



# Federal Register

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**Wednesday,  
September 16, 2009**

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## **Part II**

# **Department of Agriculture**

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**Food Safety and Inspection Service**

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**9 CFR Parts 321, 332, and 381  
Cooperative Inspection Programs:  
Interstate Shipment of Meat and Poultry  
Products; Proposed Rule**

**DEPARTMENT OF AGRICULTURE****Food Safety and Inspection Service****9 CFR Parts 321, 332, and 381**

[Docket No. FSIS-2008-0039]

RIN 0583-AD37

**Cooperative Inspection Programs:  
Interstate Shipment of Meat and  
Poultry Products****AGENCY:** Food Safety and Inspection Service, USDA.**ACTION:** Proposed rule.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is proposing regulations to implement a new voluntary cooperative program under which State-inspected establishments with 25 or fewer employees will be eligible to ship meat and poultry products in interstate commerce. In participating States, State-inspected establishments selected to take part in this program will be required to comply with all Federal standards under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), as well as with all State standards. These establishments will receive inspection services from State inspection personnel that have been trained in the enforcement of the FMIA and PPIA. Meat and poultry products produced under the program that have been inspected and passed by designated State personnel will bear an official Federal mark of inspection and will be permitted to be distributed in interstate commerce. FSIS will provide oversight and enforcement of the program.

FSIS is proposing these regulations in response to the Food, Conservation, and Energy Act, enacted on June 18, 2008. Section 11015 of the law amended the FMIA and PPIA to provide for these cooperative programs.

**DATES:** Submit comments on or before November 16, 2009.

**ADDRESSES:** FSIS invites interested persons to submit comments on this proposed rule. Comments may be submitted by either of the following methods:

*Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments.

Mail, including floppy disks or CD-ROM's, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 2-2127 George Washington Carver Center, 5601

Sunnyside Avenue, Beltsville, MD 20705.

*Instructions:* All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2008-0039. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to: <http://www.regulations.gov>.

*Docket:* For access to background documents or comments received, go to the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:**

Philip Derfler, Assistant Administrator, Office of Policy and Program Development, Room 350-E, Jamie L. Whitten Building, 1400 Independence Avenue, SW., Washington, DC 20250; Telephone (202) 720-2709, Fax (202) 720-2025.

**SUPPLEMENTARY INFORMATION:****I. Background***A. Federal-State Cooperative Inspection Programs*

FSIS has been delegated the authority to carry out the functions of the Secretary of Agriculture as provided in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*). These statutes mandate that FSIS protect the public by ensuring that meat and poultry products are safe, wholesome, unadulterated, and properly labeled and packaged.

The FMIA and the PPIA ("the Acts") provide for FSIS to cooperate with State agencies in developing and administering their own meat or poultry inspection programs (21 U.S.C. 661 and 454). The FMIA and the PPIA restrict each cooperative State meat or poultry products inspection program to the inspection and regulation of products that are produced and sold within the State (21 U.S.C. 661(a)(1) and 454(a)(1)). Under section 661 of the FMIA and section 454 of the PPIA, cooperative State inspection programs are required to operate in a manner and with authorities "at least equal to" the provisions set out in the Acts (21 U.S.C. 661(a)(1) and 454(a)(1)).

The Acts provide for FSIS to contribute up to 50 percent of the cost of the cooperative State inspection programs, as long as the State programs are effectively enforcing requirements that are "at least equal to" the Federal program (21 U.S.C. 661(a)(3) and 454(a)(3)). States that have enacted a mandatory State meat or poultry inspection law must apply to FSIS to

enter into a cooperative State inspection program agreement with the Agency.

If a State is unable or unwilling to continue to operate a cooperative State inspection program on an "at least equal to" basis, FSIS designates the State as not having an "at least equal to" program by publishing this designation in the **Federal Register**. After the expiration of thirty days of such publication, the State establishments are subject to Federal inspection (21 U.S.C. 661(c)(1) and 454(c)(1)).

The Talmadge-Aiken Act authorizes the Secretary of Agriculture to enter into cooperative arrangements with State departments of agriculture and other State agencies to assist the Secretary in the enforcement of relevant Federal laws and regulations to the extent and in the manner appropriate to the public interest (7 U.S.C. 450). Pursuant to the Talmadge-Aiken Act, FSIS enters into a separate agreement with a State agency for the State program to conduct meat, poultry, or egg products inspection or other regulatory activities on behalf of FSIS. FSIS provides 50 percent funding to the State programs for these services.

*B. The Food, Conservation, and Energy Act of 2008*

On June 18, 2008, Congress enacted The Food, Conservation, and Energy Act of 2008 (also referred to as "the 2008 Farm Bill") (Pub. L. 110-246, 112 Stat. 1651). Section 11015 of Title XI of the 2008 Farm bill amended the FMIA to add a new title V—"Inspections by Federal and State Agencies," which contains a new section 501, "Interstate Shipment of Meat Inspected by Federal and State Agencies for Certain Small Establishments (122 Stat. 2124; codified at 21 U.S.C. 683). Section 11015 also amended the PPIA to add a new section 31, "Interstate Shipment of Poultry Inspected by Federal and State Agencies for Certain Small Establishments" (122 Stat. 2127; codified at 21 U.S.C. 472). These new sections supplement the existing cooperative State meat and poultry inspection programs by establishing a new cooperative program under which certain State-inspected establishments would be permitted to ship meat and poultry products in interstate commerce.

The new law provides that the Secretary of Agriculture, "in coordination with the appropriate State agency of the State in which the establishment is located," may select State-inspected establishments with 25 or fewer employees to ship meat and poultry products interstate (Sec. 501(b) and Sec. 31(b)). Inspection services for these establishments must be provided by State inspection personnel that have

“undergone all necessary inspection training and certification to assist the Secretary with the administration and enforcement of [the FMIA or PPIA]” (Sec. 501(a)(2) and Sec. 31(a)(2)). Meat and poultry products inspected and passed by these State inspection personnel would bear a “Federal mark, stamp, tag, or label of inspection” (Sec. 501(b)(1) and Sec. 31(b)(1)). The law provides for the Secretary to “designate an employee of the Federal government” to “provide oversight and enforcement” of the program (Sec. 501(d)(1) and Sec. 31(d)(1)).

The law is to take effect “on the date on which the Secretary \* \* \* promulgates final regulations to carry out [section 11015]” (Sec. 501(j)(1) and Sec. 31(i)(1)). The law requires that the Secretary promulgate final regulations “not later than 18 months after the date of enactment” (Sec. 501(j)(2) and Sec. 31(i)(2)).

FSIS is issuing this proposed rule to implement section 11015 of the 2008 Farm Bill. Following is a summary of the provisions of section 11015 that are addressed in this proposed rule.

**Selected establishments.** The law applies to certain establishments that are already operating under a cooperative State meat or poultry inspection program. The law defines an “eligible establishment” as “an establishment that is in compliance with \* \* \* the State inspection program of the State in which the establishment is located” and the Acts, including the rules and regulations issued under the Acts (Sec. 501(a)(3) and Sec. 31(a)(3)). A “selected establishment” is defined as “an establishment that is authorized by the Secretary, in coordination with \* \* \* the appropriate State agency of the State in which the establishment is located \* \* \* to ship [meat or poultry] items in interstate commerce” (Sec. 501(a)(5) and Sec. 31(a)(5)).

The law prohibits the Secretary from selecting an establishment for interstate shipment that “on average, employs more than 25 employees (including supervisory and nonsupervisory employees), as defined by the Secretary” (Sec. 501(b)(2)(A) and Sec. 31(b)(2)(A)). The law also prohibits the selection of establishments that currently ship interstate, as well as certain former and future Federal establishments (Sec. 501(b)(2)(B), Sec. 501(b)(2)(C), Sec. 31(b)(2)(B), and Sec. 31(b)(2)(C)).

**Transition to a Federal establishment.** The law permits the Secretary to select establishments with “more than 25 employees but less than 35 employees” to participate in the program (Sec. 501(b)(3)(B)(i) and Sec. 31(b)(3)(B)(i)).

However, if selected, these establishments must transition to Federal establishments “beginning on the date that is 3 years after the effective date” if they consistently employ, on average, more than 25 employees (Sec. 501(b)(3)(B)(ii) and Sec. 31(b)(3)(B)(ii)). The law authorizes the Secretary to develop a procedure to transition certain selected establishments to a Federal establishment (Sec. 501(b)(3)(A) and Sec. 31(b)(3)(A)). The law also requires that “[a]ny selected establishment that the Secretary determines to be in violation of any requirement of the Act, be transitioned to a Federal establishment” (Sec. 501(h) and Sec. 31(g)).

**Federal-State coordination.** Under the law, the Secretary is authorized to designate a Federal employee as “State coordinator” for each State to “provide oversight and enforcement” of the interstate shipment program and to “oversee the training and inspection activities” of the State personnel providing inspection services to selected establishments (Sec. 501(d)(1) and Sec. 31(d)(1)). The law provides that if the State coordinator determines that a selected establishment under the State coordinator’s jurisdiction is in violation of the Acts, the State coordinator must “immediately notify the Secretary of the violation” and “deselect the selected establishment or suspend inspection at the selected establishment” (Sec. 501(d)(3)(C) and Sec. 31(d)(3)(C)).

This proposed rule refers to the “State coordinator” established in section 11015 of the 2008 Farm Bill as the FSIS “selected establishment coordinator” to maintain consistency with the other terminology in this proposed rule and to make clear that the “State coordinator” is a Federal employee. The term “State coordinator” is often used to refer to a State employee under the Talmadge-Aiken program, so FSIS has tentatively decided not to use this term in these proposed regulations.

**Federal reimbursement of State costs.** The law requires that the Secretary “reimburse a State for costs related to the inspection of selected establishments \* \* \* in an amount of not less than 60 percent of eligible State costs” (Sec. 501(c) and Sec. 31(c)).

**Inspection training division.** The law amended the FMIA to provide that not later than 180 days after the effective date of section 11015 of the 2008 Farm Bill, the Secretary shall establish in FSIS an inspection training division to provide outreach, education, and training to, and provide grants to appropriate State agencies to provide outreach, technical assistance,

education, and training to small and very small establishments (as defined by the Secretary) (Sec. 501(f)). FSIS implemented this provision by establishing an Office of Outreach, Education and Training. A substantive part of the program’s function is to provide training, education, and outreach services to small and very small plants.

**Transition grants.** The law permits the Secretary to provide grants to States to assist them in helping establishments operating under a cooperative State meat or poultry inspection program transition to selected establishments (Sec. 501(g) and Sec. 31(f)).

## II. The Proposed Rule

### A. General

FSIS is proposing to amend 9 CFR part 321 of the Federal meat inspection regulations and 9 CFR part 381, subpart R, of the poultry products inspection regulations to add new sections that describe the cooperative interstate shipment program established in section 11015 of the 2008 Farm Bill. FSIS is also proposing to add a new 9 CFR part 332 to the Federal meat inspection regulations and a new 9 CFR part 381, subpart Z, to the poultry products inspection regulations that prescribe the conditions under which States and establishments operating under a State-inspection program will be permitted to participate in a cooperative interstate shipment program.

When FSIS completes the rulemaking process and issues a final rule, the Federal meat and poultry products regulations will provide for three separate cooperative State meat and poultry products inspection programs: (1) Cooperative State meat or poultry products inspection programs under the FMIA and PPIA; (2) cooperative agreements for State programs to conduct meat or poultry products inspection or other regulatory activities on behalf of the Agency under the Talmadge-Aiken Act; and (3) cooperative programs for the interstate shipment of State-inspected meat and poultry products under the FMIA and PPIA as amended by section 11015 of the 2008 Farm Bill.

The proposed regulations to implement section 11015 are described in detail below.

### B. Description of Cooperative Programs—9 CFR Part 321 and 9 CFR Part 381, Subpart R

9 CFR part 321 of the Federal meat inspection regulations and 9 CFR part 381, subpart R, of the poultry products inspection regulations describe

cooperative meat and poultry products inspection programs authorized under the FMIA, PPIA, and the Talmadge-Aiken Act. These regulations reference the legal authority for each cooperative inspection program and provide a general description of each program. FSIS is proposing to amend part 321 and part 381, subpart R, to add a new § 321.3 and a new § 381.187 to describe the cooperative interstate shipment program established under section 11015 of the 2008 Farm Bill.

The amendments to the FMIA in section 501 of section 11015 of the 2008 Farm Bill have been codified at 21 U.S.C. 683, and the amendments to the PPIA in section 31 have been codified at 21 U.S.C. 472 (122 Stat. 2124, 2127). Therefore, proposed § 321.3(a) provides that under 21 U.S.C. 683(b), FSIS is authorized to coordinate with States that have cooperative State meat inspection programs to select certain establishments operating under these programs to ship carcasses, parts of carcasses, meat, and meat food products in interstate commerce. Similarly, proposed § 381.187(a) provides that under 21 U.S.C. 472(b), FSIS is authorized to coordinate with States that have cooperative State poultry products inspection programs to select certain establishments operating under these programs to ship poultry products in interstate commerce. Proposed §§ 321.3(a) and 381.187(a) both explain that this type of cooperative program is called a “cooperative interstate shipment program.”

Proposed §§ 321.3(b) and 381.187(b) contain a general description of the cooperative interstate shipment program and make clear that the Federal contribution for inspection services provided by States that have entered into such a program will be at least 60 percent of eligible State costs. Under the FMIA and PPIA, FSIS is required to contribute up to 50 percent of the cost of a cooperative State meat or poultry products inspection program (21 U.S.C. 661(a)(3) and 454(a)(3)). Thus, States that participate in the new cooperative interstate shipment program will receive additional reimbursement for costs related to inspection of selected establishments in the State.

As required under the statute, the Federal contribution for inspection services provided by States that enter into a cooperative interstate shipment program under this proposal will be at least 60 percent of eligible State costs. When the program is implemented, FSIS does not intend to reimburse States for more than 60 percent of their eligible costs unless Congress directs it, and provides the money for it, to do so.

To be reimbursed under this proposed rule, States will be expected to submit their budgets for their cooperative interstate shipment programs to FSIS for approval prior to receiving Federal funds. States will also be expected to submit a separate justification for any costs related to the cooperative interstate shipment program that were not included in their initial budget request. FSIS will also need to approve a State’s request for additional funds before the Agency will reimburse the State for not less than 60% of the cost. FSIS has tentatively decided that, for purposes of this proposed rule, eligible State costs will be those costs that a State has justified and FSIS has approved as necessary for the State to provide inspection services to selected establishments in the State. The Agency requests comments on whether the final rule resulting from this proposal should codify this definition or any other requirements related to State reimbursement for eligible costs related to inspection of selected establishments.

