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

FSIS DIRECTIVE

5220.1
Rev. 1

10/24/22

GRANT OF INSPECTION MANAGEMENT

I. PURPOSE

A. This directive provides instructions on how to manage a Federal grant of inspection (GOI) in the Public Health Information System (PHIS). These instructions apply to the Office of Field Operations (OFO) Frontline Supervisors (FLSs), District Managers (DMs), Grant Curators (GCs), and to personnel in the Office of Investigation, Enforcement and Audit (OIEA), Litigation and Enforcement Programs Staff (LEPS) and Enforcement Operations Staff (EOS). This directive includes instructions for issuing a GOI; for updating a GOI to reflect voluntary suspension or voluntary withdrawal; for how to reinstate the GOI after voluntary suspension or voluntary withdrawal; for FSIS withdrawal of inspection; for entering data related to these activities into PHIS; and for OIEA background inquiries conducted for applicants.

B. This directive has also been revised to include instructions for FSIS employees' responsibilities for egg products plants related to issuance of the Egg Products Inspection Regulations Final Rule (85 FR 68640). The title is shortened, and the instructions are reformatted for consistency and readability. The click-by-click PHIS user instructions have been removed. PHIS tutorials and user guides are maintained in PHIS Help or provided through supervisory instruction. This directive provides instructions from cancelled FSIS Directive 5220.2, *Meat and Poultry Establishment Numbering Procedures*, 9/28/98.

NOTE: In this directive, the term establishment includes official meat and poultry establishments and egg products plants. Official import inspection establishments are referred to by that name. Duties can be performed by a designee when appropriate, when the designee has the applicable role in PHIS available, and when approved by the supervisory chain.

KEY POINTS:

- *Provides instructions for FSIS employees to gather and record information related to the application for Federal inspection into PHIS*
- *Provides instructions to GCs for submitting FSIS Form 5200-2, Application for Federal Inspection, to LEPS and EOS for compliance background inquiries*
- *Provides instructions for FSIS employees' responsibilities when issuing a GOI*

II. CANCELLATION

FSIS Directive 5220.1, *Granting or Refusing Inspection; Voluntary Suspending or Withdrawing Inspection; and Reinstating Inspection under the Public Health Information System*, 5/24/19

FSIS Directive 5220.2, *Meat and Poultry Establishment Numbering Procedures*, 9/28/98

III. OFO GC RESPONSIBILITIES: GRANTING INSPECTION FOR NEW ESTABLISHMENTS AND OFFICIAL IMPORT INSPECTION ESTABLISHMENTS

A. The GC is to review submitted applications for accuracy and completeness, identify inaccurate or unclear information, and request clarification or additional information as needed. The GC is to return to the applicant any application that is not complete and specify the areas of the form that need attention. The GC is to confirm that inspection is required based on the intended activities listed on the application. Inspection is required, per 9 CFR 302.1, 9 CFR 381.6, 9 CFR 532.1, and 9 CFR 590.20, at establishments that slaughter or prepare meat food products; slaughter or process poultry; or process egg products for human food that are subsequently transported and held for sale in commerce. Examples of preparing meat or poultry products include, but are not limited to, canning, salting, rendering, boning, cutting up, or otherwise manufacturing or processing. Reinspection is also required, per 9 CFR 327.6, 9 CFR 381.199, 9 CFR 557.4, and 9 CFR 590.925 for products presented for entry to the United States for sale or distribution. These facilities are official import inspection establishments.

1. The GC is to be aware that an identification (ID) warehouse that does not prepare or process amenable products is not eligible for a GOI. An ID warehouse is a facility at which FSIS provides voluntary identification service for meat and poultry products, or egg products as described in 9 CFR 350.3(a), 9 CFR 362.2(c), and 9 CFR Part 592. 9 CFR 350.3(a)(2) and 9 CFR 362.2(c)(2) permit FSIS to provide identification service only on premises other than those of an official meat or poultry establishment.

