

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

FSIS PHIS DIRECTIVE

5220.1

4/11/11

GRANTING OR REFUSING INSPECTION; VOLUNTARY SUSPENDING OR WITHDRAWING INSPECTION; AND RESTORING INSPECTION UNDER PHIS

I. PURPOSE

This directive provides instructions to Front Line Supervisors (FLSs), District Managers (DMs), Regional Import Field Supervisors (RIFSs), and Deputy Directors of Operations (DDOs) on their roles in assessing an establishment's request to receive inspection services, to have inspection services voluntarily suspended or withdrawn, or to restore inspection after suspension or withdrawal. This directive also provides instructions to these employees on how to enter data related to these activities into the Public Health Information System (PHIS).

KEY POINTS:

- *This directive sets the Agency's policy for reviewing an application for a grant of federal meat, poultry, or import inspection.*
- *This directive clarifies FSIS employees' responsibilities for gathering and entering information related to the grant of inspection into PHIS.*
- *This directive includes instructions on how to issue a conditional grant of meat and poultry inspection and how to judge when a conditional grant of inspection is to be converted to a final grant.*

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

9 CFR Parts 304, 305, 327, 335, Part 381, subparts D, E, and W, 416, and 417
The PHIS User Guide is available via the FSIS Intranet on the PHIS page under Resources

V. GRANTING INSPECTION AT OFFICIAL MEAT AND POULTRY ESTABLISHMENTS

A. When an applicant requests a grant of inspection, the District Office (DO) is to provide the following link which contains the necessary instructions and forms to be completed:
See Users Guide

B. The DO also is to provide copies of the following:

1. The application for inspection, FSIS Form 5200-2 for Meat, Poultry, or Import Inspection;
2. The application guidelines;
3. The Sanitation Standard Operating Procedures Guidance for Meat & Poultry Establishments; and
4. FSIS PHIS Directive 5000.1, Verifying an Establishment's Food Safety System.

C. Upon receipt of an application, the DM or designee is to:

1. Review the application for completeness and check the appropriate boxes for the applicable Acts under which the establishment will operate, and
2. Return to the applicant any application that is not complete and specify the areas of the form that need attention.
3. Initiate a record in PHIS to reserve an establishment number. Refer to the PHIS Users Guide and Instructions

D. If the DM reviews the application and determines that it is complete, the DM is to:

1. Notify the Office of Program Evaluation, Enforcement, and Review (OPEER), Evaluation and Enforcement Division (EED) via e-mail of each new application and provide EED with the names of responsibly connected persons identified on the application:
2. If there is any indication that one or more of the persons responsibly connected with the application has a criminal history, forward the application, along with any related documents, to OPEER, EED, and request that EED conduct a background investigation for the individuals;
3. Advise the applicant that the application has been forwarded to EED for further evaluation;

NOTE: After EED completes its investigation, it is to respond to the DO in writing to inform it of the results and advise the DO if it should move forward with processing the application.

4. For applications where EED advises not to move forward with processing the application, indicate so, in PHIS;
5. For cases where EED advises that the DO should move forward with processing the application, complete the top portion of the recommendation for granting inspection (FSIS Form 5200-4) and forward it to the FLS;
6. Assign the FLS to visit and review the applicant's facility; and
 - a. For new applications, PHIS will automatically assign an establishment number. The number will be reserved for the current application and any subsequent application for this location for other types of inspection, e.g. meat, poultry, egg, import, and reimbursable service. Refer to the PHIS Users Guide.
 - b. For existing establishment grant holders that are applying for additional inspection services at the same location DO personnel are to add the requested inspection service to the applicant's grant page in the PHIS profile. An official establishment will have one establishment number with different prefixes indicating the type of inspection granted e.g. M00038 (meat), P00038 (poultry), I00038 (import), or G00038 (eggs).

NOTE: In certain limited circumstances, a specific establishment number can be requested and reserved, such as when a new application is submitted because of a change of location when the ownership of the establishment remains the same as set out in 9 CFR 304.1(c).

