UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

10,230.3 | 12/21/20

FSIS VERIFICATION TESTING OF DOMESTIC EGG PRODUCTS

DO NOT IMPLEMENT THIS DIRECTIVE UNTIL DECEMBER 28, 2020.

I. PURPOSE

This directive provides instructions to inspection program personnel (IPP) for the collection and submission of pasteurized dried, frozen, and liquid egg products under FSIS's routine sampling programs for *Salmonella* and *Listeria monocytogenes (Lm)*. It also includes instructions for the collection of raw or pasteurized liquid and dried egg products for chemical residue testing. This directive provides instructions previously included in FSIS notices. In addition, this directive replaces the regulatory citations from those notices to reflect the Egg Products Regulations Inspection rule issued on October 29, 2020. These revised regulatory citations will go in effect on December 28, 2020.

II. BACKGROUND

A. FSIS considers pasteurized egg products ready-to-eat (RTE) because they do not require additional preparation to ensure food safety. To verify that pasteurized egg products are safe and wholesome, FSIS analyzes them for the presence of *Salmonella* and *Lm*. Plants are required to hold or control products pending the receipt of *Salmonella* and *Lm* test results (9 CFR 590.504(e)).

B. FSIS analyzes samples of liquid or dried egg products for violative chemical residues of veterinary drugs, pesticides, or environmental contaminants. A violation occurs when a chemical residue is detected and exceeds the established tolerance or action level or when FSIS detects the residue when there is no tolerance or action level. FSIS recommends that egg products plants hold or maintain control of sampled egg products until FSIS residue sample results are found to be acceptable, but FSIS does not require that plants hold or control these products pending the receipt of residue test results.

III. SAMPLING FREQUENCIES

A. 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 from the 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.

B. FSIS samples egg products for residues under the project code "NRP_EG." The frequency of residue sampling tasks may vary from year to year. Information on egg product residue analyses and the annual sampling plan is provided in the FSIS Annual Sampling Plan.

IV. GENERAL SAMPLING INSTRUCTIONS

A. Before collecting samples, IPP are to be familiar with the random sampling methodology, which may include the use of random number tables or using computer generated random numbers. There is a random-number generator available on FSIS computers (Start Menu → FSIS Applications → Tools → Random Number Generator). When collecting a sample, IPP are to randomly select a day, shift, and time within the collection date range (sampling window) indicated in PHIS. IPP are to collect samples from all shifts at the plant, so that there is an equal chance that sampling will occur during any particular shift.

B. If an egg products plant produces more than one product group, IPP are to randomly select the egg product group to sample and then rotate through the different formulations with each sampling task so that all formulations are sampled over time.

C. IPP are to refer to FSIS Directive 13,000.2, *Performing Sampling Tasks in Official Establishments Using the Public Health Information System,* for instructions on how to add a sampling task to the task calendar, enter the sample information into PHIS, submit the sample information to the laboratory, and print a finalized sample collection form from PHIS.

C. IPP are to schedule and collect samples as assigned in PHIS. IPP have 30 days from the date of the sample request (sample collection window) to collect the sample and submit it to the FSIS laboratory.

D. If sampling tasks remain in the task list at the end of the sampling window, IPP are to cancel them from the task list and provide the appropriate reason.

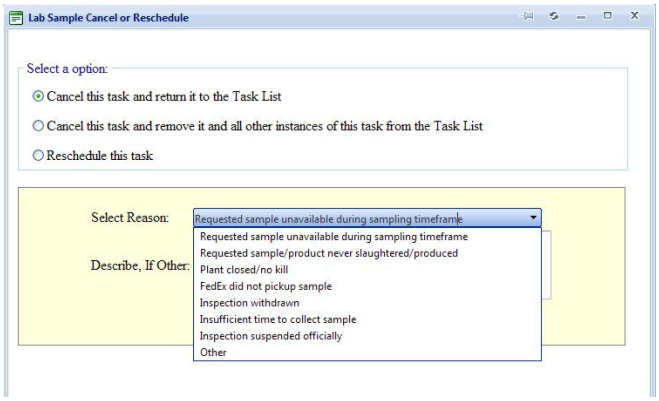


Figure 1: Screenshot of cancelling a sampling task

1. If a plant produces a product that is eligible for sampling but is not producing that product during the sampling window, IPP are to select "requested sample unavailable during the sampling timeframe."