2. The GC is to provide applicants interested in voluntary and other reimbursable services, including ID warehouses, with FSIS Form 5200-6, *Application/Approval for Voluntary Reimbursable Inspection Service*. The GC is to refer to FSIS Directive 12600.1, *Voluntary Reimbursable Inspection Services*, for instructions on processing FSIS Form 5200-6 for approving and denying voluntary or other reimbursable inspection services and on how to complete PHIS data entry for these services. This requesting of voluntary or other reimbursable services is a separate procedure from the application for mandatory Federal inspection.

B. The GC is to provide the following link to the Federal Grant of Inspection Guide to the applicant when FSIS inspection is required. The GC is also to download and provide a copy of any listed forms that require e-authentication to access them. If the applicant does not have access to a computer or requests a paper copy, the GC is to provide the applicant with paper copies of the following documents as applicable:

1. FSIS Form 5200-2, *Application for Federal Inspection* and FSIS Form 5200-15, *Hours of Operations Request/Approval*. Users need an e-authentication account to access FSIS Form 5200-15;

2. Sanitation Performance Standards Compliance Guide;

3. How to Develop a Meat and Poultry Product Recall Plan (not applicable for egg products or official import inspection establishments);

4. FSIS Compliance Guideline HACCP Systems Validation;

5. Egg Products Hazards and Controls Guide;

6. FSIS Food Safety Guideline for Egg Products;

7. FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock (for livestock slaughter establishments);

8. FSIS Functional Food Defense Plans;

9. Guidebook for the Preparation of HACCP Plans;

10. A Sanitation Standard Operating Procedure Model;

11. Appropriate HACCP Models based on the HACCP processing categories identified on the application; and

12. The Food Standards and Labeling Policy Book if requested.

C. The GC is to forward an electronic copy of the application to LEPS at AEBCorrespondence@usda.gov, follow the operating instructions in the appropriate PHIS User Guide, and request a compliance background inquiry of the applicant's business and responsibly connected persons as identified on all applications.

D. If LEPS notifies the GC that there is no basis to refuse inspection, the GC is to process the application. The GC is to:

1. Create an establishment profile in PHIS to reserve an establishment number and inform the applicant of the reserved establishment number so the business can prepare labels;

2. Provide the applicant the contact information for the FLS; and

3. Complete the top portion of FSIS Form 5200-4, *Frontline Supervisor Recommendation for Federal Inspection* (Users need an e-authentication account to access this form), forward it and the FSIS Form 5200-15 to the FLS, and instruct the FLS to initiate the review of the facility.

E. The GC is to reserve an establishment number in PHIS for all types of inspection. The requested inspection type is reserved and identified as active in PHIS, and all other types for the same numerical digits are also reserved for future use by the establishment, including V for future voluntary or other reimbursable services. The GC is to reserve the P number for poultry, M for meat, G for egg products, I for imports, and V for voluntary and other reimbursable services even when only some of these services are requested. If not all the grant types are available for a number, the GC is to select a different number with all the grant types available to be reserved. The establishment number will be reserved for a period of one year for new applicants. The reserved establishment number may be cancelled if the applicant is not actively working through the process of receiving a grant of inspection, including if the applicant does not or has not communicated its intentions during the year and none of the grant types are in use. The applicant can always reapply after the reserved number has been cancelled by resubmitting a new application for Federal inspection, FSIS Form 5200-2.

IV. OFO GC RESPONSIBILITIES: PROCESSING APPLICATIONS FOR CHANGES AND UPDATES

A. Any time one of the FSIS 5200 Forms is received or sent by the District Office (DO), the GC is to verify that the information in PHIS is updated, complete, and accurate and maintain an electronic or paper copy of the form and any related documents as instructed in FSIS Directive 2620.1, *FSIS Records Management Program*.