Proposed §§ 321.3(c) and 381.187(c) identify 9 CFR part 332 and 9 CFR part 381, subpart Z, as the regulations that prescribe conditions under which States and establishments may participate in the cooperative interstate shipment program. Proposed §§ 321.3(d) and 381.187(d) provide that the Administrator will terminate an agreement for a cooperative interstate shipment program with a State if the Administrator determines that the State is not conducting inspection at selected establishments in a manner that complies with the Acts and their implementing regulations.

### *C. Requirements for a Cooperative Interstate Shipment Program—9 CFR Part 332 and 9 CFR 381 Subpart Z*

#### 1. General

FSIS is proposing to amend title 9, Chapter III, Subchapter A of the Code of Federal Regulations (CFR) to add a new part 332 titled “Selected Establishments; Cooperative Program for Interstate Shipment of Carcasses, Parts of Carcasses, Meat, and Meat Food Products,” and to add to part 381 a new subpart Z titled “Selected Establishments; Cooperative Program for Interstate Shipment of Poultry Products.” The regulations in the proposed new part 332 and the proposed new subpart Z prescribe the requirements for a cooperative interstate shipment program.

#### 2. Definitions and Purpose

Proposed §§ 332.1 and 381.511 define the terms “cooperative interstate

shipment program,” “cooperative State meat inspection program,” “cooperative State poultry products inspection program,” “selected establishment,” and “designated personnel.” Terms used in the proposed regulations that are defined in 9 CFR 301.2 and 9 CFR 381.1 retain their same meaning.

Under proposed §§ 332.1 and 381.511, “cooperative interstate shipment program,” “cooperative State meat inspection program,” and “cooperative poultry products inspection program” are defined by providing a cross-reference to the description of these cooperative programs in 9 CFR part 321 and 9 CFR part 381 subpart R, described above. Under this proposal, “selected establishment” is defined as “an establishment operating under a State cooperative [meat or poultry products] inspection program that has been selected by the Administrator, in coordination with the State where the establishment is located, to participate in a cooperative interstate shipment program.”

FSIS is proposing to define “designated personnel” as “State inspection personnel that have been trained in the enforcement of the Acts and any additional State program requirements in order to provide inspection services to selected establishments.”

In addition to proposing new definitions, proposed §§ 332.1 and 381.511 make clear that the term “interstate commerce,” as used in the proposed regulations has the same meaning as “commerce” under 9 CFR 301.2 and 381.1. The regulations in 9 CFR 301.2 and 381.1 define “commerce” as “[c]ommerce between any State, any Territory, or the District of Columbia, and any place outside thereof \* \* \*.” Thus, under this proposal, State-inspected establishments that are selected to participate in a cooperative interstate shipment program will be permitted to distribute and sell meat or poultry products across State lines and to export these products to foreign countries.

Proposed §§ 332.2 and 381.512 state that the purpose of part 332 and part 381, subpart Z, is to prescribe the conditions under which States that administer cooperative State meat or poultry products inspection programs and establishments that operate under such programs may participate in a cooperative interstate shipment program.

#### 3. Requirements for Establishments

The proposed regulations in §§ 332.3 and 381.513 prescribe conditions that establishments operating under a

cooperative State meat or poultry products inspection program must comply with in order to apply to participate in a cooperative interstate shipment program. Proposed §§ 332.3 and 381.513 also describe establishments that are ineligible to be selected for such a program.

*Number of employees.* Under proposed §§ 332.3(a)(1) and 381.513(a)(1), an establishment operating under a cooperative State meat or poultry products inspection program may apply to participate in a cooperative interstate shipment program if the establishment employs, on average, no more than 25 employees. Standards for determining the average number of employees for purposes of this proposal are described in proposed §§ 332.3(b) and 381.513(b) below.

Under proposed §§ 332.3(a)(2) and 381.513(a)(2), establishments that employed more than 25 but fewer than 35 employees as of June 18, 2008, are also permitted to apply for a cooperative interstate shipment program. However, §§ 332.3(a)(2) and 381.513(a)(2) provide, reflecting the amended FMIA and PPIA, that if selected, these establishments must employ, on average, 25 or fewer employees as of the date three years from the date that the final rule resulting from this proposal becomes effective. If they do not, proposed §§ 332.3(a)(2) and 381.513(a)(2) require that they be deselected from the program and transition to become official establishments.

*Standards for determining number of employees.* Proposed §§ 332.3(b) and 381.513(b) establish standards for determining whether an establishment employs, on average, 25 or fewer employees for purposes of this proposed rule. FSIS developed these proposed standards to carry out Congress' intent that "[t]he term 'average' should be interpreted to provide some flexibility to these selected establishments that require seasonal employees for certain parts of the year, as long as the increase in employees are [sic] manageable by the establishment and the increase \* \* \* does not undermine food safety standards" (S. Rep. No. 220, 110th Cong., 1st Sess., at 211 (2007)).

For the most part, the proposed standards in §§ 332.3(b) and 381.513(b) reflect applicable methods used by the Small Business Administration (SBA) to calculate the number of employees of a business concern where the size standard is number of employees (13 CFR 121.105 and 121.106). In addition, as explained below, FSIS is also proposing to limit the total number of employees at any given time to 35 individuals. Under this proposal, the

standards developed by FSIS will apply to the employees of an individual establishment. The proposed standards are as follows:

- All individuals, both supervisory and non-supervisory, employed by the establishment on a full-time, part-time, or temporary basis are to be counted when calculating the total number of employees;
- All individuals employed from a temporary employee agency, professional employee organization, or leasing concern are to be counted;
- The average number of employees is calculated for each of the pay periods for the preceding calendar year;
- Part-time and temporary employees are to be counted the same as full-time employees;
- If an establishment has not been in business for 12 months, the average number of employees is calculated for the pay periods in which the establishment has been in business;
- Volunteers who receive no compensation are not considered employees; and
- The total number of employees can never exceed 35 individuals at any given time, regardless of the average number of employees.

As noted above, the standard that limits the total number of employees on any given day to 35 individuals is not derived from SBA's methods for calculating the number of employees. FSIS is proposing to limit the number of individuals employed by a selected establishment at any given time to carry out Congress' intent that any increase in the number of employees be "manageable by the selected establishment" and that the increase "does not undermine food safety standards." FSIS is proposing that this number never exceed 35 because section 11015 of the 2008 Farm Bill permits the Agency to select certain establishments that employ as many as 35 employees to participate in a cooperative interstate shipment program (Sec. 501(b)(3)(i) and Sec. 31(b)(3)(i)). Therefore, FSIS believes that a temporary increase in the number of employees of up to 35 individuals is likely to be considered "manageable" under the law, provided that the average number of employees remains at 25 or fewer.

FSIS requests comments on the proposed standards for determining an establishment's average number of employees. The Agency specifically requests comment on whether part-time and temporary employees should be counted the same as full-time employees.

*Ineligible establishments.* Proposed §§ 332.3(c) and 381.513(c) describe

establishments that are ineligible to participate in a cooperative interstate shipment program. For the most part, these establishments reflect the "prohibited establishments" described in section 11015 of the 2008 Farm Bill (Sec. 501(b)(2) and 31(b)(2)). These establishments include:

- Establishments that employ more than 25 employees on average, with a limited exception for establishments that had between 25 and 35 employees as of June 18, 2008 and that have 25 or fewer employees as of the date three years from the date that the final rule resulting from this rule becomes effective;
- Establishments operating under a cooperative inspection program under the Talmadge-Aiken Act;
- Official establishments;
- Establishments that were official establishments as of June 18, 2008, but that were reorganized on a later date by the person that controlled the establishment as of June 18, 2008;
- State-inspected establishments that employed more than 35 employees as of June 18, 2008, but that were later reorganized by the person that controlled the establishment as of June 18, 2008;
- Establishments that are transitioning to become official establishments;
- Establishments that are in violation of the FMIA or PPIA; and
- Establishments located in a State without a cooperative meat or poultry products inspection program.

In addition, the proposed regulations also include among the establishments ineligible to participate in a cooperative interstate shipment programs, establishments located in a State whose agreement for an interstate shipment program was terminated by the Administrator.

Proposed §§ 332.3(d) and 381.513(d) provide that an eligible establishment may apply for selection into a cooperative interstate shipment program through the State where the establishment is located. FSIS is proposing that establishments apply for selection into a cooperative interstate shipment program through the State because the State will be responsible for providing inspection services to the establishment if the establishment is selected for the program. Thus, establishment participation in the cooperative interstate shipment program will depend on whether the State is able, and willing, to provide the necessary inspection services to the establishment. However, if a State enters into an agreement with FSIS for a cooperative interstate shipment

program, FSIS, in coordination with the State, will make the final determination on whether to select an establishment to participate in the program.

#### 4. State Request for a Cooperative Interstate Shipment Program

Under this proposed rule, a State that does not have a cooperative interstate shipment program, but that is interested in establishing one, may submit a request for such a program to FSIS. Proposed §§ 332.4 and 381.514 prescribe the procedures for States to request an agreement for a cooperative interstate shipment program. Under this proposal, a State will submit the request through the FSIS District Office that covers the State. Proposed §§ 332.4(a) and 381.514(a) make clear that State participation in a cooperative interstate shipment program is limited to States that have cooperative State meat or poultry products inspection programs.

*Required information.* Proposed §§ 332.4(b) and 381.514(b) describe the information that States will need to include in their requests for an agreement for a cooperative interstate shipment program. Because a cooperative interstate shipment program requires participation from both States and establishments, the State's request for an agreement for a cooperative interstate shipment program must identify establishments in the State that have requested to be selected and that the State recommends for initial selection into the program (proposed §§ 332.4(b)(1) and 381.514(b)(1)). If FSIS and the State enter into an agreement for a cooperative interstate shipment program under this proposal, these establishments will be the first to be considered for the program. Other establishments operating under the State's meat or poultry products inspection program may apply to become selected establishments after the cooperative interstate shipment program has been implemented within the State.

A State's request for a cooperative interstate shipment program must also include documentation to demonstrate that the State is able to provide necessary inspection services to selected establishments in the State and conduct any related activities that would be required under a cooperative interstate shipment program (proposed §§ 332.4(b)(2) and 381.514(b)(2)). Under this proposal, this documentation would be similar to the documentation that States provide when they request an agreement for a cooperative State meat or poultry products inspection program. However, instead of demonstrating that the State's inspection program is "at least equal to"

the Federal inspection program, the statute requires that the State demonstrate that inspection services provided to selected establishments will be "the same as" the inspection services provided under the Federal program.

Thus, to qualify for a cooperative interstate shipment program under this proposal, States will need to demonstrate, among other things, that they have the authority under State law to provide the same inspection services to selected establishments in the State as the inspection services that FSIS provides to official Federal establishments. States will also need to demonstrate that they have staffing sufficient to conduct the same inspection activities in selected establishments that FSIS conducts in official Federal establishments, and that designated personnel have been properly trained in Federal inspection methodology. FSIS currently offers training courses in Federal inspection methodology to State inspection personnel. Under this proposal, States that are interested in participating in a cooperative interstate shipment program will be responsible for making arrangements for their inspection personnel to attend these courses. FSIS will also expect States to demonstrate that they can provide the necessary equipment for State personnel to provide the same inspection services to selected establishments that FSIS provides to official Federal establishments, including computers and supplies for collecting product samples.

Because the statute requires compliance with all Federal standards, meat and poultry products produced in selected establishments will be subject to the same regulatory sampling programs as those established in the Federal inspection program. Thus, to be eligible to participate in a cooperative interstate shipment program, States will need to demonstrate that State personnel will collect the same number and type of regulatory product samples from selected establishments as are collected under FSIS's inspection sampling program.

In addition, the State will need to demonstrate that the laboratory services that it intends to use to analyze product samples from selected establishments are capable of conducting the same chemical, microbiological, physical, and pathology testing as are required under the Federal meat and poultry products inspection programs. FSIS's Office of Public Health Science will provide audit assistance to the State to verify that the methodologies used by a State's laboratory services to analyze samples

from selected establishments are capable of producing the same results as the methodologies used by FSIS laboratories. FSIS will not enter into an agreement for a cooperative interstate shipment program with a State that does not meet the conditions described above.

*Additional conditions.* Proposed §§ 332.4(b)(3) and 381.514(b)(3) prescribe additional conditions that States applying for a cooperative interstate shipment program must agree to in order to qualify for the program. These proposed regulations provide that when a State submits a request to establish a cooperative interstate shipment program, the State must agree that, if it enters into an agreement with FSIS for such a program, that the State will:

- Provide FSIS with access to the results of all laboratory analyses conducted on product samples from selected establishments in the State;
- Notify the selected establishment coordinator (SEC) for the State of the results of any laboratory analyses that indicate that a product prepared or processed in a selected establishment may be adulterated or may otherwise present a food safety concern; and
- If necessary, cooperate with FSIS to transition selected establishments in the State that have been deselected from a cooperative interstate shipment program to become official establishments. FSIS will not enter into an agreement for a cooperative interstate shipment program if a State does not agree to these terms.

*Qualified States.* Under this proposal, after a State submits a request for a cooperative interstate shipment program, the FSIS Administrator will review the request and determine whether the State qualifies for such a program. If, based on the information submitted in the request the Administrator determines that a State is eligible to enter into a cooperative agreement for an interstate shipment program, the Administrator and the State will sign a cooperative agreement that sets forth the terms and conditions under which each party will cooperate to provide inspection services to selected establishments in the State (proposed §§ 331.4(c) and 381.514(c)). After the Administrator and a State have signed an agreement for a cooperative interstate shipment program, the Administrator will: (1) Appoint an FSIS employee as the selected establishment coordinator (SEC) for the State and (2) coordinate with the State to select the establishments that will participate in the program (proposed §§ 332.4(d) and 381.514(d)).

*Summary of actions needed to establish a cooperative interstate shipment program under the proposed regulations.*

The proposed regulations discussed above describe conditions that both establishments and States must meet to participate in a cooperative interstate shipment program. If FSIS adopts these proposed regulations in a final rule, the steps for establishing a new cooperative interstate shipment program will be the following.

- An establishment that is eligible for the interstate shipment program, and that is interested in participating in the program, will apply for the program through the State agency that administers the State meat and poultry products inspection program under which the establishment operates. States will develop their own application procedures.

- The State will then evaluate the establishment's application to determine whether the State will recommend the establishment for selection into the cooperative interstate shipment program.

