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9 CFR Parts 321, 332, and 381

Cooperative Inspection Programs: Interstate Shipment of Meat and Poultry Product; Final 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:** Final rule.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is amending the Federal meat and poultry products inspection regulations to establish 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). 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.

**DATES:** *Effective Date:* July 1, 2011.

**FOR FURTHER INFORMATION CONTACT:** Daniel Engeljohn, 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**

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.*) (“the Acts”) require that FSIS protect the public by ensuring that meat and poultry products are safe, wholesome, and accurately labeled. The Acts require Federal inspection and provide for Federal regulation of meat and poultry products prepared for distribution in commerce for use as human food.

*Cooperative State inspection programs.* Section 661 of the FMIA and 454 of the PPIA authorize FSIS to cooperate with State agencies in developing and administering their own meat or poultry products inspection programs for the inspection and regulation of products that are produced and sold solely within the State (21 U.S.C. 661 & 454). These cooperative State inspection programs are required to operate in a manner and with authorities “at least equal to,” but not necessarily identical to, the provisions set out in the FMIA and PPIA (21 U.S.C. 661 (a)(1) & 454 (a)(1)). The “at least equal to” standard is a concept that requires that State MPI Programs operate in a manner that is at least as effective as those standards adopted for the Federal inspection program. 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) & 454 (a)(3)).

Section 11015 of Title XI of The Food, Conservation, and Energy Act of 2008 (“the 2008 Farm Bill”), enacted on June 18, 2008, amended the Acts to establish a new cooperative inspection program under which certain State-inspected establishments will be eligible to ship meat and poultry products in interstate commerce (Pub. L. 110–246, 112 Stat. 1651; 21 U.S.C. 683 and 472). The amendments to the Acts provide that the Secretary of Agriculture (FSIS by delegation), “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 in interstate commerce (21 U.S.C. 683 (b) and 472(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 Acts]” (21 U.S.C. 683(a)(2) and 472(a)(2)). Meat and poultry products inspected and passed by the State inspection personnel would bear a “Federal mark, stamp, tag, or label of inspection” and would be permitted to be shipped in interstate commerce (21 U.S.C. 683(b)(1) and 472(b)(1)).

The law provides for the Secretary to “designate an employee of the Federal government” to “provide oversight and enforcement” of the program (21 U.S.C. 683(d)(1) and 472 (d)(1)). If the Federal employee finds that an establishment

selected for the program is in violation of the Acts, he or she is required to “deselect the selected establishment or suspend inspection at the selected establishment” (21 U.S.C. 683(d)(3)(c) and 472(d)(3)(c)). The law requires that any selected establishment that FSIS “determines to be in violation of any requirement of the Act, be transitioned to be a Federal establishment” (21 U.S.C. 683(h) and 472(g)).

The law provides that FSIS is to reimburse a State for costs related to the inspection of establishments in the State selected for the program “in an amount of not less than 60 percent of eligible State costs” (21 U.S.C. 683(c) and 472(c)). The law also states that FSIS “may provide grants to appropriate State agencies to assist the appropriate State agencies in helping establishments covered by this Act to transition to selected establishments” (21 U.S.C. 683(g) and 472(f)). The law is to take effect “on the date on which the Secretary, after providing a period of public comment (including through the conduct of public meetings or hearings), promulgates final regulations to carry out [section 11015]” (21 U.S.C. 683 (j)(1) and 472(i)(1)).

*Proposed rule.* On September 16, 2009, FSIS published proposed regulations to implement the new cooperative interstate shipment program (“*Cooperative Inspection Programs: Interstate Shipment of Meat and Poultry Products*,” 74 FR 47648).

FSIS held two public meetings by teleconference on October 27, 2009, and November 4, 2009, to solicit comments on the proposed regulations (74 FR 54493). The comment period for the proposed rule was scheduled to close on November 16, 2009, but, in response to comments, was extended to December 16, 2009.

In developing this final rule, FSIS considered all comments submitted in response to the September 2009 proposed rule, as well as those provided at the two teleconferences held in October and November 2009. Based on its analysis of the issues, and on information provided by the comments, FSIS made certain changes to the proposed regulations. Those changes are summarized below and are discussed in detail in the Agency’s responses to comments.

For a more detailed discussion of section 11015 of the 2008 Farm Bill and FSIS’s proposed implementing regulations, refer to the September 16, 2009, proposed rule.

## II. Summary of Amendments to the Proposed Rule To Implement the Cooperative Interstate Shipment Program

In this rulemaking, FSIS is finalizing, with some changes, the provisions in the September 2009 proposed rule. Specifically, the Agency is amending the proposal to:

- Revise the standards for determining an establishment's average number of employees for purposes of the cooperative interstate shipment program to exclude employees whose duties do not involve handling the meat or poultry products produced by the establishment (9 CFR 332.3(b)(1) and (2) and 9 CFR 318.513(b)(1) and (2));
- Revise the standards for determining the average number of employees for purposes of the cooperative interstate shipment program to include uncompensated volunteers who are involved in handling the meat or poultry products produced by the establishment (9 CFR 332.3(b)(6) and 381.515(b)(6));
- Allow States that have existing cooperative agreements for a State MPI program to submit a request to enter into an agreement with FSIS for a cooperative interstate shipment program before the States have identified establishments to recommend for the cooperative interstate shipment program (9 CFR 332.4(b)(1) and 381.514(b)(1));
- Identify factors that will be considered to determine the frequency with which the FSIS selected establishment coordinator (SEC) will visit selected establishments under his or her jurisdiction (9 CFR 332.7(a) and 381.517(a));
- Give establishments that were deselected from the cooperative interstate shipment program because they are located in a State whose agreement for the program was terminated the option to either revert back to operating under the cooperative State MPI program or obtain a Federal grant of inspection (9 CFR 332.11(a) and 381.521(a));
- Allow establishments that were deselected from the cooperative interstate shipment and successfully transitioned to become Federal establishments to revert back to the State MPI program after successfully operating as a Federal establishment for a year (9 CFR 332.11(b) and 381.521(b));
- Allow establishments selected to participate in the cooperative interstate shipment program to operate under both the State MPI program for the State where the establishment is located and the new cooperative interstate shipment program. State-inspected establishments

that operate under both programs must maintain an appropriate separation of time or space between operations (9 CFR 332.13 and 381.523);

- Allow selected establishments that are in full compliance with the requirements of the cooperative interstate shipment program to voluntarily end their participation in the program and revert back to the State MPI program (9 CFR 332.14 and 381.514);
- Codify the definition of "eligible State costs" to include 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 (9 CFR 321.3(b) and 381.187(b)).

## III. Comments and Responses

FSIS received approximately 90 separate comment letters in response to the September 2009 proposed regulations and approximately 5000 identical comment letters submitted by a consumer advocacy organization on behalf of private citizens. Comments submitted by consumer advocacy organizations, private citizens, State farm bureaus, trade associations representing meat processors, and a labor union representing food and commercial workers expressed general support for the proposed regulations. Comments submitted by an association of State meat and food inspection directors, an association of State Departments of Agriculture, several State Departments of Agriculture and other State agencies, farm and agriculture advocacy organizations, Congress members providing comments on behalf of the State of Wisconsin, and private citizens expressed support for the concept of a cooperative interstate shipment program but objected to several provisions in FSIS's proposed implementing regulations. Other comments submitted by FSIS inspection personnel, small federally-inspected establishments, and one consumer advocacy organization opposed any program that would permit State-inspected meat and poultry products in interstate commerce.

Following is a discussion of these comments and FSIS's responses.

### A. Development of the proposed rule

*Comment:* Several comments criticized FSIS for not consulting with State officials during the development of the proposed regulations. The comments stated that several States and organizations of State officials had offered to form an advisory committee to assist FSIS in developing the proposed regulations to implement the

cooperative interstate shipment program. As noted by the comments, FSIS determined that such a request was not practical due to the regulatory constraints and the statutory time-line for implementing this program. The comments encouraged FSIS to work closely with State inspection officials to develop final regulations to make the program as workable as possible. One comment said that creating an environment where state regulators and federal regulators work together consistently will provide the stability the program needs to be successful for all involved.

Some comments suggested that FSIS use this rulemaking as an opportunity to encourage more State involvement in addressing the nation's food safety problem. The comments encouraged FSIS to accord considerable weight to comments submitted by States with exemplary food safety inspection histories and State-inspected establishments that likewise have exemplary histories when the Agency finalizes the proposed rule.

*Response:* FSIS appreciates the States' willingness to participate in the development and implementation of the new cooperative interstate shipment program. In developing this final rule, FSIS carefully considered the comments and suggestions submitted by the States and, as a result, the Agency made certain revisions to the proposed regulations. FSIS will work closely with the States as the Agency moves forward to implement the cooperative interstate shipment program established in this final rule.

*Comment:* A few comments stated that the teleconference format for the two public meetings that were held in October and November of 2009 was not an appropriate way to generate comments on the proposed cooperative interstate shipment program. One comment noted that there were few comments presented during the teleconferences, which the commenter believed may be related to the format of the public meeting. One comment said that both teleconferences occurred on the same dates and times when FSIS was offering webinars for small and very small plant operators, which presented a conflict for those interested in participating in both meetings. Another comment complained that, although the commenter had registered for the teleconference and has a confirmation passcode to participate, the commenter was not allowed to speak during the meeting.

*Response:* FSIS chose the teleconference format for the public meetings to provide individuals with

easier access to the meeting, particularly those who may lack the resources or time to attend a meeting in person. FSIS will consider the comments submitted on this issue to determine how it can improve its use of the teleconference format to conduct public meetings in the future.

#### *B. General Support for and General Opposition to the Proposed Rule*

##### 1. Support for the Proposed Regulations

*Comment:* Comments submitted by consumer advocacy organizations, private citizens, State farm bureaus, trade associations representing meat processors, and a labor union representing food and commercial workers expressed general support for FSIS's proposed regulations to implement the cooperative interstate shipment program. Some of these comments said that the language in Section 11015 of the 2008 Farm Bill reflects an agreement reached through negotiations between various national consumer organizations, the National Association of State Departments of Agriculture, the National Farmers Union, the American Federation of Government Employees, and the United Food and Commercial Workers Union. According to these comments, the language in section 11015 was carefully crafted to meet the desire of some State-inspected meat plants to enlarge their area of sales while assuring that all meat and poultry sold across state lines meet federal inspection standards. The comments commended FSIS for writing proposed regulations that closely adhere to both the intent and specific language of the legislation.

One comment noted that the program established in the proposed regulations builds on existing State inspection programs and includes important enhancements that can lead to stronger State inspection programs. The comment approved of the fact that, like the statute, the proposed regulations would not permit "regulatory forum shopping."

*Response:* FSIS agrees that the proposed regulations are consistent with both the intent and language of the enabling legislation. The Agency also agrees that the program established in the proposed regulations will complement the existing State inspection programs.

##### 2. Support Interstate Shipment but not the Program Proposed by FSIS

*Comment:* Comments submitted by an organization of State Agriculture Departments, an organization of State meat inspection program Directors,

several State Departments of Agriculture, State agencies, farm and agriculture advocacy organizations, and private citizens expressed support for the concept of a cooperative interstate shipment program but had concerns about FSIS's proposed regulations to implement the program. Many of these comments stated that, instead of allowing for the interstate shipment of state inspected products, FSIS's proposed regulations essentially set up another Federal inspection system under more stringent and inflexible provisions than the current Federal system. According to the comments, FSIS's proposed program fails to remove unnecessary barriers for small establishments to sell their specialty products across State lines. The comments asserted that the proposed regulations will create a regulatory system that is too burdensome for either establishments or State inspection programs, which likely means that few will take advantage of the program.

To support these assertions, the comments noted that, when FSIS issued the proposed rule, the Agency estimated that approximately 60% (16 of 27) of the States with existing State MPI programs and approximately 200–600 establishments were interested in participating in the new cooperative interstate shipment program. The comments stated that after FSIS issued the proposed rule, an internal poll conducted by an organization of State officials indicates that only 2 of these 27 States, each with only a handful of establishments, now find the cooperative interstate shipment proposed by FSIS to be even potentially viable. According to the comments, without a drastic revision of the proposed regulations and active FSIS participation in cooperation with the State partners, the program is unlikely to succeed.

*Response:* After careful consideration of all comments submitted in response to the 2009 proposed rule, FSIS modified the proposed regulations to provide some added flexibility for establishments selected to participate in the cooperative interstate shipment program. For example, under this final rule, selected establishments that are in full compliance with the program will be permitted to voluntarily end their participation in the program. This final rule will also permit selected establishments to operate under both the cooperative interstate shipment program and the State's MPI program if they maintain an appropriate separation of time or space between operations. The Agency believes that these modifications, which are discussed in

more detail in the Agency's response to comments, will provide additional incentive for some establishments to participate in the program.

##### 3. Oppose any Program That Would Allow Interstate Shipment of State-Inspected Product

*Comment:* Comments submitted by FSIS inspection personnel, small federally-inspected meat and poultry processing establishments, and a consumer advocacy organization objected to any program that would permit state-inspected meat and poultry products to be shipped in interstate commerce. According to many of these comments, meat and poultry products produced in State-inspected establishments do not undergo the same level of inspection as products produced in Federal-inspected facilities, and many State MPI programs are not truly "at least equal to" the Federal inspection program. A few comments referenced a 2006 Office of Inspector General Audit Report of State-inspected meat and poultry programs that the comments said found that some State-inspected facilities had failed to operate in a sanitary manner and that FSIS had not provided consistent oversight of existing State MPI programs.

*Response:* As required by law, the cooperative interstate shipment program established under this final rule will operate under the same standards imposed under the Federal inspection program. Thus, meat and poultry products produced in State-inspected establishments selected for the cooperative interstate shipment program will undergo the same level of inspection as products produced in federally-inspected facilities.

With respect to the comment that many State MPI programs are not truly "equal to" the Federal inspection program, each year the FSIS OPEER Federal State Audit Branch reviews the State cooperative MPI programs and their requirements to verify that each State program "at least equal to" the Federal program. These comprehensive reviews consist of an annual review of the State MPI program's self assessment submission and an on-site review to verify the State's self-assessment submission. The onsite reviews are scheduled at a minimum, once every three years.

Based on the self assessment documents received during FY 2009, FSIS determined that all of the 27 State MPI programs provided adequate documentation to support that they have implemented and can maintain MPI programs "at least equal to" the Federal program. FSIS determined that

all of the 11 State MPI programs reviewed on-site were enforcing requirements "at least equal to" those imposed under the Federal Acts.

In its 2006 audit of the FSIS's cooperative State MPI programs, the OIG provided recommendations to strengthen FSIS's review of these programs. FSIS provided management decisions in response to the 2006 OIG audit recommendations, which were accepted by OIG. The Agency has implemented the 2006 management decisions.

*Comment:* One comment stated that State-inspected establishments should not be allowed to ship products interstate because the States do not have the money or staff to provide the inspection that the Federal government does. Another comment maintained that Federal inspectors undergo more extensive training than State inspection personnel and, therefore, unlike State inspectors, are continuously expanding their knowledge bases.

*Response:* As discussed in greater detail below, to qualify for the cooperative interstate shipment program, States with cooperative State MPI programs will need to demonstrate that they have staffing sufficient to conduct the same inspection activities in establishments operating under the cooperative interstate shipment program that FSIS conducts in official Federal establishments. The States will also need to demonstrate that the designated State personnel have been properly trained in Federal inspection methodology. FSIS will not enter into an agreement for a cooperative interstate shipment program with States that are unable to meet these conditions.

*Comment:* One comment submitted by a consumer advocacy organization said that while the commenter does not support State-inspected meat and poultry for either intrastate or interstate commerce, it understands that Congress amended the FMIA and PPIA to establish the cooperative interstate shipment program, and that FSIS is required to develop regulations to implement the law. The comment urged the Agency to put into place a system whereby establishments that participate in the program are held to the identical Federal standards and practices as those establishments under Federal inspection and that the Agency maintain strict oversight of such a program.

*Response:* The cooperative interstate shipment program established in these final regulations will be a State inspection program under which designated State-personnel enforce Federal food safety standards. As required by law, FSIS will provide

oversight and enforcement of the program.

*Comment:* Several comments submitted by FSIS inspection personnel and small federally-inspected meat and poultry processors maintained that instead of establishing cooperative interstate shipment program, FSIS should require that State-inspected establishments that desire to ship their meat and poultry products in interstate commerce come under Federal inspection.

One comment submitted by a small federally-inspected establishment explained that as a small company, it decided to obtain a Federal grant of inspection as an investment for the future of its business. The comment noted that the establishment did this to allow for interstate sales of its products and that the same option is available today for any company willing to make a similar investment. The comment asserted that to provide for a level playing field, all small companies that want to sell their products across state lines should be required to go through the same process and obtain a Federal grant of inspection.

*Response:* Section 11015 of the 2008 Farm Bill amended the FMIA and PPIA to establish the cooperative interstate shipment program. The amendments require that FSIS issue final regulations to implement the new program. Once the new program becomes effective, small State-inspected establishments that are interested in selling meat or poultry products across State lines will have the option to operate as a selected establishment under the cooperative interstate shipment program or as an official Federal establishment. An establishment that ships products across States lines must comply with all Federal standards regardless of the inspection program that it chooses to operate under.

*Comment:* One comment said that the cooperative interstate shipment program is not necessary because the Talmadge/Aiken program serves the same purpose.

*Response:* The Talmadge-Aiken program and the cooperative interstate shipment program serve different purposes. Under the Talmadge-Aiken program, 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. Establishments that participate in the Talmadge-Aiken program operate under a Federal grant of inspection. Under the cooperative interstate shipment program, FSIS enters into a separate agreement with a State agency to enforce Federal food safety standards at

State-inspected establishments.

Establishments that participate in the cooperative interstate shipment program are not Federal establishments operating under a Federal grant of inspection.

*Comment:* Comments submitted by a few FSIS inspection personnel opposed the proposed cooperative interstate shipment stated because the commenters believe that the program will result in a reduction in the Federal inspection force. The comments stated that under such a program, small federally-inspected establishments will want to drop their Federal grant of inspection and produce products under State-inspection, thereby taking jobs that would otherwise belong to Federal employees and giving them to State employees.

*Response:* Under the law and implementing regulations, establishments that operate under the Federal inspection program are ineligible to participate in the cooperative interstate shipment program. The new program is limited to certain small and very small State-inspected establishments. Thus, the cooperative interstate shipment program will have little effect on Federal inspection personnel.

*Comment:* One comment objected to allowing the interstate shipment of state-inspected products because, according to the comment, FSIS will no longer have control or jurisdiction over some meat and poultry products in interstate commerce. The comment noted that a State's jurisdiction is limited to the State's borders. The comment asked what would happen if product produced by a State-inspected establishment is implicated in a food safety issue resulting in a recall.

*Response:* Under the law, FSIS is responsible for providing oversight and enforcement of the cooperative interstate shipment program. Therefore, if an establishment operating under the cooperative interstate shipment program distributes meat or poultry products that present a food safety hazard or that need to be recalled for other reasons, FSIS will coordinate with the State MPI program to ensure that such product is removed from commerce. FSIS will be responsible for the overall coordination of the recall and for verifying that recalled product that has been shipped interstate has been removed from commerce.

#### *C. Establishment Participation—Conditions for Eligibility and Standards for Determining Average Number of Employees*

The proposed rule prescribed conditions that State-inspected

establishments would be required to meet to become eligible to participate in the cooperative interstate shipment program. Consistent with the law, among these proposed conditions were that an establishment be in compliance with all Federal inspection requirements under the FMIA, PPIA, and their implementing regulations, and that the establishment employ, on average, no more than 25 individuals. The proposed rule also included proposed standards for determining the average number of employees, which, for the most part, reflect applicable methods used by the Small Business Administration (SBA) to calculate the number of employees for a small business concern. FSIS received several comments on the proposed conditions for establishment eligibility and the proposed standards for determining the average number of employees.

#### 1. Compliance With Federal Standards

*Comment:* Some comments agreed that State-inspected establishments should be required to comply with Federal standards to be eligible for the cooperative interstate shipment program. The comments stated that many small and very small establishments have managed to conform to, and operate successfully under, the requirements of the Federal inspection system. Two comments noted that data obtained from FSIS's PBIS in 2007 show that 51 percent (2,878 of 5,603) of all federally-inspected establishments have 10 or fewer employees and 80% have 50 or fewer employees.

The comments also noted that all establishments that prepare or process meat and poultry products have always had the opportunity to ship their products in interstate commerce provided that they apply for and receive a Federal grant of inspection. The comments stated that small and very small establishments now under Federal inspection have invested time and money to comply with all Federal regulations and to operate under Federal standards. The comments asserted that while the new cooperative interstate shipment program is intended to offer establishments operating under their State inspection program an opportunity to broaden their distribution, any establishment that ships meat or poultry products in interstate commerce can and should meet Federal food safety standards.

Other comments stated that requiring that State-inspected establishments comply with Federal food safety standards in order to be eligible for the cooperative interstate shipment program

will establish unfair barriers for small plants to participate in the program. The comments urged FSIS to provide small State-inspected establishments with greater flexibility in achieving food safety standards. One comment from a small State-inspected establishment stated that it cannot afford Federal inspection. The comment noted that establishments operating under the State MPI system are required to adhere to very strict food safety standards but, unlike the Federal system, State inspection personnel are also available to help the small and very small establishments with education and training.

*Response:* The amendments to the Acts in section 11015 of the 2008 Farm Bill require that State-inspected establishments be in compliance with all Federal standards in order to be eligible for the cooperative interstate shipment program. The provisions in the Acts that establish the cooperative interstate shipment program define an "eligible establishment" as an establishment that is in compliance with both "\* \* \* the State inspection program of the State in which the establishment is located" and "[the FMIA or PPIA], including the rules and regulations issued under [the FMIA or PPIA]" (21 U.S.C. 472(a)(3) and 683(a)(3)).

The Senate Conference Committee report on the bill that established the cooperative interstate shipment program also makes clear that establishments selected for the program "\* \* \* must fully follow [the FMIA or PPIA], its regulations, notices, directives and policies just as would be required of a Federal establishment" (S. Rep. No. 220, 110th Cong., 1st Sess. (2007), pp. 211–214). Thus, requiring that State-inspected establishments comply with Federal food safety standards to become eligible to participate in the cooperative interstate shipment program is consistent with both the language and intent of section 11015 of the 2008 Farm Bill.

FSIS's Office of Outreach, Employee Education, and Training (OOEET) will provide technical resources, information, and guidance to small and very-small State establishments that are interested in becoming eligible to participate in the cooperative interstate shipment program.