B. The regulations 9 CFR 304.1(c), 9 CFR 381.16, and 9 CFR 590.140 require that a new application be made in cases of a change of ownership or location for meat, poultry, and egg products establishments. For Official Import Inspection Establishments, the requirements in 9 CFR 327.6 include inspection in accordance with 9 CFR Part 304, so 9 CFR 304.1(c) applies to imported meat. The import requirements in 9 CFR 381.199(g) include inspection in accordance with Subpart D of Part 9 CFR 381, so 9 CFR 381.16 applies to imported poultry. The import requirements in 9 CFR 590.900 include inspection in accordance with 9 CFR 590.140 for imported egg products.

C. The DO is also to request new applications to be submitted for other updates, such as change of officers or doing business as (DBA) designations.

D. The GC is to use the chart below to determine when to send an updated FSIS Form 5200-2 to LEPS for a background compliance check. The GC is to send the updated FSIS Form 5200-2 to LEPS when any of the conditions listed in the table below are present. For updates to existing applications/GOIs, the GC may continue to update the GOI while the LEPS background compliance check is conducted. If information comes back from LEPS or EOS informing the GC that a recipient of inspection or anyone responsibly connected to the recipient may be unfit, the GC is to inform the DM immediately. The DM is to follow the instructions in FSIS Directive 8010.5, *Case Referral and Disposition,* for referring cases to EOS to refuse or withdraw inspection in accordance with 9 CFR Part 500.

Send the FSIS Form 5200-2 to LEPS - For Review and Approval Under the Circumstances Listed Below
Block 2 - Type of Application requests or changes • *New Requests for Inspection* • *Change of Ownership*
Block 4 – Any Form of Organization updates or changes
Block 22 - Section IV. Persons Responsibly Connected with Applicant updates or changes • Any application where the applicant has entered new, added to, or otherwise changed/updated/modified the information in Box 22 as to Persons Responsibly Connected with Applicant or Ownership Percentage must be sent to LEPS.
Blocks 23 and 24 – Section IV. Persons Responsibly Connected with Applicant (continued) updates or changes • Any application where the applicant has entered new, added to, or otherwise changed/updated/modified the information in Boxes 23 and 24 related to convictions of applicants for inspection, recipients of inspection, or responsibly connected persons must be sent to LEPS.

E. In addition to those circumstances identified in the chart above, the DM may contact EOS in any other situation that the DM believes merits correlation/consultation with EOS, such as applications/GOIs related to legal cases, consent orders, and establishments where FSIS previously withdrew or denied inspection.

V. OIEA LEPS AND EOS RESPONSIBILITIES

A. Upon receipt of the request for a compliance background inquiry on an applicant, LEPS is to conduct applicable database and other inquiries related to any criminal or compliance background of the individuals or establishments listed on the application. LEPS is to respond in writing (via e-mail) to the GC and follow the operating instructions in the appropriate PHIS User Guide, with the findings for all applications received from the DO.

B. LEPS is to forward the application to EOS for review and follow the operating instructions in the appropriate PHIS User Guide, if the compliance background inquiry reveals any criminal or compliance findings for the individuals or establishments listed on the application.

C. EOS is to follow instructions in FSIS Directive 8010.5 when determining that a refusal to grant inspection or a withdrawal of inspection may be warranted. EOS is to keep the DM informed about the application evaluation process and any associated enforcement activities. EOS is to serve as the FSIS primary point of contact for the applicant during the case evaluation and enforcement process.

VI. OFO FLS RESPONSIBILITIES

When an applicant notifies the DO or FLS that they are ready for an onsite review, the FLS is to:

1. Confirm the applicant will be performing activities that require FSIS inspection. If a prospective establishment will not actually be performing activities that require inspection, the FLS is to refer the applicant to the applicable regulations for voluntary or other reimbursable services described in FSIS Directive 12600.1, if appropriate. The FLS is to refer meat and poultry handlers that do not prepare, process, or package meat or poultry to OIEA for registration using FSIS Form 5020-1, *Registration of Meat and Poultry Handlers* as needed. The FLS is to refer the applicant to the Food and Drug Administration and state and local regulatory agencies when the applicant is going to be performing activities that are not under FSIS jurisdiction;

