

Egg Product Sampling

Objectives

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

1. Describe the purpose and the regulatory requirement for each sampling program
2. Explain the procedure for handling and recording the results of *Salmonella* and *Listeria monocytogenes (Lm)* analysis
3. Explain inspection program personnel (IPP) responsibilities in handling of *Salmonella* and *Lm*-positive egg products.
4. Explain procedures and controls required when shell eggs or egg products are diverted to an egg products processing plant for further processing

References

FSIS Directive 10,230.3, *FSIS Verification Testing of Domestic Egg Products*
FSIS Notice 70-20, *Egg Products Inspection Regulatory Changes*
FSIS Notice 22-20, *Microbiological Sampling of Domestic Egg Products*
FSIS Notice 57-16, *Elimination of the EggDOM Sampling Program*
FSIS Directive 5030.1, *Inspection Methodology Utilizing PHIS... Egg Products Plants*
FSIS Directive 5030.2, *Managing the Establishment Profile in PHIS for Egg Products*
FSIS Directive 13000.2, *Performing Sampling Task in Official Establishments using PHIS*
9 CFR 590, *Eggs and Egg Products Inspection Regulations*

Introduction

There are four types of sampling programs to fulfill regulatory requirements (see Figure 1 – Statutory and Regulatory Requirements).

- Plant Sampling Program
- FSIS Verification Sampling Program
- Certification Sampling Program
- Residue Sampling Program.

These sampling programs will be discussed after we define some terms.

Definitions

Aseptic: Free from or keeping away disease-producing or putrefying microorganisms. An aseptic sample is a sample that is collected in such a way as to avoid contamination during the collection process and that is placed in a sterile container.

Production lot: a lot for liquid and frozen egg products can be defined as one day's production (physically separated pasteurization run) of each type of product within the applicable category or according to the FSIS Memorandum titled "Definition of a Product Lot" issued on January 17, 2001 (see Figure 2). Bottom line is that the plants producing egg products are required to maintain a defined procedure for the identification of a production lot in their Sampling Program.

Sampling: The act of taking samples of any product for inspection or analysis (microbiological, chemical, or physical).

Note: The majority of samples selected and analyzed for egg products are done to determine that the finished product is negative for *Salmonella* and *Lm*.

Sampling or product category: sampling categories for liquid and frozen egg product:

- whites (with or without added ingredients)
- whole eggs or yolks (with less than two percent added ingredients or no added ingredients)
- whole eggs or yolks or blends thereof (with two percent or more added ingredients other than salt or sugar)
- whole eggs or yolks or blends thereof with two percent or more salt or sugar added

Sanitize: To apply a bactericidal treatment approved as being effective in destroying microorganisms, including pathogens.

Types of Sampling and Testing

The four types of sampling programs conducted in egg products are as follows:

Plant Sampling Program

The regulatory requirement to perform *Salmonella* sampling is specified in 9 CFR 590.580 (Figure 1). This sampling program is designed to measure the effectiveness of the plant's pasteurization process and to ensure that post-pasteurization contamination has not occurred. Under this sampling program, the plant selects all samples of pasteurized egg products and tests the samples for the presence of *Salmonella*. All sampling costs (e.g., supplies, shipping, and analysis) are the responsibility of the plant.

Note: FSIS Directive 10,230.4 was cancelled. Please see Attachment 6. Egg product plants are expected to continue with the surveillance sampling.

The results of all partial and completed analyses of this section must be provided to IPP promptly upon receipt by the official plant. Positive test results must be provided to IPP immediately upon receipt by the official plant. Plants are required to hold or control products pending the receipt of *Salmonella* and *Lm* test results as per (9 CFR 590.504(e)).

Inspection program personnel (IPP) should thoroughly understand the plant's sampling program and are to verify that the program follows 9 CFR 590.580 and FSIS policies.

IPP's responsibilities are:

- To periodically examine the plant's records to make certain that the proper sampling procedures are being followed. The frequency at which IPP perform these checks will range from daily to weekly, depending upon the number of lots of product produced by the plant. IPP will enter the results in PHIS, using the appropriate task, when reviewing the laboratory reports to ensure that each sample submitted to the laboratory was analyzed individually and that the results have been reported separately (i.e., samples were not composited and only one analysis was done).
- To ensure that the plant takes the required actions when a sample is found to be *Salmonella*-positive
- To initiate appropriate action if there is evidence of noncompliance with the regulations
- To document non-compliance using the appropriate food safety task

FSIS Verification Sampling Program

The Agency's verification OPHS-directed sampling programs are addressed in Directive 10,230.3.

To ensure that pasteurized, ready-to-eat (RTE) egg products are safe and wholesome, FSIS analyzes them for the presence of *Salmonella* and *Lm*.

FSIS analyzes products for the pathogens because of public health concern over potential product adulteration. Therefore, to enhance public health protection associated with pasteurized egg products for consumers, FSIS test all domestic and imported pasteurized egg products for both *Salmonella* and *Lm*.

Note: FSIS considers pasteurized egg products as RTE. They do not require additional steps to ensure food safety. Although RTE, egg products are not subject to compliance with 9 CFR Part 430 as they are not meat or poultry products.

The Agency collects samples of dried, frozen, and liquid pasteurized egg

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products under two project codes, EGG_LQ_MIC01 and EGG_DY_MIC01. Effective June 1, 2020, FSIS consolidated its previous seven Egg Products sampling projects into these two projects. The information included in the microbiological product sampling projects is as follows:

- a project number and a project title with the appropriate information including types of products to sample,
- collection instructions
- plant management notification
- shipping instructions

Note: When scheduling the sampling task in PHIS, the system will generate the sample form that should be sent to the lab (see Figure 3).

Following are examples of potential product samples under the 2 new projects:

- EGG_LQ_MIC01, Pasteurized Liquid or Frozen Egg Products--for example: liquid and frozen egg whites with or without added ingredients.
- EGG_LQ_MIC01, Pasteurized Liquid or Frozen Egg Products--for example: plain liquid and/or frozen whole eggs or yolks, and liquid or frozen whole eggs and/or yolks with less than two percent added ingredients other than salt or sugar, respectively.
- EGG_LQ_MIC01, Pasteurized Liquid or Frozen Egg Products--for example: liquid and/or frozen whole eggs with added yolks, or whole egg blends (with more than two percent added ingredients other than salt or sugar).
- EGG_LQ_MIC01, Pasteurized Liquid or Frozen Egg Products--for example: liquid and/or frozen whole eggs or yolks with more than two percent salt or sugar added, respectively.
- EGG_DY_MIC01, Pasteurized Dried Egg Products for example: dried yellow egg products.
- EGG_DY_MIC01, Pasteurized Dried Egg Products for example: spray-dried egg whites with or without added ingredients.
- EGG_DY_MIC01, Pasteurized Dried Egg Products for example: pan-dried egg whites without added ingredients.

FSIS inspection program personnel aseptically collect egg products sample(s) (directed samples) from each plant that produces egg products. The egg product to be collected per process is indicated in the sample request in PHIS. FSIS Field Service Laboratories analyze the sample(s) for the presence of *Salmonella* and *Lm*. Sampled according to the guidance provided in FSIS Notice 22-20, Table 1, sample allocations information.

FSIS inspection personnel also need to determine what sampling categories the plant is producing and determine if they are receiving a sampling request for each category in which the plant produces a product. For example, if the plant produces product in three of the liquid product categories, but only receives requests in two of these categories, the IPP need to review the Establishment's Profile product information in PHIS to verify that it accurately reflects which products (including volume) are being produced by the plant; otherwise, inform their supervisor of this discrepancy.

Conversely, if IPP are receiving sampling requests for product that is only producing seasonally, once a year, or they no longer produce the product, IPP must immediately update the establishment profile in PHIS so that the database can be updated to reflect the current list of egg products that need to be sampled.

If IPP have received sampling boxes that are not needed, they are to send an e-mail to the Laboratory Sampling Outlook Mailbox in PHIS and request instructions and mailing labels so that the boxes and sampling supplies can be returned.

Listeria monocytogenes in egg products with shelf life claims

The Agency eliminated its domestic egg products sampling program (EGGDOM) which analyzed pasteurized liquid egg products bearing shelf-life claims for the presence of *Lm* (FSIS Notice 57-16). On September 21, 2016, FSIS immediately eliminated the EGGDOM sampling program where the Agency conducted the analysis for *Lm* quarterly and at the end of shelf-life on products with shelf-life claims. FSIS will collect samples under its two new project codes.

Egg products plants seeking initial approval to produce extended shelf-life products must **validate** that the production process achieves the shelf-life claimed on the label by gathering data for a minimum of five consecutive production lots. The validation includes the following:

- Results of examination of a minimum of four samples/lot must show that, when properly refrigerated, such products remain wholesome and organoleptically satisfactory through the claimed shelf-life.
- The data, including results of organoleptic evaluations at the end of the shelf-life, must demonstrate that the process achieves the shelf-life stated on the product label; product has tested negative for *Salmonella* and *Lm*

- immediately after packing and has tested negative for *Lm* at the end of the claimed shelf-life.
- The production process for extended shelf-life products must be validated before egg products plants may use the claim on egg products.
- Plants are to make records and other supporting documentation available to IPP upon request.

