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

FSIS DIRECTIVE

5710.1 Rev. 1

6/1/16

DESIGNATION OF A STATE OR INDIVIDUAL STATE-INSPECTED ESTABLISHMENT FOR FSIS INSPECTION

CHAPTER I – GENERAL

I. PURPOSE

This directive has been revised to provide comprehensive instructions for the Office of Field Operations (OFO): District Managers (DMs) and frontline supervisors (FLSs); personnel in the Office of Investigations, Enforcement and Audit (OIEA): Federal State Audit Branch (FSAB); the Office of Outreach, Employee Education and Training (OOEET); the Office of Policy and Program Development (OPPD): Issuances Staff (IS) and Labeling and Program Delivery Staff (LPDS); the Office of the Chief Human Resource Officer (OCHRO); the Office of the Chief Information Officer (OCIO); the Office of the Chief Financial Officer (OCFO); the Office of Public Health Science (OPHS), and the Office of Public Affairs and Consumer Education (OPACE) to follow in designating a State meat or poultry inspection (MPI) program for Federal inspection. This directive provides new procedures for designating an individual State-inspected establishment for Federal inspection, and for transferring functions and responsibilities from a State MPI program to FSIS when designating a State or an individual State-inspected establishment.

KEY POINTS:

- Updated procedures for designating a State for Federal inspection
- New procedures for designating an individual State-inspected establishment for FSIS's Federal inspection program
- New procedures for transferring State MPI program establishments to FSIS when a State or individual state inspected establishment is designated
- New procedures for notifying the Governor of a State when a State is recommended for designation

NOTE: These instructions do not apply to State establishments operating under the Cooperative Interstate Shipment (CIS) program. Instructions for terminating a State's agreement for a CIS program and procedures for deselecting an establishment operating under a CIS program are covered in <u>FSIS</u> <u>Directive 5740.1</u>, Cooperative Interstate Shipment Program.

DISTRIBUTION: Electronic OPI: OPPD

II. CANCELLATION

FSIS Directive 5710.1, Designation of States for Federal Meat or Poultry Inspection, 2/27/84

III. BACKGROUND

- A. The Federal Meat Inspection Act (FMIA, 21 U.S.C. 601-695) and the Poultry Products Inspection Act (PPIA, 21 U.S.C. 451-471) require State Cooperative MPI programs to enforce requirements that are "at least equal to" Federal requirements under the ante-mortem and post-mortem inspection, re-inspection, sanitation, and recordkeeping provisions of the Acts (FMIA, §301(a)(1), (2), 21 U.S.C. 661(a)(1), (2)) and (PPIA, §5(a)(1), (2), 21 U.S.C. 454(a)(1), (2)). State meat inspection programs must also enforce requirements "at least equal to" the Humane Methods of Slaughter Act (HMSA, §§1-6, 7 U.S.C. 1901-1906).
- B. Under the FMIA (§301(c), 21 U.S.C. 661(c)) and the PPIA (§5(c), 21 U.S.C. 454(c)), when the Secretary of Agriculture determines that a State MPI program is not enforcing requirements "at least equal to" those imposed under the FMIA or PPIA, the Secretary of Agriculture must designate the State as one in which FSIS's Federal Meat and Poultry Inspection regulations apply to operations and transactions within the State. The designation of a State may be voluntary, at the State's request, or involuntarily imposed by FSIS under the FMIA and PPIA.
- C. Designation of a State means that all establishments within the State where livestock or poultry amenable to Federal inspection are slaughtered, or their carcasses or parts are prepared or processed for use as human food under the State's inspection program must be transferred to the Federal meat and poultry inspection program overseen by FSIS.
- D. The FMIA (§301(c)(1), 21 U.S.C. 661(c)(1)) and PPIA (§5(c)(1), 21 U.S.C. 454(c)(1)) require the designation of an individual State-inspected establishment when it has been found to be producing adulterated product, thereby endangering public health, and when State officials have failed, after being notified, to take timely action to prevent a risk to public health. When FSIS designates individual State establishments, the establishments come under FSIS inspection (9 CFR 331.5(a), 381.225(a)).
- E. Under 9 CFR 331 and 9 CFR 381, Subpart V, the designation of a State applies to operations and transactions wholly within a State, and each establishment located in the designated State must be granted Federal inspection if a combined evaluation of the premises, facilities, and operating procedures finds the establishment to be capable of producing products that are not adulterated or misbranded.

