Appendix Z

Comprehensive Review and Determination Report

Fiscal Year 2021

Wisconsin

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 Wisconsin 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 Wisconsin’s MPI Program
The Wisconsin Department of Agriculture, Trade and Consumer Protection Bureau of Meat and Poultry Businesses (BMPB) administers the Wisconsin MPI program under authority of Wisconsin Statutes and Annotations (Chapters 93, 95, and 97). The program verifies compliance and enforces regulatory requirements at 227 inspected facilities and 58 custom exempt establishments. BMPB also provides inspection at 22 facilities in the Cooperative Interstate Shipment Program.

Annual Determination
Based on the desk review of the submitted self-assessment documentation, FSAS determined that BMPB is operating a meat and poultry inspection program “at least equal to” the Federal requirements. BMPB has adopted laws, regulations, and programs, and implemented them in a manner that is “at least equal to” the Federal inspection program. As noted, BMPB was not subject to an onsite review for components 1 through 9 during fiscal year (FY) 2021. The most recent onsite review performed by FSAS for components 1 through 6 occurred on June 2019.

Self-Assessment Review Methodology
Annually, FSAS will conduct a desk review of documentation submitted by a representative agent of each non-designated State demonstrating its completion of an assessment of current State laws, rules, policies, and procedures that govern the MPI program’s inspection and operation activities with those administered by FSIS and supporting the State’s determination that their MPI program meets the “at least equal to” Federal standards. A State MPI program official completes a self-assessment addressing all program inspection and operation activities using the self-assessment instruments provided by FSIS. The State agent is to submit the completed self-assessment instruments and any requested supporting documentation by November 1 of each review cycle.

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1 Custom exempt establishments are slaughter and processing establishments that are not subject to the routine inspection requirements of the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), provided the specified operations meet the exemption requirements (21 U.S.C. 623 and 464).

2 The Cooperative Interstate Shipment program permits eligible small and very small State-inspected establishments to ship meat and poultry products in interstate commerce, provided the establishments selected for this program receive inspection services from designated State personnel that have been trained in the enforcement of the FMIA and PPIA, and conduct inspection in establishments, selected for this program, in a “same as” manner that complies with the FMIA and PPIA and implementing regulations (21 U.S.C. 683 and 472).

3 Non-designated State is a State that operates an MPI program under a cooperative agreement with FSIS. The State MPI program must administer inspection and food safety requirements “at least equal to” those imposed under the Federal Meat Inspection, Poultry Products Inspection Act and the Humane Methods of Slaughter Act of 1978.
The submitted information should support the non-designated State’s self-determination that its MPI program is administered in a manner that is “at least equal to” the Federal inspection program. The self-assessment submission is to include narrative describing key MPI program inspection and operations activities and explanations supporting why the described activities meet the “at least equal to” Federal standards. Additionally, the self-assessment submission is to include evidence and documentation to support that the State MPI program’s policies and procedures for carrying out the activities currently are in effect.

At the start of each Federal fiscal year, FSIS assembles a review team comprised of subject matter experts from various FSIS program areas to review the nine components of the comprehensive review process. This FSIS review team includes staffs or personnel primarily from the following Agency program areas: OIEA, the Office of Management, the Office of Chief Financial Officer, and the Office of Public Health Science. During the review process the Office of Policy and Program Development, and the Office of Field Operations are consulted as needed to gain context and perspective on current FSIS programs, policies and procedures when determining whether a State MPI program meets Federal “at least equal to” standards.

If questions arise during the desk review or if additional documentation is needed to make a review determination regarding one or more components, FSIS will request clarifying information from the State MPI program. Upon completion of the desk review, FSIS makes one of the following three determinations for each component and for the non-designated State’s overall ability to maintain an MPI program “at least equal to” the Federal requirements:

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

Review of Wisconsin’s Self-Assessment Submission
FSAS evaluated the self-assessment documents for the applicable review components to determine whether BMPB constitutes an inspection program “at least equal to” the Federal program. The determination and rationale for each review component are listed below.

FSAS received BMPB’s complete self-assessment submission for components 1 through 6 on February 11, 2021. FSAS sent a notification to BMPB requesting additional information. BMPB 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 August 9, 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 Wisconsin Statutes and Annotations (Chapter 93, 95, and 97) and the Wisconsin Administrative Code, Department of Agriculture, Trade and Consumer Protection (ATCP, Chapters 55, 90, and 97). The Wisconsin Statutes and Annotations provide authorities for mandatory ante-mortem and post-mortem inspection; reinspection; sanitation requirements; record keeping requirements (Section 97.42); and humane methods of slaughter requirements (Section 95.80).

