Egg Products Inspection Verification

Objectives

After completing this section, the participant will be able to:

1. Explain when inspection is required including the primary responsibilities of the egg products inspector.
2. Define continuous inspection responsibilities in egg products plants.
3. Define inspection and reinspection as they pertain to egg products.
4. Explain the elements of inspection when performing the egg products verifications activities.
5. List the verification tasks to verify regulatory requirements with 9 CFR 590.
6. Briefly discuss how to document the inspection verification results.

References

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

2. 9 CFR Part 590, Subchapter I — Egg Products Inspection

Introduction

FSIS conducts inspection activities at egg products plants as required under the Egg Products Inspection Act (EPIA). The egg products regulations that federally inspected plants must meet to produce wholesome, not adulterated product, that is properly packaged and labeled are found in 9 CFR 590.

Inspection of egg products takes place in sanitary facilities under continuous inspection by FSIS. Inspectors must be fully acquainted with the plant's physical layout, sanitation procedures, food safety operations, equipment, final products, packaging, storage, and procedures for shipping the final product to another federally inspected facility or into commerce.

Your primary activities as an egg products inspector include the following:

- Verifying the sanitary conditions of the plant premises, facilities, equipment, and processing operations
- Ensuring ingredients and additives are not adulterated, are fit for human consumption, and are stored and handled in a sanitary manner

- Examining the eggs and egg products, including the plant's records to ensure compliance with applicable regulatory requirements
- Verifying that formulas and labels are accurate
- Assuring that the firm has evidence of an approved label
- Documenting and responding to regulatory noncompliance
- Collect egg products samples to be analyzed for the pathogens of concern

Egg Products Inspection Verification

The inspection activities that you use include the review of plant records and organoleptic inspection. **Organoleptic inspection** means visual and other sensory (smell) evaluation of facilities, as well as inspected and passed egg products using established criteria for characterizing the condition of egg products.

The inspector is to verify the plant's operations and products as often as necessary to assure that product is unadulterated, wholesome, properly labeled, and fit for human consumption. In addition to observing plant operations, the inspector is responsible for verifying the regulatory requirements of the sanitary conditions, processing activities and operations in the official egg products plant.

Here are the regulatory requirements for inspection and reinspection activities:

Inspection – §590.420

Continuous inspection is required for all activities performed in the egg products plant, as stated previously, except those exempted by §590.100**.** According to §590.420, continuous inspection means the "Inspector must be present at the official plant when egg products are being processed."

An inspector is required to be on duty for the following processes during the manufacture of egg products at official plants (§ 590.5 – Terms defined. Processing):

- breaking eggs or filtering
- receiving liquid eggs
- mixing and blending
- stabilizing, pasteurizing, cooling, freezing, or drying
- receiving or shipping non-denatured inedible egg products
- packaging/labeling (applying the mark of inspection) of egg products

There are a few specific exemptions from continuous inspection allowed under the regulations. The regulations that address exemptions are §590.100 and §590.600 - §590.680.

Regulatory exemptions to the continuous inspection requirement

1. The first exemption is in §590.100(b). Approval is subject to the Administrator and the requesting plant must meet the following conditions:

- assignment of an "Exempted Registration Number"
- the facilities, sanitation and operating procedures are the same as those required in official plants
- the eggs received or used to manufacture the egg products meet or exceed the official standards for U.S. Consumer Grade B shell eggs
- the exempted plant is "subject to" periodic inspections

2. The second exemption is for a poultry producer who processes and sells egg products from eggs of his own flock's production. The egg products produced must be sold directly to a household consumer for the exclusive use of the household members, nonpaying guests and employees.

3. The final exemption is for processing in nonofficial plants, such as bakeries and restaurants, which produce food products that contain eggs or egg products as an ingredient. These nonofficial plants must meet one of the two following conditions:

- the egg products used are from inspected plants

OR

- the eggs used meet or exceed the official standards for U.S. Consumer Grade B shell eggs

Reinspection – § 590.424

Regulation §590.424 states that egg products may not be brought into an official plant unless they have been prepared, handled, and labeled in accordance with the regulations. It also states that an inspector shall reinspect all products at the time they enter into the plant.

The purpose of reinspection is to ensure the product is wholesome and fit for human food. Eggs and egg products brought into the plant and finished products produced in the plant are subject to reinspection. For product brought into the plant for further processing, reinspection at receiving serves the additional purpose of verifying the conditions at the originating plant.

The inspection program personnel (IPP) should be aware of what products are arriving at the plant and when those products arrive so that reinspection can be performed. The process and extent of reinspection depends on the product entering the plant and the conditions observed by the inspector. The IPP responsibilities are as follows.

Eggs eligible for breaking and egg products subject to reinspection:

- At the time of entry to an egg products facility:

    1. For shell eggs: as per recent published policy (Notice 27-16), IPP are to verify:

        - the number of shell eggs received for breaking including the appropriate documentation as to their domestic source (e.g., amount, date shipped, name and address of shipper)
        - that the total numbers of shell eggs received correspond to the number on plant records (e.g., receipt, purchase order, bill of lading; as per 9 CFR 590.200)

        When an egg products plant receive shell eggs for breaking that originate from an off-site laying house in an Animal Plant Health Inspection Service (APHIS) control/buffer zone (because of the presence of HPAI-H5N2), IPP are to verify that:

        - the shell eggs are accompanied by a permit issued by the applicable State veterinary authority
            - Acquiring the aforementioned permit is the responsibility of plant management

        In addition, the IPP is to perform an organoleptic examination to verify that only eligible eggs are entering the breaking room.

    2. Bulk tanker loads of pasteurized or unpasteurized liquid eggs:

        - a plant employee takes a sample of the product and gives it to the inspector
        - the IPP does the following:
            - an organoleptic inspection and takes the temperature of the liquid product
            - looks at the accompanying certificate (PY-200), which specifies the dates of manufacture and the identity of the incoming product
            - sends the PY-200 back to the originating plant including the information that the product
                - arrived at the correct place
                - arrived in wholesome condition
                - temperature was or was not satisfactory, as applicable

    When seals are not intact, the integrity of the product is considered questionable. The plant needs to investigate why the seals were broken and provide proof or assurance that the egg product is eligible for human consumption. You should inform the District Office, through your supervisor,

that the plant received unsealed bulk products. The District Office will be involved in deciding if the product disposition decision is acceptable.