CHAPTER II – THE DESIGNATION PROCESS

I. VOLUNTARY DESIGNATION

- A. The Governor of a State, or the Governor's designee, may notify FSIS in writing that the State is unable or unwilling to maintain the State's MPI program and may request that USDA designate the State-inspected meat or poultry establishments to receive Federal inspection.
- B. Immediately after the FSIS Assistant Administrators (AAs) for OIEA and OFO have reviewed and approved the voluntary designation of a State, the OIEA AA is to inform the FSIS Administrator of the decision. Once the FSIS Administrator has approved the decision to designate the State, the Office of the Administrator is to notify the Under Secretary for Food Safety and the Secretary of Agriculture of the decision. After the Secretary of Agriculture approves the designation of the State, the OIEA AA is to notify the OPPD AA of the decision to designate the State MPI program. OPPD's Issuances Staff will prepare a

Federal Register notice informing the public that the State has been designated, as required by the FMIA (§301(c), 21 U.S.C. 661(c)) and PPIA (§5(c), 454(c)), and that the previously State-inspected establishments will be under Federal inspection 30 days after publication of the notice.

- C. The OPPD Issuances Staff will also draft a rule to amend the Federal meat and poultry inspection regulations to add the State to the list of designated States.
- D. The OIEA AA is to promptly notify the FSIS Chief Financial Officer of the designation so that Agency funding to the designated State MPI program can be terminated.
- E. The OIEA AA is also to notify the OPHS AA of the designation in order to (1) prepare the Field Service Laboratories for possibility that the States will not be sending samples or that the States will send additional samples to the FSIS laboratories; and (2) so that OPHS Laboratory Quality Assurance Staff (LQAS) can adjust the State laboratory audit schedule.
- F. After FSIS accepts a State's voluntary designation, Agency personnel are to follow instructions in Chapter Three (below), "Transfer of State-Inspected Establishments and Custom-Exempt Operations to the Federal Inspection Program."

II. FOR-CAUSE DESIGNATION

- A. FSIS conducts annual audits of the State MPI Programs in accordance with FSIS Directive 5720.3, Methodology for Performing Scheduled and Targeted Reviews of State Meat and Poultry Programs. Under that directive, FSAB is to notify the appropriate State MPI program officials, in writing, of any negative findings during the annual comprehensive review of the State MPI program. The notification is to summarize the review findings and detail corrective actions that the State MPI program must take to address the deficiencies. In the notification, FSAB is to request that the State include the following information in its response:
 - 1. The underlying causes of system-wide negative findings in the review report;
 - 2. Measures to correct the negative findings and prevent their recurrence;
 - 3. The verification plan or internal controls that the State MPI program will implement to verify the effective resolution of the negative findings;
 - 4. The underlying causes of specific negative findings at individual establishments and confirmation that the establishments have corrected such deficiencies;
 - 5. A timeline for full implementation if the State MPI program is unable to implement the action plan in the reasonable time frame established by FSIS as a time appropriate for the severity of the violation and in a manner that protects public health;
 - 6. Confirmation that the State MPI program has the capacity to ensure the safety of all meat and poultry products, through regulatory control actions, recalls, or enforcement actions; and
 - 7. Confirmation that the State MPI program officials have demonstrated their commitment and ability to make the corrections and to provide the resources necessary to make the required changes.
- B. Unless there is an imminent public health hazard, FSAB is to give the State MPI program a reasonable opportunity (case-by-case and based on the severity of the deficiencies) to submit and

implement a corrective action plan, in accordance with the guidelines detailed in the notification, to correct the deficiencies identified in the State's MPI program. Additionally, the notification is to clearly state that the negative findings, if not corrected, will result in the State's designation pursuant to the FMIA (§301(c), 21 U.S.C. 661(c)) and the PPIA (§5(c), 21 U.S.C. 454(c)).

