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Procedures for Evaluating

State Meat and Poultry

Inspection Programs

Under the FMIA and PPIA

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Food Safety and Inspection Service
Office of Policy, Program Development, and Evaluation
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Procedures for Evaluating State Meat and Poultry Inspection Programs Under the FMIA and PPIA¹

I. INTRODUCTION

Food safety agencies exist at all levels of government. To best ensure that consumers are protected from unsafe, unwholesome or misbranded foods, federal, state and local food safety agencies must work together cooperatively as part of an integrated national food safety system.

The Federal Meat Inspection Act (FMIA; 21 U.S.C. 351, et seq.) and the Poultry Products Inspection Act (PPIA; 21 U.S.C. 601, et seq.), provide for FSIS to cooperate with States wishing to administer state meat and poultry inspection (MPI) programs. FSIS provides funding and other assistance for state MPI programs as long as they meet the criteria specified for those programs in the FMIA and PPIA (hereinafter, the Acts), permitting assistance and making it unnecessary to designate the state as one in which federal inspection must apply to all establishments.

Background

In 1967 and 1968, respectively, the Federal meat and poultry inspection laws were revised to provide for a single, uniform, national approach to the regulation of meat and poultry. Congress passed new federal inspection laws that expressly preempt state authorities in this area of consumer protection. Federal jurisdiction was expanded to cover all meat and poultry products intended for commercial sale, including those produced and sold entirely within the same state which previously had been exempt, *unless* there is a state program meeting specified requirements under a cooperative agreement with USDA.² That is, absent a cooperative state inspection program meeting the criteria set forth in the Acts, regulation of meat and poultry within the state becomes a federal function.

¹ Supplements FSIS Directive 5720, Cooperative Agreements for State Meat and Poultry Inspection Programs.

² Cooperative Agreement(s), for purposes of this directive, means one or both written agreements (Inspection, Compliance) required for FSIS cooperation between a state agency and FSIS under the provisions of Section 301 of the FMIA and/or Section 5 of the PPIA. Cooperative agreements set forth the terms under which FSIS provides advice and assistance to the state in regulating meat and poultry within that state under paragraphs 301(a) and (b) of the FMIA and 5(a) and (b) of the PPIA. Under the cooperative agreements, the States provide information adequate to support annual certification to Congress that each state program is enforcing requirements "at least equal to" those imposed on the Federal program, as required under paragraphs 301(c) of the FMIA and 5(c) of the PPIA.

The FMIA and PPIA limit state meat and poultry inspection programs to regulation of product that is produced and sold entirely within the state. Product produced for sale in interstate commerce must be federally inspected.

States may have a meat inspection program, a poultry inspection program, or, as is the case in most instances, a meat and poultry inspection program.

FSIS provides up to 50% of the cost and other support for these cooperative state programs.

Cooperative agreements and annual certifications of state programs are conditional upon FSIS finding that each state is enforcing requirements "at least equal to" those imposed under the FMIA and PPIA. That finding is required under the Acts to permit FSIS to provide assistance for state meat and poultry inspection (Title I, FMIA, and sections 1-4, PPIA) or regulation of allied industries (Title II, FMIA, and section 11, PPIA). Such a finding also is required with regard to enforcement (Title IV--sections 401-410 of the FMIA, and sections 12-22 of the PPIA), to preclude mandated designation of the state as one in which all meat and poultry products are Federally inspected. FSIS is required to conduct reviews and report its findings to Congress at least annually.

On occasion, FSIS enters into a separate agreement for a state MPI program to conduct *federal* inspection activities on behalf of FSIS. These are outside the scope of this document.³

Some meat and poultry products are exempt from the inspection provisions of the FMIA and PPIA, but nonetheless are subject to other Federal regulation under those Acts. Such products include product from livestock and birds slaughtered by their owner for personal use at "custom" slaughter facilities, poultry sold locally by small poultry producers, and products prepared (meat) or processed (poultry) at a retail store or restaurant for direct sale to consumers.⁴

FSIS assesses whether each state program meets and maintains the mandated "equal to" standard based on its review of the program. Initially, each state program must file with FSIS a State Performance Plan (SPP), which itemizes the elements and goals of the state program and is updated when changes occur. Annual reports are submitted to FSIS by state MPI programs. FSIS determines whether state programs meet the standard based on a review the state program's annual report and updated SPP and on information from periodic, comprehensive, on-site reviews of their program.

