FSIS Review of State Meat and Poultry Inspection Programs

Fiscal Year 2011 Summary Report

Federal/State Audit Branch Internal Control and Audit Division Office of Program Evaluation, Enforcement and Review Food Safety and Inspection Service United States Department of Agriculture December 2011

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Executive Summary

This report presents the Food Safety and Inspection Service (FSIS) fiscal year (FY) 2011 review results for the 27 State Meat and Poultry Inspection (MPI) programs¹ that currently operate under cooperative agreements with FSIS². These 27 State MPI programs provide inspection to more than 1,700 small and very small establishments. The jurisdiction of the State MPI programs is limited to product that is produced and sold within the State.

The Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) provide for FSIS to cooperate with State agencies in developing and administering State MPI programs. Each State MPI program needs 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. State MPI programs are also 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). If a State fails to administer a MPI program that is "at least equal to" the program that FSIS has established under the applicable provisions of the FMIA and PPIA, the Secretary of the United States Department of Agriculture will move to designate the State in accordance with 21 U.S.C. 661 (c) and 454 (c).

The FY 2011 State MPI program reviews were based on FSIS Directive 5720.3, *Methodology for Performing Scheduled and Targeted Reviews of State Meat and Poultry Inspection Programs*³, and the companion FSIS "*At Least Equal To*" *Guidelines for State Meat and Poultry Cooperative Inspection Programs* (July 2008)⁴. The FSIS comprehensive State MPI program review 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. Each year, FSIS determines whether the State MPI program is "at least equal to" the Federal inspection program based on one or both parts of the comprehensive review.

Based on review of the self-assessment documents, FSIS determined that each of the 27 State MPI programs provided adequate documentation to support that they have adopted laws, regulations, and programs, and implemented them in a manner that is "at least equal to" the Federal inspection program. FSIS determined that each of the 7 State MPI programs that received routine on-site reviews⁵, and 1 State program that received a targeted on-site review⁶ were enforcing requirements "at least equal to" those imposed under the Federal Acts.

¹ The 27 States are Alabama, Arizona, Delaware, Georgia, Illinois, Indiana, Iowa, Kansas, Louisiana, Maine, Minnesota, Mississippi, Missouri, Montana, North Carolina, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Texas, Utah, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming.

² This report does not include egg products, which are also regulated by USDA FSIS. The Federal Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 <u>et.seq.</u>) makes no provisions for State inspections.

³ Available at <u>http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/5720.3.pdf</u>

⁴ Available at http://www.fsis.usda.gov/PDF/At_Least_Equal_to_Guidelines.pdf

⁵ FSIS conducted routine on-site reviews in the following 7 States: Alabama, Arizona, Delaware, Georgia, Illinois, Montana, and Utah.

⁶ FSIS conducted a targeted on-site review in Kansas to examine effective resolution of previous on-site review findings.

Introduction

In fiscal year (FY) 2011, the Food Safety and Inspection Service (FSIS) completed selfassessment reviews of all 27 State MPI programs, routine on-site reviews of 7 State MPI programs, and 1 targeted on-site review, for a total of 8 on-site reviews, to determine whether the State MPI programs have adopted laws, regulations, and programs, and implemented them in a manner that is "at least equal to" the Federal inspection program. The targeted on-site review examined effective resolution of previous on-site review findings. This report presents the annual review results for the 27 State MPI programs¹. Detailed review results for each State MPI program are presented as an attached appendix.

Background

Under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), FSIS sets national standards for meat and poultry inspection. Under an "at least equal to" cooperative agreement with FSIS, States may operate their own MPI programs if they meet and enforce requirements "at least equal to" those imposed under the FMIA, PPIA, and Humane Methods of Slaughter Act of 1978 (HMSA). The FMIA (21 U.S.C. 601 <u>et seq.</u>) and PPIA (21 U.S.C. 451 <u>et seq.</u>) provide that it is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and poultry products distributed to them are wholesome, not adulterated, and accurately labeled and packaged.

The FMIA and PPIA provide for FSIS to cooperate with State agencies in developing and administering State MPI programs. Each State MPI program is expected 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. State MPI programs are also expected to ensure that livestock are treated humanely by imposing humane handling requirements that are "at least equal to" that FSIS has established under the HMSA.

If a State fails to administer a MPI program that is "at least equal to" the program that FSIS has established under the applicable provisions of the FMIA and PPIA, the Secretary of the United States Department of Agriculture will move to designate the State as one in which the provisions of titles I and IV of the FMIA and sections 451 to 453, 455 to 459, and 461 to 467d of the PPIA shall apply to operations and transactions wholly within such 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, and poultry products.

