Appendix Z

Comprehensive Review and Determination Report

FY 2012

Wisconsin

Federal/State Audit Branch
Internal Control and Audit Division
Office of Program Evaluation, Enforcement and Review
Food Safety and Inspection Service
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Introduction

Purpose
This report presents the Food Safety and Inspection Service (FSIS) annual review results for the Wisconsin Meat and Poultry Inspection (MPI) program and an overview of the review methodology. FSIS determined that the Wisconsin MPI program met the "at least equal to" standard, based on its review of the self-assessment documents.

Background
The Federal Meat Inspection Act (FMIA) (21 U.S.C. 661) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 454) provide for FSIS to cooperate with State agencies in developing and administering State MPI programs. Individual State MPI programs need to operate in a manner and with authorities that are "at least equal to" the programs that FSIS has implemented under the antemortem and postmortem inspection, reinspection, sanitation, record-keeping, and enforcement provisions of the FMIA and PPIA. In addition, State MPI programs are expected to ensure that livestock are treated humanely by imposing humane handling requirements that are "at least equal to" those FSIS has established under the Humane Methods of Slaughter Act of 1978 (HMSA)(7 U.S.C. 1901 – 1906). The jurisdiction of a State MPI program is limited to product that is produced and sold within the State.

The FMIA and PPIA provide for FSIS to conduct at least annual reviews of State MPI programs and their requirements, including enforcement of those requirements, with respect to slaughter, preparation, processing, storage, handling, and distribution of livestock carcasses and parts, meat and meat food products of such animals, or poultry products (21 U.S.C. 661 (c) (4); 21 U.S.C. 454 (c) (4)). Cooperative agreements and annual certifications of State MPI programs are contingent upon FSIS determining that each State MPI program enforces requirements "at least equal to" those imposed under the Federal Acts. FSIS performs annual reviews to determine whether each State MPI program meets, and can maintain for a period of 12 months, the mandated "at least equal to" standard.

FSIS Directive 5720.3, *Methodology for Performing Scheduled and Targeted Reviews of State Meat and Poultry Inspection Programs,* and the *"At Least Equal To" Guidelines for State Meat and Poultry Cooperative Inspection Programs* describe the policies and procedures for FSIS comprehensive reviews. FSIS Directive 5720.3 provides FSIS personnel with the methodology to perform these reviews. The *"At Least Equal To" Guidelines for State Meat and Poultry Cooperative Inspection Programs* were developed to assist the State MPI programs establish and maintain inspection programs that are "at least equal to" the Federal inspection program.

Review Methodology
The comprehensive State MPI program review process consists of two parts: (1) an annual review of the State MPI program's self-assessment submission; and (2) a triennial verification on-site review to observe the State MPI program. Through the annual self-assessment and triennial verification on-site reviews, FSIS determines whether the State MPI program is "at least equal to" the Federal inspection program.

Each year, FSIS determines the "at least equal to" status of each State MPI program based on one or both parts of the comprehensive review. If the State MPI program is not scheduled for an on-site review during the fiscal year, FSIS makes an annual determination based on the results of the self-assessment review. If the State MPI program is scheduled for an on-site review during the fiscal year, FSIS makes an annual determination based on the results of both the self-assessment and the on-site review.

Description of State MPI Program
The Wisconsin Department of Agriculture, Trade and Consumer Protection, Bureau of Meat Safety and Inspection (WDATCP/BMSI) administers the Wisconsin MPI program under authority of the Wisconsin

Statutes (Chapters 93, 95, and 97). The program verifies and enforces regulatory requirements at 286 inspected facilities and 55 custom exempt establishments.[1]

Annual Determination (Based on Self-Assessment Review Only)
FSIS determined that WDATCP/BMSI is operating a meat and poultry inspection program "at least equal to" the Federal requirements. WDATCP/BMSI has adopted laws, regulations, and programs, and implemented them in a manner that is "at least equal to" the Federal inspection program for all review components. FSIS based its annual determination on review of the self-assessment documents only, since WDATCP/BMSI was not subject to an on-site review during Fiscal Year (FY) 2012. This determination is fully explained in the Self-Assessment Review Section.