³ Such agreements are governed by FSIS Directive 5721, Cooperative Agreements for Federal Activities to be Conducted by State Employees (*note: to be drafted, based on parts three and four of Directive 5720.2, Rev.2*).

⁴ Cooperative agreements with state agencies and others concerning inspection-exempt meat and poultry products are covered in FSIS Directive 5722, Cooperative Agreements to Reduce Consumers' Risks from Meat and Poultry Products (*note: to be drafted*).

Financial Audits are conducted at least every three years, independent of other aspects of the comprehensive review. Fiscal guidelines for state programs are covered under FSIS Directive 3300.1.

Initiation of State MPI Programs

FSIS upon request will advise and assist state agencies in developing a new state MPI program. New state MPI programs will be initiated upon the signing of two cooperative agreements, setting forth the conditions under which FSIS will provide funding and other assistance to the state MPI program. Upon satisfactory submission of a State Performance Plan (SPP) and completion of an initial comprehensive review (see below), the state MPI program will be certified by FSIS as meeting Federal requirements for state programs and be eligible to receive funding and other assistance under the cooperative agreement.

The State Performance Plan (SPP); Essential Program Elements

The SPP is a document that describes the mechanisms by which the state program will achieve satisfactory performance with respect to each essential program element. The SPP must be prepared and submitted to FSIS' Office of Field Operations, and revised as needed, to support initial and subsequent FSIS certification as a cooperative program meeting the requirements of the Acts. Part II below, Program Elements; Preparing and Implementing State Performance Plans, provides guidance on the preparation and revision of the SPP.

The state program must enforce requirements "at least equal to" those of the specified provisions of the Acts. The federal program is characterized by a number of infrastructure and operational elements that are fundamental to the conduct of its mission. FSIS has identified nine elements that are necessary to adequately effectuate the purposes of the Acts and that a state program must have to meet the "at least equal to" standard.

(Infrastructure)

1. Legal Authority
2. Program Resources
3. Trained Staff
4. Laboratory Support

(Operations)

5. Inspections
6. Uniformity of Inspections; Correlation
7. Compliance; Outreach and Enforcement
8. Ethics and Conduct
9. Self-Assessment

Part II provides further information on these elements, including the expected outcome or performance measure, of the program's efforts in each area, and the documents to be maintained and made available to FSIS reviewers.

The Annual State Report

The state program director submits to Office of Field Operations an annual report detailing state program activities during the preceding Federal fiscal year (October 1 through September 30) by November 15 of each year. The annual report needs to provide information and data adequate to substantiate that the state program continues to meet the requirements of the Acts and the terms of the Cooperative Agreement, and include any revisions needed to the SPP that were not submitted earlier.

II. PROGRAM ELEMENTS; PREPARING AND IMPLEMENTING STATE PERFORMANCE PLANS (SPP)

Every state program must submit an SPP to FSIS. The SPP provides the basis for FSIS to determine whether the state manages its meat and poultry inspection program adequately to permit certification that the state program meets the requirements of the FMIA and the PPIA.

Changes to the SPP are made by the state program as needed and are provided to Office of Field Operations as they occur. State MPI program directors must annually review their SPPs to ensure that they reflect current practices and procedures.

The SPP need not cover all aspects of a state MPI program's operations—only those mandated under the FMIA and PPIA. For example, many state MPI programs regulate products such as game animals not covered under the FMIA and PPIA. Also, state MPI programs routinely collaborate with state and local public health officials to prevent or ameliorate outbreaks of foodborne illness that may be associated with meat or poultry products, much as FSIS collaborates with the federal public health agencies on public health matters of mutual concern.

State programs are encouraged to include ancillary program activities, especially those related to public health and homeland security, in their SPP. This serves two purposes. First, it provides a comprehensive document more useful for agency planning and reporting purposes. Second, although these activities would not be reviewed by FSIS for purposes of state MPI program certification, they may be of interest to FSIS (and other Federal agencies) when seeking state cooperators on public health or homeland security related projects ancillary to traditional state MPI programs.

