

UNITED STATES DEPARTMENT OF AGRICULTURE  
FOOD SAFETY AND INSPECTION SERVICE  
WASHINGTON, DC

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# FSIS DIRECTIVE

5720.3

Revision 1

3/14/11

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## METHODOLOGY FOR PERFORMING SCHEDULED AND TARGETED REVIEWS OF STATE MEAT AND POULTRY INSPECTION PROGRAMS

### I. PURPOSE

This directive provides Federal State Audit Branch (FSAB) personnel in the Office of Program Evaluation, Enforcement and Review (OPEER) and other staff involved in performing scheduled and targeted reviews of State Cooperative Meat or Poultry Inspection (MPI) programs with the methodology to use in performing the reviews.

#### KEY POINTS:

- *FSIS's policy and procedures for scheduled and targeted reviews of State Cooperative MPI programs.*
- *FSIS's policy and procedures for conducting reviews of self-assessment submissions of State MPI programs.*
- *Methodology and Criteria that FSIS uses to determine whether State Cooperative MPI programs are "At Least Equal To" the Federal inspection program.*

**NOTE:** FSIS has published "At Least Equal To" Guidelines for State MPI programs (July 2008) at:

[http://www.fsis.usda.gov/PDF/At\\_Least\\_Equal\\_to\\_Guidelines.pdf](http://www.fsis.usda.gov/PDF/At_Least_Equal_to_Guidelines.pdf)

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## **II. CANCELLATION**

FSIS Directive 5720.3, Comprehensive Review Methodology of State Meat and Poultry Inspection Programs, dated 2/13/09.

## **III. REASON FOR REISSUANCE**

This directive is being reissued to update sections of the previous directive and add a new section on the targeted reviews of State MPI programs.

## **IV. REFERENCES**

Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, et seq.)  
Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, et seq.)  
Agriculture Marketing Act of 1946, as amended (7 U.S.C. 1621, et seq.)  
Humane Methods of Slaughter Act 1978 (7 U.S.C. 1901–1906)  
Title VI of the Civil Rights Act of 1964 (42 U.S.C. 200(d))  
Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794)  
Age Discrimination Act of 1990 (42 U.S.C. 12101, et seq.)  
9 CFR 306.5 (Appeals)  
FSIS Directive 1090.1, Management Controls  
FSIS Directive 1510.1, Equal Opportunity Notification on Material for the Public  
FSIS Directive 1510.2, Civil Rights Compliance and Enforcement  
FSIS Directive 3300.1, Fiscal Guidelines for Cooperative Inspection Programs  
FSIS Directive 5710.1, Designation of a State or an Individual State-Inspected Establishment for FSIS Inspection  
FSIS Directive 6900.1, Humane Handling of Disabled Livestock  
FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock  
"At Least Equal to" Guidelines for State Meat and Poultry Cooperative Inspection Programs

## **V. BACKGROUND**

A. 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 Cooperative MPI programs. Individual State Cooperative 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 ante-mortem and post-mortem inspection, reinspection, sanitation, record keeping, and enforcement provisions of the FMIA and PPIA. State Cooperative 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 USC 1901–1906).

B. The jurisdiction of a State Cooperative MPI program is limited to product that is produced and sold within the State.

C. The “at least equal to” standard requires that State Cooperative MPI programs operate in a manner that is at least as effective as the Federal inspection program. The statutes do not require that the States operate their MPI programs in a manner that is the same as or identical to the FSIS program, nor do they prohibit the State Cooperative MPI Programs from establishing safeguards that they believe to be more effective than those employed by FSIS.

D. If a State fails to administer a meat or poultry inspection program that is “at least equal to” the program that FSIS has established under the applicable provisions of the FMIA and HMSA or PPIA, FSIS will move to “designate” the State in accordance with 21 U.S.C. 661 (c) and 454 (c).

E. Under the FMIA and PPIA, FSIS may contribute up to 50 percent of the estimated total cost of the State’s Cooperative Inspection program and provide administrative support as long as the State is operating and maintaining a program that is “at least equal to” the Federal inspection program (21 U.S.C. 661 (a) (3) and 454 (a) (3)).