Alternatively, the plant may have other data available that can perform the function of supporting the process:

- Would include data generated to support the same production process for the same extended shelf-life product using the same equipment, but at a different egg products plant.
- The product may be immediately labeled with a shelf-life claim

Following instruction in Directive 5030.1, IPP are to:

- Verify that the plant has records and supporting documentation demonstrating that the production process achieves the shelf-life claimed on the label of products
- The product will test negative for *Salmonella* and *Lm* immediately after packaging and will test negative for *Lm* at the end of the claimed shelf-life
- Verify that the egg products plant has validated its production process for extended shelf-life egg products prior to the plant using such claim on the products
- Questions and concerns regarding records and supporting documentation, contact your immediate supervisor

Certification Sampling Program

Certification sampling is performed when the official egg products plant specifically requests a lot of product to be certified by FSIS. An official plant may request FSIS certification of lots of egg products to meet requests from a broker, wholesaler, exporter, or to meet specific contract specifications, military shipments, or manufacture of school lunch commodity egg products. This type of sampling is done on a fee for service basis. All costs associated with the sampling and analyses are charged to the official egg products plant requesting certification, including the cost of shipping containers, sampling materials, and shipping fees. The plant is responsible for procuring all of the needed sampling supplies. Inspection personnel are **not** to use sampling supplies received for the FSIS Verification Sampling for samples of this type. Certification involves determining compliance with the specific requirements in a purchase contract, then issuing a contract acceptance certificate verifying compliance. These certification-type examinations include:

- sampling of egg products for official analysis

- certification by USDA of the bacteriological, chemical, and physical characteristics of a specific lot
- additional requirements may also need to be verified by IPP (e.g., labeling, solids content, source of breaking stock)

FSIS IPP is to observe a designated and trained plant employee collect the sample from the specific lot(s). The sample is maintained under FSIS control until it is ready to be shipped. At the time the sample is to be shipped, IPP will complete Form PY-200 (Egg Products Inspection and Grading Certificate - see Figure 5) and include the PY-200 in the sample collection box when it is shipped to the USDA, AMS laboratory in Gastonia, NC for analysis.

Certification samples are only sent to this USDA, AMS laboratory, as FSIS laboratories do not have the ability to bill the plant for the analysis. The USDA, AMS laboratory reports the results of the analysis back to the Inspector on their official laboratory report form. A copy of the PY-200 form will also be returned to the inspector at the origin plant. When egg product is analyzed for the presence of *Salmonella*, this type of certification may be substituted for a surveillance sample if five samples have been selected and analyzed individually.

Residue Sampling Program

FSIS will collect samples of unpasteurized and pasteurized egg products at official egg product breaking plants to analyze at FSIS laboratories for chemical residues of veterinary drugs (including sulfonamides), pesticides, and environmental contaminants (such as arsenics). Unpasteurized egg products samples without added ingredients will be sampled whenever possible. Per FSIS Directive 10,230.3 in plants that combine eggs broken at that plant and at another plant before pasteurization, IPP are to collect the sample from the collection pot in the breaking room. This will ensure the collected sample is representative of only the eggs broken in that plant. IPP are not to collect samples from tankers. The plant employee should always collect the sample from tankers under the observation of IPP. A violation in a production class (food animal or egg product) occurs when a chemical residue is detected and the residue is in excess of an established tolerance or action level.

The Office of Public Health and Science (OPHS) reviews their programs annually and in concert with the Agency needs determines the level of residue sampling that will take place in each egg product sampling category. The Agency will determine, per their risk assessments and other means, what type of testing is needed. The Agency does not have a policy of notifying IPP of these changes. Consequently, the frequency of when a residue sample is requested may vary from year to year.

The collection of samples is directed and will be scheduled from FSIS Headquarters (scheduled sampling) in PHIS. FSIS samples egg products for residues under the project code "NRP_EG." The former Residue Sampling Program was held in abeyance for several years, but in March 2010 the project was last conducted by OPHS with an assigned project code for egg products. The residue testing for egg products was under the **Project Code RM10B** regardless of the egg product specimen collected and submitted for analysis. At that time, egg product samples were only tested for **sulfonamide**.

When warranted, IPP will be collecting and submitting these samples per instructions in FSIS Directive 10,230.3. If IPP have questions about a sampling request that was received or the sampling program, they are to submit their question through askFSIS. The response received will be from the subject matter expert from that program area.

Other Sampling Programs

IPP should be aware of other types of sampling programs that the Agency deems necessary. For example, these programs can be due to a food borne illness outbreak or because FSIS is conducting a nationwide raw liquid egg microbiological baseline survey. In such cases IPP will be receiving an Alert through PHIS with instruction on how to proceed.

Collecting Samples

All samples are to be selected from the finished product container (e.g.; final package). IPP need to verify that the plant always selects their *Salmonella* samples from the finished product container as well. For example, a sample selected from a silo prior to the product being pumped into a tanker is not acceptable. The *Salmonella* samples would have to be collected from the dome of the tanker, which is the finished product container.

Aseptic Sampling

IPP need to conduct sampling aseptically. An aseptic technique implies that you do not add any organisms to the sample when it is collected; it does not imply that the sample is sterile. The purpose of aseptically collecting a sample is to prevent contaminating the sample or the surrounding product/product contact area. It is important to collect a sample aseptically even when the sample is intact (final packaged form). Aseptic procedures are critical to preventing the contamination of the sample before and during sample collection, as well as during storage and transportation. General aseptic sampling procedures, as described in Attachment 1 at the back of this module, are to be followed when collecting FSIS' samples.

Procedures for Collecting Samples

Samples collected are pasteurized liquid, frozen, and dried egg products (FSIS Directive 10,230.3). The day before collecting and shipping the sample (for liquid and frozen samples), place the shipping insulated container and coolant packs in the freezer. IPP are to review all relevant directives, notices, and sampling procedures associated with each sampling verification program and follow the instructions in those documents before collecting the sample.

Note: FSIS Directive 10,210.5 gives instructions to IPP on how to access LIMS-Direct to be able to find information about the box shipping labels associated with each sampling project, and whether the appropriate sampling supplies will be sent automatically by the labs or need to be requested by IPP. All of this information is summarized on the *FSIS Sampling Projects and Supplies* chart which can be reached through the *Supplemental Sampling Info* icon on LIMS Direct homepage.

When collecting the samples it is highly recommended to ship the samples the same day it is collected.

Three more Attachments are located at the end of this module. They describe the methods for collecting specific samples.

Attachment 2 – Sampling liquid egg products (container-intact and -non-intact)

Attachment 3 – Sampling frozen egg products (using a drill or a trier)

Attachment 4 – Sampling dried egg products

The procedures described in the attachments are general. IPP must follow the specific instructions in Directive 10,230.3.

Storing and Shipping Samples

If the sample cannot be shipped to the designated FSIS laboratory on the same day it is collected, then the plant must provide a secure place with an acceptable locking device (USDA lock) for holding samples in the freezer, refrigerated or dry cool (dried samples) area where the integrity of the sample can be maintained during storage. Dried samples to be analyzed for the presence of *Salmonella* and *Lm* must be stored in a cool dry location, but are not to be refrigerated. Follow the storage/shipping instructions according to FSIS Directives.

To prepare the samples for mailing, take the following steps:

- Schedule the appropriate directed sampling task (with the project code number reflected in the task) in PHIS and enter all the sample information in the system. PHIS generates a unique sample collection form number and bar code, which can be printed (FSIS Form 8000-11; relate to Figure 3) and should be submitted with the sample. In addition, PHIS provides questions, which the sample collector must answer as part of the sampling task. (**Note:** you will learn how to schedule a directed sampling task in PHIS during your OJT).
- Seal all official samples, sample form, and shipping containers, according to the instructions in FSIS Directive 7355.1. USDA laboratories will not analyze samples that are not properly sealed.
- Ship samples to the designated lab as soon as possible after collection.
- Do not ship liquid/frozen samples to arrive on weekends or holidays. You can ship dried samples to arrive at any time.
- Make sure that when shipping the FSIS directed samples, you ship them to the lab listed in block 9 of the sample request form (FSIS Form 8000-18; generated in PHIS) and on the pre-addressed label.

When shipping the sample to the corresponding FSIS laboratory:

- Pack the samples (liquid or frozen) with frozen coolant packs in an insulated container that has been cooled. Remove the cold pack from the freezer, place the absorbent pad in the shipping container, and then place the cold pack in the bottom or on one of the sides of the shipping container.
- Place the cardboard separator between the cold pack and the sample jar to prevent the sample from freezing.
- Place the sample (in the zipper lock bag) upright inside the shipper next to the cardboard separator and the cold pack.
- For a **dried** sample, the sample is shipped at room temperature. **Do not** use coolant.
- Place the foam plug on top of the sample jar and press down slightly to secure the contents. Press the foam plug down upon the upright sample container (lid on top) as tight as possible. The foam plug is provided to reduce the risk of damage during transport of the sample. You can use additional packing material if necessary to secure the sample for shipment.
- Place FSIS Form 8000-18 or the PY-200 (if certification sample) in its plastic sleeve on top of the foam plug. Make sure that the forms are signed and have the label codes on it.

The lab will discard samples under the following circumstances:

- sample size is not sufficient for analysis
- sample was leaking when received
- sample was collected outside scheduled time frame
- type of sample submitted does not match the type of sample requested on the sample request form
- sample was sent to the wrong lab
- there is more than one sample per box
- the sample request form is not included with the sample or has been altered
- the sample request form **is not signed by the inspector (NO signature)**, ship date, or collection date

FSIS Actions after a Positive Sampling Result

If a product sample collected by IPP or by the plant tests positive for *Salmonella* or *Lm*, product in the sampled lot is considered to be adulterated (9 CFR 590.420(c)).

Results for all pasteurized egg product samples analyzed for *Salmonella* and *Lm* (if applicable) must be reported to the FSIS IPP immediately upon receipt (§ 590.580(c)), regardless if analysis was performed by a USDA, commercial, or private laboratory.

This includes results for required surveillance, extended shelf-life claims, or any other quality control samples collected by the plant, a receiver, or a buyer. Plant management must make the results of each analysis (including the method used) available to IPP for review after completion of the analyses.