Format and Content of SPP

The format and content of the SPP may vary from state to state. Where a state program has essentially identical requirements to those of FSIS, the plan need only recite the relevant state authority and identify supporting records. Where a state program differs substantially from FSIS' requirements, the state program must describe the differences and provide analysis and documentation adequate to support an FSIS finding that the program does achieve the outcome indicated for that element.

Elements

Each state program's SPP must address all nine of the essential program elements listed below to support FSIS' finding that all specified outcomes are being achieved and that the state program is, therefore, one meeting the requirements of the Acts.

1. LEGAL AUTHORITY

--A state MPI program must have adequate legal authority.

Description

A state MPI agency must operate under state law that grants the agency adequate authority to administer an inspection program that imposes mandatory ante mortem and post mortem inspection, reinspection, sanitation, and recordkeeping requirements, and enforcement authorities that are at least equal to those provided under the FMIA and PPIA.

A state program must promulgate regulations needed to administer an inspection program that imposes mandatory ante mortem and post mortem inspection, reinspection, and sanitation requirements, including appropriate enforcement provisions and supporting administrative and management regulations, thereby permitting application of state requirements that are at least equal to those imposed under the federal program, as specified in the FMIA and PPIA. See, e.g., Subchapters A and E, Chapter III of Title 9, Code of Federal Regulations.

Outcome

The state agency has authority under state law and regulations for the development and administration of an inspection program that imposes inspection requirements at least equal to those imposed under the FMIA and PPIA.

Documentation

1. Copies of current state laws and regulations governing the agency.
 2. Copies of the state’s regulations imposing requirements on facilities subject to mandatory inspection under the FMIA and PPIA.
 3. Other documents as may be needed to substantiate the adequacy of state laws and regulations to administer a program that imposes requirements at least equal to those of the federal program and to demonstrate compliance with the requirements of other federal-state cooperative agreements.
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2. PROGRAM RESOURCES.

--Funding, staffing, equipment, and information technology are adequate for the program to achieve outcomes specified in the SPP.

Description

1. Funding. Funding is adequate to ensure the uninterrupted operation of a state inspection program consistent with these criteria under a cooperative agreement providing for federal reimbursement of fifty percent of the costs.
2. Staffing: Trained staff adequate to ensure inspection coverage at official establishments and compliance with the inspection laws by persons engaged in affected businesses. Hiring, retention, and promotion practices must be in compliance with all applicable EEO laws.
3. Equipment. Program employees have adequate supplies, equipment and other logistical support.
4. Contracts. Contractual agreements for goods and services from third-parties (including local government jurisdictions) as needed to operate the program consistent with these criteria and the cooperative agreement.

Outcome:

Resources are adequate for the conduct of inspections and related activities that are required of State MPI programs operating under FMIA and PPIA authorized cooperative agreements.

Documentation:

1. Cooperative agreements
 2. Budget documents
 3. Planning and accomplishment reports
 4. State accounting reports for the program
 5. Documentation for reimbursable expenditures, such as:
 - plant listings for (1) MPI plants and (2) custom slaughter plants
 - travel policies, forms, and documentation
 - equipment accounting policies, forms, and most recent equipment inventory (incl. acquisition date and cost)
 - supply requisition policies and forms.
 - personnel roster, organization chart and hiring records.
 - training logs/certificate
 - contracts for goods or services in direct support of the program, including laboratory services and information technology support.
 6. Audit reports for any periods within that reviewed
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3. TRAINED REGULATORY STAFF.

--Inspection personnel, compliance officers, and other persons performing MPI duties have the knowledge, skills, and ability to perform required duties.

Description

Educational requirements. VMOs must be graduates of an accredited school of veterinary medicine.

Training requirements: On the same basis as FSIS inspectors and VMOs, state inspectors and VMOs must satisfactorily complete FSIS or FSIS-sanctioned courses of instruction appropriate for the job held (e.g, Livestock Slaughter Inspection; Poultry Slaughter Inspection; Meat and Poultry Processing Inspection; VMO Technical Red Meat; VMO Technical Poultry) prior to assuming duties. Personnel without such training may receive on-the-job training but must not conduct inspection activities unless under the supervision of a trained individual.

