

Egg Product Sampling

Objectives

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

1. Use the terminology related to sampling.
2. Describe the purpose and regulatory requirements for each type of sampling program.
3. Explain the steps involved in aseptic sampling.
4. List the steps involved in collecting samples for liquid, frozen, and dried egg products.
5. Describe the proper way to store and ship samples collected by FSIS.
6. Explain the procedure for handling and recording the results of *Salmonella* analysis.
7. Explain inspection program personnel's (IPP's) responsibilities in handling of *Salmonella* positive egg products.
8. Explain the procedures and controls required when shell eggs or egg products are diverted to an egg products plant for further processing.

Introduction

There are four types of sampling programs in place to fulfill regulatory requirements (see Figure 1 – Statutory and Regulatory Requirements). They are as follows:

- Plant *Salmonella* Surveillance Sampling Program
- FSIS Verification/Monitoring Sampling Program
- Certification Sampling Program
- Residue Sampling Program.

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

Definitions

Regulation § 590.5, as well as Directive 10,230.4 *Salmonella* Surveillance Program for Liquid and Frozen Egg Products define the following terms:

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: For sampling purposes under the *Salmonella* Surveillance Program (Directive 10,230.4), 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). For dried egg products, the definition of a lot is found on the Egg Product Inspector Handbook (EPIH), Section 8, Part I.A.4-C. 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 *Salmonella* Surveillance Program according to Directive 10,230.4 and EPIH.

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*.

Sampling or product category: Directive 10,230.4 sets forth the 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:

Note: Attachment 5 – Egg Product Sampling Programs – gives an overview of the *Salmonella* Surveillance Program, FSIS Verification Sampling Program, and Certification Sampling Program.

Plant *Salmonella* Surveillance Sampling

The regulatory requirement to perform *Salmonella* sampling is specified in 9 CFR § 590.580 (Figure 1) and further described in FSIS Directive 10,230.4. 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. The samples are submitted to a laboratory operating under the “Pasteurized Egg Products Recognized Laboratory Program” (PEPRLab), which is administered by the Office of Public Health and Science (OPHS) in Athens, GA. For a laboratory to be eligible to participate in the PEPRLab program they must have at least one active egg products plant that sends samples to them for *Salmonella* analysis. If the plant stops using a lab that was previously approved and the lab have no other egg products plant clients, then that laboratory will be removed from the PEPRLab list. The process of getting a lab approved takes two to three months. OPHS maintains the [List of Member Laboratories](#) on the FSIS web site. This list is updated on a regular basis. The web site also provides detailed information on the PEPRLab program requirements that a laboratory has to meet and information on the application process.

FSIS Directive 10,230.4 (see Appendix 3 – end of the participant’s handout) provides instructions for the sampling of lots of pasteurized liquid and frozen egg products. The product sampling categories under this program are defined above. Plants that can demonstrate a history of compliance by producing *Salmonella* negative product can follow the reduced sampling frequency described in the directive once the minimum number of consecutive lots at each level has been achieved (refer to Attachment 6 – *Salmonella* Surveillance Sampling Frequencies). New plants with no history of prior production or plants that introduce a new product category (new type) must begin sampling all lots of pasteurized egg products produced for *Salmonella* and determine the lot negative for the presence of *Salmonella*. This means that the plant will select samples from every lot produced based upon the sampling plan in the Directive. As a plant establishes a history of compliance, they can reduce the frequency of sampling. The sampling frequency will increase or decrease based on a plant’s history of producing *Salmonella*-negative product. Regulation 9 CFR § 590.200 requires the plant to maintain records for each lot of product produced and to make the records available to IPP upon request.

It is also important to note that a plant which produces product in multiple product categories may have a different sampling level for each of the types of product (liquid and/or frozen). For example, they may be at 1:8 sampling level for whole egg without added ingredients, 1:4 sampling level for whole egg with two percent or more salt added, and 100% sampling level for whites. The sampling levels are determined based on history of compliance and length of time the product has been produced, and the number of lots of in each category that are produced over time.

Please note that FSIS Directive 10,230.4 is for lots of liquid and frozen egg products only.

All lots of dried egg products are sampled at 100%, and no reduced sampling of dried egg products is permitted.

- The sampling levels are found in the Egg Products Handbook, Section 8, page 11
- A minimum of 3 samples or 3 composite samples are to be collected from each lot of product produced from each dryer.
- Each sample or composite sample is to be analyzed individually utilizing 100 gm of product, and the results reported individually.

