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

# FSIS DIRECTIVE	5050.1	6/2/10

DOCUMENTATION OF NONCOMPLIANCE IN EGG PRODUCTS PLANTS

Note: Upon receipt of this directive, IPP in egg products plants are to submit all NRs completed since April 1, 2010 to the new EGG NR Outlook Mailbox. IPP are to submit all NRs generated using the instructions contained in this directive daily to this new Outlook mailbox.

I. PURPOSE

The purpose of this directive is to provide inspection program personnel (IPP) with instructions on how to document noncompliance observed in egg products plants on FSIS Form 5400-4, Noncompliance Record (NR), how to submit completed NRs to an electronic database, and how to distribute and file hard copies of completed forms.

KEY POINTS:

- *How to document noncompliance on NRs.*
- *How to submit completed NRs to the designated Outlook Mailbox and distribute and file completed NRs.*
- *How to use FSIS Form 5050-1, NR Tracking Log.*
- *IPP in egg products plants will no longer document noncompliance on FSIS Memorandums.*

II. CANCELLATION

Egg Products Inspectors Handbook, Section 4, Part II. A. 2. and Part III. A.

III. [RESERVED]

IV. REFERENCES

9 CFR part 590

V. BACKGROUND

A. When IPP observe noncompliance in an egg products plant, the information documented is similar to the information documented in meat or poultry establishments. To harmonize the format of documentation of noncompliance in egg products plants with that used in meat and poultry establishments, upon receipt of this directive, IPP in egg products plants will document noncompliance on FSIS Form 5400-4, Noncompliance Record. If additional space is needed, IPP are to use FSIS Form 5400-4(a) NR continuation sheet. Both forms are available on the FSIS Intranet under the Forms tab. IPP will first need to log on to the FSIS Intranet using their e-authentication password to access the form at http://inside.fsis.usda.gov/fsis/public/static/index.jsp .

B. The forms are PDF forms that can be completed and saved electronically. IPP can download the forms to their computers and fill in the applicable blocks. The completed form can be saved as an electronic file.

VI. INSTRUCTIONS FOR COMPLETING FORMS

A. IPP in egg products plants do not fill out the "type of noncompliance" block or blocks 7, 8, and 9 on the NR. These blocks pertain to information collected only for establishments complying with 9 CFR parts 416 and 417. Egg product noncompliances are recorded in block 10 of the form. Only blocks 1-11 can be filled in and saved electronically. All blocks on the forms designated for plant management responses are not capable of being filled electronically.

B. The first block on the form, **Type of Noncompliance**, is not numbered. IPP are to leave this block blank.

C. IPP are to complete the form using the following instructions according to the block number:

1. **Date -** Record the date. (NOTE: Date should match the date on PY-203, Daily Report of Plant Operation or PY-159, Daily Report of Plant Operation).

2. **Record No. -** Each NR is given its own unique number. NRs are to be consecutively numbered as set out below:

    a. Number - The NR number will be the next available consecutive number shown on the FSIS Form 5050-1, NR Tracking Log. (See Section IX.)

    b. Calendar Year – Enter the current calendar year (e.g., 2010).

    c. Shift – For single shift plants enter G-1. For multiple shift plants enter G-1 for the designated first shift and G-2 for the designated second shift.

3. **Establishment No. –** Record the plant number (e.g., 01234 G).

4. **To (Name and Title) –** Enter the name and title of the responsible plant management representative.

5. **Personnel Notified –** Enter the name of the plant management representative who is to be notified about the noncompliance.

6. **Relevant Regulations -** Cite the specific regulatory requirements that the plant did not meet. For example, if the plant did not prevent shell eggs with adhering dirt from entering the breaking room, then 9 CFR 590.510(c) would be entered in this block.

7-9. **Do Not Complete**.

10. **Description of Noncompliance –** IPP are to identify at the beginning of the written text in block 10 the type of noncompliance being documented and the shift. (e.g., AM Shift, PM Shift) Example: Noncompliance – Adulteration, AM Shift. IPP are to select the appropriate category from the list below:

    a. **Facilities:** SPF (Facilities) – Sanitary, Processing, and Facility Operation Requirements (noncompliance for Facility).

    b. **Pre-operational sanitation:** SPF (Pre-operational) - Sanitary, Processing, and Facility Operation Requirements (noncompliance for Pre-operational Sanitation).

    c. **Sanitation–Operational:** SPF (Operational) - Sanitary, Processing, and Facility Operation Requirements (noncompliance for Operational Sanitation).

    d. **Sanitation-Other:** SPF (Other) - Sanitary, Processing, and Facility Operation Requirements (noncompliance for 'Other' causes).

    e. **Adulteration:** *Any egg product that has been adulterated (9 CFR 590.5 – Adulterated)* (e.g., foreign material, chemical, microbiological).

    f. **Ineligible Breaking Stock:** Shell eggs presented for breaking that are not eligible for use as human food (9 CFR 590.5 (c)(d)(e)(f)(g)) (e.g., dirts, leakers, loss).

    g. **Processing:** Formulation, pasteurization system problems.

    h. **Other:** Labeling, other consumer protection.

