

## Documentation and Enforcement

### Objectives

After completing this module, participants will be able to do the following:

1. Explain the procedures to follow when a noncompliance is identified.
2. Explain the enforcement actions commonly taken by FSIS.
3. Describe the purpose of “U.S. Rejected/Retained” tags and explain when to apply them.
4. Understand how to complete FSIS Form 5400-4, “Noncompliance Record” (NR)
5. Be familiar with all FSIS and PY forms IPP complete in the course of conducting daily egg product inspection activities

### Introduction

In this module, we will outline the plant’s responsibilities, inspection program personnel’s (IPP) responsibilities, and the procedures to follow in the case of a noncompliance. We will also cover the enforcement actions IPP and the District Office can take when product is adulterated or when there are unsatisfactory/insanitary conditions in the plant that can affect the safety and wholesomeness of the egg products being produced.

FSIS protects public health by maximizing compliance with laws and regulations governing the production of eggs and egg products. The egg products plant has the responsibility to comply with the regulations and to produce an unadulterated and wholesome egg product. FSIS is responsible for verifying that the plant meets regulatory requirements. The Egg Products Inspection Act (EPIA) provides the authority to inspect liquid, frozen, and dried egg products. It also provides the authority for retention, segregation, reinspection, and condemnation of any eggs and egg products found to be adulterated or misbranded in an official egg products plant, per the EPIA Section 5(b).

The EPIA and its associated regulations (9 CFR §590) set forth requirements to ensure that eggs and egg products are wholesome, not otherwise adulterated, properly labeled, and properly packaged. Plant management agrees to follow the regulatory requirements of 9 CFR §590 when they sign the Grant of Inspection application for Mandatory and/or Voluntary Egg Products Inspection.

IPP have to ensure that the plant adheres to the regulations by conducting inspection verification activities and taking enforcement action when needed to ensure food safety compliance. IPP assigned to the egg products plant observe

the facility and processing operations to determine compliance with the regulations.

Before we begin our discussions of these topics, we will clarify the meaning of some terms that are crucial for IPP to understand.

## Definitions

**Inspection** - (§590.5) the application of such inspection methods and techniques as are deemed necessary by the Secretary to carry out the provisions of the EPIA and the regulations under 9 CFR §590.

**Compliance** - When the plant's processes are working properly in accordance with laws and regulations.

**Noncompliance** – When the plant's process is not compliant with the regulations in 9 CFR §590 or the EPIA.

**Enforcement actions** - Actions the Agency takes when IPP determine that the plant processes and systems are not in compliance with laws and regulations. FSIS uses a range of enforcement actions such as regulatory control actions, suspension of inspection, or withdrawal of the Grant of Inspection.

**Regulatory control action** – The enforcement action most commonly used by FSIS inspection personnel. This term refers to any action that IPP take to control product or a process. IPP use regulatory control actions to identify regulatory noncompliance (§590.426) and prevent the movement of the product (retained product), stopping operations, or rejecting equipment or processing locations until the noncompliance has been corrected. A common example is the application of the “U.S. Rejected/Retained” tag.

## Plant and IPP Responsibilities

As mentioned above, plant management is responsible for assuring that the plant is operating in accordance with the regulations and applicable FSIS policies. Complying with the regulations requires good communication between IPP and plant management. On a daily basis, IPP are to perform their inspection duties, document noncompliance when it is observed, and inform plant management when any noncompliance is identified. IPP verify that plant management takes appropriate corrective action.

IPP have the regulatory authority (§590.420) and the responsibility to determine that the plant operates in compliance with the regulations. When IPP observe

deviations from the regulations—regulatory noncompliance—they are to follow the procedures described below.

## Procedures to Follow When a Noncompliance is Identified

### Noncompliance directly affects product

When noncompliance directly affects the product, IPP are to take the following steps:

1. If the noncompliance observed affects product, determine if the product may be adulterated. If the product is adulterated, take regulatory control action by retaining the affected product and having the operation stopped.
2. Inform the plant of the specific noncompliance and request that the plant initiate corrective action or immediate action (action that the plant takes to correct the noncompliance, including appropriate product disposition).

IPP are to apply a U.S. Rejected/Retained tag to affected equipment, room, product when needed to prevent the use of the equipment or control the movement of the affected product.

3. Document the noncompliance on FSIS Form 5400-4 (refer to Attachment 1 – page 26 below), “Noncompliance Record” (NR), following the instructions on Directive 5050.1 and attach the NR to the completed appropriate form:
  - FSIS Form 5400-12 (refer to Attachment 1 – page 21 below), “Daily Report of Plant Operations”, for liquid egg products (formerly PY-203)
  - FSIS Form 5400-11 (look at page 24 below), “Daily Report of Egg Drying Operations”, for dried egg products (formerly PY-159)

Both forms are available on the FSIS Intranet under the Form tab, and are now PDF fillable.

**Note:** Record the noncompliance on FSIS Form 5400-12 or FSIS Form 5400-11 by checking the appropriate box on the form with “N” or “No” for Unsatisfactory. In the remark section of the FSIS form state the specific line number marked as unsatisfactory; in addition, include the assigned NR tracking number (i.e., Number/Year/Shift).

If product has been retained, the company will need to provide IPP with their disposition recommendation for the affected product. Depending on the situation and on what occurred, this could include re-inspection, reworking the product into

another lot, reprocessing (repasteurizing) or condemning the product. In all cases, the company will need to support any decision that they made in regard to their proposed disposition of product to assure that the product is wholesome and properly labeled. FSIS IPP and the FLS will review the plant's recommendation to determine if the proposed disposition by the plant is acceptable. If assistance is needed in reviewing the plant's recommendation, FSIS IPP and the FLS can request assistance from PDD.

### **Noncompliance does not directly affect product**

When noncompliance does not directly affect the product, IPP are to:

1. Inform management of the noncompliance and request prompt correction of those items requiring immediate attention.
2. Document the noncompliance on a NR and provide a hard copy to plant management following the instructions in Directive 5050.1. Attach the NR to the completed FSIS Form 5400-12 or FSIS Form 5400-11.
3. IPP are to document an oral response by plant management in the NR, which needs to include any further planned action that the plant is proposing to prevent recurrence of the noncompliance.

IPP should not limit their inspection to those items listed on the FSIS 5400-12 and FSIS 5400-11 forms; if a noncompliance occurs that is not included on these forms, IPP are to take action and document the noncompliance. See examples of these forms in this module or in Appendix 4.

### **Documenting Noncompliance**

FSIS Directive 5050.1, *Documentation of Noncompliance in Egg Products Plants*, instructs IPP on how to document noncompliance observed in egg products plants on FSIS Form 5400-4, *Noncompliance Record* (NR); how to submit the completed NR; how to distribute and file hard copies. In addition, this directive provides instructions on how to track the completed NR using the "NR Tracking Log" (FSIS Form 5050-1; refer to Attachment 1 – page 27 below).

FSIS is harmonizing the format of documentation of noncompliance in egg products plants with that used in meat and poultry establishments to maintain consistency within the Agency. FSIS Forms 5400-4 and FSIS Form 5400-4(a) (NR continuation sheet) are available on the FSIS Intranet under the Form tab. Furthermore, the directive replaces instructions set forth in specific sections of the Egg Products Inspector's Handbook.

IPP will follow the instructions in the directive (Section VI) for completing the NR. IPP in egg products plants **do not** fill in blocks 7, 8, and 9 on the NR (FSIS Form 5400-4) as well as the Type of Noncompliance block at the top of the NR. Thus, IPP will complete blocks 1 – 6 and block 10 electronically. Blocks 11 – 17 cannot be filled in electronically:

- **Block 1 – Date:** Record the date; the date should match the date on the FSIS forms. Use the calendar date (e.g., 7-01-2012).
- **Block 2 – Record Number:** each NR is given a unique number and are to be consecutively numbered; for example, NR 13-2011-G-2. This would be the 13<sup>th</sup> NR written (consecutive number entered on the FSIS Form 5050-1), 2011 is the current calendar year, and G-2 correspond to the second shift for multiple shift plants. G-1 would be used for the first shift or in single shift plants.