Inspection program personnel (IPP) should thoroughly understand the plant's *Salmonella* surveillance sampling program and are to verify that the program follows FSIS Directive 10,230.4.

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 (according to Directive 5030.1) using the appropriate food safety task.

FSIS Verification/Monitoring Sampling Program

The Agency's verification/monitoring OPHS-directed sampling programs are addressed in Directive 10,210.1, Amendment 6: *Unified Sampling Form* and FSIS Notice 57-16, *Elimination of the EGGDOM Sampling Program*.

To ensure that pasteurized, ready-to-eat (RTE) egg products are safe and wholesome, FSIS analyzes them for the presence of *Salmonella*. If pasteurized egg products bear a shelf-life claim, the Agency also samples them for *Listeria*

monocytogenes (*Lm*). FSIS analyses products for the aforementioned pathogens because of public health concern over potential product adulteration. Therefore, to enhance public health protection associated with pasteurized egg products for consumers, FSIS started to test (as of September 2016) 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.

The Agency will continue to collect samples of dried, frozen, and liquid pasteurized egg products under its seven Egg Monitoring (EM) sampling projects (Directive 10,210.1), four of these categories are for liquid/frozen egg products and three projects are for dried egg products. 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 to be sent to the lab (see Figure 3).

Following is a brief description of each project number (name and egg product to sample; see Figure 4).

- EM31, *Salmonella* in Pasteurized Liquid, Frozen, or Dried Egg Products: the product to sample includes liquid and frozen egg whites with or without added ingredients.
- EM32, *Salmonella* in Pasteurized Liquid, Frozen, or Dried Egg Products: the product to sample includes plain liquid and frozen whole eggs or yolks, and liquid and frozen whole eggs or yolks with less than two percent added ingredients other than salt or sugar, respectively.
- EM33, *Salmonella* in Pasteurized Liquid, Frozen, or Dried Egg Products: the product to sample includes liquid and frozen whole eggs with added yolks, or whole egg blends (with more than two percent added ingredients other than salt or sugar).
- EM34, *Salmonella* in Pasteurized Liquid, Frozen, or Dried Egg Products: the product to sample includes liquid and frozen whole eggs or yolks with more than two percent salt or sugar added, respectively.

- EM35, *Salmonella* in Pasteurized Liquid, Frozen, or Dried Egg Products: the product to sample is dried yellow egg products.
- EM36, *Salmonella* in Pasteurized Liquid, Frozen, or Dried Egg Products: The product to sample is spray-dried egg whites with or without added ingredients.
- EM37 *Salmonella* in Pasteurized Liquid, Frozen, or Dried Egg Products: the product to sample is 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*. An egg products plant could be sampled up to seven times per month, depending on the number of production processes (product categories) occurring during the month. For example, if a plant only produces pasteurized whole egg, then they will only receive (on average) one directed sample request per month. If they produce whole eggs and egg whites (two separate categories) they would receive two directed sample requests per month (one for each category of product).

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. IPP should receive one sampling request in PHIS, per month, for each category of product the plant routinely produces.

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 which 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 is eliminating its domestic egg products sampling program (EGGDOM) which analyzes 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. As stated previously, FSIS will continue to collect samples under its seven EM sampling projects and test them for both *Salmonella* and *Lm*.

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 Monitoring samples 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, the 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 egg products at official egg product 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 (generally yellow products) without added ingredients will be sampled whenever possible. According to FSIS

Directive 10,210.1 the specimen can be either unpasteurized filtered plain whole egg or yolk as well as pasteurized dried plain whole egg or yolk. Dried samples should only be submitted if there is no other alternative. 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. The 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 10,210.1. 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.

Submitting AskFSIS Questions

When submitting a question via askFSIS regarding sampling, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field:	Enter " Sampling Question "
Question Field:	Enter your question with as much detail as possible.
Product Field:	Select General Inspection Policy from the drop-down menu.
Category Field:	Select Sampling from the drop-down menu

Policy Arena: Select **Domestic (U.S.) only** from the drop-down menu.

When all fields are complete, press the **Submit** button.