#### 2. Determining Average Number of Employees

a. *Proposed standard:* 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.

*Comment:* Several comments stated that for purposes of the cooperative interstate shipment program, an establishment's average number of employees should be based only on those directly involved in the preparation or processing of meat and poultry products. The comments noted that many small and very small establishments conduct operations other than the processing of meat or poultry products, such as grocery stores, convenience stores, or other retail outlets. According to the comments, employees that do not perform duties related to the meat or poultry processing operations of the business should not be included when calculating the average number of employees.

One comment suggested that FSIS consider basing the "value" associated with the employee on the workers compensation code that the employer designates. The commenter said that it could give FSIS a simple way of determining which workers are associated with the meat processing part of the business and which employees offer other roles for the company, such as administrative workers or retail clerks.

Other comments said that all establishment personnel, including those not involved in the actual production of meat and poultry products, should be counted when calculating the average number of employees. One comment noted that the law specifically states that supervisory and nonsupervisory employees are to be counted when calculating the average number of employees. The comment maintained that this indicates that if Congress had intended to exclude certain employees from the calculation, it would have expressly stated so in the law. The comment urged FSIS to require that temporary and part-time employees, regardless of their position in the establishment, be counted when determining the average number of employees.

*Response:* Although the law limits participation in the cooperative interstate shipment program to State-inspected establishments that employ, on average, 25 or fewer employees, it does not distinguish between employees involved in an establishment's meat or poultry processing operations from those that are not. Counting all individuals employed by the establishment would ensure that participation in the cooperative interstate shipment program is limited to very small and certain small establishments. Counting only

employees directly involved in the preparation or processing of meat and poultry products would create a more flexible standard that would expand the number of potentially eligible establishments to include those that have a small number of employees that work in meat or poultry processing but a larger number of employees that work in other areas of their business.

The 2008 amendments to the Acts give FSIS the authority to define “average number of employees” for purposes of the cooperative interstate shipment program, but they also make clear that the program is intended for State-inspected establishments that employ a limited number of individuals. Therefore, FSIS is adopting a standard for calculating the average number of employees that provides some flexibility for establishments that conduct operations other than meat or poultry processing, but that also clearly distinguishes those employees that are to be counted for purposes of the interstate shipment program from those that are not.

Therefore, instead of counting all individuals employed by the establishment as proposed, under this final rule, an establishment’s average number of employees will be calculated by counting all individuals employed by the establishment, excluding the employees that do not come into contact with the meat or poultry products produced by the establishment. For example, if the owner of a gas station produces beef jerky and sells it at the gas station, the employees that are involved in producing the jerky, as well as those that work as cashiers and sell the product, will be counted. The mechanics that work on the cars, however, will not be. Employees that perform solely administrative functions and that do not handle meat or poultry products will also not be counted.

When an establishment conducts multiple operations, it is sometimes difficult to distinguish employees associated with the meat or poultry operations from those that are not. For example, an individual employed as a cashier at an establishment’s deli operations may also slice and package meat or poultry products produced by the establishment. The standard adopted in this final rule clearly distinguishes employees whose duties are associated with the meat or poultry products produced by an establishment from those that are not. It also ensures that the cooperative interstate shipment program will remain limited to certain small and very small establishments, as intended.

*b. Proposed standard: Part-time and temporary employees are to be counted the same as full-time employees.*

*Comment:* Several comments, most submitted by consumer advocacy organizations and one submitted by a food and commercial workers union, agreed with the proposed standard to count part-time and temporary workers as full-time workers for purposes of qualifying for the cooperative interstate shipment program. The comments noted that most very small establishments have few full-time employees, and many do not operate every day. The comments maintained that counting part-time and temporary employees the same as full time employees is an effective means to assure the cooperative interstate shipment program serves the entities it was intended to serve. According to the comment, failing to count part-time and temporary employees in the average number of employees would permit substantially larger entities to participate in a program that was designed to serve very small local establishments.

Some of these comments noted that during negotiations with the States, consumer advocacy groups reluctantly agreed to the States’ request for a program with a 25 employee limit. According to the comment, none of the groups involved in the negotiations ever agreed to anything larger than 25 employees. The comments said that the primary reason that many consumer advocacy organizations had opposed the House interstate shipment bill was because the bill contained a 50 employee limit, which, according to the comment, would have expanded the number of establishments in the new cooperative program far beyond what was intended. One comment stated that, although the program’s 25 employee limit is reasonable, the commenter would have preferred a limit of 10 employees, which is similar to the current FSIS definition for very small establishments.

Several other comments, most submitted by State Departments of Agriculture and other State agencies, disagreed with the proposed standard to count part-time and temporary workers as full time employees. The comments stated that such a standard seems excessive and does not provide an accurate depiction of an establishment’s actual number of employees.

The comments noted that many small establishments in small towns hire part-time employees who work as little as a few hours a week. According to the comments, to count such employees as full-time would contradict and undercut the rural development intentions of the

enabling legislation. One comment stated that in some rural areas, especially those with small and very small establishments, meat processing has a seasonal component that provides part-time seasonal work for rural residents. The comments noted that during each part of the day, an establishment may have only 25 employees on site, even if the total number of part-time and fulltime employees employed overall during the day exceeds 25.

The comments suggested that part-time and temporary workers be counted on the basis of “full-time equivalents” or “FTEs,” *i.e.*, based on the ratio of their work-hours to those of a full-time year-round employee. The comments said that part-time and temporary employees should be grouped together and counted based on the number of hours they work each week during the year, with 40 hours per week being considered an FTE. Several comments suggested formulas for calculating the number of employees based on FTEs.

*Response:* After considering the comments, FSIS has decided to adopt the proposed standard to count temporary and part time employees the same as full-time employees. For purposes of its regulatory programs, FSIS defines small and very small establishments based on SBA criteria. A standard that counts part-time and temporary workers the same as full-time workers reflects the SBA methods for calculating the average number of employees for a small business concern and is thus consistent with FSIS’s overall approach for defining small and very small establishments.<sup>1</sup>

As noted by the comments, several very small establishments have few full-time employees, and many do not operate every day. A standard that is based on the SBA criteria that counts part-time and temporary employees the same as full time employees allows these establishments to hire seasonal workers while ensuring that only very small and certain small establishments are eligible to participate in the program.

*Comment:* Several comments stated that the standards for determining the average number of employees need to allow for more flexibility in counting temporary seasonal workers. The comments noted that small and very small establishments often have fluctuation in their employees during certain parts of the year, such as during

<sup>1</sup> See 13 CFR 121.105 and 121.106 for SBA methods to calculate the number of employees of a business concern where the size standard in number of employees.

holiday and hunting seasons, and that the term “seasonal” will have different meanings in different areas of the country. Some comments noted some establishments hire extra employees to help with seasonal activities that are not related to the processing of amenable species, such as processing game meat or for busy times in their retail shops around holidays.

The comments suggested that seasonal employees be counted based on FTE. As an example, the comments explained that a seasonal employee who works full-time for 3 months would be a 25% FTE and should be counted as one quarter of an employee.

One comment asserted that seasonal employees should not be counted at all when calculating the average number of employees. The comment suggested that the final rule define a seasonal employee as an employee that works for the establishment ninety or fewer days in a calendar year.

*Response:* When Congress amended the FMIA and PPIA to establish the cooperative interstate shipment program, it intended for FSIS to interpret the term average “...to provide some flexibility to these selected plants 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 in employees does not undermine food safety standards” (S. Rep. No. 220, 110th Cong., 1st Sess., pp. 211–214 (2007)).

As discussed below, under the proposed rule, selected establishments may temporarily employ more than 25 employees during busy seasons, as long as the average number of employees continues to be 25 and the number of employees does not exceed 35. Thus, a standard that counts temporary seasonal employees the same as full-time employees will allow selected establishments to hire seasonal employees while ensuring that the number of employees remains manageable by the establishment, as Congress intended.

FSIS disagrees with the comment that stated that seasonal employees should not be counted at all. Such an approach would be inconsistent with the language and intent of the statute.

*c. Proposed standard: The total number of employees cannot exceed 35 at any given time, regardless of the average number of employees.*

*Comment:* Some comments stated that the proposed standard that provides that the total number of employees can never exceed 35 individuals at any given time, regardless of the average number of employees, is a reasonable upper limit

for selected establishments to remain eligible to participate in the program. One comment stated that such a limit is reasonable if FSIS does not count part-time and temporary employees the same as full time.

Other comments asserted that FSIS should not limit the number of employees working at a selected establishment at any given time if the establishment maintains an average of 25 employees or fewer. The comments stated that while section 11015 of the 2008 Farm Bill requires that the average number of employees not exceed 25, the law does not prohibit a selected establishment from ever, over the course of a year, having more than 35 employees.

The comments stated that in many small establishments there may be “spikes” in employee numbers during busy periods, but the overall average number of employees is under 25. The comments asserted that, as written, the proposed rule excludes such establishments from participating in the interstate shipment program. According to the comments, section 11015 was not intended to exclude these establishments. The comments suggested that FSIS revise the proposed rule to ensure that these establishments remain eligible for the program.

One comment disagreed with the proposed 35 employees limit because, according to the comment, allowing selected establishment to have 35 employees during seasonal shifts represents, at minimum, a 40% increase in establishment personnel. The comment argued that the higher number of employees represents a huge increase in production that could overwhelm a very small establishment’s production systems, which could result in contaminated food entering commerce. The comment noted that if an establishment routinely employs 5 people and then increases this number to 10 or 20 during a certain timeframe, it will have a 100% or 400% increase in employees. The comment maintained that this level of increase is not manageable and is not what Congress intended.

The comment suggested that instead of limiting the total number of employees to 35 at any given time, FSIS should cap at 20% the increase in the number of employees that an establishment may use during a seasonal shift. The comment acknowledged that the commenter does not have data to support this number, but stated that it stands to reason that a sudden increase in production could significantly affect the dynamics within an establishment and overwhelm the

system. According to the comment, small and very small establishments have HACCP plans for a production process at a certain level that would not necessarily support a significantly higher level of production. The comment pointed out that FSIS did not provide any data to support the proposed 35 employee cap.

One comment stated that FSIS should not allow more than 25 employees in selected establishments at any given time. The comment noted that section 11015 requires that establishments that consistently employ more than 25 employees but fewer than 35 employees transition to Federal establishments within three years of the enactment date. The comment stated that this provision indicates that Congress recognized that establishments that ship product in interstate commerce and that have more than 25 employees should be under Federal inspection.

*Response:* While the 2008 amendments to the Acts do not specifically prohibit selected establishments from ever having more than 35 employees, the Senate report described above indicates that Congress intended that there be some limits on the number of employees working at a selected establishment at any given time.

As explained in the preamble to the proposed rule, FSIS proposed that the number of employees working in a selected establishment never exceed 35 at any given time because the law allows FSIS to select for the cooperative interstate shipment program establishments that employed more than 25 but fewer than 35 employees as of June 18, 2008, the date the law was enacted (21 U.S.C. 683(b)(3)(B) and 472(b)(3)(B)). To remain in the program, these establishments must employ fewer than 25 employees on average 3 years after the effective date of this final rule. Thus, while Congress did not intend to “\* \* \* routinely allow selected establishments to employ above 25 or more employees,” the fact that the law provides for some selected establishments to initially employ up to 35 individuals demonstrates that a temporary increase in the number of employees of up to 35 individuals, as long as the average number of employees remains 25 or fewer, is consistent with the language and intent of the Acts.

As noted above, when Congress established the cooperative interstate shipment program, it intended to provide some flexibility to establishments that require seasonal employees to meet consumer demands for certain parts of the year. The 20%



cap on the increase in the number of employees suggested by one of the comments would greatly restrict the number of temporary workers that a selected establishment would be allowed to hire during busy seasons. For example, an establishment that regularly employs five employees on average would be permitted to hire only one temporary employee during its busy seasons. Many small and very small establishments operate on an intermittent or seasonal basis and are accustomed to adjusting their operations to temporarily increase production without undermining food safety standards. FSIS has concluded that restricting the increase in employees to 20% is unlikely to provide the flexibility that many very small selected establishments will need to meet seasonal demands for their products.

*d. Proposed standards: Volunteers who receive no compensation are not considered employees.*

*Comment:* One comment disagreed with the proposed standard that provides that volunteers are not considered employees. The comment stated as a food safety measure, uncompensated volunteers who are engaged in meat or poultry product processing should be considered employees for the purpose of the cooperative interstate shipment program.

*Response:* FSIS agrees with this comment and has revised the standards for counting employees to include as employees, volunteers that perform duties that involve handling the meat or poultry products produced by the establishment.

*D. State Participation: "The Same as" Standard for Inspection Services Provided to Selected Establishments*

The proposed regulations provide that States interested in establishing an agreement for a cooperative interstate shipment program are required to submit a request for such an agreement to FSIS through the FSIS district office that covers the State. The proposed rule also provided that, in their requests, States are required to include documentation to demonstrate that they are 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. The preamble to the proposed rule explained that to meet this requirement, the statute requires that States demonstrate that the inspection service that they provide to selected establishments in the State will be "the same as," rather than "at least

equal to" those provided under the Federal inspection program. FSIS received a significant number of comments on the proposed "same as" standard.

*1. Support for "the same as" Standard*

Comments submitted by consumer advocacy organizations, meat processor trade associations whose members mainly operate under the Federal inspection system, a union representing food and commercial workers, two pork producer trade associations, and some private citizens expressed support for the proposed "same as" standard.

*Comment:* The comments that supported the proposed "same as" standard agreed that the language and intent of the enabling statute require that the cooperative interstate shipment program operate under standards that are the "same as" the Federal inspection system and not the "at least equal to" standard that applies to State MPI programs. The comments believed that all meat and poultry products shipped in interstate commerce should be required to comply with uniform Federal food safety standards rather than multiple State standards. The comments stated that it is especially important for State-inspected establishments that participate in the new program to be in compliance with all Federal standards because the meat and poultry products produced by these establishments will bear a Federal mark of inspection.

One comment stated that requiring that selected establishments that voluntarily request the opportunity to participate in a cooperative interstate shipment program operate in a manner that is the "same as" federally-inspected establishments is not only consistent with the provisions and intent of the law, but also ensures that the food safety standards established in the FMIA, PPIA, and their implementing regulations are applied uniformly to all meat and poultry products that are distributed in interstate commerce. The comment encouraged FSIS to retain the proposed "same as" standard to first and foremost ensure the safety of meat and poultry products distributed in interstate commerce, but also to ensure equity in the marketplace. The comment added that this fundamental proposition, that the playing field be level for all companies engaging in interstate commerce, was a critical element in securing passage of the statutory provisions that authorized the cooperative interstate shipment program. The comment asserted that the program must not provide an unfair advantage to small companies that will

not, or cannot, make the commitments necessary to comply with Federal food safety requirements.

Two comments stated that requiring that State-inspected products produced under the cooperative interstate shipment program comply with all Federal requirements is essential for maintaining domestic and international markets for U.S. meat and poultry products. Other comments said that consumers expect that products carrying the Federal mark of inspection comply with Federal standards for meat and poultry inspection. The comments stated that establishments that are not held to all aspects of the Federal requirements should not be entitled to apply the Federal mark of inspection on their products.

One comment that supported the "same as" standard noted that although establishments operating under a State MPI inspection program receive inspection services that are "at least equal to" the Federal inspection program, the methodology employed by FSIS is a critical part of the effectiveness of the Federal food safety system. The comment asserted that, as such, it is essential for States that participate in the cooperative interstate shipment program to follow Federal inspection methodology when providing inspection services to selected establishments.

*Response:* FSIS agrees that the "same as" standard is consistent with the language and intent of the statutes. The issues raised by the comments demonstrate why it is important for the cooperative interstate shipment program to operate under standards that are "the same as" those imposed under the Federal meat and poultry products inspection programs.

*2. Opposed to "same as" standard*

Several comments submitted by State Departments of Agriculture and other State agencies, as well as organizations representing these entities, objected to the proposed "same as" standard. Some farm and rural community advocacy organizations, cattle producer organizations, a trade association representing small meat processors, and an animal welfare advocacy organization also opposed the proposed standard.

*Comment:* Several comments that objected to the proposed "same as" standard claimed that such a standard is not authorized by law. These comments asserted that the Acts, as amended by the 2008 Farm Bill, do not contain any language that would require that the inspection services that States provide to selected establishments be "the same

as” or “identical to” the inspection services provided under the Federal program. The comments maintained that such an interpretation is an extrapolation of the language that does not exist in the statute.

The comments noted that under the 2008 Farm Bill amendments, the term “eligible establishment” refers to an establishment that is “in compliance with” the Acts. The comments also noted that these amendments authorize the SEC to “ensure that selected establishments are operating in a manner that is consistent with \* \* \* the Acts (21 U.S.C. 472(d)(3)(A), 683(d)(3)(A)). The comments argued that these provisions indicate that if Congress had intended to require that the State program be “the same as” or “identical to” to the Federal program, it would have specifically said so in the statute.

The comments also noted that the 2008 Farm Bill did not amend the provisions in the FMIA and PPIA that provide for cooperative State MPI programs that are “at least equal” to the Federal program. According to the comments, the fact that Congress did not amend these provisions demonstrates that State programs that are “at least equal to” the Federal program are in compliance with the Acts.

*Response:* The language in the FMIA and PPIA, as amended by the 2008 Farm Bill, is clear: Congress provided that the cooperative interstate shipment program would operate under standards that are “the same as” those imposed under the Federal program.

The 2008 amendments to the FMIA and PPIA provide that to be eligible for the cooperative interstate shipment, State-inspected establishments must be in compliance with both the State’s MPI program and “\* \* \* the requirements of this chapter, including the rules and regulations issued under this chapter” (21 U.S.C. 472(a)(3) and 683(a)(3)). As used in the statutes, the term “this chapter” refers to the FMIA at 21 U.S.C. Chapter 12, and the PPIA at 21 U.S.C. Chapter 10. The 2008 amendments also require that the State personnel designated to provide inspection services under the program undergo “\* \* \* all necessary training and certification to assist \* \* \* in the administration and enforcement of this chapter, including the rules and regulations issued under this chapter” (21 U.S.C. 472(a)(2) and 683(a)(2)). The 2008 amendments allow a meat or poultry product inspected by designated State personnel to bear a Federal mark of inspection and be shipped in interstate commerce if the product

“\* \* \* qualifies for the mark \* \* \* under the requirements of this chapter” (21 U.S.C. 472(b)(1)(A) and 683(b)(1)(A)).

The Senate Conference Committee report on the bill that established the cooperative interstate shipment program provides that “\* \* \* establishments selected for the [cooperative interstate shipment] program \* \* \* must fully follow [the FMIA or PPIA], its regulations, notices, directives and policies just as would be required of a Federal establishment” (S. Rep. No. 220, 110th Cong., 1st Sess. (2007), pp. 211–214). The report also provides that “\* \* \* [t]he inspection personnel of the State that will inspect the selected establishment must have undergone all the necessary training to carry out the requirement of [the Acts], [their] regulations, notices directives and policies, just as required of a Federal inspector.”

Thus, both the statute and the Committee report make clear that Congress intended for the cooperative interstate shipment program to operate under standards that are “the same as” those imposed under the Federal inspection program.

FSIS agrees with the comments that stated that the 2008 Farm Bill did not amend the provisions in the FMIA and PPIA that provide for cooperative State MPI programs that are “at least equal” to the Federal program. However, FSIS disagrees that this means that State programs that are “at least equal to” the Federal program are in compliance with all requirements of the Acts for purposes of the cooperative interstate shipment program. Under the FMIA and PPIA, establishments operating under an “at least equal to” State MPI program are permitted to produce meat or poultry products solely for distribution within the State where the establishment is located (21 U.S.C. 454(a)(1) and 661(a)(1)). Thus, State programs that are “at least equal to” the Federal program are in compliance with the Acts only if the establishments operating under these programs prepare and ship products solely for use within the State where they are located.

*Comment:* One comment asked whether the proposed rule requires that a State’s entire MPI program must be “identical to” the Federal program for the State to qualify for the cooperative interstate shipment program.

*Response:* No, a State’s entire MPI program does not need to be identical to the Federal program for the State to qualify for the cooperative interstate shipment program. To qualify for the program, a State must demonstrate that the inspection services that it will

provide to selected establishments in the State will be “the same as” those provided under the Federal inspection program. States that participate in the cooperative interstate shipment program may continue to operate an “at least equal to” State MPI program for establishments that produce meat and poultry products solely for distribution within the State.

*Comment:* Several comments stated that the interstate shipment program’s legislative history demonstrates that Congress intended for the program to operate under the “at least equal” standard required for the existing cooperative State MPI programs. According to the comments, the conference reports for the House and Senate versions of interstate shipment legislation indicate that Congress adopted the Senate version of the bill because the House version would have required that States implement meat and poultry inspection programs “identical to” the Federal inspection system. The comments maintained that the legislative intent was to provide current State facilities with a viable route to ship State product interstate. The comments said that the requirement for State plants to be “identical to” or “same as” a federal plant radically deviates from this.

*Response:* The comments are correct in that Congress did adopt the Senate version of the legislation that established the cooperative interstate shipment program. However, FSIS disagrees that the Senate version was adopted to permit State-inspected establishments operating under an “at least equal to” standard to ship meat and poultry products in interstate commerce.

Section 11103 of the House version of the 2008 Farm Bill would have amended the FMIA and PPIA to replace the existing “at least equal to” cooperative State MPI program with a new program that would have authorized FSIS to approve, and enter into cooperative agreement with, only those State MPI programs that adopt standards identical to those imposed under the Federal program (H. Rep. 110–256, 110th Cong., 1st Session, pp. 184–191). Under the House version, all State-inspected establishments would have been required to comply with Federal standards, the State mark of inspection would have been deemed an official mark, and all State-inspected establishments would have been allowed to ship meat or poultry products in interstate commerce.

The Senate bill, which was the version adopted in the 2008 Farm Bill, supplements, but does not replace, the

existing State MPI programs. The Senate version provides an option under which State-inspected establishments that have, on average, 25 or fewer employees, will be permitted to ship their meat or poultry products in interstate commerce. Under the Senate version, State-inspected establishments are required to comply with all Federal standards to be eligible to participate in the cooperative interstate shipment program, and designated State personnel must be trained to enforce Federal food safety standards. Under the Senate version, State-inspected establishments that choose not to participate in the cooperative interstate shipment program may continue to operate under the “at least equal to” State MPI program and ship their products within the States where they are located.

