

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

FSIS DIRECTIVE

13,000.3
Rev. 1

11/16/16

RESPONDING IN PHIS TO INDUSTRY APPEAL OF A NONCOMPLIANCE RECORD

I. PURPOSE

A. This directive provides instructions to supervisory personnel responsible for addressing appeals from official meat and poultry establishments, egg products plants, official import inspection establishments, identification (ID) warehouses, and other facilities where FSIS provides inspection service. The directive provides instructions to supervisory personnel regarding how to respond to an appeal of a noncompliance record (NR) that has been presented to FSIS by an establishment representative through the Public Health Information System (PHIS), or has been presented orally, or in writing. The directive also provides instructions to inspection program personnel (IPP) regarding how to delete or modify an NR in PHIS.

NOTE: Appeals related to other noncompliances or enforcement actions (e.g., Notices of Intended Enforcement (NOIEs), Office of Investigations, Enforcement and Audit (OIEA) actions, laboratory results) are to be appealed through the applicable supervisory chain of command.

B. This directive has been revised to incorporate all the instructions into the body of the directive. In addition, clarifications have been included based on PHIS data analysis, and from trend analysis of questions submitted through askFSIS.

C. For the purposes of this directive, “supervisory personnel” refers to any Office of Field Operations (OFO) personnel, at any level, that supervise IPP who conduct verification activities in official establishments or other facilities. This term includes Supervisory Public Health Veterinarians (SPHVs), Supervisory Consumer Safety Inspectors (SCSIs), Inspectors-in-Charge (IICs), Multi-IPPs Supervisors, Frontline Supervisors (FLS), District Managers (DMs) and Deputy District Managers (DDM).

KEY POINTS:

- *Provides instruction to supervisory personnel regarding the decision process when responding to industry appeals; how to address industry appeals submitted through PHIS; and how to address industry appeals submitted orally or in writing (i.e., not submitted through PHIS)*
- *Provides instruction to IPP regarding how to delete an NR in PHIS when an appeal has been granted and how to modify a denied appeal based on instruction from the supervisor*
- *Clarifies that there is no timeframe in which FSIS requires an appeal to be submitted by an establishment for consideration*
- *Provides instructions to IPP and supervisory personnel regarding how to get references to appeals excluded from establishment meeting agendas and weekly meeting MOIs once the appeals have been resolved*

DISTRIBUTION: Electronic

OPI: OPPD

II. CANCELLATION

FSIS PHIS Directive 13,000.3, Responding in PHIS to Industry Appeal of Noncompliance Records (July 17, 2013)

III. BACKGROUND

A. FSIS regulations [9 CFR 306.5](#) and [9 CFR 381.35](#) provide that establishments may appeal an inspection decision including enforcement actions taken in accordance with [9 CFR 500](#). [9 CFR 590.310](#) is the applicable FSIS regulation that pertains to egg products plants that wish to appeal an inspection decision.

NOTE: As per the above cited regulations, appeals are to be submitted to an immediate supervisor for a determination. IPP are not to address appeals except as instructed by their immediate supervisor and explained in this directive.

B. FSIS will accept appeals from plant management after the 48 hours cited in 9 CFR 381.35. Establishments can appeal an NR even if the NR has been designated as “NR Completed” in PHIS.

C. If an establishment decides to appeal an inspection decision it is important that it submit the appeal as soon as possible after the inspection decision has been made to ensure a timely FSIS response. The appeal is to be submitted to IPP’s immediate supervisor, with any supporting information explaining why the appeal should be granted.

NOTE: IPP should notify establishment management submitting an appeal using PHIS that once they submit their appeal in PHIS they cannot alter or adjust the information. However, if an establishment wants to augment an appeal entered into PHIS in writing, FSIS will accept the additional information in writing, scan it, and upload it into PHIS.

D. Under [9 CFR 306.5](#), [9 CFR 381.35](#), and [9 CFR 590.310](#), an inspected establishment or its representative may submit an appeal, verbally or in writing, to the immediate supervisor of any program employee for a variety of reasons, including but not limited to:

1. The establishment believes its operation was in compliance;
2. The establishment believes incorrect facts were used in the noncompliance determination;
3. The establishment believes an incorrect regulation was cited; or
4. The establishment believes other facts were not considered by the IPP prior to the determination of the noncompliance.

NOTE: IPP are to be aware that the appeals process begins with their immediate supervisor. However, as a means to encourage open communication and good business relationships, the author of the NR should be available and open to discuss any concerns regarding NRs with the establishment. Such discussions are not an appeal or part of the appeals process but instead serve as a means to resolve issues at the lowest possible level.