**Note:** 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. This form is also available on the FSIS Intranet under the Forms tab. Follow instruction set forth in Directive 5050.1, Section IX.

- **Block 3 – Establishment Number:** e.g., 01234 G
- **Block 4 – To (Name and Title):** of the responsible plant management representative.
- **Block 5 – Personnel Notified:** is the plant management representative who is to be notified about the noncompliance
- **Block 6 – Relevant Regulations:** Cite the **specific** regulatory requirement that the plant did not meet. IPP should cite the most relevant regulation. This generally means one or two regulatory citations. Do not include any word text in the citation, use only the number citation. If the plant is in noncompliance with several regulations, IPP should cite the most relevant regulation in this section, and then reference the additional citations in Block 10.

**NOTE:** It is crucial that IPP always include the applicable regulatory citation from 9 CFR §590 in this block. Do Not Leave it Blank. Do Not cite the Egg Products Inspectors Handbook, the EPIA or other regulations that are not part of 9 CFR §590 (e.g., Title 9 part 59, Title 21, 9 CFR §416, §417, or any meat or poultry regulations)

- **Block 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 or PM Shift).

As an example, Noncompliance – Adulteration, AM Shift. In addition, select the appropriate category from the list provided in the Directive (for example: facilities, pre-operational sanitation, adulteration, etc.; Section VI.C.). Describe the noncompliance in a clear, concise, specific, descriptive and thorough manner including affected product and lot number (if any), time, location, etc. of each noncompliance. If a regulatory control action was taken, include the tag number and how the tag was used. Follow the specific instructions in the directive.

Because Block 11 cannot be signed electronically, FSIS IPP should place their name (e.g. Inspector John Doe) at the end of the noncompliance description in Block 10.

- **Block 11 – Signature of Inspection Program Employee:** IPP can only sign the hard copy. IPP cannot enter their signature electronically.
- **Block 12 & 13 – Plant Management Response:** Document on the NR (manually) any oral response by plant management concerning to any immediate action or further planned action the plant is taking to correct the noncompliance, including appropriate product disposition.
- **Block 14 & 15 – Signature of Plant Management and Date:** If plant management provides a hand written response in the blocks 12 or 13, a plant management official should also sign and date the NR.
- **Block 16 & 17 – Verification Signature of Inspection Program Employee and Date:** IPP are to sign and date after he/she verifies that the plant has corrected the noncompliance.

IPP are to provide plant management with a hard copy of the NR according to the instructions specified in Directive 5050.1; attach the NR to the completed FSIS Form 5400-12 or 5400-11 and file in the government file.

Attach any written response to the NR or supporting documentation provided by the plant, including the immediate action that the plant takes, to the NR. All documentation should be attached to the FSIS file copy; file the completed NR record in the USDA government file.

**Note:** It is recommended that FSIS IPP keep the NR Tracking Log in this file as well.

IPP are only to send the electronic copy of the NR to the EGG NR Outlook Mailbox, i.e., submit the PDF fillable FSIS Form 5400-4 completed copy (blocks 1 through 10) to the Egg NR Outlook Mailbox. Make sure that blocks 1, 2, 3, 4, 5, 6, and 10 are all completed before submission.

IPP are to include the NR number in the Subject Line when submitting their NR to the Egg NR Outlook Mailbox.

IPP are **not** to send scanned copies of the NR or any of the additional information (i.e.; plant management responses, etc.) to the Egg NR Mailbox.

**Note: DO NOT submit scanned copies.** Scanned copies are like pictures and the software program cannot extract the needed data from the picture.

IPP are to send each NR separately to the Egg NR Outlook Mailbox. **DO NOT** send multiple NRs in the same e-mail. The NR copy that is submitted to the Egg NR Outlook mailbox is to be submitted the same day or the following day after it is issued. The NR may not be closed, and this is ok.

Occasionally, IPP may need to make corrections or revisions to an NR, but have already submitted it to the Egg NR Outlook mailbox. When this happens you will need to submit the corrected NR to the Egg NR Outlook mailbox. When submitting the corrected NR to the Egg NR Outlook mailbox, place the following statement in the Subject Line of the e-mail: ***Revised NR-(include number) and plant number***. This will enable the Mailbox Manager to replace the original NR with the corrected copy.

If the plant appeals the NR, and the appeal is upheld, IPP are to send an e-mail to the Egg NR Outlook mailbox with this information so the NR can be removed from the Egg NR database. IPP are to include the plant number, date of the NR, the NR number assigned to the NR and the name of the inspector who submitted the original NR to the Egg NR Outlook mailbox.

Follow up on a daily basis to ensure that the plant have taken action to correct the noncompliance and document when the noncompliance has been corrected. Only then can IPP close the NR.

## **Corrective Actions**

Corrective actions are to be taken by the plant as soon as possible, or, depending on the situation, a completion date must be provided by plant management and reflected on the forms. If the noncompliance cannot be corrected within the timeframe established, plant management must provide IPP with their intent regarding corrective actions. If management provides valid justifications, the completion date may be extended to allow for the corrections; however, the company's records need to reflect their intentions to correct the

noncompliance. IPP will document these events, including the new completion date for the applicable noncompliance item.

When the plant fails to comply with IPP's request for correction, IPP may need to take regulatory actions and inform management; in some instances, it may be necessary for the plant to delay their starting time or to stop operations until corrections are made. If the plant fails to correct noncompliance items and proceeds to start operations or to use equipment or rooms that are under regulatory control action, IPP should immediately contact the Front Line Supervisor (FLS) and report the incident. The FLS will initiate the appropriate enforcement actions described above or provide additional instructions.

### **Regulatory Control Action Using “U.S. Rejected/Retained” Tags**

The “U.S. Rejected/Retained” tag is a multi-purpose tag used to identify and control retained product, reject (unacceptable) equipment, or processing areas or rooms.

The Inspector-in-charge (IIC) at each official plant should maintain a supply of tags. These tags are serially numbered. IPP should always carry U.S. Rejected/Retained tags with them when they are conducting inspection activities in the plant. The reason for this is that when IPP identify a noncompliance during their inspection activities, they can immediately apply the tag to ensure control of the situation. For example, IPP observes an open bag of ingredients or an unlabeled container, applying the retain tag controls the product from moving or being used.

When IPP use a tag, they are to do the following:

- Fill out all the required information on the upper/lower portion of the tag.
- Attach the upper portion to the product, equipment, or room to be controlled and keep the lower portion in the file until the noncompliance is corrected. Attach the lower portion of the tag to FSIS Form 5400-12 or 5400-11. In some instances, IPP will have to use more than one tag to assure adequate control.
- Record the tag numbers used on the applicable FSIS forms (FSIS Form 5400-12 or 5400-11) and in block 10 of the NR (FSIS Form 5400-4); maintain a separate detailed log of retained product on file and retain this log sheet until all product represented by the retain tag numbers has been properly disposed of or reprocessed.
- After the plant corrects the noncompliance, destroy both portions of the tag(s) and release the regulatory control action.