*Comment:* Some comments claimed that in the past, FSIS itself concluded that it was unrealistic for States to maintain MPI programs that are “the same as” or “identical to” FSIS’s program. The comments noted that in 2003, the Agency provided an option for the States to claim that their meat and poultry inspection programs were “same as” or “identical to” FSIS inspection as part of the Agency’s annual review in which it verifies that State MPI programs are “equal to” the Federal program. The comments said that in 2006, FSIS reached the conclusion that it was logistically impossible for State programs to maintain a true “same as” or “identical to” status, so the Agency removed this option from the State Self Assessment Manual forms. The comments asserted that if only a few years ago FSIS acknowledged that it is impossible for State MPI programs to be the “same as” Federal programs, proposing such a standard now will effectively prevent States from qualifying for a cooperative interstate shipment program.

*Response:* FSIS has stated that “at least equal to” does not require that States operate their cooperative MPI programs in a manner that is “the same as” or “identical to” the FSIS program or does not prohibit States from establishing safeguards that the States believe to be more effective than those employed by FSIS. The law does not require that the cooperative State MPI programs operate under standards “identical to” the Federal program.

As noted above, the cooperative interstate shipment program will supplement the existing State MPI programs, not replace them. Thus, while States that participate in the cooperative interstate shipment program will need to provide the same inspection services

to selected establishments that FSIS provides to federally-inspected establishments, States may also continue to operate their cooperative State MPI programs in a manner that is “at least equal to” the Federal program.

*Comment:* Several comments noted that a foreign country must demonstrate that its inspection system is “equivalent” to the U.S. inspection system before FSIS will permit establishments located in the foreign country to import meat and poultry products into the United States. These comments asserted that requiring that States operate their cooperative interstate shipment programs under standards that are the “same as” those required under the Federal program subjects the States to a stricter and less flexible standard than the standard applied to foreign countries. One comment maintained that while the commenter does not support the equivalent standard for foreign facilities, there is no justification for discriminating against domestic establishments under the jurisdiction of State inspection programs by requiring that they meet more rigid standards than those imposed on foreign establishments.

*Response:* The equivalence standard applied to imported meat and poultry products and the “same as” standard applied to meat and poultry products produced under the cooperative interstate shipment program reflect the relevant provision in the FMIA and PPIA. The FMIA and PPIA require that FSIS treat as equivalent to a U.S. requirement alternative measures proposed by an exporting country if the country provides scientific evidence or other information, in accordance with risk assessment methodologies agreed to by FSIS and the exporting country, to demonstrate that the alternative measure achieves the level of protection that is appropriate for the United States (21 U.S.C. 620(e)(1)(B), 466(d)(2)(A)). These provisions reflect the U.S. Government’s obligation under the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) to accept the sanitary measures of an exporting Member country as equivalent if the exporting member demonstrates that its sanitary measures attain the same level of protection (Article 4.1, “Agreement on the Application of Sanitary and Phytosanitary Measures). FSIS evaluates foreign food regulatory systems for equivalence through document reviews, on-site audits, and port-of-entry reinspection of products at the time of

importation (9 CFR part 327 and 381 subpart T).

*Comment:* Several comments asserted that it is unnecessary to require that the inspection services that States provide to selected establishments be the “same as” inspection services provided under the Federal program because most States have incorporated the Federal requirements into their State MPI programs. The comments stated that, according to FSIS’s 2008 report on its review of the State MPI programs, these State programs have demonstrated that they can implement the Federal laws and regulations in a manner that is “at least equal to,” and thus, “in compliance with” the Federal standards without operating under a program that is “the same as” the Federal inspection program because of the smaller staff size and other administrative aspects of the State programs.

*Response:* As noted throughout this document, the 2008 amendments to the Acts require that the inspection services that States provide to selected establishments be “the same as” those provided under the Federal inspection program. The Senate report also makes clear that State inspection personnel are “\* \* \* to carry out the Federal requirements of the [the Acts], [their] regulations, notices directives and policies, just as required of a Federal inspector” (S. Rep. No. 110–220, 110th Cong., 1st Sess. (2007), pp 211–214). Thus, FSIS disagrees that State programs that have implemented the Federal laws and regulations in a manner that is “at least equal to” the Federal inspection program are “in compliance with” the Federal standard for purposes of the cooperative interstate shipment program. The law clearly requires that the inspection services that designated State personnel provide to selected establishments in States participating in the cooperative interstate shipment program be “the same as” those provided under the Federal program.

*Comment:* Several comments claimed that under the “at least equal to” standard, some States have implemented requirements for food safety and consumer protection that are stricter than those provided for under the Federal Acts. According to these comments, many States have processes for the review and evaluation of product labels that do more than FSIS’s generic label process to ensure that the labels of meat and poultry products properly inform consumers about the product, its weight and its ingredients. The comments also noted that while FSIS currently does not have the authority to levy civil penalties for violations of the

Federal Acts, many States have the authority to impose civil penalties against violators of State meat and poultry inspection laws. Some comments stated that while FSIS allows the slaughter and sale of up to 20,000 farm raised chickens annually to restaurants and retail markets without benefit of inspection, many State programs do not permit this activity. The comment claimed that requiring States to operate their MPI programs in a manner that is "identical to" the Federal program could force the States to lower their standards.

One comment stated that some states impose humane handling and slaughter requirements that go above and beyond those required by Federal law. Another comment said that some States have stricter cold storage requirements than FSIS.

*Response:* As discussed above, the cooperative interstate shipment program established in this final rule supplements rather than replaces the existing State MPI programs. States that participate in the cooperative interstate shipment program may continue to operate their "at least equal to" State MPI programs for meat and poultry products produced and sold solely within the State. Thus, this final rule does not affect requirements for labeling, civil fines, poultry inspection, humane handling, or cold storage that States have adopted as part of their cooperative State MPI programs.

*Comment:* In the preamble to the proposed rule, FSIS explained that to qualify for a cooperative interstate shipment program, States will need to demonstrate that they have the authority under State law to provide the necessary inspection services to selected establishments in the State (74 FR 47652). Some comments noted that if the final regulations require that inspection services provided to selected establishments be the "the same as" those provided under the Federal inspection system, many States will not be able to immediately change their laws to make them identical to the Federal inspection laws.

One comment noted that the ability of States interested in the new program to change their rules and adopt FSIS regulations will depend on the process the State program must follow in order to make those changes. Other comments noted that each State has its own legislative process and some State legislatures do not meet every year. One comment noted that, although the State programs are "equal to" the Federal inspection system, the terminology and precise phrasing in the laws and

regulations differ, and that State administrative systems vary.

*Response:* As discussed above, the cooperative interstate shipment program supplements the existing State MPI programs. Therefore, States are not required to amend all State inspection laws to make them identical to the Federal requirements. States interested in participating in the cooperative interstate shipment program will need to demonstrate that they have the necessary legal authority to enforce Federal food safety standards in selected establishments in the State.

As noted by the comments, State laws and regulations differ, and each State has its own legislative process. Some States may already have the necessary legal authority to participate in the cooperative interstate shipment program, while others may need to make legislative changes to provide for any additional authority that they may need.

*Comment:* Some comments asserted that the main focus of any program that provides for the interstate shipment of State-inspected products should be on the safety of the products produced in the selected establishments, not on administrative procedures for the inspection program. According to the comments, if States are required to operate their cooperative interstate shipment programs in a manner that is the "same as" the Federal program, the focus of these programs will be on the administrative procedures of the State instead of food safety. The comments stated that regulatory requirements can be met through different means and that it is not practical or effective for a State program to operate under the exact same procedures prescribed in the Federal system.

The comments suggested that an effective alternative would be to allow States to work within the existing "equal to" framework to develop food safety activities focused on problems specific to their establishments. The comments stated that the "at least equal to" standard is well accepted and has been effective in ensuring that State MPI inspection programs are comparable to the Federal program.

*Response:* As explained above, the law does not provide for the cooperative interstate shipment program to operate within the existing "at least equal to" framework. Under the 2008 amendments to the Acts, meat or poultry produced in selected establishments are permitted to bear a Federal mark of inspection and be shipped in interstate commerce only if designated State personnel find that such product qualify for a Federal mark

(21 U.S.C. 683(b)(1)(a) and 472(b)(1)(a)). While products that are inspected and passed under a State's "at least equal" MPI program qualify for a State mark, these products are not eligible for a Federal mark.

*Comment:* Some comments complained that FSIS's proposed regulations would require that States maintain two separate inspection systems, one that is "identical to" the Federal program and one that is "equal to" the Federal program. The comments said that adding an entirely new State inspection system to comply with the "same as" standard will add an extra layer of cost for the States. According to the comments, many States would need to hire additional laboratory staff to perform different methodology and complete documentation the same as FSIS. The comments also said that States would need funds to train inspectors and purchase Federal computers, and that overall State administrative costs would increase because office staff, accountants, supervisors, and managers would need to manage two systems. One comment urged FSIS to fully consider the impact that the "same as" standard will have on the administrative aspects of the State inspection programs.

*Response:* In the Preliminary Regulatory Impact Analysis (PRIA) to the proposed interstate shipment rule, FSIS acknowledged that States that choose to participate in the cooperative interstate shipment program may need to make certain modifications to their inspection program to provide inspection services to selected establishments in the State (74 FR 47657). The Agency also acknowledged that the inspection costs under the new program may differ from the costs of the existing State MPI program. As required by law, if Congress provides the necessary funding for the cooperative interstate shipment program, FSIS will reimburse States for costs related to the inspection of selected establishments in the State in an amount not less than 60 percent of eligible State cost. FSIS has updated its analysis of the State costs in the Final Regulatory Impact Analysis (FRIA) for this final rule.

As noted by the comments, the cooperative interstate shipment program established in the proposed rule may require that States maintain two separate inspection programs, one that is "the same as" the Federal program and one that is "equal to" the Federal program. States that enter into cooperative agreements under the Talmadge-Aiken program to provide Federal inspection services to Federal establishments on behalf of FSIS are

also required to maintain two separate inspection systems—one under the cooperative State “at least equal to” MPI program and the other under the cooperative Talmadge-Aiken program. Thus, FSIS does not believe that the cost to administer two separate cooperative inspection programs will prevent States that are interested in participating in the cooperative interstate shipment program from doing so.

### 3. “Same as” Computer Systems and Forms

In the preamble to the proposed rule, FSIS explained that to qualify for a cooperative interstate shipment program, the Agency expects States to demonstrate that they can provide the necessary equipment for State personnel to provide the same inspection services to selected establishment that FSIS provides to official establishments, including computers and supplies for collecting regulatory product samples (74 FR 47652).

*Comment:* A number of comments said that this statement could be interpreted to mean that State programs must obtain and use the same computers and computer programs that are used by FSIS personnel. The comments requested that FSIS clarify its expectations with regard to the type of computers and information systems the States will need to have in place to qualify for a cooperative interstate shipment program.

Some of these comments noted that many States currently use State-issued laptops computers and have developed systems that have been determined “equal to” FSIS to track and report inspection activities and other required data. One comment noted that some States have developed their own data-driven systems that mimic the Federal System, but that also allow State program personnel access to State licensing information and to view and conduct other inspection activities in facilities that are not related to meat and poultry. According to the comment, States with their own information systems are able to tailor FSIS inspection activities, which are geared towards use in larger establishments, to be effective in very small establishments.

*Response:* To qualify for the cooperative interstate shipment program, States will need to have computer programs and information systems that are “the same as” those used by FSIS to administer the Federal inspection program. Assuming that Congress provides the necessary funding, FSIS will allow States that do not have the necessary information

systems to purchase from the Agency federally-procured computers and the necessary computer programs. FSIS will reimburse the States for 60% of their eligible costs to obtain the necessary computers and software. FSIS does not intend to reimburse more than 60% of the States’ costs unless Congress directs it, and provides the money for it to do so.

*Comment:* Some comments stated that if FSIS expects States to have information systems that are identical to those used under the Federal system, some States will need to maintain two computer systems to participate in the program because the Federal computer system does not allow any State program loads, and the Federal systems cannot be operated on a computer other than a federally-sourced computer. One comment noted that federally-procured computers generally cost more than State-procured ones, and the Federal computers would only be used on a limited basis by State personnel that work in selected establishments.

*Response:* As noted above, to provide the necessary inspection services under the cooperative interstate shipment program, States that participate in the program will need to use computer programs that are “the same as” those used by FSIS to administer the Federal inspection program. Thus, if the Federal computer programs cannot be operated on State-sourced computers, the State may need to purchase new computers from FSIS. As a result, some States will need to maintain two computer systems to participate in the cooperative interstate shipment program.

*Comment:* One comment asked if states participating in the cooperative interstate shipment program will have access to all of the Federal data programs, like eADRS, Assurance Net and FSIS intranet. Another comment stated that FSIS did not explain how requiring that States have identical computer systems in order to participate in the cooperative interstate shipment program will further food safety and compliance with the Acts.

*Response:* States that participate in the cooperative interstate shipment program will have access to the computer programs that are necessary to provide inspection services that are “the same as” those provided under the Federal program. The computer systems used by States to administer the cooperative interstate shipment program need to be “the same as” those used under the Federal program to ensure that selected establishments are meeting all food safety standards that are “the same as” rather than “at least equal to”

standards imposed under the Federal program.

*Comment:* Some comments asked whether the forms used by States operating under a cooperative interstate shipment need to be identical to the Federal forms that FSIS uses under its inspection program. According to one comment, State inspection programs frequently do not have access to Federal forms and, therefore, most have developed their own forms. The comment stated that, if States are required to maintain forms that are identical to the Federal forms, many States will need to manage two different sets of documentation to participate in the cooperative interstate shipment program.

*Response:* To provide the necessary inspection services to selected establishments participating in the cooperative interstate shipment program, States will need to use forms that are the same as those used under the Federal inspection program. FSIS’s OOEET will assist the States to obtain the necessary forms.

### 4. “Same as” Training for Designated State Personnel

The preamble to the proposed rule stated that to qualify for a cooperative interstate shipment program, States will need to demonstrate that designated State personnel have been properly trained in Federal inspection methodology (74 FR 7652). The preamble also explained that FSIS offers training courses in Federal inspection methodology to State inspection personnel and that 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.

*Comment:* Several comments stated that FSIS-sponsored training is costly, lengthy, and almost always requires travel out of State for extended periods of time. The comments suggested that, instead of requiring designated State personnel to attend FSIS training, the Agency should allow States to provide training that is “equal to” FSIS’s training program. The comments explained that such training would include equivalent content as FSIS training but could be administered by the individual States, other State programs, FSIS or other qualified entities.

*Response:* The law does not provide for training that is “equal to” FSIS’s training program or that includes equivalent content. The 2008 amendments to the Acts require that designated State personnel under go “\* \* \* all necessary inspection training

and certification to assist the [FSIS Administrator] in the administration and enforcement of [the Acts], including rules and regulations issued under [the Acts]" (21 U.S.C. 683(a)(2) and 472(a)(2)). As stated in the Senate Committee report, this means that the designated State personnel " \* \* \* must have undergone all the necessary training to carry out the requirements of [the Acts], [their] regulations, notices, directives and policies, just as required of a Federal inspector" (S. Rep. No. 220, 110th Cong., 1st Sess. (2007), pp. 211–214). Thus, the law clearly requires that the training in Federal inspection methodology provided to designated State personnel be "the same as" the training provided to FSIS inspection personnel.

As noted in the preamble to the proposed cooperative interstate shipment rule, FSIS offers training courses in Federal inspection methodology to State inspection personnel. FSIS's OOEET will coordinate with States participating in the cooperative interstate shipment program to provide the necessary training for designated State personnel.

*Comment:* Some comments stated that many States conduct their own training courses, which are subject to oversight by FSIS. The commenters noted that these State courses often present the identical material that FSIS presents in its training courses. The comments suggested that FSIS consider these State courses as acceptable training for designated State personnel.

*Response:* Although some States may be providing training that includes the same content as the training provided by FSIS, designated State personnel will need to complete FSIS-sponsored training for the State to qualify for the cooperative interstate shipment program. FSIS-sponsored training courses will ensure that designated State personnel receive the necessary training to carry out the requirements of the Federal Acts, "just as required of a Federal inspector," as intended by Congress.

*Comment:* One comment asked whether State personnel will need to complete their training before the State begins its cooperative interstate shipment program. Some comments stated that State programs cannot afford the travel costs associated with sending already trained state inspectors to additional training. One comment suggested that FSIS make any required training for State inspectors available through on-line courses at no charge to the States. Two comments asked whether FSIS would be covering training and training-related expenses.

*Response:* As noted above, the preamble to the proposed rule explained that to qualify for the program, States would need to demonstrate, among other things, that designated State personnel have been properly trained in Federal inspection methodology. This means that when a State submits a request to FSIS for a cooperative interstate shipment program, the State must demonstrate either that its designated State personnel have completed the necessary training in Federal inspection methodology or that such personnel will have completed such training before they begin to provide inspection services to selected establishments in the State.

As previously noted, FSIS currently offers courses in Federal inspection methodology to State inspection personnel. 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's OOEET will coordinate with the States to help make the necessary training available to designated personnel in the State. For example, if a State has a significant number of designated personnel that need to be trained Federal inspection methodology, FSIS could arrange to conduct training courses at a location within the State so that all designated State personnel can attend.

As it does for training costs associated with the State MPI program, FSIS will reimburse States for any eligible training costs associated with the cooperative interstate shipment program, including necessary travel costs. However, instead of reimbursing the State for 50% of the eligible costs, FSIS will reimburse 60% of a State's eligible costs associated with training designated State personnel.

As discussed above, for a State to qualify for the cooperative interstate shipment program, its designated State personnel will need to attend FSIS-sponsored training in person. Thus, FSIS will not be providing the required training through on-line courses as suggested by the comment. The Agency may, however, make supplemental training materials available on-line.

##### 5. "Same as" Laboratory Testing and Analysis

The preamble to the proposed rule explained that to qualify for an interstate shipment program, States will need to demonstrate that the laboratory services that they intend to use to analyze regulatory 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 (74 FR 47652). The preamble also explains that FSIS's Office of Public Health Science (OPHS) will provide laboratory 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.

*Comment:* Some comments agreed that State-inspected establishments participating in the cooperative interstate shipment program should be subject to the same regulatory sampling programs as those established in the Federal inspection program. One comment stated that positive results on pathogen and residue testing on products produced in selected establishments should lead to the same regulatory actions that federally-inspected establishments are subjected to.

Two comments stated that they were encouraged by the requirements for regulatory sampling and laboratory analysis described in the proposed rule. The comments stated that a robust residue, microbiological, and pathological analysis capability will assure accuracy of these test results, which, according to the comments, is essential for maintaining foreign markets.

*Response:* The comments present valid reasons for requiring that the selected establishments participating in the cooperative interstate shipment program be subject to the same regulatory sampling required under the Federal program.

*Comment:* Several comments requested that FSIS clarify its expectations with regard to the laboratory services used by States to analyze samples under the cooperative interstate shipment program. Many comments specifically asked whether FSIS expects these laboratories to be (International Organization for Standards) ISO accredited. Several comments expressed concern that if FSIS requires laboratories that analyze samples for the cooperative interstate shipment program to be ISO accredited, some laboratories will have to abandon perfectly acceptable procedures, or possibly more up-to-date procedures, to perform the methodology executed at the FSIS laboratories. The comments also said that some states would need to hire additional personnel to perform the increased paperwork with no additional benefit in the quality or quantity of tests performed.

*Response:* The laboratory services that States use to analyze samples collected under the cooperative interstate shipment must be capable of producing the same results as FSIS's laboratories. Therefore, to demonstrate that the laboratory services used by a State are sufficient for the State to qualify for the cooperative interstate shipment program, the State will need to show that the laboratory is accredited by an internationally recognized organization that accredits food testing laboratories against the ISO 17025 "General Requirements for the Competence of Testing and Calibration Laboratories" and AOAC "Guidelines for Laboratories Performing Food Microbiological and Chemical Analyses of Food and Pharmaceuticals Testing" written by the Analytical Laboratory Accreditation Criteria Committee (ALACC). The assessment body that FSIS uses, the American Association for Laboratory Accreditation (A2LA), is the sole organization that incorporates ALACC into their program requirements. State labs would need to use A2LA or another accrediting body that incorporates ALACC and is a signatory and in good standing to the Mutual Recognition Arrangements of the International Laboratory Accreditation Cooperation (ILAC).

The laboratory will also need to use the protocols for analytical tests required for FSIS regulatory activities on meat and poultry products described in the FSIS Chemistry, Microbiological, and Pathology Laboratory Guidebooks. However, if the laboratory that a State intends to use to analyze samples for the cooperative interstate shipment program is unable to follow an FSIS method as written, the State may submit a justification to FSIS that: (1) Explains why the laboratory is unable to follow the FSIS methodology and (2) describes the modifications that the laboratory intends to make to the FSIS methodology. FSIS will evaluate the State's justification to determine whether the modification of FSIS methodology is minimal and supportable through validation or other evidence. FSIS will allow a State to use the modified method if the Agency determines that methodology is consistent with the original FSIS protocol and the State's method is capable of achieving results that are consistent with the corresponding FSIS method.

To assist the States in developing laboratory services that are "the same as" those provided under the Federal inspection program, FSIS is adopting a "phased in" approach for the States to become ISO 17025 accredited. OPHS

has developed a Quality Assurance (QA) checklist based on ISO 17025 and ALACC criteria. It is not as extensive as ISO 17025, but contains minimum QA practices that laboratories should follow to be able to defend their results. The checklist is included as an appendix in FSIS's guidance for "at least equal to" State MPI programs. States that use services from laboratories that are not ISO 17025 accredited but that can demonstrate that the laboratories meet the laboratory criteria in the FSIS QA checklist will be permitted to participate in the cooperative interstate shipment program if they agree to actively seek and obtain ISO accreditation within two years. However, if the laboratory fails to actively seek or does not obtain the necessary accreditation, FSIS will terminate the State's cooperative agreement for the interstate shipment program.

FSIS is developing materials to assist States whose laboratory services are pursuing ISO accreditation to meet the requirements to become accredited. States may also use an outside laboratory to analyze samples collected under the cooperative interstate shipment program if the outside laboratory has the necessary accreditation.

States that currently use laboratories with active ISO 17025 accreditations will need to submit the necessary documentation for FSIS to verify that the laboratories are ISO accredited and meet ALACC food laboratory requirements as assessed by an appropriate accreditation body. To remain eligible for the programs, States will need to demonstrate, through documented third-party audits or other appropriate documentation, that their laboratories are maintaining their accreditation and are continuing to use methods described in FSIS Laboratory Guidebooks.

