Appendix F

Comprehensive Review and Determination Report

Fiscal Year 2021

Indiana

Federal-State Audit Staff
Office of Investigation, Enforcement and Audit
Food Safety and Inspection Service
U.S. Department of Agriculture
April 2022

The USDA is an equal opportunity provider and employer.
# Table of Contents

- **Purpose** ...............................................................................................................................................1
- **Description of Indiana’s MPI Program** ...............................................................................................1
- **Annual Determination** .......................................................................................................................1
- **Self-Assessment Review Methodology** ..............................................................................................1
- **Review of Indiana’s Self-Assessment Submission** .............................................................................2
- **Self-Assessment Determination for Indiana** ....................................................................................9
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 Indiana 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 Indiana’s MPI Program
The State of Indiana Board of Animal Health (IN BOAH), Meat & Poultry Inspection Division (MPID) administers the Indiana MPI program under authority of Indiana Code (Title 15, Article 17, Chapter 5). The program verifies compliance and enforces regulatory requirements at 77 inspected facilities and 38 custom exempt establishments. In addition, IN BOAH MPID provides inspection at 16 facilities in the Cooperative Interstate Shipment Program.

Annual Determination
FSIS determined that IN BOAH MPID is operating a meat and poultry inspection program “at least equal to” the Federal requirements. IN BOAH MPID 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. Since IN BOAH MPID was not subject to an onsite review for Components 1 through 9 during fiscal year (FY) 2021, FSIS based its annual determination on review of the self-assessment documents only. This determination is fully explained in the Review of Indiana’s Self-Assessment Submissions section. The last onsite review conducted of IN BOAH MPID by FSAS was in March 2019.

Self-Assessment Review Methodology
The annual self-assessment process is designed for each State to provide sufficient information to adequately demonstrate their administration of an “at least equal to” State MPI program. The review objective is to determine whether a State continues to administer an MPI program that meets Federal standards set for ensuring meat and poultry products are safe, wholesome, unadulterated, and correctly labeled and packaged. Each review cycle, State MPI program officials are to complete and submit self-assessment component surveys, supporting documentation and other self-assessment instruments to FSIS in accordance with the State Reporting and Communication Tool User Guide and FSIS “At Least Equal To” Guideline for State Meat and Poultry Inspection Programs.

FSIS begins the annual comprehensive review by assembling a review team comprised of subject matter experts from various FSIS program areas to review the nine components of the

---

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).
comprehensive review process. The review team, comprised of Agency representatives from the Federal-State Audit Staff (FSAS); the Civil Rights Staff (CRS); Financial Reviews and Systems Branch (FRSB); Laboratory Quality Assurance Response and Coordination Staff (LQARCS); 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. During the desk 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 Indiana’s Self-Assessment Submission
FSAS evaluated the self-assessment documents for the applicable review components to determine whether IN BOAH MPID constitutes an inspection program “at least equal to” the Federal program. The determination and rationale for each review component are listed below.

FSAS received IN BOAH MPID’s complete self-assessment submission for components 1 through 6 on December 21, 2020. FSAS sent a notification to IN BOAH MPID requesting additional information. IN BOAH MPID 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 March 30, 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 FMIA, PPIA, and the Humane Methods of Slaughter Act (HMSA), and the regulations promulgated under these laws. The supporting documentation included the Indiana Code (Title 15, Article 17, Chapters 2 and 5) and Indiana Administrative Code (Title

---

3 Non-designated 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 Act, Poultry Products Inspection Act and Humane Methods of Slaughter Act of 1978.
The Indiana Code provides authorities for mandatory ante-mortem and post-mortem inspection, reinspection, sanitation requirements, and record keeping requirements (Section 15-17-5-4), and humane methods of slaughter requirements (Sections 15-17-5-1, 15-17-5-8, and 15-17-5-11).

In addition, the Indiana Code provides authorities that are “at least equal to” the FMIA and PPIA regarding adulteration (Section 15-17-2-2), misbranding (Section 15-17-2-64), prohibited acts (Sections 15-17-5-1, 15-17-5-6, and 15-17-5-16), access and examination (Sections 15-17-5-4 and 15-17-5-10), and product control actions (Sections 15-17-5-20 and 15-17-5-21). It also includes sufficient authorities for criminal, civil, and administrative sanctions to address violators.

The Indiana Code grants the authority to promulgate rules and regulations (Section 15-17-5-5). 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, 381.115-381.182, 381.189-381.194, 381.300-381.500, 416-441, and 500, in the Indiana Administrative Code (Sections 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, IN BOAH MPID 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. IN BOAH MPID uses the FSIS Public Health Information System (PHIS) to schedule inspection tasks and to collect, consolidate, and analyze inspection data. IN BOAH MPID 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 Indiana Code 15-17-2-47 and 15-17-2-87 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, IN BOAH MPID 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, IN BOAH MPID 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 plans, Sanitation Standard Operating Procedures, prerequisite programs, sampling programs, supporting documentation and records, and any other programs that constitute the establishments’ food safety systems. The PHRE and FSA records support the conclusion that State inspection personnel recognize and document noncompliance and initiate appropriate regulatory actions.