3. For non-bulk packaged pasteurized or unpasteurized liquid eggs:

    - observe the condition of the containers
    - review the container labels
    - observe the condition of the transport vehicle
    - assess the ambient air temperature of the transport vehicle
    - review the bill of lading or certificate for production dates

    If the condition of the containers, or the ambient air temperature leads to you believe that the egg products may be off condition do an organoleptic examination of a representative number of containers

- The final product inspection is the last chance for IPP to determine that the product is unadulterated, wholesome, and properly labeled before the product is eligible for shipment. The inspector will perform a final inspection on all types of egg product categories as discussed in the Plant Operation section of this training.

Elements of Inspection

There are three elements of inspection:

- Inspection thought process – GAD
- Inspection Verification tasks
- Inspection methodology

FSIS Directive 5030.1 provides instruction to inspection program personnel (IPP) regarding how they are to verify that egg products plants are meeting the 9 CFR 590 regulatory requirements. We will first discuss each of the elements of inspection.

Inspection Thought Process – GAD

The inspection thought process is essential when determining compliance with the 9 CFR 590 regulations while performing your verification activities in an egg products plant.

While performing your inspection verifications activities, you should use the GAD process (Gather, Assess, and Determine), which consists of three steps:

1. **Gather** Information from the plant by reviewing records, making direct observations, and asking questions. Observe plant conditions; observe

product and verify temperature measurements for applicable regulatory requirements.

2. **Assess** the meaning and significance of that Information. In other words, IPP are to consider what each piece of information taken separately, or with other findings, means to ensure that products are not adulterated (9 CFR 590.420(c)). IPP are to consider information that they have gathered in the context of past findings and to look for any patterns or trends in the findings.

    - Consider the history. Is this an isolated or recurring event? Look for patterns and trends. Inspectors may need to gather more information by asking the plant for additional information to determine the scope of their findings.
    - Are conditions in the plant getting worse over time? Consider what the information alone or in the context of other information says about how well the food safety practices are functioning. Many egg products production processes are very complex. Before making a compliance determination, inspectors may need to seek input from their supervisor or obtain technical or policy assistance through askFSIS.
    - Is the plant responding effectively and in a timely manner to problems that do arise (9 CFR 590.504)?

3. **Determine** compliance. Did the plant fail to meet a regulatory requirement, or produce or ship adulterated products? When inspectors are uncertain, discuss the issue with their supervisor. Notice that Policy folks in headquarters cannot make acceptability/compliance determinations for field inspectors because they are not in the plant and do not have access to all the necessary information. That is an OFO responsibility.

While performing your inspection verification activities using the GAD process, you need to understand how the components of the food safety practices relate to each other and how changes or deficiencies in one practice may affect the adequacy of other practices as well.

When considering deficiencies:

- Always consider the deficiency in the context of the food safety practices.
- What does it indicate about the adequacy of the food safety practices?

To make a proper determination, you often will need to gather further information. Consider if the food safety practices are working or not working. You should ask the following questions:

- Has adulterated product been produced and shipped?

- Are there recurring issues/trends indicating the food safety practice is not working?
- Are there findings that when considered collectively indicate the food safety practice is not working?

This thought process is key to protecting public health.

Inspection Verification Tasks

Before we proceed in discussing the second element of inspection, let us first define some Public Health Information System (PHIS) terminology.

PHIS and the associated policy directives use specific language, therefore, the egg products inspectors are to use the terms to better understand the system and operate within it. In most cases, these terms does not change policy or the inspection verification activities. (Refer to FSIS Directive 13,000.1, *Scheduling In-plant Inspection Tasks in the Public Health Information System (PHIS)* — contains instructions on how to schedule tasks and use the task calendar in PHIS)

Some terms used in PHIS include:

- Tasks – IPP conduct these verification or data recording activities.
- For egg products inspection, it includes activities such as domestic inspection tasks and sampling tasks.

There are two types of tasks:

- Routine tasks – these are inspection verifications activities conducted on a routine, on-going or planned basis under normal conditions whenever the plant is in operation. A list of the routine tasks performed on a daily basis as a part of your inspection activities is included below.

- Directed tasks – these are inspection verification activities performed on an as-needed basis, i.e., are those that do not occur on a routine basis under normal circumstances.
    - Sampling tasks are considered directed tasks because they do not occur on a routine basis.

You will learn more about this when you take the PHIS Egg Products Hands-on training, if you have not taken the Inspection Methods course.

Most tasks have specific regulations associated with them; some are administrative tasks that you complete – no regulations to verify.

Inspection Verification tasks with specific regulations associated with the task

For those that have regulations associated with the task, the IPP performs them to verify that the plant is meeting regulatory requirements. In general, the inspection verifications tasks involve (refer to FSIS Directive 5030.1, Attachment 2):

- **Sanitation** – Using the three sanitation tasks, the inspector is going to verify that sanitary conditions in the plant are such that adulteration of product does not occur by ensuring that the sanitation regulations are met.

    - Pre-Operational Sanitation – Egg Products task: verify plant maintains sanitary conditions of food contact surfaces and equipment prior to operations (590.504(n)). Perform one daily. Assess the cleanliness of areas/equipment; what has greatest risk of transferring pathogens or contaminants to product.

    - Operational Sanitation – Egg Products task: verify plant meets all operational sanitation regulatory requirements to prevent contamination of food contact surfaces or product adulteration during production (590.504-575). Perform one per shift and additional "inspector directed" as warranted by plant conditions.

    - Sanitation and Plant Facilities – Egg Products task: verify plant meets the facilities/sanitation regulatory requirements and that the plant is operating under sanitary conditions such that product adulteration does not occur (590.500 – 575). Perform one daily and additional "inspector directed" as warranted by plant conditions.

- **Food safety** – When IPP verify the plant is meeting food safety requirements, he/she will evaluate the food safety procedures and associated activities observed in the plant. Verify that the plant is meeting the applicable food safety regulatory requirements (9 CFR 590.500 – 580) to ensure products are not adulterated.