*Comment:* One comment asserted that instead of conducting the same number and type of sampling that is conducted under FSIS's sampling programs, the Agency should allow States to develop sampling programs that reflect the same number of samples over the broad spectrum of meat products produced under the cooperative interstate shipment program. According to the comment, States may very well conduct more sampling or more comprehensive sampling than Federal programs. The comment also suggested that FSIS provide States with production data to guide them in selecting the same number or more samples based on the same volumes under FSIS inspection programs.

*Response:* To qualify for the cooperative interstate shipment program States must, at a minimum, collect and analyze the same number and type of regulatory product samples from selected establishments as are collected and analyzed under FSIS's inspection sampling program. If they have met the sampling requirements provided for in FSIS's regulatory sampling programs, States may collect additional samples or conduct additional analyses if they choose to do so. FSIS will provide guidance to States in determining the appropriate number of samples that they will need to collect to be the same as the Federal regulatory sampling program.

*Comment:* Some comments noted that establishing a national laboratory program to analyze samples collected under the cooperative interstate shipment program would be more economically viable than requiring that each State program conduct a laboratory program that is "the same as" FSIS's. According to the comments, it is economically unreasonable for States to set up and maintain equipment necessary for running extremely rare samples.

*Response:* States that do not have the laboratory capability to conduct the necessary sampling and analyses required under the cooperative interstate shipment program are permitted to submit samples collected under the cooperative interstate shipment program to an outside laboratory that does. The States may rely on the sample results obtained from an outside laboratory if the State, in coordination with FSIS's OPHS, has verified that the laboratory has the necessary accreditation and is capable of producing the same results obtained by FSIS's laboratories.

*Comment:* One comment stated that the level of oversight that FSIS intends to have over State laboratories under the cooperative interstate shipment program is unnecessary. The comment suggested that, if FSIS intends to oversee the analysis of samples collected from selected establishments, it should offer to analyze all samples from eligible establishments at FSIS laboratories at no cost to the State program.

*Response:* FSIS does not intend to oversee the analysis of samples collected from selected establishments. The Agency intends to consult with the States to verify that the laboratories that States use to analyze samples from selected establishments are capable of producing the same results as FSIS's laboratories.

*Comment:* One comment included a number of questions that the commenter requested FSIS address before the



Agency issues the final rule to implement the cooperative interstate shipment program. The questions are as follows:

- Will the kidney inhibition swab (KIS) test for detecting antimicrobial drug residues be required in establishments selected for the program, or will other tests be acceptable?
- If KIS is necessary, will every facility be required to have an incubator, or can samples be sent to the state laboratory, requiring only one incubator?
- If an establishment decides to participate in both the cooperative program and the state inspection program, would the sampling program required by FSIS be sufficient, or would they also have to participate in the State's sampling program?
- Could the selected establishments be put into the FSIS sampling program, with FSIS sending sample requests and supplies, and the samples analyzed at Federal labs?
- What process must be followed if a state's laboratory wants to request audit help?
- Will the recommendations of the auditor be the official required adjustments the lab must make to allow the state to participate in the program?

*Response:* As noted above, the laboratory services that a State uses to analyze samples under the cooperative interstate shipment program must use methods that are capable of producing results that are "the same as" those obtained from the methods used by FSIS's laboratories. Therefore, the KIS test for detecting antimicrobial drug residues used by FSIS is the acceptable test. Samples may be sent to and analyzed by the State laboratory if FSIS has evaluated and approved any minor modifications to the procedures described in the FSIS Laboratory Guidebooks.

If an establishment participates in both the cooperative interstate shipment program and the cooperative State MPI program, the sampling conducted under the cooperative interstate shipment program must be "the same as" the sampling conducted under the Federal program, while the samples collected under the State MPI program must meet standards that are "at least equal to" the Federal program.

States that participate in the cooperative interstate shipment program are responsible for scheduling, collecting and analyzing samples required under the program. FSIS will not collect or analyze regulatory samples for the cooperative interstate shipment program.

The SEC assigned to the State will facilitate the process for the State to obtain the necessary audit assistance from FSIS's OPHS. As noted above, OPHS will provide guidance and advice on laboratory accreditation requirements. However, the laboratories themselves will be responsible for obtaining the necessary ISO accreditation.

#### 6. Related Activities

*Comment:* Some comments requested that FSIS clarify what States need to do to demonstrate they are able to "conduct any related activities that would be required under a cooperative interstate shipment program," as required under the proposed regulations. The comments said that the final rule must specifically describe the "related activities" required under the cooperative agreement or else the Agency should remove this statement.

One comment said that requiring that States conduct "related activities" adds requirements for a State program that are outside of what is authorized by the enabling statute, and is both unclear and unnecessary. The comment said that FSIS should not be attempting to impose ancillary requirements on the States through the cooperative agreement process. According to the comment, the State's ability to provide inspection service to selected establishments in accordance with the statute is all that is authorized and, therefore, all that is necessary.

*Response:* The term "related activities" refers to any activities that are necessary to ensure that the inspection services provided to selected establishments are "the same as" the inspection services provided to Federal establishments. Such activities include, but are not limited to, scheduling, collecting and analyzing regulatory samples, issuing export certificates for establishments that will be exporting products to foreign countries, and verifying that selected establishments are humanely handling livestock in connection with slaughter.

#### E. Additional Conditions for State Participation

In addition to requiring that a State's requests for an interstate shipment program include documentation to demonstrate that it is capable of providing the necessary inspection services to selected establishments in the State, the proposed regulations also require that, in its request, the State must agree to: (1) Provide FSIS with access to the results of all laboratory analyses conducted on product samples from selected establishments in the

State; (2) inform the SEC for the State of any laboratory results that indicate that a product produced in a selected establishment may be adulterated or may otherwise present a food safety concern; and (3) 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 (proposed 9 CFR 332.4(b)(3) and 381.187(b)(3)).

The proposed regulations also provide that when States submit their requests for an interstate shipment program, they must include a list of establishments that have requested to participate in the program and that the State recommends for initial selection into the program (proposed 9 CFR 332.4(b)(1) and 381.187(b)(1)).

*Comment:* Two comments suggested that FSIS remove the provision in the proposed regulations that requires that States give FSIS access to the results of all laboratories analyses conducted at selected establishments. The comments stated that such a requirement is unnecessary because the States are also required to notify the SEC of results that indicate that a product produced in a selected establishment may be adulterated or may otherwise present a food safety hazard.

*Response:* Although the States are required to notify the SEC of laboratory results that indicate that a product produced in a selected establishment may be adulterated or present a food safety hazard, the SEC or other FSIS personnel also need to have access to the results of the laboratory analyses conducted on products produced in selected establishments to verify that these establishments are operating in a manner that complies with the Acts.

*Comment:* One comment stated that, as written, the proposed requirement that States give FSIS "access" to all laboratory results could be interpreted as requiring that FSIS have electronic access, via a particular system, to the results of testing conducted by State programs. According to the comment, when an integrated electronic system for data sharing is developed, funded, and implemented, State programs will share laboratory results with FSIS electronically. The comment maintained that the cooperative interstate shipment program should not unintentionally limit the methods by which analytical results are shared with FSIS before an electronic system is fully operational.

*Response:* The regulations do not prescribe the methods by which States are required to share their analytical results with FSIS. States may share analytical results with FSIS



electronically or they may provide hard copies. The only requirement is that they give FSIS access to these results upon request.

*Comment:* One comment said that the proposed requirement that the State notify the SEC when laboratory results indicate that a product from a selected establishment may be “adulterated or may otherwise present a food safety concern” is overly broad and redundant. The comment asserted that any product that presents a food safety concern is, by definition, adulterated. The comment suggested that FSIS delete the phrase “may otherwise present a food safety concern” in the final regulations.

*Response:* There may be instances in which a product presents a food safety concern but it is unclear as to whether the product is adulterated under the FMIA or PPIA. For example, a preliminary laboratory result may indicate that a product that has been distributed in commerce is contaminated with a pathogen but the laboratory needs to complete the analysis to confirm these results. The SEC needs to be made aware of these situations to verify that the establishment and States have responded to the preliminary result in a manner that complies with the Federal Acts and implementing regulations.

*Comment:* One comment stated that, instead of requiring that a State’s request for a cooperative interstate shipment program include a list of establishments that have submitted requests to participate in the program and that the State recommends for the program, the final regulations should permit States to submit a request for a cooperative interstate shipment program before they have identified establishments interested in being selected for the program. According to the comment, this would allow the State and Federal programs to work out any issues with their relationship before offering the program to establishments.

*Response:* FSIS agrees with this comment. The Agency has modified the regulations to require that a State’s request for a cooperative interstate shipment program include a list of establishments that have submitted a request to participate in the program, if any. This will allow States to request an agreement for a cooperative interstate shipment program before they have identified establishments interested in participating in the program. However, FSIS will only reimburse States for 60% of their eligible costs to administer the program if, after entering into a cooperative agreement, establishments in the State are selected for, and participate in, the program.

*Comment:* A few comments stated that, in addition to verifying that States have sufficient authority, resources, personnel, training, sampling capability and laboratory capacity to provide the necessary inspection services to selected establishments in the State, FSIS will also need to monitor budget issues in participating States on an ongoing basis to ensure that States continue to have sufficient resources to participate in the program. The comments noted that many State governments are under financial duress and have had to make budget cuts in their State inspection programs. One comment said that even though FSIS is required to reimburse States for at least 60% of their eligible costs associated with the cooperative interstate shipment program, the Agency will need to verify that States interested in participating in the new program will be able to meet Federal inspection regulatory requirements during these hard economic times.

*Response:* States that enter into an agreement with FSIS for a cooperative interstate shipment program will be required to prepare annual budgets to cover the costs for the cooperative interstate shipment program, maintain complete accounting records, and conduct all other financial accountability activities just as they do for the State MPI program. FSIS will terminate a State’s agreement for a cooperative interstate shipment program if the State does not have sufficient finances to comply with all aspects of the cooperative interstate shipment program.

#### F. Selection Process

Under the proposed regulations, State-inspected establishments that are interested in participating in the cooperative interstate shipment program must apply for the program through their State (proposed 9 CFR 332.5(a)(1) and 381.515(a)(1)). 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 (74 FR 47653). The proposed rule provides that the FSIS Administrator, in coordination with the State, will decide whether to select the establishment for the program (proposed 9 CFR 332.5(b) and 381.151(b)).

*Comment:* Some comments said that the State inspection program is the government entity best suited to begin

the process of selecting establishments for the cooperative interstate shipment program. According to the comments the States, not the FSIS Administrator, should be responsible for selecting establishments to participate in the program. The comments suggested that after initiating the selection process, the State program could collaborate with the FSIS SEC, who can visit the establishments that are under consideration for selection into the cooperative interstate shipment program.

*Response:* FSIS agrees that the States are best suited to begin the process of determining which establishments in the State are eligible for selection to the cooperative interstate shipment program. Therefore, the proposed rule requires that establishments interested in participating in the cooperative interstate shipment program apply for the program through the State in which they are located (proposed 9 CFR 332.5(a) and 381.515(a)). After the State recommends establishments for the program, the law requires that the FSIS Administrator coordinate with the State to select establishments for the program (21 U.S.C. 683(b)(1) and 472(b)(1)).

*Comment:* One comment argued that the regulations do not need to include a process for selecting establishments to participate in the cooperative interstate shipment program because establishments operating under the State MPI programs are already under an inspection system that provides for food safety in a manner that is “at least equal to” the Federal inspection program. According to the comment, there is no need for selection because the entire State program has already been approved.

*Response:* The law requires that the FSIS Administrator, in coordination with the State, select establishments to participate in the new cooperative interstate shipment program (21 U.S.C. 683(b) and 472(b)). There is nothing in the law to indicate that establishments operating under the existing State MPI programs have already been approved for the cooperative interstate shipment program. Therefore, these final regulations include procedures for selecting establishments for the program.

*Comment:* One comment suggested that the final rule require that selected establishments undergo an on-site review by FSIS at least 30 days before they become eligible to participate in the cooperative interstate shipment program. The comment noted that such a review would help to guarantee that selected establishments that wish to ship their meat products in interstate

commerce are in compliance with Federal law.

*Response:* The preamble to the proposed rule explained that, as part of the selection process, the SEC assigned to a State, in coordination with the State, will verify that each establishment in the State that has applied to participate in a cooperative interstate shipment program is in compliance with all Federal standards (74 FR 47653). To verify such compliance, the SEC will coordinate with the State to conduct on-site reviews of each establishment that has applied, and that the State recommends, for selection into the program.

*Comment:* One comment said that FSIS should better explain how establishments may be selected for the cooperative interstate shipment program.

*Response:* The preamble to the proposed rule provides a detailed description of the proposed selection process. FSIS is adopting that process in this final rule.

As proposed, State-inspected establishments that are interested in participating in a cooperative interstate shipment program will be required to apply for the program through the State agency that administers the State MPI program. States are responsible for establishing their own application procedures. The State will then evaluate the establishment to determine whether it qualifies for selection. To qualify for selection to the cooperative interstate shipment program, an establishment must:

- Have the appropriate number of employees;
- Not be ineligible for a cooperative interstate shipment program <sup>2</sup>;
- Be in compliance with all requirements under the State inspection program; and
- Be in compliance with all Federal meat or poultry products inspection requirements.

If a State determines that an establishment operating under the State's MPI 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 then decide whether to select the establishment for the program.

In deciding whether to select an establishment that the State has recommended for the cooperative interstate shipment program, the Administrator will consider whether the establishment qualifies 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. Before an establishment can be selected, the SEC, in coordination with the State, must verify, through record reviews and on-site visits, that the establishment is in compliance with all Federal inspection requirements under the FMIA, PPIA, and their implementing regulations in title 9, chapter III, of the CFR.

#### *G. Mark of Inspection and Official Number*

The proposed regulations require that inspection services for selected establishments be provided by designated State personnel, and that articles prepared or processed in a selected establishment that have been inspected and passed by designated personnel bear an official Federal mark of inspection (proposed 9 CFR 332.6(c) and 381.516(c)). The proposed regulations also require that the Federal mark contain a selected establishment number assigned to the establishment by the State. The proposal provides that the number must include, as a suffix, the abbreviation for the State in which the establishment is located, as well as the abbreviation "SE" for selected establishment (e.g., "38SETX" as a number for a selected establishment in Texas). If the establishment processes poultry products, the suffix must also contain a "P," (e.g., 38 SEPND for a selected poultry establishment in North Dakota) (proposed 9 CFR 332.5(c) and 381.515(c)). The proposed regulations also state that States that fail to assign an establishment number to selected establishments in the State and report the number to the SEC for the State will not qualify to participate in the program (proposed 9 CFR 332.5(d) and 381.515(d)).

*Comment:* Some comments expressed concern that allowing State-inspected meat and poultry products to bear a Federal mark of inspection will make it difficult to maintain the integrity of the Federal mark. One comment stated that the integrity of the Federal mark will be diminished if a State-inspected product distributed in interstate commerce is

recalled or found to be adulterated. Another comment said that allowing State-inspected products to bear a Federal mark of inspection is misleading because consumers that see a Federal mark of inspection on the label of a meat or poultry product will think that the product is the same as all other federally-inspected products. The comment noted that the FMIA and PPIA both prohibit labeling that is false or misleading.

*Response:* Under the 2008 amendments to the Acts, meat and poultry products produced under the cooperative interstate shipment that designated State personnel have determined are in compliance with all Federal standards are required to bear a "Federal mark, stamp, tag, or label of inspection" (21 U.S.C. 472(b)(1) and 683(b)(1)). Thus, requiring that articles prepared or processed in a selected establishment that have been inspected and passed by designated personnel bear an official Federal mark is consistent with the law. Such a requirement will not diminish the integrity of the Federal mark or be misleading to consumers, as suggested by the comments, because all meat and poultry products that bear the Federal mark will have been produced under Federal standards.

*Comment:* Some comments maintained that it is not necessary to require that the meat and poultry products produced under the cooperative interstate shipment program bear a Federal mark of inspection because States that have MPI cooperative agreements already provide State marks. A State Department of Agriculture and a State agency commented that many State-inspected establishments prefer that their products bear the State mark of inspection. The comments claimed that requiring that selected establishments apply a Federal mark and identify the State in the establishment number is unacceptable to most plant owners. Another comment argued that requiring that a Federal mark of inspection be applied to products that have been inspected by a State inspector under a cooperative State meat inspection program is counterintuitive and does not accomplish the goal of providing for interstate shipment of State-inspected products.

*Response:* The 2008 amendments to the Acts require that meat and poultry products produced under the cooperative interstate shipment program bear a Federal mark of inspection.

As noted above, under the proposed regulations, the Federal mark is required to contain a selected establishment

<sup>2</sup> Examples of establishments that are ineligible for the cooperative interstate shipment program include official Federal establishments, establishments located in a State that has a State MPI program, establishments in violation of the FMIA or PPIA, establishments that are the subject of a transition to become a Federal plant, and establishments located in a State without a State MPI program.

number assigned to the establishment by the State. The selected establishment number is required to include, as a suffix, the abbreviation for the State in which the establishment is located, as well as the abbreviation "SE" for selected establishment (e.g., "38SETX" as a number for a selected establishment in Texas). If the establishment processes poultry products, the suffix must also include a "P" before State abbreviation (e.g., 38 SEPND for a selected poultry establishment in North Dakota). Thus, although meat and poultry products produced in selected establishments will not bear a State mark of inspection, the State in which the product was produced can be readily identified by referencing the selected establishment number that is required to appear inside the Federal mark.

*Comment:* Some comments agreed that products produced in selected establishments should bear a Federal mark of inspection but also suggested that such products be allowed to bear a State mark if the establishment so chooses. According to the comments, many State-inspected establishments believe that compliance with their State inspection program requirements along with the Federal standards provides a marketing advantage and that appearance of the State mark may add value to State-inspected products sold in interstate commerce. One comment noted that because their State mark of inspection is an outline of the State, selected establishments in the State could use the State mark to promote their products interstate.

*Response:* It is not necessary for meat or poultry products that have been processed or prepared in selected establishments to bear both a State and Federal mark because the product's State-of-origin can be identified by the selected establishment number that is required to appear in the Federal mark. Moreover, allowing products produced under Federal standards to bear both a Federal and State mark of inspection may be misleading to consumers and foreign trade partners because the law prohibits interstate shipment of products produced under State MPI programs. Allowing both Federal and State marks could also be confusing to consumers and make it difficult for them to identify products potentially implicated in outbreaks or subject to recall.

Selected establishments that were interested in using the State mark to market meat or poultry products produced under the cooperative interstate shipment program could use labeling statements information to identify where the product was

produced instead, provided that the statement is truthful and not misleading. For example, the label of a meat product produced in a selected establishment in Texas, could contain the statement "prepared in Texas," if the statement is presented in a manner that is truthful and not misleading to consumers.

*Comment:* Some comments suggested that instead of requiring that States assign a new official State establishment number to selected establishment, FSIS should allow establishments that participate in the cooperative interstate shipment program to retain their official State number in conjunction with the suffix "SE."

*Response:* There is nothing in the proposed rule that would prevent a State from allowing establishments selected for the cooperative interstate shipment program to retain their official State number, provided that the suffix "SE" is added to original State establishment number. The "SE" suffix is necessary to make clear that the establishment associated with the number is a selected establishment.

*Comment:* One comment noted that the proposed regulations identify the "SE" that is required to appear as part of a selected establishment's official State number as a suffix. The comment stated that the "SE" designation is, in fact, a prefix.

*Response:* FSIS refers to the "SE" along with the State abbreviation as a "suffix" because these abbreviations follow the number assigned to the selected establishment.

*Comment:* One comment objected to the provision in the proposed regulations that provide that a State that fails to assign an official State number to the selected establishments in the State and inform the SEC will be disqualified from participating in the cooperative interstate shipment program. The comment believed that disqualification is an overly harsh penalty for what may be a simple omission. The comment suggested that in the final rule, FSIS replace the statement that failure to assign an official number "will disqualify the State" to "may disqualify the State."

*Response:* As explained in the preamble to the proposed rule, full compliance by a State with the requirements for assigning official establishment numbers to establishments selected for the cooperative interstate shipment program is essential if the program is to succeed (74 FR 57654). FSIS will give States that inadvertently fail to assign a proper establishment number to a selected establishment an opportunity to take

corrective actions to comply with the regulations. However, failure to comply with the establishment number requirements in this final rule will disqualify a State from participating in the cooperative interstate shipment program.

*Comment:* Several comments submitted by State Departments of Agriculture and State agencies requested that in the final rule FSIS make clear that it will permit selected establishments to produce products under both the cooperative interstate shipment program and the State MPI program. The comments noted that FSIS allows establishments with both a Federal grant and State grant of inspection to operate as both a Federal plant and a State plant if they maintain an appropriate separation by time or space between the State and Federal operations and that the products are appropriately marked. The comments noted that in a letter to the National Association of State Departments of Agriculture (NASDA) dated September 15, 2009, the Deputy Secretary of Agriculture said that FSIS expects to apply a similar policy to selected establishments that are interested in continuing to produce certain products solely for distribution in the State under the State MPI program. The comments maintained that allowing for this type of flexibility will benefit rural America and is necessary for the success of the new program.

One comment said that if the final rule permits selected establishments to produce products under both the State MPI program and the cooperative interstate shipment program, FSIS should allow these establishments to continue to apply the State mark to products that are not produced under the cooperative interstate shipment program.

*Response:* FSIS has considered these comments and has decided to revise the proposed regulations to allow selected establishments to conduct operations under both the cooperative interstate shipment program and the State MPI program if those establishments implement and maintain written procedures for complete physical separation of product and process for each operation by time or space. An establishment may provide for separation by space by conducting its State MPI operations in an area that is physically separate from the area in which it conducts operations under the cooperative interstate shipment program. Alternatively, an establishment may conduct each operation in the same area provided that the separation in space is sufficient to

ensure that potential food safety hazards, such as microbiological pathogens, if present, are not likely spread from one area to another through aerosolization, air ducts, air currents, employees, or other means and that there is no co-mingling of product. Establishments that chose to conduct both operations in the same area must clearly identify and distinguish the State MPI operation from the cooperative interstate shipment operation. For example, the establishment might designate certain employees on a given day to work exclusively on the State MPI operations and have these employees wear white clothing, and designate other employees to work exclusively on the cooperative interstate shipment operations and have these employees wear yellow clothing. The establishment could also color-code knives and other equipment associated with each operation.