If a sample analysis is not completed by the laboratory, plant management must also notify FSIS IPP. FSIS IPP are to review the laboratory analysis reports and determine the reason the sample analysis was not completed or why the sample was discarded. Should an analysis of “presumptive positive” have been identified in a sample and then the analysis was stopped, FSIS IPP are to report this information through supervisory channels to their supervisor and District Office. When a “presumptive positive” *Salmonella* or *Lm* result is obtained and the analysis is not completed, FSIS policy is to require the lot of product the sample represents to be handled as “positive”.

The plant is to maintain records for **two years** for each production lot of each type of liquid and frozen egg product produced. The records must be available to IPP upon request (§ 590.200). In addition, records for each production lot of heat treated dried albumen shall be maintained for **one year** as per § 590.575 (d).

The plant is responsible for maintaining a record of all surveillance samples. On a routine basis (e.g., promptly upon receipt of laboratory results), the plant provides this information to IPP for all products produced. In addition, IPP are responsible for verifying the completion of the company’s records on a routine basis for compliance with regulatory requirements and are to document this activity in PHIS using the appropriate routine verification task.

***Salmonella* and/or *Lm*-Positive Products**

A specific lot or a day's production of a given product is considered *Salmonella* or *Lm*-positive when one or more samples are found to be *Salmonella* or *Lm*-positive by any laboratory.

- If the product is in the plant or under the company's control, retain the product using the "U.S. Rejected/Retained" tag until the product is reprocessed, tested, and found negative for both *Salmonella* and *Lm*, or until the plant condemns the product. The use of the retain/reject tag in this situation is to maintain control of the affected product. Using "U.S. Rejected/Retained" tags ensures that the product does not accidentally move in commerce since it is usually fully labeled and bears the USDA Mark of Inspection. *Salmonella* and *Lm*-positive product should always be controlled using a "U.S. Rejected/Retained" tag.
- When product is shipped from the plant, prior to receipt of laboratory result, shipments shall be made under circumstances which will assure the return of the product to the plant for reprocessing, relabeling, or under such other conditions as determined by FSIS (§ 590.504(d)). If the plant has not notified the receiving company that laboratory results were pending at time of shipment, and the product has been used or incorporated into another further processed food, the plant is in violation of the Egg Products Inspection Act (EPIA).
 - If the product has been shipped from the plant prior to completion of the laboratory analyses and is no longer under plant control, IPP and plant management are responsible for the following:
 - IPP are to request plant management to take immediate action to locate the affected product and return it to the origin plant.
 - Plant management is to inform IPP about the location of the affected product, make arrangements to remove the product from

commerce, and take appropriate action concerning the adulterated product.

- Plant management is to inform IPP of the arrangements made to take action.
- IPP are to notify their supervisor by telephone and e-mail of the *Salmonella* or *Lm*-positive test result and the action taken by the plant's management, including the location of the affected product.
- When adulterated egg products have been shipped in commerce, and the plant no longer has control of those products, IPP are to notify their supervisor and District Office (DO). The DO will notify FDA, so that a recall can be initiated.

Note: All egg products that have left the control of the official egg products plant and are in commerce fall under the joint jurisdiction of FSIS and FDA.

- o IPP need to also verify that the plant is in compliance with 9 CFR § 590.504(d), which states: "*The inspector may, prior to receipt of laboratory results for Salmonella, or for other reasons such as labeling as to solids content, permit egg products to be shipped from the official plant when he has no reason to suspect noncompliance with any of the provisions of this part. However, such shipments shall be made under circumstances that will assure the return of the product to the plant for reprocessing, relabeling, or under such other conditions as the Administrator may determine to assure compliance with this part.*"

When a lot of egg product is identified as *Salmonella* or *Lm*-positive, an investigation into the cause of the positive must be conducted by plant management and verified by the FSIS inspection team. Following notification that a lot of egg product is *Salmonella* or *Lm*-positive, IPP are to:

- Review the cause of the positive with the plant's management and discuss any problem in detail.
- Review FSIS records and the plant records associated with the affected lot and review any notes, procedures, and processing records (i.e., pasteurization charts, formulation records, packaging records, etc.) for the production date of the product. Look for unusual events during processing that may be a potential cause of initial contamination or recontamination.

- During the next weekly meeting document the results of the investigation in a Memorandum of Interview (MOI) following instructions delineated in directives 5030.1 and 5010.1. In the MOI, IPP are to include details on:
 - The affected product type, lot number, and quantity of containers in the affected lot(s)
 - The disposition of the affected product
 - If the FLS has been notified about the *Salmonella* or *Lm* positive product
 - A description of any conditions and/or additional information that the IPP found that could have contributed to the positive product.
 - The results of the plant's investigation into the probable cause and actions taken to correct the situation that triggered the positive result. If the plant does not conduct an investigation or does not provide IPP with results of the investigation, then IPP are to make a statement to this effect, notify the FLS, and **issue a Noncompliance Record (NR)** under 9 CFR 590.220, 590.420(c) and 590.422; and
 - The plant's proposed corrective measures.
- Ensure that the plant maintains a log of all affected product (for tracking purposes) of the initial number of containers affected, the lot number, and type of product (size, container type, how it is labeled). As the plant re-pasteurizes the *Salmonella* or *Lm*-positive product into new lots of egg product, the amount of egg product re-pasteurized is then deducted from the total, until the entire lot has been reprocessed and tested for *Salmonella* and *Lm*. Depending on the type of product, a plant may choose to re-pasteurize the entire lot at one time (100%), reconstitute and re-pasteurize, mix with other products and re-pasteurize, or leave in the heating room (dry egg whites) for additional time.

Note: More than one lot of egg products may be affected when a *Salmonella* or *Lm*-positive result is reported. If the plant did not have a complete clean up between pasteurization runs (e.g., the pasteurizer, all common product lines to the packaging room, and the packaging/filling equipment) then more than one lot of product may be impacted. All affected product would be considered positive, and would need to be re-pasteurized, tested, and found negative for *Salmonella* and/or *Lm* prior to being eligible for release into commerce.

In addition, FSIS inspectors need to be aware that some plants may pasteurize more than one pasteurization run (lot of product) into one pasteurized egg product silo without conducting a cleanup between lots. When this occurs, both lots of product would be considered to be positive because they are now co-mingled in one silo.

When reprocessing *Salmonella*- and/or *Lm*-positive product, either as a lot by itself or with other liquid, the plant must sample the resulting pasteurized egg product under the *Salmonella* Surveillance Sampling program and find it *Salmonella*- and *Lm*-negative before releasing it into commerce. This means that a minimum of 5 samples, selected from throughout the lot, must be selected from the final package, and then analyzed individually and found *Salmonella*- and *Lm*-negative.

Documenting Noncompliances

IPP are to refer FSIS Directive 5030.1 when verifying that the egg products plant meets food safety and regulatory requirements to ensure that products are not adulterated. IPP are to consider the following when issuing noncompliances:

1. If FSIS finds the product positive, and the plant tested the product under its documented sampling programs, IPP are to check the plant's *Salmonella* or *Lm* testing results to determine whether the plant also found the sampled product to be positive for *Salmonella* or *Lm*.
2. IPP are to determine whether the plant held the product or maintained control of the product (e.g., the plant moved the product off-site or released it into commerce under the plant's control) pending its own test results.
3. If IPP find that the plant did not hold or maintain control of the product, they are to issue an NR. The NR would be warranted because the plant shipped product before FSIS found the product was not adulterated, and because the plant did not have in place appropriate controls to release the product into commerce prior to receipt of laboratory results for *Salmonella* or *Lm* as set out in 9 CFR 590.504(d).
4. Generally, if FSIS finds the product positive for *Salmonella* and the plant also found the product to be positive for *Salmonella* and held the product, IPP are to not issue an NR but retain the product using a "U.S. Rejected/Retained" tag as previously discussed. They are to verify that the plant performs the appropriate corrective measures in accordance with 9 CFR 590.504(o)(1).
5. If FSIS finds the product positive for *Lm*, IPP are to verify that the plant performs the appropriate supportable corrective measures, similar to what would be done for *Salmonella* positive samples, in accordance with 9 CFR 590.504(o)(1). For example, reprocessing and repasteurizing the product following the time/temperature parameters of 9 CFR § 590.570 – Table 1 might not sufficiently address *Lm* (i.e., salted egg yolk) and therefore the plant needs to perform appropriate measures, providing supporting documentation, to make the product unadulterated.

NOTE: If the plant finds a positive for *Salmonella*, the plant must report it to IPP as per 590.580(c). Failure to immediately notify IPP of the positive result is a noncompliance; however, the positive result by itself is not a noncompliance. This can apply to *Lm*, if the plant includes *Lm* under its surveillance testing program. If the plant does not include *Lm* in its surveillance program and the Agency finds a positive, then IPP can issue an NR, citing 590.420(c) or 590.422.

The plant may also elect to reprocess the product to bring the product back into compliance (found to be not adulterated as per 590.422). Please refer to Figure 1 from FSIS Directive 10,230.3, a Flow Diagram for Egg Products sampling.

Reporting FSIS Sample Results

Positive results are communicated via Alerts in PHIS and the sample history is posted in PHIS as well.

Positive and negative sample results are also tracked and posted in the Laboratory Information Management System, (LIMS)-Direct. IPP may access LIMS-Direct on FSIS computers, via FSIS Applications, Internet-Intranet, LIMS Direct. LIMS-Direct is a service that provides sample status and analysis result information for samples submitted to FSIS laboratories. Data is updated every 15 minutes.

