

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. Explain how IPP will document their inspection results in PHIS.
5. Explain how to document a noncompliance and trends of noncompliance
6. List all FSIS and PY forms IPP are required to complete when conducting egg product inspection activities.

Reference

1. FSIS Directive 5030.1 *“Inspection Methodology Utilizing the Public Health Information System (PHIS) for the Verification of Regulatory Compliance in Egg Products Plants*

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 verifying compliance with laws and regulations governing the production of eggs and egg products. The egg products plant is responsible for complying with the regulations and to producing 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 dried, frozen, and liquid 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 (EPIA 21 USC 1034(b) and (c)).

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 part 590 when they sign the Grant of Inspection application for Mandatory or Voluntary Egg Products Inspection.

IPP have to ensure that the plant complies with 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 part 590.

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

Noncompliance – The plant's failure to meet a regulatory requirement; i.e., when the plant's process is **not** in compliance with the regulations in 9 CFR Part 590.

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 the use of U.S. Rejected/Retained tags (§590.426), suspension of inspection, or withdrawal of the Grant of Inspection (§590.160(f)).

Use of U.S. Rejected/Retained tags – This is 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 U.S. Rejected/Retained tags when they identify regulatory noncompliance (§590.426 and §592.90(a)(6)) to prevent the movement of the product (retained product), stop operations, or to reject equipment or processing locations until the noncompliance has been corrected.

Suspension – refers to the interruption of assignment of inspection personnel to the plant (§590.160 and §592.180). A suspension of inspection has a severe impact on an official plant because it takes away the plant's right to do business. Since a federally inspected plant cannot

legally apply the marks of inspection to products without an assigned inspector, this action stops all production, or it can be applied to a specific production process. Reasons that would prompt this type of enforcement action are shipping adulterated product produced under insanitary conditions, removing a “rejected tag” by unauthorized personnel, interfering with the inspectors performing their duties, threatening or intimidating an FSIS employee. The decision to suspend inspection is made at the District Office, or higher level of authority. 21 USC 1035(b) gives FSIS the authority to suspend plants that fail to meet sanitation regulatory requirements.

Withdrawal of the grant of inspection – is the most severe enforcement action that can be taken against an official plant. Withdrawal terminates the grant of inspection (§590.160 and §592.180). Once that happens, no portion of the plant can operate as a FSIS federally inspected plant. Withdrawal actions can be the culmination of a lengthy process, i.e., plants that have been subjected to suspensions can eventually be subject to withdrawal if the plant does not return to compliance, or if the situation is severe. The final decision to withdraw the grant of inspection is made at the Administrator’s level. (21 USC 1047)

Note: 9 CFR 590.160 and the Rules of Practice, 9 CFR Part 500, originated from 7 CFR Part 1, subpart H; same statutory authority – different regulatory citations. The Rules of Practice found in 9 CFR Part 500 do not apply to Egg Products.

Plant and IPP Responsibilities

As mentioned above, plant management is responsible for ensuring 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 verification activities, document the results of their verification tasks in PHIS, document noncompliance when it is observed, and inform plant management when any noncompliance is identified. IPP verify that plant management takes appropriate immediate and further planned actions to bring themselves back into compliance.

Documenting Verification Results in PHIS

As per FSIS Directive 5030.1, after IPP have completed a verification task, IPP must record the results of the task in PHIS. IPP will make all the appropriate entries regarding the task and their findings of regulatory compliance or

noncompliance by checking the applicable boxes, making the proper selection from lists, or typing in text as prompted by PHIS. In addition, IPP will document the specific regulatory requirements that were verified during the inspection task and record their findings for each one.

Procedures to Follow When a Noncompliance is Identified

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—IPP must follow the procedures described below.

Noncompliance directly affects product

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

1. If the noncompliance observed affects product, determine if the product may be adulterated. If the product is adulterated, IPP will retain the affected product and stop operations.
2. Inform the plant of the specific noncompliance and request that the plant initiate an immediate or further planned action (action that the plant takes to correct the noncompliance, including appropriate product disposition).
3. IPP will apply a U.S. Rejected/Retained tag to affected equipment, room, and/or product, as appropriate, when needed to prevent the use of the equipment or control the movement of the affected product.
4. Document the noncompliance in PHIS, following the instructions in Directive 5030.1 (refer to the **Steps to follow when noncompliance is found** subsection below) and provide the noncompliance record (NR) to plant management.

