, of which 3 inspectors also conduct compliance officer activities. Inspectors also perform surveillance and other consumer health activities, such as swimming pool, day care, and restaurant inspection. Though not all WDA/CHS employees routinely perform inspections in State-inspected establishments, all employees received training to provide coverage in those establishments as needed. WDA/CHS maintains contracts with local veterinarians for veterinary dispositions and coverage of slaughter inspection, if necessary.

WDA/CHS continues to implement a training program for new entry-level inspection personnel. The training covers basic slaughter techniques and all inspection techniques required to perform slaughter duties, including basic Sanitation SOPs and HACCP procedures. New entry-level inspectors receive on-the-job training with supervisors and journeyman inspectors prior to working on their own. After the inspectors complete the probationary period, supervisors work with each inspector at least eight hours every quarter. WDA/CHS employees also complete inspection methods training.

WDA/CHS incorporates the guidance in FSIS Directive 4430.3, In-Plant Performance System (IPPS), to set performance standards, and complete and record ongoing performance evaluations. WDA/CHS communicates employees’ work responsibilities, performance goals and objectives through a series of WDA/CHS procedures and policies. As a part of these procedures and policies, supervisors assess inspectors’ performance and provide feedback and guidance during quarterly establishment reviews. The supervisor documents the results of the quarterly reviews in the USA Food Safety system and database. The WDA/CHS manager reviews supervisors’ quarterly reports. In addition, Wyoming mandates a performance plan and evaluation system for all State employees. This system communicates to its employees their work responsibilities, performance goals and objectives, and the results of their annual performance evaluations.

After thorough review of the submitted documents, FSIS concluded that WDA/CHS has sufficient resources to provide the required inspection coverage at State-inspected establishments to ensure that only safe, wholesome, unadulterated, and properly labeled meat and poultry
products receive the State mark of inspection. The information supports the conclusion that inspection personnel have the education and training needed to apply WDA/CHS’s inspection methodology, to document findings, and to initiate regulatory actions when necessary. Control measures are in effect to confirm that WDA/CHS’s staffing and training systems function as intended.

Component 5 – Humane Handling
WDA/CHS schedules and performs regulatory verification procedures to assess whether establishment personnel humanely handle all livestock throughout the time the livestock are on official establishment premises, and it takes appropriate regulatory action in response to noncompliance.

WDA/CHS uses FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock, to communicate instructions to inspection personnel. Inspectors perform humane handling verification activities on each day of slaughter and document the results in the USA Food Safety system database. Supervisors assess establishments’ compliance with humane slaughter of livestock regulatory requirements and inspectors’ performance of humane handling verification procedures at least annually and use FSIS Directive 6910.1, District Veterinary Medical Specialist (DVMS) - Work Method as guidance to conduct the reviews.

In conclusion, the information supports the fact that WDA/CHS verifies compliance with the humane handling requirements and takes regulatory action “at least equal to” the Federal program. Control measures are in effect to confirm that the humane handling verification system functions as intended.

Component 6 – Compliance
WDA/CHS personnel conduct in-commerce surveillance of persons or firms that prepare, transport, sell, or offer for sale meat and poultry products in intrastate commerce to verify compliance with State statutory and regulatory requirements, and to verify that meat and poultry products in intrastate commerce are wholesome; correctly packaged and labeled; and are secure from threats or intentional acts of contamination.

WDA/CHS investigates alleged or actual statutory or regulatory violations; controls products when there is reason to believe that the products are adulterated, misbranded or otherwise in violation of the Wyoming Food, Drug and Cosmetic Safety Act or the Wyoming Food Safety Rule; and takes enforcement action, when needed, up to and including prosecution of individuals or firms that have violated the Wyoming Food, Drug and Cosmetic Safety Act or the Wyoming Food Safety Rule. WDA/CHS has procedures to maintain and preserve the legal integrity of documentary and other evidence to support legal action, and to report transportation accidents that involve State-inspected and passed meat and poultry products.