- C. After receiving the State's corrective action plan, FSAB is to analyze the corrective action plan to determine whether it:
 - 1. Adequately addresses all negative findings detailed in the review findings;
 - 2. Ensures the safety of all meat and poultry products;
 - 3. Ensures products are accurately labeled and not misbranded;
 - 4. Adequately explains how its implementation will resolve the deficiencies in the review findings;
 - 5. Includes evidence that implementation is underway or provides a timeline for expedient implementation; and
 - 6. Includes a verification plan or internal controls plan to verify effective resolution of the deficiencies, e.g., a newly contracted pest control plan that targets control of specific pests if cited for vermin or rodents; a revised HACCP plan if cited for the inability to control biological, chemical, or physical hazards in the production process; or a revised and improved product recall plan if a product recall process failed to remove adulterated or misbranded products from commerce.
- D. If FSAB determines that the corrective action plan will result in the timely correction of the State MPI program's deficiencies, the FSAB Chief is to draft a letter for the OIEA AA to notify the State MPI program officials of the decision to defer designation for a specified time period. The specified time period allows the State to implement its corrective action plan and is not to exceed 12 months from the date of the deferral notification agreed on by FSIS and State officials.
- E. After the agreed-on time period for implementing the corrective action plan expires, FSAB is to conduct a follow-up review to determine whether the plan succeeded in correcting the deficiencies. FSAB is to determine the scope and activities of the follow-up review case by case, and after consulting with other relevant FSIS Offices.
- F. After a determination that the program's negative findings have been corrected, FSAB is to notify the State MPI program officials in writing that the deficiencies detailed in the corrective action plan have been adequately addressed and that the State MPI program has maintained an "at least equal to" status.
- G. If FSAB determines that the State MPI program failed to submit a corrective action plan within 10 business days (unless the time period is extended by FSIS), or has failed to implement the necessary program changes to maintain an "at least equal to" status within 12 months, FSAB is to inform the OIEA AA and, recommend designation of the State.
- H. If the OIEA AA approves the recommendation to designate the State, the OIEA AA is to notify the FSIS Administrator of the recommendation. If in agreement with the recommendation, the FSIS Administrator is to advise the Under Secretary for Food Safety and the Secretary of Agriculture. The Secretary of Agriculture is to promptly notify the Governor of the State and allow the State an opportunity to discuss the Agency's findings and recommendation to designate the State. The OIEA AA is to follow up with the FSIS Administrator's office to ensure that the Secretary of Agriculture has notified the Governor of the State, as

required.

- I. Immediately after the Secretary of Agriculture approves the designation of the State, the OIEA AA is to notify the OPPD AA of the decision to designate the State. OPPD's Issuance Staff will prepare a *Federal Register* notice informing the public that the State has been designated, as required by the FMIA (§301(c), 21 U.S.C. 661(c) and PPIA (§5(c), 21 U.S.C. 454(c)), and that the designated State's meat or poultry product establishments will be subject to Federal inspection 30 days after publication of the notice.
- J. The OIEA AA is to promptly notify the FSIS Chief Financial Officer of the designation so that funding to the designated State MPI program can be terminated.
- K. The OIEA AA is to promptly notify the OFO AA of the pending designation so that OFO can plan on adding the State establishments to its workload.
- L. The OIEA AA is to promptly notify OPHS, ODIFP and other FSIS program areas (as needed) so that appropriate supplies, equipment, and sampling algorithms are made available for the added establishments.

III. DESIGNATION OF AN INDIVIDUAL STATE ESTABLISHMENT

- A. FSIS may designate an individual State establishment for Federal inspection if FSIS determines, either through FSAB State MPI program reviews or by other means, that the establishment is producing adulterated meat or poultry food products for distribution, thereby endangering public health, and the State MPI program failed to take action to prevent this endangerment of the public health within a reasonable time after FSIS has notified the State of the risk (9 CFR 331.5).
- B. If the FSAB Chief obtains evidence, either through the FSAB State MPI program reviews or by other means, that a State-inspected establishment is producing adulterated product and thereby endangering public health, the FSAB Chief is to advise the State MPI program officials in writing of the deficiencies and specify a reasonable time for them to take effective action under State or local law to avoid endangering public health (9 CFR 331.5(b)(1)). FSIS will provide a reasonable time period, on a case by case basis, that is appropriate for the seriousness of the deficiencies and the threat to public health.
- C. Such written notification is to specify the deficiencies deemed to result in the production of adulterated products and shall specify a reasonable time for such action under State or local law.
- D. If effective action is not taken under State or local law within the specified time, written notification is to be issued by the FSAB Chief to the State MPI program officials specifying the deficiencies involved and allowing ten days, unless there is a need to take immediate action, for the presentation of their views or for making the necessary corrections. The notification is to also advise the State MPI program officials that program deficiencies has triggered a targeted review of their program, and that failure to correct the deficiencies will result in the establishment and operator becoming subject to the provisions of titles I and IV of the Act as though engaged in commerce.
- E. If FSAB finds that effective action has not been taken under State or local law, the FSAB Chief is to provide written notification to the State MPI program officials and the establishment operator that the failure to do so may result in the designation of the individual State establishment. (9 CFR 331.5(b)(2)).
- F. At the expiration of the 10 days, FSAB is to assess the State MPI program's views and corrections and survey the establishment and determine whether it should be designated (9 CFR 331.5(b)(3)).