    - Unpasteurized Egg Products – Food Safety task: This food safety-processing category applies to plants that break shell eggs and/or receive unpasteurized raw egg products. Plants in the unpasteurized egg products processing category may produce finished products such as unpasteurized liquid eggs with no ingredients added.

    - Pasteurized-Not Shelf Stable Egg Products – Food Safety task: This food safety-processing category applies to plants that further process liquid egg products by using primarily a lethality heat process step (e.g. pasteurization) to achieve food safety. The

finished products (pasteurized liquid with or without ingredients) that plants produce under this food safety-processing category are not shelf stable. FSIS requires the products to be frozen or refrigerated for food safety purposes.

- Shelf Stable Egg Products – Food Safety task: This food safety-processing category applies to plants that further process unpasteurized and/or pasteurized liquid egg products by using a heat treatment processing step to achieve food safety. The finished products (for example, dried egg products) produced under this food safety processing category are considered pasteurized, as well as shelf stable. FSIS does not require shelf stable products to be frozen or refrigerated for food safety purposes.

- **Non-food Safety Consumer Protection (NFSCP)** - verify that the plant complies with regulatory requirements designed to protect the consumer in ways other than ensuring food safety. Includes:

  - labeling requirements - (590.411)
  - observing preparation or processing procedures (590.500-580)
  - reviewing records associated with product formulation (590.411)
  - reinspection of product (590.424)
  - condition (590.504(l)) and temperature (e.g., examining lots of frozen egg products; 590.536(b) and 590.539)
  - verifying the records and loads of domestic unpasteurized liquid egg products (590.200 and 590.424)

  There are two NFSCP tasks to verify compliance:

  - Economic/Wholesomeness of Egg Products task: verify that egg products are produced in a safe, wholesome manner and do not become adulterated. This include:

    - final condition examination on all product types liquid, frozen and dried that have been processed, pasteurized and packaged in final form
    - pasteurized/unpasteurized liquid egg products received
    - reinspection of all egg products type

  - General Labeling – Egg Products task: verify that the applicable labels, containers, and packaging materials bearing USDA identification meet the requirements in 9 CFR 590.411. This task has three parts:

    - General labeling: verify that egg products bear a label; marking products and their containers' labeling; marking

device and containers entering official plants; and reinspection and preparation of egg products.
- Labeling – Product Standards: select an appropriate product and verify compliance by reviewing plant records (including formulation) and labels, or observing the preparation of products and comparing the findings to the appropriate regulatory standard.
- Labeling – Net Weights: select an egg product and verify net weight regulatory requirements by reviewing plant records and conducting net weight checks.

- Other Inspection Requirements – Egg Products task: IPP perform this task to verify miscellaneous requirements for inspection such as presence and adequacy of inspection facilities (blueprints), accessibility to plant facilities, refrigeration and labeling of shell eggs for ultimate consumer, and time/temperature parameters for freezing and defrosting egg products.

- Review Egg Plant Data task: perform a weekly review of plant data that has an impact on food safety, as well as, the verification of the number and the source of shell eggs received for breaking. Follow instructions as per FSIS Directive 5,000.2 and FSIS Notice 27-16, respectively.

- Big 8 Formulation Verification task: as per FSIS Directive 7230.1, *Ongoing Verification of Product Formulation and Labeling Targeting the Eight Most Common ("Big 8") Food Allergens*, IPP is to verify that the meat/poultry establishments and egg products plants are accurately controlling and labeling the big 8 food allergens. Egg products plants are required to furnish IPP accurate information on product preparation and formulation for verification in accordance with 9 CFR 590.411, as well as records associated with production of product as per §590.200. IPP are to perform this verification task as a directed task at a monthly frequency; IPP are to answer specific questions related to this task in PHIS. IPP are to verify that:

  - all ingredients used in the production of the product are present on the product formulation record
  - all ingredients in the product formulation are declared in the ingredients statement on the product label by common or usual name in descending order of predominance and that the appropriate label is applied to the product
  - the applied label is consistent with the plant's label approval on file

Each time IPP perform a task, he/she will choose one or more regulations to verify. Over time, the inspector will verify all the applicable regulations for each task. If time allows, the IPP will verify multiple regulations in one or more areas of the plant. The IPP will perform routine tasks at a defined frequency.

Administrative Tasks

As mentioned previously, most tasks have specific regulations associated with them. On the other hand, the administrative tasks that the IPP complete on a monthly basis have no regulations to verify. The administrative tasks include:

- Monthly Volume Reporting Egg Products task: IPP are to perform this task monthly to verify the product volumes for all egg products produced applicable to the plant. This may include the quantity of the shell eggs broken, total liquid or frozen egg produced, total dried egg solids, and other egg products in the plant. This task will take the place of the monthly volume reporting for NASS that you have been sending to the Financial Processing Center. IPP will enter all the information of FSIS Form 5200-11 in PHIS under the 'Questionnaire' tab (refer to Attachment 1). The inspector will file form 5200-11 on the government files.

  Note: Egg product inspectors (EPIs) are to complete the monthly volume-reporting task as early in the month as possible and record the previous month's volume data. For example, enter the monthly volume for April when performing the May Monthly Volume Reporting Egg Products task. For the June Monthly Volume Reporting Egg Products task, EPIs would enter the plant's monthly volume from May, and so on. When IPP enters data into the questionnaire for the Monthly Volume Reporting Egg Products task, they must do the following:

  - use the format MM/DD/YYYY when entering dates
  - for products not produced by the plant, such as Shelf Stable Dried Egg Whites at an egg breaking plant, enter a 0 (do not leave blank or enter "NA")
  - do not enter numerical data expressed as fractions or decimal number (for example, enter 176,536 lbs instead of 176,535.7 lbs or 176,535 7/10 lbs)

- Meeting with Plant Management (EP) task: IPP will use this task to reserve time in their schedule for meeting with plant management. During the weekly meeting, IPP discusses any open non-compliance record (NR), developing trends of non-compliance, or other topics that arises. Follow instructions as per FSIS Directives 5030.1 and 5010.1 on how to conduct weekly meetings with plant management.