- If the State determines that an establishment qualifies for selection into the program, and the State is able, and willing, to provide the necessary inspection services to the establishment, the State will recommend the establishment for selection into the program. The State will need to submit its recommendation through the FSIS District Office whose jurisdiction includes the State.

- If the State has not entered into an agreement with FSIS for a cooperative interstate shipment program, but is qualified to participate in such a program, it will need to submit a request for a cooperative agreement for the program to the FSIS District Office that covers the State.

- In its request for a cooperative interstate shipment program, a State will need to: (1) Identify those establishments that have submitted a request for, and that the States recommends for, initial selection into the program and (2) demonstrate that it is able to provide the necessary inspection services to these establishments if they are selected for the program. The State will also need to agree to comply with certain conditions associated with FSIS oversight and enforcement of the program.

- After a State submits a request for a cooperative interstate shipment program, the FSIS Administrator will evaluate the request and determine whether the State qualifies for the program.

- If the Administrator determines that the State qualifies for the cooperative interstate shipment program, the Administrator and the State will sign a cooperative agreement that sets forth the terms and conditions under which each party will cooperate to provide inspection services to selected establishments in the State.

- The Administrator will then appoint an SEC for the State, and the Administrator, in coordination with the State, will begin selecting establishments for participation in the program.

##### 5. Selection of Establishments

As discussed above, under this proposal, State-inspected establishments that are interested in participating in a cooperative interstate shipment program will apply for selection into the program through the State agency that administers the State's meat or poultry products inspection program. When, and if, an establishment applies to participate in a cooperative interstate shipment program, the State will evaluate the establishment to determine whether it qualifies to become a selected establishment. Proposed §§ 332.5(a) and 381.515(a) provide that a State-inspected establishment will qualify for selection into a cooperative interstate shipment program if the establishment:

- Has submitted a request to the State to be selected for the program;
- Has the appropriate number of employees;
- Is not ineligible for a cooperative interstate shipment;
- Is in compliance with all requirements under the State inspection program; and
- Is in compliance with the all Federal meat or poultry products inspection requirements.

Establishments that do not meet all of these criteria will not qualify, and will not be selected, for the program. To participate in a cooperative interstate shipment program, an establishment that qualifies for such a program must be selected by the Administrator, in coordination with the State where the establishment is located (proposed §§ 332.5(b) and 381.515(b)).

Thus, under this proposal, if a State determines that an establishment operating under the State's meat or poultry products inspection program qualifies for selection into a cooperative interstate shipment program, and the State is able, and willing, to provide the necessary inspection services to the establishment, the State is to submit its evaluation of the establishment through the FSIS District Office that covers the

State. The FSIS Administrator, in coordination with the State, will decide whether to select the establishment for the program. When deciding whether to select and establishment for the program, the Administrator will consider whether the establishment meets the criteria needed to qualify for the program and whether the Agency has the resources that it needs to provide the required oversight of the establishment if it is selected for the program.

As stated above, to qualify to participate in a cooperative interstate shipment program, an establishment must be in compliance with all Federal inspection requirements under the FMIA, PPIA, and their implementing regulations in title 9, chapter III, of the CFR. Thus, as part of the selection process, the SEC, in coordination with the State, will verify that each establishment that has applied to participate in a cooperative interstate shipment program: (1) Meets the Federal regulatory performance standards established in 9 CFR 416.1 through 416.6; (2) has submitted all labeling material to the State for approval, and that the materials meet all Federal requirements in 9 CFR parts 316, 317, and 319 and Part 381, subparts M, N, and P; (3) has obtained the same water source and sewage system approval that FSIS requires for official establishments; (4) has developed Sanitation Standard Operating Procedures (Sanitation SOPs) that comply with 9 CFR 416.11–416.17; and (5) has conducted a hazard analysis and developed a validated Hazard Analysis and Critical Control Points (HACCP) plan that complies with 9 CFR part 417.

These criteria reflect the standards that meat and poultry products establishments are required to meet to obtain a Federal grant of inspection under 9 CFR part 304 and 9 CFR part 381. Establishments that do not meet all of these requirements are not in compliance with all Federal standards and thus will not be selected for the program.

If an establishment qualifies for, and is selected to participate in, a cooperative interstate shipment program under this proposed rule, proposed §§ 332.5(c) and 381.515(c) provide that the State is to assign the establishment an official number that reflects the fact that the establishment is a participant in the cooperative interstate shipment program. These proposed regulations provide that the State is to advise the SEC of the number assigned to each selected establishment in the State. Proposed §§ 332.5(c) and 381.515(c) go on to state that the official numbers

assigned to selected establishments need to contain the suffix "SE" to identify the establishments as selected establishments. FSIS is proposing this requirement to ensure that establishments participating in the cooperative interstate shipment program can be identified by reference to their establishment number. It will also ensure that meat and poultry products prepared in selected establishments are identified as articles produced under a cooperative interstate shipment program.

Proposed §§ 332.5(c) and 381.515(c) also provide that the selected establishment numbers must include, as a suffix, the abbreviation for the State in which the establishment is located. In addition, proposed § 381.515(c) provides that the suffix of the number for a selected poultry products establishments needs to contain the letter "P" to identify the establishment as one that processes poultry products. Thus, under this proposal, an official number for a selected establishment in Texas that prepares meat products would contain the suffix "SETX," while an official number for an establishment in North Dakota that process poultry products would contain the suffix "SEPND."

As discussed below, articles that have been inspected and passed in a selected establishment will bear an official USDA mark, stamp, tag, or label of inspection.

Finally, proposed §§ 332.5(d) and 381.515(d) provide that failure of a State to comply with §§ 332.5(c) and 381.515(c) will disqualify that State from participation in a cooperative interstate shipment program. Full compliance by a State with these provisions is essential if the program is to succeed.

#### 6. Inspection at Selected Establishments, Official Mark, and Interstate Shipment

Proposed §§ 332.6(a) and 381.516(a) provide that a cooperative interstate shipment program will commence when the Administrator, in coordination with a State that has entered into an agreement for a cooperative meat or poultry products inspection program, have selected establishments in the State to participate in the program.

Proposed §§ 332.6(b) and 381.516(b) provide that inspection services for selected establishments participating in a cooperative interstate shipment program must be provided by designated personnel, who will be under the direct supervision of a State employee. As discussed below, the FSIS

SEC will oversee the inspection activities of the designated personnel.

Proposed §§ 332.6(c) and 381.516(c) provide that articles prepared or processed in a selected establishment that have been inspected and passed by designated personnel must bear an official USDA mark, stamp, tag, or label of inspection as specified in 9 CFR 312.2 or 9 CFR 381.96. 9 CFR 312.2 and 9 CFR 381.96 are the regulations that prescribe the appropriate wording and form for use of the official Federal inspection legend on meat or poultry products. In addition, the establishment number contained in the Federal mark, stamp, tag, or label of inspection must comply with all the conditions proposed in §§ 332.5(c) or 381.515(c).

Under proposed §§ 332.6(d) and 381.516(d) meat or poultry products prepared in selected establishments may be shipped in interstate commerce if they have been inspected and by selected State personnel and bear the Federal mark of inspection.

#### 7. Federal Oversight of Cooperative Interstate Shipment Programs

Section 11015 of the 2008 Farm Bill requires that the Secretary designate an employee of the Federal government as a "State coordinator" for each State that has a cooperative State meat or poultry products inspection program (Sec. 501(d) and Sec. 31(d)). The State coordinator is required to "provide oversight and enforcement" of the program and "to oversee the training and inspection activities" of State personnel designated to provide inspection services to selected establishments (Sec. 501(d)(1) and Sec. 31(d)(1)). As noted above, when, and if, a State qualifies to participate in a cooperative interstate shipment program, proposed §§ 332.4(c)(1) and 381.514(c)(1) provide that the Administrator will appoint an FSIS employee as the FSIS SEC for the State. The SEC is the "State coordinator" prescribed by the statute.

FSIS has tentatively decided that the SEC will be an employee of the FSIS Office of Field Operations (OFO) and will be assigned to an FSIS District Office. The SEC will likely be under the direct supervision of an FSIS District Manager. The number of States in an FSIS district assigned to an SEC will likely depend on several factors, including, but not limited to: (1) The number of States and selected establishments, if any, that participate in the cooperative interstate shipment program; (2) the location of each selected establishment; (3) the number of State inspection personnel providing inspection services to selected

establishments in a State; (4) the complexity of the operations conducted at each selected establishment; and (5) the schedule of operations for each selected establishment. The number of States assigned to an SEC would also need to be based on consideration of the most effective allocation of available Agency resources.

*SEC initial responsibilities.* One of the SEC's initial responsibilities will be, in conjunction with the District Office, to coordinate with the State to select establishments to participate in the program. The SEC will coordinate with the State to verify that all State personnel selected to provide inspection services to these establishments have successfully completed the same training in the fundamentals of meat and poultry inspection, covering the Sanitation Performance Standards, Sanitation Standard Operating Procedures (SOPs), HACCP, and enforcement procedures, that is required for FSIS inspection personnel. The SEC will also coordinate with the State to verify that designated personnel have successfully completed the appropriate customized food safety training required for FSIS inspection personnel based on the types of products being produced at the establishments where designated personnel are assigned.

#### *SEC's oversight responsibilities.*

Proposed §§ 332.7 and 381.517 prescribe how the FSIS SEC is to provide Federal oversight of the cooperative interstate shipment program.

Proposed §§ 332.7(a) and 381.517(a) provide that the SEC is to visit each selected establishment in the State on a regular basis to verify that these establishments are operating in a manner that is consistent with the Acts and the implementing regulations in title 9, chapter III, of the CFR. The SEC's frequency of visits and oversight activities for each selected establishment will need to reflect the type of operations conducted by a selected establishment, as well as the establishment's production processes. FSIS requests comments on how frequently the SEC should visit each establishment under his or her jurisdiction. Proposed §§ 332.7(a) and 381.517(a) also provide that if necessary, the SEC, in consultation with the District Manager that covers the State, may designate qualified FSIS personnel to visit a selected establishment on behalf of the SEC.

Under proposed §§ 332.7(b) and 381.517(b), the SEC, in coordination with the State, will verify that selected establishments in the State are receiving the necessary inspection services from

designated personnel, and that these establishments are eligible, and remain eligible, to participate in the cooperative interstate shipment program. These proposed regulations provide that the SEC's verification activities may include:

- Verifying that each selected establishment in the State employs, and continues to employ, 25 or fewer employees on average, unless the establishment is transitioning to become an official establishment;

- Verifying that the designated personnel are providing inspection services to selected establishments in a manner that complies with the Acts and implementing regulations;

- Verifying that the State staffing levels for each selected establishment are appropriate to carry out the required inspection activities; and

- Assessing each selected establishment's compliance with the Acts and implementing regulations under title 9, chapter III, of the CFR.

To verify that designated personnel are providing inspection services in compliance with the Acts, the SEC for the establishment, in coordination with the State, will verify that the designated personnel are correctly applying Federal inspection methodology, making decisions based upon the correct application of this methodology, accurately documenting their findings, and, when authorized to do so, implementing enforcement actions in accordance with the FSIS Rules of Practice in 9 CFR part 500.

To assess each selected establishment's compliance with Federal food safety standards, the SEC will observe the condition of the establishment, observe establishment employees performing their duties, review the establishment's records, and submit product samples for analysis to determine that product produced by the establishment meets Federal food safety standards.

The SEC will have discretion to increase the frequency of visits to a selected establishment if the SEC, in consultation with the District Manager for the State where the selected establishment is located, determines that such action is necessary to ensure that the establishment is operating in a manner consistent with the Acts. The SEC will also be authorized to conduct a comprehensive food safety assessment (FSA) for a selected establishment, or to request that an FSIS Enforcement, Investigation, and Analysis Officer (EIAO) conduct an FSA, if the SEC, in consultation with the District Manager, determines that such action would help determine whether the establishment is

operating in compliance with the Acts. A comprehensive food safety assessment is an assessment that considers all the food safety aspects that relate to an establishment and all the products the plant produces.

If the SEC determines that designated personnel are not providing inspection services to selected establishments in a manner that complies with the Acts, proposed §§ 332.7(c) and 381.517(c) provide that FSIS will provide an opportunity consistent with these regulations for the State to develop and implement a corrective action plan to address inspection deficiencies identified by the SEC. These proposed regulations also provide that if the State fails to develop a corrective action plan, or if the SEC determines that the State's corrective action plan is inadequate, the Administrator will terminate the cooperative agreement with the State.

As discussed above, selected establishments in a State whose agreement for a cooperative interstate shipment program has been terminated by the Administrator are among the establishments that are ineligible to participate in the program. As such, these establishments will be deselected from the program and transitioned to become Federal establishments as described below.

*Quarterly reports.* As required under section 11015 of the 2008 Farm Bill (Sec. 501(d)(3)(b) and Sec. 31(d)(3)(b)), the SEC is to prepare a report on a quarterly basis that describes the status of each selected establishment under the SEC's jurisdiction (proposed §§ 332.8(a) and 381.518(a)).

The SEC's quarterly report will include the SEC's assessment of the performance of the designated personnel in conducting inspection activities (proposed §§ 332.8(b)(1) and 381.518(b)(1)). The quarterly report will also identify the selected establishments that the SEC has verified are in compliance with all Federal requirements, those that have been deselected, and those that are transitioning to become Federal establishments (proposed §§ 332.8(b)(1) and 381.518(b)(1)). The SEC will submit the report to the Administrator through the District Manager for the State in which the selected establishments identified in the report are located (proposed §§ 332.8(c) and 381.518(c)).

*Enforcement.* Section 11015 of the 2008 Farm Bill provides that if the SEC determines that any selected establishment is in violation of any requirement of the Acts, the SEC is required to: (1) Immediately notify the Secretary (the FSIS Administrator by delegation) of the violation and (2)

“deselect” the establishment or suspend inspection at the establishment (Sec. 501(d)(3)(C) and Sec. 31(d)(3)(C)). In adopting this language, Congress intended that the SEC “\* \* \* shall be provided all the tools necessary under the Secretary to prevent or control any food safety issue that would harm human health” (S. Rep. No. 220, 110th Cong., 1st Sess., at 211 (2007)).

Because many of the SEC's verification and enforcement activities require that the SEC have access to a selected establishment's records, proposed §§ 332.9(a) and 381.519(a) provide that to facilitate oversight and enforcement of the cooperative interstate shipment program, selected establishments must, upon request, give SECs or other FSIS officials access to all establishment records required under the FMIA, PPIA, and the implementing regulations in title 9, chapter III, of the CFR. These proposed regulations go on to state that FSIS will move to deselect an establishment that does not comply with this requirement.