2. Review the physical premises and equipment and determine if the facilities and equipment are in compliance with 9 CFR 416.1 through 9 CFR 416.5;

    a. For official import inspection establishments this includes sufficient refrigerated space to hold entire shipments of refrigerated or frozen products, as applicable. The FLS is to ensure the facility has a thaw tank and white trays, as appropriate, which are needed to be eligible to receive product from countries determined to have Foot-And-Mouth disease (FMD) or other APHIS designated program diseases; such establishments must be USDA Animal and Plant Health Inspection Service (APHIS) approved facilities. To determine whether an official import inspection establishment is an APHIS approved facility, refer to the APHIS Approved Rapid Defrost Facilities list and FSIS Directive 9900.7, *Physical Examinations of Cooked or Fresh Meat from Regions Where Foot and Mouth Disease or Other APHIS Designated Program Diseases Exist*.

3. Determine whether the applicant has developed written Sanitation Standard Operating Procedures (SOPs) in accordance with 9 CFR 416.11 through 9 CFR 416.16;

4. Determine whether the applicant for meat, poultry, or egg products has conducted a hazard analysis, or had one conducted for it, for all processes and has developed a HACCP plan covering each product produced by the establishment that according to the hazard analysis includes one or more hazards that are reasonably likely to occur, as described in 9 CFR 417.2(b);

NOTE: Applicants applying for or adding FSIS inspection for egg products are not required to conduct a hazard analysis or comply with 9 CFR Part 417 until October 29, 2022, unless they have voluntarily opted in early to HACCP requirements (85 FR 68640).

5. Determine whether the applicant for meat or poultry inspection has developed written recall procedures in accordance with 9 CFR 418.3 (not applicable for egg products or official import inspection establishments);

6. Complete all sections of FSIS Form 5200-4, including the 9 CFR Regulations/Resources section by checking “yes,” if compliant;

7. Complete FSIS Form 5200-15 with establishment management to ensure core hours of operation are consistent with other establishments on the assignment, if applicable;

8. Inform the applicant of any concerns or items observed during the review that are not in compliance with FSIS regulatory requirements. The FLS is not to recommend the facility for approval when items are not in compliance with FSIS regulatory requirements at the time of review. The FLS is to revisit the premises to complete the review if the applicant notifies the FLS that all such observations are corrected; and

9. E-mail the completed and signed FSIS Form 5200-4 and FSIS Form 5200-15, and any associated attachments, to the GC, and follow the operating instructions in the appropriate PHIS User Guide. The FLS is not to e-mail or maintain digital copies of recall plans or HACCP system documents unless specifically requested to do so by the DO. FSIS Forms 5200-4 and 5200-15 may be digitally signed.

VII. OFO DM RESPONSIBILITIES

A. The DM is to review FSIS Forms 5200-2, 5200-4, and 5200-15, and other pertinent information provided by the FLS and GC, to determine whether the applicant should be granted a conditional GOI, a final GOI, or a GOI update or if the applicant will be referred to EOS. The DM is to follow the instructions in FSIS Directive 8010.5 for case referral to EOS to withdraw or refuse inspection in accordance with 9 CFR 500.6 or 9 CFR 500.7. When the DM decides there may be a basis to refuse to provide inspection, the DM is to write or e-mail the applicant informing the applicant that the matter has been referred to OIEA EOS.

B. The DM is to instruct the GC to update the status of an official import inspection establishment to Granted once approved; conditional GOIs do not apply to official import inspection establishments.

C. The DM is to issue a signed conditional GOI, final GOI, or updated GOI on FSIS Form 5200-1, *Grant of Inspection* (users need an e-authentication account to access this form) when the DM decides that the establishment meets the regulatory requirements for inspection. For new GOIs, the DM is also to return a signed copy of FSIS Form 5200-15 to the establishment, stating the approved operating hours and agreeing with establishment management on a date to start conditional inspection. The DM is to ensure that the GC updates PHIS to reflect the GOI status as "Conditional" and include the establishment's approved operating hours. FSIS Form 5200-1 and FSIS Form 5200-15 may be digitally signed.