E. The following outlines the chain-of-command for appeal decisions:

1. Immediate Supervisor (i.e., IIC, PHV or Multi-IPPs Supervisor of IPP who made the original noncompliance determination or the FLS if that is the immediate supervisor);
2. FLS;
3. DM/DDM;

4. Executive Associate for Regulatory Operations (EARO);
5. Deputy Assistant Administrator/Assistant Administrator for Office of Field Operations (OFO); and
6. Administrator for FSIS.

NOTE: The staffs in the Office of Policy and Program Development (OPPD) (e.g., Policy Development Staff (PDS), Risk Innovation and Management Staff (RIMS), Labeling and Program Delivery Staff (LPDS)) are not part of the supervisory chain-of-command regarding the resolution of appeals. Regulatory interpretations provided by these staffs can be used to support or refute an NR but are not to be considered as denying or granting an appeal.

IV. IPP RESPONSIBILITIES - WHEN INSTRUCTED BY SUPERVISOR TO MODIFY AN NR IN PHIS

A. Login using normal login procedures

B. Prepare to modify (i.e. edit)

1. On the left menu click “Inspection Verification”;
2. Click the “Select Establishment” option to access the Domestic Inspection page;
3. From the Domestic Inspection page, select the establishment by clicking on the adjacent radio button;
4. Once an establishment is selected, select the “Noncompliance Records” option from the left Navigation Menu under “Inspection Verification”;
5. Locate the NR requiring modification using the Appeal Status column (Appealed by Plant) and click on the “Edit” pencil icon to open the Noncompliance Record (NR) page;
6. If the status of the NR subject to appeal is “NR Completed,” when the NR page opens, the message “This Noncompliance record has been completed” displays at the top of the page with a hyperlink (if the status is “Open” skip to step 13 below);

NOTE: An NR identified as “NR Completed” is “locked” for editing and requires a justification to “unlock.”

7. Select the “Click here” hyperlink to access the “Reason to Edit” on the NR page;
8. Unlock the NR for editing by selecting a justification from the dropdown list (Mandatory field) (i.e., Instructed by supervisor) and entering additional descriptive text within the text box (e.g., appeal granted, deleting per instructions by supervisor);
9. Click the “Unlock” button to save the justification and return to the NR page;

NOTE: The “Noncompliance Finalized?” checkbox will now be blank and the General tab will show the status of the NR as Open

9. The newly added justification is displayed at the bottom of the page, with a message above the grid;
10. If the NR has been finalized, once the Noncompliance Record (NR) page opens, select the noncompliance tab and then the Edit pencil icon to open the Noncompliance page;

11. The following message will be displayed at the top of the Noncompliance page:

“This noncompliance has been finalized. To unlock it, select “Click here” and provide a justification.”

12. Select the “Click here” hyperlink to access the NR page to unlock the finalized Noncompliance;

13. Select from the dropdown list the appropriate reason and enter any additional descriptive text for the reason to Edit NR, and;

14. Click “Unlock” button and now the Noncompliance page can be modified.

C. Modify (i.e. edit) the NR

1. Once the justification has been entered as above, make the changes to the NR as required by the supervisor;

2. Once all the information has been entered, click “Save” button at the bottom of the page. Then check the “Noncompliance Finalized?” box and click “Save” button again;

3. At the bottom of the Noncompliance page will appear the Justification, Reason to Edit, Edited By, and Edited Date;

4. Click “Cancel” and it will return you to the Noncompliance Record (NR) page. If you select the Noncompliance tag, you will see the “Finalized” status of the noncompliance; and

5. To complete the NR, place a check in the “NR Completed” checkbox and click Save. This returns you to the Noncompliance Records page and the NR status will now display as “Completed”.

D. If the establishment uses the Industry Module in PHIS, they can review changes to the NR and decide whether or not to “Accept FSIS’s decision.” If they accept the modification, then the NR status will no longer show it is under appeal.

NOTE: If the establishment has elected not to use PHIS, the next line of OFO supervisory chain-of-command is to enter the information for the establishment in PHIS.

E. If IPP observe that an NR number continues to be included on the weekly meeting MOI after the NR appeal has been resolved (e.g., the establishment chooses not to further appeal the NR), they are to inform their immediate supervisor. The supervisor is to follow the instructions in Section VI.F below to resolve the issue.