IN BOAH MPID verifies establishment compliance with the non-food safety (i.e., labeling) consumer protection regulatory requirements. IN BOAH MPID 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 IN BOAH MPID inspectors correctly apply the inspection methodology and document noncompliance.

IN BOAH MPID has developed and implemented 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 obtain approval from IN BOAH MPID by submitting a completed application for label approval and a label sketch. IN BOAH MPID provides labeling guidelines for inspection personnel and establishments early in the process of an establishment applying for inspection. The oversight of this process is through the processing manager.

IN BOAH MPID enforces the Indiana Administrative Code 345 articles 9 and 10, 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. IN BOAH MPID maintains procedures to document relevant facts of administrative actions and ensure that administrative actions are legally supportable and based on relevant facts.

IN BOAH MPID has a system for reviewing custom exempt operations that is in accordance with FSIS Directive 8160.1, Custom Exempt Review Process. New Custom Exempt (CE) establishments are reviewed every four to eight weeks to verify they are meeting the regulatory requirements. New CE visits continue until the area supervisor is satisfied regulatory requirements are being met. Established CE facilities are reviewed at least annually, most are reviewed twice a year. Area supervisors or their inspection personnel may perform CE reviews. A category one risk finding on a CE review triggers a followup within 14 days.

The submitted documents support the conclusion that IN BOAH MPID:

- 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 IN BOAH MPID’s sampling protocols, procedures, and results to Federal policies and procedures.

IN BOAH MPID 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; *Campylobacter* Performance Standards in raw classes of poultry; and
- Other consumer protection standards.

The sampling plans include procedures for sample collection, sample integrity, and laboratory analysis. IN BOAH MPID developed policies to respond to positive results. These policies include actions to prevent adulterated product from entering commerce. IN BOAH MPID 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 IN BOAH MPID 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, Training, and Supervision
IN BOAH MPID 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 area supervisor is responsible for their inspection personnel assignments, establishment and inspector reviews, on-the-job-training, and evaluations. Assignments are based on facility schedules of operations as well as ongoing communication to provide inspection as needs change week to week and updated as needed daily. Supervisors provide weekly assignment schedules for their facilities utilizing MPI inspection personnel in the most efficient manner. Relief is provided by the other inspectors in the area or by the supervisors themselves.

At the start of the FY 2021 review cycle, IN BOAH MPID indicated they employ a director, a deputy director, a food scientist/EIAO, a program manager, 6 supervisors, 33 inspectors, 9 part time veterinary medical officers (from the Veterinary Services Division), and 3 compliance officers.
IN BOAH MPID continues to implement a training program for new entry-level inspection personnel. New inspectors are provided a minimum two-week training orientation. The first week is dedicated to didactic materials: State Personnel Department information and enrollment procedures; State and agency policies; inspection related DVDs and CDs; and printed resources. The following week is typically in-plant training under a supervisor and staff in a different area from where the inspector will be assigned. The IN BOAH MPID has developed 24 topics to be covered by trainers in the field. Training in the subsequent week(s) will be in plants where the inspector will be stationed, but will be with the supervisor or mentor to work together until such time the trainers are confident in the new inspector’s ability to perform on his/her own. Training for each new inspector is tailored to the individual’s experience and needs as determined by the training team, made up of the central office staff and field trainers. IN BOAH MPID also provides employees with inspection methods training as it becomes available. IN BOAH MPID maintains a record keeping system to track participation and completion of training.

Slaughter inspection competency is evaluated by area supervisors at least every year and includes ante-mortem and post-mortem procedures. This is utilized as a management control tool for inspector evaluations. This allows for frequent training reviews and feedback during an inspector’s tenure with the program. All meat inspectors are cross-trained and expected to be knowledgeable in processing and slaughter. In addition, Indiana 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 IN BOAH MPID 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 IN BOAH MPID’s inspection methodology, to document findings, and to initiate regulatory actions, when necessary. Control measures are in effect to confirm that IN BOAH MPID’s staffing and training systems function as intended.

Component 5 – Humane Handling
IN BOAH MPID 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.

