

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

FSIS DIRECTIVE

5740.1
Revision 1

5/11/21

COOPERATIVE INTERSTATE SHIPMENT PROGRAM

CHAPTER I--GENERAL

I. PURPOSE

This directive provides the instructions that FSIS personnel are to follow in implementing, overseeing, and enforcing the Cooperative Interstate Shipment (CIS) Program for the interstate shipment of certain State-inspected meat and poultry products. FSIS is reissuing this directive to reflect changes in FSIS organizational structure and to clarify certain policies.

KEY POINTS:

- *Procedures to review a State's request to participate in the CIS program and enter into an agreement*
- *Procedures to select and deselect establishments for the CIS program*
- *Procedures to oversee and to enforce the requirements of the CIS program*
- *Procedures to terminate a State's agreement to participate in the CIS program*
- *Roles of the Office of Field Operations (OFO) and other FSIS program personnel in implementing the CIS program*

II. CANCELLATION

FSIS Directive 5740.1 *Cooperative Interstate Shipment Program*, 9/27/12

III. BACKGROUND

A. 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 Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) to establish a cooperative inspection program under which certain small and very small 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 law provides 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)). Thus, establishments selected for this program (selected establishments) are permitted to ship their products across State lines and may have the opportunity to export them to foreign countries, provided the CIS participating State has entered into a supplemental agreement that addresses the export of CIS inspected products. No states currently have a supplemental agreement for exporting product.

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B. FSIS published a final rule to implement the CIS program on May 2, 2011, [Cooperative Inspection Programs Interstate Shipment of Meat and Poultry Products](#). The regulations that implement the CIS program are in 9 CFR 321.3, Part 332, 381.187, and Part 381 subpart Z. The CIS program does not cover operations for the slaughter or processing of species that are not amenable to the FMIA or PPIA.

CHAPTER II—EVALUATING A STATE’S REQUEST TO PARTICIPATE IN THE CIS PROGRAM AND ENTERING INTO AN AGREEMENT WITH THE STATE

I. RECEIPT OF A STATE REQUEST TO PARTICIPATE IN THE CIS PROGRAM: DISTRICT MANAGER (DM) AND CIS PROGRAM COORDINATOR RESPONSIBILITIES

A. States that are interested in entering into an agreement with FSIS to participate in the CIS program are required to submit a written request for such a program through the FSIS District Office (DO) that covers that State (9 CFR 332.4 and 381.514). The State’s written request should describe the Hazard Analysis and Critical Control Points (HACCP) categories, species, and type of products that the State intends to include in its CIS program.

B. When a State submits a request, the DM is to:

1. Send a written response to the State to acknowledge receipt of the request. The response is to be sent no later than 3 business days after the request is received;
2. Provide a copy of the response to the OFO Headquarters (HQ) CIS program coordinator and the Office of the Assistant Administrator for Field Operations or their designee. The CIS program coordinator is the primary OFO HQ contact for the CIS program;
3. Designate an FSIS DO contact to work with FSIS HQ to evaluate the State’s request; and
4. Forward a copy of the request and all supporting materials to the CIS program coordinator and give the CIS program coordinator the name of the DO contact;

C. The CIS program coordinator is to coordinate with the DO and other FSIS offices to form a CIS Review Committee comprised of relevant subject matter experts (SMEs) for each of the CIS program elements described below. The Review Committee is to evaluate the State’s request and to determine whether the State qualifies to enter into an agreement with FSIS to participate in the CIS program.

II. VERIFYING THAT A STATE HAS AN “AT LEAST EQUAL TO” COOPERATIVE STATE MEAT OR POULTRY INSPECTION (MPI) PROGRAM

A. Participation in the CIS program is limited to States that have implemented an “at least equal to” State MPI program (9 CFR 332.4(a) and 381.514(a)). FSIS expects State MPI programs to resolve any deficiencies in their “at least equal to” status before requesting participation in the CIS program.

B. The FSIS Office of Investigation, Enforcement, and Audit (OIEA), Federal State Audit Branch (FSAB), performs ongoing annual reviews to determine whether each State MPI program meets the “at least equal to” standard (see [FSIS Directive 5720.3, Methodology for Performing Scheduled and Targeted Reviews of State Meat and Poultry Inspection Programs](#)). When a State submits a request to participate in the CIS program, the CIS program coordinator is to consult with the FSAB to verify the State MPI program’s “at least equal to” status.

C. If FSAB has determined that the State MPI program does not meet the “at least equal to” requirements or is aware of conditions or events that evidence program deficiencies (e.g., ongoing foodborne illness investigations or other credible, verifiable information), the DM or designee is to inform the State that FSIS will not consider the CIS program request until FSAB determines that the State MPI program has resolved the deficiencies and meets the “at least equal to” standard.

III. VERIFYING THAT A STATE MEETS EACH “SAME AS” CIS PROGRAM ELEMENT

A. A State that requests to participate in the CIS program is to demonstrate that the State is able to provide the necessary inspection services to selected establishments in the State and to conduct any related activities required under the CIS program (9 CFR 332.4(b)(2) and 381.514(b)(2)). The 2008 amendments to the FMIA and PPIA make clear that the inspection services that the State provides to selected establishments are to enforce all requirements of the FMIA or PPIA rather than requirements that are “at least equal to” those of the Federal program.

B. After the CIS program coordinator verifies the State MPI program’s “at least equal to” status, the CIS Review Committee (i.e., the reviewers) will proceed with the remainder of the evaluation of the State’s request and accompanying materials to assess whether the State’s proposed CIS program is the “same as” the FSIS inspection program. The CIS program coordinator and DO will coordinate with the review committee’s FSIS Program Area SMEs, as appropriate, and the affected State MPI program to verify the “same as” element criteria below. Any communication between the Program Area SMEs and the State is to include the CIS program coordinator and the DO.