In addition to separation by space, an establishment may conduct the State MPI operations and cooperative interstate shipment operations at separate times if the establishment's procedures for separation address clean-up between operations. Establishments that conduct both operations in the same facility and on the same equipment, and that separate the operations by time, will need to fully clean and sanitize the facilities and equipment in between operations as set out in their Sanitation SOPs.

Establishments that conduct operations under both the State MPI program and the cooperative interstate shipment program will also need to establish written procedures to ensure that product produced under the State MPI program will not become co-mingled with product produced under the cooperative interstate shipment program. The procedures will need to ensure that products produced under each program are appropriately identified as State MPI product or cooperative interstate shipment products, and that each product bears the appropriate mark of inspection.

Establishment will also need to maintain physical separation of product produced under the State MPI program from products produced under the cooperative interstate shipment program throughout the process, either through the use of separate facilities or by designated areas for holding or storing products produced under separate operations.

The meat or poultry products produced when the establishment is operating under the State MPI program will be required to bear the State mark of inspection and will only be permitted

to be distributed within the State. Meat or poultry products produced when the establishment is operating under the cooperative interstate shipment program will be required to bear a Federal mark and may be shipped in interstate commerce.

#### *H. Oversight and Enforcement— Selected Establishment Coordinator*

The preamble to the proposed rule explained that the statute requires that FSIS appoint a "state coordinator" to "provide oversight and enforcement" of the cooperative interstate shipment program and "to oversee the training and inspection activities" of State personnel designated to provide inspection services to selected establishments (74 FR 47654). When FSIS issued the proposed rule, the Agency explained that the "state coordinator" required by statute would be referred to as the "selected establishment coordinator" (SEC) in the proposed regulations to avoid confusion with the "State coordinator" under the Talmadge-Aiken program, which is a State employee. In the preamble to the proposed rule, FSIS also explained that the Agency had tentatively decided that the SEC would be an employee of the FSIS Office of Field Operations (OFO) and would be assigned to an FSIS district office.

#### **1. SEC Definition and FSIS Program Area**

*Comment:* One comment stated that the codified text in the final rule should clarify that the term "selected establishment coordinator" as used in the implementing regulations is synonymous with the term "state coordinator" under the statute. The comment said that there should not be both a State coordinator and an SEC.

*Response:* As noted in the preamble to the proposed rule, the term "State coordinator" is often used to refer to a State employee under the Talmadge-Aiken program. Therefore, to make clear that the "State coordinator" for the cooperative interstate shipment program is an FSIS employee, this final rule identifies that employee as the FSIS "selected establishment coordinator" in the codified text. The codified text in the final rule does not provide for both a State coordinator and an SEC.

*Comment:* Some comments stated that, instead of being under the direct supervision of an FSIS District Manager, as FSIS tentatively decided in the proposed rule, the SEC should be under the direct supervision of the Secretary of Agriculture as provided under the statute.

Other comments agreed with FSIS's tentative determination that the SECs operate out of the district offices. One comment noted that the SEC is a Federal employee. The comment stated that, as such, it is appropriate that the SEC be stationed at the district office and report to a District Manager and ultimately, FSIS headquarters. The comment asserted that the SEC should not be stationed at the State meat and poultry inspection agency, but should maintain frequent communication with State agency officials.

*Response:* The Secretary of Agriculture has delegated the administration and enforcement of the cooperative interstate shipment program to FSIS. Since the SEC will be an FSIS employee that operates out of the FSIS district office, it is appropriate for the SEC to be under the direct supervision of the FSIS District Manager.

*Comment:* Several comments were concerned about the Agency's tentative decision to assign the SEC to an FSIS district office. According to the comments, FSIS district offices are not always consistent in their interpretation and enforcement of the Agency's policies. The comments stated that administering the cooperative interstate shipment program from different district offices will make it difficult for FSIS to implement and enforce the program in a consistent manner. The comment suggested that, instead of assigning SECs to multiple district offices, FSIS should designate a single entity within the Agency to implement and enforce the cooperative interstate shipment program.

Some comments suggested that FSIS create a branch in OPEER, similar to the Federal/State Audit Branch (FSAB), or assign the FSAB to administer, review, and enforce the cooperative interstate shipment program. The comments noted that the OPEER/FSAB is already responsible for verifying that the State MPI programs are operating in a manner that is "equal to" the Federal standards, and States now spend a considerable amount of time providing information to OPEER/FSAB. The comments stated that allowing a centralized Agency branch, such as the OPEER/FSAB, to administer and enforce the cooperative interstate shipment program will promote consistency in the program by providing the FSIS SECs, the State programs, and selected establishments with a single point of contact for guidance, policy implementation, and enforcement.

*Response:* The FSIS SEC is required to provide "oversight and enforcement" of the cooperative interstate shipment program and "to oversee the training

and inspection activities” of State personnel designated to provide inspection services to selected establishments (21 U.S.C. 683(d)(1) and 472(d)(1)). As noted above, when FSIS issued the proposed rule, it had tentatively decided that the SEC would be an employee of the FSIS Office of Field Operations (OFO) assigned to an FSIS District Office. Because OFO has expertise in management and enforcement of Federal inspection standards, FSIS is affirming that decision. The SEC will be an OFO employee assigned to an FSIS district office as proposed.

As noted by the comments, the OPEER/FSAB is responsible for conducting comprehensive audits of Federal and State MPI programs. OPEER/FSAB verifies that State MPI programs are operating in a manner that is “at least equal to” the Federal program. Although OPEER/FSAB will not have direct oversight and enforcement of the cooperative interstate shipment program, once the cooperative interstate shipment program is fully implemented, the OPEER/FSAB will be responsible for auditing that program to verify that it is operating in a manner that is “the same as” the Federal inspection program.

## 2. Number of SECs per State

In the preamble to the proposed rule, FSIS explained that 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 (74 FR 47654). The preamble also noted that 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.

In the PRIA to the proposed rule, FSIS also estimated that 13 full-time equivalent FSIS employees would be needed to perform the SEC functions for the 16 States expected to participate in the cooperative interstate shipment program (74 FR 47660). If 400 establishments participate in the new program, the Agency estimated each SEC will be responsible for 31

establishments in a geographically-limited area.

*Comment:* Several comments, most submitted by consumer advocacy organizations, stated that 13 SECs to oversee cooperative interstate shipment programs in 16 States is not sufficient to provide adequate oversight of the new program. The comments urged FSIS to assign a separate SEC to each State that participates in the program. The comments asserted that to effectively verify that selected establishments operating in a manner consistent with the Acts, the SECs need to be spending most of their time in these establishments rather than driving from state-to-state. One comment said that when the provisions of the law were negotiated, the parties understood that there was to be one SEC per State.

Other comments questioned whether the Agency’s estimate of one SEC for 31 establishments is adequate to ensure that these establishments are operating in a manner that complies with the Acts. The comments stated that FSIS must provide enough flexibility to reduce the number of establishments covered by an SEC if circumstances warrant.

One comment expressed concern over the statement in the proposed rule that “[t]he number of States assigned to an SEC would also need to be based on consideration of the most effective allocation of available Agency resources.” The comment stated this sentence demonstrates that there is reason to be concerned that the new program may not receive adequate resources to best protect public health and safety. The comment maintained that there should be at minimum one SEC per participating State and that the SEC’s sole function should be oversight and enforcement of the program, unless the State has so few participating establishments that a full-time SEC is not warranted.

*Response:* As noted in the preamble to the proposed rule, the number of SECs needed to provide effective oversight of the cooperative interstate shipment program will depend on several factors, all of which are intended to ensure that there is sufficient Federal oversight of the program. FSIS agrees with the comments that stated that the SECs should be spending most of their time overseeing activities in selected establishments, and the Agency intends to structure the SEC’s assignment in a manner that will, to the greatest extent possible, limit the time spent traveling between selected establishments. In some instances, this will require that an SEC cover selected establishments located in different States, particularly

in States with selected establishments located near the State borders.

As noted above, FSIS estimated that there would be one SEC for 31 establishments in a geographically-limited area. This number is an estimate and assumes a certain level of participation by State-inspected establishments that employed fewer than 35 employees when the 2008 Farm Bill was enacted. The actual number of establishments assigned to an SEC will depend on a number of factors, including the complexity of the operations conducted at the selected establishments and the schedule of operations for each selected establishment.

## 3. Frequency of SEC Visits

As required under the statute, the proposed regulation provided that the FSIS 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 (proposed 9 CFR 332.7(a) and 318.517(a)). In the preamble to the proposed rule, FSIS noted that 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 (74 FR 47654). The Agency requested comments on how frequently the SEC should visit each establishment under his or her jurisdiction.

*Comment:* Several comments said that, since the law requires that the SECs file quarterly reports on the status of the selected establishment under their jurisdiction, they should visit each selected establishment at least quarterly. Some comments stated that requiring that the SEC visit selected establishments more often than once a quarter would seem overly burdensome and ineffective. One comment suggested that FSIS modify the proposed regulation to read that the SEC will visit, “each selected establishment in the State on a regular basis, but no less frequently than quarterly, to verify that the establishment is operating in a manner that is consistent with the Act.”

One comment stated that requiring quarterly or bi-annual visits will allow the SECs to both cover their assigned establishments and conduct the day-to-day operations of managing the program for their region. The comment said that if a problem arises, the SEC can visit the establishment more frequently. The comment suggested that SECs also rely on State inspection personnel to advise them if additional visits are needed.

Many comments stated that the frequency of the SEC's visits should be based on the performance of the establishment. The comments noted that the number of visits may need to be higher when the program is first implemented while the State inspection personnel gain experience with the program's regulatory requirements. Two comments suggested that initially, the visits should be weekly and that subsequent visits should be based on the establishment's performance.

One comment said that the final regulations should clearly state that the frequency of the SEC's visits shall be based on the performance of the establishment's food safety control systems. The comment maintained that such a statement will ensure judicious use of FSIS resources and create an additional incentive for the establishment to effectively operate their food safety control systems.

One comment stated that the SEC should visit selected establishments no more frequently than FSIS front line supervisors typically visit federally-inspected establishments in their circuit. Another comment said that the SECs will need to visit selected establishments quite frequently to ensure that they are in compliance with Federal standards. One comment stated the goal in determining how frequently SECs should visit establishments under their jurisdiction should be to provide a statistically relevant sample to check on the level of compliance and performance of inspections by state inspectors.

One comment suggested that in addition to prescribing the frequency of SEC visits, the final regulations should specify that the SEC's visits to selected establishments are to occur at different times and be unannounced.

*Response:* The comments submitted on this issue indicate that there is a general lack of consensus on how frequently the SEC should visit selected establishments in the States. As noted above, some comments suggested that the SEC conduct quarterly or even bi-annual visits, while others suggested that the SEC visit each selected establishment at least weekly.

The 2008 amendments to the Acts do not specify how frequently the SECs are to visit selected establishments, but they do provide that the SEC " \* \* shall visit selected establishments with a frequency that is appropriate to ensure that selected establishments are operating in a manner that is consistent with this Chapter (including regulations and policies under this Chapter (21 U.S.C. 683(d)(3)(a) and 472(d)(3)(a)). The Senate Committee report that

explains this provision states that "[i]t is the Committee's intent that the [SEC] inspect selected establishments frequently each month" (S. Rep. No. 110–20, 110th Cong., 1st Sess. (2007), pp 211–214)).

Therefore, after considering the comments on this issue, as well as the language in both the statute and the Senate Committee report, FSIS has decided not to prescribe how frequently SECs are to visit selected establishments under their jurisdiction. Instead, the Agency is revising the proposed rule to clarify that the frequency with which the SEC will visit selected establishments under the SEC's jurisdiction will be based on a number of factors, including the complexity of the operations conducted at the selected establishment, the establishment's schedule of operations, and the establishment's performance under the cooperative interstate shipment program. The Agency has concluded that such an approach will ensure that the number of SEC visits reflects the appropriate level of oversight needed for each selected establishment.

FSIS agrees with the comments that noted that the number of SEC visits may need to be higher when the program is first implemented in order for the State personnel to gain experience in enforcing Federal food safety standards. FSIS also intends to schedule some unannounced SEC visits to selected establishments, as suggested by the comments. However, the SEC will also conduct scheduled visits to selected establishments to give State personnel the opportunity to prepare to discuss issues related to their role in enforcing Federal standards.

Although FSIS is not prescribing a specific minimum number of SEC visits, based on the statement in the Senate Committee report, FSIS has concluded that bi-annual or quarterly visits to selected establishments, as suggested by some comments, are most likely not frequent enough to carry out the intent of the statutes.

*Comment:* One comment stated that the provision in the proposed rule that allows the SEC, in consultation with the District Manager, to designate qualified FSIS personnel to visit a selected establishment on behalf of the SEC is an appropriate use of Agency resources. The comment said that assigning other designated FSIS personnel to visit establishments on behalf of the SEC makes sense from a practical and financial standpoint. The comment stated that FSIS could use inspection personnel who are already out in the field to conduct visitations to check

compliance on a more frequent basis than sending the SEC into the field.

*Response:* FSIS agrees that providing for qualified FSIS personnel to visit selected establishment on behalf of the SEC is an appropriate use of Agency resources.

#### 4. SEC Duties—Oversight

*Comment:* Some comments supported the level of Federal oversight provided for in the proposed regulations as necessary to maintain the safety and security of all meat and poultry products distributed in interstate commerce. One of the comments stated that any cooperative interstate shipment program must be federally driven and that FSIS must be in charge.

Other comments complained that the proposed rule would give the SEC an excessive and unnecessary level of Federal oversight over the cooperative interstate shipment program. The comments stated that FSIS currently evaluates "at least equal to" State MPI programs through reviews of State self-assessment and through an on-site evaluation of the State's program every three years. The comments asserted that this evaluation methodology has proven effective for assuring that State programs are in compliance with Federal requirements. The comments said that FSIS should, to the extent allowed by statute, consider using this same method for evaluating a State's performance under the new cooperative interstate shipment program.

*Response:* FSIS disagrees with the comments that stated that the proposed rule would give the SEC an excessive and unnecessary level of Federal oversight over the cooperative interstate shipment program. As noted throughout this document, under the Acts, as amended by the 2008 Farm Bill, the FSIS Administrator is required to designate an FSIS employee as an SEC for each State to "provide oversight and enforcement of the program" and to "oversee the training and inspection activities" of the designated State personnel providing inspection services to a selected establishment. (21 U.S.C. 683(d)(1) and 472(d)(1)). The Acts also require that the SEC visit selected establishments as frequently as necessary to ensure that these establishments are operating in a manner consistent with the Federal Acts (21 U.S.C. 683(d)(3) and 472(d)(3)). Thus, the level of Federal oversight that the proposed rule provides for the cooperative interstate shipment program reflects the level of oversight that is required by law.

FSIS disagrees with the comments that suggested that the Agency use

OPEER/FSAB's evaluation methodology to oversee a State's performance under the new cooperative interstate shipment program. As noted by the comments, the OPEER/FSAB conducts comprehensive audits of the State MPI programs to verify that States are enforcing laws and regulations that "are at least equal to" requirements of the Federal Acts. The evaluation methodology used by the OPEER/FSAB is designed to provide a comprehensive annual assessment of the State MPI programs rather than continuous Federal oversight and enforcement of these programs. Thus, this methodology would not provide the necessary level of oversight that the Acts require for the cooperative interstate shipment program.

*Comment:* Some comments expressed concern that the proposed rule would give "de facto constant regulatory oversight authority" to the FSIS SEC. The comments stated that this would basically give State personnel working in selected establishments two supervisors. According to the comments, this chain-of-command will create confusion and needless redundancy.

One comment said that the SEC needs to work with the States to coordinate Federal oversight of the program to reduce the burden on the selected establishments to the extent possible. The comments stated that the program should not become one in which both Federal and State officials are routinely inspecting the same facilities.

Another comment agreed with the provision in the proposed rule that stated that the SEC's role is limited to oversight and enforcement of the program. The comment also agreed that the State program should continue to be responsible for the direct supervision of designated State personnel.

*Response:* The proposed rule makes clear that inspection services for selected establishments participating in the cooperative interstate shipment program must be provided by designated personnel, who will be under the direct supervision of a State employee (proposed 9 CFR 332.6(b) and 381.516(b)). Although the SEC will be responsible for overseeing the inspection activities of the designated personnel, the State program will continue to be responsible for the direct supervision of all designated State personnel. Thus, the comment that stated that the proposed rule would give State personnel working in selected establishments two supervisors is inaccurate.

## 5. SEC Duties—Enforcement

The proposed regulation gave the SEC the authority to initiate any appropriate enforcement action provided for in the FSIS rules of practice in 9 CFR part 500 if the SEC determines that a selected establishment under his or her jurisdiction is operating in a manner that is inconsistent with the Acts (proposed 9 CFR 332.9(b) and 381.189(b)). As noted in the preamble, such actions include regulatory control actions, withholding actions, and suspensions (74 FR 47655).

*Comment:* Some comments supported the proposed enforcement provisions. One comment stated that it is appropriate for the SECs to have the same authority to initiate enforcement actions with respect to selected establishments as FSIS inspection personnel are authorized to do with federally-inspected establishment. The comment also supported the proposed requirement that selected establishments provide FSIS officials with "access to all establishment records required under the Act and the implementing regulations in this chapter."

Some comments said that the proposed rule's enforcement provisions go beyond what is authorized under the statute and will result in duplicative efforts. The comments asserted that the designated State personnel, not the SEC, should be responsible for initiating enforcement action in selected establishments.

*Response:* Under the proposed rule, designated State personnel are responsible for providing the necessary inspection services to selected establishments in the State. The SEC is responsible for verifying that the designated personnel are providing inspection services in compliance with the Acts.

In the preamble to the proposed rules, FSIS explained that to verify that designated personnel are providing the necessary inspection services, 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 (74 FR 47655). Thus, the proposed rule makes clear that, as part of their inspection activities, designated State personnel are responsible for initiating enforcement actions in selected

establishments if such personnel determine that an enforcement action is authorized under 9 CFR part 500.

The 2008 amendments to the Acts provide 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 Administrator and (2) "deselect" the establishment or suspend inspection at the establishment (21 U.S.C. 683(d)(3)(C) and 472(d)(3)(C)). As explained in the preamble to the proposed rule, in adopting this language, Congress intended that the SEC " \* \* \* shall be provided all the tools necessary \* \* \* to prevent or control any food safety issue that would harm human health" (S. Rep. No. 220, 110th Cong., 1st Sess., at 211 (2007)). Therefore, to ensure that the SEC has the appropriate authority to address any food safety issues as required by the statutes, the proposed rule authorizes the SEC to initiate any appropriate enforcement action provided for 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.

Thus, under the proposed rule, designated State personnel are responsible for taking appropriate enforcement action for violations of Federal food safety standards in selected establishments when such actions are authorized under 9 CFR part 500. The SEC covering a selected establishment is also authorized to take any necessary enforcement actions if the SEC identifies the need to take such action when conducting oversight activities at a selected establishment.

*Comment:* One comment agreed with the proposed enforcement provisions and stated that selected establishments should be subject to Food Safety Assessments (FSAs) just as federally-inspected establishments are. The comment also maintained that NRs issued to selected establishments and other enforcement action should be made available through the Freedom of information Act (FOIA).

*Response:* States that participate in the cooperative interstate shipment program will need to conduct comprehensive FSAs in order to properly enforce Federal food safety standards. As discussed in the preamble to the proposed rule, the SEC will also be authorized to conduct an FSA, 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.

Any records that the States and selected establishment are required to provide to FSIS to allow the Agency to provide the necessary oversight and enforcement of the cooperative interstate shipment program, including NRs issued to selected establishments, will be made available to the public through the FOIA if the records are not subject to an exemption under the FOIA.

*Comment:* One comment stated that the final rule needs to specify an appeals process for non-compliances to ensure that all establishments that participate in the program understand the process and their rights.

*Response:* The proposed rule provided that selected establishments participating in the cooperative interstate shipment program would be subject to the notification and appeal procedures set out in 9 CFR part 500 (proposed 9 CFR 332.9(b) and 381.519(b)). Thus, the proposed rule did provide for an appeals process for non-compliances.

#### 6. SEC Duties—Quarterly Reports

As provided for in the law, the proposed rule provides that 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 9 CFR 332.8 and 381.518).

*Comment:* Some comments requested clarification on the type of information the SECs will be required to include in their quarterly reports. One comment asked whether the quarterly reports will include the SEC's assessment of the performance of the designated State personnel or of the selected establishments. One comment stated that the quarterly report should include the SEC's assessment of the State program's performance in providing inspection services to selected establishments and not be limited to the performance of the designated personnel.

*Response:* The proposed rule provided that the SEC quarterly report will: (1) Include the SEC's assessment of the performance of the designated personnel in conducting inspection activities at selected establishments and (2) 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 9 CFR 332.8(b) and 381.518(b)). Thus, the quarterly report includes the SEC's

assessment of the performance of both the selected establishments and the designated State personnel.

The designated personnel's ability to provide inspection services to selected establishments in a manner that complies with Federal standards reflects the State's ability to administer the cooperative interstate shipment program. Thus, the quarterly report will reflect the SEC's assessment of the State program's performance in providing inspection services to selected establishments.

*Comment:* One comment asserted that the SEC's do not need to visit selected establishments on a quarterly basis to complete the quarterly report. The comment stated that SECs will be able to determine the status of selected establishments based on routine reports and other documentation submitted by designated State personnel. Another comment stated that requiring an assessment on a quarterly basis would establish a burdensome Federal oversight process for States that participate in the program.

*Response:* As discussed above, the 2008 amendments to the Acts require that SECs visit selected establishments with a frequency that is appropriate to ensure that selected establishments are operating in a manner that is consistent with the Federal Act. There is nothing in the law to indicate that the SEC is to determine the status of selected establishments based on routine reports and other documentation submitted by designated State personnel, as suggested by the comments.

FSIS disagrees with the comment that stated that requiring an assessment on a quarterly basis would establish a burdensome Federal oversight process for States that participate in the program. As noted above, the 2008 amendments to the Acts require that the SECs prepare a quarterly report.

*Comment:* Some comments asked whether the State MPI programs would have a role in preparing the quarterly reports. One comment asked whether the States will receive copies of the quarterly reports from the SECs.