IN BOAH MPID uses FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock, to communicate instructions to inspection personnel. Inspectors document humane handling verifications in PHIS. Area supervisors evaluate establishments’ humane handling procedures and inspectors’ humane handling task performance and 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 IN BOAH MPID 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

The Legal Affairs Division of BOAH conducts in-commerce surveillance of persons or firms who 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 secure from threats or intentional acts of contamination. They use the tier-based system outlined in FSIS Directive 8010.1, Methodology for Conducting In-Commerce Surveillance Activities, to prioritize and determine which in-commerce firms will be surveilled. To minimize overlaps in surveillance activities, the Legal Affairs Division of BOAH works closely with FSIS, Compliance Investigation Division (CID) to set the priority of random surveillance activities conducted at firms in the State. The Legal Affairs Division of BOAH limits the focus of their surveillance activities to firms producing meat or poultry products from State-inspected source materials. Since all tier 1 in-commerce firms (e.g., warehouses and distributorships) produce products exclusively from Federally inspected source materials, the Legal Affairs Division of BOAH directs State investigators to prioritize tier 2 firms when scheduling surveillance review activities. State investigators are expected to conduct, as needed, investigations, followup reviews, food recall checks, foodborne illness investigations, referrals from another agency, and product sampling. The Legal Affairs Division of BOAH initiates an investigation after it has been determined that a violation has occurred. To verify the violation has been corrected, a followup review is scheduled to occur three months after violation occurrence; if another violation is found, a return followup review will take place in an additional three months. However, if there are no violations, a return followup would be scheduled for nine months. And then, if there are no violations, the next followup would be in 12 months. If no violation is found at the last followup visit, no further followup would be scheduled.

Usually, investigations are initiated from consumer complaints, surveillance activities and inquiries by local health departments and Indiana State Department of Health, Food Protection Division authorities during their routine inspections of food banks, restaurants, retailers, and institutions. The Legal Affairs Division of BOAH 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 Indiana Code (Title 15, Article 17, Chapters 2 and 5); and takes enforcement action, when needed, up to and including prosecution of individuals or firms that have violated the Indiana Code (Title 15, Article 17, Chapters 2 and 5). The Legal Affairs Division of BOAH 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.

IN BOAH divides compliance work among two internal groups, MPID and the Legal Affairs Division. MPID relays tips regarding apparent violations and consumer complaints with the Legal Affairs Division for investigation and manages the administrative paperwork for the State investigators, such as, work logs, itineraries, vehicle telemetry, email communications, and
investigative reports are some methods of management control. The Legal Affairs Division oversees legal documentation and activities associated with investigations, cease and desist orders, warnings, fines, or referrals for civil or criminal prosecution.

IN BOAH’s recall committee will determine the need for a recall. The recall committee consists of the State veterinarian, IN BOAH MPID’s director and deputy director, MPI processing manager, and BOAH’s Legal Affairs/Compliance Division. The recall committee and inspection personnel consider all available information to determine whether product is in commerce, and whether any product that has been distributed in commerce has reached retail facilities, restaurants, or consumers. The recall committee considers the human health hazard presented by the product subject to recall to determine the appropriate recall classification. The recall committee allows establishments to present information about the hazard or concern associated with the product. BOAH expects the establishment to provide its recall strategy, including how it intends to notify and instruct its consignees to retrieve or dispose of product.

IN BOAH established methods to record, triage, analyze, and track consumer complaints related to State-regulated meat or poultry products. Consumer complaints may come through local health departments or Indiana State Department of Health, Food Protection Program. These complaints related to meat and poultry products are communicated via phone and email to IN BOAH MPID’s director or deputy director, who then send information via email to the compliance officer who covers the area of the complaint. Once the complaint is received, an urgent surveillance review is made a priority. The consumer complaint is then recorded into the USA HERDS tracking system. 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 IN BOAH MPID 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 Indiana State Department of Health Laboratories (Indiana) 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 “same as” program, Indiana meets the requirements of the State MPI “at least equal to” Program Laboratory Quality Management System Checklist. Indiana conducts microbiological testing for *Salmonella*, *Campylobacter*, *L. monocytogenes*, *E. coli* O157:H7 and non-O157 STEC. Indiana conducts food chemistry testing for the measurement of moisture, protein, fat, and salt.

FSIS compared the Indiana Laboratory Quality Assurance Program to the State MPI Program Laboratory Quality Management System Checklist and evidence of laboratory proficiency and
analyst training was evaluated. Based on their self-assessment, Indiana met all laboratory quality assurance requirements including analysts’ training and related proficiency testing.

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

Based on the Component 7 methods and quality assurance program review, Indiana 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 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 BOAH MPID submitted the required FSIS Form 1520-1, Civil Rights Compliance of State Inspection Programs, to demonstrate adherence to Federal civil rights laws and USDA’s civil rights regulations. On November 30, 2021, CRS concluded that IN BOAH MPID functions “at least equal to” the Federal civil rights requirements.

Component 9 – Financial Accountability
IN BOAH MPID 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. FRSB determined that IN BOAH MPID is “at least equal to” Federal standards for financial accountability for FY 2021.

Self-Assessment Determination for Indiana
Based on the evidence and review results described above, FSIS determined that IN BOAH MPID provided adequate documentation to show it is operating a meat and poultry inspection program “at least equal to” the Federal requirements.