If product has been retained, the company will need to provide IPP with its 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 it made in regard to its 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 Front Line Supervisor (FLS) can request assistance from the Policy Division Staff (PDS).

Noncompliance does not directly affect product

When noncompliance does not directly affect the product, IPP must follow the steps below.

1. Notify a representative of plant management as soon as possible (before documenting the findings);
2. Document the noncompliance in PHIS, mark the noncompliance as “final”, print the NR, sign it, and present it to plant management. Note that PHIS will allow IPP to document one or more instances of noncompliance as separate documents within a single NR. IPP are to finalize each individual noncompliance and present it to plant management as soon as practical, even if they have not finished the inspection task.
3. Verify that the plant takes necessary actions to return to compliance with the applicable regulations with which it is not in compliance.
4. When the plant has returned to compliance with all regulations with which it was not found to be in compliance as documented in the NR, IPP are to mark the NR and the associated inspection task as “completed.” Record the plant’s return to compliance in PHIS. PHIS **will not allow** IPP to mark the inspection task complete until the inspector first documents that the plant has returned to compliance by marking the NR complete;
5. Perform a directed inspection task to follow up and verify that the plant continues to comply with the applicable regulatory requirements. PHIS will automatically direct that a follow-up task be performed. When IPP perform this directed inspection task, they are to verify the same regulatory requirements with which the plant was found to be not in compliance in the original task and conduct the task on the same type of product that they did when they originally identified the noncompliance.

You will learn more about how to document a noncompliance in PHIS when taking the PHIS Egg Products Hands-on Training.

Documenting Noncompliance

FSIS Directive 5030.1, Chapter IV, Section II, instructs IPP on how to document noncompliance observed in egg products plants in PHIS. The directive replaces instructions set forth in specific sections of the Egg Products Inspector’s Handbook.

FSIS Form 5400-4, *Noncompliance Record* (NR) is automatically generated by PHIS (electronic format).

When IPP find noncompliance with one or more regulatory requirements, IPP must complete an NR in PHIS (FSIS Form 5400-4). Attachment 1 gives examples of NRs generated by PHIS.

- The date, NR number, plant number, and inspection task are automatically completed by PHIS (Blocks 1, 2, 3 and 8).
- Relevant Regulations (Block 6)—IPP must select one or more of the regulatory citations offered on the noncompliance page in PHIS. PHIS will offer the regulatory citations based on the earlier recording of the regulations verified on the task results page. IPP are to verify that the regulatory citation includes all of the specific regulations and requirements that the plant did not meet. If a particular regulatory citation is not available in PHIS, IPP are to type it in the description text block.
- Description of Noncompliance (Block 10)—IPP must include the following elements in their description:
 - Describe each noncompliance in clear, concise terms and describe the problem, time of occurrence, location, and effect on the product, if any. The description needs to clearly explain how the inspector's findings support the determination that the plant did not meet regulatory requirements.
 - Provide an explanation of how IPP notified plant management of the noncompliance (e.g., written or oral).
 - State whether actions were taken to retain product or reject equipment and how that was done (e.g., applying a tag to equipment or stopping operations).
 - Explain any immediate actions the plant has taken and any proposed actions communicated by plant management to IPP.
 - Describe any activities performed by IPP to verify plant action (e.g., equipment was re-inspected and released).
 - When there is a developing trend of noncompliance, include the number of the previous NR with the same cause and a description of how the NR derived from the same cause. PHIS allows IPP to review recently issued NRs. IPP can then select the most recently issued NR with a similar cause (when applicable). IPP will associate only one NR with the new NR. In addition, IPP will describe any unsuccessful further planned actions taken by the plant to address the noncompliance. Further, IPP will state whether they have discussed the developing trend of noncompliance with plant management.
- Affected Product Information (Block 9a) – IPP must record approximate weight and product name, lot number, or other information available to identify the specific amount of product affected by the noncompliance, if any.

- Product adulteration – IPP must use the product adulteration check box on the noncompliance page to indicate if the documented noncompliance resulted in any adulterated product being produced.
- Rejected Tags/Retained Tags (Block 9b) – If IPP used US Rejected/Retained tags in response to the noncompliance, IPP must to enter the tag numbers.