C. Legal Authority: The Office of Policy and Program Development (OPPD) SME is to verify that the State’s request includes the following documentation to demonstrate that the State has the necessary legal authority to administer and enforce a “same as” CIS program:

1. A copy of a State law that incorporates the FMIA or PPIA and the implementing regulations explicitly or by reference;
2. A copy of a law that gives State inspection personnel the authority to enforce Federal food safety standards for purposes of the CIS program;
3. A legal opinion from the State Attorney General that confirms that State inspection personnel have such authority; or
4. Any other documents that demonstrate that the State MPI program is authorized to administer and enforce Federal food safety standards in establishments selected for the CIS program.

The OPPD SME is to verify that the State has the authority to enforce Federal food safety standards in the same manner that FSIS is authorized to act under the FSIS Rules of Practice in 9 CFR Part 500. If the State has not incorporated the FSIS Rules of Practice explicitly or by reference the OPPD SME is to verify that the State designated personnel are otherwise authorized to take actions that are the same as those provided for in the FSIS Rules of Practice.

D. Computer Systems and Forms: The Office of the Chief Information Officer (OCIO) SME is to verify that the State’s request includes documentation to demonstrate that the State intends to use the Public Health Information System (PHIS) to administer the CIS program.

1. If the State is not using PHIS when it submits its request to participate in the CIS program, the State will need to transition to PHIS as a condition for entering into a CIS program agreement. In its request for a CIS program, a State is required to agree to develop a plan to transition to use of PHIS in selected establishments.
2. A State may be authorized to participate in the CIS Program prior to PHIS implementation; however, no establishment will be selected by FSIS into the CIS program until the State has implemented use of PHIS in that establishment.

E. Laboratory Services: The Office of Public Health Science (OPHS) laboratory method SMEs are to verify that the State's request contains documentation to demonstrate that the laboratory services that the State intends to use to analyze regulatory food chemistry and microbiological samples under the CIS program have or are actively seeking to be accredited by an internationally recognized organization that accredits food testing laboratories against the International Standards Organization (ISO) document 17025, "*General requirements for the competence of testing and calibration laboratories*," and against the Association of Official Agricultural Chemists (AOAC) International document "*Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals*" written by the Analytical Laboratory Accreditation Criteria Committee (ALACC).

1. If the laboratory services that the State intends to use for the CIS program are ISO 17025 accredited, verify that the State's request includes an authentic copy of the ISO certificate and other documentation to demonstrate that the laboratory has the necessary accreditation; or
2. If the laboratory services that the State intends to use for the CIS program are not ISO 17025 accredited, verify that:
 - a. The laboratory is actively seeking, and has provided a timeline for obtaining, ISO 17025 accreditation within 2 years; and
 - b. The laboratory has demonstrated that it can meet the criteria in the State Meat and Poultry Inspection Program Laboratory Quality Assurance (QA) Checklist while it seeks to obtain ISO 17025 accreditation.

F. Laboratory Methods: The OPHS laboratory method SMEs are to verify that the State's request contains documentation to demonstrate that the laboratory that the State intends to use to analyze samples for the CIS program will follow the applicable protocols described in the [FSIS Chemistry, Microbiology, and Pathology Laboratory Guidebooks](#).

1. If the laboratory cannot follow an FSIS method as written, verify that the State has submitted a justification to modify an FSIS method and that OPHS laboratory method SMEs have reviewed any modifications made to the FSIS method, and determined that the methodology is consistent with the original FSIS protocol. The State's method is to be capable of achieving results that are consistent with the corresponding FSIS method;
2. If a State's laboratory is ISO 17025 accredited, but some of the analyses that it conducts are not under its scope of accreditation, the State may still qualify for a CIS Program if the laboratory can demonstrate proficiency in FSIS Laboratory Guidebook methods, and the laboratory agrees to actively seek and obtain scope of accreditation for the analyses during the next accreditation cycle; or
3. Inquiries from States or laboratories on laboratory accreditation or methods should be submitted to OPHS through the following e-mail address: statelabinquiry@usda.gov.

G. Sample Collection: The OPHS sample collection SMEs are to verify that the State's request includes documentation to demonstrate that designated State personnel utilizing the same collection methods as FSIS will collect the same number and type of regulatory samples from selected establishments in the State that FSIS collects from official Federal establishments. Reviewers are to:

1. Verify that the State developed its sampling plan using the same algorithm that FSIS uses to determine the number and type of microbiological samples to collect each year; and
2. Verify that the State developed its sampling plan using the same algorithm that FSIS uses to determine the number and type of chemical residue samples to collect each year.

H. **Staffing:** The OFO SMEs are to verify that the State's CIS program request includes the following documentation to demonstrate that the State MPI program has staffing sufficient to conduct the same inspection activities in selected establishments as FSIS conducts in official Federal establishments:

1. The method that the States will use to assign inspectors, including veterinarians, to each selected establishment in the State.
 - a. If selected establishments in the State will be conducting slaughter activities, verify that the State can staff livestock slaughter at the level provided for in 9 CFR 310.1 or poultry slaughter at the level provided for in 9 CFR 381.68 and 381.76; and
 - b. If selected establishments in the State will be conducting processing activities, the CIS program coordinator and the DO are to verify that the State will be able to assign a designated State inspector to all selected processing establishments on a per-shift basis whenever each establishment is conducting activities requiring inspection.
2. The methods that the State will use to determine the inspectors' workloads and assignments;
3. The methods that the State will use to verify achievement of adequate staffing; and
4. The method that the State will use to ensure relief inspection coverage in the selected establishments

I. **Training:** The Office of Employee Experience and Development (OEED), Center for Learning (CFL) SME is to verify that the designated State personnel have completed and passed the minimum FSIS-sponsored training requirements necessary for the State to begin to administer a CIS program. The State is responsible for ensuring that assignments for designated State personnel are based on the training that the State personnel have completed. FSIS requires designated State personnel to complete training courses administered by FSIS.