- c. In circumstances where existing official establishments are sold or there are changes in ownership or responsible individuals a new application must be made as set out in 9 CFR 304.1(c) and 381.16. DMs are to treat the application as a new application and follow the instructions set out in this directive to process the application.

D. The FLS is to:

1. Visit the prospective establishment to review the facility and equipment and determine whether they comply with 9 CFR 416.1 through .5;
2. Determine whether the prospective establishment has developed written Sanitation Standard Operating Procedures (Sanitation SOPs) as set out in 9 CFR 416.11 through 416.16;

3. Determine whether the prospective establishment has conducted a hazard analysis, or has had one conducted, for all processes and has developed a HACCP plan for the processes that it intends to conduct where one or more hazards are reasonably likely to occur, as described in 9 CFR 417;
4. Complete FSIS Form 5200-4 entitled "Recommendation on Application for Inspection" with recommendations for correcting any noncompliance observed; and
5. Return the completed FSIS Form 5200-4 to the DM.

E. The DM is to review the returned FSIS Form 5200-4 and other pertinent information provided by the FLS to determine whether the establishment should be provided with a conditional grant of inspection services.

F. If the DM decides that inspection service should be provided to the establishment, he/she is to issue a conditional grant of inspection. The DM is to issue FSIS Form 5200-1, which provides conditional inspection, and also is to update PHIS to reflect the conditional status of the grant.

G. Approximately 90 days after he/she issues the conditional grant of inspection, in accordance with 9 CFR 304.3(b) and 381.22(b), before issuing a final grant of inspection, the DM is to determine, using information in PHIS, from the FLS, and from the Inspector-in-Charge (IIC) and the assigned Enforcement Investigations and Analysis Officer (EIAO), whether the establishment has met the terms of the conditional grant of inspection. The DM is to ensure that IPP perform a hazard analysis verification procedure (HAV) as described in FSIS Directive 5000.1 as the establishment nears the end of the conditional grant period. The DM will also assign an EIAO to perform an FSA at the establishment as set out in FSIS Directive 5100.1 to verify that the establishment has validated its HACCP system. When the DM determines that the establishment has validated its HACCP system as required by 417.4(a), he or she will sign and issue a Grant of Inspection, FSIS Form 5200-1, and update PHIS to reflect the establishment's status. If at the end of the conditional grant, the DM determines that the establishment has not validated the HACCP system, he or she is to suspend inspection at the establishment and document the reason for the suspension in a letter to plant management.

H. For establishments that normally operate 5 days per week, EIAO's are to review approximately 60 working days of records to determine if the establishment has validated its HACCP plans.

I. For establishments that normally operate less than 5 days per week, EIAO's are to review at least 13 available production days of records to determine if the establishment has validated its HACCP plan. To allow such establishments the time necessary to gather data to validate their HACCP plans, the DM may allow an establishment to operate up to 120 days under the conditional grant of inspection before an establishment.

J. When the DM grants inspection services, she or he is to send the Grant of Inspection and application to the following persons:

1. Original to the applicant;
2. Copy to the official establishment if the establishment and the applicant have different mailing addresses;
3. Inspector-In-Charge;
4. DO staff for entry into PHIS; and
5. For Talmadge-Aiken establishments the appropriate state meat or poultry inspection program personnel.

K. The DO is to maintain official file copies of the application, recommendation, grant, and related documents. In addition, the DM is to ensure that PHIS is updated to accurately reflect the status of the establishment. Refer to the PHIS Users Guide.

L. When the DM becomes aware of any changes in an establishment or its operations, the DM is to request a new application from the establishment that is making the changes (e.g., new mailing address, corporate structure, type of operation).

M. The DM is to maintain the updated application on file and verify that the updates are reflected in the PHIS Establishment Profile.