WDA/CHS management reviews all compliance reports for correctness, extracts pertinent information for reporting purposes, enters this information in a database, and files the hard copies. The WDA/CHS manager reviews all violations and relevant evidence and determines the appropriate case disposition and course of action.
WDA/CHS maintains procedures for the recall of meat and poultry products subject to its jurisdiction that are “at least equal to” the procedures described in FSIS Directive 8080.1, Recall of Meat and Poultry Products. These procedures include health hazard evaluation, recall classification, public notification, effectiveness checks, and closure. Firms are required to notify WDA/CHS within 24 hours of initiating a recall. WDA/CHS oversees the recall activities, coordinates actions to determine whether adulterated product was removed from commerce, and issues news releases as necessary to serve the interest of public health.

WDA/CHS established methods to record, triage, analyze, and track consumer complaints related to State-regulated meat or poultry products. Compliance personnel either investigate these complaints or refer them to the local health authority. The investigative methods include procedures to collect and safeguard evidence; conduct interviews; submit product samples to the laboratory; initiate recall procedures and/or regulatory and enforcement actions; and report potential food safety threats.

WDA/CHS reviews custom exempt operations in accordance with FSIS Directive 8160.1, Custom Exempt Review Process. WDA/CHS has a system for reviewing custom exempt operations that is in accordance with FSIS Directive 8160.1, Custom Exempt Review Process. WDA uses an “at least equal to” document, Meat Plant Inspection Policy, as guidance to perform custom exempt inspections. To clarify the terminology used, a custom exempt “inspection” is equivalent to a custom exempt review. A custom exempt “review” is equivalent to the management controls in place by the State.

The submitted documents support the conclusion that WDA/CHS maintains a system to verify compliance of meat and poultry products in intrastate commerce and takes appropriate enforcement actions in the event that adulterated or misbranded products enter intrastate commerce. Control measures are in effect to confirm that the compliance program functions as intended.

Component 7 – Laboratory Methods and Quality Assurance Program
An off-site records review of the Wyoming Department of Agriculture – Analytical Services Laboratory (WDA-ASL) was performed during FY21 to evaluate laboratory quality assurance programs and method equivalence under the State MPI Program.


FSIS compared the WDA-ASL 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. Based on their self-assessment, WDA-ASL met all laboratory quality assurance (QA) requirements including analysts’ training and related proficiency testing.

WDA-ASL has demonstrated adequate food chemistry capability for the measurement of moisture, protein, fat, and salt. WDA-ASL has demonstrated adequate microbiological
capabilities for detection of *Salmonella, E. coli O157:H7, L. monocytogenes*, and non-O157 STEC.

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

- At beef establishments producing raw ground beef and bench trim, and at beef slaughter establishments producing manufactured trim, provided the State collects and submits the appropriate number of samples that are tested for *Salmonella, E. coli O157:H7, and non-O157 STEC*.

- At ready-to-eat meat and poultry establishments, provided the State collects and submits the appropriate number of samples that are tested for *Salmonella and L. monocytogenes*.

- At poultry slaughter establishments, provided the State collects and submits the appropriate number of samples 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 the raw product for *Salmonella and Campylobacter* since it is not required at similar federally inspected plants. However, States should consider testing at a risk hierarchy that is commensurate with their establishment sizes and production volumes. Note: Analytical methods for *Salmonella* and *Campylobacter* in raw poultry products were not evaluated as Wyoming is not currently inspecting MPI program poultry establishments slaughtering at least 20,000 chickens and/or turkeys per year.

**Component 8 – Civil Rights**

WDA/CHS 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. CRS concluded that WDA/CHS functions “at least equal to” the Federal civil rights requirements.

**Component 9 – Financial Accountability**

WDA/CHS submitted quarterly and final Federal Financial Reports (SF-425), and an annual Indirect Cost Proposal to demonstrate it conforms to 7 CFR, Part 3016, Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments, and follows FSIS Directive 3300.1, Rev.2, Fiscal Guidelines for Cooperative Inspection Programs. FRSB determined that WDA/CHS is “at least equal to” Federal standards for financial accountability for FY 2021.

**Self-Assessment Determination for Wyoming**

Based on the submitted self-assessment documents and desk review results described above, FSAS determined that WDA/CHS provided adequate documentation to show it is operating a meat and poultry inspection program “at least equal to” the Federal requirements.
Part II. Targeted Onsite Review

Part II includes:

- A description of the onsite review methodology followed for all State MPI programs;
- An onsite review of Wyoming; and
- An onsite determination for Wyoming.