Example of information to be included in the description of noncompliance:

At approximately 0600 hours, after the plant's pre-operational inspection and before the start of production, I performed a pre-operational Sanitation verification procedure. I observed the following instances of noncompliance: Heavy organic matter of liquid egg residue from previous day's production located inside multiple pipes, inlet valves, and gaskets of the High Temperature Short Time (HTST) pasteurization system. Because these surfaces are actual or potential product contact surfaces, organic matter and product residue in these areas could cause product to become contaminated at the start of operations. I applied U.S. "Reject" tag # B1469277 to the HTST pasteurization system and verbally informed the sanitation foreman, Karl Kleener, who immediately had the affected equipment appropriately cleaned and sanitized. A similar noncompliance was documented on NR number 0001103051203N/1, dated February 13, 2015. The further planned action of including procedures for cleaning the HTST pasteurization system, pipes, valves, and gaskets in a manner that will prevent organic residue formation were not implemented or were ineffective in preventing recurrence. (9 CFR 590.522(a))

- To (Name and Title; Block 4) – PHIS will provide a list of names from the PHIS Plant Profile Contact tab information to select from or enter the name and title of the responsible plant official, if not listed. IPP are to enter the name of the plant official responsible for responding to the NRs.
- Personnel Notified – IPP are to enter the names of the plant management personnel who were notified about the noncompliance. IPP are to select one or more names from the list offered in PHIS. If IPP notified someone other than one of the listed contacts, they are to enter that name in the fields.
- Signature of Inspection Program Employee (Block 11) – IPP are to sign the paper NR form after the noncompliance has been finalized and printed.
- Plant Management Response (Block 12) – On the printed NR, this block may be completed by the plant.
- Signature of Plant Management and Date (Blocks 13 and 14) – If plant management responds in writing on block 12, a plant official should sign and date the NR.
- Verification Signature of Inspection Program Employee and Date (Blocks 15 and 16) – Once a plant has returned to compliance with all the regulatory

noncompliances documented in the NR, IPP are to navigate to that NR in PHIS and designate it as completed. IPP sign and date the paper NR.

NOTE: The NR can be marked completed only after IPP have verified that the plant has brought itself into compliance with the regulatory requirement that was not met and resulted in the issuance of the NR.

The plant is not required to indicate its immediate and further planned actions on the NR, and IPP may need to verify those by review and observation or reviewing records prepared by the plant.

Attach any written response 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.

Follow up on a daily basis to verify that the plant has taken action to correct the noncompliance and document when the plant has returned to compliance. Only after the plant has returned to compliance with all the regulations cited as being noncompliant in the NR can IPP complete the NR.

It is the Agency's expectation that immediate or further planned actions will be taken by the plant as soon as possible, or, depending on the situation, a completion date must be provided by plant management for further planned actions. If the noncompliance cannot be corrected within the timeframe established, plant management must provide IPP with their intent regarding further planned 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 its intentions to correct the noncompliance. IPP will document these events, including the new completion date for the applicable noncompliance item, but until the plant brings itself back into compliance with all the regulations cited, the NR cannot be completed.

When the plant fails to comply with the proposed correction, IPP may need to take regulatory actions such as retaining product or rejecting equipment (if warranted) and inform management. In some instances, it may be necessary for the plant to delay its 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 tagged with U.S. Rejected/Retained tags, IPP should immediately contact the FLS and report the incident. The FLS will initiate the appropriate enforcement actions described above or provide additional instructions.

Using “U.S. Rejected/Retained” Tags

The “U.S. Rejected/Retained” tag is a multi-purpose tag used to identify and control retained product and reject (unacceptable) equipment, 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 verification activities, they can immediately apply the tag to ensure control of the situation. For example, if IPP observe an open bag of ingredients or an unlabeled container, applying the U.S. Rejected/Retained tag controls the product from moving or being used.

When IPP use a tag, the following must be done:

- Fill out all the required information on the upper/lower portions 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 the hard copy of the NR in the government file. In some instances, IPP will have to use more than one tag to ensure adequate control.
- Record the tag numbers used in blocks 9b and 10 of the NR (FSIS Form 5400-4) when documenting the noncompliance in PHIS; maintain a separate detailed log of retained product on file and keep 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, remove the tag(s), destroy both portions of the tag(s), and release control of product, equipment, rooms, etc.