In addition, the Wisconsin Statutes and Annotations provide authorities that are “at least equal to” the FMIA and PPIA regarding adulteration (Section 97.02), misbranding (Section 97.03), prohibited acts (Sections 95.80 and 97.42), access and examination (Section 97.42), and product control actions (Section 97.42). It also includes sufficient authorities for criminal, civil, and administrative sanctions to address violators.

The Wisconsin Statutes and Annotations grant the authority to promulgate rules and regulations (Sections 93.07 and 97.42). Wisconsin adopts by reference Title 9, Code of Federal Regulations Chapter III, Subchapters A and E in the Wisconsin Administrative Code (ATCP 55.07).

In conclusion, BMPB provided evidence showing that it operates under State laws and regulations that provide legal authority “at least equal to” that provided under the FMIA, PPIA, and HMSA, and the accompanying regulations.

Component 2 – Inspection
FSAS compared the self-assessment submission and supporting documentation regarding inspection policies and procedures and regarding verification of establishments’ compliance, to the Federal requirements. BMPB uses the FSIS Public Health Information System (PHIS) to schedule inspection tasks and to collect, consolidate, and analyze inspection data. BMPB administers inspection for any meat or poultry product intended for human consumption, wholly or in part, from the carcass or parts of any animal defined as “livestock” or “poultry” in the Wisconsin Statutes and Annotations and governing rules and regulations. The State inspection program impose regulations and perform inspection duties that ensure animals intended to be used in meat and poultry products sold commercially, are slaughtered and processed in the presence of State inspection personnel, and the resulting meat food products are inspected and passed for human consumption. Furthermore, BMPB administers a food safety verification program that meets the intent of FSIS Directive 5000.1, Verifying an Establishment’s Food Safety System. Food safety verification activities are performed to ensure establishments’ compliance with applicable pathogen reduction, sanitation, and Hazard Analysis and Critical Control Point (HACCP) regulations.

In addition to performing inspections and food safety verifications, BMPB schedules and performs a comprehensive food safety assessment (FSA) at each inspected establishment in accordance with FSIS Directive 5100.1, Enforcement, Investigations and Analysis Officer (EIAO) Food Safety Assessment (FSA) Methodology, and 5100.4, Enforcement, Investigations
and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology. These FSAs examine the design and validity of establishments’ food safety systems, which include hazard analyses, HACCP, Sanitation Standard Operational Procedures (Sanitation SOP), prerequisite programs, sampling programs, supporting documentation and records, and any other programs that constitute the establishments’ food safety systems. The PHRE and FSA records indicate that BMPB is performing FSAs for cause and support the conclusion that State inspection personnel recognize and document noncompliance and initiate appropriate regulatory actions.

BMPB verifies establishment compliance with the non-food safety (i.e., labeling) consumer protection regulatory requirements. BMPB uses applicable FSIS directives to instruct inspection personnel and uses PHIS to schedule ongoing verifications and document noncompliance. A thorough review of the PHIS data supports the conclusion that BMPB inspectors correctly apply the inspection methodology and document noncompliance.

BMPB maintains a label approval policy and process to verify that labels are accurate and meet regulatory requirements. The food scientists review and approve all product formulations and ingredient statements. Prior to applying a label, mark, or device to an inspected meat or poultry product, an establishment representative must generically approve it or submit a completed application for label approval and a label sketch to obtain BMPB approval.

BMPB enforces the Wisconsin Administrative Code (ATCP 55.07), 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. BMPB maintains procedures to document relevant facts of administrative actions and ensure that administrative actions are legally supportable and based on relevant facts.

BMPB has a system for reviewing custom exempt operations that is in accordance with FSIS Directive 8160.1, Custom Exempt Review Process. Custom exempt establishments are visited quarterly, when in operation according to ATCP 55.04(2)(a).

The submitted documents support the conclusion that BMPB:

- Performs inspection and regulatory verification procedures to confirm that State-inspected establishments comply with applicable regulations;
- Maintains a system to carry out administrative enforcement actions when establishments do not comply with State authorities that are “at least equal to” the FMIA and PPIA;
- Conducts inspection activities “at least equal to” the Federal requirements; and
- Monitors these activities through control measures to verify that the inspection system functions as intended.
Component 3 – Sampling Programs
FSAS compared BMPB’s sampling protocols, procedures, and results to Federal policies and procedures.

BMPB 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 poultry;
- Other consumer protection standards.

The sampling plans include procedures for sample collection, sample integrity, and laboratory analysis. BMPB developed policies to respond to positive results. These policies include actions to prevent adulterated product from entering commerce. BMPB 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 BMPB 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. BMPB has control measures in effect to confirm that its product sampling system functions as intended.