2. If the plant has never produced the product or discontinues producing an eligible product, IPP are to select "requested sample/product never slaughtered/produced." Because sampling tasks are assigned based on the information provided in the Establishment Profile, IPP are to verify that the Establishment Profile in PHIS accurately represents the plant's operations and product groups. This includes product volumes and days of production to ensure that the correct number of sampling tasks is assigned. IPP are to refer to FSIS Directive 5300.1, *Managing the Establishment Profile in the Public Health Information System,* for instructions on managing the Establishment Profile.

3. If the appropriate reason for cancellation is not available, IPP are to select "Other" and clearly specify the reason for the cancellation.

E. For microbiological analyses, IPP are to be aware that plants are required to hold or control the lot(s) of egg products represented by the samples until FSIS *Salmonella* and *Lm* sample results are found to be acceptable. If product is shipped from a plant prior to receiving the results, shipments must be made under circumstances which will ensure the return of the product to the plant (9 CFR 590.504(e)). If the plant has not notified the receiving company that laboratory results were pending at the time of shipment, the plant is in violation of the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*). IPP are to issue a noncompliance citing 9 CFR 590.504(e).

F. For FSIS residue analysis, IPP are to be aware that egg products plants are NOT required to hold or control the lot(s) of egg products represented by the samples until FSIS sample results are found to be acceptable; however, IPP are to recommend that establishments hold or control the lots represented by these samples. If violative levels of residue are detected, then appropriate disposition of the product may include destruction of the lot represented by the sample.

V. SAMPLING SUPPLIES

A. Microbiological sampling supplies will be automatically returned to the plant after each sample is received by the laboratory. However, if IPP need to request additional sampling supplies, they are to follow the instructions provided in FSIS Directive 13,000.2 for ordering sampling supplies through PHIS. IPP may also submit requests for sampling supplies via e-mail using the following e-mail addresses:

FSIS - Sampling Supplies - Midwestern Lab (SamplingSupplies-MidwesternLab@usda.gov);

FSIS - Sampling Supplies - Eastern Lab (SamplingSupplies-EasternLab@usda.gov); or

FSIS - Sampling Supplies - Western Lab (SamplingSupplies-WesternLab@usda.gov)

To request sampling supplies by e-mail, IPP are to enter "Egg Products Sampling Supplies" in the e-mail subject heading and, in the e-mail body, include the plant name and number, the project code (EGG_LQ_MIC01 and/or EGG_DY_MIC01), and the IPP contact name and telephone number.

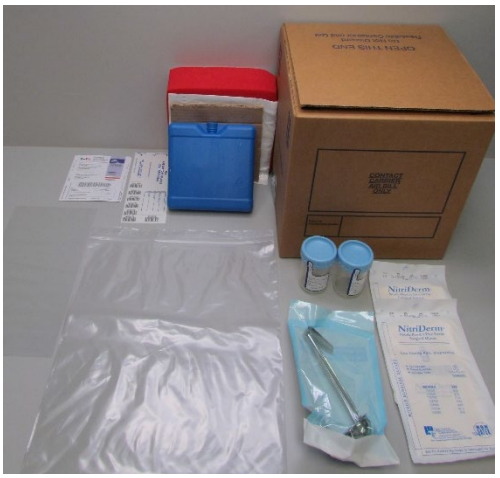
B. Residue sampling supplies are not sent automatically. IPP are to request sampling supplies at least three business days before sampling is to begin. IPP are to follow the instructions provided in FSIS Directive 13,000.2 for ordering sampling supplies through PHIS. IPP may also submit requests for sampling supplies to the Western Laboratory (WL) via e-mail using the following e-mail address:

FSIS - Sampling Supplies - Western Lab (SamplingSupplies-WesternLab@usda.gov)

To request sampling supplies by e-mail, IPP are to enter "Egg Products Sampling Supplies" in the e-mail subject heading and, in the e-mail body, include the plant name and number, the project code (NRP_EG), and the IPP contact name and telephone number.