- G. If the establishment is recommended for designation the FSAB Chief is to provide written notice of the recommendation to the State MPI program officials and the establishment operator. Products on hand at the time of designation are subject to detention, seizure, and condemnation as outlined in 9 CFR 331.5(c) and FSIS Directive 8410.1, Detention and Seizure.
- H. The FSAB Chief is to recommend to the OIEA and OFO AA that an individual establishment should be designated. If the AA agrees with the FSAB Chief's recommendation to designate the individual establishment, the OIEA and OFO AAs are to:
 - 1. Notify the FSIS Administrator and the Undersecretary for Food Safety of the decision;
 - 2. Explain to the Administrator the requirement for the Secretary of Agriculture to notify the Governor of the State and the National Advisory Committee on Meat and Poultry Inspection of the findings and the recommendation for designation of the establishment under 21 U.S.C 454(c)(1) or 661(c)(1);
 - 3. Provide the FSIS Administrator with a draft of the notification to the Governor;
 - 4. Notify the appropriate State MPI program officials of the decision; and
 - Ensure that the necessary steps, outlined in Chapter III of this directive, are taken for the
 establishment to become an official Federal establishment if the establishment owner or operator
 intends to slaughter livestock or poultry, or prepare meat or poultry products for human food incommerce.

CHAPTER III – TRANSFER OF STATE-INSPECTED ESTABLISHMENTS AND CUSTOM-EXEMPT OPERATIONS TO THE FEDERAL INSPECTION PROGRAM

I. GENERAL

- A. The designation of a State MPI program may result in the Agency having to assume the jurisdiction and inspection responsibility over a large number of State-inspected establishments in a short period of time. The OFO District Office (DO) with jurisdiction in the State has primary responsibility for overseeing the transfer of State-inspected establishments to Federal jurisdiction, although many other FSIS offices have critical roles. In the interest of public health and because of the many details and short time available to accomplish the transfer, it is essential that all offices do their part to communicate and cooperate with other offices and stakeholders involved in the transition.
- B. Before the effective date of designation, FSIS's OFO, DO personnel in the affected district are to determine if the establishment operators intend to apply for a Federal grant of inspection, operate under custom or retail exemption, or discontinue operations, and if so, ensure they comply with the Federal requirements. They are to also document any issues or concerns, and share them with the establishment operators. OFO personnel are to follow the procedures as detailed in Section III below.

II. FSIS COORDINATION

A. The Deputy Director of the Outreach and Partnership Division (OPD) in OOEET is to coordinate the designation procedures with OFO's Headquarters and DO personnel. The OPD Deputy Director is to notify the appropriate personnel in the following FSIS organizations of the impending designation:

- 1. Resource Management and Planning Staff (RMPS) and the OFO DO with jurisdiction in the State:
- 2. Office of Management (OM) OCHRO, Human Resources Operations (HRO), and OCFO;
- 3. OPPD LPDS and IS:
- 4. OIEA;
- 5. OCIO:
- 6. OPACE:
- 7. OPHS Executive Associate for Laboratory Services (EALS) and Director of LQAS; and
- 8. OCFO.
- B. Also, the Deputy Director of OPD is to:
 - 1. Work with the appropriate State officials, DMs, and other FSIS personnel in offices with responsibilities in the designation procedures;
 - Identify all State-inspected establishments and custom-exempt operations within the State and provide a list of State establishments to the appropriate DM that includes, at a minimum, the following:
 - a. Name and address of the establishment or custom-exempt facility;
 - b. Establishment or facility operator's contact information;
 - c. Products produced (meat, poultry, meat food products, or poultry products); and
 - d. Type of operations (inspected slaughter/processing or custom-exempt slaughter/processing);
 - 3. Inform OPPD/LPDS of the impending designation, its effective date, and the projected number of establishments that may apply for federally approved labels;
 - 4. Notify OIEA's Enforcement and Litigation Division (ELD) of the impending designation and the effective date;
 - 5. Notify OIEA's, ELD of the projected number of establishments that may apply for a Federal grant of inspection, as a result of the designation;
 - 6. Notify each State-inspected establishment and custom-exempt operator, as soon as practicable, of the designation and the impending transfer of State establishments that have been approved for a conditional grant of inspection.
 - a. If the DM decides that there may be a basis for refusing to provide inspection and for not granting conditional inspection, he or she is to inform the applicant in writing that the