VI. GRANTING INSPECTION AT OFFICIAL IMPORT INSPECTION ESTABLISHMENTS

A. When an applicant requests an import grant of inspection, the RIFS is to provide the following link which contains the necessary instructions and forms to be completed:
See Users Guide

B. The IID HQ is to also provide copies of the following:

1. Application for import inspection, Form 5200-2;
2. Application guidelines;
3. Sanitation Standard Operating Procedures Guidance for Meat & Poultry Establishments;
4. Chapter 1 of FSIS directive 5000.1, "Verifying an Establishment's Food Safety System;" and
5. Contact information for the RIFO that will be reviewing the establishment

C. Upon receipt of an application, the IID Director or designee is to:

1. review the application for accuracy and completeness and check the appropriate boxes for applicable Acts under which the establishment will operate; or
2. return to the applicant any application that is not complete and specify the area of the form that needs attention; and
3. Initiate a record in PHIS to reserve an establishment number. Refer to the PHIS Users Guide.

D. If the IID Director reviews the application and determines that it is complete, the IID Director or designee is to:

1. Notify OPEER, EED via e-mail of each new application and provide EED with the names of responsibly connected persons identified on the application
2. If there is any indication that one or more of the persons responsibly connected with the application has a criminal history forward the application along with any related documents to OPEER, EED and request that EED conduct a background investigation for the individuals.
3. Advise the applicant that the application has been forwarded to EED for further evaluation;

NOTE: After EED completes its investigation it is to respond to the IID Director in writing to inform him or her of the results and advise the IID Director if he or she should move forward with processing the application.

4. For applications where EED advises not to move forward with processing the application indicate so In PHIS;
5. For cases where EED advises that the IID Director move forward with processing the application, complete the top portion of the recommendation for granting inspection (FSIS Form 5200-4) and forward it to the RIFS with a copy to the DDO; and
6. Assign the RIFS to conduct an initial visit and review of the applicant's facility; and
 - a. For a new applicant, PHIS will automatically assign an establishment number. The number will be reserved for the current application and any subsequent applications for this location for other types of inspection, e.g. meat, poultry, import, egg and reimbursable service. (Refer to the PHIS Users Guide.)

- b. For existing establishment grant holders that are applying for additional inspection services at the same location, IID personnel are to add the requested inspection service to the applicant's grant page in the PHIS profile. An official import establishment will have one establishment number with different prefixes indicating the type of inspection granted, e.g. M00038 (meat), P00038 (poultry), I00038 (import), G00038 (eggs).

NOTE: In certain limited circumstances, a specific establishment number can be requested and reserved, such as when a new application is submitted because of a change of location but the ownership of the establishment remains the same as set out in 9 CFR 304.1(c).

- c. In circumstances where existing official establishments are sold, or there are changes in ownership or responsible individuals, a new application shall be made as set out in 9 CFR 304.1(c) and 381.16. IID Directors are to treat the application as a new application and follow the instructions set out in this directive to process the application.

E. When the prospective import establishment notifies the RIFS that it is ready to start operations, the RIFS is to:

1. Visit the prospective import establishment to review the facility and equipment and determine whether they comply with 9 CFR Part 416.1 through 416.5.
2. Determine whether the prospective import establishment has developed written Sanitation Standard Operating Procedures (Sanitation SOPs) as set out in 9 CFR 416.11 through 416.16;
3. Determine whether the prospective import establishment has the equipment necessary to complete the import inspections identified on the application. This includes space to hold an entire shipment of refrigerated or frozen products, scales, and office space. Determine whether the establishment intends to handle products from Animal and Plant Health Inspection Service (APHIS) restricted countries;
4. Complete FSIS Form 5200-4 entitled "Recommendation on Application for Inspection" with recommendations for correcting any noncompliance observed: and;
5. Return the completed FSIS Form 5200-4 to the DDO and IID Director.
6. Revisit the facility when the establishment notifies you that all noncompliant observations are corrected and forward the RIFS approved completed FSIS Form 5200-4 to the IID Director.