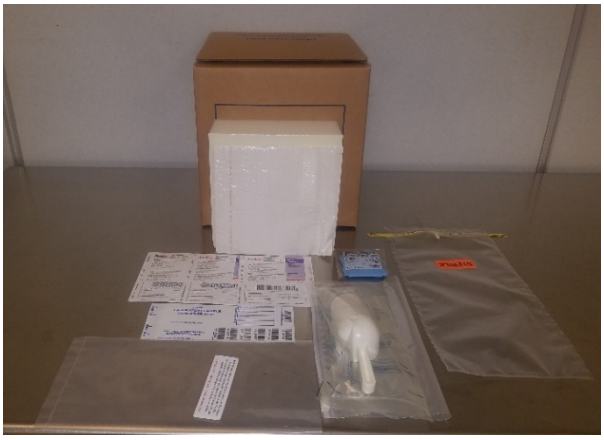
C. For the EGG_LQ_MIC01 (liquid or frozen products) project code, sampling supplies do not include a ladle. If a ladle is required for aseptic sample collection where a valve is not present, IPP are to request a ladle. The request for a ladle is to be included in the comment section of the dialog box when using PHIS, or in the body of the email when using the laboratory mailing list. The shipping container for the EGG_LQ_MIC01 project code should include the following sampling supplies:

1. Pair of gloves (1);
2. 120-ml sterile plastic sample jars with screw cap (2);
3. 1-gallon zipper lock bag (1);
4. Plastic sleeve or zipper lock bag for sample form (FSIS form 8000-18) (1);
5. FSIS Laboratory Sample Container Seal (FSIS Form 7355-2A/2B) (1);
6. Absorbent pad (1);
7. Gel coolant pack (1 or more);
8. Cardboard separator (1);
9. FedEx (pre-printed) billable stamps (3; one per FSIS laboratory for submitting the sample); and
10. When requested, a ladle.



D. The shipping container for the EGG_DY_MIC01 (dried egg products) project code should include the following sampling supplies:

1. Pair of gloves (1);
2. Sterile Whirl-Pak® bag (1);
3. Sterile scoop (1);
4. 1-gallon zipper lock bag (1);
5. Plastic sleeve or zipper lock bag for sample form (FSIS form 8000-18) (1);
6. FSIS Laboratory Sample Container Seal (FSIS Form 7355-2A/2B) (1);
7. Absorbent pad (1); and
8. FedEx (pre-printed) billable stamps (3; one per FSIS laboratory for submitting the sample).



E. For the NRP_EG (either liquid or dried egg product) project code, sampling supplies do not include a sterile scoop or sterile ladle. If a scoop (for dried egg products) or ladle (for collection of liquid egg product where a valve is not present) is needed for aseptic sample collection, IPP are to request the scoop or ladle. The request for a scoop or ladle is to be included in the comment section of the dialog box when using PHIS, or in the body of the email when using the laboratory mailing list. The shipping container for the NRP_EG project code should include the following sampling supplies:

1. Pair of gloves (1);
2. 120-ml sterile plastic sample jar with screw cap for liquid egg product (2);

3. Quart-size sterile resealable zipper lock bag for dried egg product (1);

4. 1-gallon zipper lock bag (1);

5. Plastic sleeve or zipper lock bag for sample form (FSIS form 8000-18) (1);

6. FSIS Laboratory Sample Container Seal (FSIS Form 7355-2A/2B) (1);

7. Absorbent pad (1);

8. Gel coolant pack (1 or more);

9. Cardboard separator (1);

10. FedEx (pre-printed) billable stamp (1); and

11. When requested, a ladle or scoop.

Figure 5: Photo of ladle and scoop

F. IPP are to ensure that all the supplies needed for sample collection are inside the box. If any of the sampling supplies are missing or damaged, IPP are to contact one of the laboratories using the instructions provided in Section V.A. and Section V.B of this directive to request the missing or damaged item(s).