Information reported in LIMS-Direct includes:

- Collection Date
- Sample Form number
- LIMS Number
- Whether product is held, as specified in the sample form
- Status of analysis
- Result
- Last Update

Egg products plants may get individual sample results via e-mail if their e-mail addresses are entered into PHIS. The IIC should still inform the plant of the results he or she obtains from LIMS-Direct or PHIS. Additionally, FSIS posts quarterly summaries of aggregate establishment set results on its website as an indicator of nationwide trends.

Sampling of Egg Product Produced from Shell Eggs Diverted under the FDA's – Prevention of *Salmonella* Enteritidis in Shell Eggs – Final Rule (2009) or When a Heightened Food Safety Risk is Identified

FSIS IPP need to be aware that other types of situations may occur where by the finished egg product may be required to be sampled, and the lot held, and found *Salmonella* negative prior to being released into commerce (hold and test). It is important for inspection personnel to understand that IPP are not required to release egg products into commerce prior to the receipt of laboratory results for *Salmonella* even if they have no reason to suspect noncompliance with any

provisions of the egg products inspection regulations (9 CFR § 590.504(d)). Therefore, IPP are to hold all lots of egg products produced from shell eggs or egg products identified in the list below.

A complete discussion of the circumstances, which require finished egg product to be held and tested, as well as the verification responsibilities of the IPP, is found on **Attachment 7** of this module.

Reference: 21 CFR Parts 16 and 118, Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation; Final Rule, July 9, 2009

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Eggs/ucm170615.htm>

Figure 1 – Statutory and Regulatory Requirements

The Egg Product Inspection Act (EPIA) of 1970 requires the mandatory inspection of the processing of liquid, frozen, and dried egg products. Section 2 (21 U.S.C. 1031) of the EPIA states, “Eggs and egg products are an important source of the Nation’s total supply of food, and are used in various forms... It is essential, in the public interest, that the health and welfare of consumers be protected by the adoption of measures prescribed herein for assuring that eggs and egg products...are wholesome, otherwise not adulterated, and properly labeled and packaged.”

According to the 9 CFR Part § 590 regulations, pasteurized egg products shall be sampled and analyzed for the presence of *Salmonella*. Following are the regulatory requirements with which the plant must comply:

§ 590.200 Records and related requirements.

- (a) *(a) Persons engaged in the transporting, shipping, or receiving of any eggs or egg products in commerce, or holding such articles so received, and all egg handlers, except producer-packers with an annual egg production from a flock of 3,000 layers or fewer, must maintain records documenting, for a period of 2 years, the following, to the extent applicable:*
- (1) The date of lay, date and time of refrigeration, date of receipt, quantity and quality of eggs purchased or received, and from whom (including a complete address, unless a master list is maintained). Process records documenting that the temperature and labeling requirements in 590.50(a) have been met must also be kept;*
 - (2) The date of packaging, ambient air temperature surrounding product stored after processing, quantity and quality of eggs delivered or sold, and to whom (including a complete address, unless a master list is maintained);*
 - (3) If a consecutive lot numbering system is not employed to identify individual eggs, containers of eggs, or egg products, record the alternative code system used, in accordance with § 590.411(c)(3);*
 - (4) The date of disposal and quantity of restricted eggs, including inedible egg product or incubator reject product, or given away for animal food or other uses or otherwise disposed of, and to whom (including a complete address, unless a master list is maintained);*
 - (5) The individual or composite (running tally) record of restricted egg sales to household consumers. Records should show number of dozens sold on a daily basis. The name and address of the consumer is not required;*
 - (6) The date of production and quantity of egg products delivered or sold, and to whom (including a complete address, unless a master list is maintained);*

- (7) *The date of receipt and quantity of egg products purchased or received, and from whom (including a complete address, unless a master list is maintained);*
- (8) *The production records by categories of eggs such as graded eggs, nest-run eggs, dirties, checks, etc.; bills of sale, inventories, receipts, shipments, shippers, receivers, dates of shipment and receipt, carrier names, etc.*
- (b) *All records required to be maintained by this section must be made available to an authorized representative of the Secretary for official review and copying.*
- (c) *Records of all labeling, along with the product formulation and processing procedures as prescribed in §§ 590.410 through 590.412, must be kept by every person processing, except processors exempted under § 590.100.*

§ 590.504(d) General operating procedures. *The inspector may, prior to receipt of laboratory results for Salmonella, or for other reasons such as labeling as to solids content, permit egg products to be shipped from the official plant when he has no reason to suspect noncompliance with any provisions of this part. However, such shipments shall be made under circumstances, which will assure the return of the product to the plant for reprocessing, relabeling, or under such other conditions as the Administrator may determine to assure compliance with this part.*

§ 590.504(o)(1) General operating procedures. *To assure adequate pasteurization, egg products shall be sampled and tested for the presence of Salmonella. Sampling for the presence of Salmonella shall be in accordance with § 590.580 and product found to be Salmonella positive shall be reprocessed, pasteurized and analyzed for the presence of Salmonella, or denatured.*

§ 590.580 Pathogen reduction standards testing.

- (a) *Official plants must test to determine that the production of egg products is in compliance with the Act and the egg products inspection regulations.*
- (b) *To ensure adequate pasteurization:*
- (1) *Pasteurized liquid, frozen, and dried egg products, and heat treated dried egg whites must be sampled and analyzed for the presence of Salmonella spp. Such testing by the official plant must be performed in a manner sufficient such that it is possible for the official plant to verify that the system is capable of eliminating Salmonella spp. at the time that the annual reassessment occurs, and as regularly as necessary between annual reassessments, to show that the system, when tested, is working.*
 - (2) *Samples must be analyzed for the presence of Salmonella spp. with such frequency and using such laboratory methods as is sufficient to ensure that product is not adulterated. For each category of product, sampling should be conducted on a rotating basis.*
 - (3) *Samples must be drawn from the final packaged form.*

(c) Results of all partial and completed analyses performed under paragraph (b) of this section must be provided to inspection program personnel promptly upon receipt by the official plant. Positive test results must be provided to inspection program personnel immediately upon receipt by the official plant.

Figure 2 – Definition of a Product Lot



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

January 17, 2001

Mr. Al Pope
President
United Egg Association
Suite 200
1303 Hightower Trail
Atlanta, GA 30350

Dear Mr. Pope:

I am responding to your December 11, 2000, letter regarding a recently issued Food Safety and Inspection Service (FSIS) memorandum titled Definition of a Production Lot. The memorandum, which was issued on November 9, 2000, was intended to clarify what constitutes a separation or complete physical break between lots of egg products for the purpose of establishing separate lots. The memorandum was targeted to a specific set of conditions, specifically, a one step rinse and sanitizing application. This letter more fully describes what the Agency will consider as a complete physical break between lots of egg products when performing this verification activity.

Regulatory requirements pertaining to establishments producing egg products requires each company to maintain a defined procedure for the identification of a production lot in their Salmonella Surveillance Program. To distinguish a pasteurization run as an individual lot, the egg product must be processed and packaged using sanitized equipment. As you pointed out, egg products plants usually achieve this physical separation by flushing the pasteurizer with cold water, followed by a sanitizer, followed by another cold water flush. If this procedure is used, however, it is essential that all equipment, including the packaging system, liquid storage tank(s), and the common pipelines between the pasteurizer and the packaging equipment, be cleaned and sanitized between each lot, not just the pasteurizer. Note that FSIS is *not* requiring plants to perform a cleaning in place procedure between each lot of production. As indicated in the November 9, 2000, memorandum, however, if egg products are stored or packaged using common pipelines and equipment that has not been effectively cleaned and sanitized prior to establishing another individual lot, FSIS cannot recognize the resulting production as a physically separated lot.

Egg products plants using the clean and flush process described above must also have data demonstrating its effectiveness. In accordance with 9 CFR 590.552(b)(ii), the concentration of the sanitizing solution used in the clean and flush process must contain a maximum strength of 200 p.p.m. The solution must be changed whenever its strength drops to 100 p.p.m. or less.

Note that FSIS will also be developing inspection program personnel verification activities for the cleaning and sanitizing procedure discussed in the November 9, 2000, memorandum. I hope this letter clarifies the intent of that memorandum. If you have further questions, feel free to contact to me.

Sincerely,

/s/Wm. C. Smith 1/17/2001

William C. Smith, Assistant Deputy Administrator
District Inspection Operations
Office of Field Operations

cc: K. Klippen
R. Green

ecc: M. Mina
J. McCutcheon
J. Riggins
K. Henderson
P. Thompson
District Managers
V. Levine
J. Carlson
R. Glasshoff
M. Thibodeaux
S. Hasiak
D. Wagner
M. Lathrop

Figure 2 - picture of letter

Figure 3 – FSIS Form 8000 – 18 Generated by PHIS

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

SAMPLE ANALYSIS REQUEST FORM

Form ID:

Place
Sample Seal
Label Here



-- For Lab Use Only --

COLLECTION INFORMATION

1. SAMPLE FORM ID: <input type="text"/>	7. ESTABLISHMENT ID: <input type="text"/>
2. PROJECT CODE: <input type="text" value="EGG_LQ_MIC01"/>	8. ESTABLISHMENT NAME: <input type="text"/>
3. SAMPLE SOURCE: Pasteurized Eggs-Whole < 2% added ingredients other than salt or sugar-Whole	9. COLLECTION DATE: 10/11/2016
4. ANALYSIS: Salmonella & L. monocytogenes	10. SHIPMENT DATE: 10/11/2016
	11. COLLECTOR NAME: <input type="text"/>
	12. COLLECTOR PHONE: <input type="text"/>
5. ASSIGNED LAB: Eastern Laboratory (Athens,GA)	
6. DISTRICT/CIRCUIT: 25 - Des Moines, IA / 2529	