matter has been referred to OIEA ELD. The DM will provide pertinent information to ELD in accordance with <u>FSIS Directive 8010.5</u>, Case Referral and Disposition.

- b. If the DM decides that inspection service should be provided to the establishment, he or she is to issue a conditional grant of inspection. The DM is to issue FSIS Form 5200-1, Grant of Inspection Application, checking the box indicating "conditional," meaning conditional inspection. The DM is to return a signed copy of FSIS Form 5200-15, Hours of Operation Request/Approval, to the establishment, stating the approved operating hours and agreeing with establishment management on a date to inaugurate conditional inspection. The DM is then to ensure that his or her staff updates the Public Health Information System (PHIS) to reflect the conditional status of the grant and the establishment's approved operating hours (see PHIS Users Guide).
- c. During the 90 days following the issuance of the conditional grant of inspection, in accordance with 9 CFR 304.3(b) and 381.22(b), the DM is to gather information that will assist in determining whether the establishment meets the terms of the conditional grant of inspection. In addition to drawing on information in PHIS, the DM is to direct IPP to verify that the establishment has validated its HACCP plans as instructed by <u>FSIS</u> <u>Directive 5000.1</u>, Verifying an Establishment's Food Safety System.
- 7. Inform meat and poultry establishment owners and operators that OFO DO personnel will further explain the designation process, the procedures to follow in applying for Federal inspection, and the label application process; and
- 8. Provide each State-inspected establishment with appropriate guidance materials, applications for Federal inspection and Federal labels, including:
 - a. The Federal Grant of Inspection Guide at http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/apply-for-a-federal-grant-of-inspection; and
 - b. The Label application guidance at: The Label application guidance at: http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-procedures/label-application-quidance

III. OFO INSTRUCTIONS

A. When an applicant requests a grant of inspection, the DO is to provide the following link which contains the necessary instructions and forms to be completed: http://www.fsis.usda.gov/Regulations & Policies/Grant of Inspection Guideline/index.asp

- B. The DM or designee is to:
 - Assign a FLS or designee to the State establishments that slaughters livestock or poultry, prepares or processes carcasses and parts or products thereof for use as human food, prior to the official designation date to:
 - a. Determine the establishment operator's intentions for applying for Federal inspection, operating under a custom or retail exemption, or discontinuing operations;
 - b. Assess whether or not the establishment meets Federal regulatory requirements,

document any deficiencies, and schedule follow-up visits, as needed; and

- c. Determine the staffing requirements for Federal inspection.
- 2. Notify each State establishment owner or operator of the pending assessment before the visit;
- 3. Notify each State establishment owner or operator of:
 - a. The effective date of designation and the date that they can no longer operate under a State program;
 - b. The role and contact information for the FLS; and
 - c. Any deficiencies identified during the establishment visit that require corrective action before the establishment is eligible for inspection services;
- Notify each establishment owner or operator who intends to continue operating under a custom
 or retail exemption of the need to meet Federal exemption requirements by the effective date of
 designation;
- 5. Review and process the applications for Federal inspection as instructed in <u>FSIS Directive</u> <u>5220.1</u>, Granting Or Refusing Inspection; Voluntary Suspending or Withdrawing Inspection;Reinstating Inspection Under PHIS, including initial review for completeness, providing an electronic copy to ELD with a request for a compliance background inquiry, and continued processing only after completion of ELD's evaluation and notification of the findings;
- 6. Ensure his or her staff initiates records in PHIS to reserve establishment numbers as instructed in the PHIS Users Guide and Instructions. For each new applicant, PHIS will automatically assign an establishment number, and all corresponding types of operation (meat, poultry, and reimbursable service) will be reserved for the establishment under the same number for future use. (Refer to FSIS Directive 5220.2, Meat and Poultry Establishment Numbering Procedures, and the PHIS Users Guide);
- 7. Order temporary carcass and meat food product brands for the use of each establishment that is granted Federal inspection until the establishment obtains its own brands;
- 8. Order adhesive inspection legends for each establishment granted Federal inspection;
- 9. Work with OFO Headquarters staff and HRO to determine how many additional full-time employees are needed, staff the positions, and train personnel, as needed;
- 10. Assign inspectors and FLS to establishments that have been granted inspection; and
- 11. Work with OCIO to install computers, phone lines, and high-speed Internet connections, where necessary.
- C. The FLS or designee who performs the establishment visits (described in Section III.B.1) is to:
 - 1. Conduct entrance and exit meetings with establishment management to:

- a. Explain the purpose of the visit;
- b. Find out if the establishment's owner or operator plans to apply for Federal inspection;
- c. Explain the process for obtaining a Federal grant of inspection;
- d. Determine the establishment's conformity with Federal regulatory requirements;
- e. Provide an itemized list of any observed deficiencies that must be corrected to meet the requirements; and
- f. Answer any question from the establishment management;
- 2. Immediately notify the DM if an establishment's management is uncooperative;
- Discuss the FMIA at: http://www.fsis.usda.gov/wps/portal/fsis/topics/rulemaking/poultry-products-inspection-acts/PPIA, and the current revision of Title 9 CFR, Parts 300 599, with each establishment operator and provide them with the FSIS link to access copies of each on FSIS's website;
- 4. Explain the Federal Grant of Inspection application process to establishment operators that intend to operate under Federal inspection and to those who are undecided at this time;
- 5. Provide establishment operators with FSIS Form 5200-2, Application for Federal Meat, Poultry, or Import Inspection, FSIS Form 5200-15, the Sanitation Standard Operating Procedures (SOPs) Guidelines for Meat and Poultry Establishments, and <u>FSIS Directive 8080.1</u>, Recall of Meat and Poultry Products, including Attachment 1, Product Recall Guidelines for Firms. Advise establishment operators to submit hours of operation to the DM for approval, and indicate that any operations that require inspection are to be conducted under the supervision of FSIS personnel;
- Explain to establishment management the process for obtaining Federal inspection brands and marking devices, and determine how many adhesive inspection legends the establishment will need for use on generically approved labels for the next 90 days;
- 7. Perform the following during on-site visits of establishments that intend to apply for Federal inspection service:
 - a. Review the facilities and equipment and determine whether the establishment complies with 9 CFR 416.1 through 416.5;
 - If the establishment is performing slaughtering activities, assess whether the establishment can handle and slaughter livestock humanely as set out in 9 CFR, part 313;
 - c. Check to make sure that the establishment has developed written Sanitation Standard Operating Procedures (Sanitation SOPs) as required by 9 CFR 416.11 through 416.16;
 - d. Check to make sure that the establishment has conducted, or has had conducted for