Under proposed §§ 332.9(b) and 381.519(b), the SEC is authorized to initiate any appropriate enforcement action provided for in the FSIS rules of practice in 9 CFR part 500 if he or she determines that a selected establishment under his or her jurisdiction is operating in a manner that is inconsistent with the Acts or their implementing regulations. Such actions include, among others, regulatory control actions, withholding actions, and suspensions. The proposed regulations provide that selected establishments participating in a cooperative interstate shipment program are subject to the notification and appeal procedures set out in part 500 (proposed §§ 332.9(b) and 381.519(b)).

Proposed §§ 332.9(c) and 381.519(c) provide that if inspection at a selected establishment is suspended for any of the reasons specified in 9 CFR 500.3 or 9 CFR 500.4, FSIS will provide an opportunity for the establishment to implement corrective actions and remain in the cooperative interstate shipment program, or the Agency will move to deselect the establishment. The decision to deselect a selected establishment under a suspension will be made on a case-by-case basis (proposed §§ 332.9(d) and 381.519(d)). In making this decision, the Administrator, in consultation with the State where the selected establishment is located, will consider, among other factors: (1) The non-compliance that led to the suspension; (2) the selected establishment's compliance history, which will be documented in non-compliance reports prepared by the designated personnel and the SEC's

quarterly reports; and (3) the corrective actions proposed by the establishment (proposed §§ 332.9(d) and 381.519(d)).

The Administrator will have the discretion to allow a selected establishment that has been suspended to remain in the program if the establishment implements corrective actions to address any non-compliance. The Administrator will consider the criteria described above in determining whether to provide an opportunity for corrective actions. Establishments that are given an opportunity to take corrective actions but that are unable to effectively implement these actions will be deselected.

FSIS will also consider the State's recommendation as to whether a selected establishment in the State should be deselected. However, the final decision to deselect an establishment for violations of the FMIA or PPIA will be made by FSIS. As discussed below, consistent with the law, this proposed rule requires that deselected establishments be transitioned to become official establishments.

#### 8. Deselection

There may be circumstances in which an establishment that initially qualifies to be selected to participate in a cooperative interstate shipment program later acquires characteristics that would cause it to become ineligible for the program. For example, an establishment may hire additional employees after it has been selected, or, as discussed above, FSIS may determine that a selected establishment is in violation of the Acts. Therefore, proposed §§ 332.10(a) and 381.520(a) provide that the Administrator will deselect an establishment that becomes ineligible to participate in a cooperative interstate shipment program. Proposed §§ 332.10(b) and 381.520(b) provide that an establishment that has been deselected from a cooperative interstate shipment program must be transitioned to become an official establishment.

FSIS is proposing to require that deselected establishments be transitioned to become official Federal establishments as provided for in the law. Section 11015 of the 2008 Farm Bill allows the Agency to establish a procedure to transition selected establishments that employ, on average, more than 25 employees to become Federal establishments, and it requires that selected establishments that the Administrator determines to be in violation of any provision of the Acts, be transitioned to Federal establishments in accordance with the procedure developed for establishments that employ more than 25 employees

(Sec. 501(b)(3), 501(h), 31(b)(3) and 31(g)).

Thus, as required by the law, under this proposal, establishments that become ineligible to participate in the cooperative interstate shipment program because they violated Federal food safety standards will not be permitted to avoid implementing appropriate corrective actions by withdrawing from the cooperative interstate shipment program and reverting back to the State inspection program. In addition, requiring that deselected establishments transition to become official Federal establishments will help to ensure that the resources that FSIS and the States provide to establish and maintain a cooperative interstate shipment program are used most effectively to provide inspection services to establishments that are committed to maintaining Federal food safety standards.

#### 9. Transition Procedures for Deselected Establishments

As discussed above, under the law, FSIS is authorized to develop a procedure to transition selected establishments to become official establishments if they employ more than 25 employees on average, or if the Agency determines that they are in violation of any provision of the Acts (Sec. 501(b), Sec. 501(h), Sec. 31(b) and Sec. 31(g)). At a minimum, a procedure to transition a selected establishment to an official establishment would include: (1) Adding the establishment to an FSIS circuit within the FSIS District that covers the State where the establishment is located; (2) replacing the establishment's State establishment number with a Federal establishment number, and (3) replacing the designated personnel with FSIS inspection personnel. Other actions needed to successfully transition a selected establishment to become an official establishment are likely to depend on the reason the establishment was deselected. For example, an establishment that was deselected from a cooperative interstate shipment program for violating provisions of the Acts would likely need to develop a corrective action plan as part of its process to transition to an official establishment, while an establishment that was deselected for hiring additional employees would not.

Therefore, instead of prescribing a specific procedure to transition selected establishments to official establishments, proposed §§ 332.11 and 381.521 provide that if a selected establishment is deselected, FSIS will coordinate with the State where the establishment is located to develop and

implement a plan to transition the establishment to become an official establishment. The SEC with jurisdiction over the deselected establishment will likely be charged with coordinating with the State and the FSIS District Office to develop and implement the transition plan.

#### 10. Technical Assistance Division and Transition Grants

Section 11015 of the 2008 Farm Bill amended the FMIA to require that FSIS establish a "technical assistance division" to coordinate the initiatives of other USDA agencies to provide "outreach, education, and training to certain small and very small establishments" and to provide "grants to States to provide outreach, technical assistance, education, and training to certain small and very small establishments" (Sec. 501(f)). As noted earlier in this document, FSIS fulfilled this requirement by establishing the Office of Outreach Employee Education and Training (OOEET).

OOEET is responsible for directing outreach, education, and training programs for FSIS to ensure public health and food safety through both inspection and enforcement activities. OOEET is also responsible for coordinating with other USDA agencies, such as the Rural Development Mission Area and the Cooperative State Research, Education, and Extension Service.

The OOEET State Outreach and Technical Assistance Division promotes State programs and activities to achieve national food safety, food security, and other consumer protection goals by planning, organizing, coordinating, and supporting FSIS cooperative activities with State agencies with responsibility for State meat, poultry and egg product public health assurance inspection programs. It also provides technical expertise, information, and advice to small and very small plant owners and operators on the interpretation, application, implementation and enforcement of the statutes and regulations that FSIS implements.

*Transition grants.* In addition to requiring that FSIS establish a "technical assistance division" to coordinate the initiatives of other USDA agencies to provide grants to States, section 11015 of the 2008 Farm Bill authorizes FSIS to provide "transition grants" to States to assist the States in helping State-inspected establishments transition to selected establishments (Sec. 501(g) and Sec. 31(f)). The Agency has tentatively decided to use this authority, subject to the availability of funds, to grant funds to States that

participate in a cooperative interstate shipment program to reimburse selected establishments in the State for their costs to train one individual in HACCP and associated training in Sanitation SOP requirements.

The regulations that prescribe conditions for receiving Federal inspection, which represent the conditions that selected establishments must meet to be in compliance with Federal standards, require that an establishment develop written Sanitation SOPs as required by 9 CFR part 416, and that it have conducted a hazard analysis and developed and validated a HACCP plan as required in 9 CFR 417.2 and 417.4 (9 CFR 304.3 and 381.22). Under 9 CFR 417.7 of the HACCP regulations, the individual that develops the HACCP plan for an establishment must have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.

State-inspected establishments that apply to participate in a cooperative interstate shipment program will be required to have an individual trained in HACCP in order to transition to a selected establishment. Therefore, for purposes of this proposed rule, FSIS has tentatively concluded that it is appropriate to provide funds to a State for the purpose of reimbursing selected establishments for the cost of this training. Accordingly, proposed §§ 332.12(a) and 381.522(a) provide that these “transition grants” are funds that a State participating in a cooperative interstate shipment program must use to reimburse selected establishments in the State for the cost to train one individual in the HACCP principles applicable to meat or poultry processing as required under 9 CFR 417.7 and associated training in the development of Sanitation SOPs required under 9 CFR part 416.

Proposed §§ 332.12(b) and 381.522(b) make clear that States must use transition grants only for this described purpose. Once a selected establishment receives such funding from the State, the State may not use additional transition grant funds to reimburse that establishment’s training costs in the future.

Under this proposal, establishments that train an individual in HACCP or Sanitation SOP requirements as part of their transition to become selected establishments may request reimbursement for these training costs through the State agency that administers the State’s cooperative

interstate shipment program. These selected establishments will need to submit a training certificate or other documentation to demonstrate that an individual completed the appropriate training. The State would then submit the documentation to FSIS, and request a “transition grant” to reimburse the establishment for its training costs.

*Executive Order 12866 and Regulatory Flexibility Act:*

This proposed rule has been reviewed under Executive Order 12866. It has been determined to be significant, but not economically significant for purposes of E.O. 12866 and, therefore, has been reviewed by the Office of Management and Budget (OMB).

Currently, 27 States administer cooperative State meat or poultry inspection programs. These States have approximately 1,873 establishments that would be eligible to apply for selection into the new cooperative interstate shipment program. However, because participation in the new program will be voluntary, FSIS will not know how many States and establishments will apply to participate until final implementing regulations become effective and establishments are selected for the program. Information obtained through the Agency’s outreach activities indicates that, as of July 2008, about 170 establishments in sixteen States have approached the State Meat and Poultry programs to indicate that they are interested in the new program. These sixteen States have in total 1,133 establishments that could potentially be eligible for the new program.

*Expected Benefits of the Proposed Action:* State-inspected establishments selected to participate in the new cooperative interstate shipment program will be permitted to ship and sell their meat and poultry products in interstate and foreign commerce. Thus, the proposed action would benefit these establishments by opening new markets for their products.

The proposed action would also benefit consumers by generating more product choices, as more products can be shipped to new markets. In addition, the Federal inspection legend and official State establishment inspection number may facilitate traceback of these products if such products are ever the subject of an investigation or recall.

States that participate in the program would benefit because FSIS would reimburse them for at least 60% of their costs related to inspection of selected establishments in the State. FSIS provides up to 50% of the costs of existing cooperative State inspection programs. The Agency has tentatively concluded that most States will benefit

from the 10% increase in reimbursement for the cooperative interstate shipment program because, as explained below, for many States, the costs to administer the new program are not expected to exceed the costs to administer the State meat and poultry inspection programs.

*Expected Costs of the Proposed Action:*

*Costs to the participating establishments.* To be eligible to participate in the cooperative interstate shipment program, a State-inspected establishment must be in compliance with: (1) The State-inspection program of the State in which the establishment is located and (2) the FMIA or PPIA, and their implementing regulations. Before State-inspected establishments can be selected to participate in a cooperative interstate shipment program, they will need to apply for selection into the program and demonstrate that they comply with both State and Federal requirements.

Thus, an establishment that chooses to apply for selection into the program will incur one-time start-up costs associated with filing an application, training employees, meeting regulatory performance standards, obtaining label approval, and implementing a food safety system that complies with all Federal requirements (e.g., Sanitation SOP and HACCP requirements).

In addition, to qualify for a cooperative interstate shipment program, some State-inspection establishments may need to invest in structural modifications to their facilities in order to comply with Federal standards. Based on information obtained through FSIS’ outreach activities with the States, the Agency estimates that the cost for State-inspected establishments to fully comply with Federal standards, as required by the law, will range from \$1,500 to \$50,000. According to most State Directors, the cost to very small establishments that do not need to make structural modifications to their facilities is likely to be in the range of \$5,000 to \$10,000. On the other hand, if the establishments need to make structural modifications or perform new construction then the range would be about \$15,000 to \$30,000.<sup>1</sup> However, because this is a voluntary program, establishments that choose to incur the costs associated with participating in the program will most likely do so because they anticipate that such

<sup>1</sup> Note that under this proposed rule, establishments selected for the program will be eligible to be reimbursed the cost to train one employee in HACCP and Sanitation SOPs.

participation will provide an overall net benefit for them. The Agency welcomes comments on these estimates.

Looking at the potential for the establishments to experience new (incremental) burden or expenses due to State inspection under the proposed cooperative interstate shipment program, FSIS believes that there will be essentially no change. FSIS is aware that the cooperative State meat and poultry products inspection programs are not identical to Federal inspection, as they must be under the cooperative interstate shipment program. So FSIS anticipates that State inspection procedures will need to be changed somewhat to comply with the requirements of the cooperative interstate shipment program. However, since the State programs are required to be equal to the Federal inspection programs now, FSIS anticipates that changes will largely be procedural, and there will not be any particular increase or decrease in overall State effort that would change the burden of the inspection regimen on the establishments.

#### *Costs to the participating States.*

States that choose to participate in the program will be required to pay 40 percent of the eligible costs related to inspection of establishments in the State that are selected for the program. Under the current cooperative program, the States are paying 50 percent of the eligible inspection costs. Although the inspection costs under the new program may be different from the costs under the existing program, the States' share of 40 percent or less is unlikely to be higher than its current share.

States that choose to participate in the interstate shipment program may need to make certain modifications to their State inspection programs to provide inspection services to selected establishments in a manner that is the same as the Federal inspection program. However, most States that have implemented State meat and poultry products inspection (MPI) programs have incorporated the Federal requirements into their programs.<sup>2</sup> Thus, State costs to train State personnel are likely to be minimal because many State personnel have received training in Federal inspection

methodology as part of the State MPI program.

States may incur some costs associated with the processing and evaluation of applications submitted by establishments requesting to be selected for the cooperative interstate shipment program. However, because the States will develop their own application procedures, FSIS is unable to estimate these costs with any certainty. The Agency requests comments on potential State costs associated with the processing and evaluation of these applications.

FSIS anticipates that State inspection procedures will need to be changed somewhat to comply with the requirements of the proposed cooperative interstate shipment program. However, since the State programs are required to be at least equal to the Federal inspection programs now, FSIS anticipates that changes will largely be procedural, and there will not be any particular increase or decrease in overall State effort or cost. FSIS has no basis on which to assume anything else. FSIS requests input from State Program officials that might be useful to refine this estimate.

#### *Expected FSIS Budgetary Effects:*

The new Federal-State cooperative inspection program option which section 11015 of the 2008 Farm Bill requires the Secretary to create and which we propose to implement via this regulatory action is expected to have budgetary effects on FSIS to support about 16 full-time equivalent new staff. This section discusses the baseline costs and activities, *i.e.*, what is happening now before the cooperative interstate shipment program option is available, and then lays out the incremental effects on FSIS. FSIS staff have worked with the 27 directors of the Federal-State meat and poultry inspection program to gauge the level of interest at the State and establishment level. Their input has been incorporated into the assumptions here.