Onsite Review Methodology

The onsite review determines whether the State implements its MPI program in a manner that is “at least equal to” the Federal inspection program and maintains program policies and procedures in accordance with those submitted in the annual self-assessment documents. The FSIS onsite review team is comprised of representatives from FSAS, CRS, FRSB, LQARCS, and other program areas as needed. FSIS Directive 5720.3, Methodology for Performing Scheduled and Targeted Reviews of State Meat and Poultry Inspection Programs, outlines the comprehensive State MPI program review process.

As the primary contact for State MPI program officials and FSIS review team members, the lead FSAS program auditor is to coordinate and track components 1 through 6 onsite review activities and to monitor the status of components 7 through 9 reviews through communications with LQARCS, CRS, and FRSB. The FSAS auditor schedules the onsite review, for components 1 through 6, with State MPI program officials. FSAS will send written notification to State MPI program officials at least 30 days prior to the start of the onsite review. LQARCS, CRS, and FRSB are to schedule onsite reviews of components 7 (laboratory methods and quality assurance program), 8 (civil rights), and 9 (financial accountability), respectively.

Upon completion of an onsite review, FSIS is to make one of the following three determinations for each component and the State’s overall ability to maintain its MPI program “at least equal to” the Federal requirements:

1. “At Least Equal To” means the State MPI program has adopted laws, regulations, and programs, and implemented them in a manner that is “at least equal to” FSIS’ Federal inspection program for all review components.
2. “At Least Equal To” with Provisions means FSIS makes a provisional determination of the State MPI program’s “at least equal to” status provided the program takes additional action to resolve review findings.
3. Not “At Least Equal To” means the State MPI program has not adopted laws, regulations, or programs, or does not implement them in a manner that is “at least equal to” FSIS’ Federal inspection program for one or more of the review components.

Onsite Review of Wyoming

From January 25, 2021 to February 5, 2021, FSAS conducted a targeted onsite review of the Wyoming MPI program. The scope of the review focused primarily on operational and program inspection activities performed at custom exempt operations and the MPI program’s enforcement of the Wyoming Food, Drug and Cosmetic Safety Act (to include all applicable requirements of 9 CFR Part 300 to end) as related to transactions conducted under the WFFA since its amended enactment date of July 1, 2020.
The targeted onsite review activities included directly observing the performance of WDA/CHS inspections of custom exempt operations. Custom exempt operations are defined as any slaughter and processing operations that are not subject to the routine inspection requirements of the FMIA and the PPIA, provided the specified operations meet the exemption requirements (21 U.S.C. 623 and 464). Thus, a representative sampling of Wyoming State inspected establishments that provide custom exempt services were reviewed. To verify custom exempt products are not presented for sale to the public, retail areas were included in facility examinations. All establishments selected for onsite review were eligible to operate under the slaughter inspection exemption for shared animal-ownership outlined in the provisions of the WFFA. For this purpose, the scope included examinations of WDA/CHS program records (e.g., cases, reports, etc.) documenting inspection results, performance trend analyses, enforcement actions relating to custom exempt inspections, and interviews of WDA/CHS officials responsible for documenting and reviewing program records.

FSIS analyzed all information gathered during the onsite review, to determine whether WDA/CHS had implemented and maintained its MPI program “at least equal to” the Federal requirements, and was enforcing regulatory requirements “at least equal to” those imposed under the Federal Acts. The determination and rationale for each review component are listed below.

**Component 2 – Inspection**

FSAS evaluated WDA/CHS during two State inspected establishment reviews and ten custom exempt reviews. WDA/CHS personnel did not identify noncompliance at the State inspected establishments during the onsite review. The FSAS program auditor did not identify noncompliance that State MPI program officials did not recognize.

FSAS reviewed the conditions and documents onsite. The onsite documents reviewed at the State inspected establishments, included, but were not limited to, Sanitation SOPs and associated records; HACCP plans and associated records; generic 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, FSAS reviewed the non-food safety consumer protection documents and procedures to determine whether WDA/CHS enforces non-food safety consumer protection regulatory standards “at least equal to” the Federal requirements. This review included, but was not limited to, ongoing regulatory verification tasks, label approvals, labels, and product formulations.