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* surveillance 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 5 (five) *Salmonella* Surveillance 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 being collected are pasteurized liquid, frozen, and dried egg products (FSIS Directive 10,210.1). 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 recently issued Notice 11-16 giving instructions to IPP 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 back 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 10,210.1 and the Egg Products Inspector's Handbook when IPP or the plant collects samples of egg products.

Note: IPP will also collect residue samples when instructed, but these samples are unpasteurized and collected from egg product that is in process and prior to pasteurization or heat treatment.

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 Directive 10,210.1.

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; refer 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 in the PHIS Egg Products course).
- 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

Results of *Salmonella* Analysis and Records (9 CFR § 590.580(c) and FSIS Directive 10,230.4)

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 is 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* 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 egg product produced. The records must be available to IPP upon request. FSIS Directive 10,230.4 (See Appendix III) specifies the information that must be maintained in the records.

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 monitoring the completion of the company's records on a routine basis for compliance with regulatory requirements and are to document this monitoring activity in PHIS using the appropriate routine verification task.

***Salmonella* Positive Products**

A specific lot or a day's production of a given product is considered *Salmonella* positive when one or more samples are found to be *Salmonella* positive by any laboratory. For *Salmonella* positive samples, the following procedures should be followed (refer to Section 9 of the Egg Products Inspector's Handbook):

- 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, 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* positive product should always be controlled using a “U.S. Rejected/Retained” tag (9 CFR § 590.504(o)(2) and § 590.426).

- If the product has been shipped from the plant prior to completion of the laboratory analyses, IPP and plant management are responsible for the following:
 - IPP are to request plant management 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* positive test result and the action taken by the plant's management, including the location of the affected product.
- 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).
- 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.
- 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”.

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

When a lot of egg product is identified as *Salmonella* positive, an investigation into the cause of the positive must be conducted by both the plant and the FSIS inspection team. Following notification that a lot of egg product is *Salmonella* 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; review any notes, procedures, and processing records (i.e., pasteurization charts, formulation records, packaging records, etc.) for the date the product was produced; look for unusual events during processing that may be a potential cause of initial contamination or recontamination.
- Ensure that plant provides a letter confirming the *Salmonella* positive, including product type, lot number, number of containers in the affected lot (or lots), location, and proposed disposition.
- Ensure that the plant conducts an investigation into the cause of the positive result. Request that plant management provide IPP with a letter (on company letterhead), with the results of their investigation and their proposed corrective measures.

Note: This is voluntary and is not a regulatory requirement.

- Ensure that the plant keeps 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 labeled). As the plant re-pasteurizes the *Salmonella* 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. Depending on the type of product, a plant may choose to re-pasteurize the entire lot at one time (100%), but for other types of product (e.g. 10% Salted Yolk) the plant will re-pasteurize this product at a much lower percentage (5-10%) due to the gelation (thickening) of the product after processing and during storage.

Note: More than one lot of egg products may be affected when a *Salmonella* 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 to be *Salmonella* positive, and would need to be re-pasteurized, tested and found negative for *Salmonella* 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 tank.

When reprocessing *Salmonella*-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* 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* negative.

Salmonella positive product must be re-pasteurized and retested prior to being eligible to be released into commerce.

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)** *Persons engaged in the business of transporting, shipping, or receiving any eggs or egg products in commerce, or holding such articles so received, and all egg handlers, including hatcheries, shall maintain records showing, for a period of 2 years, to the extent that they are concerned therewith, the receipt, delivery, sale, movement, and disposition of all eggs and egg products handled by them, and shall, upon the request of an authorized representative of the Secretary, permit him, at reasonable times, to have access to and copy all such records.*
- (b)** *Production records by categories of eggs such as graded eggs, nest-run eggs, dirties, checks, leakers, loss, inedible, etc., bills of sale, inventories, receipts, shipments, shippers, receivers, dates of shipment and receipt, carrier names, etc., as determined by the Administrator, shall be maintained by all egg processing operations, except that, official egg products plants which use all shell eggs received and do not reship any shell eggs need only to maintain records indicating the amount of eggs received, date received, and the name and address of the shipper.*

§ 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 Laboratory tests and analyses. *The official plant, at their expense, shall make tests and analyses to determine compliance with the Act and the regulations.*