PRODUCT INFORMATION

13. PRODUCT NAME: Pasteurized Frozen Whole Eggs With Citric Acid
14. PRODUCTION DATE: 10/11/2016
15. LOT NUMBER: 235-020
16. IS PRODUCT HELD: Yes
17. COLLECTION REMARKS:
18. QUESTIONNAIRE (if applicable)
1. Is sample submitted in a final, intact package? <input type="checkbox"/> NO
2. Was plant management notified of sample collection? <input type="checkbox"/> YES

SIGNATURE: _____ TITLE: _____ DATE: _____

FOR LABORATORY USE ONLY

Date Received	Analyst Code	Receipt Temperature	Not-Analyzed Code	Not-Analyzed Explain

PAGE 1 OF 1
FSIS FORM 8000 - 18 (12/17/12)

Picture of Form 8000-18

Figure 4 – Egg Products Sampling Categories

Project Number	Examples of product to Sample	Types of product Included
EGG_LQ_MIC01	Egg Whites with or without added ingredients	<ul style="list-style-type: none"> -Plain Egg whites -Egg whites with added ingredients
EGG_LQ_MIC01	<p>Whole Eggs (with less than 2% added ingredients other than salt or sugar), or</p> <p>Yolks (with less than 2% added ingredients other than salt or sugar)</p>	<ul style="list-style-type: none"> -Plain whole egg (natural proportion or standardized) -Plain Yolk -Whole eggs with less than 2% added ingredients other than salt or sugar -Yolk with less than 2% added ingredients other than salt or sugar
EGG_LQ_MIC01	Whole Eggs with added yolks, or Whole egg Blends (with more than 2% added ingredients other than salt or sugar)	<ul style="list-style-type: none"> -Whole Eggs with added yolks, -Whole egg blends (whole eggs, egg whites, and/or yolks – no other ingredients) -Whole egg blends with more than 2% added ingredients other than salt or sugar <ul style="list-style-type: none"> -whole eggs and yolks, with more than 2% added ingredients other than salt or sugar, or -whole eggs and whites, with more than 2% added ingredients other than salt or sugar, or - whole eggs, yolks and whites with more than 2% added ingredients other than salt or sugar
EGG_LQ_MIC01	Whole Eggs (with more than 2% salt or sugar added), or Yolks with more than 2% salt or sugar added)	<ul style="list-style-type: none"> -Whole egg with more than 2% salt or sugar added (e.g., 10% salted whole egg, 10% sugared whole egg) -Yolk with more than 2% salt or sugar added (e.g. 10% salted yolk, 10% sugared yolk)
EGG_DY_MIC01	Dried Yellow Egg Products	<ul style="list-style-type: none"> -Dried whole egg -Dried whole egg blends -Dried yolk -Dried yolk blends <p>Note: All types would be either with or without added ingredients</p>

EGG_DY_MIC01	Dried Egg Whites (with or without added ingredients)	-Dried egg whites (with or without added ingredients)
EGG_DY_MIC01	Pan Dried Egg Whites	-Pan Dried Egg Whites

Table describing sampling categories

Figure 5 – FSIS PY-200 Form: Egg Product Inspection and Grading Certificate

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) May Break Easy 1234 Egg Rd Anywhere, USA 12345			PLACE INSPECTED, SAMPLED, OR WEIGHED Same as applicant									
NAME AND ADDRESS OF SHIPPER OR SELLER Same as applicant			APPLICANT/PLANT NO. ABC	PLACE ISSUED Des Moines, IA								
NAME AND ADDRESS OF RECEIVER OR BUYER USDA, Agency XYZ, Eggsville, MN 55555			KIND OF PACKAGE 48/6oz. pouches/corrugated fiber master container - Pasteurized									
			TYPE OF PRODUCT Dried All purpose Egg Mix									
			PACKAGES IDENTIFIED WITH (Shield, plant no., etc.) USDA Shield, Plant ABC									
ORGANOLEPTIC INSPECTION				WEIGHING REPORT								
LOT NUMBER	DATE MANUFACTURED	NO. OF PACKAGES IN LOT	NO. OF PACKAGES EXAMINED	ORGANOLEPTIC CONDITION		Type Grading (O or P)	TOTAL MARKED WEIGHT	TEST SHORTAGE	TOTAL NET WEIGHT			
2362 Z-1	12-28-08	604	Continu- ous During Processing	All	None	0	10,872					
Gov. Contract - Request for Analysis												
LABORATORY ANALYSIS												
LOT NUMBER	TOTAL SOLIDS	MOISTURE	STANDARD PLATE COUNT PER GRAM	COLI-FORMS PER GRAM	YEAST PER GRAM	MOLD PER GRAM	FAT	pH	SALMONELLA	STAPHYLOCOCCUS	E. COLI	PALATABILITY
REMARKS												
Contact Number: 123-456-7890, Analysis in accordance with Announcement PY-260 dated Nov 2002. Analyze for moisture, standard plate count, Coliform, Salmonella and palatability. Inside container sealed with USDA seal number: USDA-A PY-118819												
INSPECTOR			CERTIFICATION STATEMENT				CHEMIST					
F/S	UNITS	RATE CODE	AMOUNT		In compliance with the Regulations of the Secretary of Agriculture Governing the Inspection of Eggs and Egg Products (7 CFR Part 55) 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 55), issued pursuant to the Agricultural Marketing Act of 1946, as amended, and any other Act of Congress conferring like authority, it is certified that the product(s) listed hereon were examined (product(s) at the time and on the date 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.				UNITS	RATE CODE	AMOUNT	
			DOLLARS	CENTS					DOLLARS	CENTS		
	EXPENSE											
	EXPENSE											
	TOTAL		Resident									
INSPECTOR (Signature)			DATE	CHEMIST (Signature)			DATE	ADDRESS				
Leghorn Hen			12-29-08									

Picture of PY-200 Form

Sampling Aids

Attachment 1 – Aseptic Sampling Techniques

Aseptic sampling techniques can be successfully accomplished if strict attention is paid to the following steps:

1. Collect samples in areas that meet the processing room requirements and have air filtration systems.
2. Clean and sanitize work surfaces. Allow sanitizer (100-200 ppm hypochlorite solution) to contact the work surfaces for enough time to ensure sanitization.
3. Ensure that equipment used to collect and manipulate samples (spoons, cups, ladles, and tins) is clean and sanitized (sterile where applicable).
4. Properly label sample containers **before** sampling. Protect sampling instruments from cross contamination at all times and ensure sample container cleanliness during sampling.
5. Use an appropriate sample container for each type of sample. Containers should be dry, leak proof, wide mouthed, and of a size suitable for the samples.

Table 1

Sample	Container
Whole liquid egg	Sterile Cup
Liquid egg whites/yolks	Sterile Cup
Dried eggs	Sterile Whirl-pack bag
Frozen	Sterile Cup

Table - containers for samples

6. Wear a clean lab coat and a hair net to avoid contamination.
7. Wash hands to the mid forearm and sanitize. Sterile gloves must be worn while collecting samples. A step-by-step procedure for putting on the gloves can be found at http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/Salmonella_Analysis.pdf. The only items that should contact the external surface of the sterile glove on your sampling hand are the sample being collected and the sterile sampling utensil. Remember that the outside surfaces of the sample container are not sterile. Maintain glove sterility once gloves are on. Dispose of the gloves appropriately after use.
8. Follow the sample protocol and maintain aseptic practices when collecting and handling the sample to ensure the identity of the sample. Be sure to maintain the same conditions as when the sample was collected.

9. Organoleptically examine the product prior to sampling. **Do not** sample product that is not organoleptically satisfactory. If organoleptic examination determines the product is not satisfactory, take appropriate regulatory action.
10. Before collecting the sample, sanitize the outside covering of the immediate sterile sample container. Collect all samples in clean, sterile containers.
11. When collecting samples in a container with a lid, open the container sufficiently to place the sample directly in the container. Hold the lid and container in one hand while collecting the sample and do not hold the sample container directly over the container being sampled while filling.
Note: The lid should **NOT** be completely removed (held separately or placed on a counter)
12. Fill the sample container no more than 3/4 full to prevent overflow.
13. Seal the sample container immediately after placing the sample in the container. Secure screw-on or snap-on lids of filled containers with tape to prevent leakage while the sample is in transit to the lab.
14. When using plastic bags as sample containers, expel the air when sealing.
15. Store collected samples properly, under the storage conditions below, to maintain integrity.

Table 2

Sample type	Storage Conditions
Frozen egg or egg whites	Frozen
Liquid egg whites	Refrigerated
Dried eggs	Room temperature/ cool dry place

Table - storage of samples

16. Ship samples to the laboratory promptly. Keep the temperature of perishable material between 32 and 40 °F. Use sealed coolant packs to avoid contamination from melting ice.