Documents reviewed at the custom exempt establishment included, but not limited to, brand inspection documentation, bills of sale, livestock receiving documentation, processing cut sheets, not for sale labels, and customer pick up logs.

The focus of the targeted review is geared towards the custom exempt operators, therefore HACCP, Sanitation SOPs, sampling, staffing, and training were not observed in 10 of the 12 establishments selected for the onsite review. Custom exempt establishments are not required to maintain a HACCP plan, Sanitation SOP’s or sample program. However, they are required to maintain sanitation requirements during custom exempt production. The additional two
establishments are State inspected establishments and also produce products using custom exemption. WDA/CHS does not conduct a specific custom exempt inspections or custom exempt reviews at State inspected facilities, as there is an inspector present during production, regardless of the production schedule, to ensure the establishment is meeting the sanitation requirements; the separation of custom exempt, retail and State inspected products; and/or HACCP requirements. Specifically, if the establishment is producing both State inspected and custom exempt products, the IIC inspects all products as being State inspected. Therefore, all inspection activities are documented on the Daily Inspection Report.

Based on records and procedures reviewed, FSAS determined WDA/CHS was able to confirm the program is being implemented as described in self-assessment.

Component 3 – Sampling Programs
FSAS reviewed and found acceptable, WDA/CHS’ product sampling documents, protocols, procedures, and results presented onsite. 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, Salmonella performance standards in raw classes of meat, economic samples, violative drug residues, State laboratory activity reports, and sample seals.

Based on records and procedures reviewed, FSAS determined WDA/CHS was able to confirm the program is being implemented as described in self-assessment.

Component 4 – Staffing, Training, and Supervision
FSAS reviewed the staffing and training program onsite to assess whether WDA/CHS carries out its staffing, training, and supervisory systems consistent with the self-assessment documents and “at least equal to” the Federal requirements. After further analysis of data from the WDA/CHS office and establishment reviews, FSAS concluded that it has an adequate number of trained persons to provide the required inspection coverage in the establishments, perform compliance activities, and provide supervisory oversight, and has implemented procedures to ensure daily inspection coverage in operating establishments. Inspection personnel apply inspection methodology, make decisions based upon the correct application of inspection methodology, document findings, and initiate regulatory action. The training program includes measures to ensure that inspection personnel receive training in the areas of meat and poultry ante-mortem and post-mortem inspection, humane handling, processed products, HACCP, Sanitation SOPs, rules of practice, IPPS guidelines, compliance, and Inspection Methods training.

Based on records and procedures reviewed, FSAS determined WDA/CHS was able to confirm the program is being implemented as described in self-assessment.

Component 5 – Humane Handling
FSAS reviewed and found acceptable the humane handling program and documents presented onsite to determine whether WDA/CHS 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. FSIS reviewed humane
handling of livestock, stunning methods, and the condition of livestock pens, driveways, and ramps.

Based on records and procedures reviewed, FSAS determined WDA/CHS was able to confirm the program is being implemented as described in self-assessment.

Component 6 – Compliance
FSAS conducted an onsite review of the compliance program activities and all specified documents to determine whether WDA/CHS implements a compliance program in accordance with the submitted self-assessment documentation. These included, but were not limited to, Reports of Investigation, Daily Activity Reports, Programmed Compliance Plans, Incident Reports, Case Reports, Reports of Apparent Violations, and Notices of Warning.

The review of compliance documents and case files support the conclusion that WDA/CHS 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.

WDA/CHS 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 that the products are adulterated, misbranded, or otherwise in violation of the Wyoming Food, Drug, and Cosmetic Safety Act. The Reports of Investigation were completed in accordance with FSIS Directive 8010.4, Report of Investigation. WDA/CHS uses the investigative findings and evidence to pursue enforcement actions for administrative, civil, or criminal sanctions.


WDA/CHS maintains a system to review, analyze, and triage consumer complaints. WDA/CHS gathers information pertinent to these complaints, directs the compliance division to investigate these complaints, and files completed investigation documents in the State office.