- Update Establishment Profile Egg Products task: IPP will review the egg products plant profile information in PHIS and make any needed corrections to reflect current operations. Refer to FSIS Directive 5030.2 for the instructions concerning to the plant profile.

Inspection Methodology

The third element of inspection is the inspection methodology. As part of the data entry for the inspection verification tasks in PHIS, IPP will have to record what component they used to verify regulatory compliance, or record any other PHIS task, such as administrative and food defense (will be discussed later in training).

There are two components in PHIS:

1. Review and observation, and
2. Recordkeeping

Let us explain what the inspector actually does for each of these components.

The **review and observation** component has two parts:

- Review – a "hands-on" type verification activity – or something that the inspector does. For example, calculate and verify holding time and flow rate for the pasteurizer (food safety task) to determine if the plant is in compliance with the time/temperature requirements of pasteurization for the product being produced; or perform pre-operational sanitation inspection (sanitation task).

- Observation – observing the plant employee perform an activity. For example: making observations whether the plant's continuous recording device is recording the actual time/temperature measurements as required by regulation; observing plant employees taking other measurements; or observing product or conditions within the plant.

The **recordkeeping** component is a review of the records associated with the specific task. For example, you may review the recording charts of the continuous pasteurizer-recording device (paper or electronic chart), review data recording devices, or look at the records of testing results associated with food safety as per regulatory requirements, as well as any additional relevant records generated by the plant.

Documentation – Verification Results

IPP are to use PHIS to document the results of their verification tasks by making the appropriate entries regarding the task and their findings of regulatory compliance or noncompliance through checking appropriate boxes, making appropriate selections from lists, or typing in text as prompted by the system. If noncompliance is found the inspector will electronically generate a Noncompliance Record (Form 5400-4) in PHIS.

When IPP document noncompliance, they are to describe why the findings led them to a determination of noncompliance. If IPP are uncertain whether the information supports a particular determination, they are to discuss the issue with their immediate supervisor.

If IPP have concerns about circumstances that may indicate systemic problems, or there is reason to believe that product may have become adulterated, IPP are to bring these issues to the attention of their supervisor immediately.

You will get more information on how to enter inspection results in PHIS when you take the PHIS Egg Products Hands-on Training.

Egg Products Inspection Forms

A form that the inspector uses regularly is FSIS Form PY-200, *Egg Product Inspection Certificate* (refer to Attachment 2). Directive 5040.1, *Uses of FSIS Form PY-200 Egg Products Inspection Certificate*, provides instruction to FSIS IPP assigned to an egg product plant on the uses of this form.

Void (obsolete) FSIS Forms

Since PHIS was implemented in the egg products inspection verification activities, FSIS Form 5400-12, "*Daily Reports of Plant Operations*" (previously PY-203), and/or FSIS Form 5400-11, "*Daily Report of Egg Drying Operations*" (previously PY-159), are not used anymore to record inspection activities (refer to attachments 3 and 4). Nevertheless, you can still download them from the FSIS Intranet site and used these as a job aid (optional).

Instead of using the daily forms 5400-11 and 5400-12 to guide and document your verification activities, the egg products inspectors are going to use inspection verification tasks and document the results in the Public Health Inspection System or PHIS. The inspector can still use the daily forms as an unofficial worksheet as he/she goes about their daily activities, though it will not be the official documentation of the in-plant actions. For example, instead of using the Operational Checklist part of FSIS Form 5400-12 to verify operational sanitation, the inspector is going to verify that the plant is maintaining operational sanitation throughout the production day as part of the Operational Sanitation Verification task.

Use of New Technology in Egg Products Plants

FSIS Directive 11,000.2, *Verification Activities for the Use of New Technology in Meat and Poultry Establishments and Egg Products Plant,* provides instruction to IPP on how they are to verify that a plant is following the procedures outlined in its new technology protocol.

FSIS defines a "new technology" as new or new application of, equipment, substances, methods, processes, or procedures affecting the slaughter of livestock and poultry or the processing of meat, poultry, or egg products. The Agency reviews new technology protocols to determine whether the new technology could affect product safety; violate FSIS regulations; interfere with inspection procedures; or jeopardize the safety of IPP. If, after review, the Agency does not object to the proposed use of a new technology, then the Agency will furnish a no objection letter (NOL) for the use of the new technology. If applicable, the NOL may permit in-plant trials and waive specified provisions of the regulations.

"New technology" also includes alternative procedures in lieu of waived regulations. Under 9 CFR 590.10, the FSIS Administrator may (in specific classes of cases) waive any provisions of the regulations for limited periods to permit experimentation. During the experimentation period the new procedures, equipment, and processing techniques may be tested to facilitate definite improvements, if such waivers of the provisions of such regulations are not in conflict with the purposes or provisions of the Egg Products Inspection Acts.

IPP Responsibilities

IPP must do the following:

- review the New Technology Summaries list on Inside FSIS to inform themselves about the technologies establishments may employ in their food safety system
- when the plant informs the IPP that it plans to implement a new technology, IPP will discuss the technology with plant management at the next weekly meeting as per Directive 5030.1
- using the appropriate PHIS verification task (i.e., Operational Sanitation, Economic/Wholesomeness, or Other Inspection Requirements task), IPP are to review alternative procedures and any new technology protocol to verify that egg plants are meeting the regulatory requirements of 9 CFR 590 in accordance with FSIS Directive 5030.1

As mentioned earlier, the Agency may waive certain provisions of the regulation. IPP must review the waivers as well as the NOL for the use of alternative procedures. Alternative procedures are those that a plant will use in place of

certain provisions of the regulations. Each regulation or provision of a regulation waived will require certain relevant alternative procedures.

Documentation and Enforcement

When documenting the task performed, IPP are to follow the instructions above and record 9 CFR 590.10 in egg products plants when verifying whether the plant is following its alternative procedures in place of certain provisions of the regulations (regulatory waivers). If IPP identify noncompliance, the manner in which the plant has addressed the new technology within its food safety system will affect how IPP document any noncompliance found. IPP must follow the instructions in FSIS Directive 5030.1, including also citing 9 CFR 590.10, when documenting noncompliance with alternative procedures used in place of certain provisions of the regulations (regulatory waivers).