Overview of Review Methodology

The review methodology is published in two companion documents: FSIS Directive 5720.3, (March 14, 2011), *Methodology for Performing Scheduled and Targeted Reviews of State Meat and Poultry Inspection Programs*, and the *"At Least Equal To" Guidelines for State Meat and Poultry Cooperative Inspection Programs* (July 2008). These documents describe the methodology used by FSIS' reviewers and provide information to State MPI programs on the criteria that FSIS uses to make its annual determination of whether State MPI programs are "at least equal to" the Federal inspection program. This review process consists of an annual review of the State MPI program's self-assessment submission and a triennial on-site review.

In addition to the annual reviews of each State MPI program, FSIS may perform a targeted review of a State MPI program in response to a condition or event that evidences program weaknesses, or as a reaction to a situation that could clearly result in a risk to public health. These targeted reviews may be conducted in addition to the scheduled reviews or may be performed at the same time. FSIS focuses the scope and activities of the targeted review on the conditions and evidence that triggered the need for the review and analyzes the review results to determine if the State MPI program is maintaining an "at least equal to" MPI program.

The comprehensive review process evaluates the following nine components:

1. Statutory Authority and Food Safety Regulations – This component evaluates whether the State MPI program operates under laws and regulations that provide legal authorities "at least equal to" those provided under the FMIA, PPIA, and HMSA.

2. Inspection – This component evaluates whether State MPI program personnel perform inspection activities to verify whether establishments comply with applicable regulations and take appropriate enforcement actions when establishments are not in compliance with provisions that are "at least equal to" those of FSIS.

3. Product Sampling – This component evaluates whether State MPI program personnel sample meat or poultry products to verify whether they are free of adulterants (e.g., *E. coli* O157:H7 in non-intact, raw beef products and raw ground beef components, Shiga Toxin-producing *Escherichia coli* (STEC) serotypes in beef manufacturing trimmings, *Listeria monocytogenes* and *Salmonella* in ready-to-eat products, or drug residues at violative levels), comply with *Salmonella* Performance Standards in raw

[1] Custom exempt establishments are slaughter and processing establishments, which are not subject to the routine inspection requirements of the FMIA and PPIA, provided the specified operations meet the exemption requirements of Section 23 of the FMIA and Section 15 of the PPIA.

classes of meat and poultry, comply with other consumer protection standards, and are accurately labeled (e.g., with nutrition information).

4. Staffing and Training – This component evaluates whether the State MPI program provides competent inspection coverage in each establishment on days the establishment produces products that, if found to be safe, wholesome, unadulterated, and properly labeled, are to bear the State mark of inspection.

5. Humane Handling – This component evaluates whether State MPI program personnel perform regulatory verification procedures to assess whether establishment personnel humanely handle all livestock and take appropriate regulatory actions in response to noncompliance. State MPI program personnel are to also perform regulatory verification procedures to assess whether poultry carcasses showing evidence of having died from causes other than slaughter are considered adulterated and condemned, and to assess whether poultry is slaughtered in accordance with good commercial practices, in a manner that results in thorough bleeding of the poultry carcass and ensures that breathing has stopped before scalding so that the birds do not drown.

6. Non-Food Safety Consumer Protection – This component evaluates whether State MPI program personnel perform verification procedures to confirm that meat and poultry products are wholesome, not economically adulterated, truthfully labeled, and meet the non-food safety regulatory requirements; and take appropriate actions in response to noncompliance.

7. Compliance – This component evaluates whether State MPI program personnel perform surveillance activities with respect to meat or poultry products in intrastate commerce and take appropriate enforcement actions in the event that adulterated or misbranded products enter intrastate commerce.

8. Civil Rights – This component evaluates whether the State MPI program adheres to Federal civil rights laws and U.S. Department of Agriculture (USDA) civil rights regulations.

9. Funding and Financial Accountability[2] – This component evaluates whether the State MPI program conforms to 7 CFR 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.*

FSIS determines whether the State's MPI program constitutes an inspection program "at least equal to" the Federal requirements based on the aforementioned criteria.