*Response:* The proposed rule provides that the SEC, in coordination with the State, will verify that selected establishments in the State are receiving the necessary inspection services from designated State personnel and that these establishments are eligible, and remain eligible, to participate in the cooperative interstate shipment program (proposed 9 CFR 332.8(b) and 381.517(b)). Although the SEC is responsible for preparing the quarterly reports, the SEC will coordinate with the State to assess the status of selected

establishments under the SEC's jurisdiction. FSIS will provide the State copies of the SEC's quarterly reports on the status of selected establishments in the State upon request.

#### *I. Deselection and Transition To Become Federal Establishment*

The proposed regulations provide that the FSIS Administrator will "deselect" a selected establishment that becomes ineligible to participate in the cooperative interstate shipment program (proposed 9 CFR 332.10(a) and 381.520(a)). The preamble to the proposed rule explained that an establishment could become ineligible for the program for various reasons, such as hiring additional employees or for violating the Federal Acts (74 FR 47656). The preamble also noted that establishments located in a State whose cooperative interstate shipment program was terminated would also be ineligible for the program. Consistent with the statute, the proposed regulations require that a deselected establishment be transitioned to become a Federal establishment (proposed 9 CFR 332.11 and 381.521).

##### 1. Establishment Deselection

*Comment:* One comment requested that FSIS provide more specific information on the circumstances in which an establishment will be deselected for non-compliance with the Acts. The comment asked whether a non-compliance report (NR) or a Notice of Intended Enforcement (NOIE) could result in deselection. According to the comment, NRs and NOIEs can sometimes be subjective depending on the inspection program personnel writing them. The comment encouraged FSIS and State inspection program directors to work with selected establishments that have non-compliances or enforcement actions against them to help those establishments come back into compliance and successfully continue within the program. The comment also asked FSIS to provide proper oversight and training to the SECs to ensure that the standards for non-compliances and enforcement actions are applied consistently across the country.

*Response:* As noted above, under the proposed rule, the SEC is authorized to initiate any appropriate enforcement actions authorized under the Agency's Rules of Practice in 9 CFR part 500, which include, among others, regulatory control actions, withholding actions, and suspensions (proposed 332.9(b) and 381.189(b)). The proposed regulations provide that if inspection at a selected establishment is suspended for any of



the reasons specified in 9 CFR 500.3 or 500.4, the Agency 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 (proposed 9 CFR 332.9(c) and 381.519(c)).

The proposed rule provides that the decision to deselect a selected establishment under a suspension will be made on a case-by-case basis (proposed 9 CFR 332.9(d) and 381.519(d)). The proposed rule also states that in making this decision the FSIS Administrator, in consultation with the State, 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 establishment (proposed 9 CFR 332.9(d) and 381.519(d)). Thus, under certain conditions, the proposed rule does authorize the FSIS Administrator to coordinate with the States to help selected establishments with non-compliances come back into compliance and successfully continue within the program.

FSIS will provide the SECs with the training they need to oversee and enforce the cooperative interstate shipment program in a manner that is consistent with the law and these implementing regulations.

*Comment:* One comment asserted that the State, not the SEC, should initiate deselection of a selected establishment. The comment noted that some States have not incorporated 9 CFR part 500 into their State laws or regulations. The comment suggested that instead of referencing 9 CFR part 500, the final regulations should give States the authority to take "appropriate enforcement action" against selected establishments when necessary.

*Response:* Consistent with the law, under the proposed regulations, designated State personnel are required to provide inspection services in compliance with the Federal Acts and implementing regulations. Part of the designated personnel's inspection duties involves taking appropriate enforcement actions when authorized to do so. The FSIS Rules of Practice in 9 CFR part 500 identify the conditions under which inspection personnel are authorized to take enforcement actions and include the criteria for when those actions are warranted. Thus, unless they follow the procedures prescribed in the FSIS Rules of Practice, designated State personnel will be unable to properly

enforce Federal standards in selected establishments.

Because States are responsible for providing inspection services to selected establishments participating in the cooperative interstate shipment program, the States may recommend that an establishment be deselected from the program if the State determines that the establishment is not complying with the requirements of the program. FSIS is likely to accept the State's recommendation.

## 2. Deselected Establishments To Become Official Establishment

*Comment:* Some comments supported the provisions in the proposed rule that require that establishments that become ineligible for the cooperative interstate shipment program be transitioned to become Federal establishments. These comments said that such a requirement is necessary to prevent establishments from attempting to move into and out of the program with no long-term commitment.

Several comments stated that requiring that a deselected establishment transition to become a Federal establishment is a disincentive for establishments to participate in the program and could force deselected establishments that choose not to come under Federal regulation out of business. One comment suggested that instead of requiring that deselected establishments transition to become Federal establishments, FSIS should allow them to implement corrective actions and revert back to State inspection.

*Response:* The 2008 amendments to the Acts authorize the Agency to establish a procedure to transition selected establishments that employ, on average, more than 25 employees to become Federal establishments (21 U.S.C. 683(b)(3)(A) and 472(b)(3)(A)). The 2008 amendments also require that selected establishments that the Administrator determines to be in violation of any provision of the Acts be transitioned to become Federal establishments in accordance with the procedure developed to transition selected establishments that employ more than 25 employees (21 U.S.C. 683(h) and 472(g)). Thus, requiring that deselected establishments be transitioned to become Federal establishments is necessary to implement the law. The law does not authorize FSIS to allow deselected establishments to revert back to the State MPI program without transitioning to become a Federal establishment, even if such establishments implement corrective actions.

*Comment:* Many comments stated that FSIS should allow establishments that have been deselected and successfully transitioned to become Federal establishments to revert back to the State MPI program if they choose. The comments stated that if FSIS is concerned that establishments might find it advantageous to periodically switch from under one jurisdiction to under another, the Agency could establish a reasonable time period, such as one-year, before an establishment that has transitioned to become a Federal establishment could revert back to a State's jurisdiction. One comment suggested that FSIS give establishments that have successfully transitioned to become Federal establishments the option to either revert to the State MPI program or be reselected for the cooperative interstate shipment program.

*Response:* After considering these comments, FSIS has decided to amend the proposed regulations to allow establishments that were deselected from the cooperative interstate shipment and that have successfully transitioned to become Federal establishments to revert back to the cooperative State MPI program after operating as a Federal establishment for one year.

As noted above, the 2008 amendments to the Acts require that establishments that are in violation of the Acts be transitioned to Federal establishments. The amendments also authorize FSIS to deselect and transition to Federal establishments selected establishments that consistently employ more than 25 employees on average. However, the statutes are silent on whether establishments that have successfully transitioned to become Federal establishments must remain in the Federal program or whether they can later revert back to the State program. Therefore, FSIS has determined that the law does not prohibit such an action.

Allowing deselected establishments that have successfully transitioned to become Federal establishments to revert back to the State MPI program will provide flexibility for establishments to determine which inspection system (Federal or State) best meets their needs. In addition, requiring that deselected establishments operate under Federal inspection for a year will promote food safety by ensuring that these establishments can perform in accordance with Federal standards before reverting back to the State program.

The statutes provide that the Administrator, in coordination with the States, shall not select for the

cooperative interstate shipment program, an establishment that is a Federal establishment (21 U.S.C. 683(b)(2)(C)(i), 683(b)(2)(F)). Thus, FSIS does not believe that the law would allow establishments that have been deselected from the cooperative interstate shipment program and transitioned to become a Federal establishment to be re-selected for the program at a later date.

### 3. Establishments Deselected for Exceeding Employee Threshold

*Comment:* A few comments suggested that FSIS allow selected establishments that were deselected and transitioned to become Federal establishments because they now have more than 25 employees on average to revert back to the State MPI program at a later date if they reduce their average number of employees to fewer than 25. One of these comments noted that it is not inconceivable that a selected establishment could quickly exceed its employee-based eligibility threshold, forcing it to transition to an official Federal establishment, only to later discover that it does not desire to maintain the larger operation. The comment stated that in such case, the establishment should not be prohibited from reverting back to State jurisdiction or from participating in the cooperative interstate shipment program if it reduces its average number of employees to fewer than 25.

One comment stated that selected establishments that have more than 25 employees on average should be required to transition to become Federal establishments, and that once they have transitioned, they should not be permitted to revert back to the State MPI program. The comment stated that selected establishments should anticipate that as they grow and add additional employees beyond the 25 employee limit, they will be transitioned to the Federal inspection system. The comment stated that it is essential that establishments not be permitted to “forum shop” for regulatory oversight. According to the comment, if establishments are meeting the requirements of the new program and are succeeding, there should be no reason why the establishments that outgrow this special program should not operate under Federal inspection.

One comment asked whether an establishment that was deselected because its average number of employees exceeded 25 rather than for food safety violations will remain ineligible to participate in the program in the future.

*Response:* As discussed above, FSIS has decided to amend the proposed rule to allow deselected establishments that have been transitioned to become Federal establishments to revert back to the State MPI program after successfully operating as a Federal establishment for one year. This amendment will apply to establishments that have been deselected for exceeding the average number of employees limit regardless of whether they reduce their average number of employees to fewer than 25 or not.

As noted above, because the law prohibits Federal establishments from being selected for the cooperative interstate shipment program, FSIS does not believe that it should permit establishments that have been deselected from the program and transitioned to become Federal establishments to be re-selected for the program at a later date, regardless of the reason for the deselection.

### Deselection and State Operations

*Comment:* One comment stated that if the final regulations resulting from the proposal allow selected establishments to produce some products under State inspection and other products under the cooperative interstate shipment program, FSIS must make clear that the provision that requires that deselected establishments transition to become Federal establishments only applies to operations conducted under the cooperative interstate shipment program. The comment asserted that selected establishments that produce certain products under a State MPI program should be permitted to continue these operations without transitioning to become a Federal establishment if the establishment is deselected from the cooperative interstate shipment program.

*Response:* The requirements associated with the cooperative interstate shipment program only apply to operations that State-inspected establishments conduct as part of that program. Thus, deselected establishments that conduct operations under both the cooperative interstate shipment program and the cooperative State MPI program will be required to transition the operations subject to the cooperative interstate shipment program to become a Federal establishment. These establishments may continue to produce products under the State MPI program if they maintain an appropriate separation by time or space between operations.

### 4. Voluntary Withdrawal

*Comment:* Several comments requested that FSIS give selected establishments that continue to be eligible for the cooperative interstate shipment program the option to voluntarily leave the program and revert back to operating under the State MPI program. The comments noted that after being selected for the cooperative interstate shipment program, some establishments may find that their businesses have changed such that they no longer need to ship their products interstate. The comments asserted that it makes no sense to force establishments that are in full compliance with the program's requirements but that no longer need to participate in the program to become Federal establishments.

Most of the comments that requested that selected establishments be permitted to voluntarily leave the cooperative interstate shipment program and revert back to their State MPI programs also said that FSIS should allow these establishments to re-enter the program at a later date. These comments acknowledged that the rules should prohibit State-inspected establishments from freely moving into and out of the program and suggested that the final regulations prescribe a waiting period that establishments that voluntarily leave the program must comply with before they may re-apply for the program. Most comments suggested a one-year waiting period, and one suggested a five year wait. One comment asked whether an establishment that voluntarily leaves the program will be allowed to re-apply for the program if it comes under new ownership at a later date.

*Response:* FSIS has considered these comments and has concluded that it would not be inconsistent with the law to allow a selected establishment that is in full compliance with the cooperative interstate shipment program to voluntarily leave the program and operate under a State grant of inspection.

The 2008 amendments to the Acts require that any establishment selected for the cooperative interstate shipment program that is in violation of any requirement of the Federal Acts be “transitioned to a Federal establishment” (21 U.S.C. 683(h) and 472(g)). However, the statutes do not address situations in which an establishment that is in full compliance with the Federal Acts elects to voluntarily withdraw from the program for business reasons, e.g., the establishment is in compliance with all

Federal standards but has been unable to establish a market for its products outside of the State. FSIS has concluded that allowing these establishments to voluntarily end their participating in the cooperative interstate shipment program will give them the flexibility they need to determine which inspection program can best meet their business needs.

FSIS has also decided to permit establishments that have voluntarily left the cooperative interstate shipment program to apply for and be re-selected for the program at a later date. Allowing these establishments to be re-selected for the program presents little concern about regulatory forum shopping because they would be leaving the program for business reasons and not because they are having difficulty meeting Federal food safety standards.

In addition, establishments that voluntarily withdraw from the cooperative interstate shipment program would need to re-apply through the State and be re-selected by the FSIS Administrator in coordination with the State in order to participate in the program again at a later date. Both FSIS and the States are unlikely to select an establishment that has a history of applying for and then withdrawing from the program. Therefore, FSIS has decided that the one-year waiting period suggested by the comment is a reasonable amount of time for establishments that voluntarily leave the program to wait before they may re-apply for the program. Such a policy will give establishments that are in full compliance with the program flexibility to re-apply for the program if, at a later date, they find that there may be a market for their products in other States.

*Comment:* One comment recommended that FSIS distinguish between selected establishments that want to withdraw completely from the program, and those that want to withdraw temporarily and resume operations under the program at a later date. According to the comment, such a distinction is necessary because many very small establishments operate on a seasonal basis or part of the year. The comment stated that the final regulations should include a process in which entities that operate on a seasonal basis could apply for a temporary withdrawal from the program. The comments said that the process could be similar to the process used by Federal establishments to apply for a temporary withdrawal of inspection.

One comment stated that it is not uncommon for very small establishments to operate infrequently or in response to local consumer demands. The comment noted that State

MPI programs are generally able to offer a great amount of flexibility in providing inspection services to these small establishments upon request. The comment recommended that FSIS provide for this type of practice in the final regulations implementing the cooperative interstate shipment program. The comment also stated that the decision to provide infrequent or sporadic inspection should be the State's.

*Response:* As explained above, selected establishments that are in compliance with the cooperative interstate shipment will be permitted to voluntarily withdraw from the program. However, if these establishments want to resume operations as a selected establishment, they will need to re-apply and be re-selected for the program by the FSIS Administrator in coordination with the States.

On the other hand, selected establishments that operate on a seasonal basis may also request a voluntary suspension of inspection from the State to cover times when the establishment does not operate. Selected establishments that are granted a voluntary suspension will not need to re-apply for selection to resume operations under the cooperative interstate shipment program. As suggested by the comment, the decision to provide infrequent or sporadic inspection in response to a request from a selected establishment will be the State's.

*Comment:* One comment suggested that FSIS consider implementing an open enrollment period during which State-inspected establishments could get in or out of the interstate shipment program without penalties, so long as they are qualified for the program. The comment said that FSIS could limit the number of times that establishments are allowed to make such changes. The comment claimed that such a program would give State-inspected establishments the option to take advantage of the program when it worked best for their business.

*Response:* The proposed regulations specified how State-inspected establishments that are interested in participating in the cooperative interstate shipment program are to apply for the program, and FSIS is amending the proposed regulations to allow selected establishments that are in compliance with the program to voluntarily end their participation. Therefore, FSIS has concluded that it is unnecessary to establish an open enrollment period in which State-inspected establishments that qualify for the cooperative interstate shipment

program could enter or withdraw from the program.

The proposed regulations require that State-inspected establishments that are interested in participating in the cooperative interstate shipment program apply for the program through the State in which the establishment is located (proposed 9 CFR 332.5(a)(1) and 381.515(a)(1)). The preamble to the proposed rule makes clear that States participating in the cooperative interstate shipment program will develop their own application procedures (74 FR 47653). Thus, State-inspected establishments that are interested in participating in the cooperative interstate shipment program will follow their State's application procedures to request that they be selected for the program.

As explained above, an establishment that has been selected for the cooperative interstate shipment program and that is in compliance with all of the programs requirements may voluntarily end its participation at any time. Such establishments will be permitted to re-apply for the program after a waiting period of one year.

#### 5. Termination of State's Cooperative Agreement

*Comment:* Several comments asserted that selected establishments that become ineligible for the cooperative interstate shipment program because their State's agreement for the program was terminated should not be required to transition to become Federal establishments. Instead, the comments suggested that FSIS give these establishments the option of either applying for a Federal grant or reverting back to the State MPI program. The comments said that establishments that are deselected because the State agreement is terminated have no control over the circumstances under which they were deselected and, therefore, it is unfair to require that they become Federal establishments.

A few comments asked FSIS to consider the impact of requiring that selected establishments transition to Federal establishments if the State's agreement for a cooperative interstate shipment program is terminated. According to the comments, such a requirement could affect the future viability of some of these establishments. The comments said that it would be devastating to local markets if deselected establishments had to shut down because they are not allowed to revert back to the State MPI program.

*Response:* The 2008 amendments to the Acts do not require that establishments that are no longer

eligible to participate in the cooperative interstate shipment program because they are located in a State whose agreement for such a program was terminated transition to become Federal establishments. Therefore, FSIS is amending the proposed rule to give these establishments the option to either revert back to the State MPI inspection program or obtain a Federal grant of inspection.

If a State's agreement for a cooperative interstate shipment program is terminated, some establishments that were operating under the cooperative interstate shipment program may be willing to forgo interstate shipment and revert back to the State MPI program because they prefer to receive inspection services from State personnel. Other establishments may prefer to continue to market their products interstate under a Federal grant of inspection. It only seems fair to give establishments that are in compliance with the requirements of the program, but that become ineligible because of a situation that is beyond their control, the option of transitioning to become a Federal establishment or reverting back to the State program.

*Comment:* One comment stated that the decision to terminate a State's agreement for a cooperative interstate shipment program should not be taken lightly or without considering circumstances unique to the State and its selected establishments. The comment suggested that FSIS revise the provision in proposed rule that states: "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 \* \* \*" to change "will" to "may." The comment stated that this revision will provide an appropriate degree of flexibility for the Administrator in deciding whether to terminate an agreement for a cooperative interstate shipment program.

*Response:* The proposed regulation provides that if the SEC determines that designated State personnel are providing inspection services to selected establishments in the State in a manner that is inconsistent with the Federal Acts and implementing regulations, the Administrator will provide an opportunity for the State to develop and implement a corrective action plan to address inspection deficiencies identified by the SEC (proposed 9 CFR 332.7(c) and 381.517(c)). The SEC will advise the State on the issues that the State needs

to address to ensure that the corrective action plan adequately addresses the deficiencies identified by the SEC. However, if the State fails to develop a corrective action plan that adequately addresses the issues identified by the SEC, FSIS believes that the Administrator has no choice but to terminate the cooperative agreement. Therefore, the Agency is not changing "will" terminate the agreement to "may" terminate the agreement, as suggested by the comment.

#### 7. Transition Procedures

*Comment:* The proposed regulations 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. One comment stated that FSIS needs to clearly state the procedures needed to transition a selected establishment to become a Federal establishment to ensure that all States and establishments that are interested in participating in the program agreement fully understand all of the requirements and potential consequences of deselection.

*Response:* The 2008 amendments to the Acts authorize FSIS to develop a procedure to transition selected establishments to become Federal establishments if they employ more than 25 employees on average, or if the Administrator determines that they are in violation of any provision of the Acts (21 U.C.S. 683(b), 683(h), 472(b) and 472(h)). In the preamble to the proposed rule, the Agency explained that it was not prescribing specific procedures to transition selected establishments to become official establishments because the actions needed to successfully make such a transition are likely to depend on the reason the establishment was deselected (74 FR 47656). As an example, FSIS noted that an establishment that was deselected for violating the Acts would likely need to develop a corrective action plan to transition to an official establishment, while an establishment that was deselected for hiring additional employees would not.

Therefore, consistent with the proposal, FSIS has decided to not prescribe specific procedures to transition selected establishments to become Federal establishments, as suggested by the comment. As was proposed, if a selected establishment is deselected from the cooperative interstate shipment program, FSIS will coordinate with the State where the establishment is located to develop and implement a plan to transition the

establishment. As noted in the preamble, at a minimum, such a plan will include: (1) Adding the establishment to an FSIS circuit; (2) replacing the establishment's State establishment number with a Federal number; and (3) replacing the designated personnel with FSIS personnel.

*Comment:* One comment noted that in the proposed rule FSIS outlined some general procedures that would be necessary to transition a selected establishment to become a Federal establishment (e.g., changing the establishment number and replacing state personnel with FSIS inspection personnel) but that the Agency also explained it would collaborate with the States to implement specific transition procedures on a case-by-case basis. The comments stated that while this approach may be appropriate in dealing with individual establishments in a State, FSIS should develop specific procedures for instances when the State's agreement for a cooperative interstate shipment program is terminated.

*Response:* As discussed above, under this final rule, establishments that are no longer eligible to participate in a cooperative interstate shipment because they are located in a State whose agreement for such a program was terminated will have the option to either revert back to the State MPI inspection program or obtain a Federal grant of inspection. Selected establishments that choose to operate under Federal inspection will need to transition to become a Federal establishment. FSIS will coordinate with the State where the establishment is located to develop and implement a plan for the establishment to obtain a Federal grant of inspection. Selected establishments that choose to revert to the State MPI program will need to obtain a State grant of inspection through the State in which they are located.

#### J. Federal Contribution, Technical Assistance, and Transition Grants

##### 1. Federal Contribution 60% State Costs

As noted in the preamble to the proposed rule, the statute requires that the Federal contribution for inspection services provided by States that enter into an agreement for a cooperative interstate shipment program be at least 60% of eligible State costs. In the preamble, FSIS also explained that the Agency had tentatively concluded that eligible State costs are 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 (74 FR 47650). The Agency requested comments on whether it should codify this definition or any other requirements related to State reimbursement for eligible costs in the final rule.

*Comment:* Comments submitted by both State Departments of Agriculture and consumer advocacy organizations stated that FSIS should codify requirements related to reimbursement of States for at least 60% of their eligible costs associated with the cooperative interstate shipment program. According to some comments, codifying these requirements would provide both States and FSIS personnel with consistent guidance on the level of reimbursement and requirements for receiving payment under the program. The comments also said that codifying the reimbursement requirements will prevent ad hoc interpretations and inequitable reimbursement policies over time.

Some comments requested that FSIS more clearly define "eligible costs." The comments specifically asked whether the following State costs would be considered eligible costs under the final rule: (1) Federal Indirect Cost Reimbursement to pay for office and administrative support services; (2) rent for computers, (3) administrative offices and field staff offices; and (4) fees associated with information technology and laboratory services.

One comment supported the proposed definition of eligible State costs as those direct 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 comment argued that these are Federal taxpayer dollars that should be spent on Federal programs. The commenter stated that it understands that the law requires FSIS to reimburse States not less than 60% of eligible State costs but, according to the comment, such reimbursement should be confined to direct costs only. The comment asserted that costs that fall under Federal Indirect Cost Reimbursement definitions should not be included.