There are many reasons to apply “U.S. Rejected/Retained” tags to identify and segregate noncompliant product and, when necessary, to control product being held for further processing, examination or testing. Examples of product to retain include:

- *Salmonella* positive product
- Product produced or held under insanitary conditions
- Product known or suspected to be adulterated
- Cases or lots of inedible/loss type shell eggs brought into/accumulated in the plant that are unidentified by the plant.
- Improperly labeled product (misbranded)
- Control of product still in process (e.g.; dried egg whites being held in a hot room undergoing heat treatment)

Other reasons to apply these tags are to identify insanitary equipment, utensils, rooms, or storage areas. Some examples include:

- improperly cleaned shell egg washer
- improperly cleaned pumps or valves
- improperly cleaned refuse room or refuse containers
- unsatisfactory equipment such as a rusted tank or silo
- torn bags of ingredients
- unlabeled ingredient containers

**DO NOT** place tags on electrical controls, switches, or equipment that is in operation.

Once IPP place a “U.S. Rejected/Retained” tag on product or equipment, they are to advise plant management; it is management’s responsibility to notify plant employees of the regulatory action taken by FSIS. When the noncompliance is corrected, IPP will remove the tag(s).

IPP are to report immediately to their supervisor when a violation regarding a regulatory control action occurs. For example:

- “U.S. Retain/Reject” tags are removed by unauthorized persons.
- The plant uses equipment or rooms on which a rejected tag has been placed.
- Retained product is shipped from the plant without authorization.

Further enforcement measures may be taken as a result of the violation.

Furthermore, IPP have to be alert to where product can become adulterated due to chemical contamination or willful product tampering. If this type of contamination occurs, IPP are to take immediate regulatory control action to

prevent product from entering commerce. IPP must immediately inform management and their supervisor of the situation and of the actions they have taken, and FSIS Directive 5420.1, *Homeland Security Threat Condition Response - Food Defense Verification Procedures*

## Associating NR

You should associate an NR to provide notification to the plant that the further planned actions are ineffective in preventing the noncompliance from recurring and that, if the trend continues, the repetitive NR would support an enforcement action. You should be linking NR together only when the noncompliances are from the **same cause**.

When you link one NR to another, you should **document**:

- **The previous NR number and date**
- The **further planned action** that was ineffective in preventing recurrence of the noncompliance.
- Any discussion with establishment management during the weekly meeting, concerning the trend.

NR should be associated **as they are issued**. Each noncompliance that you believe is associated to a previous noncompliance should be documented as associated at the time the NR is completed. Do not link the current noncompliance to more than one previous noncompliance.

You should continue to associate NR's together that derive from the same cause **until you determine that an enforcement action is necessary** to bring the plant into compliance with the regulations. When you determine that enforcement action is necessary, you should contact the District Office and always keep your supervisor apprised of the situation.

## Conducting Weekly Meetings

IPP are to conduct a weekly meeting with plant management to discuss issues of concern. . Plant management may also wish to share information or concerns that it has at the meeting.

On a periodic basis at the meeting (about once a month), IPP should ask plant management whether it has made any changes in how it is processing product or other changes that would affect the safety of the product. If IPP learn that the

plant has made a change in its process, based on the nature of the change, they are to determine whether all regulatory requirements have been met, and whether the product produced is eligible to bear the mark of inspection for distribution in commerce. If IPP are unsure of how to proceed, they are to contact the District Office through supervisory channels and request guidance and further instructions.

IPP should review FSIS Notice 33-12, *Conducting Weekly Meeting in Egg Products Plants*, for more detailed instructions on the possible topics for discussion. A wide variety of topics can be discussed at the meetings, including individual noncompliances, developing trends of noncompliance, and findings by IPP that do not represent regulatory noncompliance but that need to be brought to the attention of the plant. For example, discussion of information from external sources, such as customer or consumer complaints, can provide information to alert plant management about a safety risk or about other information that is relevant to the plant's food safety system.

IPP will document the weekly meeting in a Memorandum of Interview (MOI). The MOI should contain the following information:

- Who was present at the meeting;
- Date and time of the meeting;
- Plant management's responses to FSIS findings that do not rise to the level of noncompliance but that warrant discussion (e.g., less than perfect conditions); and
- All issues or topics discussed.

IPP in multi-inspector/multi-shift plants are to seek guidance from the FLS to determine how to conduct weekly meetings so that IPP from all shifts have an opportunity to conduct and participate in the meetings.

IPP are to maintain a copy of the MOI in the official government file and provide a copy to plant management.

## **Egg Products Inspection Forms**

As discussed earlier, there are several official forms that IPP need to be familiar with and know how to complete. Some forms are completed daily, or weekly, or monthly. Some forms are completed only once or when a change is identified, while others are completed as needed depending upon the task at hand. Most of these forms are available in a PDF fillable format and are available on the FSIS Intranet under the Forms Tab. They can be saved as a blank copy on your computer. After completing the form electronically, you can save the form as its

own unique file by giving it a new name and using the “Save As” function to save the file folder you designate on your computer.

The following is a brief summary and explanation of each form and how it is used in egg products.

1. *Application for Service, FSIS Form 5200-12*. This form is completed in conjunction with FSIS Forms 5200-1, 5200-4, and 5200-6 for the Grant of Inspection process, and part of the forms required to be completed before the inauguration of service when a plant requests a mandatory or voluntary egg products inspection at their egg products plant. The form would also be completed when a change occurs in the ownership of the plant. The plant completes the form and then submits the form to the District Office.
2. *Application for Off-Premise Freezing of Egg Products, FSIS Form 5200-10*. This form is unique in that it is completed by the origin plant, the off-premise freezing location and the authorized FSIS personnel (usually the FLS).

Egg products plants can request to move egg products that are to be frozen to an off-premise location for further processing (freezing). A request may be made for several reasons such as the plant does not have sufficient freezing facilities to accommodate the volume of product they produce. Or, they have an approved off-premise freezing location in case of emergency. The off-premise freezer is considered to be an extension of the official egg products plant and, therefore, does not have an official plant number.

When an off-premise freezer is approved, the plant has to make arrangements with the FLS and/or District Office to have an inspector travel to the location to conduct the final condition examination of the finished egg product. It is important to remember that when egg products are moved to the off-premise location, they still must be frozen in the required regulatory time frame (60 hours from the time of production). The clock starts at the end of the shift on which the egg products were produced and packaged.

The FLS conducts an inspection of the off-premise freezing facility, prior to the final approval to allow the origin plant to use this facility to ensure that all provisions of the approval are in place. This usually includes ensuring applicable facilities, record keeping, and control of the product to ensure it does not move into commerce until the final condition examination has been made, and FSIS IPP determine that the product has met all of the regulatory requirements set forth in 9 CFR §590. All FSIS inspection verification activities are conducted under voluntary inspection and the

origin plant is billed for this service. FSIS IPP does not bill the off-premise freezer for this service.

3. *Egg Products Grading Weekly Report, FSIS Form 5200-9*. This form is to be completed weekly in all egg products plants which are breaking shell eggs. The type of information entered in this document includes the quantity of shell eggs broken, total liquid and/or frozen eggs produced, total dried egg solids produced as well as other information. If a plant is only receiving unpasteurized egg products for further processing and they do not break, they will not complete this report.

The report will be completed at the end of the week, and faxed to AMS Market News.

4. *Egg Products Volume Report, FSIS Form 5200-11*. This form is completed monthly by the plant. FSIS IPP is to review the information contained in the report for accuracy, and then the completed form is then faxed to the Financial Processing Center.

IPP are to follow the instructions in the *Guideline for Completion and Submission, Egg Products Volume Report, Form PY-240* (now FSIS Form 5200-11), dated 12-26-2001. ALL official egg products plants are to complete this form monthly. Even if the plant only repackages previously inspected and passed egg products (e.g., pasteurized liquid egg products, dried egg products) IPP are to verify that the form is being completed and submitted as required.

The information collected on this form is forwarded to the National Agriculture Statistics Service (NASS) who publishes a summary of this data monthly. Industry uses the data to help set the price of egg products being sold in commerce. The data is also used as part the Agencies Annual Report to Congress.