- it, a hazard analysis for all processes and has developed Hazard Analysis and Critical Control Point (HACCP) plans for the processes where one or more hazards are reasonably likely to occur, in accordance with 9 CFR, part 417:
- e. Determine whether the establishment has prepared and maintains written procedures for the recall of any meat, meat food, poultry, or poultry product produced and shipped by the establishment, in accordance with 9 CFR 418.3;
- f. Document any deficiencies that need to be corrected in order to meet Federal inspection requirements, and share a copy of the documentation with establishment management;
- g. Complete the portion of FSIS Form 5200-4 entitled "Recommendation on Application for Inspection" with recommendations for correcting any noncompliance observed or a recommendation that a conditional grant of inspection be issued; and
- h. Forward the completed FSIS Form 5200-4 to the DM;
- 8. Inform the applicant establishment, in writing, that its application has been referred to OIEA ELD, in accordance with <u>FSIS Directive 8010.5</u>, if the DM decides there may be a basis for refusing to provide inspection;
- 9. Discuss future plans for the establishment with the establishment owner, and forego assessing establishment facilities, equipment, Sanitation SOPs, or HACCP systems if the establishment operator intends to discontinue operations;
- 10. Examine all labeling and marking devices to determine their compliance with Federal requirements. Document any noncompliance and share the results with establishment management. Advise establishment management on which labels may be generically approved, and on those that require FSIS sketch approval and provide a copy of the compliance guideline for labeling that can be accessed at: http://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Comp-Guide-Labeling-Evaluation-Approval.pdf?MOD=AJPERES;
- 11. Explain how to obtain Federal label approval and that FSIS Form 7234-1 can be accessed at http://www.fsis.usda.gov/wps/wcm/connect/4aeeca8c-8ba6-4288-a222-e6ca8764a9f7/FSIS 7234-1 Approval of Labels.pdf?MOD=AJPERES;
- 12. Schedule and complete follow-up visits, before the official date of designation, to all establishments that were not recommended for Federal inspection approval during the initial visit because of noncompliance findings to determine whether the establishments have made necessary corrections and comply with Federal regulations. Summarize the noncompliances identified during the visit and any other notable observations, and state whether the establishment is recommended for Federal inspection. Provide establishment management with a copy of the noncompliances that were identified during the follow-up visit. If the establishment is not recommended for Federal inspection, do not deliver temporary brands or inspection legends; and
- 13. If the DM decides that there may be a basis for refusing to provide inspection and for not granting conditional inspection, he or she is to write to the applicant informing him or her that the matter has been referred to OIEA ELD. The DM will provide any pertinent information to ELD in accordance with *FSIS Directive* 8010.5.

IV. OCHRO, HRO INSTRUCTIONS

OCHRO HRO is to:

- 1. Work with the OFO DM in determining personnel requirements and in announcing any staff positions;
- 2. Contact State MPI program officials to obtain names and contact information for State inspectors who are interested in Federal employment; and
- 3. Send a Federal employment information packet to State employees who are interested in Federal employment and provide information on how to apply for a Federal position.

V. OCIO INSTRUCTIONS

OCIO is to:

- 1. Provide additional IT equipment (computers, printers) to appropriate inspection personnel within established time limits;
- 2. Order telephone lines and Internet connections for the establishments granted Federal inspection within the established time limits. The OCIO's order is contingent on the availability of services at the establishment locations; and
- 3. Set up the FSIS network and computer accounts as needed and within established timelines.

VI. OPPD INSTRUCTIONS

A. LPDS is to:

- 1. Evaluate for approval all label applications from State establishments converting to Federal inspection by the effective date of designation; and
- 2. Provide guidance and information to establishment operators on labeling requirements and standards of composition.
- B. IS is to publish a notice in the Federal Register announcing the State's designation and informing the public that, beginning 30 days after publication, official State establishments will be subject to Federal inspection.

VII. OPACE INSTRUCTIONS

OPACE is to advise appropriate Congressional staffs of the designation of a State or an individual State establishment and take the lead in requesting any required supplemental appropriations.

VIII. OOEET INSTRUCTIONS

OOEET is to:

- 1. Assist the OFO DO in scheduling the necessary program training for newly-hired inspection program personnel and FSIS personnel assuming new positions as a result of the designation; and
- 2. Assist the OFO DO, as needed, in providing information and outreach materials for new and prospective federally-inspected establishments.

IX. OPHS INSTRUCTIONS

OPHS is to:

- 1. Assist the OFO DO in the review and acceptance of the HACCP plans submitted, based on the current hazards connected with the species being slaughtered;
- 2. Assist OFO DO in determining the supplies needed for any chemical (residue), microbial or pathological sampling and/or testing at any and all State facilities being converted to Federal inspection; and
- 3. Work with ODIFP in determining the scientific sample algorithms necessary to verify food safety.

X. QUESTIONS

Refer questions regarding this directive to the Policy Development Staff through <u>askFSIS</u> or by telephone at 1-800-233-3935 or through Supervisory channels. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter **Directive 5710.1**

Question Field: Enter question with as much detail as possible.

Product Field: Select **General Inspection Policy** from the drop-down menu.

Category Field: Select Cooperative State Inspection Programs from the drop-down menu.

Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press Continue and at the next screen press Finish Submitting Question.

NOTE: Refer to FSIS Directive 5620.1, Using askFSIS, for additional information on submitting questions.

Assistant Administrator

Office of Policy and Program Development