F. The FMIA and PPIA provide for FSIS to conduct at least annual reviews of State Cooperative 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)).

G. Under its authority to conduct reviews of State MPI programs, the FMIA and PPIA also provide FSIS with the authority to conduct prompt unscheduled or unannounced reviews of State MPI programs 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 scheduled reviews or may be performed at the same time as the scheduled review of a State MPI program (see section X).

H. A scheduled FSIS comprehensive review of a State’s Cooperative MPI program consists of two parts: (1) an annual review of the State Cooperative MPI program’s self-assessment submission, and (2) at a minimum, a triennial on-site review verification to observe the State MPI program. These comprehensive reviews determine whether a State has developed and is maintaining a meat or poultry inspection program that imposes requirements “at least equal to” those imposed by FSIS under specified provisions of the FMIA, PPIA, and HMSA. The comprehensive reviews also determine whether State Cooperative MPI programs are adhering to Federal civil rights laws and applicable USDA civil rights regulations and whether they conform to the Uniform Administrative

## Requirements for Grants and Cooperative Agreements to State and Local Governments.

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

## VI. REVIEW METHODOLOGY AND CRITERIA

The FSIS review team, comprised of staff from the Civil Rights Division (CRD), the Financial Review and Analysis Branch (FRAB), the FSAB, and representatives of other program areas as needed, evaluates each State Cooperative MPI program to determine whether it meets the “at least equal to” criteria for the following nine components:

1. Statutory Authority and Food Safety Regulations—State Cooperative MPI programs operate under laws and regulations that provide legal authorities at least equal to those provided under the FMIA, PPIA, and HMSA.
2. Inspection—State Cooperative 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. Product Sampling—State Cooperative 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; *Listeria monocytogenes*, *Salmonella*, or *E. coli* O157:H7 in ready-to-eat products; or drug residues at violative levels) and are accurately labeled (e.g., with nutrition information).
4. Staffing and Training—State Cooperative MPI programs provide 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—State Cooperative 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 Cooperative MPI program personnel also 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 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—State Cooperative 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. State Cooperative MPI program personnel take appropriate actions in response to noncompliance.
7. Compliance—State Cooperative 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—State Cooperative MPI programs adhere to Federal civil rights laws and USDA civil rights regulations. (Reviewed by CRD)
9. Financial Accountability—State Cooperative MPI programs conform with 7 CFR 3016, Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments, and follow FSIS Directive 3300.1, Rev. 2, Fiscal Guidelines for Cooperative Inspection Programs. (Reviewed by FRAB)

## **VII. SELF-ASSESSMENT REVIEW**

A. FSIS expects State Cooperative MPI programs to submit self-assessments to FSIS by November 15th of each year. The FSIS review team (described in section VI above) is to verify that the State’s annual self-assessment submission demonstrates that the State Cooperative MPI program is “at least equal to” the Federal inspection program (e.g., laws, rules, policies, procedures, and programs), and that it includes evidence and documentation that support the processes are in effect and current with FSIS policies.

B. The review team is to verify that the State Cooperative MPI program has control measures in place to substantiate that its program is functioning throughout the year as intended.

C. The review team is to analyze the submission from each State thoroughly and use the previous year's self-assessment submission as a reference for the current year.

**NOTE:** States are to submit any changes that they have made to their MPI programs during the previous 12 months and provide evidence that the State's Cooperative MPI program is current with FSIS statutes, regulations, and policies.

D. The review team is to request clarifying information from a State Cooperative MPI program if questions arise during the self-assessment review or if more information is needed before a determination as to whether the State Cooperative MPI program is "at least equal to" the Federal inspection program can be made. The review team is to analyze the supplemental information and continue to communicate its concerns to State Cooperative MPI program officials and continue to review supplemental information and corrective measures, until the review team determines whether the State Cooperative MPI program meets the "at least equal to" standard.