The most common error that has been identified when FSIS Form 5200-11 is completed is Block 01 – Shell Eggs Broken (30 dozen cases). This block must be completed when there is data in blocks 02 through 05. IPP are to have the form **faxed to 515-334-2042**. Please note that this is a NEW fax number, implemented in June 2012.

5. *Noncompliance Record for Egg Products, FSIS Form 5400-4* and *Noncompliance Record for Egg Products* (continuation sheet), **FSIS Form 5400-4(a)**. FSIS IPP is to follow the instructions for completion and distribution of this form in FSIS Directive 5050.1.

6. *Egg NR Tracking Log, FSIS Form 5050.1*. This form is to be complete whenever IPP issue a noncompliance record to the plant. Refer to the instructions in FSIS Directive 5050.1.
7. *Daily Report of Egg Drying Operation, FSIS Form 5400-11* (Previously PY-159). This form is now PDF fillable and can be saved as its own unique file. This form is completed by IPP assigned to egg products plant that dry amenable egg products. IPP complete the applicable section of the form at a minimum one time every two hours of production for their assigned shift. Each inspector assigned to a shift is to complete this form for that shift to which they are assigned. Consequently, in an egg products plant with two shifts, there will be two forms completed per day when those shifts are operational. IPP maintain a copy of the completed form in the USDA official government file.
8. *Daily Report of Plant Operations, FSIS Form 5400-12* (Previously PY-203). This form is now PDF fillable and can be saved as its own unique file. This form is completed by those IPP assigned to an egg product plant that breaks, pasteurizes or further process liquid or frozen amenable egg products. This form has two parts for recording sanitation conditions in the official plant. The first part covers the plant in general – pre-operational sanitation/program monitoring and operational (checklist) inspection. The second part covers the liquid egg product processing operations for recording the observations and actions during the inspector's tour of duty. IPP complete the applicable sections of the form at a minimum one time every two hours of production for their assigned shift. This report must reflect an accurate and objective picture of the operation and conditions as they existed during that shift. If necessary, add any note of clarification to the report. Each inspector assigned to a shift is to complete this form for the shift to which they are assigned. Consequently, in an egg products plant with two shifts, there will be two forms completed per day when those shifts are operational. IPP maintain a copy of the form in the USDA official government file.
9. *Consignment, Receipt and Disposition, Form PY-185*. This form is used for IPP to track the serially numbered accountable Form PY-200, *Egg Products Inspection and Grading Certificate*.
10. *Egg Products Inspection and Grading Certificate, Form PY-200*. This form is a USDA-FSIS serially numbered official certificate that has multiple uses within the egg products inspection program. As stated above, FSIS Form PY-200 is an accountable form that the inspector must track using the FSIS Form PY-185. IPP assigned to an egg products plant issue FSIS Form PY-200 for various reasons as described in FSIS Directive 5040.1, *Uses of FSIS Form PY-200 Egg Products Inspection Certificate*. The form is used to record inspection results, such as information indicating that IPP

have examined the type (e.g. frozen whole eggs, liquid egg yolks, dried egg whites) and condition of egg products to be shipped, and that the egg product meets the requirements of 9 CFR §590 and any applicable voluntary specification requirements. IPP issue a completed FSIS Form PY-200 to certify that the product meets the FSIS regulatory requirements, at the request of an applicant (e.g., egg products plant manager), to accompany a shipment of egg products.

Following is a list of applications for the PY-200 form:

- For egg products shipped between official egg product plants
- Shipment of non-denatured inedible egg products
- Shipment of egg product samples to the Agricultural Marketing Services (AMS) laboratory for analysis
- Certification of voluntary program specification and commodity requests
- To control the movement of egg products to an approved off-premise freezer for further processing  
To verify information for exported egg products

Included in this section is the *Disposition Schedule for Egg Products Inspection Records*, which provides IPP with the information that is needed on how long each record indicated above should be maintained and when it can be destroyed (refer to Attachment 2).

## Case Studies

Read the following scenarios and answer the discussion questions with your group. (**Note:** Work through the scenarios first and on pages 28 – 35 are documentation examples of Daily Reports and Noncompliance Reports.)

### Scenario 1

An inspector enters the breaking room to observe operation of the breaking machine. As the inspector observes the shell eggs on the transfer rollers that are entering the breaking room, she sees several eggs with adhering dirt moving to the breaking machine. The shells of these eggs have large pieces of chicken manure on the surface. The machine operator notices the manure on the shells and stops the equipment. The operator locates each dirty egg, removes each cracker and cup assembly along with each egg, and reinstalls clean and sanitized equipment before resuming the operation of the machine.

### Scenario 1 Questions

1. Has the machine operator taken appropriate corrective action to handle the dirty eggs?
2. What should the inspector do next, if anything, in this situation? Describe in detail these next steps.
3. Is there noncompliance? Explain your answer.

## Scenario 2

It is Monday morning and the breaking room supervisor has just informed the inspector that the breaking room is ready for pre-operational inspection. The plant completed operations the previous Friday and did not work any overtime over the weekend. The inspector enters the breaking room and observes that there is egg residue on the floor, along with shells left over from Friday. Numerous flies are also observed all over the room.

### Scenario 2 Questions

1. Has the inspector observed a noncompliance? If so, what part of the scenario constitutes noncompliance? Cite the applicable regulatory reference, if possible.
2. If there is a noncompliance, will it affect product?
3. What should the inspector do next in this situation? Describe in detail the steps the inspector should take.

### **Scenario 3**

When the inspector comes to work each morning, he enters the plant through the tanker bay. On this morning, he notices trash (items such as boxes and bags) stacked in the corner of the tanker bay. No tanker shipments are scheduled for this day.

### **Scenario 3 Questions**

1. Is this a noncompliance? If so, what part of the scenario constitutes noncompliance? Explain. Cite the regulatory reference, if possible.
  
2. If there is a noncompliance, will it affect product?
  
3. What should the inspector do next in this situation? Describe these steps in detail.

## Scenario 4

An inspector enters the breaking room and while observing the operations in the room notices a foul, pungent odor coming from one of the breaking machines. Upon further investigation, he determines that an exploding type of inedible egg, a black rot, has been broken on this machine. The operator has stopped the machine and removed the cracker and cup assembly that held the black rot and has installed a clean and sanitized cup and cracker assembly. He then sits down and is ready to resume operating the breaking machine.

## Scenario 4 Questions

1. Is this a noncompliance? If so, what part of the scenario constitutes noncompliance? Cite the regulatory reference, if possible.
2. If there is a noncompliance, will it affect product?
3. Has the machine operator taken appropriate corrective action in response to the exploding black rot? If not, what should he have done in this situation?
4. What should be the inspector's next steps? Describe these steps in detail.

## **Scenario 5**

During preoperational inspection activities, the inspector asks plant personnel to disconnect one of the elbow assemblies on a set of holding tubes. When the elbow section is removed, a sour smelling liquid drains from the open pipe.

### **Scenario 5 Questions**

1. Is this a noncompliance? If so, cite the regulatory reference, if possible.
2. If there is a noncompliance, will it affect product?
3. What should be the inspector's next steps? Describe these steps in detail.

## **Scenario 6**

A relief inspector is detailed to an egg products plant to cover for the resident inspector who is on leave. He is touring the outside of the building as part of his preoperational inspection duties and notices that weeds and other vegetation along the north wall of the shell egg cooler have not been cut or mowed for some time. The area has experienced a tremendous amount of rain and the plant has not mowed.