Cooperative agreements and annual certifications of State MPI programs are contingent upon FSIS determining that the State MPI program is enforcing requirements "at least equal to" those imposed under the Federal Acts. FSIS performs annual reviews to determine whether each State

¹ This report does not include egg products, which are also regulated by USDA, FSIS. The Federal Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 <u>et.seq.</u>) makes no provisions for State inspections.

MPI program meets, and can maintain for a period of 12-months, the mandated "at least equal to" standard.

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. The 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 comprehensive reviews of each State MPI program, FSIS may perform a targeted review of a State MPI program any time evidence or conditions suggest there are program weaknesses that may result in unacceptable risk to public health or that the program is not maintaining "at least equal to" status. 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 program components:

- 1. <u>Statutory Authority and Food Safety Regulations</u> 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, HMSA, and the regulations that FSIS has promulgated under these laws.
- 2. <u>Inspection</u> 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 adopted by FSIS.
- 3. <u>Product Sampling</u> 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 raw, non-intact beef products and raw ground beef components, *Listeria monocytogenes* and *Salmonella* in ready-to-eat 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. <u>Staffing and Training</u> This component evaluates whether the State MPI program provides competent inspection coverage in each establishment on days the establishment produces product that, if found to be safe, wholesome, unadulterated, and properly labeled is to bear the State mark of inspection.

- 5. <u>Humane Handling</u> 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. Additionally, this component evaluates whether State MPI program personnel perform regulatory verification procedures to assess whether carcasses of poultry showing evidence of having died from causes other than slaughter are considered adulterated and condemned, and 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. <u>Non-Food Safety Consumer Protection</u> 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. <u>Compliance</u> This component evaluates whether State MPI program personnel perform surveillance activities with respect to meat or poultry products in intrastate commerce and take appropriate actions in the event that adulterated or misbranded products enter intrastate commerce.
- 8. <u>Civil Rights</u> This component evaluates whether the State MPI program adheres to Federal civil rights laws and USDA civil rights regulations.
- 9. <u>Financial Accountability</u> This component evaluates whether the State MPI program conforms with 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 assembles multi-disciplinary review teams to perform the reviews. The review teams include subject matter experts in meat and poultry inspection systems, compliance and enforcement programs, staffing, civil rights, and financial accountability. Subject matter experts in meat and poultry inspection systems, staffing, and compliance and enforcement programs review components 1 through 7. A civil rights specialist reviews component 8. A financial specialist reviews component 9.

The comprehensive review process consists of two parts: (1) an annual review of the State MPI program's self-assessment submission; and (2) at a minimum, a triennial verification on-site review to observe the State MPI program. Each year, FSIS determines whether the State MPI program is "at least equal to" the Federal requirements and can maintain its program based on one or both parts of the comprehensive review.

Part 1 – Self-Assessment Review

In the first part of this methodology, State MPI programs are required to submit annual selfassessment documentation and certification statements by November 15 of every year. The selfassessment submission provides documentation concerning the rules, regulations, and policies within the State MPI program to provide a basis for FSIS to determine whether the State MPI program meets the mandated "at least equal to" Federal requirements. FSIS considers the information provided to represent an auditable description of how the State MPI program is currently functioning and will continue to function.

FSIS reviews the State MPI program's annual self-assessment submission to determine whether it demonstrates that the State MPI program is "at least equal to" the Federal inspection requirements and that it includes evidence and documents that support that the processes are in effect and current with FSIS policies. As questions arise during the self-assessment review, FSIS requests clarifying information or supporting documentation from the State MPI program. The FSIS review team then makes a determination based on review of the entire self-assessment submission.

Part 2 – On-Site Review

In the second part of this methodology, FSIS conducts triennial verification on-site reviews to observe the State MPI program and verify that the State MPI program has implemented and can maintain its inspection system, and to determine whether the State MPI program is enforcing requirements "at least equal to" the Federal requirements. During the on-site review, FSIS reviews State MPI program records at the State MPI program office and a sample set of establishments, resulting in an overall annual determination.²

Before traveling to the on-site review location, the review team begins preparation for the on-site review with a thorough review of the State MPI program's most recent self-assessment submission. Prior to the scheduled start of the review, the review team sends written notification to the State MPI program director to announce the scheduled dates for the forthcoming on-site review. Both parties usually agree upon the dates prior to this notification.