There are many reasons to apply “U.S. Rejected/Retained” tags to identify and segregate product affected by the noncompliance 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/accumulating 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, IPP must inform 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 must report immediately to their FLS or IIC when a violation regarding a U.S. Rejected/Retained tag occurs. For example:

- “U.S. Rejected/Retained” 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 situations where product can become adulterated due to chemical contamination or willful product tampering. If this type of contamination occurs, IPP are to take immediate action to prevent product from entering commerce by retaining affected product. IPP must immediately inform management and their supervisor of the situation and of the actions they have taken. Refer to FSIS Directive 5420.1, *Food Defense Verification Tasks and Threat Notification Response Procedures for the Office of Field Operations*, for more information.

Associating NRs

IPP 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 NRs would support an enforcement action.

IPP must associate two or more NRs when they indicate an ongoing trend of related (same cause) noncompliance or systemic problems with the plant's food safety practices. The following characteristics may help IPP to identify NRs that may be associated, but these factors, by themselves, do not justify associating the NRs:

1. Two or more NRs have the same regulatory citation,
2. Two or more NRs resulted from the same type of inspection task or,
3. Two or more similar NRs occurred within a reasonably close period of time.

IPP must associate NRs when they demonstrate one or more of the following trends:

- One NR indicates that the plant's further planned actions for a previous NR were not implemented or did not prevent recurrence of the same noncompliance,

Associating NR Example 1: *IPP documented noncompliance with 9 CFR 590.515(a)(4) this week at Plant A when they observed that the wash water for the shell egg washer was not changed approximately every 4 hours and resulted in wash water that was insanitary. Upon reviewing the NR history prior to the weekly meeting, IPP noted another noncompliance with 9 CFR 590.515(a)(4) last week that also documented the same issue. After reviewing the plant's proposed further planned actions from the previous noncompliance, IPP find that the plant did not implement its proposal to increase the frequency of changing wash water to every 3 hours. IPP concluded that the plant failed to implement the proposed further planned actions, resulting in the recurrence, so they associate the two NRs.*

- Two or more NRs demonstrate repetitive failures of the same aspect of the plant's food safety operations.

Associating NR Example 2: *IPP documented noncompliance with 9 CFR 590.510(c) this week at Plant C when they observed that the transfer room operator was allowing ineligible leakers and dirty eggs (9 CFR 590.5) to enter the breaking room. The plant determined that the employee monitoring the shell eggs exiting the washer had not been properly trained in how to identify and remove all ineligible shell eggs exiting the washer. The further planned action was to retrain the employee. Upon reviewing the NR history in preparation for the weekly meeting, IPP noted a noncompliance with 9 CFR 590.510(c) from the previous week. In that case, the breaking machine operator was not stopping the machine and removing the contents of broken shell eggs that were of inedible interior quality. The plant had determined that that employee was also not properly trained to handle the equipment and re-trained the employee. Even though these two noncompliances involved different employees at different*

locations in the plant, IPP decide to associate them because they both indicate that the plant had a loss of process control, and that the plant's employees had not been properly trained for their assigned duties.

When you associate one NR with 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.

NRs should be associated **when issued**. Each noncompliance that you believe is associated with a previous noncompliance should be documented as associated at the time the NR is completed. Do not associate the current noncompliance with more than one previous noncompliance.

You should continue to associate NRs 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 must conduct a weekly meeting with plant management to discuss topics pertinent to food safety or other issues of concern, as per FSIS Directive 5030.1 and FSIS Directive 5010.1 (Food Safety Related Topics for Discussion During Weekly Meetings). 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 perform the appropriate verification activities outlined in FSIS Directive 5030.1. If IPP are unsure of how to proceed, IPP are expected to contact their supervisor for guidance and further instructions.

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 practices.

IPP will document the weekly meeting in a Memorandum of Interview (MOI) in PHIS as a part of performing the Meeting with Establishment Management (Egg Products) task. The MOI generated in PHIS should contain the following information:

- Who was present at the meeting;
- Date and time of the meeting;
- Discuss/document any open NR and/or any identified association between current and past noncompliances describing to the plant management why the associated NRs indicate a trend of noncompliance.
- Plant management's responses to FSIS findings including those 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 and document any outcomes.

IPP must provide a copy to plant management.

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.