*Response:* To be reimbursed for 60% of their eligible costs to administer the cooperative interstate shipment program, States will need to follow the same financial accountability and budget submission requirements needed to receive the maximum 50% Federal reimbursement under the cooperative State MPI program. These requirements include, but are not limited to, the administrative rules for Federal grants and cooperative agreements prescribed in USDA's Uniform Administrative Requirements for Grants and

Cooperative Agreements to State and Local Governments regulations (7 CFR part 3016), as well as the principles provided in the Office of Management and Budget's (OMB) circular A-87 "*Cost Principles for State, Local, and Indian and Tribal Governments*" (2 CFR Part 225); OMB circular A-102, "*Grants and Cooperative Agreements with State and Local Governments*"; and OMB circular A-133, "*Audits of States, Local Governments, and Non-Profit Organizations*".

FSIS will only reimburse 60% of a State's costs to administer the cooperative interstate shipment program if the State can justify that the costs are necessary to provide inspection services to selected establishments in the State and that the costs are allowable under the applicable Federal cost principles or other terms and conditions of the cooperative agreement. To make this clear, FSIS is codifying the definition of eligible State costs that it had tentatively decided on in the proposed rule. Thus, 9 CFR 321.3 and 381.187 of this final rule provide that for purposes of the cooperative interstate shipment program, eligible State costs are 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 Federal requirements and procedures for the financial administration and operation of cooperative State agreements are described in FSIS Directive 3300.1 "*Fiscal Guidance for Cooperative Inspection Programs*". These requirements and procedures apply to all cooperative inspection program agreements, including agreements for the cooperative interstate shipment program. FSIS will update directive 3300.1 to specifically address the cooperative interstate shipment program.

*Comment:* One comment asked whether a State's administrative costs to begin an interstate shipment program will be eligible for at least 60% reimbursement from FSIS. The comment also asked whether there is anything in the program that would prohibit a State from charging an establishment a fee to participate in the program to help cover the State's additional costs. Another comment asked whether the final rule will require that States submit separate financial reports for inspection costs associated with the State MPI program and for costs associated with the cooperative interstate shipment program.

*Response:* As noted above, FSIS will only reimburse 60% of a State's costs to administer the cooperative interstate

shipment, including the administrative costs to begin the program, if the State can justify that the costs are necessary to provide inspection services to selected establishments in the State and that the costs are allowable under the applicable Federal cost principles or other terms and conditions of the cooperative agreement. The 2008 amendments to the Acts are silent on whether a State may charge an establishment a fee to participate in the cooperative interstate shipment program. The proposed rule provides that States are responsible for developing their own procedures for establishments to apply to be selected for the cooperative interstate shipment program.

The agreement between FSIS and a State for a cooperative interstate shipment program is separate from the cooperative State MPI agreement. Therefore, States that participate in the cooperative interstate shipment program will be required to submit separate financial reports for inspection costs associated with the State MPI program and for costs associated with the cooperative interstate shipment program. The States must also clearly document the time and cost that they spent to provide administrative support for the State MPI program versus the time and cost needed to provide administrative support for the cooperative interstate shipment program.

*Comment:* Some comments supported the requirement that Federal reimbursement for the cooperative interstate shipment program be in an amount of not less than 60% of eligible State costs. The comments urged FSIS to provide more funding if, and when, the budget allows.

One comment stated that in order for the program to succeed, it is critically important for FSIS, the Obama Administration, and Congress to commit sufficient resources to carry out the program. The comment stated that under no circumstances should FSIS be required to absorb these resources from its existing budget.

One comment stated that the higher the Federal contribution, the more likely it is that State programs will be able to participate in the interstate shipment program. The comment encouraged FSIS to be creative in finding ways to increase the Federal contribution to the program. The comment noted that cash infusions are the best way to support the program, but that other contributions, such as equipment (including computers discussed above) and services (including training and

laboratory services), would also be helpful.

*Response:* FSIS agrees that the success of the cooperative interstate shipment program will depend on the level of funding that Congress provides for the Agency to administer the program.

## 2. Technical Assistance and Outreach

As required by the statute, FSIS established the Office of Outreach Employee Education and Training (OOEET) 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” (21 U.S.C. 683(f)).

In the preamble to the proposed rule, FSIS explains that the Agency 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. FSIS received several comments and suggestions on how OOEET should provide outreach and technical assistance to support the cooperative interstate shipment program. FSIS has included a general description of these comments below. However, OOEET’s outreach and assistance activities were not specifically addressed in the proposed rule. Thus, these comments are outside the scope of this rulemaking.

*Comment:* Some comments encouraged OOEET to work with other Federal agencies to assist establishments that are interested in participating in the cooperative interstate shipment program to acquire grants or loans to fund modifications that they may need to make to their facilities in order to comply with Federal standards. The comments noted that in the preamble to the proposed rule, FSIS estimated that establishments that need to make structural modifications or perform new construction could incur costs in the range of \$15,000 to \$30,000. The comments said that the States should not be expected to fund these costs.

A few comments suggested that FSIS use USDA’s “Know Your Farmer, Know Your Food” initiative to provide information about USDA grant and loan programs to help small and very small facilities upgrade their infrastructure.

The consumer advocacy organization Food and Water Watch submitted identical comment letters on behalf of 5,083 private citizens. The comment letters supported FSIS’s proposed

regulation implementing the cooperative interstate shipment program. The comments also suggested that FSIS take a number of actions to ensure that the change to the new program goes smoothly and is feasible for States and small establishments.

Three comments reference a report issued by Food and Water Watch entitled “Where’s the Local Beef?” The comments stated that the report provides a number of recommendations that FSIS should consider for the technical assistance required under the statute. The comments encouraged FSIS to consider these recommendations.

One comment stated that to ensure that States and establishments receive the assistance that they need to participate in the program, the Administration must budget, and Congress must appropriate, adequate funding for outreach and training activities. The comment said that, in particular, OOEET will need sufficient resources to conduct workshops, training sessions, and other activities to ensure that small and very small establishments in the new program understand the requirements they are expected to meet.

*Response:* As noted above, the issues raised by these comments are outside the scope of this rulemaking. However, the Agency will take them into consideration when it implements this final rule.

## 3. Transition Grants

Under the statute, FSIS is authorized to provide “transition grants” to States to assist the States in helping State-inspected establishments transition to selected establishments (21 U.S.C. 683(g) and 472(f)). In the proposed rule, FSIS explained that it has tentatively decided to define transition grants as 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 individual in HACCP requirements for meat and poultry products and associated training in the development of Sanitation SOPs.

FSIS received several comments on the proposed definition of transition grants.

*Comment:* Some comments supported FSIS’ tentative conclusion to use its transition grant authority to reimburse States for the costs of HACCP training for establishment employees as an appropriate use of these funds. According to one comment, FSIS has already created a division to provide technical assistance for small and very small establishments, *i.e.*, OOEET, so it is not necessary to provide transition

grants to the States to use for duplicative outreach services.

Other comments said that the proposed transition grant definition is too narrow, unnecessarily restrictive, and does not reflect the fact that training may be more urgently needed in other areas essential to food safety, such as microbiological sampling, process control, validation, determination of HACCP Critical Limits, or use of modern monitoring techniques. The comments suggested that FSIS revise the definition to allow the funds to be used to provide outreach, technical assistance, education, and training that establishments may need to become selected establishments and maintain this designation.

Other comments stated that while HACCP training is an appropriate use of transition grants, it should not be the only use permitted for these funds. The comments asserted that transition grants could be used in some States for relevant state and local agencies to convene workshops and listening sessions on the application of local, State and Federal food safety regulations on small and very small processing establishments. The comments asserted that these workshops could generate approaches to improve and streamline food safety regulations, including HACCP requirements, to ensure that they are appropriate for achieving food safety standards in smaller facilities.

A few comments stated that FSIS should permit transition grant funds to be used for tangible items, such as facility upgrades or other one-time start up costs for establishments to become eligible for the cooperative interstate shipment program. One comment said that, if necessary FSIS could limit the amount it would provide to States to reimburse selected establishments to \$5,000 per establishment, which was the Agency’s estimated cost to train an individual in HACCP.

Two comments submitted by animal welfare advocacy organizations stated that, in addition to HACCP training, FSIS should also allow States to use transitions grant funds to reimburse selected establishments for their costs to train personnel in humane handling and humane slaughter.

*Response:* The comments indicate that there is a general lack of consensus on the appropriate use of transition grant funds. Therefore, because the comments offered no compelling reason to change it, FSIS is adopting the proposed definition of transition grant as 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 HACCP requirements for meat and poultry products and associated training in the development of Sanitation SOPs.

FSIS has very limited authority for and experience in administering grants for financial assistance outside the scope of cooperative inspection programs, and its food safety focus suggests that it would be of limited value for the Agency to gain such experience. Other USDA agencies, such as Rural Development and the National Institute for Food and Agriculture provide loans and grants of the kind that might be useful for establishments that may need to make modifications to their facilities to become eligible for the cooperative interstate shipment program. FSIS will coordinate with these other USDA agencies in developing and publicizing such programs, but will defer to them as USDA's loan and grant program specialists.

A limited grants program to provide Federal funds to States so that they may reimburse selected establishments for HACCP training is, however, consistent with FSIS's authorities and capabilities. It will help to ensure that establishments that participate in the cooperative interstate shipment program are able to comply with Federal food safety standards. Limiting the use of transition grants to HACCP training for one individual will ensure that the costs associated with these grants are limited, predictable, and simple to monitor.

*Comment:* One comment requested that FSIS provide more details on the transition grants. The comment noted that while funds from transition grants will be available to help establishments with the costs of training on HACCP and SSOPs, some establishments are likely to have already completed the necessary HACCP training. For those establishments, the comment asked whether States could use transition grant funds to reimburse the establishment's costs to send an employee to advanced HACCP training courses or to send another employee for training in basic HACCP and SSOPs. The comment also asked if the grant includes all costs associated with the training, from travel costs to the cost of registration or materials.

*Response:* The proposed rule requires that States use transition grant funds to reimburse selected establishments for their costs to train one individual in HACCP requirements for meat and poultry products as required under 9 CFR 417.7 of the HACCP regulations and associated training in the development of Sanitation SOPs. These regulations require that the individual

successfully complete a course of instruction in the application of the seven HACCP principles to meat or poultry product processing. Thus, transition grant funds may be used to reimburse the costs associated with the basic training required to comply with 9 CFR 417.7, which does not include advanced HACCP training. The transition grant would include any costs that the establishment can demonstrate were necessary to provide HACCP training to one individual.

#### *K. Potential Benefits*

FSIS received several comments on the potential benefits of allowing small and very small State-inspected establishments to ship meat and poultry products in interstate commerce. Following is a general description of these comments categorized by potential benefit.

##### **1. Expand Markets for Small Establishments**

Several comments said that allowing State-inspected products to ship meat and poultry products interstate will benefit small and very small State-inspected establishment by providing new markets for their products. The comments also stated that, as small processors expand their markets, consumers will also benefit from an increase in product choice.

##### **2. Rural Development**

Some comments stated that, if implemented correctly, the cooperative interstate shipment program will provide opportunities for rural development. One comment said that a workable cooperative interstate shipment program will stimulate small business sales, expand rural development and jobs, and increase local tax bases, strengthening the stability of rural communities. Another comment noted that increasing the market opportunities for small processors is important to rural development because it will help to maintain and increase jobs in the rural areas where many of these small processors are located.

##### **3. Small Farmers and Livestock Producers**

Several comments stated that allowing State-inspected processing plants to ship products interstate will benefit small farmers and local livestock and poultry producers by providing them with access to processing plants that can sell meat and poultry products across State lines. The comments noted that farmers rely on processing plants to sell their products to consumers, and

that allowing interstate shipment of State-inspected products will help family farmers raising livestock and poultry, as well as small processing plants, to increase their access to larger markets.

One commenter had conducted a survey of farmers across the country in spring 2009 to identify barriers to local food marketing. The comment noted that by far, the number one barrier mentioned was access to processing plants for meat, poultry, and value-added crops.

Several comments said that, in addition to expanding markets for local livestock and poultry producers, allowing small State-inspected processing plants to ship products interstate will also benefit these local producers by reducing travel costs that many must incur to send their livestock to a federally-inspected establishment. One comment said that a producer in central Wyoming estimated that he could save almost \$220,000 per year if he could have his animals processed locally in a state-inspected establishment. Some comments noted that many small livestock and poultry producers prefer to have their products processed in small State-inspected establishments, but that for some of these producers, the closest small processing establishment may be located across State lines.

Some comments stated that the cooperative interstate shipment program could benefit cattle producers by increasing the demand for beef. The comment said that allowing state-inspected establishments to ship interstate will provide many smaller packing plants with an opportunity to expand into new markets. According to the comment, growth and new opportunities for these smaller plants means that they will have the opportunity to buy more cattle from producers. The comment asserted that this further demand for cattle will provide more competition in the market and will potentially provide more opportunities for cattlemen.

One comment stated that the increased market opportunities for small processors will be passed on to livestock and poultry producers, which will lead to increased on-farm revenues.

A few comments stated that the proposed cooperative interstate shipment program will offer independent family farmers and niche producers whose operations use humane and sustainable animal agricultural practices greater opportunity to market their products to a broader range of consumers. One comment believed that the proposed



rule has the potential to benefit small organic livestock operations. According to the comment, it is often difficult for these producers to find local slaughter or processing facilities.

One comment stated that the proposed interstate shipment program has the potential to benefit not only family farmers but the animals they raise by reducing the stress associated with long transport times to slaughter.

Some comments stated that the proposed rule will enhance the USDA's "Know Your Farmer, Know Your Food" initiative by helping to break down structural barriers that have inhibited local food systems from thriving.

#### 4. Protect Public Health

One comment stated that the proposed program will protect public health by facilitating traceback of State-inspected products that may be the subject of a recall.

*Response:* FSIS agrees that these comments all identify potential benefits associated with the cooperative interstate shipment program.

##### *L. Interstate Shipment and Humane Handling of Livestock*

*Comment:* A few comments noted that the proposed rule did not mention the Federal Humane Methods of Slaughter Act (HMSA). One comment stated that, while the FMIA incorporates the HMSA by reference, it is imperative that FSIS make clear in the final rule's codified text that establishments must be in compliance with the HMSA and all State humane handling requirements to be eligible for the cooperative interstate shipment program.

One comment stated that in May 2008, the commenter published a report on the enforcement of humane slaughter laws in the United States. The comment explained that the report included results from a series of public records requests that the commenter made to the 30 States accredited to administer the Federal humane slaughter laws (the 27 States with cooperative agreements for State MPI programs and 3 States with cooperative programs for custom plants).

Based on this report, the comment concluded that most states that operate meat inspection programs are not enforcing the HMSA at state-inspected establishments. The comment said that small state-inspected establishments are probably less likely to have staff and management with training in humane handling and slaughter as Federal establishments, and that small state-inspected establishments are also probably less likely to have specialized equipment for proper animal handling

or a facility design that promotes humane handling and slaughter.

*Response:* To qualify for the cooperative interstate shipment program, establishments will need to comply with, and States will need to enforce, standards that are "the same as" those imposed under the Federal Acts and implementing regulations. As noted by the comments, the FMIA incorporates the HMSA by reference. Therefore, selected establishments must comply with, and participating States must enforce, humane handling procedures that are "the same as" those imposed under the HMSA and FSIS's implementing regulations.

Because the FMIA incorporates the HMSA, it is not necessary to include additional requirements to implement the HMSA in the regulations implementing the cooperative interstate shipment program.

*Comment:* One comment suggested that as part of its outreach efforts to small and very small establishments, FSIS include training in the humane handling of livestock and poultry during slaughter and processing. One comment suggested that FSIS grade and identify establishments based on how humanely they raise their livestock.

*Response:* These comments are outside the scope of the proposed rule.

##### *M. Miscellaneous Comments*

*Comment:* A few comments noted that many small and very small establishments process bison, elk, and other species that are not amenable to the Federal Acts. The comments asked whether FSIS would address the processing of these species in the final rule implementing the cooperative interstate shipment program. One comment asked whether the final regulations will permit selected establishments to continue to slaughter non-amenable species under the State inspection program. The comment also asked whether the "same as" standard proposed for the cooperative interstate shipment program will affect State-inspected operations related to non-amenable species.

*Response:* The cooperative interstate shipment program does not cover operations for the processing of bison, elk, and other species that are not amenable to the FMIA or PPIA. However, as discussed above, this final rule will allow State-inspected establishments to operate under both the State MPI program and the cooperative interstate shipment program. Under this final rule, selected establishments may continue to slaughter and process non-amenable species under the State inspection

program as long as they maintain an appropriate separation of time or space between these operations and the operations conducted under the cooperative interstate shipment program. Because operations associated with non-amenable species are not eligible for the cooperative interstate shipment program, these operations are not affected by the "same as" standard required for the program.

*Comment:* One comment stated that FSIS must make clear in the final rule that state-inspected horse slaughter facilities are not eligible to participate in the new cooperative interstate shipment program. The comment noted that currently there are no such facilities in operation in the United States, but expressed concern that providing certain state-inspected establishments access to the interstate market may encourage some small establishments to initiate new horse slaughter operations. The comment stated that Congress has made its intent clear that Federal funding must not be used to inspect such facilities, and FSIS must not allow establishments to use the cooperative interstate shipment program to circumvent the law.

The comment also stated that any attempt by FSIS to regulate horse slaughter facilities must comply with the National Environmental Policy Act, 42 U.S.C. 4231 *et seq.*, and cited *Humane Society of the United States v. Johanns* (520 F.Supp.2d 8 (D.D.C. 2007)) to support this statement. The comment asserted that unless FSIS makes clear that the final rule does not encompass horse slaughter, the Agency will need to prepare an Environmental Impact Statement or Environmental Assessment before finalizing the rule to avoid a potential violation of a federal court order.

*Response:* As noted by the comment, the FY 2010 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act prohibits the use of appropriated funds and user fees to pay the salaries of expenses of personnel to inspect horses prior to slaughter for human food (Pub. L. 111–80, § 739). FSIS will comply with these and any future restrictions on the use of appropriated funds as it implements the cooperative interstate shipment program.

*Comment:* One comment suggested that, when developing the final rule to implement the cooperative interstate shipment program, FSIS should review its data on FSAs, NRs, suspensions, HACCP deviations, number of lab tests, and laboratory results to compare FSIS regulatory oversight of very small State-



inspected establishments with large and small establishments. According to the comment, this information may help identify specific areas of concern that the Agency should address in the final rule.

*Response:* FSIS believes that this final rule provides the appropriate level of Federal oversight required under the 2008 amendments to the Acts. The data identified by the comment will be useful to FSIS in overseeing the program.

*Comment:* One comment asked whether the labels for products produced in establishments selected to participate in the cooperative interstate shipment program will be granted expedited review so that they can begin to operate under the new program more quickly. The comment also asked whether such labels would be approved by the FSIS Labeling and Program Delivery Division (LPDD). The comment stated that it would be disappointing if an establishment's ability to participate in the cooperative interstate shipment program was delayed because of the label approval process.

*Response:* The labels of meat and poultry products produced under the cooperative interstate shipment program will be subject to FSIS' prior label approval system to ensure that such labels comply with Federal labeling requirements. The SEC for the State where a selected establishment is located will coordinate with the State to facilitate the label submission process. The SEC will also verify that the labels applied to meat and poultry products produced under the cooperative interstate shipment program have been evaluated and approved by LPDD, except for generically approved labeling authorized for use in Title 9 of the Code of Federal Regulations (CFR), §§ 317.5 and 381.133. Because the labels of meat and poultry products produced in selected establishments are required to bear a Federal mark, it is essential that these labels comply with all Federal labeling requirements.

*Comment:* One comment requested that FSIS explain whether, under the final rule, *E. coli* O157:H7 would be considered an adulterant if detected on an intact muscle cut of beef. The comment asserted that if *E. coli* O157:H7 is only considered an adulterant if it is detected in a ground beef sample, selected establishments whose operations are limited to further processing will be subject to enforcement action, i.e., deselection, for upstream contamination over which they have no control.

Two comments suggested that in the final rule, FSIS add a provision to

ensure that selected establishments whose operations are limited to further processing are not subject to enforcement actions for product contamination that originated in an upstream slaughter facility.

*Response:* These comments address issues associated with FSIS's existing policies with respect to *E. coli* O157:H7. They are outside the scope of this rulemaking.

*Comment:* One comment stated that processors and regulatory staff have been trained to recognize "shall" as an indication of mandatory requirements. The comment inserted suggested revisions to the proposed codified text, such as replacing "will" with "shall." According to the comment, the suggested revisions are needed to make clear which provisions of the regulations are mandatory.

*Response:* This is the only comment to make these suggested revisions. FSIS believes that the language in the codified text clearly articulates the requirements associated with the cooperative interstate shipment program.

*Comment:* One comment noted that throughout the proposed regulations FSIS uses the terms such as "in compliance with the Acts" or "consistent with the Acts." The comment stated that since State meat and poultry inspection programs already comply with the FMIA and PPIA, FSIS needs to make clear that most references to "the Act" in the proposed regulation are intended to refer to the new legislation, i. e., Title V of these Acts. According to the comment, Section 11015 of the 2008 Farm Bill did not amend the existing sections of FMIA and PPIA, but rather created a new section in each of these Acts. The comment suggested that FSIS revise "in compliance with the Acts" to "in compliance with this Act" to make this clear.

*Response:* In the final codified text, "this Act" was changed to "this chapter." As used in the statutes, "this chapter" means the FMIA and PPIA, not section 11015 of the 2008 Farm Bill (see 21 U.S.C.A. 683 and 472, Historical and Statutory Notes, References in Text). Thus, the terms "in compliance with the Acts" or "consistent with the Acts" better reflect the intent of the statutes than "in compliance with this Act" meaning section 11015 of the 2008 Farm Bill.

Executive Order 12866 and Regulatory Flexibility Act

This final 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 (MPI) 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 is voluntary, FSIS will not know how many States and establishments will apply to participate until this final rule becomes effective and establishments are selected for the program.

In the proposed rule's Preliminary Regulatory Impact Analysis (PRIA), FSIS explained that information obtained through the Agency's outreach activities indicated that, as of July 2008, about 170 establishments in sixteen States had approached the State MPI programs to express interest in the new cooperative interstate shipment program. These sixteen States have in total 1,133 establishments that could potentially be eligible for the new program. However, more recent Agency outreach activities conducted after the proposed rule was published indicate that there now may be only four States interested in participating in the cooperative interstate shipment program.<sup>3</sup> The four States that have recently expressed interest in the program are North Dakota, Ohio, Wisconsin, and Vermont. According to the State Directors of these four States, the total number of establishments in these States that might participate is between 27 and 102, and the actual number will depend on the language of the final rule. This finding is consistent with information provided in the public comments submitted in response to the proposed rule that indicated that the participation number we estimated in the proposed rule was too high. Therefore, we have adjusted the budget impact downward by incorporating the new information.