IPP are to describe each noncompliance in clear, concise terms by:

    i. Describing the exact problem, time, location, and effect on product

    ii. Indicating whether regulatory control actions were taken and how (e.g., applying a tag to boxes or stopping a line).

iii. Listing the name or title of the plant employee that was informed and observed the cited noncompliance

iv. Indicating how plant management received notification (i.e., written or oral)

v. Explaining any immediate actions the plant has taken and any proposed actions

vi. Describing plant management response to any previous notification

vii. Describing any previous corrective actions that were unsuccessful

viii. Describing any activities performed by IPP to verify plant action (e.g., equipment was reinspected and released)

EXAMPLE: Classification - Pre-operational sanitation. AM Shift. At approximately 0410 hours, I was informed after the plant had conducted its pre-operational inspection, the breaking room was ready for FSIS pre-operational inspection. I observed the following noncompliances: Breaking machine #1: Observed dried egg meat residue on several cracker heads and cups. I also observed egg shell fragments in the bottom of the whole egg collection pot. I applied "U.S. Reject" tags #B1469277 to breaking machine #1 and U.S. Reject tag #B1469278 to the whole egg collection pot. The floor supervisor was informed and observed both cited noncompliances and immediately had the equipment appropriately cleaned to restore sanitary conditions. The floor supervisor stated that the plant would have QA increase the amount of time it spent conducting pre-operational inspection before determining the room was ready for FSIS inspection. It would also direct QA to relay its findings to the cleaning supervisor, so that he or she could instruct the cleaning crew. Both pieces of equipment were re-inspected, and IPP removed the USDA tags at 0430 hours.

11. **Signature of Inspection Program Employee –** Sign the completed NR and then print out a hard copy.

12 & 13. **Plant Management Response -** (Immediate action): The "immediate action" is the action that the plant takes to correct the noncompliance, including appropriate product disposition. IPP are to document any oral response by plant management, including the action the plant takes to correct the noncompliance and the appropriate product disposition.

(Further planned action): The "further planned action" is the action taken by the plant to prevent a recurrence of the noncompliance. IPP are to document an oral response by the plant management, which needs to include any "further planned action" that the plant is proposing to take to prevent recurrence of the noncompliance.

14 & 15. **Signature of Plant Management and Date –** If plant management provides a hand written response in block 12 or block 13, a plant management official should also sign and date the NR.

16 & 17. **Verification Signature of Inspection Program Employee and Date –** IPP are to sign and date these lines after completing the NR.

NOTE: Information cannot be entered into or saved electronically in blocks 12, 13, 14, and 15. Plant management may respond to the NR orally or in writing on the hard copy of the NR provided by the IPP, or in writing in a letter or memo to the inspector.

D. FSIS form 5400-4(a), Continuation Sheet is used only when IPP need extra space. When using the Noncompliance Continuation Sheet, IPP are to check the box next to the word "Attachment" in the top right corner of the form and complete blocks 1-3, 10, 11, and 12. Blocks 7, 8, and 9 are not to be completed.

VII. HOW TO SAVE THE FORMS

A. Use the "Save As" function after completing the forms.

B. Use the unique record number (block #2) as the file name. For example if the NR has a record number of NR-01-09 this will be the first part of the file name.

C. Add the PDF extension (.pdf) to the end of the file name. The complete file name would be NR-01-09.pdf.

D. Select the folder in which the file will be saved.

E. Press the "Save" button.

VIII. FORM DISTRIBUTION

A. IPP are to:

1. Provide plant management with a hard copy of the NR;

2. Attach the NR to the completed PY-203 or PY-159 and file in the official government file;

    a. Record the noncompliance on the PY-203 or PY-159 by checking the appropriate box on the form with "N" or "No" for "Unsatisfactory" and

    b. In the remarks section of the PY-203 or PY-159 state the specific line number marked as unsatisfactory and add the assigned NR tracking number (e.g., NR-01-2009).