IPP must report through supervisory channels if they observe a clear trend of repetitive NRs related to alternative procedures. The FSIS Administrator may revoke waivers when repeated NRs documenting failure of an establishment to maintain its alternative procedures occur.

List of References

Attachment 5 provides a list of the most relevant and updated policies to equip the egg inspection personnel with the necessary tools to perform the daily inspection activities in their assignments.

A detailed discussion on documentation efforts will be provided in the “Documentation and Enforcement” section of this training.

Workshop

1. What plant operations require that an inspector be on duty?

2. What does continuous inspection and reinspection mean?

3. Explain the term “organoleptic inspection”.

Attachments

Attachment 1 – Questionnaire items associated with the Monthly Volume Reporting Task

Note: The answers to the questions come from the FSIS Form 5200-11, *Egg Product Volume Report*, as indicated below; as well as other sources.

PHIS Questionnaire:

Month Ending
(Free Text) This volume data is for the month ending on date:
(Please type date in MM/DD/YYYY format).

Shell Eggs Broken
(Free Text) Number of shell eggs broken - record in units of 30 dozen cases.
BLOCK 01 from 5200-11 goes here

Pounds Liquid Whole
(Free Text) Record pounds of liquid produced from shell eggs broken as whole egg. BLOCK 02 from 5200-11 goes here

Pounds Liquid White
(Free Text) Record pounds of liquid produced from shell eggs broken as egg whites. BLOCK 04 from 5200-11 goes here

Pounds Liquid Yolk
(Free Text) Record pounds of liquid produced from shell eggs broken as egg yolks. BLOCK 03 from 5200-11 goes here

Pounds Liquid Inedible
(Free Text) Record pounds of liquid produced from shell eggs broken as inedible egg. BLOCK 05 from 5200-11 goes here

Pounds Unpast Whole Ship Bulk
(Free Text) Record pounds of liquid unpasteurized whole egg shipped in bulk (i.e. totes, tankers) for further processing.
Need to determine how much of the total in Block 13 is whole egg.
Add totals from weekly reports to get the total for whole egg.

Pounds Unpast White Ship Bulk
(Free Text) Record pounds of liquid unpasteurized egg whites shipped in bulk (i.e. totes, tankers) for further processing.
Need to determine how much of the total in Block 13 is egg whites.
Add totals from weekly reports to get the total for egg whites.

Pounds Unpast Yolk Ship Bulk
(Free Text) Record pounds of liquid unpasteurized egg yolks shipped in bulk (i.e. totes, tankers) for further processing.
Need to determine how much of the total in Block 13 is egg yolks.
Add totals from weekly reports to get the total for egg yolks.

Pounds Unpast Ined Ship Bulk
(Free Text) Record pounds of liquid inedible egg (denatured and un-denatured) shipped in bulk (i.e. totes, tankers). Obtained from plant's shipping records.

Pounds Unpast Whole Receive Bulk
(Free Text) Record pounds of liquid unpasteurized whole egg received in bulk (i.e. totes, tankers) for further processing.
BLOCK 06 from 5200-11 goes here

Pounds Unpast White Receive Bulk
(Free Text) Record pounds of liquid unpasteurized egg whites received in bulk (i.e. totes, tankers) for further processing.
BLOCK 08 from 5200-11 goes here

Pounds Unpast Yolk Receive Bulk
(Free Text) Record pounds of liquid unpasteurized egg yolks received in bulk (i.e. totes, tankers) for further processing.
BLOCK 07 from 5200-11 goes here

Pounds All Past Liquid
(Free Text) Record pounds of all pasteurized liquid egg products produced for distribution in commerce. BLOCK 14 from 5200-11 goes here

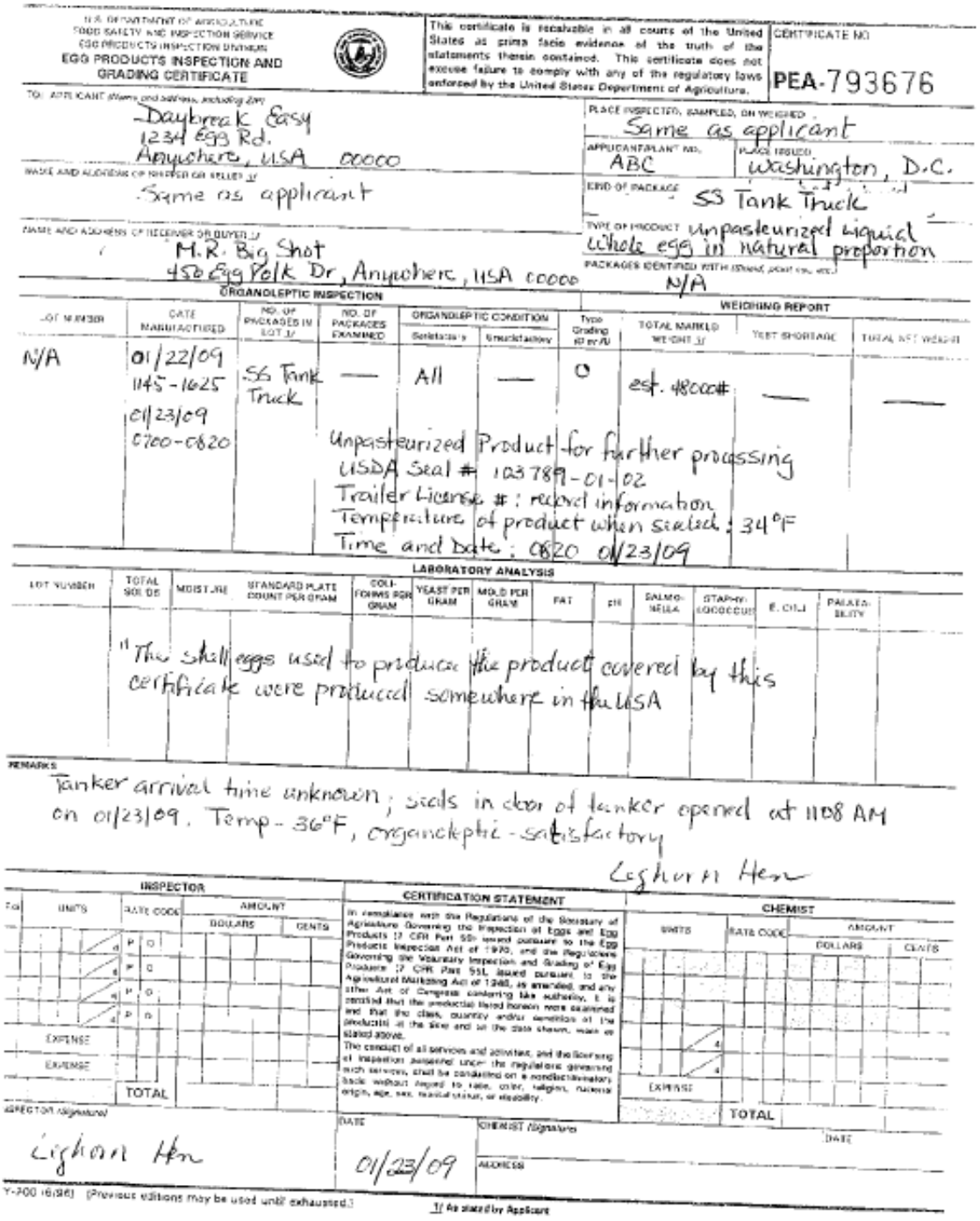
Pounds All Past Frozen
(Free Text) Record pounds of all pasteurized frozen egg products produced for distribution in commerce. BLOCK 15 from 5200-11 goes here