Egg Products Inspection Forms

As discussed earlier, there are several official forms with which IPP need to be familiar 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 Federal Inspection, FSIS Form 5200-2, and/or FSIS Form 5200-6 (Application/Approval for Voluntary Reimbursable Inspection Service; if it applies).* These forms are completed 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 its egg products plant. The forms would also be completed when any change occurs. The plant completes the form(s) and then submits the form(s) to the District Office (DO). During the initial process, the FLS or designee completes FSIS Form 5200-4 (*Recommendation on Application for Inspection*) once his/her survey of the plant is finalized and gives the recommendation for granting inspection services. Thereafter, once the initial process is completed, then the DO will issue FSIS Form 5200-1 (*Grant of Inspection*) as a “regular” Type of Grant. All the information will be entered into PHIS by the grant curator.

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, it has 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 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 or time specified in a waiver 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 that 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 Part 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 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 it does not break, they will not complete this report.

The report will be completed at the end of the week, verified by the IPP for information accuracy, and faxed by the plant 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 enter the information in PHIS through the Questionnaire Tab in the Monthly Volume Reporting task. Three important things to remember about entering data on this questionnaire are:
 - Enter the date as MM/DD/YYYY, not MM-DD-YYYY.
 - If no product in a category was produced, enter a single 0, not NA.
 - Don't use fractions or decimals, for example, if the weight is 1007.5 lbs. then enter 1008 lbs.

Once the questionnaire is completed, submit the questionnaire electronically through PHIS and then complete the task. This will allow FSIS to collect, process, and report the information to appropriate stakeholders in a more efficient and timely manner. Inspectors will file FSIS Form 5200-11 in the government files.

The most common error that has been identified when FSIS Form 5200-11 is completed is the failure to complete Block 01 – Shell Eggs Broken (30 dozen cases). This block must be completed when there is data in blocks 02 through 05.

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 that the information is entered in PHIS as required. IPP should file the form in the government files.

The National Agriculture Statistics Service (NASS) will access the aforementioned information and publish 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 Agency's Annual Report to Congress.

5. *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. FSIS Form PY-200 is an

accountable form that the inspector must keep secured under official lock. 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, and dried egg whites) and condition of egg products to be shipped, and that the egg product meets the requirements of 9 CFR Part 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

6. *Use of FSIS Form 9060-5EP, Egg Products Export Certificate of Wholesomeness, Form 9060-5EP*. IPP are to use FSIS Form 9060-5EP to certify egg products for export, which replaces FSIS Form PY-200. In those cases where a replacement export certificate is requested, IPP are to issue FSIS Form 9060-5EP to replace the FSIS Form PY-200 originally issued. The instructions for completing FSIS Form 9060-5EP are posted in the Export Library on the FSIS website.

FSIS Form 9060-5EP is an accountable property form and can only be ordered by IPP through the Beltsville Supply Catalog using their designated eAuthentication Login and account number. IPP are to use the following link when ordering: www.bsc.usda.gov.

IPP are to maintain accurate inventory records of export certificates received, issued, stolen, transferred, or voided. IPP also are to maintain export certificates and inventory records under official lock or seal at all times. IPP are to follow the direction in FSIS Directive 2532.1, *Security Procedures*, in the event export certificates are determined to have been stolen.

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).

Obsolete egg product inspection PY and FSIS Forms

PHIS for egg products inspection was implemented in May 2014. Therefore, FSIS Forms 5400-11 and 5400-12 have been retired. All the information gathered while doing your daily inspection verification activities will now be recorded in PHIS, under the appropriate inspection verification task. You will select the regulatory requirements which you verified that the plant is or is not in compliance.

However, these forms can still be downloaded from the FSIS Intranet Web site and IPP can use the forms as memory joggers or to record their own observations (job aids/worksheets). Remember, the forms will **no longer** need to be filled out as part of your inspection verification activities.

1. *Daily Report of Egg Drying Operation, FSIS Form 5400-11* (previously PY-159). This form is a PDF-fillable form and can be saved as its own unique file. This form was used for egg products plants that dry amenable egg products. The applicable section of the form was completed at a minimum one time every two hours of production per shift. This form has been retired, but IPP can complete it as a job aid or worksheet, if they choose and keep a copy of the completed form as a personal record. The information previously captured on this form is now entered into PHIS.
2. *Daily Report of Plant Operations, FSIS Form 5400-12* (previously PY-203). This form is a PDF-fillable and can be saved as its own unique file. This form was used for egg product plants that break, pasteurize, 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 and records the observations and actions. The applicable sections of the form were completed at a minimum one time every two hours of production per shift. This report reflected an accurate and objective picture of the operation and conditions as they existed during that shift. If necessary, notes of clarification were added to the report. This form has been retired, but IPP can complete it as a job aid or worksheet, if they choose and keep a copy of the completed form as a personal record. The information previously captured on this form is now entered into PHIS.