V. IPP RESPONSIBILITIES - WHEN NOTIFIED BY SUPERVISOR TO DELETE AN NR IN PHIS

A. Login using normal login procedures

B. Prepare to delete

1. Follow the instructions in Section IV. B above, to unlock the NR;

2. Once the NR is unlocked, uncheck the regulations identified on the Noncompliance page; and

3. Click “Save” and then Click “Cancel”. This returns the user to the NR page.

C. Delete the NR

1. Click on the “Noncompliances” tab;
2. Select the NR to be deleted, the status should be ‘open’;
3. Click on the “Trash can.” A warning message will appear: “This action will delete the Noncompliance. Are you sure?”
4. In the warning box click “OK” to permanently delete the noncompliance;

NOTE: This action cannot be reversed once the noncompliance is deleted

5. In the “Task Calendar,” if the task is “yellow,” it will now show that it is no longer noncompliant;
6. Document that the task is completed by opening it and checking “Inspection Completed” box; and
7. Click “Save” and then close. The task should now be displayed as “green” in the “Task Calendar”

NOTE: Once the electronic copy of the NR is removed from PHIS, IPP are to remove the paper NR with any associated correspondences from the government file system.

VI. SUPERVISORY PERSONNEL - GENERAL RESPONSIBILITIES

A. Supervisory personnel will receive notification of an appeal in one of the following ways:

1. The appeal will appear under the “My Tasks” tab on the supervisors Home Page in PHIS; or
2. The supervisory personnel will receive written or oral notification from an establishment.

B. The supervisor can grant the appeal in its entirety, because they believe that the NR, as written, does not support regulatory noncompliance or they can deny the appeal because they believe that the entire NR, or some portion of it, supports regulatory noncompliance.

NOTE: Granting the appeal does not remove the NR from the PHIS system. It removes the NR from view and no longer allows any changes. The NR remains within the PHIS system and can still be subject to Freedom of Information Act (FOIA) requests.

C. Supervisory personnel are to respond promptly to each appeal received by doing the following.

1. Obtain all relevant factual information and review pertinent notices, directives, or regulations; and
2. Communicate the appeal decision to the establishment and to any IPP involved with the appeal.

D. FSIS responses to appeals are to be provided as soon as possible, within the suggested timeframes below. However, because each appeal case presents a unique set of facts that require consideration, the response times may need to be extended.

1. Immediate Supervisor of IPP who made the original determination - Within 2 weeks from receipt of appeal;
2. FLS - Within 2 weeks from receipt of appeal;
3. DDM/DM - Within 2 weeks from receipt of appeal;
4. EARO - Within 30 days from the receipt of the appeal;

5. OFO Deputy Assistant Administrator/ OFO Assistant Administrator - Within 30 days from the receipt of the appeal; and
6. FSIS Administrator - Within 30 days from the receipt of the appeal.

NOTE: As indicated in PHIS, appeals to the EARO, OFO Deputy Assistant Administrator, OFO Assistant Administrator, or the FSIS Administrator are not conducted through PHIS and must be presented in writing directly to those officials.

E. Supervisory personnel are to obtain the following information from the responsible establishment employee:

1. The original NR under appeal, if the appeal was not made through PHIS;
2. A narrative explanation of why establishment management disagrees with the inspection decision;
3. Any supporting documentation that establishment management believes will assist supervisory personnel in evaluating of the situation under appeal;
4. Copies of any previous FSIS responses; and
5. Any records (e.g., HACCP, SSOP, or prerequisite program) that may contain relevant information on the issue being appealed.

F. Due to the functionality of PHIS, any NR under appeal will continue to be included on the weekly meeting agenda and subsequent MOI until it is resolved and marked "accepted FSIS decision" in PHIS. If IPP observe that an NR number continues to be present on the weekly meeting agenda and MOI after the NR appeal has been resolved (e.g., the establishment chooses not to further appeal the NR), they are to notify their immediate supervisor. The immediate supervisor will then notify the supervisor that is next in the OFO chain-of-command who has not addressed the appeal is to do the following:

1. Login using normal login procedures;
2. Click on "Inspection Verification";
3. Click on "Select Establishment" and choose an establishment;
4. Click on "Plant Management";
5. Select the NR in question;
6. Click on the "Response" icon;
7. Select the radio button "Accepted FSIS Decision." Enter the name of the responsible establishment employee that indicated the establishment no longer wishes to appeal the NR further; and
8. Click on "Save", click "Submit" and then click "OK."

NOTE: The responses to all appeals, (e.g. those provided to the establishment) are to be entered into PHIS using the following instructions and those in Section VII below.

G. Supervisors at all levels are to include the following information within their written response to the establishment when addressing an NR appeal.

1. Identify the PHIS NR number and the date the appeal was received;
2. Identify each issue under appeal, the reasons the issue(s) is under appeal and the action requested;
3. For each issue under appeal, provide the following:
 - a. Information, details and facts used to formulate and support the decision;
 - b. Identification of any misapplied policy;
 - c. The final decision; and
 - d. All actions to be taken as a result of the decision.