The on-site review begins with an entrance meeting teleconference with FSIS and State MPI program officials. During this meeting, FSIS introduces the team members, explains the purpose and methodology of the review, and answers any questions. At this time, the FSIS team leader requests that State MPI program officials submit the following information within 10 business days of the teleconference:

- Descriptions of any changes in the MPI program that occurred since the most recent selfassessment submission
- A current list of establishments receiving inspection from the State MPI program
- A description of each State supervisor's area of responsibility
- The Hazard Analysis Critical Control Point (HACCP) processing categories for each Stateinspected establishment and a ranking of the highest volume producers for each HACCP processing category

² The review team schedules and conducts the main on-site review for components 1 - 7. The on-site reviews for components 8 and 9 – Civil Rights and Funding and Financial Accountability – are scheduled separately and conducted, respectively, by the FSIS Civil Rights Division and FSIS Financial Management Division.

- A list of all State-inspected establishments that the State MPI program has reviewed within the preceding 12 months
- A list of all State-inspected establishments with a history of any of the following within the preceding 12 months:
 - Positive sample results for pathogens (e.g., *E. coli* O157:H7 in non-intact, raw beef products; *Listeria monocytogenes, Salmonella*, or *E. coli* O157:H7 in ready-to-eat products)
 - *Salmonella* verification sample set results that exceed the performance standard or guideline established by FSIS
 - Enforcement actions
 - Recalls
 - Structural damage to State-inspected establishments caused by a natural or other disaster

For each State MPI program, the FSIS review team initially calculates the minimum number of establishments for the on-site review using a statistically valid sampling method. After determining the total number of establishments for the on-site review, the review team selects specific establishments for review based largely on the following criteria:

- All establishments with a history of any of the following within the preceding 12-months are selected:
 - Positive sample results for pathogens (e.g., *E. coli* O157:H7 in non-intact, raw beef products; *Listeria monocytogenes, Salmonella* or *E. coli* O157:H7 in ready-to-eat products)
 - *Salmonella* verification sample set results that exceed the performance standard or guideline established by FSIS
 - Enforcement actions
 - Recalls
 - Structural damage to State-inspected establishments caused by a natural or other disaster
- At least 3 establishments that the State MPI program reviewed during the preceding 12months are selected
- Selection of additional establishments is prioritized based on concerns identified during the self-assessment review, inherent product risk, production volume, and HACCP-processing categories

The FSIS review team provides State MPI program officials with a list of the selected establishments at least 5 business days before the on-site review.

During the on-site review, FSIS begins each establishment review with an entrance meeting with State MPI program officials and establishment management to explain the purpose of and methodology for the review, as well as to answer any questions. During the establishment reviews, FSIS review team members observe State MPI program officials executing the State MPI program to determine if they enforce requirements and implement product-sampling programs "at least equal to" the Federal program. At each establishment, FSIS reviews the State MPI program's verification of compliance with applicable State requirements on Sanitation Standard Operating Procedures (SOP), Sanitation Performance Standards (SPS), HACCP, nonfood safety related consumer protection, control of specified risk material, humane handling, and custom/retail exempt requirements. The FSIS review team members observe the State MPI program inspectors as they perform antemortem and postmortem inspection procedures. Based on observation and records review, the FSIS review team members document any establishment noncompliance that the State MPI program failed to recognize or for which the State MPI program has failed to take an appropriate regulatory action. At the conclusion of each establishment review, the FSIS review team members report the findings to State MPI program officials.

After completion of the establishment reviews, the FSIS team reviews documents at the State MPI program office. This review provides additional information to determine whether the results of the review support a determination that the State MPI program is "at least equal to" the Federal inspection program with respect to product sampling, staffing, training, and compliance, and that the State MPI program has an internal control system that identifies and addresses risk and ensures the program functions as intended.

After the on-site review of State establishments and document review at the State MPI program office, the FSIS review team returns to its office and assembles for the final analysis. The review team analyzes all information gathered during the review, as well as the results of the current year's self-assessment review, asks any follow-up questions, requests any additional information needed, and then identifies the findings, including any program deficiencies. Findings are based on reviewers' independent assessment during the on-site review, comparison of the on-site review findings with the State MPI program's operations and records, as well as the State MPI program's self-assessment submissions. The review team's findings are to focus on implementation of food safety policy and procedures, and on whether the State MPI program meets the criteria for each of the nine components detailed in the Review Methodology section.

The FSIS review team leader presents the adverse findings to State MPI program officials at the exit-meeting teleconference. The State MPI program is to submit a written action plan to correct all the adverse review findings within 10 business days of the date of the exit conference. The action plan is to:

- Identify the underlying causes of the adverse findings that may be system-wide and ensure Statewide rectification of such findings
- Identify the underlying causes of specific adverse findings at individual establishments and ensure that the State MPI program verifies that the establishments address such findings
- Identify the verification plan or controls that the State MPI program will implement throughout the year to verify the effectiveness of the corrective actions.

Determination Process

Each year, FSIS determines whether each State MPI program meets the "at least equal to" standard, 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, then FSIS makes an annual determination based on the results of both the self-assessment and on-site review.