#### *Baseline:*

Federal-State cooperative inspection programs operated in 27 States and 1,873 establishments in FY 2008, the baseline year for this analysis. Actual Federal spending for the Federal-State cooperative inspection programs was \$63,959,709 for FY 2008 as reported in the FY 2010 President's Budget, which also projected \$64,703,000 for FY 2009 and \$65,654,000 for FY 2010. By statute, the States may be reimbursed for up to 50 percent of the cost of their State cooperative inspection programs.

Federal reimbursements to State programs reported in the FY 2010 budget, included in the above figures, are \$49,061,068 for FY 2008, \$50,332,000 for FY 2009, and \$50,332,000 for FY 2010. In fact, actual total State spending for the Federal-State cooperative inspection programs for FY 2008 was \$104 million with \$49 million of that reimbursed by FSIS, as noted above.

FSIS extends these figures into years 2010 through 2014, see table below, the 5-year analysis period for this rule, by assuming that, had the cooperative interstate shipment program option not been enacted, State cooperative programs operations would continue through the period on a generally stable basis. The Agency assumes that the same 27 States would continue to participate and the program would inspect about the same number of establishments as were inspected in FY 2008, *i.e.*, 1,873. This appears reasonable because, among the 27 States in the program the number of establishments has been relatively stable. Since the number of establishments and States is assumed to remain unchanged, and no significant changes in program requirements are expected, baseline program costs are assumed to change only with the cost of inflation.

Turning to FSIS administrative costs, we note that FSIS staffing has been stable in the 28 to 33 person range for the past decade, and is expected to remain at 29 for the foreseeable future. Consistent with State level activities, since the number of States is expected to remain the same with no particular change in the number of establishments, and since no significant changes in program requirements are expected, FSIS administrative costs are expected to change consistent with the cost of inflation, *i.e.*, the Agency anticipates no significant increase or decrease in FSIS administrative activity during the five years in the baseline scenario (*i.e.*, the baseline assumes no cooperative interstate shipment program). FSIS spending to administer Federal-State cooperative inspection programs, excluding the reimbursement costs, was \$14,898,641 for FY 2008 as reported in the FY 2010 budget, and is projected at \$14,371,000 for FY 2009 and \$15,322,000 for FY 2010. For the years out to 2014, these costs would change with inflation and are shown in the following table.

<sup>2</sup> Based on Agency's most recent (FY 2008) review of the 27 States' self-assessment reports (including the State Laboratory Activity Tables) by the Federal State Audit Branch, Internal Control and Audit Division of the Office of Program Evaluation, Enforcement, and Review.

TABLE 1—BASELINE: COST FEDERAL-STATE COOP PROGRAM WITH NO CHANGE

| FSIS Level Costs, Fiscal Year | 2010<br>(Budget) | 2011   | 2012   | 2013   | 2014   | Total 5-year |
|-------------------------------|------------------|--------|--------|--------|--------|--------------|
| FSIS costs .....              | \$15.3           | \$15.9 | \$16.5 | \$17.1 | \$17.8 | \$82.5       |
| Reimburs. to States .....     | 50.3             | 52.1   | 54.1   | 56.2   | 58.4   | 271.1        |
| Total .....                   | 65.7             | 68.0   | 70.5   | 73.3   | 76.1   | 353.6        |
| FSIS Staff Years .....        | 29               | 29     | 29     | 29     | 29     | .....        |

  

| State Level Costs, Fiscal Year | 2010<br>(Budget) | 2011   | 2012   | 2013   | 2014   | Total 5-year |
|--------------------------------|------------------|--------|--------|--------|--------|--------------|
| Federal reimbursement .....    | \$50.3           | \$52.1 | \$54.1 | \$56.2 | \$58.4 | \$271.1      |
| State program spending .....   | 50.3             | 52.1   | 54.1   | 56.2   | 58.4   | 271.1        |
| Total MPI program .....        | 100.7            | 104.2  | 108.1  | 112.4  | 116.7  | 542.1        |
| Number of plants .....         | 1,873            | 1,873  | 1,873  | 1,873  | 1,873  | .....        |

  

| Economic Assumptions From OMB for the 2010 Budget |     |     |     |     |     |       |
|---|-----|-----|-----|-----|-----|-------|
| State & Local Exp, % .....                        | 3.1 | 3.5 | 3.8 | 3.9 | 3.9 | ..... |
| FSIS civilian pay, % .....                        | 5.1 | 4.1 | 4.1 | 4.1 | 4.1 | ..... |
| Non-Pay Expenditure, % .....                      | 0.8 | 1.2 | 1.4 | 1.6 | 1.6 | ..... |

*Interstate Scenario:*

To evaluate this scenario, we must estimate the number of establishments and States that will seek to participate and be selected for the new cooperative interstate shipment program. Then we will discuss the likely incremental changes in activity that could reasonably suggest any changes in cost or burden for FSIS, the States, or establishments.

Here is how we determined the number of establishments that are likely to participate in the proposed cooperative interstate shipment program. The first cut is to look at all establishments and determine the number with fewer than 25 employees. The statute limits participation to these smaller establishments. Of the total 1,873 plants in the current Federal-State cooperative inspection program there are 1,811 that meet the size criterion for eligibility for the cooperative interstate shipment program. However, as noted earlier, sixteen States have expressed an interest in the new cooperative interstate shipment program, and these States have a total of 1,133 establishments that could potentially be eligible for the new program. The eleven States that have not indicated an interest in the cooperative interstate shipment program include all nine States that have establishments operating under the Talmadge-Aiken (TA) program. The TA States account for the remaining 678 eligible establishments.

Because participation in the cooperative interstate shipment program

is voluntary, the Agency cannot estimate with certainty the number of eligible establishments that will choose to participate. Therefore, for illustration purposes, and to obtain a reasonable range of possible budget impacts, given the uncertainty, the Agency estimated the costs for three scenarios: 200, 400 and 600 establishments. A five-year cost estimate was completed covering the FY 2010 through FY 2014. We further assume that the participating establishments will be evenly distributed among the participating States and, just as the baseline assumes, we anticipate no particular change in the numbers of establishments in the overall program over the 5 years and no change in the cooperative interstate shipment program establishments.

At this time, we turn to the change in Federal costs for the program caused by the new statutory reimbursement level. For the cooperative interstate shipment program the law requires that FSIS reimburse State for costs related to the inspection of selected establishments in an amount not less than 60 percent of eligible State costs, as opposed to current law which allows reimbursement of up to 50 percent of costs for the regular, and continuing, Federal-State cooperative inspection program. This analysis projects the effects of the different reimbursement rate on FSIS fiscal requirements assuming no change in State level activity over the baseline. FSIS assumes that States will not change their level of activity associated with selected

establishments in the cooperative interstate shipment program as discussed above. FSIS determined that Agency reimbursements to States would increase by about \$2.2 million in a fully operational cooperative interstate shipment program in FY 2011 (not all plants will be in the cooperative interstate shipment program for all of FY 2010).

In all years, the amount of increase in this component of Federal reimbursement would offset State spending by the same amount. (FY 2011 is used because it is the first, fully operational year, explained further below.) To calculate this figure, FSIS estimated average per establishment spending for the Federal-State Cooperative Inspection Program by States for the 1,873 establishments in the baseline scenario. For FY 2011, the average per establishment is \$55,626, including State and Federal reimbursement. Reviewing the budget for FY 2008 and 2009, we see that average Federal reimbursement is currently running about 50 percent of total State costs. The reimbursement ratio is expected to remain stable for the 5-year period both for inspecting establishments in the baseline scenario, and for inspecting establishments that stay with the existing program, while 400 establishments seek and are selected to operate with the cooperative interstate shipment program. Reimbursement will increase to 60 percent for inspection services to the 400 establishments that move into the

cooperative interstate shipment program option. So, for example, FY 2011 State reimbursement for inspection of the average Interstate establishment would change from the average \$27,813 it would receive for an establishment continuing in the regular Federal-State cooperative inspection programs, to \$33,376 per establishment for inspection of an Interstate plant, an increase of \$5,563 per plant, which yields \$2.2 million for the 400 establishments. This and analogous figures are reflected in the tables below in the "Total grants to States" line for the 200, 400 and 600 establishment scenarios.

Under section 11015 of the Farm Bill, in addition to the increased reimbursement rates that will increase the grants to States for inspection of establishments participating in the cooperative interstate shipment program, FSIS is required to oversee the State inspectors doing the inspections for the cooperative interstate shipment program more intensively than the Agency typically does for the current, and the continuing MPI program. FSIS also expects to incur new costs for outreach and training. This will result in increased demand for FSIS staff and resources. In summary, this includes state coordinators, Deputy District Managers (DDM), outreach and training staff, and lab analysts to certify State laboratories, transition grants to hone establishment staff skills with HACCP and SOPs and associated operating expenses and travel expenses.

The statute requires FSIS to appoint a Federal employee to be a State Coordinator. As explained earlier in this document, the State Coordinator prescribed by the statute is referred to as the "selected establishment coordinator" (SEC) in this proposed rule. The SEC is required by statute to visit selected establishments with a frequency that is appropriate to ensure that such establishments are operating in a manner that is consistent with the FMIA and PPIA, including regulations and policies there under and to: (1) Provide oversight and enforcement of the program, and (2) to oversee the training and inspection activities of State-personnel designated to provide inspection services to the selected establishments. SECs will further provide quarterly reports on each selected establishment under his or her jurisdiction to document their level of compliance with the requirements of the Acts.

We estimate that a total of 13 full time equivalent FSIS employees will be able to perform the SEC functions for the 16 States expected to participate in the

cooperative interstate shipment program. We anticipate that about one-quarter of the total establishments will enter the cooperative interstate shipment program each quarter during FY 2010, reaching the full complement toward the end of that year. So, for example, in the 400 establishment scenario, 100 establishments will initiate inspection under a cooperative interstate shipment program sometime in the first quarter, another 100 in the second quarter, another in the third quarter, and the final group of 100 in the fourth quarter. It is expected that early in 2010 SEC time will initially focus on outreach and start-up activities (including establishment selection) and shift over until it is more completely the oversight activities stipulated in the Acts. While there may be one SEC per State from the beginning, we believe that contiguous States and establishments that are in relative close proximity could make it appropriate to have less than 16 full time equivalent SECs. Note that if 400 establishments convert into the cooperative interstate shipment program in FY 2010 and continue in the following years, each SEC will be responsible for 31 establishments in a geographically-limited area. This is approximately equal to the number of Federal establishments over which frontline FSIS supervisors have oversight responsibilities.

In the start-up period, in FY 2009 and FY 2010, the first year of the cooperative interstate shipment program, in addition to SEC outreach efforts, FSIS expects to incur costs for outreach and training, and administration from OOEET for the small and very small establishments that are considering the cooperative interstate shipment program, that decide to apply for the program, and for those who are selected to participate in the program. OOEET will conduct face-to-face workshops in every State to provide information to establishment owners and operators about the requirements of the new cooperative interstate shipment program. These workshops will not only educate the interested owners and operators about the requirements, they will also help them meet the requirements. This allocation will cover the cost of developing, printing, and shipping the workshop materials, as well as the cost of traveling Agency personnel to conduct the workshops, and the cost of meeting space. The cost is reflected in the tables below in the "Training/Outreach" line. The reason these costs do not change in the various scenarios—200, 400 or 600 establishments—is because the

information will be provided in a classroom. Costs are expected to be largely the same whether attendance is high or low. Also note that these costs drop sharply for each subsequent year as the cooperative interstate shipment program specific effort changes to operating training for establishments selected to participate in the program.

In the start-up period, transition grant authority under 9 CFR 332.12 and 9 CFR 381.522 will be used to provide States funds to reimburse selected establishments in the State for their costs to train one individual in HACCP and associated training in Sanitation SOP requirements. The Agency estimates that the cost of training each establishment specialist will average about \$5,000, including staff time and travel necessary for the training. Since this is a new expense necessary to implement the cooperative interstate shipment program and since statute authorizes it without State matching funds, these costs will be entirely new costs for FSIS that are part of "Total grants to States" in FY 2010 in Table 2 below. Thus, the cost to FSIS will total about \$1 million, \$2 million and \$3 million for the 200, 400 and 600 establishment scenarios respectively. This training will only be needed in the start-up period and, accordingly, appears only in FY 2010 in Table 2.

SECs are likely to be supervised by Deputy District Managers (DDMs) at the equivalent of about 1 DDM per 300 establishments. This is similar to the ratio of DDM effort used to manage frontline FSIS supervisors in the Federal programs. For the three establishment levels, this would mean 1 DDM for 200 establishments and 2 DDMs for 400 or 600 establishments. This is reflected in the "DDM" line of the tables below.

FSIS estimates that two laboratory staff will be needed to complete periodic audits of the State inspection program laboratory systems and otherwise coordinate with the laboratories to ensure the sampling and testing programs are equivalent to the Federal program. It is anticipated that the two lab staff will be needed regardless of whether 200, 400 or 600 establishments eventually participate since the same number of State labs will need to be reviewed regardless of the volume of work they do under the cooperative interstate shipment program. This is reflected in the "Lab staff" line of the tables below.

Travel costs are included on the "Travel—SC & lab staff" line in the tables below. The SECs will need to travel a fair amount to complete their duties and the lab staff will need to travel some. Travel for SECs and lab

staff starts in FY 2010 and will run higher for the first year, after which time the start-up effort will diminish. Since we are assuming the selected establishments are evenly distributed in the participating States, we anticipate that the number of participating establishments would only have slight impact on the cost of travel for each SEC. We project about \$6,150 for training and travel for each SEC in the first and \$630 for subsequent years.

For the lab staff we based our trips to the State program laboratories on one audit of each laboratory to make an initial assessment, so that would be one trip to the labs for each of the 27 eligible States. Because most of the labs typically have a chemistry residue

program and a microbiology program, two lab-auditors will go on each trip—one chemist and one microbiologist. These labs would also need a follow-up the next year and then we would make a judgment as to whether there needed to be annual visits after that. The audit will be based on the program that FSIS developed several years ago, which is similar to the program that the Agency uses to assess the Pasteurized Egg Product Recognized Laboratory program. We based the number of audits on the figures that we had regarding the number of states that will participate, 16. Each trip ran about \$1,500 for each auditor.

Finally, there are the normal operating expenses associated with field

operations including office space, communications costs, information technology costs (such as laptop computers), other equipment, office supplies, etc. FSIS estimates \$3,500 per new staff for laptop, LincPass, Black Berries, etc. These costs are generally stable over time, although they inflate and, of course, are a little higher in the start-up year. These costs are found in the “Equipment and admin” line of the tables below.

Table 2, below, summarizes the incremental costs to FSIS to operate the new cooperative interstate shipment program in the three scenarios 200, 400 and 600 establishments, with the 400 establishment level assumed to be the likely level.