Form **PY-185** (*Consignment, Receipt and Disposition*) was another form that has been cancelled. This form was used by IPP to track the serially numbered

accountable Form PY-200, *Egg Products Inspection and Grading Certificate*.
However, the Agency will not be replacing this form.

Case Studies

Read the following scenarios and answer the discussion questions with your group.

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 vegetation is overgrown.

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 – Examples of Noncompliances Generated by PHIS

Example of FSIS Form 5400-4: Documenting Noncompliance (Food Safety)

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 DC 20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budget.

US Department of Agriculture FOOD SAFETY AND INSPECTION SERVICE NONCOMPLIANCE RECORD		TYPE OF NONCOMPLIANCE <input checked="" type="checkbox"/> Food Safety <input type="checkbox"/> Other Consumer Protection	
1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.	
6/4/2014	0002204062304N / 1	[REDACTED]	
4. TO (Name and Title)		5. PERSONNEL NOTIFIED	
[REDACTED] Food Safety Manager		[REDACTED], supervisor, [REDACTED], supervisor	
6. RELEVANT REGULATIONS 590.500(c) Building be in sound construction and good repair to prevent entrance of vermin		6a. ASSOCIATED NR(s)	
7. TITLE(S) OF HACCP OR SSOP PLAN or OTHER SUPPORTING DOCUMENTATION		7a. NAME OF HACCP CCP(S) or PREREQUISITE PROGRAM	
8. INSPECTION TASK Sanitation and Establishment Facilities - Egg Products		9. VERIFICATION ACTIVITY <input type="checkbox"/> Review & Observation <input type="checkbox"/> Record Keeping <input checked="" type="checkbox"/> Both	
		9a. AFFECTED PRODUCT INFORMATION No product was affected	
		9b. RETAIN/REJECT TAGS B37497482	
10. DESCRIPTION OF NONCOMPLIANCE			
<p>At approximately 4:10 AM on Wednesday 06/04/2014, while doing routine inspection of the plant facilities it was observed in plant 3 that there was standing water in the upstairs hallway from water dripping from the ceiling. The water was across the entire hallway and it extended from the spiral staircase door and over halfway down the hallway with standing water blocking entrance to the locker rooms and restroom area. Someone had placed buckets in the hallway, but were not placed under the leaks. No one was observed to be mopping up the excess water or attempting to control the situation at the time the observation was made. The area was tagged off with USDA Retain tag B37497482.</p> <p>[REDACTED] and [REDACTED] were both shown the area. The supervisors got more buckets and placed them under the leaks. The area was mopped to remove the excess water and then the area was mopped again using a cleaning agent, with chlorine added to sanitize the floor area. a fan was also placed in the hallway to dry the floor. after inspecting the area, and finding the plant in control of the leaks and the hallway was free of standing water, the tag was released so that the hallway could be utilized again.</p>			
11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE			
<p>You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.</p>			
12. ESTABLISHMENT MANAGEMENT RESPONSE:			
<p>This document serves as written notification that your failure to comply with regulatory requirements(s) could result in additional regulatory or administrative action.</p>			
FSIS FORM 5400-4		DISTRIBUTION: Original & 1 Copy to Establishment, 1 Copy to Inspector	
		Page 1 Of 2	

13. SIGNATURE OF ESTABLISHMENT MANAGEMENT

14. DATE

15. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

16. DATE

[Faint, mostly illegible text and lines representing the main body of the form, including signature lines and checkboxes.]

FSIS FORM 5400-4

DISTRIBUTION: Original & 1 Copy to Establishment, 1 Copy to Inspector

0002204062304N - *[Redacted]* Inspector's Name

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

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 DC 20250: and to the Office of Information and Regulatory Affairs, Office of Management and Budget.

