Appendix F

Comprehensive Review and Determination Report

FY 2012

Indiana

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 Indiana Meat and Poultry Inspection (MPI) program and an overview of the review methodology. FSIS determined that the Indiana 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 Indiana State Board of Animal Health (BOAH) administers the Indiana MPI program under authority of the Indiana Code (Title 15, Article 17, Chapter 5). The program verifies and enforces regulatory requirements at 90 inspected facilities and 43 custom exempt establishments.[1]

Annual Determination
FSIS determined that BOAH is operating a meat and poultry inspection program "at least equal to" the Federal requirements. BOAH 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. For the most part, FSIS based its annual determination on review of the self-assessment documents only, since BOAH was not subject to an on-site review, for components 1 through 8, 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

[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.

products, or drug residues at violative levels), comply with *Salmonella* Performance Standards in raw 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 Indiana's self-assessment submission.
- The self-assessment determination for Indiana.

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

FSAB received BOAH's self-assessment submission, for components 1 through 7, on November 10, 2011. On June 11, 2011, FSAB requested additional clarifying information from the BOAH staff, which was provided on June 12, 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 Indiana Code (Title 15, Article 17, Chapter 5) and the Indiana Administrative Code. The Indiana Code provides statutory authorities for mandatory antemortem and postmortem inspection, and reinspection; sanitation, and record-keeping requirements (§15-17-5-4); and humane methods of slaughter requirements (§§15-17-5-1 and 15-17-5-8).

The Indiana Code provides authorities that are "at least equal to" the FMIA and PPIA regarding adulteration and misbranding (§15-17-5-1), prohibited acts (§15-17-5-6), access and examination (§§15-17-5-10 and 15-17-5-22), and product control actions (§15-17-5-20), as well as criminal, civil, and administrative sanctions to address violators.

The Indiana Code grants the authority to promulgate rules and regulations (§15-17-5-5) and Indiana adopts by reference Title 9, Code of Federal Regulations (9 CFR), Chapter III, Parts 301, 303 – 311, 313 – 320, 325, 362, 381.1, 381.10, 381.11 – 381.95, 381.155 – 381.182, 381.189 – 381.194, 381.300 – 381.500, 416 – 441, and 500, in effect as of January 2010, in the Indiana Administrative Code (§§345 IAC 9-2.1-1 and 10-2.1-1),with exceptions and modifications to better suit the meat and poultry inspection program.

In conclusion, BOAH 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. BOAH 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, BOAH reviews custom exempt operations in accordance with FSIS Directive 5930.1, *Custom Exempt Review Process.*

BOAH verifies that establishments develop, implement, and maintain Sanitation Standard Operating Procedures (SOPs) and Hazard Analysis and Critical Control Point (HACCP) systems. BOAH routinely schedules and performs a comprehensive Food Safety Assessment (FSA) at each inspected establishment at least once every four years. The FSAs examine establishments' food safety systems to include hazard analyses, supporting documents, HACCP plans, Sanitation SOPs, prerequisite programs, sampling programs, and any other programs that constitute the establishments' HACCP systems. The noncompliance records, FSA records, notices of intended enforcement, and verification plans support the conclusion that BOAH personnel recognize and document noncompliance, and initiate appropriate regulatory actions.

BOAH enforces the Indiana Administrative Code (§§345 IAC 9-2.1-1 and 10-2.1-1), 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. BOAH 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 BOAH:

- 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 BOAH's sampling protocols, procedures, and results to the Federal policies and procedures.

BOAH 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. BOAH 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. BOAH developed an action plan to respond to positive results. This action plan includes actions to prevent adulterated product from entering commerce.

In conclusion, detailed review of the sampling protocols, procedures, and results confirmed that BOAH 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

BOAH 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 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. BOAH analyzes the establishments' inspection requests and available funds to determine the entire workforce. The administrative assistant fills the operations and data coordinator role to manage personnel and oversee overall staffing throughout the State. As part of the management controls, the administrative assistant analyzes staffing data to verify achievement of inspection coverage. As part of the day-to-day operations, area supervisors schedule daily inspection coverage in operating establishments and provide relief inspection during scheduled- and emergency-leave situations. The management control policies and procedures require BOAH supervisors to schedule inspectors' weekly assignment itineraries, document supervisory visits, and perform PBIS verifications. BOAH employees are to sign in at each establishment and complete timesheets to record the actual hours worked, and the supervisors review these timesheets for accuracy.

As of November 15, 2011, BOAH employed a director, a deputy director, a processing manager, an administrative assistant, an EIAO, 37 full-time inspectors, 10 part-time veterinary medical officers, and 2 full-time compliance officers. The director and deputy director are public health veterinarians, and the deputy director functions as an EIAO and performs FSAs.