E. The review team is to verify that the State Cooperative MPI program has completed and submitted the following documents, as provided for in the *"At Least Equal To" Guidelines for State Meat and Poultry Cooperative Inspection Programs*:

1. Annual Certification "at least equal to" the Federal Meat and Poultry Inspection Program;
2. Annual Statement of Defensible Laboratory Results;
3. State Laboratory Activity Table;
4. State Establishment Profile;
5. State Assignment and Employment Report;
6. Compliance Activity Report; and
7. Certification Statement for Component 9.

F. At the conclusion of each self-assessment review, the FSIS review team is to determine whether the State Cooperative MPI program meets the "at least equal to" standard (See Part IX). If the State Cooperative MPI program is not scheduled for an on-site review, during the current fiscal year FSIS is to make an annual determination based only on the results of the self-assessment review. If the State Cooperative MPI program is scheduled for an on-site review during the current fiscal year, FSIS is to base the annual determination of the results of both the self-assessment and on-site reviews. The FSIS review team is to schedule the on-site review after the team determines that the results of the self-

assessment review support that the State Cooperative MPI program meets the “at least equal to” standard. If the FSIS review team determines that the State Cooperative MPI program is “not at least equal to” the Federal inspection program or identifies unacceptable risk to public health, the FSAB Branch Chief will assign a targeted review (see part X).

## **VIII. ON-SITE REVIEWS**

A. Before traveling to the on-site review locations, the review team is to begin preparation for the on-site review with a thorough review of the State Cooperative MPI program’s most recent self-assessment submission(s).

B. At least 30 days before the scheduled start of the review, the review team leader is to send written notification to the Director of the State Cooperative MPI program to announce the scheduled dates for the forthcoming on-site review. Dates have usually been agreed upon by both parties prior to this notification.

C. Prior to traveling to the on-site review location, the review team and Cooperative MPI program officials are to mutually agree upon a time for an entrance meeting teleconference to introduce the team members to the State MPI officials with whom they will work during the review. The team is to explain the review process, answer any questions, and request that the State Cooperative MPI program officials submit the following information within 10 business days of the teleconference:

1. Descriptions of any changes that have occurred in the MPI program since the most recent self-assessment submission;
2. A current list of establishments receiving inspection from the State Cooperative MPI program;
3. A description of each State field supervisor’s area of responsibility;
4. The Hazard Analysis and Critical Control Point (HACCP) processing categories for each State-inspected establishment and a ranking of the highest-volume producers for each HACCP processing category;
5. A list of all State-inspected establishments that the State Cooperative MPI program has reviewed (e.g., through a review similar to an FSIS food safety assessment or other State review) within the previous 12 months;
6. A list of all State-inspected establishments that have had a history of any of the following within the preceding 12 months:

- a. Positive sample results for pathogens (e.g., *E. coli* O157:H7 in non-intact, raw beef products or *Listeria monocytogenes*, *Salmonella*, or *E. coli* O157:H7 in ready-to-eat products);
- b. *Salmonella* verification sample set results that exceed the performance standard or guideline established by FSIS;
- c. Enforcement actions;
- d. Recalls; and
- e. Structural damage to State-inspected establishments caused by a natural or other disaster.

D. The review team is to select the total number of establishments for the on-site review using a statistically valid sampling method to the extent possible.

E. After determining the total number of establishments for the on-site review, the review team is to select specific establishments for review based largely on adverse public health risks identified in C (6) above, including at least three establishments that the State Cooperative MPI program has reviewed during the preceding 12 months.

F. The review team is to provide State Cooperative MPI program officials with a list of the selected establishments at least 5 working days before the on-site review.

G. The review team is to begin each establishment review with an entrance meeting with State Cooperative MPI program officials and establishment management to explain the purpose of and methodology for the review as well as to answer any questions.

H. During the on-site establishment reviews, a member of the review team is to observe State Cooperative MPI program personnel executing the State Cooperative MPI program.

I. At each establishment, the review team member is to review the State Cooperative MPI program's verification of compliance with applicable State requirements on Sanitation Standard Operating Procedures (Sanitation SOPs), HACCP, non-food safety related consumer protection, control of specified risk materials, humane handling, and custom exempt/retail exempt requirements.