Attachment 2 – Aseptic Sampling of Liquid Egg Products

1. Randomly select a sampling time. When collecting a sample, notify plant management. IPP must collect samples from finished product container (in its final packaging).
2. Inform the plant management that the product must be placed on hold or the plant must maintain control of the product until the sample results are deemed acceptable.
3. Discuss the plants lotting procedures and determine the amount of notice that the plant will need prior to sample collection. FSIS allows plants to define the lot size of their egg products.
4. IPP are to collect the sample aseptically. Instructions on performing aseptic sampling are provided in [IPP Help](#) (Start Menu--FSIS Applications--IPP Help) under the “Sampling” tab--“Aseptic Sampling” tab. Also refer to FSIS Notice 22-20, FSIS Directives 7355.1 and 13,000.2.
5. IPP are to examine the product organoleptically prior to sampling it and are not to sample product that is found unsatisfactory. Unsatisfactory product includes product that is off-condition (e.g., it contains shell particles, meat, or blood spots) or has an off-odor.
6. When collecting samples in final packaging of five pounds or less (e.g., consumer-ready packages, cartons), IPP must wash and sanitize hands, and randomly select the required number of final packages to achieve a minimum of 200 mL of product.
7. When collecting samples from final packages greater than five pounds, IPP must wash and sanitize hands, and have the plant short-fill or slack-fill packages in plant-supplied packaging to achieve a collection of 200 mL of product.
8. When collecting samples not in consumer-ready packaging (e.g., bulk packaging such as totes), IPP must:
 - If possible, collect the sample directly from the valve as it pours into the bulk packaging;
 - If not possible, then select the bulk package for sampling;
 - Gather sampling supplies and proceed to the sampling area;
 - Aseptically open the bulk package by using a sanitized lid removal tool;
 - Prepare the sample container and utensils; and
 - Fill the two sample jars no more than $\frac{3}{4}$ full (~ 100 mL in each sample jar for a total volume of 200 mL) to prevent overflow. Immediately close and

- seal the sample jar after collecting the sample, taking care to ensure a tight seal of the sample jar.
9. IPP should not collect sample from tanker. When plant employees must always collect samples from a tanker (this type of sample collection is taken when pasteurized egg products are shipped to another official plant for further processing), IPP are to:
 - Gather sampling supplies and proceed to the tanker bay location; and;
 - Observe the plant employee aseptically collect the sample (two sample jars to achieve a total volume of 200 mL) from the tanker and hand the sample to IPP.
 10. After collecting the sample, store it appropriately. Pre-cool chilled products to 2.0°C prior to shipment.
 11. Complete the sample task in PHIS and ship the sample as per instructions in FSIS Directives 7355.1 and 13000.2.
 12. IPP are to review the test results and inform the plant of the results upon receipt.

Attachment 3- Aseptic sampling of frozen egg products

1. Randomly select a sampling time. When collecting a sample, notify plant management.
2. Inform the plant management that the product must be placed on hold or the plant must maintain control of the product until the sample results are deemed acceptable.
3. Discuss the plants lotting procedures and determine the amount of notice that the plant will need prior to sample collection. FSIS allows plants to define the lot size of their egg products.
4. IPP are to collect the sample aseptically. Instructions on performing aseptic sampling are provided in [IPP Help](#) (Start Menu--FSIS Applications--IPP Help) under the "Sampling" tab --"Aseptic Sampling" tab. Also refer to FSIS Notice 22-20, FSIS Directives 7355.1 and 13,000.2.
5. IPP are to examine the product organoleptically prior to sampling it and are not to sample product that is found unsatisfactory. Unsatisfactory product includes product that is off-condition (e.g., it contains shell particles, meat, or blood spots) or has an off-odor.
6. If possible, collect the sample during the packaging process and before freezing (while the product is still in liquid form). If this is not possible, try to collect either a final five-pound package or a smaller final size package.
 - If it is not possible to collect a liquid sample during packaging and before freezing or to collect a final package five pounds or less, then select a bulk package for sampling:
 - Take sampling supplies and bulk package into the sampling area;
 - Aseptically open the bulk package by using a sanitized lid removal tool;
 - Prepare the sample jar and utensils; and
 - Remove gloves, wash and sanitize hands again, and put on a new pair of gloves; remove the sampling utensils from the wrapper or sanitizer solution.
7. IPP are to collect two sample jars. When filling the jars with frozen egg product, both jars will need to be packed down tightly and with no free space at the top. Filling the jars completely to the top will compensate for the decrease in volume that occurs when the product thaws and will ensure enough product is available to conduct the laboratory analyses.

- 8.** When collecting frozen egg product samples using a drill, a designated plant employee will drill the product with a sanitized drill bit and the inspector will aseptically collect shavings and place them into the sample containers. IPP are to:
 - Designate where the sample is to be collected, ensuring that the sample will not be collected through the hump that is created due to the freezing process;
 - Observe plant personnel use a sanitized spoon to remove all frost and ice crystals from the top of the frozen unit to be sampled;
 - Observe plant personnel drill at approximately a 45-degree angle, starting near the edge of the container;
 - Verify that plant personnel drill down to within 1 inch of the bottom of the container or, for large containers, as far down as the drill bit can safely go without causing potential product contamination;
 - Ensure that the shavings do not touch any part of the container that may have been previously exposed to potential contamination;
 - Ensure that the plant's drill operator does not spin the drill at high speed, in the hole, to prevent heating of the sample; and remove gloves, wash and sanitize hands again, and put on a new pair of gloves. IPP are to collect the shavings while wearing gloves, which have not been used to collect any prior samples and have not made contact with any previous surfaces or product.
 - Collect the shavings that are produced from the drillings, packing the shavings down to ensure that the jar is filled, leaving no free space at the top of the jar. IPP should organoleptically examine product.
 - Keep sample frozen at all times.

- 9.** Keep the sample frozen at all times.

- 10.** When collecting egg product samples that do not freeze solidly enough to be drilled, e.g., salted or sugared product, IPP are to use a trier (shown at right). A trier is a tapered plug sampler. As the trier is twisted into the product, the trough collects a plug of product. IPP are to insert the sanitized trier fully into the product and twist rapidly to collect the sample. Aseptically remove the product sample from the trier by scraping the plug from the trier with a sanitized spoon (not included with the sample supplies) and placing it into a sample container.

- 11.** Complete the sample task in PHIS and ship the sample as per instructions in FSIS Directives 7355.1 and 13000.2.

- 12.** IPP are to review the test results and inform the plant of the results upon receipt.

Attachment 4- Aseptic sampling of dried egg products

1. Randomly select a sampling time. When collecting a sample, notify plant management. IPP must collect samples from finished product container (in its final packaging)
2. Inform the plant management that the product must be placed on hold or the plant must maintain control of the product until the sample results are deemed acceptable.
3. Discuss the plants lotting procedures and determine the amount of notice that the plant will need prior to sample collection. FSIS allows plants to define the lot size of their egg products.
4. IPP are to collect the sample aseptically. Instructions on performing aseptic sampling are provided in [IPP Help](#) (Start Menu--FSIS Applications--IPP Help) under the "Sampling" tab--"Aseptic Sampling" tab. Also refer to FSIS Notice 22-20, FSIS Directives 7355.1 and 13,000.2.
5. Select dried product in final packages for sampling;
6. If a final package is not available, then select a bulk package for sampling. Samples are to be collected during packaging, when possible;
7. Take the sampling supplies and bulk package into the sampling area;
8. Ensure that the sampling area is free of dust and moisture;
9. Aseptically open the product package and pull back the liner;
10. Remove gloves, wash and sanitize hands again, and put on a new pair of gloves; remove the sampling utensils from the wrapper;
11. Open the sterile Whirl-Pak[®] bags and set aside. Use a sterile scoop;
12. For yellow egg products, collect product from different locations in the top portion of the package;
13. For white egg products, use a sterile scoop to move product aside and select product from the center of the package; and
14. Fill sterile Whirl-Pak[®] to above the fill line (approximately 150 grams per each bag). Carefully shake the sample to the bottom and expel the excess air from the sample bag. Fold over the top edge and secure it with the attached wire.
15. After collecting the sample, store it appropriately in at room temperature in a cool dry place.

16. Complete the sample task in PHIS and ship the sample as per instructions in FSIS Directives 7355.1 and 13000.2.

17. IPP are to review the test results and inform the plant of the results upon receipt.

NOTE: Dried yellow egg products and dried white egg products are sampled differently due to the differences in how they are processed. Dried yellow egg products are pasteurized uniformly and then dried. Dried white egg products are heat-treated in a box, with the center portion being heated up last.

Attachment 5 – Overview of Egg Products Sampling Programs

- 1. Salmonella Surveillance Sampling Program:** Required by regulation to be conducted by each Official Egg Products Plant (9 CFR § 590.580(a), (b), (c)).

Program Summary: Each plant is required to select samples from the lots of pasteurized egg products that they produced and determine the lots negative for the presence of *Salmonella* before that product is eligible to move in commerce. Plants that can demonstrate a history of compliance by producing *Salmonella* negative product can reduce the number of lots sampled for liquid and frozen product. FSIS has established a program that sets forth the level, frequency and number of samples that have to be analyzed for liquid and frozen egg products. All dried egg products must be tested at 100%; there is no reduced sampling permitted for dried egg products.

Laboratory Conducting Analysis: *Each plant may continue to send its samples to a laboratory that is registered under the FSIS Pasteurized Egg Products Recognized Laboratory (PEPRLab) Program. The laboratory may be company owned (located on or off site) or the plant may contract with a third party laboratory. For the Salmonella Surveillance Sampling Program, a plant may use an approved PEPRLab to analyze egg products samples.*

- 2. FSIS Microbiological Testing Program for Pasteurized Egg Products:**
This FSIS program samples and tests pasteurized egg products to determine if egg products plants are adequately pasteurizing egg products as required by 9 CFR § 590.570 and 575 and the Egg Products Inspection Act (EPIA) (9 CFR § 590.580(d)).

Program Summary: Under the Microbiological Testing Program for Pasteurized Egg Products, FSIS collects and analyzes samples of pasteurized egg products for the presence of salmonellae and *Listeria monocytogenes (Lm)*. By testing for the presence of salmonellae and *Lm* in pasteurized egg products, this program verifies the efficacy of each egg products plant's *Salmonella* surveillance program and enhances public health protection against pathogens associated with pasteurized egg products. All amenable egg products (pasteurized liquid, frozen, and dried egg products) are tested under the FSIS Microbiological Testing Program. Under the program, egg products are classified into two product categories. FSIS inspection program personnel collect samples monthly from each product category produced by the plant. Samples are submitted to one of three FSIS Field Service Laboratories for *Salmonella* and *Lm* analysis. The categories of product are as follows:

FSIS samples egg products for microbiological contamination (Salmonella and Lm) under two sampling codes. The project code “EGG_LQ_MIC01” pertains to frozen and liquid pasteurized egg products. The project code “EGG_DY_MIC01” pertains to dried egg products. Each month, samples are assigned based on the plant’s monthly production volume(calculated fromthe average daily production and days of production provided in the Public Health Information System (PHIS) Establishment Profile). If a plant produces both liquid/frozen and dried egg products, the plant’s total sample allocation will be divided between both project codes.

