



**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Public Health Service
Food and Drug Administration

Memorandum

Date: February 3, 2011 **updated February 4, 2011**
Amended February 8, 2011

From: Consumer Safety Officer, Division of Field Programs and Guidance, OC
Thru: Team Leader, Field Programs Branch, HFS-615

Subject: **Amended Assignment** - FY11--Inspection of Egg Farms for Monitoring
Compliance with Egg Safety Rule, DFPG Assignment # 11-04, ORA
Concurrence # 2011012601
FACTS No. 1258067
Freedom Of Information Act Version (FOIA)

To: DIBs: All
DCBs: All
District Food Team Leaders: All
ORA Lab Directors and Lab Supervisors

Info: RFDDs: All
DDs: All

**Note: Original assignment issued February 3, 2011.
This amended version contains revised sampling instructions
(pp 8-11), and revised Biosecurity information on waste disposal
(p 15).**

Note: Material that is not releasable under the Freedom of Information Act (FOIA) has been redacted/deleted from this electronic version of the program. Deletions are marked as follows: (#) denotes one or more words were deleted; (&) denotes one or more paragraphs were deleted; and (%) denotes an entire attachment was deleted.

BACKGROUND

Salmonella Enteritidis (SE) is among the leading bacterial causes of foodborne illness in the United States and shell eggs are considered a primary source of human SE infections.

On July 9, 2009, the Agency published in the Federal Register a final rule entitled Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Transportation, and Storage (74 FR 33030)(<http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/EggSafety/EggSafetyActionPlan/ucm170746.htm>) (hereinafter referred to as the Egg Rule). The Egg Rule requires that shell egg producers implement measures to prevent *Salmonella* Enteritidis (SE) from contaminating eggs on the farm and from further growth during storage and transportation, and requires these producers to maintain records concerning their

compliance with the rule and to register with the FDA. In July 2010, producers with greater than 50,000 or more laying hens became subject to the Egg Rule.

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USDA/AMS, a federal partner in shell egg oversight, has been advised of FDA's inspectional approach from a national perspective. During inspections, FDA investigators, and state regulatory partners accompanying FDA or performing inspections under FDA contract, will contact any USDA/AMS inspectors on site.

OBJECTIVES

- **To conduct a TARGETED egg farm inspection at a majority of firms to determine if the firm has implemented basic controls to comply with 21 CFR 118: Prevention of Salmonella Enteritidis (SE) in Shell Eggs During Production, Storage and Transportation Rule (Egg Rule)**
- **To conduct a COMPREHENSIVE egg farm inspection, which includes environmental sampling, at higher-risk firms to evaluate the firm's SE plan implementation and compliance with the Egg Rule.**
- **To gather data about the firms for determining their future inspectional priority based on risk assessment tools**
- **To document inspectional findings and initiate compliance action as warranted**

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INSPECTIONAL APPROACH

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Conduct inspections of the egg production facilities of each firm listed on Attachment C. Inspections are to be conducted with a team of Investigators. Lead Investigators must have attended DHRD course FD107 Egg Safety Inspection Training. The course training manual provides specific instructions for how to conduct these inspections.

1. For comprehensive inspection, a minimum of 3 investigators are needed per team, 5 are preferable, especially for larger facilities.
2. For targeted inspections, a minimum of 2 investigators are needed per team.

ORA/DDFI will provide a master tracking schedule indicating the week of the inspections for districts. Firms that are to receive a comprehensive inspection will be highlighted on the schedule. This will be included as a separate attachment sent with the assignment.

Pullet houses are not to be inspected or sampled as part of this assignment.

If a farm also has an egg-breaking facility on-site, that aspect of their operations is under USDA jurisdiction and will not be inspected by FDA. Some farms with an egg packing facility will be under contract with USDA/AMS for egg grading. Such farms are also evaluated by USDA/AMS for sanitation. During inspections, FDA investigators, and state regulatory partners

accompanying FDA or performing inspections under FDA contract, will touch base with any USDA inspectors on site. The packing facility will not be covered during this assignment. Additionally, pullet houses are not to be inspected or sampled as part of this assignment

Targeted Inspections

Targeted inspections under this assignment are to include the following components:

- Review the written SE prevention plan to assure that it includes:
 - Procurement of pullets that are SE monitored
 - Biosecurity measures
 - Rodent/Pest control measures
 - Cleaning and disinfecting measures
 - Adequate refrigeration of shell eggs
 - Environmental and egg sampling/testing program
- Review of a subset of the firm's environmental testing results
 - If the firm had any positive results in the past year, determine if they implemented egg testing or diversion as required.
- Evaluation of the firm's implementation of its rodent/pest control measures

(#) This will serve as the main reporting mechanism for this inspection. This attachment should be completed and inserted into the Additional information section of the establishment inspection report (EIR). This information will be utilized to determine future inspectional priority of a firm.