J. The review team member is to also observe State Cooperative MPI program inspectors as they perform ante-mortem and post-mortem inspection procedures.

K. Based on observation and records review, the review team member is to document on FSIS Form 5000-9 any establishment noncompliance that the State



Cooperative MPI program failed to identify or for which the State Cooperative MPI program has failed to take appropriate corrective action. The review team member is also to document on FSIS Form 5000-9 other findings that indicate that the State Cooperative MPI program is not “at least equal to” the Federal program (e.g., State Cooperative MPI program personnel do not perform humane handling verification tasks or do not perform specific inspection procedures that are “at least equal to” those that FSIS inspection program personnel perform related to HACCP, SSOP).

L. At the conclusion of each establishment on-site review, the review team member is to report the findings to the State Cooperative MPI program officials.

M. The review team member is to observe the State Cooperative MPI program officials as they lead the exit conference with plant management and discuss the findings of each establishment review, including any noncompliances identified.

N. Before leaving an establishment, the review team member is to ensure that the State Cooperative MPI program officials have taken appropriate actions with respect to all noncompliances observed during the establishment review.

O. After completion of the establishment reviews, the review team is to assess product sampling, staffing, training, compliance program records (e.g., surveillance, investigations, and enforcement records), and management control documents at the State Cooperative MPI program office. This assessment of documents at the State Cooperative MPI program office is to include a representative sample of current MPI program records and is necessary to determine whether the documents evidence that the State Cooperative MPI program is implementing these programs in a manner consistent with the self-assessment documents, and whether the State Cooperative MPI program maintains and carries out its program in a manner that is “at least equal to” the Federal inspection program.

P. After the on-site review of State establishments and the assessment of documentation at the State offices, the review team is to return to its office and assemble for final analysis and report writing. To make an annual determination, the review team is to analyze all information gathered during the on-site review, as well as the results of the current fiscal year’s self-assessment review; ask any follow-up questions; request any additional information needed; and then identify findings, including any program deficiencies. Findings are based on the reviewer’s independent assessment during the on-site review and comparison of the on-site review findings with the State Cooperative MPI program’s operations and records as well as its self-assessment submission(s). The review team’s findings are to focus on implementation of food safety policy and procedures and on whether the program meets the criteria for the nine components detailed in Section VI.

Q. The review team leader is to:

1. Schedule an exit meeting with State Cooperative MPI program officials within 10 business days after completion of the on-site review.
2. Present the review team's findings to State Cooperative MPI program officials at the scheduled exit meeting. The review team leader will send the findings via e-mail prior to the exit meeting.
3. Request that the State Cooperative MPI program officials submit a written action plan for taking corrective action on all of the review team's findings within 10 business days of the date of the exit conference.
4. Explain to the State Cooperative MPI program officials that the State's action plan needs to:
  - a. Identify the underlying causes of any findings that may be system-wide and ensure that Statewide corrective action is taken on such findings;
  - b. Identify the underlying causes of specific findings at individual establishments and ensure that the State MPI program verifies that the establishments address such findings or noncompliances; and
  - c. Identify the verification plan and/or management controls that will be implemented throughout the year so that corrective actions may be adequately verified.

## **IX. DETERMINATION PROCESS FOR "AT LEAST EQUAL TO" STATUS**

A. Each year, FSIS is to determine whether each State Cooperative MPI program meets the "at least equal to" standard, based on the self-assessment and on-site reviews, if applicable. If the State Cooperative MPI program is not scheduled for an on-site review during the fiscal year, FSIS is to make an annual determination based on the results of the self-assessment review. If the State Cooperative MPI program is scheduled for an on-site review during the fiscal year, then FSIS is to make an annual determination based on results of both the self-assessment and on-site review.

B. Following each self-assessment and on-site review, FSIS is to make a determination on each State Cooperative MPI program based on the "at least equal to" standard. FSIS is to make one of the following three determinations for each component listed in section VI and on the State's overall ability to maintain its MPI program for the next 12 months.