Pounds All Dried
(Free Text) Record pounds of all dried egg products produced for distribution in commerce. BLOCK 16 from 5200-11 goes here

Pounds Non-Egg Ingrid
(Free Text) Record pounds of all non-egg ingredients added to pasteurized egg products produced for distribution in commerce.
BLOCK 11 from 5200-11 goes here

Pounds Inedible Receive Bulk
(Free Text) Record pounds of liquid inedible egg (denatured and un-denatured) received in bulk (i.e. totes, tankers).
BLOCK 09 from 5200-11 goes here

Attachment 2 – Form PY 200



U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
EGG PRODUCTS INSPECTION DIVISION

EGG PRODUCTS INSPECTION AND GRADING CERTIFICATE

This certificate is receivable in all courts of the United States as prima facie evidence of the truth of the statements therein contained. This certificate does not excuse failure to comply with any of the regulatory laws enforced by the United States Department of Agriculture.

CERTIFICATE NO. PEA-793676

TO: APPLICANT (Name and address, including ZIP)
Daybreak Easy
1234 Egg Rd.
Anywhere, USA 00000

PLACE INSPECTED, SAMPLED, OR WEIGHED
Same as applicant

APPLICANT/PLANT NO. ABC

PLACE ISSUED Washington, D.C.

NAME AND ADDRESS OF SHIPPER OR SELLER 1/
Same as applicant

KIND OF PACKAGE SS Tank Truck

TYPE OF PRODUCT Unpasteurized liquid whole egg in natural proportion

NAME AND ADDRESS OF CONSIGNEE OR BUYER 1/
M.R. Big Shot
456 Egg Folk Dr, Anywhere, USA 00000

PACKAGES IDENTIFIED WITH (Stencil, plant no., etc.) N/A

ORGANOLEPTIC INSPECTION

LOT NUMBER	DATE MANUFACTURED	NO. OF PACKAGES IN LOT 1/	NO. OF PACKAGES EXAMINED	ORGANOLEPTIC CONDITION: Satisfactory	ORGANOLEPTIC CONDITION: Unsatisfactory	Type Grading ID or AU
N/A	01/22/09 1145-1625 01/23/09 0700-0820	SS Tank Truck	—	All	—	O

WEIGHING REPORT

TOTAL MARKED WEIGHT 1/	TEST SHORTAGE	TOTAL NET WEIGHT
est. 48000#	—	—

Unpasteurized Product for further processing
USDA Seal # 123789-01-02
Trailer License #: record information
Temperature of product when sealed: 34°F
Time and date: 0820 01/23/09

LABORATORY ANALYSIS

LOT NUMBER	TOTAL SOLIDS	MOISTURE	STANDARD PLATE COUNT PER GRAM	COLIFORMS PER GRAM	YEAST PER GRAM	MOLD PER GRAM	FAT	pH	SALMONELLA	STAPHYLOCOCCUS	E. COLI	PASTEURIZABILITY

"The shell eggs used to produce the product covered by this certificate were produced somewhere in the USA"

REMARKS
Tanker arrival time unknown; seals in door of tanker opened at 1108 AM on 01/23/09. Temp - 36°F, organoleptic - satisfactory

Leghorn Hen

INSPECTOR

TO	UNITS	RATE CODE	AMOUNT DOLLARS	AMOUNT CENTS
		P O		
		P O		
		P O		
		P O		
EXPENSE				
EXPENSE				
		TOTAL		

DIRECTOR (Signature) Leghorn Hen

CERTIFICATION STATEMENT

In compliance with the Regulations of the Secretary of Agriculture Governing the Inspection of Eggs and Egg Products (7 CFR Part 59) issued pursuant to the Egg Products Inspection Act of 1970, and the Regulations Governing the Voluntary Inspection and Grading of Egg Products (7 CFR Part 56), issued pursuant to the Agricultural Marketing Act of 1946, as amended, and any other Act of Congress conferring like authority, I hereby certify that the products listed hereon were examined and that the class, quantity and/or condition of the product(s) at the time and at the place shown, were as stated above.

The conduct of all services and activities, and the licensing of inspection personnel under the regulations governing such services, shall be conducted on a nondiscriminatory basis without regard to race, color, religion, national origin, age, sex, marital status, or disability.