TABLE 2—COOPERATIVE INTERSTATE SHIPMENT PROGRAM COST ESTIMATES—THREE SCENARIOS

| Interstate Program—Summary of Incremental Cost Estimates (\$ Millions) |        |        |        |        |        |        |         |
|--|--------|--------|--------|--------|--------|--------|---------|
| Fiscal Year  | 2009   | 2010   | 2011   | 2012   | 2013   | 2014   | 5-Year  |
| Costs if 200 establishments .....                                      | \$1.93 | \$5.55 | \$4.07 | \$4.22 | \$4.40 | \$4.58 | \$22.83 |
| Costs if 400 establishments .....                                      | 1.93   | 7.11   | 5.34   | 5.55   | 5.77   | 6.00   | 29.77   |
| Costs if 600 establishments .....                                      | 1.93   | 8.79   | 6.53   | 6.79   | 7.06   | 7.33   | 36.50   |

  

| Interstate Program with 200 Establishments (\$ Millions) |      |        |        |        |        |        |        |
|--|------|--------|--------|--------|--------|--------|--------|
| Fiscal Year  | 2009 | 2010   | 2011   | 2012   | 2013   | 2014   | 5-Year |
| Number of establishments * .....                         |      | 200    | 200    | 200    | 200    | 200    |        |
| Total grants to States ** .....                          |      | \$1.54 | \$1.11 | \$1.15 | \$1.20 | \$1.25 |        |
| Total salaries & benefits .....                          |      | 2.20   | 2.17   | 2.25   | 2.35   | 2.45   |        |
| DDM .....  |      | 0.15   | 0.16   | 0.16   | 0.17   | 0.18   |        |
| State coordinator (SC) .....                             |      | 1.69   | 1.76   | 1.83   | 1.91   | 1.98   |        |
| Lab staff .....  |      | 0.24   | 0.25   | 0.26   | 0.27   | 0.29   |        |
| Operating expenses .....                                 |      | 1.81   | 0.79   | 0.82   | 0.85   | 0.89   |        |
| Travel-SC & lab staff .....                              |      | 0.16   | 0.09   | 0.09   | 0.10   | 0.10   |        |
| Training/Outreach .....                                  | 1.43 | 1.25   | 0.35   | 0.36   | 0.38   | 0.39   |        |
| Equipment and admin .....                                | 0.50 | 0.40   | 0.35   | 0.36   | 0.38   | 0.39   |        |
| Total .....  | 1.93 | 5.55   | 4.07   | 4.22   | 4.40   | 4.58   | 22.83  |

  

| Interstate Program with 400 Establishments (\$ Millions) |      |        |        |        |        |        |        |
|--|------|--------|--------|--------|--------|--------|--------|
| Fiscal Year  | 2009 | 2010   | 2011   | 2012   | 2013   | 2014   | 5-Year |
| Number of establishments * .....                         |      | 400    | 400    | 400    | 400    | 400    |        |
| Total grants to States ** .....                          |      | \$3.07 | \$2.23 | \$2.31 | \$2.40 | \$2.49 |        |
| Total salaries & benefits .....                          |      | 2.23   | 2.32   | 2.42   | 2.52   | 2.62   |        |
| DDM .....  |      | 0.30   | 0.31   | 0.33   | 0.34   | 0.35   |        |
| State coordinator (SC) .....                             |      | 1.69   | 1.76   | 1.83   | 1.91   | 1.98   |        |
| Lab staff .....  |      | 0.24   | 0.25   | 0.26   | 0.27   | 0.29   |        |
| Operating expenses .....                                 |      | 1.81   | 0.79   | 0.82   | 0.85   | 0.89   |        |
| Travel-SC & lab staff .....                              |      | 0.16   | 0.09   | 0.09   | 0.10   | 0.10   |        |
| Training/Outreach .....                                  | 1.43 | 1.25   | 0.35   | 0.36   | 0.38   | 0.39   |        |
| Equipment and admin .....                                | 0.50 | 0.40   | 0.35   | 0.36   | 0.38   | 0.39   |        |
| Total .....  | 1.93 | 7.11   | 5.34   | 5.55   | 5.77   | 6.00   | 29.77  |

  

| Interstate Program with 600 Establishments (\$ Millions) |      |        |        |        |        |        |        |
|--|------|--------|--------|--------|--------|--------|--------|
| Fiscal Year  | 2009 | 2010   | 2011   | 2012   | 2013   | 2014   | 5-Year |
| Number of establishments * .....                         |      | 600    | 600    | 600    | 600    | 600    |        |
| Total grants to States ** .....                          |      | \$4.67 | \$3.34 | \$3.46 | \$3.60 | \$3.74 |        |
| Total salaries & benefits .....                          |      | 2.23   | 2.32   | 2.42   | 2.52   | 2.62   |        |
| DDM .....  |      | 0.30   | 0.31   | 0.33   | 0.34   | 0.35   |        |
| State coordinator (SC) .....                             |      | 1.69   | 1.76   | 1.83   | 1.91   | 1.98   |        |
| Lab staff .....  |      | 0.24   | 0.25   | 0.26   | 0.27   | 0.29   |        |
| Operating expenses .....                                 |      | 1.89   | 0.87   | 0.90   | 0.94   | 0.97   |        |

TABLE 2—COOPERATIVE INTERSTATE SHIPMENT PROGRAM COST ESTIMATES—THREE SCENARIOS—Continued

|                             |       |      |      |      |      |      |       |
|-----------------------------|-------|------|------|------|------|------|-------|
| Travel-SC & lab staff ..... | ..... | 0.24 | 0.17 | 0.18 | 0.18 | 0.19 | ..... |
| Training/Outreach .....     | 1.43  | 1.25 | 0.35 | 0.36 | 0.38 | 0.39 | ..... |
| Equipment and admin .....   | 0.50  | 0.40 | 0.35 | 0.36 | 0.38 | 0.39 | ..... |
| Total .....                 | 1.93  | 8.79 | 6.53 | 6.79 | 7.06 | 7.33 | 36.50 |

Economic Assumptions from OMB for the 2010 Budget

|                              |       |     |     |     |     |     |       |
|------------------------------|-------|-----|-----|-----|-----|-----|-------|
| State & Local Exp, % .....   | ..... | 3.1 | 3.5 | 3.8 | 3.9 | 3.9 | ..... |
| FSIS Civilian pay, % .....   | ..... | 5.1 | 4.1 | 4.1 | 4.1 | 4.1 | ..... |
| Non-Pay Expenditure, % ..... | ..... | 0.8 | 1.2 | 1.4 | 1.6 | 1.6 | ..... |

State Grant Incremental Increase in FSIS Reimbursement to the State

|                         |       |         |         |         |         |         |       |
|-------------------------|-------|---------|---------|---------|---------|---------|-------|
| Per Establishment ..... | ..... | \$5,374 | \$5,563 | \$5,774 | \$5,999 | \$6,233 | ..... |
|-------------------------|-------|---------|---------|---------|---------|---------|-------|

\* Note that in FY 2010 about one quarter of establishments are expected to enroll each quarter. In subsequent fiscal years, all establishments will be in the program for the full year.

\*\* Note "Total grants to States" includes funding for Transition Grants in 2010 for States to use to help plants train one person in HACCP and SOPs per § 332.12 and § 381.522.

Effect on Small Entities

This proposed action will primarily affect very small and certain small establishments that operate under cooperative State meat or poultry inspection programs. Under section 11015, State-inspected establishments that employ on average 25 or fewer employees would be permitted to be selected to participate in a cooperative interstate shipment program. The law also permits the Secretary to select State-inspected establishments that employ, on average, more than 25 but less than 35 employees to participate in the program. However, to remain in the program, these establishments must employ, on average, 25 or fewer employees three years after the regulations implementing the new cooperative interstate shipment program become effective. FSIS provides for the selection of State-inspected establishments that employ, on average, more than 25 but fewer than 35 employees in the proposed implementing regulations. Thus, this proposed rule will benefit these very small and small State-inspected establishments by allowing them to ship meat and poultry products in interstate and foreign commerce, thereby opening new markets for their products.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to

ensure that minorities, women, and persons with disabilities are aware of this proposed rule, FSIS will announce it online through the FSIS Web page located at [http://www.fsis.usda.gov/Regulations\\_Policies/2009\\_Proposed\\_Rules\\_Index/index.asp](http://www.fsis.usda.gov/Regulations_Policies/2009_Proposed_Rules_Index/index.asp). FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. Through the Listserv and Web page, FSIS is able to provide information to a much broader and more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at [http://www.fsis.usda.gov/news\\_and\\_events/email\\_subscription/](http://www.fsis.usda.gov/news_and_events/email_subscription/). Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995, the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB).

Title: "Cooperative Inspection Programs: Interstate Shipment of Meat and Poultry Products"

Type of collection: New.

Abstract: FSIS has reviewed the paperwork and recordkeeping requirements in this proposed rule in accordance with the Paperwork Reduction Act. Under this proposed rule, FSIS is requiring certain information collection and recordkeeping activities.

FSIS is proposing that States that are interested in participating in the cooperative interstate shipment program submit a request for an agreement to establish such a program through the appropriate FSIS District Office. In their requests, States must: (1) Identify establishments in the State that the State recommends for initial selection into the program; (2) include documentation to demonstrate that the State is able to provide necessary inspections services to selected establishments in the State and conduct any related activities that would be required under a cooperative interstate shipment program; and (3) agree to comply with certain conditions to assist with enforcement of the program. FSIS is also proposing that States that have entered into an agreement with FSIS for a cooperative interstate shipment program submit, through the FSIS District Office, an evaluation of each State-inspected establishment that has applied, and that the State recommends be selected, for the cooperative interstate shipment program.

Under this proposal, State inspected establishments selected to participate in the cooperative interstate shipment program will be required to develop and maintain the same records that are required under the Acts and their implementing regulations. Selected

establishment will also be required to give the FSIS selected establishment coordinator (SEC) access to all establishment records required under the Acts and implementing regulations. Most States that have cooperative State meat or poultry products inspection programs have incorporated the Federal standards into their programs. Thus, most establishments selected to participate in the interstate shipment program are currently required to maintain records that comply with Federal standards. However, establishments located in States that have implemented recordkeeping requirements that are "at least equal to" but not identical to Federal requirements will need to modify their recordkeeping procedures to comply with Federal standards. All selected establishments will be required to give the FSIS SEC access to their records upon request.

*Estimate of Burden:* FSIS estimates that 16 of the 27 States that currently have agreements for cooperative State meat or poultry products inspection programs will prepare and submit a request to FSIS to establish a cooperative interstate shipment program. The Agency also estimates that approximately 400 establishments will apply for the program. Thus, FSIS estimates that each of the 16 States mentioned above will need to prepare and submit, on average, 25 evaluations for the State-inspected establishments that have applied for, and that the State recommends, for selection into the program, for an estimated total of 400 evaluations.

FSIS estimates that it will take approximately 40 hours for each State to prepare and submit a request to establish a cooperative interstate shipment program, for a total burden of 640 hours. The Agency estimates that it will take each State approximately 24 hours to prepare an evaluation of a State-inspected establishment's qualifications to be selected for a cooperative interstate shipment program, for a total burden of 9,600 hours.

FSIS estimates that if all of the 400 establishments that apply are selected for the program, approximately 100 of these establishments will need to modify their recordkeeping procedures to come into compliance with Federal standards. The extent to which these establishments will need to modify their recordkeeping procedures will depend on requirements under the State inspection program. Because recordkeeping requirements under the State inspection program must be "at least equal to" the Federal requirements,

these modifications should be minor. FSIS estimates that it will take approximately 16 hours for each establishment that is currently maintaining records under State standards to review and revise its recordkeeping procedures, and about 5 minutes for each establishment to file these records, for a total burden of approximately 1,608.3 hours.

All of the estimated 400 establishments that participate in the program will be required to give the SEC access to all records required under the Federal Acts. FSIS estimates that it will take each establishment approximately 15 minute to assist the SEC to locate the necessary records for review on the initial visit, for a total burden of 100 hours. FSIS estimates that these establishments will need to spend and approximately 5 minute to assist the SEC locate records for review for each subsequent visit. If the SEC visits each selected establishment at least one a month, the total burden per establishment per year will be 1 hour, for a total estimated annual burden of 400 hours.

*Respondents:* State agencies that administer cooperative State meat and poultry products inspection programs and State-inspected establishments selected to participate in a cooperative interstate shipment program.

*Estimated number of respondents:* 416 (16 States and 400 State-inspected establishments).

*Estimated number of responses per respondent:* One request to establish a cooperative interstate shipment program per State and 25 evaluations of State-inspected establishments per State, on average.

A one-time modification of records for each selected establishment whose recordkeeping does not comply with all Federal standards. One initial SEC visit in which each selected establishment will need to provide the SEC with access to all required records. Each establishment selected for the program will need to provide the FSIS access to its records on an ongoing basis.

*Estimated Total Annual Burden on Respondents:* 12,348.3 hours to establish and implement the cooperative interstate shipment program in 16 States. Once the program has been implemented, an estimated annual burden of 400 hours for selected establishments to provide the SEC access to establishment records on-going basis.

Copies of this information collection assessment can be obtained from John O'Connell, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 1400 Independence

Avenue, SW., Room 3532 South Building, Washington, DC 20250.

*Comments are invited on:* (a) Whether the proposed collection of information is necessary for the proper performance of FSIS' functions, including whether the information will have practical utility; (b) the accuracy of FSIS' estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology.

Comments may be sent to both John O'Connell, Paperwork Reduction Act Coordinator, at the address provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

To be most effective, comments should be sent to OMB within 60 days of the publication date of this proposed rule.

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or record keeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB).

## Proposed Regulations

### List of Subjects

#### 9 CFR Part 321

Grant programs—agriculture, Intergovernmental relations, Meat inspection.

#### 9 CFR Part 332

Grant programs—agriculture, Intergovernmental relations, Meat inspection.

#### 9 CFR Part 381

Grant programs—agriculture, Intergovernmental relations, Poultry and poultry products.

For the reasons discussed in the preamble, FSIS is proposing to amend 9 CFR Chapter III as follows:

### PART 321—COOPERATION WITH STATES AND TERRITORIES

1. The authority citation for part 321 is revised to read as follows:

**Authority:** 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

2. A new § 321.3 is added to read as follows:

**§ 321.3 Cooperation of States for the interstate shipment of carcasses, parts of carcasses, meat, and meat food products.**

(a) The Administrator is authorized under 21 U.S.C. 683(b) to coordinate with States that have meat inspection programs as provided in § 321.1 of this part to select certain establishments operating under these programs to participate in a cooperative program to ship carcasses, parts of carcasses, meat, and meat food products in interstate commerce. A cooperative program for this purpose is called a “cooperative interstate shipment program.”