### **Scenario 6 Questions**

1. Is this a noncompliance? If so, cite the regulatory reference, if possible.
  
2. If there is a noncompliance, will it affect product?
  
3. What should be the inspector's next steps? Describe these steps in detail.

# Attachment 1 – FSIS Forms

## Copy of FSIS Form 5400-12 “Daily Report for Plant Operation”

UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE EGG PRODUCTS INSPECTION					
DAILY REPORT OF PLANT OPERATION					
NAME OF PLANT		ADDRESS OF PLANT		PLANT NUMBER	
SIGNATURE OF INSPECTOR		INSPECTOR'S BADGE NUMBER	DATE	CODE DATE	
PROCESSING OPERATIONS				INSPECTOR'S HOURS OF DUTY	
BREAKING FROM:	A.M. TO:	P.M.	PASTEURIZATION FROM:	A.M. TO:	P.M.
INSTRUCTIONS: Give exact figures where applicable. Mark "Y" for "Yes" or "Satisfactory" and "N" for "No" or "Unsatisfactory".					
PRE-OPERATIONAL SANITATION/PROGRAM MONITORING			OPERATIONAL CHECKLIST		
TIME OF INSPECTION:			TIME OF INSPECTION:		
1. Cleanliness and sanitizing of equipment used for pasteurized liquid (pipelines, gaskets, valves, pumps, etc.)			21. Organoleptic inspection and pour test.		
2. Cleanliness and sanitizing of equipment prior to start up.			22. Health and cleanliness of employees (uniforms, hair nets, clean hands, etc.)		
3. Cleanliness of shell egg washers and conveyors.			23. Breaking or breaking machines operating in sanitary manner		
4. General sanitation of other areas			24. Organoleptic examination of individual eggs.		
5. Premises, receiving, and shipping areas.			25. Breaking procedure when inedible is encountered (segregate inedible, change equipment, wash hands, etc.)		
6. Refuse removal and disposal.			26. Segregation of leakers, dities and loss for breaking.		
7. Rest rooms and lunch rooms			27. Denaturing and labeling of inedible eggs and liquid.		
8. CIP cleaning of pipelines and equipment.			28. Hydrogen peroxide test.		
9. a. Are breaking and packaging room, compressor, air filters, etc., satisfactory?			29. Sanitation - packaging room and equipment.		
9. b. Are air lines to product contact surfaces blown out and clean prior to use?			30. Product containers clean and sanitarly filled.		
10. Edible ingredient storage			31. Container identification and labeling.		
11. Insecticides, rodenticides, etc., isolated from chemical compounds.			32. Accuracy of weighing product.		
12. Insecticides, rodenticides, and chemical compounds isolated from edible products.			33. Positive flow of air in processing and packaging rooms.		
13. Package material storage.			34. Processing rooms free from flies and odors.		
14. Freezers, clean, containers properly spaced, and air circulation adequate.			35. Equipment clean and sanitized prior to use.		
15. Is the exhaust system operable in the rest-room, transfer and refuse rooms?			36. Sanitation - breaking and processing rooms and equipment.		
16. Tanker truck area.			37. Shell strainers, egg filters efficient and cleaned.		
17. Shell egg rooms and coolers.			38. Sanitation - transfer room, wash water and equipment		
18. Fly and rodent control inside and outside plant.			39. Show ppm of sanitizing spray for shell eggs.		
19. Verify Plant's Salmonella Surveillance Record			40. Show temperature of shell egg wash water.		
20. Verify Product Formulation/Refractometer			41.		
			42.		
			43.		
			44.		
			45.		
			46.		
			47.		

FSIS FORM 5400-12 (8/28/2012)

REPLACES PY 203 (3/16/2005), WHICH IS OBSOLETE.

FSIS FORM 5400-12 (8/28/2012) Page 2

TEMPERATURES	Time:				Time:				Time:				Time:			
	WHOLE EGGS	YOLKS	WHITES	EGG PROD.	WHOLE EGGS	YOLKS	WHITES	EGG PROD.	WHOLE EGGS	YOLKS	WHITES	EGG PROD.	WHOLE EGGS	YOLKS	WHITES	EGG PROD.
<b>UNPASTEURIZED LIQUID</b>																
a. 2 hrs. after breaking - to be held under 8 hrs.																
b. 2 hrs. after breaking - to be held over 8 hrs.																
c. Held for shipment or processing																
a. Recorder - controller																
b. Indicating thermometer																
c. Flow-diversion valve setting																
d. Flow-rate per minute																
e. Holding time (minutes)																
<b>PASTEURIZED LIQUID</b>																
a. 2 hrs. after pasteurizing - to be held under 8 hrs.																
b. 2 hrs. after pasteurizing - to be held over 8 hrs.																
c. Held for shipment																
<b>FREEZER OR LIQUID HOLDING ROOM</b>																

REMARKS: (Explain any deviations from above. Use reverse, if necessary.)



Copy of FSIS Form 5400-11 "Daily Report of Egg Drying Operations"

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE EGG PRODUCTS INSPECTION		PLANT NAME AND ADDRESS (Print)		DATES		Code Date	
DAILY REPORT OF EGG DRYING OPERATIONS		PLANT NUMBER		PROCESSING OPERATIONS			
INSPECTOR'S BADGE NUMBER		SIGNATURE(S) OF INSPECTOR(S)		FROM a.m. TO a.m.	FROM p.m. TO p.m.	FROM	TO
INSTRUCTIONS: Give exact figures or method where applicable. Place a "Y" for "Yes", a "N" for "No", "S" for "Satisfactory" and a "U" for "Unsatisfactory". Explain deficiencies under "REMARKS".							
OPERATIONAL SANITATION CHECKLIST				TIME OF INSPECTION			
1. Organoleptic inspection of liquid and powder?							
2. Packaging room, equipment, containers and liners and product sterility packaged?							
3. Air packaging and processing rooms, etc., air filtration systems and air flow suitability?							
4. Health and cleanliness of employees (uniforms, hairnets, clean hands, food handling practices, etc.)?							
5. Other and processing rooms and equipment?							
6. Cleaning and handling of tanker trucks?							
7. Container identification, labeling, and accuracy of weighing?							
8. Air openings (do not, joints, cracks, etc., sealed or unsealed) is not drawn into other systems?							
9. Reconstituting, free feeding, adding and mixing ingredients?							
10. Particulate and equipment used for particulate dust (spokes, pistons, valves, pumps, etc.)?							
11. High pressure pumps, lines, valves, nozzles, cones, etc., and CIP dosing of liquid?							
12. Fly, rodent and odor control?							
13. Control, demarking and labeling of feedlot?							
14. Heat free feed room, spacing of product and air circulation?							
15. Other (Specify)?							
16. Other (Specify)?							
TEMPERATURES		TIME OF INSPECTION		PRODUCT			
17. UNPASTEURIZED LIQUID							
a. Received - held over 8 hours							
b. Received - held over 8 hours							
c. Held for processing							
18. STABILIZATION							
a. Escalator - Controller							
b. Indicating thermo meter							
c. Flow-vent on valve setting							
d. Flow rate per minute							
e. Holding time (minutes)							
20. PASTEURIZED LIQUID							
a. Direct to filler							
b. To be held under 8 hours							
c. To be held over 8 hours							
d. Held for processing							
e. Other (Specify)?							
INDICATING THERMOMETER		Accuracy		Thermometric response		Seconds	
RECORDER-CONTROLLER		Accuracy		Thermometric response		Seconds	
FLOW/DMERSION VALVE		Response Time		Does valve's set properly?		Seconds	
				YES		NO	
				YES		NO	
				YES		NO	
				Response to Manual Chamber			

FSIS FORM 5400-11 (05/2012) REPLACES PP-109 (04/07), WHICH MAY BE USED UNTIL EXHAUSTED.