G. IPP are to place the gel coolant pack(s) in a freezer for a minimum of 12 hours prior to sample collection, if collecting liquid or frozen egg products. Gel packs are not required for dried egg products.

H. FSIS laboratory sampling supplies do not include drills, drill bits, or triers. If needed, the plant is to provide these items and designate them for sampling only. These items are not to be used for any other purpose, such as plant maintenance. IPP are to ensure that the plant thoroughly cleans and sanitizes the drills, drill bits, and triers immediately before and after they are used for sample collection. While IPP are to operate the plant-provided trier, the plant employees are to operate the drill for sample collection and IPP are to collect the shavings produced. IPP are to ensure that the drill bit is 11/16 inches or larger in diameter and not less than 12 inches in length.

I. IPP are to use only the shipping materials provided by the FSIS laboratory.

VI. SAMPLE SELECTION

A. Before collecting a sample, IPP are to officially notify the plant management that they will be collecting a sample and explain the reason that they are collecting the sample (either microbiological sampling or residue sampling). Prior to initiating the sampling task, IPP are to:

1. Discuss the plant's lotting procedures and determine the amount of notice the plant will need prior to collecting these samples. Generally, IPP are to provide one (1) days' notice prior to collecting these samples. IPP may provide two (2) days' notice if necessary;

2. Consider the plant's request for more than two days' notice, in the rare cases that more notice is needed based on the plant's product and process flow. If the plant can support that more notice is necessary because of the innate characteristics of the process (e.g., less than daily sanitation, or processes that span more than two days), IPP may provide more than two days' notice. If IPP

have questions about a plant's basis for requesting more notice, they are to submit them through askFSIS;

3. Inform the plant that IPP may provide less than one days' notice if the plant changes its routine practices without a justification for doing so;

4. Discuss where IPP can store the collected sample (see Table 1) until FedEx picks up the sample; and

5. Inform plant management that, if the sample is for microbiological analyses, the plant is required to hold or maintain control of the egg products lot(s) represented by the samples until all FSIS microbiological sample results are found to be acceptable. If the sample is for residue analysis, recommend that the plant hold or maintain control of the egg products lot(s) represented by the samples until FSIS residue sample results are found to be acceptable; however, IPP are to be aware plants are not required to hold or control product FSIS tests for residues.

B. The sampled lot is product that is represented by the sample collected by FSIS. Plants are to define the lot size of their egg products. If a lot is adulterated due to a pathogen-positive test or violative residue, other lots or other egg products may be affected if the plant is unable to support independence between lots or products. The sampled lot definition may differ based on microbiological versus chemical analyses. For microbiological analyses, a typical lot can be defined as one day's production (physically separated pasteurization run) of each type of product. A physically separated pasteurization run means that product has been separated from other production lots by cleaning and sanitizing, such that there is no potential contamination between separate lots of product. This may include cleaning the entire system (pasteurizer, clean-in-place (CIP) lines to packaging room, and final packing/filling equipment). IPP are to be aware of the following factors or conditions that may determine a sampled lot:

1. FSIS does not require egg products plants to perform a CIP procedure between each lot of production. However, if egg products are stored or packaged using common pipelines and equipment that have not been cleaned and sanitized prior to establishing another individual lot, FSIS cannot recognize the product subsequently produced as a separated product lot;

2. The egg products plant may store multiple lots in a common area. IPP are to be aware that the plant must maintain sanitary conditions to prevent contamination of the product(s) during storage and consider possible cross-contamination if products from different lots are stored in the same cooler, freezer, or dry egg products cool storage;