DATE 01/23/09

CHEMIST

UNITS	RATE CODE	AMOUNT DOLLARS	AMOUNT CENTS
EXPENSE			
	TOTAL		

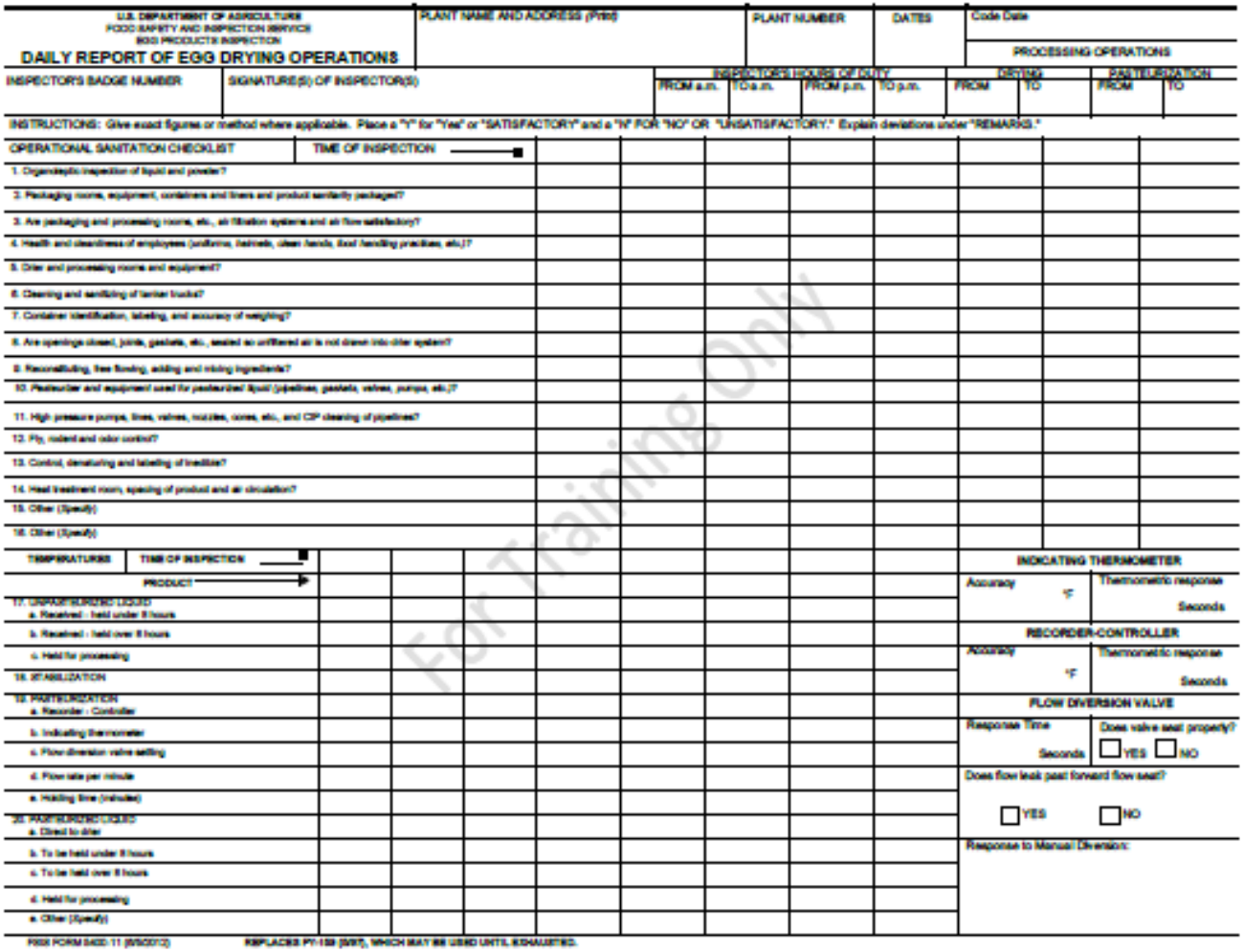
CHEMIST (Signature) DATE

ADDRESS

Y-200 (6/96) (Previous editions may be used until exhausted.) 1/ As stated by Applicant

Form PY-200 -Att 1

Attachment 3 – FSIS Form 5400-11 (page 1 of 2) – to be used as an inspection aid



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

DAILY REPORT OF EGG DRYING OPERATIONS

PLANT NAME AND ADDRESS (Print) | PLANT NUMBER | DATES | Code Date

PROCESSING OPERATIONS

INSPECTOR'S BADGE NUMBER | SIGNATURE(S) OF INSPECTOR(S) | INSPECTOR'S HOURS OF DUTY: FROM a.m. / TO a.m. / FROM p.m. / TO p.m. | DRYING: FROM / TO | PASTEURIZATION: FROM / TO

INSTRUCTIONS: Give exact figures 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 — TIME OF INSPECTION →									
1. Organoleptic inspection of liquid and powder?									
2. Packaging rooms, equipment, containers and liners and product sanitarily packaged?									
3. Are packaging and processing rooms, etc., air filtration systems and air flow satisfactory?									
4. Health and cleanliness of employees (uniforms, hairnets, clean hands, food handling practices, etc.)?									
5. Odor and processing rooms and equipment?									
6. Cleaning and sanitizing of tanker trucks?									
7. Container identification, labeling, and accuracy of weighing?									
8. Are openings closed, joints, gaskets, etc., sealed so unfiltered air is not drawn into other system?									
9. Reconditioning, free flowing, adding and mixing ingredients?									
10. Pasteurizer and equipment used for pasteurized liquid (pipelines, gaskets, valves, pumps, etc.)?									
11. High pressure pumps, lines, valves, nozzles, cones, etc., and CIP cleaning of pipelines?									
12. Fly, rodent and odor control?									
13. Control, denaturing and labeling of inedible?									
14. Heat treatment room, spacing of product and air circulation?									
15. Other (Specify)									
16. Other (Specify)									

TEMPERATURES — TIME OF INSPECTION → / PRODUCT →									
17. UNPASTEURIZED LIQUID a. Received - held under 8 hours									
b. Received - held over 8 hours									
c. Held for processing									
18. STABILIZATION									
19. PASTEURIZATION a. Recorder - Controller									
b. Indicating thermometer									
c. Flow diversion valve setting									
d. Flow rate per minute									
e. Holding time (minutes)									
20. PASTEURIZED LIQUID a. Direct to dryer									
b. To be held under 8 hours									
c. To be held over 8 hours									
d. Held for processing									
e. Other (Specify)									

INDICATING THERMOMETER: Accuracy °F | Thermometric response Seconds

RECORDER-CONTROLLER: Accuracy °F | Thermometric response Seconds

FLOW DIVERSION VALVE: Response Time Seconds | Does valve seat properly? ☐ YES ☐ NO

Does flow leak past forward flow seat? ☐ YES ☐ NO

Response to Manual Diversion:

FSIS FORM 5400-11 (6/5/2012) REPLACES PY-159 (6/97), WHICH MAY BE USED UNTIL EXHAUSTED.