(b) Establishments selected to participate in a cooperative interstate shipment program described in this section must receive inspection services from designated State personnel that have been trained in the enforcement of the Act. If the designated personnel determine that the carcasses, parts of carcasses, meat, and meat food products prepared in establishments selected to participate in the cooperative interstate shipment program comply with all requirements under the Act, these items will bear an official Federal mark of inspection and may be shipped in interstate commerce. The Administrator will assign an FSIS “selected establishment coordinator,” who will be an FSIS employee, to each State that participates in a cooperative interstate shipment program to provide Federal oversight of the program and enforcement of the program’s requirements. The Federal contribution for inspection services provided by States that enter into a cooperative interstate shipment program under this section will be at least 60 percent of eligible State costs.

(c) Part 332 of this subchapter prescribes conditions under which States and establishments may participate in the cooperative interstate shipment program.

(d) The Administrator will terminate a cooperative interstate shipment agreement with a State if the Administrator determines that the State is not conducting inspection at selected establishments in a manner that complies with the Act and the implementing regulations in this chapter.

3. A new Part 332 is added to read as follows:

**PART 332—SELECTED ESTABLISHMENTS; COOPERATIVE PROGRAM FOR INTERSTATE SHIPMENT OF CARCASSES, PARTS OF CARCASSES, MEAT, AND MEAT FOOD PRODUCTS**

Sec.

- 332.1 Definitions.
- 332.2 Purpose.
- 332.3 Requirements for establishments; ineligible establishments.
- 332.4 State request for cooperative agreement.
- 332.5 Establishment selection; official number for selected establishments.
- 332.6 Commencement of a cooperative interstate shipment program; inspection by designated personnel and official mark.
- 332.7 Federal oversight of a cooperative interstate shipment program.
- 332.8 Quarterly reports.
- 332.9 Enforcement authority.
- 332.10 Deselection of ineligible establishments.
- 332.11 Transition to official establishments.
- 332.12 Transition grants.

**Authority:** 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

**§ 332.1 Definitions.**

The following definitions apply to the regulations in this part:

*Cooperative interstate shipment program.* A cooperative meat inspection program described in § 321.3 of this subchapter.

*Cooperative State meat inspection program.* A cooperative State-Federal meat inspection program described in § 321.1 of this subchapter.

*Designated personnel.* State inspection personnel that have been trained in the enforcement of the Act and any additional State program requirements in order to provide inspection services to selected establishments.

*Interstate commerce.* “Interstate commerce” has the same meaning as “commerce” under § 301.2 of this subchapter.

*Selected establishment.* An establishment operating under a State cooperative meat inspection program that has been selected by the Administrator, in coordination with the State where the establishment is located, to participate in a cooperative interstate shipment program.

**§ 332.2 Purpose.**

This part prescribes the conditions under which States that administer cooperative State meat inspection programs and establishments that operate under such programs may participate in a cooperative interstate shipment program.

**§ 332.3 Requirements for establishments; ineligible establishments.**

(a) An establishment that operates under a cooperative State meat inspection program may apply to participate in a cooperative interstate shipment program under this part if:

- (1) The establishment employs on average no more than 25 employees based on the standards described in paragraph (b) of this section, or
- (2) The establishment employed more than 25 employees but fewer than 35 employees as of June 18, 2008. If selected to participate in a cooperative interstate shipment program, an establishment under this paragraph must employ on average no more than 25 employees as of [insert date 3 years after effective date of final rule] or it must transition to become an official establishment as provided in § 332.11 of this part.

(b) An establishment that has 25 or fewer employees based on the following standards is considered to have 25 or fewer employees on average for purposes of this part.

(1) All individuals, both supervisory and non-supervisory, employed by the establishment on a full-time, part-time, or temporary basis are counted when calculating the total number of employees.

(2) All individuals employed by the establishment from a temporary employee agency, professional employee organization, or leasing concern are counted when calculating the total number of employees.

(3) The average number of employees is calculated for each of the pay periods for the preceding 12 calendar months.

(4) Part-time and temporary employees are counted the same as full-time employees.

(5) If the establishment has not been in business for 12 months, the average number of employees is calculated for each of the pay periods in which the establishment has been in business.

(6) Volunteers who receive no compensation are not considered employees.

(7) The total number of employees can never exceed 35 individuals at any given time, regardless of the average number of employees.

(c) The following establishments are ineligible to participate in a cooperative interstate shipment program:

(1) Establishments that employ more than 25 employees on average (except as provided under paragraph (a)(2) of this section);

(2) Establishments operating under a Federal-State program as provided in § 321.2 of this subchapter as of June 18, 2008;

(3) Official establishments;

(4) Establishments that were official establishments as of June 18, 2008, but that were re-organized on a later date by the person that controlled the establishment as of June 18, 2008;

(5) Establishments operating under a cooperative State meat inspection that employed more than 35 employees as of June 18, 2008, that were reorganized on a later date by the person that controlled the establishment as of June 18, 2008;

(6) Establishments that are the subject of a transition under § 332.11 of this part;

(7) Establishments that are in violation of the Act;

(8) Establishments located in States without a cooperative State meat inspection program; and

(9) Establishments located in a State whose agreement for a cooperative interstate shipment program was terminated by the Administrator as provided in § 321.3(d) of this subchapter.

(d) An establishment that meets the conditions in paragraph (a) of this section and that is not an ineligible establishment under paragraph (c) of this section may apply for selection into a cooperative interstate shipment program through the State in which the establishment is located.

#### **§ 332.4 State request for cooperative agreement.**

(a) State participation in a cooperative interstate shipment program under this part is limited to States that have implemented cooperative State meat inspection programs.

(b) To request an agreement for a cooperative interstate shipment program under this part, a State must submit a written request to the Administrator through the FSIS District Office for the FSIS District in which the State is located. In the request the State must:

(1) Identify establishments in the State that have requested to be selected for the program that the State recommends for initial selection into the program;

(2) Demonstrate that the State is able to provide the necessary inspection services to selected establishments in the State and conduct any related activities that would be required under a cooperative interstate shipment program established under this part; and

(3) Agree that, if the State enters into an agreement with FSIS for a cooperative interstate shipment program, that the State will:

(i) Provide FSIS with access to the results of all laboratory analyses conducted on product samples from selected establishments in the State;

(ii) Notify the selected establishment coordinator for the State of the results of any laboratory analyses that indicate that a product prepared in a selected establishment may be adulterated or may otherwise present a food safety concern; and

(iii) When necessary, cooperate with FSIS to transition selected establishments in the State that have been deselected from a cooperative interstate shipment program to become official establishments.

(c) If the Administrator determines that a State that has submitted a request to participate in a cooperative interstate shipment program qualifies to enter into a cooperative agreement for such a program, the Administrator and the State will sign a cooperative agreement that sets forth the terms and conditions under which each party will cooperate to provide inspection services to selected establishments located in the State.

(d) After the Administrator and a State have signed an agreement for a cooperative interstate shipment program as provided in paragraph (c) of this section, the Administrator will:

(1) Appoint an FSIS employee as the FSIS selected establishment coordinator for the State and

(2) Coordinate with the State to select establishments to participate in the program as provided in § 332.5(b) of this part.

#### **§ 332.5 Establishment selection; official number for selected establishments.**

(a) An establishment operating under a cooperative State meat inspection program will qualify for selection into a cooperative interstate shipment program if the establishment:

(1) Has submitted a request to the State to be selected for the program;

(2) Has the appropriate number of employees under § 332.3(a) of this part;

(3) Is not ineligible to participate in a cooperative interstate shipment program under § 332.3(c) of this part;

(4) Is in compliance with all requirements under the cooperative State meat inspection program; and

(5) Is in compliance with all requirements under the Act and the implementing regulations in this chapter.

(b) To participate in a cooperative interstate shipment program, an establishment that meets the conditions in paragraph (a) of this section must be selected by the Administrator, in coordination with the State where the establishment is located.

(c) If an establishment is selected to participate in a cooperative interstate shipment program as provided in

paragraph (b) of this section, the State is to assign the establishment an official number that reflects the establishment's participation in the cooperative interstate shipment program and advise the FSIS selected establishment coordinator for the State of the official number assigned to each selected establishment in the State. The official number assigned to every selected establishment must contain a suffix, *e.g.*, "SE," that identifies the establishment as a selected establishment and that identifies the State, *e.g.*, "SETX," for "selected establishment Texas."

(d) Failure of the State to comply with paragraph (c) of this section will disqualify the State from participation in the cooperative interstate shipment program.

#### **§ 332.6 Commencement of a cooperative interstate shipment program; inspection by designated personnel and official mark.**

(a) A cooperative interstate shipment program will commence when the Administrator, in coordination with the State, has selected establishments in the State to participate in the program.

(b) Inspection services for selected establishments participating in a cooperative interstate shipment program must be provided by designated personnel, who will be under the direct supervision of a State employee.

(c) Carcasses, parts of carcasses, meat, and meat food products prepared in a selected establishment and inspected and passed by designated State personnel must bear an official Federal mark, stamp, tag, or label of inspection in the appropriate form prescribed in part 312 of this subchapter that includes the information specified in § 332.5(c) of this part.

(d) Carcasses, parts of carcasses, meat, and meat food products prepared in a selected establishment that comply with the conditions in paragraph (c) of this section may be distributed in interstate commerce.

#### **§ 332.7 Federal oversight of a cooperative interstate shipment program.**

(a) The FSIS selected establishment coordinator for a State that has entered into an agreement for a cooperative interstate shipment program will visit each selected establishment in the State on a regular basis to verify that the establishment is operating in a manner that is consistent with the Act and the implementing regulations in this chapter. If necessary, the selected establishment coordinator, in consultation with the District Manager that covers the State, may designate qualified FSIS personnel to visit a

selected establishment on behalf of the selected establishment coordinator.

(b) The selected establishment coordinator, in coordination with the State, will verify that selected establishments in the State are receiving the necessary inspection services from designated personnel, and that these establishments are eligible, and remain eligible, to participate in a cooperative interstate shipment program.

The selected establishment coordinator's verification activities may include:

(1) Verifying that each selected establishment employs, and continues to employ, 25 or fewer employees, on average, as required under § 332.3(a) of this part, unless the establishment is transitioning to become an official establishment;

(2) Verifying that the designated personnel are providing inspection services to selected establishments in a manner that complies with the Act and the implementing regulations in this chapter;

(3) Verifying that that State staffing levels for each selected establishments are appropriate to carry out the required inspection activities; and

(4) Assessing each selected establishment's compliance with the Act and implementing regulations under this chapter.

(c) If the selected establishment coordinator determines that designated personnel are providing inspection services to selected establishments in the State in a manner that is inconsistent with the Act and the implementing regulations in this chapter, the Administrator will provide an opportunity for the State to develop and implement a corrective action plan to address inspection deficiencies identified by the selected establishment coordinator. If the State fails to develop a corrective action plan, or the selected establishment coordinator for the State determines that the corrective action plan is inadequate, the Administrator will terminate the agreement for the cooperative interstate shipment program as provided in § 321.3(d) of this chapter.

#### **§ 332.8 Quarterly reports.**

(a) The selected establishment coordinator will prepare a report on a quarterly basis that describes the status of each selected establishment under his or her jurisdiction.

(b) The quarterly report required in paragraph (a) of this section will:

(1) Include the selected establishment coordinator's assessment of the performance of the designated personnel in conducting inspection activities at selected establishments and

(2) Identify those selected establishments that the selected establishment coordinator has verified are in compliance with the Act and implementing regulations in this chapter, those that have been deselected under § 332.10 of this part, and those that are transitioning to become official establishments under § 332.11 of this part.

(c) The selected establishment coordinator is to submit the quarterly report to the Administrator through the District Manager for the State where the selected establishments identified in the report are located.

#### **§ 332.9 Enforcement authority.**

(a) To facilitate oversight and enforcement of this part, selected establishments operating under a cooperative interstate shipment program must, upon request, give the FSIS selected establishment coordinator or other FSIS officials access to all establishment records required under the Act and the implementing regulations in this chapter. The Administrator may deselect any selected establishment that refuses to comply with this paragraph.

(b) Selected establishment coordinators may initiate any appropriate enforcement action provided for in part 500 of this chapter if they determine that a selected establishment under their jurisdiction is operating in manner that is inconsistent with the Act and the implementing regulations in this chapter. Selected establishments participating in a cooperative interstate shipment program are subject to the notification and appeal procedures set out in part 500 of this chapter.

(c) If inspection at a selected establishment is suspended for any of the reasons specified in § 500.3 or § 500.4 of this chapter, FSIS will:

(1) Provide an opportunity for the establishment to implement corrective actions and remain in the cooperative interstate shipment program, or

(2) Move to deselect the establishment as provided in § 332.10 of this part.

(d) The decision to deselect a selected establishment under a suspension will be made on a case-by-case basis. In making this decision, FSIS, in consultation with the State where the selected establishment is located, will consider, among other factors:

(1) The non-compliance that led to the suspension;

(2) The selected establishment's compliance history; and

(3) The corrective actions proposed by the selected establishment.

#### **§ 332.10 Deselection of ineligible establishments.**

(a) The Administrator will deselect a selected establishment that becomes ineligible to participate in a cooperative interstate shipment program for any reason listed under § 332.3(c) of this part.

(b) An establishment that has been deselected must transition to become an official establishment as provided in § 332.11 of this part.

#### **§ 332.11 Transition to official establishment.**

If an establishment is deselected from a cooperative interstate shipment program as provided in § 332.10 of this part, FSIS, in coordination with the State where the establishment is located, will develop and implement a plan to transition the establishment to become an official establishment.

#### **§ 332.12 Transition grants.**

(a) Transition grants are funds that a State participating in a cooperative interstate shipment program under this part may apply for to reimburse selected establishments in the State for the cost to train one individual in the seven HACCP principles for meat or poultry processing as required under § 417.7 of this chapter and associated training in the development of sanitation standard operating procedures required under part 416 of this chapter.

(b) A State participating in a cooperative interstate shipment program that receives a transition grant must use grant funds to reimburse the training costs of one employee per each selected establishment in the State. Any other use of such funds is prohibited.