D. For meat and poultry slaughter establishments only, during the 90 calendar days following the issuance of the conditional GOI, the DM is to ensure that the District Veterinary Medical Specialist (DVMS) verifies that livestock are being handled humanely at livestock slaughter establishments and that poultry are being handled in a manner consistent with poultry good commercial practices (GCPs) at poultry slaughter establishments. The DVMS is to follow the instructions in FSIS Directive 6910.1, *District Veterinary Medical Specialist (*DVMS*) – Work Methods* and issue a Memorandum of Interview (MOI).

E. During the 90 calendar days following the issuance of the conditional GOI to establishments, in accordance with 9 CFR 304.3(b), 9 CFR 381.22(b), and 9 CFR 590.149, the DM is to decide whether the establishment meets the terms of the conditional GOI by drawing on information in PHIS and information gathered by the FLS and the Inspector-in-Charge (IIC). The DM is to ensure inspection program personnel (IPP) at meat and poultry establishments, and egg products plants after October 29, 2022, have performed a Hazard Analysis Verification (HAV) task as instructed in FSIS Directive 5000.6, *Performance of the Hazard Analysis Verification (HAV) Task* and verified that the establishment has validated its HACCP plans as required by 9 CFR 304.3(c), 9 CFR 381.22(c), 9 CFR 590.149(c), and 9 CFR 417.4.

F. No sooner than 90 calendar days after issuing the conditional GOI, if the DM determines that the meat or poultry establishment (and egg products plants after October 29, 2022) has validated its HACCP system as required by 9 CFR 417.4 and has met all other applicable regulatory requirements, he/she is to sign and issue a final GOI on FSIS Form 5200-1 and ensure the GC updates PHIS to reflect the establishment's grant status as "Granted."

1. For most establishments, an initial 90 calendar day validation period corresponds to approximately 60 working days of records for review. Some small and very small establishments may operate less than five days per week. However, at least 13 production days of records need to be available for review by FSIS for the Agency to determine whether an establishment operating less than five days per week has validated its HACCP system adequately. To allow such small and very small establishments the time necessary to gather data to validate their HACCP systems, a written request from the establishment may be sent to the DM directly or through the FLS to extend the validation period. Specifically, depending on the specific facts of the situation, the DM may allow an additional 30 calendar days under the conditional GOI for an establishment to complete validation of its HACCP system.

2. The DM is to consider an enforcement action in accordance with the 9 CFR Part 500, Rules of Practice if at the end of the conditional GOI period the DM determines that the establishment has not validated the HACCP system in accordance with 9 CFR 417.4.

G. The DM is to instruct the GC to send an electronic copy or paper copy of FSIS Form 5200-1, FSIS Form 5200-2, and FSIS Form 5200-15 to the:

1. Applicant;

2. Official establishment if the establishment and the applicant have different addresses;

3. IIC at the establishment;

4. FLS;

5. FSIS Financial Services Center in Urbandale, Iowa (electronic copy to FSIS.Billing@usda.gov); and

6. Appropriate State meat or poultry inspection program personnel, for Talmadge-Aiken establishments.

VIII. PROCESSING REQUESTS FOR CHANGES IN APPROVED WORK SCHEDULES

The FLS is to request that an official establishment that wishes to alter the approved hours of operation, including a request for an additional shift or the elimination of a shift, submit a revised FSIS Form 5200-15 to the FLS. The FLS is to send the revised form, along with their recommendation, to the DM for review. The DM is to consider the request for change in hours of operation, or shifts, as set out in 9 CFR 307.4, 9 CFR 381.37, and 9 CFR 590.124. If the DM approves the request, the GC is to send an electronic copy or paper copy of the approved FSIS Form 5200-15 to the establishment, the FLS, and the IIC and is to update PHIS accordingly.