FSIS courses of instruction are provided without cost for state as well as federal MPI personnel by the FSIS Center for Learning, College Station, Texas. Course offerings, distance learning, as well as classroom courses, are found on the agency's "Food Safety Virtual University" web site: www.fsis.usda.gov/ofo/hrds/fsvu.html

State programs may themselves conduct required training courses if the courses are given by trainers certified by the FSIS Center for Learning to conduct the courses. To be

certified, state trainers must satisfactorily have completed courses at the Center that are designated for such trainers as well as the specific courses to be taught. In addition, state trainers are responsible for maintaining training records for their program.

Outcome

All personnel have education and training needed to conduct duties assigned.

Documentation

1. Verification of required academic prerequisites
 2. Certificates earned from completion of required courses
 3. Reports of training audits
 4. Continuing education certificates
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4. LABORATORY SUPPORT

--The state program must have access to laboratory services qualified to identify and quantify accurately as needed organisms, substances, and other conditions of regulatory and public health concern.

Description

Each program must have access to laboratory services, either state laboratories or private laboratories under contractual agreements, to conduct chemical, microbiological, physical, and pathology testing required by their regulatory program.

Laboratories conducting official chemistry analyses for state programs need not be accredited laboratories under 21 CFR 318.21 and 381.153, but are expected to operate in accord with those requirements. FSIS' Laboratory Quality Assurance Division provides guidance to state programs on submission of check samples and other activities needed to establish adequate quality assurance.

Outcome

Reliable, timely laboratory analyses of samples as required to support program operations.

Documentation

1. Laboratory records
2. Accreditation documents
3. Proficiency sample results

5. INSPECTIONS.

--The state meat/poultry inspection program inspects establishments and their product to ensure that the establishments have developed, implemented, and are maintaining a HACCP system that produces only safe, wholesome, and properly marked and labeled products.

Description

A state program, at a minimum:

1. Prohibits commercial slaughter of livestock and commercial poultry, and the processing of meat and poultry products, unless conducted by an official establishment under a grant of inspection.
2. Ensures that qualified inspectors are conducting appropriate tasks during operations at each official establishment. Ensures inspectors are present to conduct ante-mortem and post-mortem inspection tasks during all slaughter operations and to ensure compliance with the Humane Slaughter Act and the provisions of 9 CFR 313. Ensures inspectors perform appropriate inspection at processing facilities during operations, with the frequency and focus of inspection based on hazards presented. Ensures, for both slaughter and processing, that its inspectors:
 - a. determine compliance with sanitation SOPs in accord with 9 CFR Part 416;
 - b. verify conduct of appropriate hazard analysis and operation in conformance with validated HACCP plans covering each product produced, in accord with 9 CFR Part 417;
 - c. determine compliance with marking, labeling and other requirements of 9 CFR, Ch. III, SubCh. A (Parts 301-381) applicable to the specific products being produced.
3. Collects and analyzes samples to verify conformance with applicable standards. Ensures sampling procedures, sampling frequency, and methods of analysis conform to Federal program standards.
4. Documents findings sufficiently to support appropriate enforcement actions under state law.

Frequency of tasks in each plant is determined by a system that establishes priorities in consideration of (1) kind of operations conducted, (2) volume of product produced, and (3) past inspection results. In-plant inspection tasks are conducted daily during plant operations. Tasks are consistent with FSIS inspection tasks, as set forth in the current edition of FSIS' "Regulatory Process for HACCP-Based Inspection, Reference Guide."

Outcome

The desired outcome of this standard is an inspection system that ensures production only of safe, wholesome, and properly marked and labeled meat and poultry products.

Documentation

1. Establishments maintain records that document implementation and monitoring of sanitation SOPs and any corrective actions taken (9 CFR 416.16).
2. Establishments maintain records that document its hazard analysis and implementation of its HACCP plan, as specified for Federal establishments (9 CFR 417.5).
3. Establishments maintain records relating to business transactions (9 CFR 320.1-.5; 355.20 &.21; 381.175-.179, & .194).
4. Program managers provide inspection data showing that inspectors conduct assigned inspection tasks.
5. Inspectors document all conditions that may subject an establishment to an enforcement action.

6. UNIFORMITY OF INSPECTION; CORRELATION

--Program management ensures uniformity in the interpretation and application of regulatory requirements, program policies, and procedures.