## FSIS Form 5400-4 "Noncompliance Record"

The request for this information is voluntary. It is needed to monitor defects found in this inspection system. It is used by FSIS to determine whether establishments are in compliance. 9 CFR 301 and 9 CFR 301 FORM APPROVED OMB NO. 0503-0099 OMB DISCLOSURE STATEMENT: Public reporting burden for this collection of information is estimated to average 7 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of the collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, D.C. 20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503. If the OMB clearance number does not appear on this form, you are not obligated to complete it.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE		TYPE OF NONCOMPLIANCE	
<b>NONCOMPLIANCE RECORD</b>		<input type="checkbox"/> Food Safety	<input type="checkbox"/> Other Consumer Protection
1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.	
4. TO (Name and Title)		5. PERSONNEL NOTIFIED	
6. RELEVANT REGULATION(S)			
7. RELEVANT SECTION/PAGE OF ESTABLISHMENT PROCEDURE/PLAN ➔		HACCP	SOP
8. ISP CODE			
9. NONCOMPLIANCE CLASSIFICATION INDICATORS			
PLANT PROCESS	A. <input type="checkbox"/> SSOP	<input type="checkbox"/> Monitoring	<input type="checkbox"/> Corrective Action
	B. <input type="checkbox"/> HACCP	<input type="checkbox"/> Monitoring	<input type="checkbox"/> Corrective Action
C. <input type="checkbox"/> PRODUCT	<input type="checkbox"/> Economic	<input type="checkbox"/> Misbranding	<input type="checkbox"/> Protocol
D. <input type="checkbox"/> FACILITY	<input type="checkbox"/> Lighting	<input type="checkbox"/> Structural	<input type="checkbox"/> Outside Premises
E. <input type="checkbox"/> E. COLI	<input type="checkbox"/> Other	<input type="checkbox"/> Recordkeeping	<input type="checkbox"/> Implementation
		<input type="checkbox"/> Recordkeeping	<input type="checkbox"/> Plant Verification
10. DESCRIPTION OF NONCOMPLIANCE:			
11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE			
You are hereby advised of your right to appeal this decision as delineated by 306.6 and/or 301.36 of 9 CFR.			
12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):			
13. PLANT MANAGEMENT RESPONSE (further planned action(s)):			
<b>This document serves as written notification that your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.</b>			
14. SIGNATURE OF PLANT MANAGEMENT		15. DATE	
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE		17. DATE	
FSIS FORM 5400-4 (7/98) Replaces FSIS Form 5400-4 (9/97), which may be used until exhausted. DISTRIBUTION: Original & 1 copy - Establishment 1 copy - Inspector			

**FSIS Form 5050-1 “NR Tracking Log”**

U.S. DEPARTMENT OF AGRICULTURE  
FOOD SAFETY AND INSPECTION SERVICE

**NR TRACKING LOG**

NR # Number/Date/Shift			DATE	INITIALS	NR # Number/Date/Shift			DATE	INITIALS
1	01-2009-G-1		06-01-2009	fmf	44				
2	02-2009-G-1		06-01-2009	fmf	45				
3	03-2009-G-1		06-01-2009	fmf	46				
4					47				
5					48				
6					49				
7					50				
8					51				
9					52				
10					53				
11					54				
12					55				
13	13-2011-G-2		01-11-2011	IMI	56				
14					57				
15					58				
16					59				
17					60				
18					61				
19					62				
20					63				
21					64				
22					65				
23					66				
24					67				
25					68				
26					69				
27					70				
28					71				
29					72				
30					73				
31					74				
32					75				
33					76				
34					77				
35					78				
36					79				
37					80				
38					81				
39					82				
40					83				
41					84				
42					85				
43					86				

FSIS FORM 5050-1 (09/14/2009)

## Example of FSIS Form 5400-4: Documenting Noncompliance (Dirty Eggs)

The request for this information is Voluntary. It is needed to monitor defects found in this inspection system. It is used by FSIS to determine whether establishments are in compliance. 9CFR 301 and 9CFR 381 FORM APPROVED OMB NO. 0583-0089 OMB DISCLOSURE STATEMENT: Public reporting burden for this collection of information is estimated to average 7 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, D.C. 20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503. If the OMB clearance number does not appear on this form, you are not obligated to complete it.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE NONCOMPLIANCE RECORD		TYPE OF NONCOMPLIANCE	
		<input type="checkbox"/> Food Safety	<input type="checkbox"/> Other Consumer Protection
1. DATE 06/01/2009	2. RECORD NO. 01-2009-G-1	3. ESTABLISHMENT NO. 0000-G	
4. TO (Name and Title) Mr. Egg, Plant Manager		5. PERSONNEL NOTIFIED Mr. Egg	
6. RELEVANT REGULATION(S) 9 CFR 590.510 (c)			
7. RELEVANT SECTION/PAGE OF ESTABLISHMENT PROCEDURE/PLAN →		HACCP	SOP
8. ISP CODE			
9. NONCOMPLIANCE CLASSIFICATION INDICATORS			
PLANT PROCESS	A. <input type="checkbox"/> SSOP	<input type="checkbox"/> Monitoring	<input type="checkbox"/> Corrective Action
	B. <input type="checkbox"/> HACCP	<input type="checkbox"/> Monitoring	<input type="checkbox"/> Corrective Action
C. <input type="checkbox"/> PRODUCT	<input type="checkbox"/> Economic	<input type="checkbox"/> Misbranding	<input type="checkbox"/> Protocol
D. <input type="checkbox"/> FACILITY	<input type="checkbox"/> Lighting	<input type="checkbox"/> Structural	<input type="checkbox"/> Outside Premises
E. <input type="checkbox"/> E. COLI	<input type="checkbox"/> Other		
10. DESCRIPTION OF NONCOMPLIANCE: Noncompliance - Ineligible Breaking Stock - AM Shift  During inspection round #1 at 7:00 am, USDA observed 3% out of the 100 shell eggs examined on the transfer rollers prior to Breaker #1 contaminated with 1/2 to 3/4 inch fecal material. Breaker #1 was shut down. Mr. Egg, plant manager, was informed. Mr. Egg removed affected eggs prior to entering the breaking machine, and transfer rollers were cleaned by the washing action. Mr. Egg elected to add additional pick-off employees in the transfer room to prevent any further occurrences. Additional observation showed no more unacceptable eggs presented for breaking. Breaking machine #1 was allowed to re-start for production.			
11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE			
<i>You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.</i>			
12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):			
13. PLANT MANAGEMENT RESPONSE (further planned action(s)):			
This document serves as written notification that your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.			
14. SIGNATURE OF PLANT MANAGEMENT		15. DATE	
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE		17. DATE	

FSIS FORM 5400-4 (7/98)

Replaces FSIS Form 5400-4 (9/97), which may be used until exhausted.

DISTRIBUTION: Original & 1 copy - Establishment  
1 copy - Inspector

Example of FSIS Form 5400-12: Documenting Noncompliance (Dirty Eggs)