### **PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS**

4. The authority citation for part 381 continues to read as follows:

**Authority:** 7 U.S.C. 138f, 450; 21 U.S.C. 451–470; 7 CFR 2.7, 2.18, 2.53.

5. A new § 381.187 is added to subpart R to read as follows:

#### **§ 381.187 Cooperation of States for the interstate shipment of poultry products.**

(a) The Administrator is authorized under 21 U.S.C. 472(b) to coordinate with States that have poultry products inspection programs as provided in § 381.185 of this subpart to select certain establishments operating under these programs to participate in a cooperative program to ship poultry products in interstate commerce. A cooperative program for this purpose is called a "cooperative interstate shipment program."

(b) Establishments selected to participate in a cooperative interstate shipment program described in this section must receive inspection services from designated State personnel that have been trained in the enforcement of the Act. If the designated personnel determine that the poultry products prepared in establishments selected to participate in the cooperative interstate shipment program comply with all requirements under the Act, these items will bear an official Federal mark of inspection and may be shipped in interstate commerce. The Administrator will assign an FSIS "selected establishment coordinator," who will be an FSIS employee, to each State that participates in a cooperative interstate shipment program to provide Federal oversight of the program and enforcement of the program's requirements. The Federal contribution for inspection services provided by States that enter into a cooperative interstate shipment program under this section will be at least 60 percent of eligible State costs.

(c) Subpart Z, of this part 381 prescribes conditions under which States and establishments may participate in the cooperative interstate shipment program.

(d) The Administrator will terminate a cooperative interstate shipment agreement with a State if the Administrator determines that the State is not conducting inspection at selected establishments in a manner that complies with the Act and the implementing regulations in this chapter.

5. A new subpart Z is added to part 381 to read as follows:

**Subpart Z—Selected Establishments; Cooperative Program for Interstate Shipment of Poultry Products**

Sec.

- 381.511 Definitions.
- 381.512 Purpose.
- 381.513 Requirements for establishments; ineligible establishments.
- 381.514 State request for cooperative agreement.
- 381.515 Establishment selection; official number for selected establishments.
- 381.516 Commencement of a cooperative interstate shipment program; inspection by designated personnel and official mark.
- 381.517 Federal oversight of a cooperative interstate shipment program.
- 381.518 Quarterly reports.
- 381.519 Enforcement authority.
- 381.520 Deselection of ineligible establishments.
- 381.521 Transition to official establishment.
- 381.522 Transition grants.

**Subpart Z—Selected Establishments; Cooperative Program for Interstate Shipment of Poultry Products**

**§ 381.511 Definitions.**

The following definitions apply to the regulations in this part:

*Cooperative interstate shipment program.* A cooperative poultry products inspection program described in § 381.187 of this part.

*Cooperative State poultry products inspection program.* A cooperative State-Federal poultry products inspection program described in § 381.185 of this part.

*Designated personnel.* State inspection personnel that have been trained in the enforcement of Act and any additional State program requirements in order to provide inspection services to selected establishments.

*Interstate commerce.* "Interstate commerce" has the same meaning as "commerce" under § 381.1 of this part.

*Selected establishment.* An establishment operating under a State cooperative poultry products inspection program that has been selected by the Administrator, in coordination with the State where the establishment is located, to participate in a cooperative interstate shipment program.

**§ 381.512 Purpose.**

This subpart Z prescribes the conditions under which States that administer cooperative State poultry products inspection programs and establishments that operate under such programs may participate in a cooperative interstate shipment program.

**§ 381.513 Requirements for establishments; ineligible establishments.**

(a) An establishment that operates under a cooperative State poultry products inspection program may apply to participate in a cooperative interstate shipment program under this subpart if:

- (1) The establishment employs on average no more than 25 employees based on the standards described in paragraph (b) of this section, or
- (2) The establishment employed more than 25 employees but fewer than 35 employees as of June 18, 2008. If selected to participate in a cooperative interstate shipment program, an establishment under this paragraph must employ on average no more than 25 employees as of [insert date 3 years after effective date of final rule] or it must transition to become an official establishment as provided in § 381.521 of this subpart.

(b) An establishment that has 25 or fewer employees based on the following

standards is considered to have 25 or fewer employees on average for purposes of this subpart.

(1) All individuals, both supervisory and non-supervisory, employed by the establishment on a full-time, part-time, or temporary basis are counted when calculating the total number of employees.

(2) All individuals employed by the establishment from a temporary employee agency, professional employee organization, or leasing concern are counted when calculating the total number of employees.

(3) The average number of employees is calculated for each of the pay periods for the preceding 12 calendar months.

(4) Part-time and temporary employees are counted the same as full-time employees.

(5) If the establishment has not been in business for 12 months, the average number of employees is calculated for each of the pay periods in which the establishment has been in business.

(6) Volunteers who receive no compensation are not considered employees.

(7) The total number of employees can never exceed 35 individuals at any given time, regardless of the average number of employees.

(c) The following establishments are ineligible to participate in a cooperative interstate shipment program:

(1) Establishments that employ more than 25 employees on average (except as provided under paragraph (a)(2) of this section);

(2) Establishments operating under a Federal-State program as provided in § 381.186 of this part as of June 18, 2008;

(3) Official establishments;

(4) Establishments that were official establishments as of June 18, 2008, but that were re-organized on a later date by the person that controlled the establishment as of June 18, 2008;

(5) Establishments operating under a cooperative State poultry products inspection program that employed more than 35 employees as of June 18, 2008, that were reorganized on a later date by the person that controlled the establishment as of June 18, 2008;

(6) Establishments that are the subject of a transition under § 381.521 of this subpart;

(7) Establishments that are in violation of the Act; and

(8) Establishments located in States without a cooperative State poultry products inspection program.

(9) Establishments located in a State whose agreement for a cooperative interstate shipment program was terminated by the Administrator as provided in § 381.187(d) of this part.

(d) An establishment that meets the conditions in paragraph (a) of this section and that is not an ineligible establishment under paragraph (c) of this section may apply for selection into a cooperative interstate shipment program through the State in which the establishment is located.

**§ 381.514 State request for cooperative agreement.**

(a) State participation in a cooperative interstate shipment program under this subpart is limited to States that have implemented cooperative State poultry products inspection programs.

(b) To request an agreement for a cooperative interstate shipment program under this subpart, a State must submit a written request to the Administrator through the FSIS District Office for the FSIS District in which the State is located. In the request the State must:

(1) Identify establishments in the State that have requested to be selected for the program that the State recommends for initial selection into the program;

(2) Demonstrate that the State is able to provide the necessary inspection services to selected establishments in the State and conduct any related activities that would be required under a cooperative interstate shipment program established under this subpart; and

(3) Agree that, if the State enters into an agreement with FSIS for a cooperative interstate shipment program, that the State will:

(i) Provide FSIS with access to the results of all laboratory analyses conducted on product samples from selected establishments in the State;

(ii) Notify the selected establishment coordinator for the State of the results of any laboratory analyses that indicate that a product prepared in a selected establishment may be adulterated or may otherwise present a food safety concern; and

(iii) When necessary, cooperate with FSIS to transition selected establishments in the State that have been deselected from a cooperative interstate shipment program to become official establishments.

(c) If the Administrator determines that a State that has submitted a request to participate in a cooperative interstate shipment program qualifies to enter into a cooperative agreement for such a program, the Administrator and the State will sign a cooperative agreement that sets forth the terms and conditions under which each party will cooperate to provide inspection services to selected establishments located in the State.

(d) After the Administrator and a State have signed an agreement for a cooperative interstate shipment program as provided in paragraph (c) of this section, the Administrator will:

(1) Appoint an FSIS employee as the FSIS selected establishment coordinator for the State and

(2) Coordinate with the State to select establishments to participate in the program as provided in § 381.515(b) of this subpart.

**§ 381.515 Establishment selection; official number for selected establishments.**

(a) An establishment operating under a cooperative State poultry products inspection program will qualify for selection into a cooperative interstate shipment program if the establishment:

(1) Has submitted a request to the State to be selected for the program;

(2) Has the appropriate number of employees under § 381.513(a) of this subpart;

(3) Is not ineligible to participate in a cooperative interstate shipment program under § 381.513(c) of this subpart;

(4) Is in compliance with all requirements under the cooperative State poultry products inspection program; and

(5) Is in compliance with all requirements under the Act and the implementing regulations in this chapter.

(b) To participate in a cooperative interstate shipment program, an establishment that meets the conditions in paragraph (a) of this section must be selected by the Administrator, in coordination with the State where the establishment is located.

(c) If an establishment is selected to participate in a cooperative interstate shipment program as provided in paragraph (b) of this section, the State is to assign the establishment an official number that reflects the establishment's participation in the cooperative interstate shipment program and advise the FSIS selected establishment coordinator for the State of the official number assigned to each selected establishment in the State. The official numbers assigned to every selected establishment must contain a suffix, e.g., "SE," that identifies the establishment as a selected establishment; that includes the letter "P," which identifies the establishment as a poultry establishment; and that identifies the State, e.g., "SEPND," for "selected establishment poultry North Dakota."

(d) Failure of a State to comply with paragraph (c) of this section will disqualify the State from participation

in the cooperative interstate shipment program.

**§ 381.516 Commencement of a cooperative interstate shipment program; inspection by designated personnel and official mark.**

(a) A cooperative interstate shipment program will commence when the Administrator, in coordination with the State, has selected establishments in the State to participate in the program.

(b) Inspection services for selected establishments participating in a cooperative interstate shipment program must be provided by designated personnel, who will be under the direct supervision of a State employee.

(c) Poultry products processed in a selected establishment and inspected and passed by designated State personnel must bear an official Federal mark, stamp, tag, or label of inspection in the appropriate form prescribed in subpart M of this part that includes the information specified in § 381.515(c) of this subpart.

(d) Poultry products processed in a selected establishment that comply with the conditions in paragraph (c) of this section may be distributed in interstate commerce.

**§ 381.517 Federal oversight of a cooperative interstate shipment program.**

(a) The FSIS selected establishment coordinator for a State that has entered into an agreement for a cooperative interstate shipment program will visit each selected establishment in the State on a regular basis to verify that the establishment is operating in a manner that is consistent with the Act and the implementing regulations in this chapter. If necessary, the selected establishment coordinator, in consultation with the District Manager that covers the State, may designate qualified FSIS personnel to visit a selected establishment on behalf of the selected establishment coordinator.

(b) The selected establishment coordinator, in coordination with the State, will verify that selected establishments in the State are receiving the necessary inspection services from designated personnel, and that these establishments are eligible, and remain eligible, to participate in a cooperative interstate shipment program. The selected establishment coordinator's verification activities may include:

(1) Verifying that each selected establishment employs, and continues to employ, 25 or fewer employees, on average, as required under §§ 381.513(a) of this part, unless the establishment is transitioning to become an official establishment;

(2) Verifying that the designated personnel are providing inspection services to selected establishments in a manner that complies with the Act and the implementing regulations in this chapter;

(3) Verifying that that State staffing levels for each selected establishment are appropriate to carry out the required inspection activities; and

(4) Assessing each selected establishment's compliance with the Act and implementing regulations in this chapter.

(c) If the selected establishment coordinator determines that designated personnel are providing inspection services to selected establishments in the State in a manner that is inconsistent with the Acts and the implementing regulations in this chapter, the Administrator will provide an opportunity for the State to develop and implement a corrective action plan to address inspection deficiencies identified by the selected establishment coordinator. If the State fails to develop a corrective action plan, or the selected establishment coordinator for the State determines that the corrective action plan is inadequate, the Administrator will terminate the agreement for the cooperative interstate shipment program as provided in § 381.187(d) of this part.

**§ 381.518 Quarterly reports.**

(a) The selected establishment coordinator will prepare a report on a quarterly basis that describes the status of each selected establishment under his or her jurisdiction.

(b) The quarterly report required in paragraph (a) of this section will:

(1) Include the selected establishment coordinator's assessment of the performance of the designated personnel in conducting inspection activities at selected establishments and

(2) Identify those selected establishments that the selected establishment coordinator has verified are in compliance with the Act and implementing regulations in this chapter, those that have been deselected under § 381.520 of this subpart, and those that are transitioning to become

official establishments under § 381.521 of this subpart.

(c) The selected establishment coordinator is to submit the quarterly report to the Administrator through the District Manager for the State where the selected establishments identified in the report are located.

**§ 381.519 Enforcement authority.**

(a) To facilitate oversight and enforcement of this subpart, selected establishments operating under a cooperative interstate shipment program must, upon request, give the FSIS selected establishment coordinator or other FSIS officials access to all establishment records required under the Act and the implementing regulations in this chapter. The Administrator may deselect any selected establishment that refuses to comply with this paragraph.

(b) Selected establishment coordinators may initiate any appropriate enforcement action provided for in part 500 of this chapter if they determine that a selected establishment under their jurisdiction is operating in manner that is inconsistent with the Act and the implementing regulations in this chapter. Selected establishments participating in a cooperative interstate shipment program are subject to the notification and appeal procedures set out in part 500 of this chapter.

(c) If inspection at a selected establishment is suspended for any of the reasons specified in § 500.3 or § 500.4 of this chapter, FSIS will:

(1) Provide an opportunity for the establishment to implement corrective actions and remain in the cooperative interstate shipment program, or

(2) Move to deselect the establishment as provided in § 381.520 of this subpart.

(d) The decision to deselect a selected establishment under a suspension will be made on a case-by-case basis. In making this decision, FSIS, in consultation with the State where the selected establishment is located, will consider, among other factors:

(1) The non-compliance that led to the suspension;

(2) The selected establishment's compliance history; and

(3) The corrective actions proposed by the selected establishment.

**§ 381.520 Deselection of ineligible establishments.**

(a) The Administrator will deselect a selected establishment that becomes ineligible to participate in a cooperative interstate shipment program for any reason listed under § 381.513(c) of this subpart.

(b) An establishment that has been deselected must transition to become an official establishment as provided in § 381.521 of this subpart.

**§ 381.521 Transition to official establishment.**

If an establishment is deselected from a cooperative interstate shipment program as provided in § 381.520 of this subpart, FSIS, in coordination with the State where the establishment is located, will develop and implement a plan to transition the establishment to become an official establishment.

**§ 381.522 Transition grants.**

(a) Transition grants are funds that a State participating in a cooperative interstate shipment program under this subpart may apply for to reimburse selected establishments in the State for the cost to train one individual in the seven HACCP principles for meat or poultry processing as required under § 417.7 of this chapter and associated training in the development of sanitation standard operating procedures required under part 416 of this chapter.

(b) A State participating in a cooperative interstate shipment program that receives a transition grant must use grant funds to reimburse the training costs of one employee per each selected establishment in the State. Any other use of such funds is prohibited.

Done at Washington, DC, on September 7, 2009.

**Alfred V. Almanza,**  
*Administrator.*

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