3. IPP are to be aware that a plant may reduce its lot size on a day when FSIS collects a routine egg product sample to facilitate holding the product. This may be accomplished, for example, through conducting sanitation of all pipelines and equipment between lots;

4. The egg products plant may define a lot differently based on the product group and formulation. For example, dried egg whites undergo a heat treatment, rather than a pasteurization run. In this case, the sampled lot would be all products present in the same heat treatment room at the same time; and

5. Shared equipment (pasteurizers, piping, silos, packaging machines, etc.) is the primary reason a pathogen-positive lot affects other lots or other "unrelated" egg products. FSIS will consider the following factors to determine products or lots represented by the positive result:

    a. *Salmonella* is typically found because of underprocessing. If one lot of egg product tests positive by FSIS, then other lots of product receiving the same lethality treatment may also be affected;

b. The most common cause of contamination by *Lm* is post lethality cross contamination. If one lot of egg product tests positive by FSIS, then other lots exposed to the same potential cross contamination may be affected; and

c. In addition, some plants may store more than one lot of pasteurized product in one pasteurized egg product silo without conducting a cleanup between lots. When this occurs, the sampled lot may consist of all co-mingled pasteurized runs.

C. For chemical analyses, FSIS considers the sampled lot to represent all products originating from the same poultry farm. In general, poultry management practices result in the entire flock being treated at the same time rather than individually. Therefore, an entire flock would be exposed to the same residues. Most plants will combine eggs from multiple poultry farms into a single production run. In this case, all poultry farms represented in the sampled lot would be implicated unless the plant provides justification for the exclusion of certain farms.

D. IPP are to collect microbiological samples from the finished product container (i.e., in its final packaging, typically a carton or pouch). 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. IPP are to refer to FSIS Directive 5030.1, *Inspection Methodology Utilizing the Public Health Information System (PHIS) for the Verification of Regulatory Compliance in Egg Products Plants,* for instructions on how to handle organoleptically unsatisfactory product.

E. IPP are to collect residue samples from liquid or dried egg products from shell eggs broken at that plant. This may include unpasteurized or pasteurized whole eggs, eggs whites, or egg yolks. Egg products produced from eggs previously broken at another plant are not eligible for residue sampling. In plants that combine eggs broken at that plant and eggs broken 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.

F. IPP are to collect the sample aseptically. Instructions on aseptic sampling are provided in IPP Help (Start Menu → FSIS Applications → IPP Help) under the "Sampling" tab → "Aseptic Sampling" tab.

VII. SAMPLE COLLECTION

A. When sampling liquid egg products, IPP are to:

1. Randomly select samples in packaging of five pounds or less (e.g., consumer-ready packages, cartons), if available, to achieve a minimum of 200 mL;

2. If a package of five pounds or less is not available, have the plant short-fill or slack-fill packages in plant-supplied packaging to achieve 200 mL;

3. If samples are not in consumer-ready packaging (e.g., bulk packaging such as totes, collection pots for residue sampling), IPP are to:

    a. If possible, collect the sample directly from the valve as it pours into bulk packaging;

    b. If not possible, then select a bulk package for sampling;

    c. Gather sampling supplies and proceed to the sampling area;

    d. Prepare the sample container and utensils;

e. Wash hands and put on gloves;

f. Aseptically open the bulk package by using a sanitized lid removal tool; and

g. Fill the two sample jars no more than ¾ 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 not to cross thread the sample jar.

Figure 6: Photo of pouring liquid egg product into a sample jar.

Figure 7: Photo of two filled sample jars.

4. When pasteurized egg products are shipped in a tanker to another official plant for further processing, IPP are to:

   a. Gather sampling supplies and proceed to the tanker bay location; and

   b. 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. IPP are not to collect samples from tankers. The plant employee will always collect the sample from tankers under the observation of IPP.