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Based on the findings from the targeted inspection, the District will determine priority (1,2,3) for

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* If a State inspection results trigger a comprehensive inspection, State counterparts should contact the appropriate District. The District will use the above priorities to determine when to conduct a comprehensive inspection, if necessary.

*If a district needs to schedule a firm for a comprehensive inspection which includes environmental sampling, they should work with DDFI and DFS to schedule these sample collections in order to identify a laboratory.

Comprehensive Inspections

Comprehensive inspections are to be conducted using (#) is an inspectional tool to help guide the Investigator through the inspection. It provides useful citations to Part 118 of the regulation, covers questions and areas of significance, and will help the Investigator to prepare the FDA-483. When completed it must be inserted into the EIR under the heading, "Additional Information". This tool will form a significant portion of the EIR.

Comprehensive inspections under this assignment are to minimally include the following components:

- Evaluate the SE prevention plan
 - Procurement of pullets that are SE monitored

- Biosecurity measures
- Rodent/Pest control measures
- Cleaning and disinfecting measures
- Adequate refrigeration of shell eggs

NOTE: If there is no written plan, determine if preventative controls are in place. Lack of a written SE prevention plan is a significant deviation from the Egg Rule and must be noted on the FDA 483. (See Regulatory Follow-up for other significant deviations.)

- Determine if the environmental testing and appropriate actions were taken, accordance with the rule , if a positive sample was found
- Determine if the plan has been implemented
- Review records (monitoring, sanitation)
- Determine if the SE prevention measures are being practiced
- Conduct environmental sampling
- Verify the firm's registration
- Issue an FDA-483 to cover any significant objectionable conditions observed during the inspection and prepare the EIR in accordance with established procedures.

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Environmental sampling is to be conducted during all comprehensive inspections. The information below outlines the number of houses to sample as well as environmental sample collection.

INSPECTION CLASSIFICATION FOR EGG FACILITY INSPECTIONS

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ENVIRONMENTAL SAMPLE COLLECTION

Environmental samples in the poultry houses will be collected during the inspections under this assignment to assess conditions and obtain baseline information about the state of the industry.

Egg farms can have multiple physical locations (sites with different addresses), which can contain a number of separate henhouses. In order to assess the conditions in a representative manner, **the Investigator must conduct environmental sampling in the *same number* of houses (#) in which they conduct a walk through. The same number of *different* houses may be environmentally sampled.**

During a walk through, if the Investigator determines that those particular houses should be environmentally sampled, the same houses can be sampled.

If conditions warrant, the investigator can walk through all the houses to determine which ones to sample.

If a house is determined to be SE positive based on the firm's environmental testing, the investigator must not select or enter that house for testing.

Sampling Technique:

Drag swabs of manure are the preferred environmental sample (water, feed or egg samples are NOT to be collected as part of this surveillance assignment). Detailed instructions are available at the following two websites:

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodSafety/ucm222469.htm>

<http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/ucm114716.htm>

The following information includes swab type and preparation, assembling/use of a drag swab, and sampling approaches depending on the farm's approach to manure management.

a. Swab Type

4x4, 12 ply sterile gauze pad with string (manure samples) – drag swab

4x4, 12 ply sterile gauze pad without string (for egg belt samples) – hand swab

b. Swab Prep

When the swabs are ready to be used, the investigator must aseptically moisten them with canned evaporated milk (investigator should use evaporated milk from the same lot for each house). Multiple cans/vials may be needed with the same lot codes preferred. Sanitize the tops of the milk cans prior to opening with a 70% ethanol solution. Closed control samples of the milk will be submitted with the sample.

c. Drag Swab Assembly

Assembly of a drag swab will assist in collection. Districts should purchase metal poles, suitable for sanitation (stainless steel preferred). The moistened drag swab with string should be aseptically and securely tied to the metal pole. The metal pole must be thoroughly sanitized between rows and between houses.

d. Sample Collection Method

For the purposes of this section:

Row means a group of cages that runs the length of a house.