WDA/CHS has a system for reviewing custom exempt operations that is in accordance with FSIS Directive 8160.1, Custom Exempt Review Process. WDA uses an “at least equal to” document, Meat Plant Inspection Policy, as guidance to perform custom exempt inspections. To clarify the terminology used, a custom exempt “inspection” is equivalent to a custom exempt review. A custom exempt “review” is equivalent to the management controls in place by the State. Findings from the review can either be categorized as non-critical or critical. Below outlines the WDA/CHS State policy.

WDA/CHS classifies all custom exempt establishment into one of three categories, “high risk”, “medium risk,” and “low risk.” The categories are based on conditions in the establishment and production volume.
• Low risk establishment – a custom exempt inspection is conducted by the Inspector in Charge (IIC) once a year. A custom exempt review is conducted by the IIC’s supervisor once a year. Any followup reviews will be conducted by the IIC as assigned.
• Medium risk establishment - a custom exempt inspection is conducted by the IIC twice a year. A custom exempt review is conducted by the IIC’s supervisor once a year. Any followup reviews will be conducted by the IIC as assigned.
• High risk establishment - a custom exempt inspection is conducted by the IIC three times a year. A custom exempt review is conducted by the IIC’s supervisor once a year. Any followup reviews will be conducted by the IIC as assigned.

WDA/CHS classifies the findings from the custom exempt inspections and reviews as either critical or non-critical. Followup inspections are scheduled based on the findings.

• Non-critical findings are minor findings in the establishment. If the non-critical finding is addressed and found acceptable the day of the inspection/review, a followup review will not be scheduled. If the non-critical finding cannot be addressed the day of the review, the IIC will follow the guidance set forth by the WDA and schedule a followup inspection.
• Critical findings are more severe findings in the establishment. If the critical finding is addressed and found acceptable the day of the inspection/review, a followup review will not be scheduled. If the critical finding cannot be addressed the day of the review, the IIC will follow the guidance set forth by the WDA and schedule a followup inspection.
• Followup inspections – followup inspections occur when a critical or non-critical finding is not addressed and found acceptable the day of the inspection or review. The guidance set forth by the WDA gives the establishment up to 90 days to address the non-critical findings and up to 10 days to address the critical findings. The Supervisor can extend the time frames, if necessary.

The WDA/CHS program management team is aware of the differences in the WFFA and the FMIA/PPIA. When calls are fielded in reference to the herd share, the State analyzes the information received and determines if a followup visit by the compliance investigators is warranted. At the time of the targeted onsite review, establishments under the State MPI program's purview were not interested in the participating in producing products following the herd share bill.

During the 10 custom exempt reviews, carcasses, as well as finished product, were randomly selected from coolers and freezers. The IIC was able to trace back all raw product to the owner through a bill of sale or brand inspection. All other requirements of the WDA/CHS Meat Inspection Policy were verified at each establishment. The program auditor did not identify any overall trends during the onsite review.

WDA/CHS identified deficiencies with SPS, Sanitation SOPs, inspection requirements, and slaughter and processing operations. The identified deficiencies were consistent to previous years audit findings. A Program Action plan is not needed, as all findings were identified and addressed by the State MPI program. However, FSAS requested followup documentation for all establishments visited. All WDA/CHS findings were discussed with plant management at the
end of each review. A custom exempt review was written for each establishment visited. The findings were documented as ‘non-compliant.’ Copies of all custom exempt reviews and followup reviews were emailed to FSAS as requested.

Based on records and procedures reviewed, FSAS determined WDA/CHS was able to confirm the program is being implemented as described in self-assessment.

Component 7 – Laboratory Methods and Quality Assurance Program
LQARCS did not conduct an onsite review of WDA-ASL in FY 2021. Therefore, the annual determination will be based on the self-assessment review results only. The next onsite review will be conducted in FY22.

Component 8 – Civil Rights
CRS did not conduct an onsite review of WDA/CHS in FY 2021. Therefore, the annual determination will be based on the self-assessment review results only. The next onsite review will be conducted in FY22.

Component 9 – Financial Accountability
FRSB did not conduct an onsite review of WDA/CHS in FY 2021. Therefore, the annual determination will be based on the self-assessment review results only. The next onsite review will be conducted in FY23.

Onsite Determination for Wyoming
Based on the evidence and results discussed above, FSIS determined that WDA/CHS operates its MPI program “at least equal to” the Federal requirements for all review components and enforces requirements “at least equal to” those imposed under the Federal Acts.