B. When sampling frozen egg products (using a drill or a trier), IPP are to:

1. Collect the sample during the packaging process and before freezing, if possible. If this is not possible, try to collect either a final five-pound package or a smaller final size package;

2. 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. IPP are to:

   a. Gather sampling supplies and proceed to the sampling area;

   b. Prepare the sample container and utensils;

   c. Wash hands and put on gloves;

   d. Aseptically open the bulk package by using a sanitized lid removal tool; and

   e. Fill two sample jars, ensuring both jars are packed down tightly and with no head space. Filling the jars completely to the top will compensate for the decreased volume that occurs when the product thaws and will ensure enough product is available to conduct the laboratory analyses.

3. 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:

a. 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;

b. Observe plant personnel use a sanitized spoon to remove all frost and ice crystals from the top of the frozen unit to be sampled;

c. Observe plant personnel drill at approximately a 45-degree angle, starting near the edge of the container;

d. 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;

e. Ensure that the shavings do not touch any part of the container that may have been previously exposed to potential contamination;

f. Ensure that the plant's drill operator does not spin the drill at high speed, in the hole, to prevent heating of the sample;

g. Wash and sanitize hands and put on a pair of gloves;

h. Collect the shavings that are produced from the drillings, packing the shavings down to ensure that the jar is filled, leaving no head space at the top of the jar; and

i. Keep the sample frozen at all times.

4. 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.

Figure 8: Photo of trier.

C. When sampling dried egg products, IPP are to:

1. Select dried product in final packages for sampling;

2. If a final package in not available, then select a bulk package for sampling. Samples are to be collected during packaging, when possible;

a. Gather sampling supplies and proceed to the sampling area;

b. Prepare the sample container and utensils;

c. Wash hands and put on gloves;

d. Asceptically open the bulk package by using a sanitized lid removal tool;

e. Open the sterile Whirl-Pak® bags and set aside. Use a sterile scoop;

f. For yellow egg products, collect product from different locations in the top of the package;

g. For white egg products, use a sterile scoop to move product aside and select product from the center of the package; and

h. Fill the sterile Whirl-Pak® to about ¾ full. 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.

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.

D. Immediately close and seal the sample container after collecting the sample. Place the sealed sample jars or Whirl-Pak® into the non-sterile secondary zipper-lock bag.

E. After collecting the sample, store it appropriately, under USDA lock, and under the conditions below in Table 1 until shipment to maintain integrity.

Table 1: Storage conditions for egg products prior to shipping

Frozen eggs	Frozen

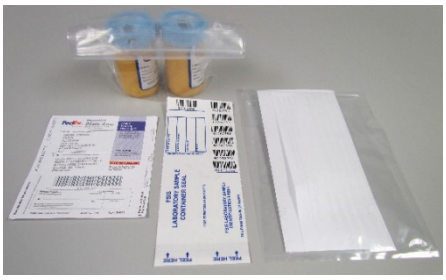
VIII. COMPLETE THE SAMPLE TASK AND SHIP THE SAMPLE

A. IPP are to follow the instructions provided in FSIS Directive 13,000.2 for completing sampling tasks in PHIS and FSIS Directive 7355.1, *Use of Sample Seals for Laboratory Samples and Other Applications,* on the use of sample seals (FSIS Form 7355-2A/2B) to maintain sample security and identification.

B. To pack the shipping container, IPP are to:

1. Retrieve the frozen gel coolant packs from the freezer (for liquid and frozen egg products) and the shipping container;

NOTE: For dried samples, a coolant and cardboard separator will not be included since these samples are to be maintained at room temperature.



2. Retrieve the samples from the secured location and apply the sample seals on the sample jars and sample form;

3. Place the absorbent pad on the bottom of the shipping container and, if shipping liquid or frozen samples, place the frozen gel coolant pack in the bottom or on one of the sides of the shipping container;

4. Place the sample (in the zipper lock bag) upright inside the shipper with the cardboard separator separating it from the cold pack;

5. Review the information on the pre-printed FedEx billable stamp provided with the sampling supplies and select the air bill with the laboratory name and address that corresponds to the FSIS laboratory name and address printed on the FSIS sample form (FSIS Form 8000-18) to ensure delivery of the sample to the correct FSIS laboratory. Enter the return address information on the FedEx billable stamp;

6. Place the completed, signed, and dated sample form in the plastic sleeve provided. Place the completed sample form and any unused sample seals in the shipping container;

7. Place the foam plug down upon the upright sample container (lid on top) as tight as possible. If the shipping container does not have a foam plug, place the insulated lid on the container. Do not overfill the shipping container;

NOTE: Do not tape or wrap the samples or use any newspaper or similar material as packing material. Use of such materials may result in a sample discard by the laboratory.