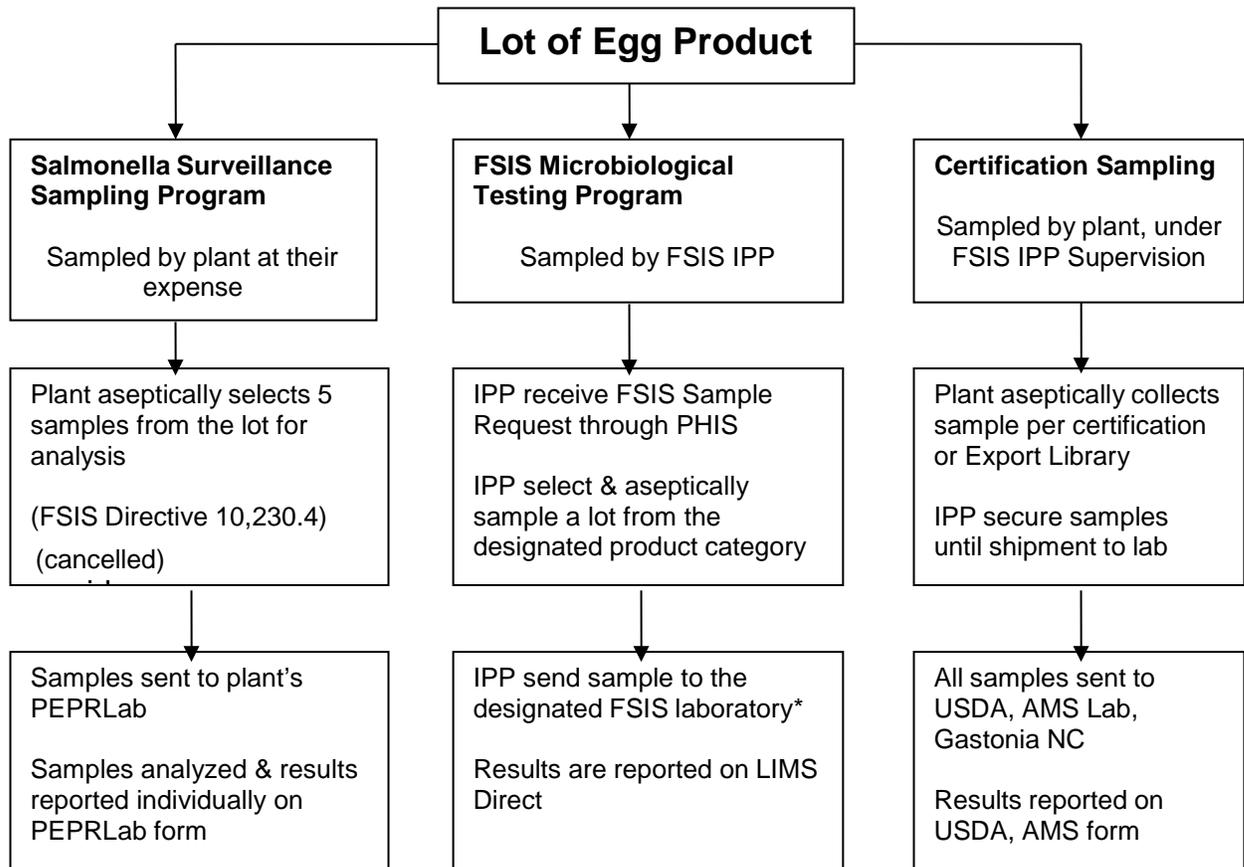
Laboratory Conducting Analysis: All egg products samples selected by FSIS IPP are submitted to one of three (Eastern, Midwestern, and Western) FSIS Field Service Laboratories for *Salmonella* and *Lm* analysis.

3. Sampling of Egg Products for Certification or Export: When egg products are sampled for certification (e.g., school lunch program) or are destined to be exported, they are sampled by the plant under FSIS IPP supervision per the requirements of the certification program or the Export Library for the importing country. All inspection activities that are required outside the scope of mandatory inspection are to be billed to the plant under the Voluntary Egg Products Inspection Program. (9 CFR § 592)

Program Summary: FSIS verifies that the plant has collected the samples per certification program requirements or the Export Library. Plant employees, under FSIS supervision aseptically collect the samples. FSIS then stores the samples under FSIS control until they are shipped to the AMS Laboratory by the plant. Samples are accompanied by an FSIS PY-200 certificate form and sample seal to ensure sample integrity. All sampling and shipping supplies are the plant’s responsibility. The plant is also financially responsible for sample analysis.

Laboratory Conducting Analysis: All samples collected for certification or export are to be submitted to the USDA, AMS Laboratory, Gastonia, NC for analysis.

Sampling Flow Diagram:



Description of sampling flow diagram

*FSIS laboratories only conduct analyses on samples required to be selected by FSIS regulation or policy.

Attachment 6-Salmonella Surveillance Sampling Frequencies

FSIS Directive 10,230.4 (recently cancelled) sets forth the instructions for the sampling of lots of pasteurized egg products at a reduced rate. Plant's that can demonstrate a history of compliance by producing *Salmonella* negative product can follow this reduced sampling frequency.

New plants with no history of prior production or plants that introduce a new product category (new type) are required to sample each lot of pasteurized egg product and determine the lot negative for the presence of the *Salmonella* pathogen. This means that the plant will select samples from every lot produced. As plants establish a history of compliance, they are permitted to reduce the frequency of sampling. The frequency of sampling moves from each lot to every other sample or a ratio of 1:2. After establishing a history of compliance at the 1:2 ratio the plant can then move to a 1:4 ratio, and eventually a 1:8 ratio. The 1:8 ratio is the lowest level of sampling permitted.

Example	Sam-pling Rate or Level	Number of Lots to be Sampled	Number of Consecutive Production Lots	Number of Samples to be Selected & Analyzed Individually	Total Number of Samples that Must be Determined Negative Before Moving to the Next Lower Sampling Level
Egg White	100% or each lot	60 (Sample each lot produced)	60	5 per lot	300 samples (Once 300 samples are determined negative move to 1:2 level)
	1:2 or 50%	60 (For every 2 consecutive production lots select one lot at random to be sampled)	120	5 per lot	300 samples (Once 300 samples are determined negative move to 1:4 level)
	1:4 or 25%	60 (For every 4 consecutive production lots select one lot at random to be sampled)	240	5 per lot	300 samples (Once 300 samples are determined negative move to 1:8 level)
	1:8 or 12.5%	(For every 8 consecutive production lots select one lot at random to be sampled)	Continuous	5 per lot	Continuous

Table - Description sampling frequencies

Example of random sampling of consecutive production lots at the 1:2 ratio:

1	2
3	4
5	6
7	8

Diagram Random sampling of 1:2 ratio

Example of random sampling of consecutive production lots at the 1:4 ratio:

1	2	3	4
5	6	7	8
9	10	11	12
13	14	15	16

Diagram Random sampling 1:4 ratio

Example of random sampling of consecutive production lots at the 1:8 ratio:

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24
25	26	27	28	29	30	31	32
33	34	35	36	37	38	39	40
41	42	43	44	45	46	47	48

Diagram Random sampling 1:8 ratio

Lot selection should always be made at random. Random selection is more representative of the process. Biased sampling is not recommended.

The 5 samples selected from each lot also need to be representative of the lot. Samples should represent the entire lot **from the beginning to the end of the production run.**

Attachment 7 – Additional Control Procedures Required When Shell Eggs or Egg Products Are Identified To Have a Heightened Food Safety Risk

FSIS IPP need to be aware that other types of situations may occur where by the finished egg product may be required to be sampled, and the lot held, and found *Salmonella* negative prior to being released into commerce (hold and test). It is important for inspection personnel to understand that IPP are not required to release egg products into commerce prior to the receipt of laboratory results for *Salmonella* even if they have no reason to suspect noncompliance with any provisions of the egg products inspection regulations (9 CFR § 590.504(d)). Therefore, IPP are to hold all lots of egg products produced from shell eggs or egg products identified in the list below.

Circumstances, which require finished egg product to be held and tested following pasteurization, are as follows:

- Egg product produced from shell eggs that were diverted under the FDA's Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation Final Rule (21 CFR Part 16 and 118, July 9, 2009)
- Egg products produced from imported shell eggs
- Egg products produced from shell eggs diverted for breaking by APHIS due to identified animal health concerns (e.g., Flock identified as positive for *Salmonella* Enteritidis)
- Egg products identified with a heightened food safety risk (e.g.; subjected to smoke from fire)
- Shell eggs or egg products recalled by FDA and diverted to an official egg products plant for breaking and pasteurization
- Shell eggs retained and diverted to official egg products plants for regulatory noncompliance under the FDA's Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation Final Rule (e.g. temperature noncompliance or exceed 36 hour refrigeration regulatory requirement from time of lay). Shell eggs of this type may be retained and diverted by AMS, FSIS, FDA or other local or state government authorities verifying compliance with this rule.

Note: Shell Eggs retained and diverted to an official egg products plant for breaking and pasteurization under the AMS Shell Egg Surveillance Sampling Program for grading or quality deficiencies (e.g.; do not meet the

grade standard or contain more restricted eggs than are permitted) are not subject to the hold and test requirement. Shell eggs retained and diverted to an official egg products plant for regulatory noncompliance with FDA's Shell Egg Rule are subject to the hold and test requirements.