#### 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, this final

<sup>3</sup> These four States have each signed an agreement with the Agency to conduct a comparative analysis to determine what the States would need to do to meet the "same as" requirements for the cooperative interstate shipment program. FSIS provided funds for the States to conduct the assessment.

rule will benefit these establishments by opening new markets for their products.

This final rule will also benefit consumers by generating more product choices, as more products can be shipped to new markets. In addition, requiring that products produced under the cooperative interstate shipment program bear a Federal inspection legend that includes an official State selected establishment inspection number will allow consumers to identify that these products were produced under the cooperative interstate shipment program if such products are ever the subject of an investigation or recall.

States that participate in the program will benefit because the law requires that FSIS reimburse them for at least 60% of their eligible costs related to inspection of selected establishments in the State. FSIS provides up to 50% of the costs to provide inspection under the existing cooperative State MPI programs. States are likely to 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 greatly exceed the costs to administer the State MPI programs.

The Agency received several comments that identified additional potential benefits of allowing small and very small State-inspected establishments to ship meat and poultry products in interstate commerce. These benefits include:

1. Rural development: Allowing certain small and very small State-inspected establishments to ship their products across State lines may stimulate small business sales, expand rural development and jobs, and increase local tax bases, strengthening the stability of rural communities, where many of these small establishments are located.

2. Benefits for small farmers and livestock producers: Allowing State-inspected processing plants to ship products in interstate commerce will benefit small farmers and local livestock and poultry producers by providing them with access to processing plants that can sell meat and poultry products across State lines. It will also benefit local producers by reducing travel costs that many must incur to send their livestock to a federally-inspected establishment, as the closest small processing establishment may be located across State lines.

#### Expected Costs of the Proposed Action

1. *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 in 2008, in the PRIA of the proposed rule, the Agency estimated 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. FSIS did not receive any comments or new information in response to the proposed rule to suggest changes to these estimates.

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. If the establishments need to make structural modifications or perform new construction, the estimated range would be about \$15,000 to \$30,000.<sup>4</sup> However, because the cooperative interstate shipment program 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 participation will provide an overall net benefit for them.

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 MPI programs are not identical to the Federal inspection program. FSIS anticipates that States may need to modify their existing inspection procedures when providing inspection services to selected establishment in the State to ensure that these establishments receive inspection services that are "the same as" those required under the Federal program. However, since the State programs are required to be "at least equal to" the Federal inspection programs now, FSIS anticipates that changes that States will need to make to provide inspection to selected establishments 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.

2. *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.

One area the States will have to address is the laboratory services that they will be using to analyze samples collected under the cooperative interstate shipment program. To demonstrate that the laboratory services used by a State are sufficient for the State to qualify for the cooperative interstate shipment program, the State will need to show that the laboratory is accredited by an internationally recognized organization that accredits food testing laboratories against the ISO 17025 "General requirements for the competence of testing and calibration laboratories" and AOAC "Guidelines for Laboratories Performing Food Microbiological and Chemical Analyses of Food and Pharmaceuticals Testing" written by the Analytical Laboratory Accreditation Criteria Committee (ALACC). The assessment body that FSIS uses, the American Association for Laboratory Accreditation (A2LA), is the sole organization that incorporates ALACC into their program requirements. State labs would need to use A2LA or another accrediting body that incorporates ALACC and is a signatory and in good standing to the Mutual Recognition Arrangements of

<sup>4</sup> Note that under this final rule, establishments selected for the program will be eligible to be reimbursed the cost to train one employee in HACCP and Sanitation SOPs.

the International Laboratory Accreditation Cooperation (ILAC).

Currently three State labs are ISO 17025 accredited—Minnesota, North Carolina, and Florida (FL does not have a State MPI program), four States are actively seeking ISO 17025 accreditation—Ohio, Wisconsin, North Dakota, and Vermont, and four States use commercial labs that are ISO accredited.

States that use laboratories that do not use the methods described in FSIS's Laboratory Guidebooks may incur costs to adopt such methods to analyze samples under the cooperative interstate shipment program. If a test or product described in the FSIS Guidebook is not commercially available, FSIS will assist the laboratory in developing an appropriate alternative method.

To assist the States in developing laboratory services that are “the same as” those provided under the Federal inspection program, FSIS is adopting a “phased in” approach for the States to become ISO 17025 accredited. FSIS's Office of Public Health Science (OPHS) intends to provide advice and answer questions from State labs as they seek ISO accreditation. FSIS estimates the cost for a State lab to obtain the necessary accreditation to be “the same as” to be somewhere between \$28,000 and \$350,000. These costs reflect the costs associated with purchasing additional equipment, hiring additional staff (QC manager for Chemistry, QC manager for Microbiology, Document

Control Clerk, and additional analysts,) the initial application fee to apply for ISO 17025 accreditation, the annual fee to maintain accreditation, and the accrediting body's assessment fee.

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>5</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. In addition, as noted above, FSIS offers training courses in Federal inspection methodology to State inspection personnel. FSIS's OOEET will coordinate with States participating in the cooperative interstate shipment program to provide the necessary training for designated State personnel.

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.

FSIS anticipates that States may need to revise their State inspection procedures when providing inspection services to selected establishments in the State to ensure that these inspection services are “the same as” those provided under the Federal program. However, since the cooperative State MPI 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.

#### Expected FSIS Budgetary Effects

The new cooperative interstate shipment program that we are implementing in this final rule is expected to have budgetary effects on FSIS. 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. The PRIA in the proposed rule presented a baseline scenario outlining the Agency's spending for the Federal-State cooperative inspection programs for FY 2009 through 2014 in case the cooperative interstate shipment program option is not enacted (see table below).<sup>6</sup> We did not receive any data or comment in response to the proposed rule to suggest changes to these numbers.

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

FSIS level costs, fiscal year	2010 (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	.....
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	.....

<sup>5</sup> Based on Agency's most recent (FY 2009) 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.

<sup>6</sup> For details, including assumptions, for the baseline scenario, please see the proposed rule

“Cooperative Inspection Programs: Interstate Shipment of Meat and Poultry Products,” September 16, 2009, 74 FR 47658–47659.

### 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.

As noted above, in the proposed rule, through its outreach activities, FSIS had identified sixteen States that expressed an interest in the new cooperative interstate shipment program. These States have a total of 1,133 establishments that could potentially be eligible for the new program. Because participation in the cooperative interstate shipment program is voluntary, the Agency could not estimate with certainty the number of eligible establishments that will choose to participate. Therefore, in the proposed rule, for illustration purposes, the Agency estimated the costs for three scenarios: 200, 400 and 600 establishments.

However, comments received in response to the proposed rule suggested that the Agency overestimated both the number of States and establishments that were interested in participating in the program. The most recent Agency outreach activities confirmed this assertion. As of November 2010, only four States (North Dakota, Ohio, Wisconsin, and Vermont) expressed interest in participating and, according to the State Directors, about 27 to 102 establishments may apply for selection into the program through these four States. Therefore, we revised the three scenarios to be (1) 27 establishments in four States participating from FY 2011 through 2014, (2) 102 establishments from four States from FY 2011 through 2014, and (3) 102 establishments from 4 States in FY 2011, then the participation increases to 200 establishments from all 27 eligible States in FY 2012 through 2014. The Agency understands that there are many other possible scenarios. Nevertheless, it is difficult to determine with any certainty which scenarios are more likely to occur than others; and the farther out (in terms of fiscal years) the projection, the greater the uncertainty. These three scenarios are for illustration purposes only as the number of participating States and establishments can go up or down depending on the perception of the final rule, the experience of the program once it starts, and other socio-economic factors.

We started with 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 States for their eligible costs related to the inspection of selected establishments in the State in an amount not less than 60 percent of eligible State costs. Under the existing law, FSIS may reimburse a State for up to 50 percent of eligible State costs to administer and enforce the cooperative State MPI. 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.

To calculate this figure, FSIS estimated average per establishment spending for the cooperative interstate shipment program for the establishments in four States. For FY 2011, the estimated additional State reimbursement for inspection of an establishment selected for the cooperative interstate shipment program compared to the reimbursement for an establishment operating under the cooperative State MPI program, is \$12,415 (per establishment) in North Dakota, \$5,283 in Ohio, \$16,123 in Wisconsin, and \$3,314 in Vermont.<sup>7</sup> This and analogous figures are reflected in the tables below in the "Total grants to States" line for the 27, 102, and 102–200 establishment scenarios.

Under section 11015 of the 2008 Farm Bill, FSIS is required to oversee the inspection activities of State personnel designated to provide inspection to selected establishments in the State. FSIS will incur costs associated with providing the necessary oversight. 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 FMA and PPIA, including regulations and policies there under and to: (1) Provide oversight and enforcement of the program, and (2) 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 2 to 3 full-time equivalent FSIS employees will be able to perform the SEC functions for the 4 States interested in participating in the cooperative interstate shipment program. It is expected that early in the program the 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.

In the start-up period, 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 between the scenarios of 27 and 102 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.

<sup>7</sup> For methodology of calculating this please see 74 FR 47659–47660.

To summarize, for each State we took the allocation for FY 2010 under the cooperative State MPI program, divided by the number of establishments, and then multiplied it by 1.2.

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 Table 2 below. This training will only be needed in the start-up period and, accordingly, appears only in FY 2011 in Table 2 for all three scenarios, and again in FY 2012 in the 102–200 establishments scenario when more establishments participate.

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 four States scenario, though, since the numbers of establishments are less than 300, there

will be one DDM. 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 "the same as" the Federal program. We anticipate that the program needs two lab staff regardless of how many establishments eventually participate because most of the labs typically have a chemistry residue program and a microbiology 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 2011.

As noted above, early in the program the SEC's duties will initially focus on outreach and start-up activities and later will shift to the oversight activities stipulated in the Acts. Thus, we project about \$6,150 for travel for each SEC in the first year and \$6,300 per year for subsequent years.<sup>8</sup>

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 4 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. We based the number of audits on the figures that we had regarding the number of States that will participate. 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, and office supplies. FSIS estimates \$3,500 per new staff for laptop, LincPass, and Black Berries. 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: 27, 102 and 102-to-200 establishments.

TABLE 2—COOPERATIVE INTERSTATE SHIPMENT PROGRAM COST ESTIMATES—THREE SCENARIOS (\$ MILLIONS)

Fiscal year	2011	2012	2013	2014	4-Year
<b>Interstate Program—Summary of Incremental Cost Estimates</b>					
Costs if 27 establishments .....	1.09	0.95	0.83	0.87	3.74
Costs if 102 establishments .....	1.94	1.43	1.34	1.40	6.11
Costs if 102, then 200 establishments .....	1.94	4.22	4.40	4.58	15.14
<b>Interstate Program with 27 Establishments</b>					
Number of establishments .....	27	27	27	27	.....
Total grants to States * .....	0.28	0.15	0.15	0.16	.....
Total salaries & benefits .....	0.51	0.53	0.55	0.58	.....
DDM .....	0.09	0.10	0.10	0.11	.....
State coordinator (SC) .....	0.16	0.17	0.17	0.18	.....
Lab staff .....	0.25	0.26	0.27	0.29	.....
Operating expenses .....	0.31	0.26	0.12	0.12	.....
Travel—SC & lab staff .....	0.02	0.02	0.03	0.03	.....
Training/Outreach .....	0.21	0.19	0.04	0.04	.....
Equipment and admin .....	0.07	0.07	0.07	0.07	.....
Total .....	1.09	0.95	0.83	0.87	3.74
<b>Interstate Program with 102 Establishments</b>					
Number of establishments .....	102	102	102	102	.....
Total grants to States * .....	0.99	0.50	0.52	0.54	.....
Total salaries & benefits .....	0.59	0.61	0.63	0.67	.....
DDM .....	0.09	0.10	0.10	0.11	.....
State coordinator (SC) .....	0.24	0.25	0.26	0.27	.....
Lab staff .....	0.25	0.26	0.27	0.29	.....

<sup>8</sup> The PRIA stated that the estimated travel cost per SEC's in subsequent years would be \$630. This was a technical error and should have read \$6,300.

TABLE 2—COOPERATIVE INTERSTATE SHIPMENT PROGRAM COST ESTIMATES—THREE SCENARIOS (\$ MILLIONS)—Continued

Fiscal year	2011	2012	2013	2014	4-Year
Operating expenses .....	0.36	0.30	0.18	0.18	.....
Travel—SC & lab staff .....	0.03	0.3	0.03	0.03	.....
Training/Outreach .....	0.21	0.19	0.05	0.05	.....
Equipment and admin .....	0.12	0.11	0.11	0.11	.....
Total .....	1.94	1.43	1.34	1.40	6.11
<b>Interstate Program with 102, then 200 Establishments</b>					
Number of establishments .....	102	200	200	200	.....
Total grants to States* .....	0.99	1.64	1.20	1.25	.....
Total salaries & benefits .....	0.59	2.25	2.35	2.45	.....
DDM .....	0.09	0.16	0.17	0.18	.....
State coordinator (SC) .....	0.24	1.83	1.91	1.98	.....
Lab staff .....	0.25	0.26	0.27	0.29	.....
Operating expenses .....	0.36	0.82	0.85	0.89	.....
Travel—SC & lab staff .....	0.03	0.09	0.10	0.10	.....
Training/Outreach .....	0.21	1.40	1.12	0.35	.....
Equipment and admin .....	0.12	0.36	0.38	0.39	.....
Total .....	1.94	4.22	4.40	4.58	15.14

\* Note “Total grants to States” includes funding for Transition Grants to help establishments train one person in HACCP and SOPs per § 332.12 and § 381.522.

#### Effect on Small Entities—Regulatory Flexibility Analysis

Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the FSIS Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities. This certification is based primarily on the fact that (1) the program is voluntary, and (2) the rule will benefit very small and certain small establishments that operate under cooperative State MPI programs. Based on FSIS’s HACCP (Hazard Analysis and Critical Control Points) size definitions, very small establishments have fewer than 10 employees or generate less than \$2.5 million in annual sales; small establishments have 10 or more but fewer than 500 employees and generate more than \$2.5 million in annual sales; and establishments having 500 or more employees are large establishments. Thus, very small State-inspected establishments and small State-inspected establishments that have fewer than 25 employees on average will be eligible to participate in the cooperative interstate shipment program.

This final rule will benefit very small and certain small establishments that operate under cooperative State MPI 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 implementing regulations. Thus, this 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.

Currently, 27 States administer cooperative State meat or poultry inspection (MPI) programs. These States have approximately 1,873 establishments that would be eligible to apply for selection into the new cooperative interstate shipment program. As mentioned earlier in the preamble to this final rule, the Agency’s most recent outreach activities indicate that four States may be interested in participating in the program and the number of establishments in these States that might participate is between 27 and 102. However, because participation in the new program is voluntary, FSIS will not know how many States and establishments will apply to participate until this final rule

becomes effective and establishments are selected for the program.

As discussed above, costs to the participating establishments are likely to be small. 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 in 2008, in the PRIA of the proposed rule, the Agency estimated 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. 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 did not receive any comments or new information in response to the proposed rule to suggest changes to these estimates.

Because the cooperative interstate shipment program 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 participation will provide an overall net benefit for them.

#### Executive Order 12988

This final 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.

#### E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to government information and services, and for other purposes.

#### Executive Order 13175

This final rule has been carefully evaluated for potential tribal implications in accordance with Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments." FSIS has concluded based on its evaluation that this final rule will not have any direct or substantial effects on Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power or responsibilities between the Federal Government and Indian Tribes. This final rule implements the Congressional enactment providing that States with approved MPI programs, that is State established and administered meat or poultry inspection programs, approved by FSIS pursuant to the Federal meat and poultry inspection laws, may now be eligible in their discretion to participate in the cooperative interstate shipment program established by this final rule. Accordingly, because this program is only authorized under law and this rule is for States with approved MPI programs, there are no significant tribal implications. Nonetheless, FSIS will include Tribes and intertribal organizations, involved in or interested in the meat and poultry sectors, in the Agency's outreach efforts associated with implementation and administration of this final rule. In addition, if and when a State, with an MPI program approved by FSIS, satisfies the requirements of this final rule and enters into an agreement with FSIS

regarding a cooperative interstate shipment program, FSIS will conduct outreach to Tribes and intertribal organizations to ensure that they are fully aware of the cooperative interstate shipment program in that State, and to ensure that meat or poultry establishments on Tribal lands have the opportunity to participate in the approved State interstate shipment program if they are interested in doing so.

#### USDA Nondiscrimination Statement

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (Not all prohibited bases apply to all programs.)

Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's Target Center at 202-720-2600 (voice and TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue, SW., Washington, DC 20250-9410 or call 202-720-5964 (voice and TTY). USDA is an equal opportunity provider and employer.

#### Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in particular minorities, women, and persons with disabilities, are aware of this final rule, FSIS will announce it on-line through the FSIS Web page located at [http://www.fsis.usda.gov/regulations/2011\\_Interim\\_Final\\_Rules\\_Index](http://www.fsis.usda.gov/regulations/2011_Interim_Final_Rules_Index).

FSIS also will 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 our constituents and stakeholders. The *Update* is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The *Update* also is available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader, 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\\_events/email\\_subscription/](http://www.fsis.usda.gov/news_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 and recordkeeping requirements included in this rule were submitted for approval to the Office of Management and Budget (OMB) when the proposed rule was published. OMB preapproved the information collection; the OMB Control number is 0583-0144.

The estimated number of respondents in the preapproved information collection reflects the number of States and establishments that FSIS estimated would participate in the cooperative interstate shipment program when the Agency issued the proposed rule. FSIS believes that it overestimated the participation by States and establishments in the proposed rule. However, the Agency's final estimated hours of paperwork burden per respondent is the same as the estimate provided in the proposed rule.

**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 final rule in accordance with the Paperwork Reduction Act. Under this final rule, FSIS is requiring certain information collection and recordkeeping activities.

States that are interested in participating in the cooperative interstate shipment program are required to 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, if any; (2) 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; and (3) agree to comply with certain conditions to assist with enforcement of the

program. States that have entered into an agreement with FSIS for a cooperative interstate shipment program must 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 final rule, 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 (MPI) 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:** When it proposed these regulations, FSIS estimated 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 estimated that approximately 400 establishments will apply for the program. Thus, FSIS estimated 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 1608 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 minutes 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 minutes to assist the SEC locate records for review for each subsequent visit. If the SEC visits each selected establishment at least once 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:** 11,848 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.

## 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 amending 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. Section 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. Eligible State costs are 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.

(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. 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 establishment.
- 332.12 Transition grants.
- 332.13 Separation of operations.
- 332.14 Voluntary withdrawal.

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

**§ 332.1 Definitions.**

*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 July 1, 2014, 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 whose duties involve handling the meat or meat food products prepared by the establishment 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 whose duties involve handling the meat or meat food products prepared by the establishment 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 unless their duties involve handling the meat or meat food products prepared by the establishment.

(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; and

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

(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, if any;

(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, 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. The frequency with which the SEC will visit selected establishments under the SEC's jurisdiction will be based on factors that include, but are not limited to, the complexity of the operations conducted at the selected establishment, the establishment's schedule of operations, and the establishment's performance under the cooperative interstate shipment program. 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 the 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 a 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.**

(a) 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.

Except that an establishment that was deselected from a cooperative interstate shipment program because it is located in a State whose agreement for such a program was terminated may either transition to become an official establishment or transition to become a State-inspected establishment under the cooperative State meat inspection program.

(b) An establishment that has been deselected from a cooperative interstate shipment program and successfully transitioned to become an official establishment may withdraw from the Federal inspection program and resume operations under the cooperative State meat inspection program after operating as an official establishment in full compliance with the Act for a year.

#### **§ 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.

#### **§ 332.13 Separation of operations.**

A selected establishment may conduct operations under the cooperative State meat inspection program if the establishment implements and maintains written procedures for complete physical separation of product and process for each operation by time or space.

**§ 332.14 Voluntary withdrawal.**

A selected establishment that is in full compliance with the requirements in this part may voluntarily end its participation in a cooperative interstate shipment program and operate under the cooperative State meat inspection program. Establishments that voluntarily end their participation in the cooperative may re-apply for the program after operating under the cooperative State meat inspection program for one year.

**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. Add § 381.187 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. Eligible State costs are 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.

(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.

- 6. Add subpart Z 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.
- 381.523 Separation of operations.
- 381.524 Voluntary withdrawal.

**Subpart Z—Selected Establishments; Cooperative Program for Interstate Shipment of Poultry Products****§ 381.511 Definitions.**

*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 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 § 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 July 1, 2014, 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 whose duties involve handling the poultry products prepared by the establishment 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 whose duties involve handling the poultry products prepared by the establishment 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 unless their duties involve handling the poultry products prepared by the establishment.

(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, if any;

(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, 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. The frequency with which the SEC will visit selected establishments under the SEC's jurisdiction will be based on factors that include, but are not limited to, the complexity of the operations conducted at the selected establishment, the establishment's schedule of operations, and the establishment's performance under the cooperative interstate shipment program. 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 the 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 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 establishment 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.**

(a) 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. Except that an establishment that was deselected from a cooperative interstate shipment program because it is located in a State whose agreement for such a program was terminated may either transition to become an official establishment or transition to become a State-inspected establishment under the

cooperative State poultry products inspection program.

(b) An establishment that has been deselected from a cooperative interstate shipment program and successfully transitioned to become an official establishment may withdraw from the Federal inspection program and resume operations under the cooperative State poultry products inspection program after operating as an official establishment in full compliance with the Act for a year.

**§ 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.

**§ 381.523 Separation of operations.**

A selected establishment may conduct operations under the cooperative State poultry products inspection program if the establishment implements and maintains written procedures for complete physical separation of product

and process for each operation by time or space.

**§ 381.524 Voluntary withdrawal.**

A selected establishment that is in full compliance with the requirements in this part may voluntarily end its participation in a cooperative interstate shipment program and operate under the cooperative State poultry products inspection program. Establishments that voluntarily end their participation in the cooperative may re-apply for the program after operating under the cooperative State poultry products inspection program for one year.

Done at Washington, DC, on: March 31, 2011.

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

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