8. Apply the FSIS Laboratory Sample Container Seal (FSIS Form 7355-2A) to the inner flap of the shipping container as described in FSIS Directive 7355.1. IPP are to close the box flaps so that the container closure system is secure. IPP are not to tape the box if there are tapeless closures;

9. Affix the FedEx billable stamp on the shipping container and remove any old stamp receipts and carrier shipping bar codes from the container; and

10. Ensure that the samples collected remain under FSIS control prior to pick-up by FedEx.

C. IPP are to ship samples on the day of collection or the next day, but are not to ship samples on a Saturday, or the day before a federal holiday.

D. IPP are to return any unused shipping containers and sampling supplies after the sampling window closes, including the FedEx billable stamp, to the FSIS Laboratory that provided the IPP with these materials. IPP are to send a request to the FSIS Laboratory for a pre-addressed return FedEx ground-shipping bill, using the e-mail address provided in Section V.A. or Section V.B of this directive.

IX. SAMPLE RESULTS REPORTING AND FSIS ACTIONS

A. Sample results will be reported in PHIS. IPP are to review the results and inform the plant of the results upon receipt.

B. If any product tests positive for *Salmonella* or *Lm*, regardless of whether FSIS collected the sample or the plant collected the sample as part of the plant's sampling program, all product in the sampled lot is adulterated. If the results are from a plant program sample collection, IPP are to refer to FSIS Directive 5030.1, Chapter III, Section I, and Chapter IV, Section II for instructions on how to verify food safety regulatory requirements and to document noncompliance, respectively. The instructions below in Section IX.C apply strictly to FSIS sampling results.

NOTE: If the plant sampling identifies a positive for *Salmonella* or *Lm*, the plant must report it to IPP in accordance with 9 CFR 590.580(c). Failure to promptly notify IPP of the positive result is a noncompliance; however, the positive result by itself is not a noncompliance.

C. For microbiological test results reported as "Negative," IPP are to inform the plant that the test result is "in compliance."

D. When FSIS sampling identifies an egg product lot as positive for *Salmonella* or *Lm*, IPP are to determine if the plant also tested the product under its documented sampling programs.

1. If the plant did not also test the product, IPP are to issue a noncompliance citing 9 CFR 590.5 – Adulterated – under the appropriate Egg Products Food Safety task for the product sampled. If the plant also tested the product, 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. If the plant sampling also identified the product to be positive and the plant held the product, IPP are to verify that the plant performed the appropriate corrective measures in accordance with 9 CFR 590.422. IPP are to issue an NR only if the plant failed to perform appropriate corrective measures.

NOTE: More than one lot of egg products may be affected by a positive test result if the plant did not conduct a complete clean up between pasteurization runs from the pasteurizer, all common product lines to the packaging room, and the packaging/filling equipment. All affected product would be considered positive and would need to be re-pasteurized prior to being eligible for release into commerce.

E. For residue test results reported as "Not Detected" or "Detected – non-violative," IPP are to inform the plant that the test result is "in compliance."