NOTE: It is important that supervisory personnel include information that supports the decision for granting or denying an appeal. However, they only need to summarize the basis for their decision when entering information into PHIS to enable data analysis of NR appeal outcomes.

VII. SUPERVISORY PERSONNEL - RESPONDING TO AN APPEAL IN PHIS

NOTE: If the establishment appeals in writing, FSIS supervisors are to include the information in PHIS either by scanning or including the written document as an attachment.

A. When the establishment management, or their representative, elects to request access to PHIS and subsequently submits an appeal electronically into PHIS, FSIS supervisory personnel are to do the following:

1. Review the establishment's response by accessing the Plant Management page within PHIS.

Note: The appeal and response text boxes do not have a designated character limit to facilitate thorough and complete entries by establishment management and FSIS supervisory personnel.

2. Respond to the establishment's appeal in PHIS after evaluating the establishment's reason for appeal, the initial inspection findings, and the pertinent regulatory provisions as they apply to the documented noncompliance.

3. Follow the instructions below to Grant or Deny the appeal in PHIS:

- a. Log in using normal login procedures;
- b. Select establishment;
- c. From the left menu, click "Inspection Verification" then "Plant Management";
- d. Find the NR that was appealed and click the red arrow in "Response" column;
- e. View establishment's appeal; and
- f. Grant or Deny using the instructions below

4. Grant

- a. Click "Grant";

- b. Enter an FSIS response regarding why the appeal is being granted in the text field or upload an attachment;
- c. Click the “Save” button to save the information;
- d. Click “Submit.” A message will display asking “Are you sure want to submit?”;

NOTE: The same message is displayed for granting or denying, so be sure that the correct radio button is selected.

- e. Click “OK” if you are sure that you want to “Grant” the appeal;

NOTE: This action **cannot** be reversed once the appeal is granted.

and

- f. Notify the IPP author of the NR, through supervisory channels, that the appeal has been granted. IPP will follow the instructions in Section V to delete the NR.

5. Deny

- a. Click “Deny”;
- b. Enter an FSIS response regarding why the appeal is being denied in the text field or upload an attachment;

NOTE: If an attachment is added, be sure that the radio button still indicates “Deny” and does not default to “Grant”.

- c. Click the “Save” button to save the information;
- d. Click “Submit.” A message will display asking “Are you sure want to submit?”; and
- e. Click “OK.”

NOTE: If supervisory personnel determine that modifications need to be made to the denied NR, they are to notify the IPP author of the NR, through supervisory channels, regarding the necessary modifications. The IPP author of the NR will follow the instructions in Section IV above to make the modifications in PHIS.

6. If multiple issues are documented as separate noncompliances on the NR, supervisors are to:
 - a. Deny the appeal if the supervisor decides that any part of an NR is supportable.
 - b. Grant the appeal if the supervisor decides the entire NR, as documented is not supportable.

B. When establishment appeals an NR but elects not to request access to PHIS (i.e., cannot submit an appeal electronically into PHIS), supervisory personnel are to do the following:

1. Log in using normal login procedures;
2. Click “Inspection Verification” then “Select Establishment”;
 - a. From the left menu click “Plant Management “;

- b. Find the NR that was appealed and click the red arrow in “Response” column;
- c. Click “Appeal”;
- d. Enter the name of the establishment representative that is making the appeal in the text field. If there is an establishment appeal in writing, the supervisor will attach either a scanned copy or if it was electronically sent, the electronic version;
- e. Click “Save”;
- f. Click “Submit”; and
- g. At the “Are you sure want to submit?” prompt, click “OK.”

3. Follow Steps 4 and 5 in Section VI A. above to “Grant” or “Deny” the appeal.

NOTE: When the DM or DDM denies an appeal, the following message will be visible at the top of the “Plant Management Response” page:

“The District Manager/Deputy District Manager has denied your appeal. If you wish to continue the appeal process to the next level of supervision, please submit your appeal and any associated documents to the Executive Assistant for Regulatory Operations (EARO) for your district. For appeal guidance, please refer to the [FSIS website](#).”

VIII. DATA ANALYSIS

Upon request, the Office of Data Integration and Food Protection (ODIFP) will analyze appeals data as needed to assess the utilization of PHIS by establishments for appeals and to analyze trends in outcomes of appeals to develop strategies for minimizing the number of appeals. FSIS will periodically report aggregated results of the percent of appeals granted in its Quarterly Enforcement Report.

IX. QUESTIONS

Refer questions regarding this directive to the Policy Development Staff through [askFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

- Subject Field: Enter **Directive 13,000.3**
- Question Field: Enter your question with as much detail as possible.
- Product Field: Select **General Inspection Policy** from the drop-down menu.
- Category Field: Select **Regulations/Agency Issuances** 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