3. Attach any written responses received from plant management to the NR. Plant

management does not have to respond in writing to an NR;

4. Send an electronic copy of the completed NR (with attachments) to the EGG NR Outlook Mailbox; and

5. If IPP are unable to submit completed NRs electronically to the EGG NR Outlook Mailbox, forward a copy of the NRs completed each week to the District Office (DO).

B. The DO will scan the NRs received and send them to the EGG NR Outlook mailbox or forward copies via FedEx, weekly, to the following address:

George Washington Carver Center (GWCC)
USDA, FSIS, OPPD
Policy Analysis Division
5601 Sunnyside Ave., Mail Stop 5275
Beltsville, MD 20705-5275

NOTE: IPP are not to send an electronic copy of the NR to plant management.

IX. FSIS FORM 5050-1, NR TRACKING LOG

A. FSIS Form 5050-1 NR Tracking Log is designed to manage NR numbers issued and to ensure that each NR has its own unique number. The form is available on the FSIS Intranet under the Forms tab. IPP will first need to log on to the FSIS Intranet using their e-authentication password to access the form at http://inside.fsis.usda.gov/fsis/public/static/index.jsp.

B. IPP are to complete the NR Tracking Log by entering the date the NR is issued, the number assigned, and their name or initials.

C. Only one NR Tracking Log is to be maintained for each plant. Plants with multiple shifts are to use the same tracking log for all shifts. IPP in multiple shift plants will select the next consecutive number from the list when issuing an NR.

D. IPP are to maintain FSIS Form 5050-1 in the government file. Logs are to be maintained by fiscal year and retained for 3 years following the close of the fiscal year in which it is created.

X. DATA ANALYSIS

The Office of Policy and Program Development (OPPD) is to analyze trends in egg noncompliances by NR category on a quarterly basis. Noncompliance will be categorized into 8 distinct types: Sanitation of Processing Facilities (SPF) will include four categories – Facilities, Pre-operational sanitation, Sanitation-Operational, and Sanitation-Other. The other four categories are Adulteration, Ineligible Breaking Stock, Processing, and Other (Labeling and other consumer protection). The OPPD quarterly analysis is to include a review of repetitive noncompliance within individual plants to assess the effectiveness of corrective actions. The analysis is also to provide quarterly

averages of plant-specific total NRs by establishment, establishment size, and district.

Refer questions regarding this directive to the Policy Development Division through askFSIS or by telephone at 1-800-233-3935.

Assistant Administrator
Office of Policy and Program Development

Instructions for Completion and Saving of FSIS Form 5400-4 and 5400-4(a) Electronically

FSIS Forms 5400-4, Noncompliance Record, and 5400-4(a), Noncompliance Continuation Sheet, are available on the FSIS Intranet under the Forms tab. IPP will first need to log on to the FSIS Intranet using their e-authentication password to access the form at http://inside.fsis.usda.gov/fsis/public/static/index.jsp .

The forms are in PDF fillable format. IPP can download a copy of the forms to their computer and fill in the applicable blocks. (Only blocks 1-11 can be filled in and saved electronically.) The completed form can then be saved as an electronic file.

NOTE: All blocks on the forms designated for plant management responses are not capable of being filled in electronically. When IPP open the PDF form file they will see a "*Document Rights and Instruction"* window at the top of the form. Use the bar on the right hand side of the window to move up and down in the instructions. Within this window are the following instructions to IPP on how to use and move about in the form:

Document Rights and Instructions

NOTE: FSIS PDF form files are only to be used by FSIS Employees. Do not distribute this file to anyone outside the Agency.

If you plan to cut and paste information from another document, change font to Courier New 10 pt. before you copy and paste into the PDF form.

HOW TOs:

- To save, use the "Save As" function.
- To move from field to field, press the "Tab" button on your keyboard.
- To select a checkbox, tab and click inside the box with your left mouse button or press your spacebar.
- To enter a date, use the following format: MM/DD/YYYY (i.e., 12/12/2006)
- To add an attachment click the "Attachment" tab located at the left of the document, select the "Add" icon on the attachment menu bar, navigate to your document and select the attachment.
- To access the Adobe Screen Reader to "Edit" on the menu. Select "Preferences". On the left column, select "Reading" and at the bottom, check "Read From Fields". Next Select "View", "Read Out Loud", then "Activate Read Out Loud", Tab in the form fields.

NOTE: OCIO also provides more expanded instructions in two formats: MS Word and PowerPoint. The expanded instructions are currently located in MS Outlook at: Public Folders/All Public Folders/Agency Issuances/Forms/User Instructions Folder.