Description

The state program has procedures to ensure:

1. Routine oversight and evaluation of inspectors by their supervisors.
2. Periodic reviews of records kept by field supervisors, with the inspection documentation prepared by each to be evaluated for accuracy and for consistent interpretation and application of the appropriate laws, regulations, policies and procedures.
3. In addition to the records review, new Inspectors in Charge and new Compliance Officers will be evaluated on their job performance.
4. Identification and correction of inconsistencies in how inspection and enforcement staff interpret regulatory requirements. Program management develops an action plan

that specifies performance goals to address inconsistencies among regulatory staff. The action plan documents progress toward achieving the performance goals.

Outcome

The agency demonstrates uniform application of inspection requirements and enforcement activities by its personnel.

Documentation

Documentation includes:

1. Inspection reports
2. Non-compliance reports, including corrective actions, and resolution of findings
3. Documentation of record reviews.
4. Documentation of performance evaluations.
5. Remedial training plans or other plan of action, if applicable.

7. COMPLIANCE; OUTREACH AND ENFORCEMENT.

--The state program supports and enforces compliance with all applicable laws and takes appropriate enforcement action in the event of non-compliance.

Description

A. General Requirements.

1. The state program promotes compliance with the regulatory requirements by providing appropriate guidance.
2. The state program effectively enforces state laws equivalent to the FMIA and PPIA in the following particulars:
 - Provides assurance that no persons are conducting prohibited acts associated with the safety, wholesomeness or labeling of product (requirements imposed by the Federal program under §§10, 11 and 22 of the FMIA [21 U.S.C. 610, 611, and 622] and §9 of the PPIA [21 U.S.C. 9]), by identifying violators and imposing appropriate sanctions

(requirements imposed by the Federal program under §§ 401, 405 and 406 of the FMIA, and §§ 12 & 18 of the PPIA).

- Ensures appropriate control of product in commerce where there is reason to believe that it may be adulterated or misbranded and is capable of use as human food, or that it has not been inspected (requirements imposed by the Federal program under §402 of the FMIA; §19 of the PPIA), and proper disposition of such product, including seizure, condemnation and destruction where appropriate (requirements imposed by the Federal program under §403 the FMIA and §20 of the PPIA).
- Provides assurance that related industries as well as inspected establishments handling animal carcasses, carcass parts, or their products not intended for use as human food, do not divert such carcasses, carcass parts or products to human food uses (requirements imposed by the Federal program under §§ 201, 202, 203 of the FMIA; §11 of the PPIA.)

3. The state program ensures recalls of product by establishments under state MPI inspection are conducted when appropriate using protocols consistent with FSIS recall protocols.

Outcome: Public assurance that affected persons and businesses are complying with regulatory requirements.

Documentation:

1. Laws, regulations, and related materials cited in Element No. 1, including rules of practice that ensure due process of law.
2. Guidance and outreach procedures and materials used to promote voluntary compliance.
3. An official inventory of facilities.
4. Records of monitoring and surveillance activities, including sample collection records
5. Records of regulatory action taken
6. Records of recalls.

8. ETHICS AND CONDUCT

--The state program ensures that employees are aware of and apply ethical standards of conduct.

Description

The state program has policies and procedures in place to promote and enforce among employees high standards of ethical conduct. Specific areas of emphasis include:

1. Bribery and acceptance of things of value
2. Disgraceful conduct; substance abuse
3. Falsification, misuse, or destruction of official reports or property
4. Outside employment
5. Restrictions on political activity

Outcome

Personnel are aware of applicable codes of conduct and adhere to them.

Documentation

Personnel communications, training courses

.9. PROGRAM SELF ASSESSMENT

--The state program assesses its performance.

Description

The state program assesses annually how well its program conforms to each element. This includes:

1. Preparation of an annual State Performance Plan (SPP) describing how the state plans to apply each of the other eight elements in administering and managing its inspection program in the coming year.
2. Annual review of the program's performance as measured against the description and goals of each element in the plan. Identify areas of non-conformance.
3. Take corrective actions to ensure future conformance, as needed. Record actions in state's annual review report and amend following year's SPP as appropriate. Conduct special follow-up review to ensure corrective actions are working.

Outcome

State program is performing in conformance with these criteria, and demonstrating adherence to requirements "at least equal" to those of the FMIA and PPIA.