- (a) Samples shall be drawn from liquid, frozen or dried egg products and analyzed for compliance with the standards of identity (if any) and with the product label.*
- (b) To assure adequate pasteurization, pasteurized egg products and heat treated dried egg whites shall be sampled and analyzed for the presence of Salmonellae in accordance with such sequence, frequency, and approved laboratory methods as prescribed by the AMS Science Division Director (the correct reference now is FSIS). The samples of pasteurized egg products and heat treated dried egg whites shall be drawn from the final package form.*
- (c) Results of all analyses and tests performed under paragraphs (a) and (b) of this section shall be provided to the inspector promptly upon receipt by the plant. If samples of pasteurized products or heat treated dried egg whites, in addition to those in paragraphs (a) and (b) of this section, are analyzed for the presence of Salmonella, the plant shall immediately advise the inspector of any such samples determined to be Salmonella positive.*
- (d) USDA will draw confirmation samples (now referred to under FSIS as verification/monitoring samples) and submit them to AMS Science Division (the correct reference now is FSIS) laboratory at USDA's expense to determine the adequacy of the plant's tests and analyses.*

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 3 – FSIS Form 8000 – 18 Generated by PHIS

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE		Form ID: 100814464
SAMPLE ANALYSIS REQUEST FORM		
— For Lab Use Only —	Place Sample Seal Label Here	 100814464
COLLECTION INFORMATION		
1. SAMPLE FORM ID:	100814464	7. ESTABLISHMENT ID:
2. PROJECT CODE:	EM34	8. ESTABLISHMENT NAME:
3. SAMPLE SOURCE:	Product-Eggs-With >2% salt or sugar added-Whole Eggs	9. COLLECTION DATE:
4. ANALYSIS:	Salmonella	10. SHIPMENT DATE:
		11. COLLECTOR NAME:
		12. COLLECTOR PHONE:
5. ASSIGNED LAB:	Eastern Laboratory	(Athens, GA)
6. DISTRICT/CIRCUIT:	25 - Des Moines, IA / 2529	
PRODUCT INFORMATION		
13. PRODUCT NAME:	Pasteurized Frozen Sugared Egg Yolks, Approx 10% Sugar added	
14. PRODUCTION DATE:	08/04/2014	
15. LOT NUMBER:	155-42	
16. IS PRODUCT HELD:	Yes	
17. COLLECTION REMARKS:		
18. QUESTIONNAIRE (If Applicable)		
1. Is sample submitted in a final, intact package?		: No
2. Was plant management notified of sample collection?		: 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)		

Figure 4 – Egg Products Sampling Categories

Project Number	Product to Sample	Types of product Included
EM31	Egg Whites with or without added ingredients	-Plain Egg whites -Egg whites with added ingredients
EM32	Whole Eggs (with less than 2% added ingredients other than salt or sugar), or Yolks (with less than 2% added ingredients other than salt or sugar)	-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
EM33	Whole Eggs with added yolks, or Whole egg Blends (with more than 2% added ingredients other than salt or sugar)	-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 -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
EM34	Whole Eggs (with more than 2% salt or sugar added), or Yolks with more than 2% salt or sugar added)	-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)
EM35	Dried Yellow Egg Products	-Dried whole egg -Dried whole egg blends -Dried yolk -Dried yolk blends Note: All types would be either with or without added ingredients
EM36	Dried Egg Whites (with or without added ingredients)	-Dried egg whites (with or without added ingredients)
EM37	Pan Dried Egg Whites	-Pan Dried Egg Whites

[Egg Products Sampling Categories Table 1](#)

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 1

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 2

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.
2. Label sample containers as per instructions on the Egg Products Inspector's Handbook.
3. Organoleptically examine product prior to sampling.
4. When collecting container-intact five pounds or less:
 - Wash, sanitize hands. Use of a hand sanitizer facilitates aseptic drying of the hands.
 - Randomly select the required number of intact packages.
 - Collect intact packages greater than five pounds as short-fill or slack- filled packages.
5. When collecting container-non-intact:
 - Gather sampling supplies and proceed to the sampling area.
 - Select non-intact package(s) for sampling.
 - Prior to entering the sampling area, remove outer protective clothing worn in other areas of the facility, following aseptic techniques.
 - Take sampling supplies and non-intact packages into the sampling area.
 - Using aseptic techniques, open the package with a sanitized lid removal tool and prepare the sample container and utensils
 - Remove gloves, wash and sanitize hands again, and put on a new pair of sterile gloves.
 - Aseptically collect a sample, as described above, taking the precaution of thoroughly sanitizing utensils, tools, and outside wrappers; immediately close and seal the sample container after collecting the sample.
6. When collecting container-tanker (This type of sample collection is taken ONLY if necessary and the inspector has safe access to the tanker):
 - Gather sampling supplies and proceed to the tanker location.
 - Remove your hat and remove all loose objects from your pockets to prevent them from falling into the tanker during sampling.
 - Aseptically collect the sample.
 - In the event that the inspector is not able to collect the sample, a designated plant employee will aseptically collect the sample from the tanker and will hand it to you; handle the sample aseptically.
7. After collecting the sample, store it appropriately. Pre-cool chilled products to 2°C prior to shipment.