[2] In light of the current economic conditions, some State governments are experiencing financial challenges, which may result in overall budget cuts that could effect their meat and poultry inspection programs. To ensure the safety of State-inspected meat and poultry products, FSIS has initiated more vigilant monitoring to track and analyze circumstances and conditions that adversely affect the State MPI program's financial resources. When FSIS identifies concerns with a State MPI program's financial resources, the Agency will further examine each situation to determine the impact on the State MPI program's inspection activities, product sampling programs, staffing, and compliance activities, and determine if the State MPI program is maintaining its "at least equal to" status.

Self-Assessment Review

This section includes:

- A description of the self-assessment review methodology followed for all State MPI programs.
- The review of Wisconsin's self-assessment submission.
- The self-assessment determination for Wisconsin.

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 representatives from the Federal State Audit Branch (FSAB), Civil Rights Division (CRD), Financial Review and Analysis Section (FRAS), and other program areas, as needed, evaluates each State MPI program's self-assessment submission to determine whether it meets the "at least equal to" criteria for all nine review components.

As questions arise during the self-assessment review, or if more information or supporting documentation is needed, FSIS requests clarifying information from the State MPI program. The FSIS review team then makes a determination based on review of the entire self-assessment submission. For each State MPI program, FSIS makes one of the following three determinations for each component and the State's overall ability to maintain a 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 equivalent to the Federal inspection program for all review components.

(2) 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 equivalent to the Federal inspection program for one or more of the review components.

(3) Deferred: Means FSIS is unable to make a determination of the State MPI program's status because of the program's inability to immediately implement corrective actions resulting from the review findings.

Review of Wisconsin's Self-Assessment Submission
FSIS evaluated the self-assessment documents for the nine review components to determine whether WDATCP/BMSI constitutes an inspection program "at least equal to" the Federal program. The determination and rationale for each review component are listed below.

FSAB received WDATCP/BMSI's self-assessment submission, for components 1 through 7, on December 2, 2011. On July 26, 2012, FSAB requested additional clarifying information from the WDATCP/BMSI staff, which was provided on August 20 and 23, 2012.

Component 1 – Statutory Authority and Food Safety Regulations

FSAB compared the submitted self-assessment and supporting documentation to the legal authority provided under the FMIA, PPIA, and HMSA, and the regulations promulgated under these laws. The supporting documentation includes the Wisconsin Statutes (Chapters 93, 95, and 97), and the Wisconsin Administrative Code, Agriculture, Trade and Consumer Protection (ATCP, Chapters 55 and 57). The Wisconsin Statutes provide authorities for mandatory antemortem and postmortem inspection, and reinspection (§97.42); sanitation and record-keeping requirements (§97.42); and humane methods of slaughter requirements (§95.80).

The Wisconsin Statutes provide authorities that are "at least equal to" the FMIA and PPIA regarding adulteration (§97.10), misbranding (§97.10), prohibited acts (§97.10), access and examination (§97.42), and product control actions (§97.09), as well as "at least equal to" criminal, civil, and administrative sanctions to address violators.

The Wisconsin Statutes grant the authority to promulgate regulations (§§93.07 and 97.42(4)) and Wisconsin adopted by reference Title 9, Code of Federal Regulations (9 CFR), Parts 307 – 311, 313 – 315, 317, 319, 381 subchapters G, H, I, J, K, L, O, and P, 416, 417, 430, 441, and 442 in the Wisconsin Statutes (§97.42(4)(m)) and Wisconsin Administrative Code (ATCP 55.07).

In conclusion, WDATCP/BMSI provided evidence to show 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 issuances.

Component 2 – Inspection

FSAB compared the self-assessment submission and supporting documentation regarding inspection policies and procedures, and verification of establishments' compliance to the Federal requirements. WDATCP/BMSI uses the Performance Based Inspection System (PBIS) to guide inspection program activities, collect establishment information, establish and maintain in-plant inspection procedure plans, and document establishment noncompliance. In addition, WDATCP/BMSI reviews custom exempt operations in accordance with FSIS Directive 5930.1, *Custom Exempt Review Process.*

WDATCP/BMSI verifies that establishments develop, implement, and maintain Sanitation Standard Operating Procedures (SOPs) and Hazard Analysis and Critical Control Point (HACCP) systems. In addition to the inspectors' ongoing verification procedures, WDATCP/BMSI veterinarians perform Food Safety Assessments (FSAs) to examine establishments' food safety systems. These FSAs examine hazard analyses, HACCP plans, Sanitation SOPs, prerequisite programs, sampling programs, and any other programs that constitute the establishments' HACCP systems. The noncompliance records, FSA records, PBIS summary reports, letters requesting Administrative Conferences, and consent orders support the conclusion that WDATCP/BMSI personnel recognize and document noncompliance, and initiate appropriate regulatory actions.