Bank means half of a cage row (one side of a row – left or right).

Tier means a level of cages in each row.

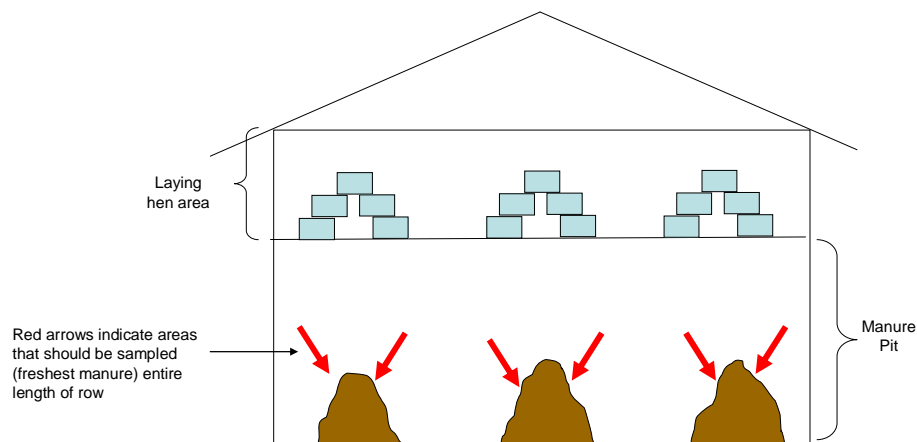
Manure is the preferred sample type. Use a 4 in x 4 in, 12 ply sterile gauze pad which is aseptically attached to a drag pole, which should be disinfected before each use with 70% ethanol. Drag the moistened gauze pad over the manure the entire length of one side of the row/bank. Take another gauze pad and drag the other side of the row/bank. Repeat this procedure on all rows/banks of the house.

Place each pad in a separate Whirl-Pak[®]-type bag with sufficient milk to keep the pad wet (no more than a tablespoon or approximately 15 ml).

Manure Management - High-Rise Poultry House (Pit Style House):

This style of house has two stories with the laying hens placed in the second floor and the first floor being the “pit” where manure collects in a cone shape under each row. Sampling should occur from left to right from the front of the house and the area toward the top of the cone where the freshest manure accumulated should be the area sample on **each** side of every row (Figure 1). The entire length of each row should be sampled, with the investigator walking the length of the row **and** back. Poles that can be easily sanitized may be used if it facilitates sampling, if multiple swabs are taken at once care should be taken that the swabs stay on the same side of the row on the trip to the end of the row and back. In situations where the pit can not be sampled, see instructions below (i.e. Manure Management -- Pits Unsuitable for Drag Swabbing).

Figure 1: Sampling a High-Rise (Pit Style House)



Manure Management - Shallow Pit

Shallow pit poultry houses will have some type of manure scraper. Some have scrapers under each tier, some have a floor scraper only, and some have a combination of both. This style of house may be configured as a “flush” type house where water is flushed through the pit to aid in the removal of manure in conjunction with the main floor scraper blade or they may be a dry system where the blades themselves remove the manure. Only the solid manure on the scrapers should be sampled, as ammonia in the pit liquid may inhibit SE growth. Sampling of this style of house can take place either while the scrapers are running or stationary. In flush style houses sampling should take place while stationary unless the pit is dry. When sampling this style of house extreme caution should be taken, and communication with farm management is imperative to insure the blades are not operated while they are being sampled.

When scraper is running

Attach two drag swabs onto the main manure scraper assembly, so that one drags on the left bank (side of row) and the other on the right bank of that row, and run the scraper assembly to the opposite side of the house and back. Remove the swabs and place them into appropriately labeled Whirl-Pak[®] bags (one swab per bag).