IX. OFFICIAL ESTABLISHMENT VOLUNTARY SUSPENSION

A. A voluntary suspension of inspection occurs when an establishment submits a written (i.e., fax, electronic, or paper) request to the DM for a temporary suspension of operations (e.g., for purposes of sale, major structural changes, or remodeling). A voluntary suspension of inspection is temporary and normally does not exceed 120 calendar days. A voluntary suspension by the establishment does not prevent FSIS from proceeding with an enforcement action such as a suspension.

B. The DM is to issue FSIS Form 5200-3, *Voluntary Suspension or Voluntary Withdrawal of Inspection Service* (Users need an e-authentication account to access this form) when a voluntary suspension is requested by the establishment. After 120 calendar days under voluntary suspension, the DO is to follow the instructions found in FSIS Directive 5220.3, *Issuance of a Ten-Day Letter for Inactive Operations*.

C. An establishment under a voluntary suspension of inspection may need to remain under voluntary suspension more than 120 days due to circumstances that are beyond its control (e.g., inability to obtain equipment on schedule or inability to complete major structural changes because of weather conditions). In such cases, the DM may extend the 120 day voluntary suspension period but is to assign a FLS to conduct another review of the establishment before resuming inspected operations when they determine it is appropriate. When an extension is granted, the DM is to issue another FSIS Form 5200-3 to update the date when inspection will be reinstated.

D. The DM may grant establishments that operate on a seasonal basis a voluntary suspension of inspection of more than 120 days based on the effective and efficient use of FSIS personnel. If a seasonal establishment has gone one year or more without conducting any operations, the DM is to follow instructions in FSIS Directive 5220.3.

E. When an establishment submits a written request for reinstatement of inspection to the DM after a voluntary suspension, the DM is to instruct the FLS to visit the establishment, if necessary, to determine whether the written plans, facilities, and equipment warrant the reinstatement of inspection. Based on the observations made at the FLS visit, the FLS is to:

1. E-mail a recommendation to the DM to reinstate inspection when the establishment is in compliance with all applicable FSIS regulatory requirements; or

2. E-mail a recommendation to the DM to not reinstate inspection when the establishment is not in compliance with all applicable FSIS regulatory requirements.

F. To reinstate inspection, the DM is to instruct the GC to change the status in PHIS to “active” and complete FSIS Form 5200-1 to return the Grant to active status.

X. OFFICIAL ESTABLISHMENT VOLUNTARY WITHDRAWALS

The DM is to issue FSIS Form 5200-3 when an establishment requests a voluntary withdrawal. A voluntary withdrawal of inspection is permanent, and establishments that later want to reinstate inspection must reapply for a new GOI by completing and submitting FSIS Form 5200-2.

NOTE: A voluntary withdrawal of inspection occurs when an establishment submits a written request to cease FSIS inspected operations.

XI. WITHDRAWAL OF INSPECTION

A. The DM is to notify the Director of EOS in accordance with FSIS Directive 8010.5 when there is regulatory support for FSIS to withdraw inspection from an establishment under the 9 CFR Part 500 Rules of Practice. The DM is to provide pertinent information (e.g., information regarding withdrawal of inspection for failure to maintain sanitary conditions, HACCP violations, or inhumane slaughter or handling) to EOS to support the withdrawal of inspection. The DM is also to write or e-mail the applicant informing the applicant that the matter has been referred to OIEA EOS.

B. The GC is to email RISHelp@usda.gov to request a grant status change from Withdrawn to Reserved when the grant status is Withdrawn in PHIS but the grant has not been Withdrawn by the DM. The GC is to edit the status to the accurate status after RISHelp reverts the status to Reserved.

XII. QUESTIONS

Refer questions regarding this directive to your supervisor or as needed to the Office of Policy and Program Development through askFSIS or by telephone at 1-800-233-3935. When submitting a question, complete the web form and select Import or General Inspection Policy as applicable for the Inquiry Type.

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

Assistant Administrator
Office of Policy and Program Development