1. "At Least Equal To"—The State Cooperative 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 Cooperative 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 Cooperative MPI program’s status because of the program’s inability to immediately implement corrective actions resulting from the review findings.

C. If the determination based on the self-assessment or on the on-site review is that the State Cooperative MPI program is “at least equal to” the Federal inspection program, FSAB will promptly notify the State Cooperative MPI program officials in writing of this fact.

D. If FSAB needs additional information from State Cooperative MPI program officials to make a determination, FSAB is to request the information from the State Cooperative MPI Program officials. A determination will not be made until all necessary information has been collected and analyzed.

E. In the event that a State Cooperative MPI program’s corrective action plan cannot be implemented immediately, but the State is committed to making the corrections and has the resources to support the changes, then, on a case by case basis, FSAB may recommend to the Assistant Administrator of OPEER a deferral of the determination on the State Cooperative MPI program’s “at least equal to” status. FSAB is to establish an oversight system and perform a follow-up review(s) to verify the State Cooperative MPI program’s effective implementation of its corrective action plan before making a determination.

F. If FSAB 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, FSAB is to notify the Assistant Administrator of OPEER, who in turn is to notify the FSIS Administrator of this conclusion. Reviews enable FSIS to determine whether a State has developed and is maintaining a meat and poultry inspection program that imposes requirements “at least equal to” those imposed by FSIS under the FMIA and PPIA. When States can no longer effectively administer and enforce meat and poultry inspection requirements that are “at least equal to” Federal requirements, they will be designated by the Secretary to receive Federal inspection. (See NOTE on page 12.)

## **X. TARGETED REVIEWS OF STATE MPI PROGRAMS**

A. Based on information from the States' annual self-assessment submissions, outbreak investigations, on-site reviews, or other available information, the FSAB Branch Chief may assign an FSAB review team to conduct a targeted review of a State MPI program when there is evidence that one or more of the following conditions exist:

1. A foodborne disease outbreak incident that is associated with or attributed to a State-inspected product;
2. Adverse trends in inspection activities, such as short-staffing situations or lack of trained inspection personnel;
3. Concerns raised during the self-assessment review process;
4. A rise in the number of product recalls;
5. An increase in surveillance and enforcement cases;
6. An increase in positive pathogen results; and
7. The presence of any other incident or condition that imposes a clear risk to public health.

**NOTE:** The FSAB review team assigned to conduct targeted reviews may be composed of the same staff members as described in Section VI and VIII, a smaller team (e.g., with only one program auditor or a subject matter expert from another program area), or a larger team, depending on the scope and urgency of the review.

B. For such targeted on-site reviews, the FSAB review team is to:

1. Follow the methodology in section VIII, but focus the scope and activities of the review on the conditions and evidence that triggered the need for the review.
2. Inform the State Cooperative MPI program officials of the upcoming targeted review, explain the scope and activities of the targeted review, request any needed information and materials, and determine acceptable review dates.
3. Upon completion of a targeted review, follow the instructions listed in Section VIII (P and Q) and Section IX to identify the findings, determine if the State MPI program is imposing requirements "at least equal to" the Federal requirements, and present the results of the review, along with any other information that accurately summarizes the program's "at least equal to" status, to appropriate State officials.

**NOTE:** See FSIS Directive 5710.1 at <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/5710-1.pdf> for the procedures for Designation of a State or an individual establishment within a State Cooperative MPI program.

## **XI. DATA ANALYSIS AND REPORTING**

FSAB will develop an end-of-year report that summarizes the findings and final determinations for all State Cooperative MPI Programs; highlights the components in Section VI with which States had difficulty complying; and sets out any other noteworthy findings. FSIS will post this report on the FSIS Web site.

Refer questions regarding this directive through supervisory channels.

A handwritten signature in black ink, appearing to read "David Joseph". The signature is written in a cursive style with a prominent loop at the end.

Assistant Administrator  
Office of Policy and Program Development