1. Upon request, OEED CFL is to provide a list of the current FSIS sponsored trainings to the requesting State through the DM. The list is to include former FSIS trainings that satisfy the requirement in lieu of the current training courses offered.
2. OEED CFL reviewers are to verify that State inspection personnel have completed the necessary FSIS training(s) prior to providing inspection services to establishments selected for the CIS program, with the exception of the FSIS livestock and poultry slaughter inspection trainings. Reviewers are to be aware that those personnel assigned to provide CIS slaughter inspection must complete and pass the FSIS slaughter training within 12 months of beginning inspection at such establishments, which is consistent with the training required for assigned personnel at a federally-inspected establishment.

J. If the State's request for a CIS program does not contain sufficient information to demonstrate that the designated State personnel will provide the same inspection services to selected establishments as those that FSIS provides under the Federal inspection system, the DM and CIS program coordinator are to prepare a letter to the State signed by the DM that describes in detail the information that FSIS needs to complete its review of the State's CIS program request.

IV. ENTERING INTO A COOPERATIVE AGREEMENT FOR STATE PARTICIPATION IN THE CIS PROGRAM

A. If FSIS approves the State's request, the Administrator or designee and an appropriate State Agriculture official will sign the cooperative agreement prepared by the CIS program coordinator and submitted through the Enterprise Content Management (ECM) process.

B. The CIS program coordinator is to verify the appropriate State Point of Contact and request the Office of Public Affairs and Consumer Education (OPACE) update the FSIS online directory of participating CIS States.

C. The State's CIS program cooperative agreement is subject to annual renewal and is contingent on renewal of the State's "at least equal to" MPI Program agreement. Therefore, on an annual basis, the CIS program coordinator is to verify that the CIS eligibility criteria are met and to prepare the CIS agreement renewal for signature by the designated FSIS and State Agricultural officials.

CHAPTER III--SELECTING ESTABLISHMENTS FOR PARTICIPATION IN THE CIS PROGRAM

I. GENERAL

A. After FSIS has entered into an agreement with a State to participate in the CIS program, the FSIS oversight DO is to coordinate with the State to assess and select establishments to participate in the program (9 CFR 332.4, 381.514).

B. The DO is to ask the State to identify the State's internal processes for evaluating and recommending establishments for a CIS program and providing the inspection necessary for each recommended establishment. The DO should also verify with the State whether the State has any additional internal processes which are not required but the State may implement to manage the program. For example, there may be a State labeling review process to verify FSIS labeling approval is required and the applicable Federal requirements are met prior to the selected establishment submitting labels to FSIS for approval. The DO is to request that the State communicate this information to the State inspected establishments, as appropriate.

C. The DM is to appoint a Selected Establishment Coordinator (SEC). The SEC is the Federal employee assigned to provide oversight and enforcement of the CIS program in the District.

II. DO ROLE IN SELECTING ESTABLISHMENTS TO PARTICIPATE IN THE CIS PROGRAM

A. The DM or designee is to conduct the following activities to determine whether a State-inspected establishment recommended by the State is eligible to be selected to participate in the CIS program:

1. Verify the State has determined that each recommended establishment has the appropriate number of employees and complies with all other Federal requirements needed to be eligible for a CIS program. For example, the State may assess compliance with all HACCP, Sanitation Standard Operations Procedures (Sanitation SOP), and Sanitation Performance Standards (SPS) requirements through the Public Health Risk Evaluation (PHRE) and Food Safety Assessment (FSA) process described in relevant FSIS issuances and include a copy of the PHRE/FSA report with the recommendation;
2. Arrange a meeting or conference call with the SEC or designee and the MPI State Director to discuss the procedures for assessing the State-inspected establishments;
3. Ensure the State MPI provides the establishment the electronic links to the FMIA, PPIA, and Humane Methods of Slaughter Act on the FSIS website or provide hard copies of these documents for establishments that do not have online access;
4. Coordinate with the State to notify each of the State-inspected establishments of the approximate survey, i.e., the FSIS onsite review, date at least two weeks in advance;
5. Compile all materials from the establishment survey, including the *Plant Information* FSIS Form 9020-2, the *Survey Report* FSIS Form 9020-3. If the establishment is planning to conduct slaughter operations under a CIS program, the FSIS District Veterinary Medical Specialist

(DVMS) is to conduct a Humane Handling and/or Good Commercial Practices audit. The findings from the audit are to be considered along with the State's selection recommendation for CIS slaughter inspection; and

6. Inform the CIS program coordinator of the status of each establishment recommended by the State for the CIS program and state whether the establishment was selected or not selected for the program.

III. SEC ROLE IN SELECTING ESTABLISHMENTS FOR THE CIS PROGRAM

A. The SEC or designee, in coordination with State MPI officials, is to conduct an initial and, if necessary, a follow-up survey of each State-inspected establishment that the State has recommended for selection into the CIS program. The purpose of the survey is to verify that each establishment recommended by the State is in compliance with all Federal laws and regulatory requirements and is otherwise eligible to participate in the CIS program.