OPERATIONS

UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE EGG PRODUCTS INSPECTION			
DAILY REPORT OF PLANT OPERATION			
NAME OF PLANT Happy Camper Farmers		ADDRESS OF PLANT PO Box 12345	
SIGNATURE OF INSPECTOR <i>Jane R. Roberts</i>		INSPECTOR'S BADGE NUMBER 000000	PLANT NUMBER 00000-G
PROCESSING OPERATIONS		DATE 01/06/13	CODE DATE 13-152
BREAKING FROM: 6:00 A.M. TO: _____ P.M. PASTEURIZATION FROM: ** A.M. TO: _____ P.M.		INSPECTOR'S HOURS OF DUTY 5:00 A.M. TO: _____ P.M.	
INSTRUCTIONS: Give exact figures where applicable. Mark "Y" for "Yes" or "Satisfactory" and "N" for "No" or "Unsatisfactory".			
PRE-OPERATIONAL SANITATION/PROGRAM MONITORING		OPERATIONAL CHECKLIST	
TIME OF INSPECTION:		TIME OF INSPECTION:	7:00
1. Cleanliness and sanitizing of equipment used for pasteurized liquid (pipelines, gaskets, valves, pumps, etc.)		21. Organoleptic inspection and pour test.	Y
2. Cleanliness and sanitizing of equipment prior to start up.		22. Health and cleanliness of employees (uniforms, hair nets, clean hands, etc.)	Y
3. Cleanliness of shell egg washers and conveyors.		23. Breaking or breaking machines operating in sanitary manner	Y
4. General sanitation of other areas		24. Organoleptic examination of individual eggs.	Y
5. Premises, receiving, and shipping areas.		25. Breaking procedure when inedible is encountered (segregate inedible, change equipment, wash hands, etc.)	Y
6. Refuse removal and disposal.		26. Segregation of leakers, dirties and loss for breaking.	N
7. Rest rooms and lunch rooms		27. Denaturing and labeling of inedible eggs and liquid.	Y
8. CIP cleaning of pipelines and equipment.		28. Hydrogen peroxide test.	----
9. a. Are breaking and packaging room, compressor, air filters, etc., satisfactory?		29. Sanitation - packaging room and equipment.	Y
9. b. Are air lines to product contact surfaces blown out and clean prior to use?		30. Product containers clean and sanitarily filled.	Y
10. Edible ingredient storage		31. Container identification and labeling.	Y
11. Insecticides, rodenticides, etc., isolated from chemical compounds.		32. Accuracy of weighing product.	Y
12. Insecticides, rodenticides, and chemical compounds isolated from edible products.		33. Positive flow of air in processing and packaging rooms.	Y
13. Package material storage.		34. Processing rooms free from flies and odors.	Y
14. Freezers, clean, containers properly spaced, and air circulation adequate.		35. Equipment clean and sanitized prior to use.	Y
15. Is the exhaust system operable in the rest-room, transfer and refuse rooms?		36. Sanitation - breaking and processing rooms and equipment.	Y
16. Tanker truck area.		37. Shell strainers, egg filters efficient and cleaned.	Y
17. Shell egg rooms and coolers.		38. Sanitation - transfer room, wash water and equipment	Y
18. Fly and rodent control inside and outside plant.		39. Show ppm of sanitizing spray for shell eggs.	160
19. Verify Plant's Salmonella Surveillance Record		40. Show temperature of shell egg wash water.	100
20. Verify Product Formulation/Refractometer		41. Food Security Monitoring	
		42. Egg Solids Determined	
		43.	
		44.	
		45.	
		46.	
		47.	

FSIS FORM 5400-12 (8/28/2012) REPLACES PY 203 (3/16/2005), WHICH IS OBSOLETE.

FSIS FORM 5400-12 (8/28/2012) Page 2

TEMPERATURES	Time: 7:00				Time:				Time:				Time:			
	WHOLE EGGS	YOLKS	WHITES	EGG PROD.	WHOLE EGGS	YOLKS	WHITES	EGG PROD.	WHOLE EGGS	YOLKS	WHITES	EGG PROD.	WHOLE EGGS	YOLKS	WHITES	EGG PROD.
<b>UNPASTEURIZED LIQUID</b>																
a. 2 hrs. after breaking - to be held under 8 hrs.																
b. 2 hrs. after breaking - to be held over 8 hrs.	34/36	38	40	Mix 34												
c. Held for shipment or processing																
a. Recorder - controller	#1 149															
b. Indicating thermometer	149															
c. Flow-diversion valve setting	146															
d. Flow-rate per minute	645															
e. Holding time (minutes)	4.32															
<b>PASTEURIZED LIQUID</b>																
a. 2 hrs. after pasteurizing - to be held under 8 hrs.																
b. 2 hrs. after pasteurizing - to be held over 8 hrs.	34/35	36		Blend 36												
c. Held for shipment																
<b>FREEZER OR LIQUID HOLDING ROOM</b>																

REMARKS: (Explain any deviations from above. Use reverse, if necessary.)

\*\*Pst #1 – Eggs in @ 6:30 AM

Eggs out @ 8:30 AM

## Example of FSIS Form 5400-4: Documenting Noncompliance (Trash)

The request for this information is Voluntary. It is needed to monitor defects found in this inspection system. It is used by FSIS to determine whether establishments are in compliance. 9CFR 301 and 9CFR 381 FORM APPROVED OMB NO. 0583-0089 OMB DISCLOSURE STATEMENT: Public reporting burden for this collection of information is estimated to average 7 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, D.C. 20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503. If the OMB clearance number does not appear on this form, you are not obligated to complete it.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE		TYPE OF NONCOMPLIANCE	
NONCOMPLIANCE RECORD		<input type="checkbox"/> Food Safety	<input type="checkbox"/> Other Consumer Protection
1. DATE 06/01/2009	2. RECORD NO. 02-2009-G-1	3. ESTABLISHMENT NO. 0000-G	
4. TO (Name and Title) Mr. Egg, Plant Manager		5. PERSONNEL NOTIFIED Mr. Egg	
6. RELEVANT REGULATION(S) 9 CFR 590.500 (b) & (d)			
7. RELEVANT SECTION/PAGE OF ESTABLISHMENT PROCEDURE/PLAN →		HACCP	SOP
8. ISP CODE			
9. NONCOMPLIANCE CLASSIFICATION INDICATORS			
PLANT PROCESS	A. <input type="checkbox"/> SSOP	<input type="checkbox"/> Monitoring	<input type="checkbox"/> Corrective Action
	B. <input type="checkbox"/> HACCP	<input type="checkbox"/> Monitoring	<input type="checkbox"/> Corrective Action
C. <input type="checkbox"/> PRODUCT	<input type="checkbox"/> Economic	<input type="checkbox"/> Misbranding	<input type="checkbox"/> Protocol
D. <input type="checkbox"/> FACILITY	<input type="checkbox"/> Lighting	<input type="checkbox"/> Structural	<input type="checkbox"/> Outside Premises
E. <input type="checkbox"/> E. COLI	<input type="checkbox"/> Other		
10. DESCRIPTION OF NONCOMPLIANCE: Noncompliance - Preoperational Sanitation - AM Shift			
During preoperational inspection at 7:00 am, USDA observed several trash containers by the trash compactor in the warehouse that were overflowing. Mr. Egg, plant manager, was informed of this insanitary condition. All trash containers were emptied and cleaned. Mr. Egg stated that these containers will be monitored and emptied daily, by the 2nd shift Sanitation Supervisor, Mr. Shellegg, to prevent future occurrences.			
11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE			
<i>You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.</i>			
12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):			
13. PLANT MANAGEMENT RESPONSE (further planned action(s)):			
This document serves as written notification that your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.			
14. SIGNATURE OF PLANT MANAGEMENT		15. DATE	
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE		17. DATE	

FSIS FORM 5400-4 (7/98)

Replaces FSIS Form 5400-4 (8/97), which may be used until exhausted.