BOAH developed a training program for new entry-level inspection personnel. The initial training prepares new inspectors to perform antemortem and postmortem inspection in slaughter establishments and covers basic slaughter techniques and all inspection techniques required to perform slaughter duties, including basic Sanitation SOPs and HACCP procedures. BOAH routinely assigns new inspectors to antemortem and postmortem inspection assignments. Prior to beginning these assignments, new inspectors work with supervisors and journeymen inspectors for two to three weeks and complete basic slaughter inspection training. This training includes methods to verify compliance with the humane slaughter of livestock regulatory requirements.

BOAH requires that new entry-level inspectors serve a six-month probationary period. To complete the probationary period and become a permanent employee, they must successfully complete trainings in slaughter inspection, basic HACCP, and food safety regulatory essentials. Additionally, new entry-level inspectors receive training on PBIS, sample collection procedures for animal disease control programs, Sanitation SOPs, HACCP, and pathogen reduction. The training program includes noncompliance documentation, tracking and verifying resolution of establishment noncompliance, and taking immediate regulatory control actions when public health safety is imminently threatened.

BOAH developed the Employee Work Profile/Performance Plan to establish work responsibilities, performance goals and objectives, and evaluate and provide feedback on job performance. As part of this performance evaluation system, Indiana mandates that BOAH supervisors conduct performance evaluations and appraisals after three and six months of employment, and annually thereafter. Trainees remain on probationary employment status until the supervisors complete the six-month performance appraisals and recommend permanent employment status. Supervisors record performance evaluation results for each State employee on Employee Performance Appraisal Reports and share these reports with employees.

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

Component 5 – Humane Handling

The PBIS records demonstrate that BOAH 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.

BOAH uses FSIS Directive 6900.2 *Humane Handling and Slaughter of Livestock,* and applicable slaughter DVDs to inform inspectors and establishment managers of the humane handling requirements and verification procedures. To make inspectors aware of recent humane handling issues, the BOAH director periodically distributes informational e-mails. When inspectors observe noncompliance, they are to issue noncompliance records, inform both establishment management and BOAH supervisors, and take appropriate regulatory action in response to inhumane handling or slaughter or livestock. BOAH supervisors review inspectors' performance of verification tasks during routine establishment visits and during specific biannual visits to examine each establishment's compliance with the humane handling requirements. BOAH supervisors document the results of these biannual visits.

In conclusion, the information made evident that BOAH 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

BOAH verifies establishment compliance with the non-food safety consumer protection regulatory requirements. BOAH uses applicable FSIS 7000 series Directives to communicate instructions to inspection personnel, and PBIS to schedule ongoing verifications and to document noncompliance. A thorough review of the PBIS data for a 12-month period supports the conclusion that BOAH inspectors correctly apply inspection methodology and document noncompliance.

BOAH established 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 BOAH approval.

In conclusion, the submitted documents provided evidence to show that BOAH 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

BOAH conducts in-commerce surveillance 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; investigates alleged or actual statutory or regulatory violations; and controls products when there is reason to believe that the products are adulterated, misbranded, or otherwise in violation of the Indiana Code.

The BOAH compliance review procedures are consistent with FSIS' Surveillance, Investigations, and Enforcement Methodology (SIEM). The BOAH compliance officers, who completed SIEM training, conduct compliance activities in accordance with the following FSIS Directives: 8010.1, *Methodology for Conducting In-Commerce Surveillance Activities*; 8010.2, *Investigative Methodology;* 8010.3, *Procedures for Evidence Collection, Safeguarding and Disposal;* and 8010.4, *Report of Investigation.*

The compliance program director, within the Legal Affairs and Compliance Division of BOAH, reviews the compliance reports for accuracy, determines whether the applied enforcement actions were appropriate and justified, and verifies that BOAH meets its management control standards and objectives.

BOAH maintains procedures for the recall of meat and poultry products subject to its jurisdiction that are 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 BOAH within 24 hours of initiating a recall. BOAH 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.

BOAH has established methods to record, triage, analyze, and track consumer complaints related to State-regulated meat or poultry. 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 or regulatory enforcement actions, and report potential food safety threats. The compliance program director oversees the consumer complaint investigations and reviews the associated documents.

The submitted documents support the conclusion that BOAH maintains a system to verify compliance of meat and poultry products in intrastate commerce and take 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 10, 2011, BOAH 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 BOAH functions "at least equal to" the Federal civil rights requirements.

Component 9 – Financial Accountability

BOAH submitted quarterly and final Financial Status Reports (SF-425) 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 BOAH is "at least equal to" Federal standards for financial accountability for FY 2012.

On April 9 – 13, 2012, FRAS conducted an on-site fiscal review of BOAH. This review encompassed Federal fiscal years 2009, 2010, and 2011. As a result of this review, FRAS determined that BOAH is operating in full compliance with the financial and administrative provisions of FSIS Directive 3300.1, Rev.2, and the criteria outlined in the FSIS *"At Least Equal To" Guidelines for State Meat and Poultry Cooperative Inspection Programs* (July 2008).

Self-Assessment Determination for Indiana

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