F. When FSIS sampling identifies an egg product lot as "Detected – Violative" or "Detected but not Quantified, Violation" for residues, all product in the sampled lot is adulterated. IPP are to issue an NR citing 9 CFR 590.5 – Adulterated – under the appropriate Egg Products Food Safety task for the product sampled;

G. If FSIS sampling identifies *Salmonella, Lm,* or violative residues in the sampled lot, then IPP are to:

1. Retain the product using the "U.S. Rejected/Retained" tag until the product is reprocessed (for *Salmonella* or *Lm*) or destroyed (for *Salmonella, Lm,* or residues) (9 CFR 590.426 and 590.422), if the product is in the plant or under the plant's control. If the plant elects to reprocess the product for *Salmonella* or *Lm*, it would need to use methods appropriate to the pathogen detected;

2. Review and discuss the cause or any potential cause of the positive or the violative residue with the plant's management;

3. Document the results of the plant management's investigation in a Memorandum of Interview (MOI). At a minimum, in the MOI, IPP are to include details on:

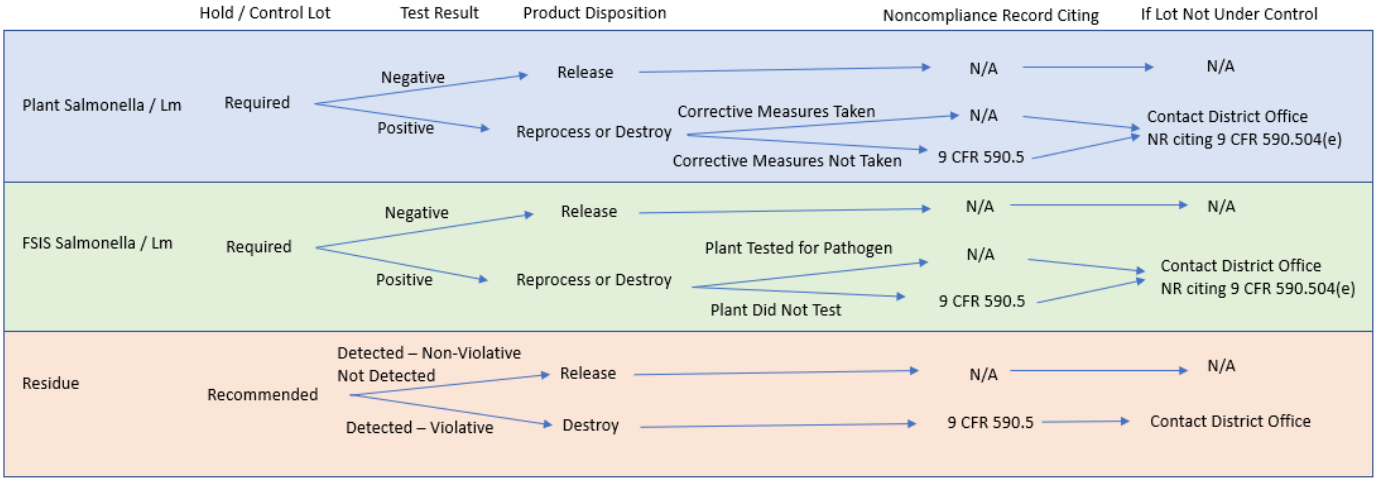
    a. The affected product type, lot number, and quantity of containers in the affected lots; and

    b. The retention tag number of the affected product;

4. Verify that the plant maintains a record of all affected product (for tracking purposes), including the initial number of containers affected, the lot number, and type of product (size, container type, how it is labeled). If the plant re-pasteurizes the *Salmonella* or *Lm*-positive product into new lots of egg product, the amount of egg product re-pasteurized will be 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, reconstitute and re-pasteurize, mix with other products and re-pasteurize, or leave in the heating room for additional time.

G. If the product sampled is positive for *Salmonella* or *Lm* or violative for residues and is no longer under plant control, IPP are to immediately notify their supervisor. The supervisor will notify the District Office. In addition, IPP are to issue a noncompliance citing 9 CFR 590.504(e) if product is positive for *Salmonella* or *Lm* and is no longer under plant control.

Figure 1. Flow Diagram for Egg Products Sampling



X. QUESTIONS

Refer questions regarding this directive to the Office of Policy and Program Development through askFSIS or by telephone at 1-800-233-3935.

Assistant Administrator
Office of Policy and Program Development