DISTRIBUTION: Original & 1 copy - Establishment  
1 copy - Inspector



## Example of FSIS Form 5400-1: Documenting Noncompliance (Container Identification)

The request for this information is Voluntary. It is needed to monitor defects found in this inspection system. It is used by FSIS to determine whether establishments are in compliance. 9CFR 301 and 9CFR 381 FORM APPROVED OMB NO. 0583-0089 OMB DISCLOSURE STATEMENT: Public reporting burden for this collection of information is estimated to average 7 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, D.C. 20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503. If the OMB clearance number does not appear on this form, you are not obligated to complete it.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE		TYPE OF NONCOMPLIANCE	
NONCOMPLIANCE RECORD		<input type="checkbox"/> Food Safety	<input type="checkbox"/> Other Consumer Protection
1. DATE 06/01/2009	2. RECORD NO. 03-2009-G-1	3. ESTABLISHMENT NO. 0000-G	
4. TO (Name and Title) Mr. Egg, Plant Manager		5. PERSONNEL NOTIFIED Mr. Egg	
6. RELEVANT REGULATION(S) 9 CFR 590.411 (c) (3)			
7. RELEVANT SECTION/PAGE OF ESTABLISHMENT PROCEDURE/PLAN →		HACCP	SOP
8. ISP CODE			
9. NONCOMPLIANCE CLASSIFICATION INDICATORS			
PLANT PROCESS	A. <input type="checkbox"/> SSOP	<input type="checkbox"/> Monitoring	<input type="checkbox"/> Corrective Action
	B. <input type="checkbox"/> HACCP	<input type="checkbox"/> Monitoring	<input type="checkbox"/> Corrective Action
C. <input type="checkbox"/> PRODUCT	<input type="checkbox"/> Economic	<input type="checkbox"/> Misbranding	<input type="checkbox"/> Protocol
D. <input type="checkbox"/> FACILITY	<input type="checkbox"/> Lighting	<input type="checkbox"/> Structural	<input type="checkbox"/> Outside Premises
E. <input type="checkbox"/> E. COLI	<input type="checkbox"/> Other		
10. DESCRIPTION OF NONCOMPLIANCE: Noncompliance - Other - AM Shift			
During inspection round #1 at 8:00 am, USDA observed 10- 50 lb containers of Plain Eggs that did not have a legible lot number on the primary panel of the container, and Mr. Egg, plant manager, was notified. The 10- 50 lb containers were segregated and placed under US Retention tag #DB00. Mr. Egg stated that the containers would be relabeled and ready to be reinspected on 06/02/09. On 06/02/09 at 9:00 am Mr. Egg requested the 10- 50 lb containers be reinspected. USDA found the lot number to be acceptable; tag #DB00 was removed and product released.			
11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE			
<i>You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.</i>			
12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):			
13. PLANT MANAGEMENT RESPONSE (further planned action(s)):			
<b>This document serves as written notification that your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.</b>			
14. SIGNATURE OF PLANT MANAGEMENT		15. DATE	
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE		17. DATE	

FSIS FORM 5400-4 (7/98)

Replaces FSIS Form 5400-4 (9/97), which may be used until exhausted.

DISTRIBUTION: Original & 1 copy - Establishment  
1 copy - Inspector

### Example of FSIS Form 5400-11: Documenting Noncompliance (Container Identification)

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE EGG PRODUCTS INSPECTION		PLANT NAME AND ADDRESS (Print)		PLANT NUMBER		DATES		Code Date	
<b>DAILY REPORT OF EGG DRYING OPERATIONS</b>		Happy Camper Farms Happy Camper, NE 33333		0000-G		06/01/09		9-152 PROCESSING OPERATIONS	
INSPECTOR'S BADGE NUMBER 111111	SIGNATURE(S) OF INSPECTOR(S) /Ready Koester	FROM a.m. 7:00	TO a.m. 7:00	FROM p.m. 4:00	TO p.m. 4:00	DRIVING Continued	FROM Continued	TO Continued	PASTEURIZATION TO
INSTRUCTIONS: Give exact figure or method where applicable. Place a "Y" for "yes" or "SATISFACTORY" and a "N" for "no" or "UNSATISFACTORY." Explain deviations under "REMARKS."									
OPERATIONAL SANITATION CHECKLIST									
1. Organoleptic inspection of liquid and powder?	TIME OF INSPECTION	8:00							
2. Packaging rooms, equipment, containers and lines and product suitably packaged?	Y								
3. Are packaging and processing rooms, etc., air filtration systems and air flow satisfactory?	Y								
4. Health and cleanliness of employees (uniforms, hairnets, clean hands, food handling practices, etc.)?	Y								
5. Health and processing rooms and equipment?	Y								
6. Cleaning and sanitizing of tanker truck?	-----								
7. Container identification, labeling, and accuracy of weighing?	N								
8. Are openings closed, joints, gaskets, etc., sealed so unfiltered air is not drawn into other systems?	Y								
9. Reconstituting, low foaming, adding and mixing ingredients?	Y								
10. Pasteurizer and equipment used for pasteurized liquid (pipelines, gaskets, valves, pumps, etc.)?	Y								
11. High pressure pumps, lines, valves, nozzles, cones, etc., and CIP cleaning of pipeline?	Y								
12. Fly, rodent and other control?	Y								
13. Control, demitting and labeling of feedlot?	Y								
14. Heat treatment room, spacing of product and air circulation?	Y								
15. Other (Specify) Product	Plain								
16. Other (Specify) Code Date	91522								
TEMPERATURES	TIME OF INSPECTION	8:00							
17. UNPASTEURIZED LIQUID	PRODUCT	Plain							
a. Recirculated - held over 8 hours									
b. Recirculated - held over 8 hours		34/38							
c. Held for processing		38							
18. STABILIZATION		36/90							
19. PASTEURIZATION		#2-149							
a. Recorder - Controller		149							
b. Indicating thermometer		146							
c. Flow diversion valve setting		645							
d. Flow rate per minute		4.32							
e. Holding time (minutes)									
20. PASTEURIZED LIQUID									
a. Direct to other									
b. To be held under 8 hours		36							
c. To be held over 8 hours									
d. Held for processing									
e. Other (Specify)									
FSIS FORM 5400-11 (6/20/12) REPAIRS PY-189 (6/97), WHICH MAY BE USED UNTIL EXHAUSTED.									



## Attachment 2 – Disposition Schedule for Egg Products Inspection Records

FSIS FORM NUMBER	OLD FORM NUMBER	TITLE OF FORM	DISTRICT OFFICE	PLANT LEVEL
<b>PY-185</b>		Consignment, Receipt & Disposition		Maintain with PY-200 Certificates
<b>PY-200</b>		EGG PRODUCTS INSPECTION AND GRADING CERTIFICATE		3C(R)
<b>5200-9</b>	PY-235	EGG PRODUCTS GRADING WEEKLY REPORT		1/2C (R)
<b>5200-10</b>	PY-38	APPLICATION FOR OFF-PREMISE FREEZING OF EGG PRODUCTS	1B	
<b>5200-11</b>	PY-240	GRADING VOLUME REPORT (POULTRY, SHELL EGGS, AND EGG PRODUCTS)	6YRS 3MOS (R)	1/2C
<b>5200-12</b>	PY-32	APPLICATION FOR SERVICE	1B	
<b>5400-11</b>	PY-159	REPORT OF EGG DRYING OPERATIONS		1C(R)
<b>5400-12</b>	PY-203	DAILY REPORT OF PLANT OPERATIONS (EGG PRODUCTS)		1C(R)
<b>7234-1</b>	PY-221	PY-221 - LABEL NOTICE (Paper Submission) or FSIS Form 7234-1 - APPLICATION FOR APPROVAL OF LABELS, MARKING or DEVICE (Electronic Submission)		P
<b>9540-1</b>	<b>5200-8</b>	IMPORT REQUEST (EGGS AND EGG PRODUCTS)		1C
		FEDERAL STANDARDS AND REGULATIONS	D	D
		FSIS DIRECTIVES, NOTICES, INSPECTOR'S HANDBOOK, CORRESPONDENCE REGARDING PROGRAMS, PROCEDURES, ALTERNATIVE APPROVED PROCEDURES	D	D
		PLANT BLUEPRINTS	PDD-D	P-D
		PURCHASING SPECIFICATIONS OF GOVERNMENT INSTITUTIONS AND AGENCIES	D	D

## **EXPLANATION OF RETENTION SCHEDULES**

- A - Means permanent retention. (This applies only to the national office.)
  - B - Record is to be disposed of (number of) years after the close of the Fiscal Year.
  - C - Record is to be disposed of (number of) years after the close of the Fiscal Year in which it was created or received.
  - D - Record is to be retained while active and disposed of when it becomes inactive, obsolete, or superseded.
  - P - Indicates the plant retains the record copy.
  - E - Indicates the employee retains the record copy.
  - R - Indicates which office retains the record copy.
- PDD – OPPD, Policy Development Division