When scraper is stationary

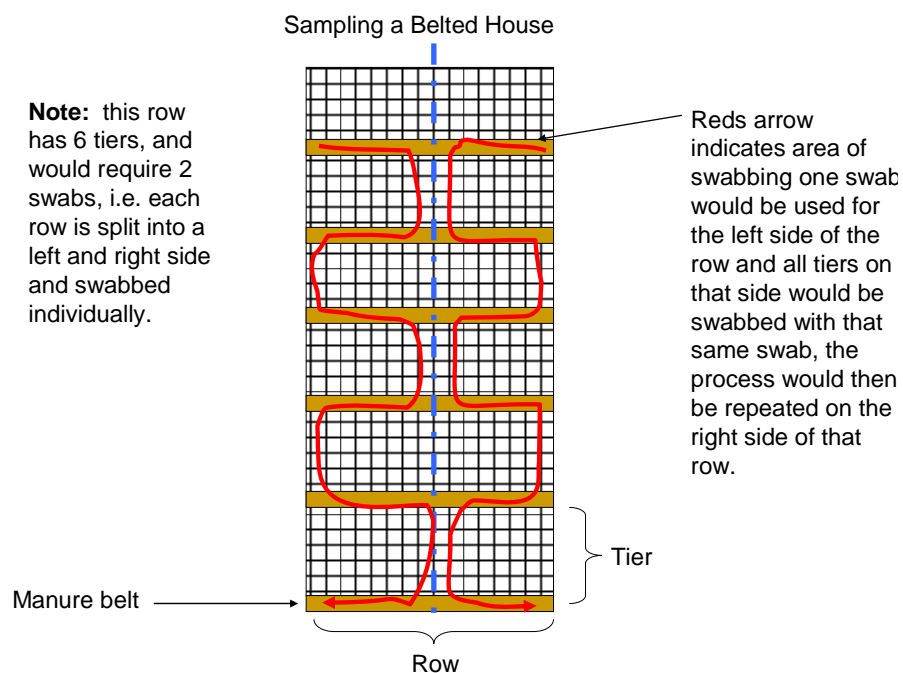
Use hand swabs to swab the solid manure on all tiers of scraper blades and place the swabs into separate appropriately labeled Whirl-Pak[®] bags (one swab per bag). The scraper blades under each tier should be sampled along with the main pit scraper using one swab. This swabbing method should be performed for each bank of the scraper blade (left and right side) in a row. If the shallow pit has a narrow walkway beneath it, use a drag pole to collect drag swab samples underneath the row of cages, and place swabs into appropriately labeled Whirl-Pak[®] bags (one swab per bag).

Manure Management - Belt System

* (#). A change has recently been implemented on how these houses are sampled to more closely match FDA's Guidance for Industry and represents a significant change from the method taught during these training sessions. This change is outlined below. Please contact Gerardo Ramirez if you have any questions.

When sampling a belted house each bank (side of the row) should be sampled. Sampling should **always** occur from the topmost tier, in consecutive order, to the bottommost tier. Use one swab for the left bank of all tiers in a row and a separate swab for right side of all tiers in a row. Swab the area around the scraper blade on each tier (Figure 2). Each swab should be placed in its own individually labeled Whirl-Pak[®] bag. If the belted house has a second story (often referred to as a stacked deck house), the process should be repeated on the second floor. Sampling should be from left to right when facing the **front** of the house, therefore when looking at the rows from the back of the house the right side of each row would be on your left side and the left side of each row would be on your right side. In situations where the upper tiers can not be reached, some type of extension device will need to be used, such as a solid graphite rod with an alligator clip glued to one end or a metal broom handle that is capped at both ends. The device should be sanitized between each bank of a row, between rows and between houses. Avoid selecting anything with grooves, nooks, or crevices that may make sanitation difficult.

Figure 2: Sampling scheme for belted houses (Sample from top to bottom)



Manure Management -- Pits Unsuitable for Drag Swabbing

If Investigators encounter manure pits that are unsuitable for drag swabbing – that is, manure that is piled very high or is liquid or semi-liquid – as an alternative, representative egg belt and walkway sampling should be conducted.

Egg belts: Hand-swab the egg belts (swab approximately 10-12 feet per belt on each cage level, this can be accomplished by swabbing approximately 6-10 inches every 5-10 feet for the length of the belt) and the de-escalator for the corresponding tier. Use a separate swab for each egg belt/tier (including de-escalators) for each side of the bank. Place each swab into its own Whirl-Pak[®] bag. This process should be continued until all egg belts in a house have been sampled.

Walkways: Drag two swabs along the length of each walkway and back. Care should be taken to maintain the swabs on the same side of the walkway on the walk to the end of the row **and** on the way back. Place each swab into its own Whirl-Pak[®] bag.