FSIS Form 5400-1 1

Attachment 4 – FSIS Form 5400-12 (page 1 of 3) – to be used as an inspection aid

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

BREAKING FROM: _____ A.M. TO: _____ P.M. PASTEURIZATION FROM: _____ A.M. TO: _____ P.M.

INSPECTOR'S HOURS OF DUTY

_____ 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, dirties 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 sanitarily 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 5400-1 2

Attachment 5 – FSIS Directives and Notices Applicable to Egg Products Plants Inspection and Other Resources

FSIS Directives and Notices are written to FSIS Inspection Program Personnel to provide them with guidance and verification instructions. Compliance guides are written for industry; they provide guidance and suggested procedures for industry to follow to obtain regulatory compliance.

FSIS Directives and Notices that are applicable to mandatory inspection activities in egg products plants:

FSIS Directives

5000.2	Review of Establishment Data by Inspection Personnel (policy is applicable although the 9 CFR 590 regulations are not referenced)
5000.3	Identification and Segregation of Product
5000.9	Verifying Video or Other Electronic Monitoring Records (policy is applicable, although the 9 CFR 590 regulations are not referenced)
5010.1	Food Safety Related Topics for Discussion during Weekly Meetings with Establishment Management
5020.1	Verification Activities for the Use of New Technologies in Meat and Poultry Establishments and Egg Products Plants
5030.1	Inspection Methodology Utilizing the Public Health Information System (PHIS) for the Verification of Regulatory Compliance in Egg Products Plants
5030.2	Managing the Establishment Profile in the Public Health Information System (PHIS) for Egg Products Inspection
5030.5	Review of Egg Products Plants Drawings and Specifications Note: There are associated guidance document and sample letters with this Directive.
5040.1	Uses of FSIS Form PY-200 Egg Products Inspection Certificate
5060.1	Hygiene and Biosecurity Practices
5220.1	Granting or Refusing Inspection; Voluntary Suspending or Withdrawing Inspection; and Reinstating Inspection under PHIS
5220.2	Meat and Poultry Establishment Numbering Procedures

5220.3	Issuance of a Ten-Day Letter for Inactive Operations
5420.1	Food Defense Verification Tasks and Threat Notification Response Procedure for the Office of Field Operations
5500.2	Significant Incident Response
5500.4	Products Intentionally Adulterated with Threat Agents
5500.4	Products Intentionally Adulterated with Threat Agents
5620.1	Using AskFSIS
5730.1	Responsibilities in Dual Jurisdiction Establishments
6400.1	Fowl Ova
7000.2	Experimental and Sample Products Policy
7120.1	Safe and Suitable Ingredients Used in the Production of Meat, Poultry and Egg Products
7230.1	Ongoing Verification of Product Formulation and Labeling Targeting the Eight Most Common (“Big 8”) Food Allergens
7355.1	Use of Sample Seals for Program Samples and Other Applications
9000.1	Export Certification
9000.6	Export Certification of Egg Products from Other than Official Egg Product Plants
9000.8	Audits of U.S. Meat, Poultry, and Egg Products Inspection System by Officials of Foreign Countries
9010.1	Export Products Returned to the United States
9040.5	Procedures for Evaluating and Verifying Implementation of Corrective Actions in Response to Detained or Rejected Export Product
9900.2	Import Reinspection of Meat, Poultry, and Egg Products
9900.5	Label Verification of Imported Meat, Poultry, and Egg Products

9900.6	Laboratory Sampling Program for Imported Meat, Poultry, and Egg Products
9900.8	Meat, Poultry, and Egg Products Refused Entry into the United States
10,210.1	Unified Sampling Form - Amendment 1 – 6
10,230.4	*Salmonella* Surveillance Program for Liquid and Frozen Egg Products
11,000.2	Verification Activities for the Use of New Technology in Meat and Poultry Establishments and Egg Products Plants
12,600.1	Voluntary Reimbursable Inspection Services
12,700.1	Operations Occurring Outside Approved Hours
13,000.1	Scheduling In-Plant Inspection Tasks in the Public Health Information System (PHIS)
13,000.2	Performing Sampling Tasks in Official Establishments Using the Public Health Information System
13,000.3	Responding in PHIS to Industry Appeal of a Noncompliance Record (NR)

Notices

57-16	Elimination of the EGGDOM Sampling Program
55-16	Public Health Information System Dashboard Alerts Widget
54-16	Voluntary Labeling Statement that Bioengineered or Genetically Modified Ingredients or Animal Feed Were Not Used in Meat, Poultry, or Egg Products
50-16	Updates to the Inspection Program Personnel (IPP) Help Button
27-16	Enhanced Verification Activities When Egg Products Plants Receive Shell Eggs for Breaking
19-16	Inspection Program Personnel (IPP) Help Button
11-16	Supplemental Information on Sampling Projects and Supplies

Compliance Guides

Sanitation Procedures –
Less Than Daily Sanitation Procedures Compliance Guideline

Labeling Procedures –
http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-procedures

A guide to Federal Food Labeling Requirements for Meat and Poultry Products
(Egg products were added to this document, as Appendix A, but the title was not changed. Eggs start on page 105)

New Technology –
FSIS Compliance Guideline Procedures for New Technology Notifications and Protocols

Other Resources

LIMS Direct –
http://limsdirect/Reports/Pages/Report.aspx?ItemPath=%2fLIMS-Direct%2fLIMS-Direct

Requirements for Exporting Processed Egg Products –
http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products/requirements-for-processed-egg-products

Food Safety Issues in Areas Affected by Natural Disasters –
Technical Guidance Document Identifying Possible Issues in Processing Establishments