US Department of Agriculture FOOD SAFETY AND INSPECTION SERVICE NONCOMPLIANCE RECORD		TYPE OF NONCOMPLIANCE <input type="checkbox"/> Food Safety <input checked="" type="checkbox"/> Other Consumer Protection	
--------------------------------------------------------------------------------------------	--	-----------------------------------------------------------------------------------------------------------------------------	--

1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
5/7/2014	0003419054607N / 1	[REDACTED]

4. TO (Name and Title)	5. PERSONNEL NOTIFIED
[REDACTED] Plant Manager	[REDACTED]; K [REDACTED]

6. RELEVANT REGULATIONS 590.504(l) Wholesomeness of egg products	6a. ASSOCIATED NR(s)

7. TITLE(S) OF HACCP OR SSOP PLAN or OTHER SUPPORTING DOCUMENTATION	7a. NAME OF HACCP CCP(S) or PREREQUISITE PROGRAM

8. INSPECTION TASK Economic Wholesomeness of egg products	9. VERIFICATION ACTIVITY <input type="checkbox"/> Review & Observation <input type="checkbox"/> Record Keeping <input checked="" type="checkbox"/> Both
--------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------

9a. AFFECTED PRODUCT INFORMATION	245985 pounds of Premium Scrambled Egg Mix in Silo 9.
9b. RETAIN/REJECT TAGS	B34467756

10. DESCRIPTION OF NONCOMPLIANCE

At Approximately 1800 hours on 5/7/14 I was notified by Supervisor [REDACTED] that the mix room pump and strainers had been opened and several orange pieces of what looked like a scissor handle had been found in this equipment. I took a control action and tagged all product with U.S Retained.# B34467756 from the Premium Scrambled Egg Mix that was in silo #9. When meeting with the Night Shift Production Manager [REDACTED] on this issue it was discussed that the mix pump was opened and checked because a knife had fallen into the mix tank. This had happened at a shift change at approximately 600 A.M. Discussed also was the company has a policy in place that a strainer be in place when adding ingredients in a mix formulation to prevent any foreign material from falling into the blender tank. The question I have is the company did a complete CIP of the mix room and associated equipment before any mixing was further performed, but the inspection personal did not get to verify this because they were not notified. Night Shift Production Manager said they can produce all documentation that this equipment was cleaned and sanitized before another mix was done. Immediate Corrective Action The company personal will strain all affected PSEM from silo #9 to Silo# 11. They will visually inspect all mesh strainers for any foreign material and notify inspection upon any findings. Night Shift Production Manager [REDACTED] was informed that a NR would be documented. The establishment is not meeting the requirements 590.504.

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. ESTABLISHMENT MANAGEMENT RESPONSE:

This document serves as written notification that your failure to comply with regulatory requirements(s) could result in additional regulatory or administrative action.

13. SIGNATURE OF ESTABLISHMENT MANAGEMENT	14. DATE
_____	_____

FSIS FORM 5400-4 DISTRIBUTION: Original & 1 Copy to Establishment, 1 Copy to Inspector
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15. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	16. DATE
<p><i>[Signature]</i></p>	<p><i>[Date]</i></p>
<p><i>[Faint text]</i></p>	

FSIS FORM 5400-4

0003419054607N - *[Redacted]* *Inspector's Name*

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Attachment 2 – Disposition Schedule for Egg Products Inspection Records

FSIS FORM NUMBER	OLD FORM NUMBER	TITLE OF FORM	DISTRICT OFFICE	PLANT LEVEL
PY-185 [†]		Consignment, Receipt & Disposition	D	Maintain with PY-200 Certificates
PY-200		EGG PRODUCTS INSPECTION AND GRADING CERTIFICATE		3C(R)
5200-9	PY-235	EGG PRODUCTS GRADING WEEKLY REPORT		1/2C (R)
5200-10	PY-38	APPLICATION FOR OFF-PREMISE FREEZING OF EGG PRODUCTS	1B	
5200-11	PY-240	GRADING VOLUME REPORT (POULTRY, SHELL EGGS, AND EGG PRODUCTS)	6YRS 3MOS (R)	1/2C
5200-12	PY-32	APPLICATION FOR SERVICE	1B	
5400-11*	PY-159	REPORT OF EGG DRYING OPERATIONS		1C(R)
5400-12*	PY-203	DAILY REPORT OF PLANT OPERATIONS (EGG PRODUCTS)		1C(R)
7234-1	PY-221	PY-221 - LABEL NOTICE (Paper Submission) or FSIS Form 7234-1 - APPLICATION FOR APPROVAL OF LABELS, MARKING or DEVICE (Electronic Submission)		P
9540-1	5200-8	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

†The Agency will no be replacing this form.

*FSIS Forms 5400-11 and 5400-12 have been retired due to the implementation of PHIS for egg products inspection.