When FSIS IPP become aware that shell eggs or egg products have been received by the plant that are for the reasons noted above, IPP must verify the following:

1. Plant has established controls to ensure that the movement and processing of egg products produced from shell eggs suspected of containing *Salmonella* Enteritidis or having a heightened food safety risk to public health are controlled. This would include the segregation of the shell eggs, and controls for ensuring that all liquid egg products produced from broken shell eggs is pasteurized, and tested to ensure that the finished egg product is *Salmonella* negative. The finished lot of egg product is not eligible for release into commerce until the results of the *Salmonella* test has been received and determined to be negative.
2. Plant maintains daily records sufficient to document the implementation and monitoring of the control of the shell eggs or unpasteurized egg products manufactured from the types of shell eggs noted above. Plant records should include all shipping records accompanying any shipments of shell eggs received under FDA's final rule referenced above. Under 590.200(a), official egg products plants that receive any eggs in commerce must maintain records showing the receipt, delivery, sale, movement, and disposition of all eggs they handle. Under § 590.200(b), they must maintain production records by categories of eggs, bills of sale, inventories, receipts, shipments, names and addresses of shippers and receivers, and dates of shipment and receipt. This would include the amount of shell eggs received and the date they were received.
3. Each lot of egg product is sampled under the *Salmonella* Surveillance sampling program at an approved PEPRLab. For liquid egg product, this means that five individual samples are selected (from throughout the lot), and tested individually for *Salmonella* and found negative. Compositing of samples is not permitted. For dried egg products, 100% of all lots are sampled following the sampling procedures for dried egg products.
4. Shell eggs that are diverted under the FDA's Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation Final Rule are required by FDA to bear special labeling. The pallet, case or other shipping container must be labeled and all documents accompanying the shipment must contain the following statement:
"Federal law requires that these eggs must be treated to achieve a 5-log

destruction of Salmonella Enteritidis or processed as egg products in accordance with the Egg Products Inspection Act, 21 CFR 118.6(f).” The statement must be legible and conspicuous.

When a plant produces unpasteurized egg product and then ships that product to another official egg products plant for further processing, then the receiving plant and the FSIS IPP must be notified of the hold and test requirements associated with the unpasteurized egg product being shipped. Therefore, IPP at the origin plant must also verify:

5. Plant has notified the receiving plant that the unpasteurized egg product contains shell eggs, which have either been diverted in accordance with FDA’s Prevention of *Salmonella* Enteritidis in Shell Eggs final rule.
6. The unpasteurized shipment is accompanied by an FSIS PY-200, “Egg Products Inspection Certificate”, and the tanker must be sealed with USDA seals.
7. If the unpasteurized egg product was produced from shell egg diverted in accordance with FDA’s Prevention of *Salmonella* Enteritidis in Shell Eggs final rule, the following statements must also appear on the FSIS PY-200 Egg Products Inspection Certificate: “The unpasteurized egg product covered by this PY-200 certificate was produced from shell eggs diverted for *processing* in accordance with FDA’s Prevention of *Salmonella* Enteritidis in Shell Eggs final rule. The egg products plant receiving this product must maintain daily records showing the segregation, processing, and sampling for *Salmonella* of egg products manufactured from diverted shell eggs.”
8. Shell eggs diverted to an official egg products plant due to heightened food safety concerns (e.g.; subjected to smoke from fire, eggs under disease restriction) would be subject to the same type of controls set forth in 3 through 7 above. If shell eggs are broken at one official plant and then the resulting liquid is shipped to another official egg products plant for pasteurization, the origin plant is still required to notify the receiving plant of the source of the shell eggs that were broken. The unpasteurized lot must be shipped under USDA PY-200 Egg Products Inspection Certificate and USDA seal. The FSIS Inspector will include a statement on the certificate that states, “The unpasteurized egg product covered by this PY-200 certificate was produced from shell eggs diverted for *heightened food safety concerns for processing* in an official egg products plant. The egg products plant receiving this product must maintain daily records showing the segregation, processing, and sampling for *Salmonella* of egg products manufactured from these shell eggs.”

IPP at the receiving plant would verify that the plant is meeting numbers 1 and 2 above, and that the pasteurized egg product is held, tested and found negative for *Salmonella* prior to being released into commerce. All egg products that have been tested and found negative for *Salmonella* are free to move in commerce and no additional labeling or controls are needed.

If IPP are in a plant that produces egg product for export, they will also need to verify the requirements for all egg produced identified for Export. Some countries will not accept product produced from certain types of shell eggs, so it is important that FSIS IPP review the country requirements to determine if any restrictions apply. When lots of processed egg products are identified for export, all of the sampling, and verification tasks that IPP perform fall under Voluntary Egg Products Inspection and the time needed to complete these tasks is reimbursable. Refer to the **Certification Sampling Program** instructions of this module.

Posted AskFSIS Q&A

The following are posted askFSIS questions (<http://askfsis.custhelp.com/>) that provide policy clarification on this topic:

1. Breaking of Shell Eggs Diverted to Official Egg Products Plants in Accordance with FDA's Prevention of *Salmonella* Enteritidis in Shell Eggs Final Rule

Published 08/25/2010 05:09 PM | Updated 04/20/2016 01:18 PM

May shell eggs diverted to an official egg products plant in accordance with FDA's [Prevention of *Salmonella* Enteritidis in Shell Eggs final rule](#) be broken to produce an unpasteurized egg product that will be shipped to another official egg products plant for pasteurization?

Yes. Official egg products plant may break shell eggs that have been diverted for processing in accordance with FDA's Prevention of *Salmonella* Enteritidis in Shell Eggs final rule for the production of unpasteurized egg product. The unpasteurized egg product may be shipped to another official egg products plant for pasteurization under the following conditions:

- The plant producing the unpasteurized egg product must notify the receiving plant that the unpasteurized liquid egg product contains shell eggs diverted in accordance with FDA's Prevention of *Salmonella* Enteritidis in Shell Eggs final rule.

- The unpasteurized egg product must be accompanied by an FSIS PY-200 Egg Products Inspection Certificate and the tanker must be sealed with USDA seals.
- The FSIS PY-200 Egg Products Inspection Certificate must contain the following statement:

"The unpasteurized egg product covered by this PY-200 certificate was produced from shell eggs diverted for processing in accordance with FDA's Prevention of *Salmonella* Enteritidis in Shell Eggs final rule. The egg products plant receiving this product must maintain daily records showing the segregation, processing, and sampling for *Salmonella* of egg products manufactured from diverted shell eggs."

2. Processing of Shell Eggs Diverted to Official Egg Products Plants in Accordance with FDA's Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation Final Rule.

Published 08/24/2010 03:52 PM | Updated 04/20/2016 01:19 PM

Are shell eggs that are diverted to an official egg products plant as required by the [FDA's Prevention of *Salmonella* Enteritidis in Shell Eggs final rule](#) to be processed differently than other shell eggs entering such plants?

No. The Egg Products Inspection Act ([EPIA](#)) was enacted in 1971 to deal specifically with situations where health hazards are potentially identified with certain qualities of shell eggs. Under the EPIA, FSIS regulates the processing and distribution of shell eggs and egg products by prohibiting or limiting the use of certain categories of shell eggs which could pose a risk to public health. Shell eggs diverted to an official egg products plant under the FDA final rule are eggs that could pose a risk to public health. Therefore, they should be processed in the same manner as other shell eggs entering such plant. FSIS inspection program personnel are to verify that the plant has established controls to ensure that any egg product produced using shell eggs diverted in accordance with FDA's *Prevention of Salmonella Enteritidis in Shell Eggs* final rule are segregated, pasteurized, and tested to ensure that the finished egg product is *Salmonella* negative.

3. *Salmonella* Testing of Shell Eggs Diverted to Official Egg Products Plants

Published 02/02/2011 08:23 PM | Updated 04/18/2016 04:22 PM

Are egg products plants required to hold lots of egg products produced from shell eggs that have been labeled to require processing as egg products in accordance with the Egg Products Inspection Act (21 CFR 118.6(f)) and diverted to an official egg products plant until the plant's *Salmonella* surveillance test results have been received?

No. An egg products plant is not required to hold lots of egg products produced from shell eggs labeled to require processing as egg products in accordance with the Egg Products Inspection Act and diverted to an official egg products plant until *Salmonella* test results have been received. However, an egg products plant is required to maintain control of such lots until the *Salmonella* results have been received.

An egg products plant may maintain control of lots of egg products produced from shell eggs labeled to require processing as egg products in accordance with the Egg Products Inspection Act and diverted to an official egg products plant by holding them at the plant until it receives negative *Salmonella* test results. However, a plant does not have to physically hold the product at the plant, provided the plant has effective controls in place for it to move elsewhere under its control so that the product does not enter into commerce until the plant receives negative *Salmonella* results. Egg products plants are to maintain the integrity of the lot and use an effective mechanism to control the product so that it does not go into commerce until negative results are available. Adequate controls may include company seals. Egg products plants that ship lots of egg products produced from shell eggs labeled to require processing as egg products in accordance with the Egg Products Inspection Act and diverted to an official egg products plant prior to the receipt of negative *Salmonella* results must be able to document and support that they can control the product pending the availability of test results. If the plant does not maintain control of the product, the plant would not be in compliance with the egg products inspection regulations. For example, an egg products plant could ship pasteurized product containing the mark of inspection to a non-official establishment or facility (e.g., bakery) while the testing is being done. However, the producing plant must maintain control of the product so the bakery does not start using the product until the test results are returned and are negative.