Following each self-assessment and on-site review, FSIS determines whether each State MPI program meets the "at least equal to" standard. FSIS makes one of the following three determinations for each of the nine components and on the State's overall ability to maintain its MPI program for the next 12 months:

- (1) "At least equal to" The State MPI program 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.
- (2) Not "at least equal to" 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 the Federal inspection program for one or more of the review components.
- (3) Deferred 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.

If the results of the self-assessment or of the on-site review are that the State MPI program is "at least equal to" the Federal inspection program, FSIS promptly notifies State MPI program officials in writing of this fact. If FSIS needs additional information from State MPI program officials to reach a determination, FSIS requests that State MPI program officials provide that information. FSIS does not make a determination until all necessary information is collected and analyzed. If FSIS determines that a State MPI program is unable or unwilling to maintain an inspection program that is "at least equal to" the Federal inspection program, the Secretary of the United States Department of Agriculture will promptly notify the Governor of the State of this fact. If a State MPI program becomes subject to the designation process, FSIS will rescind the cooperative agreement between FSIS and the subject State, and all meat and poultry establishments within the State will become subject to Federal inspection.

Review Findings

The findings of the FSIS review teams are summarized here and in Tables 1 and 2. Detailed findings for each State MPI program are available in the attached appendices. Based on the 27 self-assessments received during FY 2011, FSIS determined that all State MPI programs have provided adequate documentation to support that they have implemented and can maintain a MPI program "at least equal to" the Federal requirements. These determinations are summarized in Table 1 – FSIS' FY 2011 Determinations of the 27 State MPI Programs, Based on the Self-Assessment Review Results Only.

In addition, FSIS performed routine on-site reviews of 7 State MPI programs (Alabama, Arizona, Delaware, Georgia, Illinois, Montana, and Utah), and a targeted on-site review in Kansas, for a total of 8 on-site reviews. Based on the FY 2011 self-assessment and the respective on-site review results, FSIS determined that all 8 State MPI programs are enforcing requirements "at least equal to" those imposed under the Federal Acts. These determinations are summarized in

Table 2 – FSIS' FY 2011 Determinations for 8 State MPI Programs, Based on the Verification On-Site Review Results.

Next Steps

FSIS will continue to work with State MPI program officials to improve their programs and the State MPI program review process.

During FY 2012, FSIS will conduct annual reviews of all 27 State MPI programs. FSIS will send written notification to the directors of the State MPI programs selected for on-site reviews at least 30 days before the scheduled start of the review.

At the end of calendar year 2012, FSIS will complete an end-of-year report that summarizes the findings and final determinations for all 27 State MPI programs, and make this report and the individual reports for each State MPI program available on the FSIS Web site.

In light of adverse economic conditions which may affect State budgets, FSIS will continue to monitor the financial health of each on the 27 State MPI programs to include financial expenditures, general management, operations, and management control systems to assure that State MPI programs effectively use the funds to meet the "at least equal to" standard.

Table 1 - FSIS' FY 2011 Determinations for the 27 State MPI ProgramsBased on the Self-Assessment Review Results Only

State	"At Least Equal To" ¹	Not "At Least Equal To" ²	Deferred ³
Alabama	✓		
Arizona	\checkmark		
Delaware	✓		
Georgia	✓		
Illinois	\checkmark		
Indiana	\checkmark		
Iowa	\checkmark		
Kansas	✓		
Louisiana	\checkmark		
Maine	\checkmark		
Minnesota	\checkmark		
Mississippi	✓		
Missouri	✓		
Montana	\checkmark		
North Carolina	\checkmark		
North Dakota	\checkmark		
Ohio	\checkmark		
Oklahoma	✓		
South Carolina	✓		
South Dakota	\checkmark		
Texas	\checkmark		
Utah	✓		
Vermont	✓		
Virginia	\checkmark		
West Virginia	\checkmark		
Wisconsin	\checkmark		
Wyoming	\checkmark		

¹ "At least equal to" – 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" – 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 – 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.

Table 2 - FSIS' FY 2011 Determinations for 8 State MPI ProgramsBased on the Verification On-Site Review Results

State	"At Least Equal To" ¹	Not "At Least Equal To" ²	Deferred ³
Alabama	\checkmark		
Arizona	\checkmark		
Delaware	\checkmark		
Georgia	\checkmark		
Illinois	\checkmark		
Kansas ⁴	\checkmark		
Montana	\checkmark		
Utah	\checkmark		

¹ "At least equal to" – 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" – 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 – 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.

⁴ FSIS performed a targeted on-site review in Kansas to assess effective resolution of previous on-site review findings.