WDATCP/BMSI enforces the Wisconsin Statutes (Chapters 93, 95, and 97) and Wisconsin Administrative Code (ATCP 1 and 55), which provide laws and rules analogous to 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. WDATCP/BMSI established procedures for progressive enforcement, which include procedures for regulatory control actions and documenting relevant facts to support administrative actions.

The submitted documents support the conclusion that WDATCP/BMSI:

- 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.
- Achieves inspection activities "at least equal to" the Federal requirements.
- Monitors these activities through control measures to verify that the inspection system functions as intended.

Component 3 – Product Sampling

FSAB compared WDATCP/BMSI's sampling protocols, procedures, and results to the Federal policies and procedures.

WDATCP/BMSI provided documentation to show that it maintains sampling programs with sound rationale and goals for *E. coli* O157:H7 in raw non-intact beef products and raw ground beef components, *Listeria monocytogenes* and *Salmonella* in ready-to eat products, *Salmonella* Performance Standards in raw classes of meat and poultry, and other consumer protection standards. WDATCP/BMSI participates in the National Residue Program, and collects and analyzes inspector-generated samples for violative drug residues. The sampling plans include procedures for sample collection, sample integrity, and laboratory analysis. WDATCP/BMSI developed an action plan to respond to positive results. That plan includes actions to prevent adulterated product from entering commerce.

In conclusion, detailed review of the sampling protocols, procedures, and results confirmed that WDATCP/BMSI maintains verification testing to address adulterants, other measures of properly operating food safety systems, and other consumer protection standards "at least equal to" the Federal requirements and has control measures in effect to confirm that its product sampling system functions as intended.

Component 4 – Staffing and Training

WDATCP/BMSI developed methods to determine staffing requirements, which consider the inspector's workloads and the number of inspectors required to provide daily inspection coverage in each establishment on days 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. To achieve daily inspection coverage, each circuit supervisor assigns inspectors' work schedules weekly, with instructions for daily visits to operating establishments. Each week, the field services director reviews the inspection assignment schedules. Circuit supervisors also arrange relief inspection during routine- and emergency-leave situations. Inspectors alert supervisors when relief inspection is necessary and record inspection activities on weekly activity reports. Inspectors submit these reports to circuit supervisors, who review these reports to verify daily inspection coverage. WDATCP/BMSI provided management control staffing reports for the first two quarters of FY 2012 that describe steps to monitor daily inspection coverage.

As of December 2, 2011,WDATCP/BMSI employed a division administrator, a meat bureau director, a field service director, a veterinary service section manager, a regulatory and technical services section chief, a program and policy analyst, 6 meat safety consultants, 4 veterinarians, 7 meat safety supervisors, 60 inspectors, and 2 regulatory specialists.

WDATCP/BMSI developed a training program for new entry-level inspection personnel. This training includes livestock inspection, slaughter inspection, processing inspection, HACCP, Sanitation SOPs, sanitation performance standards, and Food Safety Regulatory Essentials (FSRE). Veteran staff members may attend the classroom slaughter school, FSRE training, and processing school for refresher training, based on individual requests or training needs. WDATCP/BMSI records employees' completed training courses and total hours spent in training. Each quarter, meat safety supervisors meet with inspectors to discuss new State and Federal issuances, and review existing policies and procedures.

Wisconsin 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. Supervisors also conduct performance reviews that are similar to FSIS' In-Plant Performance System assessments, throughout the year, and document results on Supervisor Audit forms.

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

Component 5 – Humane Handling

The PBIS records demonstrate that WDATCP/BMSI schedules and performs regulatory verification procedures to assess whether establishment personnel humanely handle all livestock throughout the time they are on official establishment premises and takes appropriate regulatory action in response to noncompliance.