F. The IID Director is to review the returned FSIS Form 5200-4 and other pertinent information provided by the RIFS to:

1. Determine whether to grant the establishment import inspection services;
2. Issue the Grant of Import Inspection (FSIS Form 5200-1) as appropriate;
3. Send the original of the Grant of Inspection document to the applicant, along with a copy of the application. The Director of IID is to also send the official import establishment copies of the grant and application if the establishment and applicant have different mailing addresses;
4. Send copies of the grant and application to the RIFO and the IID staff for entry into PHIS;
5. Maintain official copies of the application, recommendation, grant, and related documents; and
6. Notify APHIS if the import establishment has been granted inspection and is eligible to inspect APHIS restricted shipments of products (pink juice, MIT).

G. When the inspector or RIFS become aware of any changes in an official import establishment or its operations, the inspector or RIFS is to request a new application from the official import establishment that is making the changes (e.g., new mailing address, corporate structure, type of operation).

H. The IID Director is to maintain the updated application on file and verify that the updates are maintained in the PHIS Establishment Profile by OIA Headquarters.

VII. OFFICIAL ESTABLISHMENT OR OFFICIAL IMPORT INSPECTION ESTABLISHMENT VOLUNTARY SUSPENSION OR WITHDRAWAL OF INSPECTION

A. The FLS or RIFS is to accept each written request for a voluntary suspension or withdrawal of inspection services. The FLS or RIFS is to explain that a voluntary withdrawal of inspection is permanent, and establishments wishing to reinstate inspection will need to reapply for inspection services. A voluntary suspension of inspection services is temporary and, except for establishments that operate on a seasonal basis, normally should not exceed 120 calendar days.

NOTE: An establishment may request such suspensions for purposes of resale, major structural changes, or remodeling.

B. When situations arise that are beyond the establishment's control (such as inability to obtain equipment on schedule, inability to complete major structural changes because of weather conditions, or other valid reasons), the DM and the IID Director may extend the 120-day period, if the Assistant Administrator, OFO or OIA, concurs. Meat or poultry establishments that traditionally operate on a seasonal basis may be in suspension status beyond the 120-day period, but the suspension may not exceed 1 year.

C. The FLS or RIFS is to forward the establishment's request letter, including the effective date of the letter, to the DM or the Director of IID for processing.

D. The DM or IID Director or designee is to issue the voluntary suspension or withdrawal of inspection form (FSIS Form 5200-3) and forward the original to establishment management. The DM and the Director of IID are to maintain a copy of the form and any related documents.

E. The DM or the IID Director or designee is to verify that the suspension or withdrawal is properly recorded and documented in PHIS.

F. After being contacted by the establishment, the FLS or RIFS is to notify the DM or the IID Director that the establishment has requested that inspection be reinstated.

G. Before inspection is reinstated, the FLS or RIFS is to visit the establishment to determine whether its facilities and equipment warrant the reinstatement of inspection.

H. In cases where the establishment is in appropriate condition for reinstatement of inspection, the FLS or RIFS is to recommend reinstatement of inspection service to the DM or IID Director. In cases where the establishment does not warrant reinstatement of inspection, the DM or IID Director is not to authorize reinstatement of inspection.

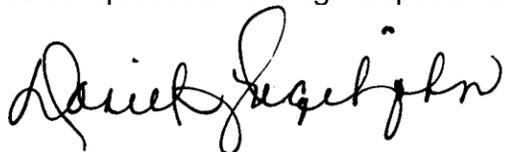
I. The DO or the IID Director is to ensure that the data in PHIS is updated to reflect the establishment's status.

VIII. REFUSAL OR WITHDRAWAL OF INSPECTION SERVICE

A. The DM or the IID Director is to notify the Director of EED when there is a reason to believe inspection services should be refused to an applicant or withdrawn from an establishment.

B. The DM or the IID Director is responsible for initiating inquiries, assembling documentation, and maintaining contact with OPEER, EED, regarding the refusal or withdrawal of inspection services. In those instances when the DM or the IID Director has a basis, under the FSIS rules of practice, to refuse to provide, or to initiate action for the withdrawal of, inspection services, the DM or the IID Director is to refer the matter to EED for review and appropriate action.

Refer questions through Supervisory Channels.



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