Component 4 – Staffing, Training, and Supervision
BMPB 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. Each circuit supervisor maintains a Meat Safety Inspection Plant Assignment, which details the routine inspection assignments for inspection personnel. The circuit supervisors also arrange relief inspection during routine and emergency leave situations.

At the start of the FY 2021 review cycle, BMPB indicated they employ 1 bureau director, 4 administrative managers in the headquarters office, 8 circuit supervisors, 66 inspectors, 3 veterinary medical officers, 6 EIAOs, and 5 compliance officers.

BMPB continues to implement a training program for new entry-level inspection personnel. The training subjects include slaughter inspection, inspection methods (IM) training, HACCP, Sanitation SOPs, and sanitation performance standards. Veteran staff members may attend the
refresher classroom slaughter school or IM training as needed. Training needs are also based on BMPB initiatives, individual requests, or supervisory assessments. BMPB circuit supervisors also conduct staff meetings to discuss new State and Federal issuances and provide training. BMPB maintains a record keeping system to track participation and completion of training.

BMPB administers an employee performance review system that is mandated for all State employees. This system communicates employees’ work responsibilities, performance goals and objectives, and annual performance evaluation results. Supervisors evaluate performance during the initial probationary period and annually thereafter. BMPB also implements the FSIS In-Plant Performance System review to assess the knowledge and competency of in-plant inspection personnel.

After thorough review of the submitted documents, FSIS concluded that BMPB 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 BMPB’s inspection methodology, to document findings, and to initiate regulatory actions when necessary. Control measures are in effect to confirm that BMPB’s staffing and training systems function as intended.

Component 5 – Humane Handling
BMPB 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.

BMPB uses FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock, to communicate instructions to inspection personnel. Inspectors document humane handling verifications in PHIS. As a part of the veterinary oversight process, BMPB veterinarians evaluate establishments’ humane handling procedures and inspectors’ understanding of the humane handling requirements. BMPB veterinarians and circuit supervisors review all documented humane handling noncompliances involving injury or distress of animals and discuss enforcement actions with the State Office. BMPB veterinarians also perform annual humane handling reviews at slaughter facilities in accordance with FSIS Directive 6910.1, District Veterinary Medical Specialist (DVMS) -Work Methods.

In conclusion, the information supports the fact that BMPB 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
BMPB personnel conduct in-commission 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.

BMPB 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 Wisconsin Statutes and Annotations; and takes enforcement action, when needed, up to and including prosecution of individuals or firms that have violated the Wisconsin Statutes and Annotations. BMPB has procedures to maintain and preserve the legal integrity of documentary and other evidence to support legal action.

A BMPB regulatory specialist is responsible for organizing, reviewing, and filing all compliance reports. The regulatory services director reviews all violations and relevant evidence, and determines the appropriate case disposition and course of action.

BMPB 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 BMPB within 24 hours of initiating a recall. BMPB 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.

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

The submitted documents support the conclusion that BMPB 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 Wisconsin Department of Agriculture, Trade, and Consumer Protection Bureau of Laboratory Services (WDATCPBLS) was performed during FY21 to evaluate laboratory quality assurance programs and method equivalence under the State MPI Program.

As a participant in the Cooperative Interstate Shipment (CIS) “same as” program, WDATCPBLS meets the requirements of the State Meat and Poultry Inspection (MPI) “at least equal to” Program Laboratory Quality Management System Checklist. WDATCPBLS conducts microbiological testing for *Salmonella*, *L. monocytogenes*, *E. coli* O157:H7, non-O157 STEC
and *Campylobacter*. WDATCPBLS conducts food chemistry testing for the measurement of moisture, protein, fat and salt.

FSIS compared the WDATCPBLS 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, WDATCPBLS met all Laboratory QA requirements including analyst’s training and related proficiency testing (PT).

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

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

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

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

- At poultry slaughter establishments, provided the state collects and submits the appropriate number of samples are tested for *Salmonella* and *Campylobacter*. MPI states with no participating facilities slaughtering at least 20,000 chickens and/or 20,000 turkeys per year are not required to test that 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.

**Component 8 – Civil Rights**

In December 2020, BMPB 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’ Civil Rights Staff concluded that BMPB functions “at least equal to” the Federal civil rights requirements.

**Component 9 – Financial Accountability**

BMPB 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.
(March 2004). FRSB determined that BMPB is “at least equal to” Federal standards for financial accountability for FY 2021.

**Self-Assessment Determination for Wisconsin**

Based on the submitted self-assessment documents and desk review results described above, FSIS determined that BMPB provided adequate documentation to show it is operating a meat and poultry inspection program “at least equal to” the Federal requirements.