Attachment 3 – Aseptic Sampling of Frozen Egg Products

(If possible, sample before freezing when the product is still in liquid form)

1. Randomly select a sampling time. When collecting a sample, notify plant management.
2. Label sample containers as per instructions in the Egg Product Inspector's Handbook.
3. Gather sampling supplies and proceed to the sampling area.
4. Select non-intact package(s) for sampling.
5. Prior to entering the sampling area, remove outer protective clothing worn in other areas of the facility, following aseptic techniques.
6. Take sampling supplies and non-intact packages into the sampling area.
7. Using the aseptic techniques described above, open the package(s) with a sanitized lid removal tool; prepare the sample container and utensils.
8. Remove gloves, wash and sanitize hands again, and put on a new pair of sterile gloves; remove the sampling utensils from the wrapper or sanitizer solution.
9. If possible, collect either an intact five-pound package or smaller intact size package or eight ounces in a sample cup (depending of the type of product and package) of the liquid egg product before the packaging step during processing. Freeze the sample overnight before sending it to the corresponding FSIS Field Service Laboratory.
10. 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 sample cup(s). Frozen samples require twice the amount of liquid needed for other samples because when defrosted, their volume is decreased by half. The inspector will take and record the frozen product temperature.
11. When collecting frozen egg product samples using a trier, insert the trier fully into the product and twist rapidly to collect the sample.
12. Organoleptically examine the product after removing the frozen sample.
13. Remove the product sample from the trier by scraping the plug from the trier with a sterile or sanitized spoon and placing it into a sample cup(s).
14. Immediately close and seal the sample container after collecting the sample.
15. After collecting the sample, store the sample appropriately until shipment.

Attachment 4 – Aseptic Sampling of Dried Egg Products

1. Randomly select a sampling time. When collecting a sample, notify plant management.
2. Label sample containers as per instructions on the Inspector's Handbook.
3. Gather sampling supplies and proceed to the sampling area.
4. Select package(s) for sampling.
5. Prior to entering the sampling area, remove outer protective clothing worn in other areas of the facility; wash, sanitize, and dry hands.
6. Take sampling supplies and non-intact packages into the sampling area; determine if the sampling area is free of dust. **Do not** use liquid agents to prepare the sample work surface.
7. Wash, sanitize, and dry hands; use of a hand sanitizer will facilitate aseptic hand drying. Open the package and pull back the liner. (Do not touch the inside of the liner). Aseptically prepare the sample container and utensils.
8. Wash, sanitize, and dry hands. Put on sterile gloves.
9. Open the Whirl-pack bag and set it aside. Use a sterile scoop.
10. For yellow egg products, collect product from different locations in the top portion of the package. Samples may be collected during packaging when possible.
11. For white egg products, use a sanitized scoop to move product aside and select product from the center of the package for the sample (for bacteriological analyses and moisture). For other types of analyses, the sample may be collected from different locations in the top portion of the container.
12. Collect no less than six ounces of product and place it into the Whirl-pack or an appropriate sample bag. 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.
13. When sampling dried egg products for the plant's *Salmonella* surveillance program, a minimum of three samples or three composites should be submitted from each lot in order to analyze, minimum of 100 grams, the individual samples to obtain individual results. Follow the instructions in section 8, part C 5 of the Egg Product Inspector's Handbook.
14. After collecting the sample, store it appropriately until shipment.