B. The SEC is to conduct the following activities to complete the onsite survey:

1. Prepare to lead the onsite review teams. The onsite review teams are to include the FSIS and State MPI officials who will be administering the CIS program for the State;
2. Coordinate with the State MPI officials to conduct entrance and exit meetings with establishment management. Establishment management is to be made aware that FSIS conducts the onsite review in order to recommend selection into the program;
3. Prepare a Memorandum of Interview (MOI) to document that establishment management has received information on inspection requirements under the CIS program, and that the establishment agreed that it will not use Federal brands or labels until notified by the SEC or designee, or produce product intended for the Federal marks of inspection unless the product is produced under CIS inspection provided by the designated State MPI personnel. Forward the original copy of the MOI to the DM and one copy to the State for the establishment file and establishment management;
4. Complete "Plant Information" sheet, FSIS Form 9020-2, and ensure that it includes the establishment name, address, and telephone number; establishment operator and title; and nature of operations, hours of operations, types of species slaughtered, types of processing operations, and distribution information. If the establishment intends to produce products under both the CIS program and the State MPI program, specify the information for hours of operations, types of species slaughtered, and processing operations for both programs; and
5. Review establishment employment documentation to verify that the establishment employs on average fewer than 25 employees as determined by the standards for counting employees in 9 CFR 332.3(b) and 381.513(b).

C. During the onsite review, the SEC or designee, in coordination with the State personnel, is to:

1. Review the establishment grounds, facilities, and equipment and determine whether the establishment complies with 9 CFR 416.1 through 416.5;
2. If the establishment conducts slaughter activities, include the FSIS DVMS audit assessment findings whether the establishment is capable of handling and slaughtering livestock humanely as set out in 9 CFR Part 313, or whether it is capable of following humane methods of handling and slaughter that are consistent with good commercial practices for poultry slaughter;
3. If the establishment conducts processing operations, verify that the source materials used to produce products under the CIS program are from an official Federal establishment or from another selected establishment in good standing under the CIS program;

4. Verify that the establishment has developed written Sanitation SOPs as set out in 9 CFR 416.11 through 416.16;
5. Verify that the establishment conducted, or had conducted for it, a hazard analysis and has developed HACCP plans applicable to its products in accordance with 9 CFR Part 417. If applicable, evaluate the establishment control programs for Specified Risk Materials (SRM) and *Listeria monocytogenes*;
6. Verify that the establishment has written recall procedures in accordance with 9 CFR 418.3;

If the establishment intends to conduct operations under both the CIS program and the State MPI program, verify that the establishment has written procedures for complete physical separation of product and process for each operation by time or space as required under 9 CFR 332.13 and 381.523. Establishments which produce product under State MPI operations will need to fully clean and sanitize the facility and equipment prior to utilizing the equipment under CIS operations.

- a. Separation by space: If the establishment chooses to separate operations by space, it may either conduct each operation in separate physical areas, or it may conduct each operation in the same area, provided that the separation in space is sufficient to ensure that potential food safety hazards, if present, are not likely to spread from one area to the other. For example, an establishment may designate certain employees on a given day to work on the State MPI operations on a designated production line and have these employees wear white clothing, and it may designate other employees to work exclusively on the CIS program operations on a separate designated production line and have these employees wear yellow clothing. The establishment could also color-code knives, food contact surfaces, and other equipment associated with each operation;
 - b. Separation by time: If an establishment chooses to conduct the State MPI operations and CIS program operations at separate times, the establishment's procedures for separation will need to address clean-up between operations.
 - c. Separation of product: Establishments that choose to conduct operations under both the State MPI program and the CIS program will 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 CIS program. These procedures must ensure that products produced under each program are appropriately identified as State MPI products or CIS program products, and that each product bears the appropriate mark of inspection.
7. Verify the establishment is maintaining labeling records for labels that the establishment intends to use on products produced under the CIS program. These records include the product formulation, processing procedures, any additional documentation and a copy of the final labeling, as prescribed in 9 CFR 320.1(b)(11), 381.175(b)(6), and 412.1;
 8. Verify that all labels comply with all labeling regulations per 9 CFR 317.2 and 381 subpart N and are not false or misleading.
 9. Provide establishment management with access to the [FSIS Compliance Guideline for Label Approval](#), inform establishment management that LPDS is responsible for the review and approval of labels, per 9 CFR 412.1(a), and provide establishment management with contact information for LPDS through [askFSIS](#) or by phone at (301)504-0878.
 10. The SEC is to inform the establishment that LPDS may be contacted with any questions related to labeling, including but not limited to, labeling features, the label submission process, and standards of identity, and that these questions may also be submitted through

[askFSIS](#). The following are to be discussed during the initial survey:

- a. If the submitted CIS labels meet one of the four categories in 9 CFR 412.1(b) and are required to be submitted to LPDS for approval, they will receive priority review by LPDS;
 - b. Ask the State MPI representative to describe to the establishment how the State intends to implement the labeling submission process for purposes of the CIS program. Either the selected establishment or the State MPI on behalf of the selected establishment will send label submissions to LPDS and provide LPDS notification of the submission through the FSIS SEC;
 - c. Labels that require FSIS label approval, are to be submitted either electronically through the [Label Submission Approval System](#) (LSAS) or by mailing the paper label application forms and labels to LPDS;
 - d. For all labels submitted to LPDS, CIS selected establishments should enter "CIS Participant" under "Other" when completing the [FSIS Form 7234-1- Application for Approval of Labels, Marking or Device](#); and
 - e. The State may order Federal brands displaying the CIS program selected establishment number if the products produced by a selected slaughter establishment require brand application as described in 9 CFR 316.9 and 381.96.
11. After completing the initial onsite review, identify that the State-inspected establishment has met the necessary Federal standards and all other requirements to qualify for selection into the CIS program.
- a. Discuss the onsite review results with the establishment and State MPI officials;
 - b. On FSIS Form 9020-3, write "Recommend State-inspected establishment be selected for the CIS program." Forward the original copy to the DM and one copy to the State. The State provides one copy to establishment management;
 - c. Issue FSIS 5200-7, "Authorization Certificate," to order Federal metal carcass brands for State-inspected slaughter establishments that FSIS will select to participate in the CIS program; and
 - d. Verify that State brands, and any other voluntary inspection brands, are inventoried and kept under security by the designated State personnel at the State-inspected establishment.
12. Verify that the State has assigned an official selected establishment (SE) number to each establishment that has been selected to participate in the CIS program. The official number assigned to a selected establishment is to 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" (9 CFR 332.5(c)). The number for a poultry establishment is to also include the letter "P" in the suffix that identifies the establishment as a poultry establishment, e.g., "SEPND," for "selected establishment poultry North Dakota" (9 CFR 381.515(c)); and
13. Notify the FSIS OPACE website contact to update the FSIS online CIS directory.
- D. If an establishment does not meet all Federal standards on the initial onsite review, the SEC is to instruct the State MPI program officials to contact the FSIS DO when the State MPI program has verified that the establishment has completed the necessary actions to comply with Federal standards.

1. Discuss the onsite review results with the establishment and State MPI officials.
2. On the FSIS Form 9020-3, write “Do not recommend selection of State-inspected establishment for the CIS program,” and document the reason for not recommending the establishment. Identify all actions that the establishment will need to take to comply with the necessary Federal standards to qualify for selection into the CIS program. Forward original copy to the DM and one copy to the State to give to establishment management; and
3. If during any type of onsite visit, a State-inspected establishment is found to be producing misbranded or adulterated products for distribution within the State that would clearly endanger the public health, the FSIS personnel are to immediately inform the State MPI program officials of the need to control the adulterated products. Verify that the State officials have taken appropriate product control actions to protect public health and notify the DM.

CHAPTER IV—FEDERAL OVERSIGHT OF THE CIS PROGRAM, ESTABLISHMENT DESELECTION, AND TERMINATION OF A STATE’S PARTICIPATION IN THE CIS PROGRAM

I. FEDERAL OVERSIGHT OF THE CIS PROGRAM: SEC RESPONSIBILITIES

A. The SEC, or designee, is to conduct onsite visits at 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 FMIA and PPIA and in compliance with the applicable regulations in 9 CFR Part 300 to end (9 CFR 332.7(a) and 381.517(a)). Frequency of visits is determined by the SEC in consultation with the DM according to considerations such as the complexity of the selected establishment’s operations, the selected establishment’s schedule of operations, and the selected establishment’s performance under the CIS program (9 CFR 332.7(a) and 381.517(a)).

B. The SEC, or designee, is to request that the State provide the following information for the purposes of FSIS DO oversight planning:

1. The date the selected establishment will first operate under the CIS program after initial selection into the program and all applicable labels and brands that are available to be applied to products produced under the program;
2. Anytime the selected establishment voluntarily elects to stop producing products for one or more HACCP categories approved for the CIS program; and
3. Anytime the selected establishment requests to produce products under the CIS program that are in HACCP categories which were not part of the SEC initial verification visit to select the establishment into the program.

C. The SEC, or designee, in coordination with the State, is to verify that each selected establishment in the State is receiving the necessary inspection services from the designated State personnel, and that each selected establishment is eligible, and remains eligible, to participate in a CIS program (9 CFR 332.7(b) and 381.517(b)). When scheduling permits, the SEC is to perform onsite verification visits on days when designated State personnel are conducting inspection activities for CIS inspected products in the selected establishment. The SEC is to:

1. Verify that each selected establishment employs, and continues to employ, 25 or fewer employees, on average;
2. Verify that the designated State personnel are providing inspection services to selected establishments in a manner that complies with the FMIA or PPIA and the regulations in 9 CFR Part 300 to end as applicable to the selected establishment. The SEC is to review the designated State inspection personnel’s noncompliance records (NRs), MOIs, weekly meeting notes, and enforcement records with the selected establishment’s food safety systems and associated records. The SEC is to also assess documentation related to the selected establishment’s performance as documented in

PHIS and laboratory sampling results. This can be done before, after, or during the visit. This SEC record review, along with any direct observation of State personnel performing “same as” inspection during the onsite visit are used by the SEC to verify that the designated State personnel:

- a. Apply appropriate Federal inspection methodology;
 - b. Use effective decision making to determine whether there is non-compliance with Federal requirements;
 - c. Appropriately document findings and, when necessary, initiate appropriate enforcement actions authorized under the FSIS Rules of Practice in 9 CFR Part 500;
 - d. Collect product samples in the same manner as FSIS regulatory sampling programs based on guidance provided by OPHS. The SEC is to verify the analyses of “same as” inspection samples were performed by the OPHS verified “same as” laboratory; and
 - e. Schedule and conduct PHREs and FSAs in selected establishments in the same manner that FSIS schedules and conducts PHREs and FSAs in official Federal establishments.
3. Verify that the State staffing levels for each of the selected establishments are appropriate to carry out the required inspection activities in the same manner as Federal inspection. The SEC is to compare the selected establishment’s hours of operation to the inspection records to determine whether an establishment received the necessary inspection services whenever the Federal mark of inspection was applied under the CIS program;
4. Assess each selected establishment’s compliance with the FMIA and PPIA and compliance with the regulations in 9 CFR Part 300 to end as they apply to the selected establishment;
- a. Review the written sanitation SOP and a sample of daily records documenting the implementation of the sanitation SOP and any corrective actions taken;
 - b. Observe the condition of the selected establishment’s grounds and facilities, equipment and utensils, employee hygiene, and sanitary operations to determine whether the establishment complies with sanitation performance standards in 9 CFR 416.1 through 416.6;
 - c. Observe the establishment employees perform their duties;
 - d. Review the establishment’s HACCP system and associated records (e.g., hazard analyses, HACCP plans, prerequisite programs, critical control points (CCP), critical limits, monitoring and verification procedures and frequencies, corrective actions, and supporting documentation);
 - e. Verify that any operations program or process that is required to be approved by the OPPD Risk Management and Innovations Staff (RMIS) under the Federal inspection program has been approved by RMIS when conducted in a selected establishment under a CIS program.
 - f. Review other food safety, economic and non-food safety specific processes that require regulatory oversight such as labeling, product formulations, and use and control of restricted ingredients;
 - g. Review the establishment’s compliance with all applicable Federal regulatory requirements (e.g., condemned product handling, humane handling, and removal, segregation, and disposition of specified risk materials); and
 - h. Submit product samples for analysis, if needed as instructed by the DM, to verify that the product produced by the selected establishment meets Federal food safety standards.

5. Initiate appropriate enforcement action if the SEC determines that an establishment is not operating in compliance with the FMIA or PPIA including implementing the applicable regulations in 9 CFR part 300 to end. The SEC is authorized to initiate any appropriate enforcement action provided for in the FSIS Rules of Practice under 9 CFR Part 500 if the SEC determines that a selected establishment is operating in a manner that is inconsistent with the Acts (9 CFR 332.9(b) and 381.519(b));
6. Consult with the DM to determine the need to request that an FSIS Enforcement, Investigation, and Analysis Officer (EIAO) conduct an FSA or the need to request that an FSIS DVMS assess humane handling and slaughter at the selected establishment;
7. In a verification report to the DM, the SEC or designee is to document the OFO verification visit to the selected establishment. The OFO verification visit may be conducted by the SEC or other employees that the DO has designated to perform SEC duties. The report is to include an overview description to summarize the SEC's verification activities, findings, and assessment of the compliance of the selected establishment with all applicable Federal requirements. This overview description will also serve as the confirmation that all onsite verification activities, as instructed in this directive, were completed. The SEC's documentation in the verification report is to provide the level of detail necessary to support the compliance conclusion and the Quarterly Report as described in Chapter IV. I. Part D below, and as instructed in this directive.

D. The SEC is to provide an electronic copy of this verification report to the State MPI Director. The SEC is to also include in the individual selected establishment OFO oversight verification report:

1. Selected establishment number, name of the establishment, and physical address;
2. Date of onsite visit;
3. FSIS and State inspection personnel present;
4. Selected establishment CIS program operations on the day of the visit and specify which were directly observed by the SEC;
5. Specifically, whether the establishment was producing products under the CIS program on the day of the SEC verification visit or if the CIS inspected operations had concluded prior to the SEC arrival;
6. Specifically, which inspection activities the SEC directly observed the designated State personnel performing during the visit; and
7. Whether CIS regulatory compliance or noncompliance with all applicable Federal standards was observed;
 - a. If regulatory noncompliance was observed, the SEC is to identify the type of regulatory noncompliance, the designated State MPI personnel's response, and outcome (e.g., "HACCP recordkeeping noncompliance was observed for CIS raw intact CCP monitoring and documented by the designated State personnel in a NR; no additional regulatory actions required.").

When regulatory compliance is observed, the SEC should identify the same types of applicable information as when noncompliance is observed. For example, "During the onsite visit, the selected establishment produced raw intact beef products under the CIS program. I directly observed the State designated personnel perform SPS, Sanitation SOP, HACCP, and labeling verification of raw intact operations. I reviewed the selected establishment's written programs for these processes and directly observed that the appropriate inspection methodology was applied and concurred with the State designated personnel's assessment of the selected establishment's regulatory compliance with applicable Federal requirements."

- b. Ensure that all State MPI personnel documentation has been reviewed (e.g., PHIS Reports, Noncompliance Records, MOI, Laboratory Sampling Result Records). The SEC is to specifically identify the name and date period of each report and documentation type reviewed.
 - i. For example, “I requested and reviewed the PHIS Reports *Establishment Data Summary, Establishment Profile, MOIs for an Establishment, Noncompliance Records for an Establishment, and Task Summary for an Establishment*, as well as the State MPI raw ground beef sampling records for 1/1/2019– 4/15/2019.”
 - ii. The SEC may review electronic versions of the documentation in advance of the onsite rather than requesting the materials be printed and made available at the time of the onsite visit; and
 - iii. If a PHRE and/or FSA was performed, the SEC is to state whether the designated State personnel are performing these activities in a manner that is “same as” that of FSIS.