Documentation

1. State Performance Plan
 2. Annual review, including assessment findings, corrective actions and follow-up review
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III. FSIS REVIEW AND EVALUATION OF STATE PROGRAMS

General

FSIS reviews state programs annually to ensure that the state programs are enforcing requirements “at least equal to” those of the Acts, and that the program are in compliance with the terms of the applicable cooperative agreements. There are two types of review that FSIS performs: review of documentation and data available to FSIS, which it does on an annual basis, and periodic on-site visits to verify the documentation.

Administrative Reviews

The Office of Field Operations (OFO) will conduct an administrative review of each state program annually and, before March 1, will provide documentation to the Deputy Administrator, OFO, to support a judgment as to whether each cooperative state MPI program should be certified as being in good standing based on its review of the program’s activities.

At a minimum, such annual review will include evaluation of documents at FSIS headquarters, including the annual state program report and SPP revisions discussed in Part II above, together with any other data, correspondence, and other documents that may bear on the status under the Acts of the state MPI program. Annual reviews will include evaluation of the results of any comprehensive or other review conducted during the affected year.

On-Site Reviews

On-site reviews are conducted by FSIS subject matter experts at state government facilities and at state-inspected meat and poultry establishments.

1. During the course of the review, FSIS will evaluate all or most elements of the state program.

2. In-plant reviews are conducted at 1 to 5 year intervals, depending on the results of the previous review.
3. The inspection operations elements of the review (element numbers 5 and 6) are conducted by review teams, including at least one Technical Service Center reviewer and at least one state program official. Selection of the official establishments for the in-plant phase of the review will be made by the TSC reviewer, using criteria consistent with those used for FSIS reviews of the Federal inspection program.
4. The in-plant phase of the review is part of the assessment of the state program, not of the specific establishment. Nonetheless, it is expected that the state program official at the scene will ensure that prompt corrective action is taken in the event any deficiencies in the establishment are noted that suggest a potential food safety hazard.

Scheduling On-site Reviews.

1. On-site reviews are scheduled by OFO in consultation with FSIS offices responsible for conducting such reviews.
2. Notice of planned on-site reviews for the current and subsequent Federal fiscal years will be posted on the OFO Web site.
3. OFO will provide written notice to the program director at least 60 days in advance of any on-site review. Such notice will include protocols for the review, including needed records, scope, approximate times, and duration of different parts of the review, and reviewers' names. It will also include a date for the pre-review conference with the state program officials.

Variations in Scheduling Reviews of Certain Elements

Although OFO tries to schedule the review of all elements together, some components of FSIS' review may be conducted separately from others.

1. Reviews of compliance activities (element number 7) normally are scheduled on a three-year cycle. The review schedule is established by OFO in consultation with the Program Evaluation, Enforcement, and Review Office.
2. Reviews of laboratory support (element number 4) normally are also scheduled in a three-year cycle. The review schedule is established by OFO in consultation with the Laboratory Services Division.

3. Financial audits (element number 3) are scheduled, conducted, and evaluated at least every three years by FSIS' Financial Management Division, as set forth in Directive 3300.1, in consultation with FSLGRS.
4. Other reviews are conducted on selected elements of the program as deemed appropriate by FSIS.

Reports

1. On-site reviewers will conduct an exit conference with attending state officials at the close of their special review or their part of a comprehensive review.
2. FSIS reviewers will report on their review activity to OFO by an agreed upon date.
3. OFO will evaluate the reviewers' reports and provide a consolidated report, together with appropriate recommendations, to the Deputy Administrator, OFO. The recommendations will include one or more of the following:
 - a. Commendation for notable accomplishments, in particular innovations that could be replicated by other state programs.
 - b. Suggestions for improvements in the conduct of or documentation on specific elements.
 - c. Specific corrective actions needed in order to maintain certification.
 - d. Scheduling of future special and comprehensive reviews.
 - e. De-certification and termination of applicable cooperative agreements and issuance of notice of intent to designate state as one Federally inspected.

Annual Certification

The Deputy Administrator, OFO, will annually certify his/her finding with regard to each state program found to be meeting the terms of the cooperative agreement and the requirements of the Acts. Notice of the certification should issue to the state MPI program director the first quarter of each calendar year. OFO will report to the Administrator on the certification of all state programs no later than April 15 of each calendar year.