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 sends its samples to a laboratory that has been registered under the FSIS Pasteurized Egg Products Recognized Laboratory (PEPRLab) Program to perform *Salmonella* analysis on pasteurized egg product samples. The laboratory may be company owned (located on or off site) or the plant may contract with a third party laboratory. The *Salmonella* Surveillance Sampling Program requires that a plant 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 seven 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:

1. whites (EM31),

2. whole eggs/yolks with <2% added ingredients (EM32),
3. whole eggs/yolks with ≥2% added ingredients (EM33),
4. whole eggs/yolks with ≥2% salt or sugar (EM34),
5. dried yellow egg (EM35),
6. spray dried whites (EM36), and
7. dried egg whites (EM37)

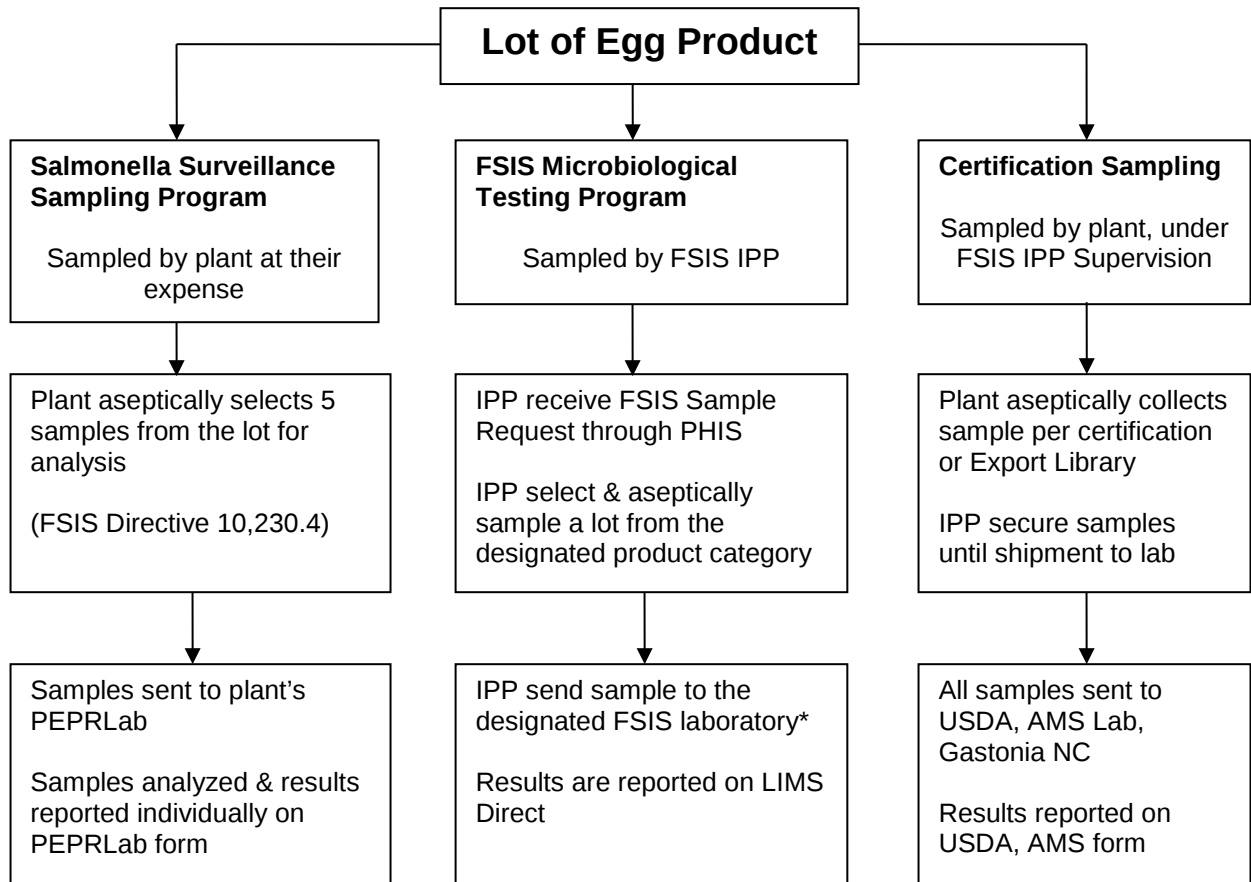
Laboratory Conducting Analysis: All egg products samples selected by FSIS IPP are submitted to one of three (Eastern, Midwestern, and Western) FSIS Field Service Laboratories for *Salmonella* and *Lm* analysis.

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:



Sampling Flow Diagram 1

*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 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 Indivi- dually	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 3

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

1	2
3	4
5	6
7	8

Figure 1

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

Figure 2

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

Figure 3

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.