E. Quarterly Reports: The SECs are to prepare a report on a quarterly basis that describes the status of each selected establishment under the SEC’s jurisdiction (9 CFR 332.8(a) and 381.518(a)) to be submitted to the FSIS Administrator through the applicable DM (9 CFR 332.8(c) and 381.518(c)). For the purpose of this submission, the CIS Program Coordinator is to verify the accuracy of the report, resolve any errors with the SEC(s) and DMs, and distribute the finalized report to the OFO Assistant Administrator (AA), or designee, for submission to the Administrator. The quarterly report is to include:

1. An assessment of the performance of the designated State inspectors in conducting inspection activities. The report is to identify whether the activities of designated State inspectors accurately depict each selected establishment’s level of compliance with the FMIA or PPIA and 9 CFR 300 to end;
2. A list of selected establishments that SECs have verified are in compliance with all Federal requirements;
3. A list of selected establishments that have been deselected under 9 CFR 332.10 and that are transitioning to become official Federal establishments under 9 CFR 332.11;
4. The CIS program coordinator is to work with the SECs to prepare a single consolidated quarterly report representing all Districts. In addition to the above, a consolidated quarterly report representing more than one district is to include:
 - a. A summary table identifying the number of selected establishments by State;
 - b. A summary table identifying the number of SEC visits performed during the quarter by State and type; and
 - c. The information as above in C. 1 -3 organized by District.

F. Oversight of Recalls under a CIS Program: As part of administering a “same as” program, the State MPI program is to notify the FSIS DO within 24 hours of learning that a CIS establishment has shipped or received adulterated or misbranded products in commerce produced under the CIS program. The SEC is to enter an Agency Report of Adulteration (ARA) in PHIS, notify the FSIS OFO Recall Management and Technical Analysis Division (RMTAD) via FORecalls@usda.gov and provide an awareness summary of the situation. RMTAD will manage the event as per [FSIS Directive 8080.1, Recall of Meat and Poultry Products](#). The SEC that covers the State where the potential recalling establishment is located will serve as the District Recall Officer (DRO). The DRO is the official responsible for coordinating field recall activities and providing direction to inspection program personnel. The SEC performs all functions of the DRO as per

FSIS Directive 8080.1 and coordinates activities for both the State officials and FSIS inspection program personnel (IPP).

1. If a selected establishment agrees to an FSIS voluntary recall recommendation of meat or poultry product produced under the CIS program, the SEC is to follow the instructions in Directive 8080.1 and act as the point of contact between the State MPI program and FSIS.
2. The SEC is to:
 - a. Coordinate with State officials to ensure that the appropriate designated State personnel for the selected establishment recalling the product are available to participate on the recall committee call;
 - b. Coordinate the information and documentation distribution between the State MPI and FSIS; and
 - c. Coordinate with the State MPI officials and FSIS to complete the effectiveness checks.

II. DESELECTION OF ESTABLISHMENTS FROM THE CIS PROGRAM: SEC AND DM RESPONSIBILITIES

A. Selected establishments that become ineligible to participate in the CIS program for any reason (e.g., they are no longer in compliance with the Federal Acts or they employ more than 25 employees on average) will be deselected from the CIS program (9 CFR 332.10(a) and 381.520(a)). An establishment that has been deselected from a CIS program that intends to continue to produce products amenable to the FMIA and PPIA is required to transition to become an official Federal establishment (9 CFR 332.10(b) and 381.520(b)). Establishments deselected from the program may elect to cease any inspected operations rather than transition to become an official Federal establishment, but they may not conduct operations under a State Grant of Inspection after they have been deselected.

B. Violating the Acts: If inspection at a selected establishment is suspended for any of the reasons specified in 9 CFR 500.3 or 500.4, the SEC, in consultation with the DM, is to provide an opportunity for the establishment to implement corrective actions and remain in the CIS program or move to deselect the establishment (9 CFR 332.9(c) and 318.519(c)). In making this determination, the SEC and DM are to consider:

1. The noncompliance that led to the suspension;
2. The selected establishment's compliance history;
3. Whether the establishment's proposed corrective actions will adequately address all the deficiencies and will resolve the deficiencies if properly implemented; and
4. Whether the selected establishment's proposed corrective actions will ensure the safety of all affected meat and poultry products.

C. If an establishment is deselected for violating the Acts, the SEC, in consultation with the DM, is to orally notify both the establishment and the State MPI program officials. The SEC is to follow-up the oral notification with a written notification. The written notification is to clearly state the violations that led to the deselection and explain that the establishment will need to develop and implement a corrective action plan to address all violations to transition to become an official Federal establishment.

D. The SEC, in consultation with the DM, is to develop and implement a plan to coordinate with the State to transition the deselected establishment to become an official Federal establishment.

III. DESELECTION FOR EMPLOYING MORE THAN 25 EMPLOYEES ON AVERAGE

- A. If the SEC determines that a selected establishment employs more than 25 employees on average, based on the standards in 9 CFR 332.3 or 381.513, the SEC is to notify the DM.
- B. The SEC, in consultation with the DM, is to provide written notification to the establishment and State MPI program officials that the establishment is being deselected from the CIS program because it has employed more than 25 employees on average.
- C. The SEC, in consultation with the DM, is to develop and implement a plan to coordinate with the State MPI program to transition the deselected establishment to become an official Federal establishment.

IV. TERMINATION OF A STATE'S AGREEMENT TO PARTICIPATE IN THE CIS PROGRAM- SEC AND DM RESPONSIBILITIES

A. FSIS will terminate a State's CIS program agreement if the State fails to conduct inspection services at selected establishments in a manner that complies with the FMIA or PPIA and the implementing regulations (9 CFR 321.3(d) and 381.187(d)).

B. SEC Role in Termination of a CIS program: If the SEC, in consultation with the DM, determines that State personnel are not providing inspection services in the same manner that Federal inspection personnel do, the SEC is to orally notify the State MPI program officials and follow-up the oral notification with a written notification. The written notification is to clearly specify the deficiencies and specify a date by which the State MPI program is to submit a corrective action plan.