To instruct inspection staff, WDATCP/BMSI includes humane handling expectations in the slaughter-training course, and uses FSIS Directive 6900.2, *Humane Handling and Slaughter of Livestock*. Veterinarians verify humane handling compliance and emphasize the importance of humane handling with inspection personnel during routine monthly establishment visits, and when performing antemortem or postmortem dispositions. The veterinarians document humane handling observations and discussions on Veterinary Oversight Reports. The veterinary services section manager reviews the Veterinary Oversight Reports.

In conclusion, the information made evident that WDATCP/BMSI 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 – Non-Food Safety Consumer Protection

WDATCP/BMSI verifies establishment compliance with the non-food safety consumer protection regulatory requirements. WDATCP/BMSI uses PBIS to schedule ongoing verification procedures and to document noncompliance; and uses applicable FSIS Directives to instruct inspection personnel. A thorough review of the PBIS data for a 12-month period supports the conclusion that WDATCP/BMSI inspectors correctly apply inspection methodology and document noncompliance.

WDATCP/BMSI maintains a label-approval policy and process to verify that labels are accurate and meet regulatory requirements. The meat safety consultants review and approve all product formulations and ingredient statements prior to label approval. The regulatory and technical services section chief oversees the label-approval process.

In conclusion, the submitted documents provided evidence to show that WDATCP/BMSI protects consumers from meat and poultry products that are unwholesome, economically adulterated, or not truthfully labeled, and is "at least equal to" the Federal program. Control measures are in effect to confirm that the non-food safety consumer protection verification system functions as intended.

Component 7 – Compliance

WDATCP/BMSI personnel conduct surveillance activities to verify that persons or firms who prepare, transport, sell, or offer for sale meat and poultry products in intrastate commerce comply with State statutory

and regulatory requirements, and that meat and poultry products in intrastate commerce are wholesome, correctly packaged and labeled, and secure from threats or intentional acts of contamination.

WDATCP/BMSI investigates apparent violations and food safety incidents; detain products when there is reason to believe that the products are adulterated, misbranded, or otherwise in violation of the Wisconsin Statutes; and takes enforcement action when needed, up to and including prosecution of individuals or firms that violate the Wisconsin Statutes. WDATCP/BMSI maintains procedures to obtain 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.

WDATCP/BMSI management reviews the compliance reports for correctness, extracts pertinent information for reporting purposes, enters the information in a database, and files the hard copies. The regulatory and technical services section chief reviews all violations and relevant evidence and determines the appropriate case dispositions and course of actions.

WDATCP/BMSI developed procedures for the recall of meat and poultry products subject to its jurisdiction 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 to notify WDATCP/BMSI within 24 hours of initiating a recall. WDATCP/BMSI oversees the recall activities, coordinates actions to determine whether adulterated product was removed from commerce, and issues press releases, as necessary, to serve the interest of public health.

WDATCP/BMSI established methods to record, triage, analyze, and track consumer complaints related to State-regulated meat or poultry products. The meat safety supervisors investigate the establishments that produced the alleged products and report to both the field service director and the regulatory and technical services section chief. The investigative methods include procedures to collect and safeguard evidence, conduct interviews, submit product samples to the laboratory, initiate recall procedures or regulatory enforcement actions, and report potential food safety threats.

The submitted documents support the conclusion that WDATCP/BMSI 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 8 – Civil Rights

On November 18, 2011, WDATCP/BMSI 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. CRD concluded that WDATCP/BMSI functions “at least equal to” the Federal civil rights requirements.

Component 9 – Financial Accountability

WDATCP/BMSI submitted quarterly and final Financial Status 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, *Fiscal Guidelines for Cooperative Inspection Programs.* On October 24, 2012, FRAS determined that WDATCP/BMSI is “at least equal to” Federal standards for financial accountability for FY 2012.

Self-Assessment Determination for Wisconsin

Based on the evidence and review results described above, FSIS determined that WDATCP/BMSI provided adequate documentation to show it is operating a meat and poultry inspection program "at least equal to" the Federal requirements.