- 1. The SEC, in consultation with the DM, is to review the State MPI program's corrective action plan to determine whether it:
 - a. Includes corrective actions that will adequately address all the deficiencies identified by the SEC if properly implemented;
 - b. Ensures that meat and poultry products being produced by selected establishments in the State are safe, wholesome, and not adulterated or misbranded;
 - c. Includes a timeline for implementation; and
 - d. Includes a plan to verify effective resolution of all identified deficiencies.
 - 2. The SEC is to verify that the State has effectively implemented the corrective action plan within the timeframe identified in the plan.
 - 3. If the State MPI program's written corrective action plan is inadequate, or if the State MPI program fails to develop or effectively implement the corrective action plan, the SEC and the DM are to notify the OFO Executive Associate for Regulatory Operations (EARO) for the district and recommend that the State's CIS program be terminated. If the OFO Assistant Administrator (AA) agrees with the recommendation, they are to inform the Administrator.
 - 4. If FSIS decides to terminate a State MPI program's agreement for the CIS program, the SEC is to identify which selected establishments in the State plan to transition to become official Federal establishments and which selected establishments plan to operate under the State's "at least equal to" intrastate MPI program. The SEC is to inform the DM.
- C. DM Role in Termination of a CIS program
- 1. If FSIS decides to terminate a State's agreement for a CIS program, the DM is to orally notify the State MPI program officials and follow-up with a written Notice of Program Termination. The Notice of Termination is to:

- a. Describe the reasons for terminating the State's cooperative agreement for a CIS program;
 - b. Identify the effective date of the termination;
 - c. Identify the selected establishments that will transition to become official Federal establishments and those that will revert to the State MPI program; and
 - d. Inform State MPI program officials that they may appeal the decision to the OFO EARO for the CIS program and inform them that if they do not appeal within 30 days from the date of the Notice of Termination, the decision will be final.
2. When a State's agreement for a CIS program is terminated, the DM, in consultation with the SEC, is to develop a plan to transition selected establishments that choose to continue to ship products interstate to become official Federal establishments and to transition establishments that choose to revert back to the State MPI program, and become eligible to ship products intrastate only, to that program.
 3. The DM is to notify the FSIS programs listed in Chapter V of the State's Notice of Termination from the CIS program.

CHAPTER V--ESTABLISHING THE CIS PROGRAM AND THE ROLES OF OTHER FSIS PROGRAMS

I. OPPD, LABELING AND PROGRAM DELIVERY STAFF (LPDS)

A. LPDS is to evaluate the labels of meat and poultry products that will be produced in selected establishments participating in the CIS program if such labels are not eligible for generic approval per 9 CFR 412.2 and including:

1. Labels for religious exempt products 9 CFR 412.1 ((c) (1));
2. Labels with special statements and claims 9 CFR 412 ((c) (3)); and
3. Labels for temporary approval 9 CFR 412.1 ((c) (4)).

B. LPDS will provide clarification and assistance in answering questions concerning the Federal requirements for labels submitted.

C. If LPDS determines that the labels from a selected establishment comply with all Federal requirements and are truthful and not misleading, it will approve the labels. LPDS will email a copy of the approved label and label summary to the selected establishment submitter, State MPI Director, and the District SEC with oversight of the participating State. LPDS retains an electronic copy of all label applications and labels for each selected establishment in LSAS.

D. LPDS will return the labels that cannot be approved to the selected establishment submitter, the State MPI Director, and the District SEC with oversight of the participating State and include an explanation of why the label was not approved.

II. OCIO STATE COORDINATOR

The OCIO State Coordinator is to establish an annual supplemental cooperative agreement between the State MPI program and FSIS OCIO for the CIS program.

III. OEED

OEED is to:

1. Provide for the timely announcement of FSIS inspection program training sessions and the enrollment of designated State MPI inspectors into those sessions;
2. Provide outreach and updates to State CIS program officials on how to obtain student training materials as applicable to the required FSIS trainings; and
3. Provide assistance to CIS program personnel on how to complete and document trainings through the USDA AgLearn system.

IV. OPHS

A. OPHS/Laboratory accreditation: The OPHS laboratory methods SME is to:

1. Provide guidance and answer questions from State or State-contracted laboratories that are actively seeking ISO 17025 accreditation;

NOTE: States or laboratories should use the following e-mail address to submit questions or requests for guidance to OPHS: statelabinquiry@usda.gov

2. Work with the CIS program coordinator to verify that State or State-contracted laboratories that do not have, but that are actively seeking, the required ISO 17025 accreditation can demonstrate that they meet the criteria in the State Meat and Poultry Inspection Program Laboratory QA Checklist until they obtain the ISO 17025 accreditation;
3. Review justifications submitted by laboratories that are unable to follow an FSIS method as written to determine whether the modified method can achieve results that are consistent with the corresponding FSIS method; and
4. Conduct initial and periodic laboratory audits or record reviews of performance of methods and critical QA/QC activities.

B. OPHS/Sampling plan: When contacted by a State, the OPHS sample collection SME is to assist the State in developing a microbiological and chemical sampling plan for the establishments that the State will be utilizing in inspection under the CIS program. OPHS is to work with the CIS program coordinator to verify that the State's sampling plan provides for the State to collect and analyze the same number and type of samples that FSIS collects under the Federal regulatory sampling program.

V. QUESTIONS

IPP are to refer questions regarding this directive to their supervisor. Follow-up questions can be sent to OPPD through [askFSIS](#) or by telephone at 1-800-233-3935.



Assistant Administrator
Office of Policy and Program Development