Manure Management -- Cage-free Operations

Sampling of cage free poultry houses is a function of the width of the house. The following number of swabs should be collected per house, based on the width of the house, as follows:

- 55 or more feet wide = 12 swabs
- 46 – 54 feet wide = 10 swabs
- 37 – 45 feet wide = 8 swabs
- 28 – 36 feet wide = 6 swabs

Divide the house in half and swab each half of the house with half the number of swabs required. Use drag swab poles with multiple drag swabs on a pole, up to a maximum of 3 drag swabs per pole at one time. Swab the litter and slat area the full length of the house.

If a house has multiple floors, divide the number of swabs evenly to cover each floor equally. Place each swab in a separate Whirl-Pak bag.

Sample Numbering System

Samples collected in one house in one day will have a unique sample number with the requisite number of subsamples. To promote consistency and understanding of the results, a specific subsample identification system is recommended, with examples as follows:

Manure:

3 L M

3 = Row number

L = Left side of the bank

For the right side of a bank use the letter R

M = Manure

Egg belt:

1 R 3

1 = Row number

R = Right side of the bank

For the left side of a bank use the letter L

3 = Tier number (if multi-tiered house)

Walkway:

2 L W

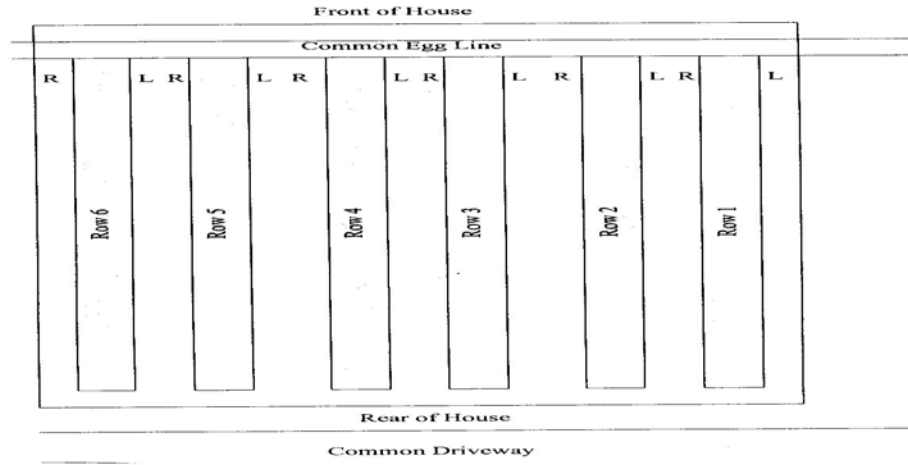
2 = Walkway/aisle number

L = Left side of bank

For the right side of a bank use the letter R

W = walkway

Figure 3: Diagram of typical egg house



Note: As stated above, do not collect both manure and egg belt/walkway samples. Collection of egg belt and walkway samples is to be done only when the manure is inaccessible.

Pre-assembled sterile drag swabs (12ply 4x4) for the use in environmental sampling have been purchased and investigators can obtain these drag swabs through their districts and/or servicing laboratories. For questions on how to obtain the drag swabs please contact Norma Duran (DFS).

Sample Shipment/Serviceing labs:

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NOTE: Changes to the assigned schedule should be arranged in advance with DDFI and DFS Scheduling contacts identified below.

*If an inspection results in FDA positive SE environmental samples, the district should first inform the State regulatory agency of the findings. FDA and the State should jointly contact the firm immediately following the State notification. Per FMD-147, positive results should also be shared with the firm in writing.

SAMPLE ANALYSIS

Analyzing laboratories:

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Environmental samples will be analyzed for *Salmonella* Enteritidis (SE) according to the following methods:

Salmonella Isolation:

Use method entitled “Environmental Sampling and Detection of *Salmonella* in Poultry Houses,” October 2008. This method is available at the following website:

<http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/ucm114716.htm> Conduct biochemical identification tests to presumptive *Salmonella* isolates.

Serogrouping of *Salmonella* spp.:

Proceed to section E.6.b of Bacteriological Analytical Manual (BAM) Online: Chapter 5

<http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/UCM070149> and test each of the TSI isolates for *Salmonella* (O) group D₁ activity. If the

isolates do not display Group D₁ activity, then the isolates should be considered non-*S. Enteritidis*. All non-*S. Enteritidis* isolates from surveillance environmental samples (not associated with an

outbreak) can be discarded; if the isolate is from environmental samples associated with an outbreak the laboratory should retain/archive all non-*S. Enteritidis* isolates for further testing. All isolates that display Group D₁ activity should proceed to confirmation/speciation.

Salmonella Enteritidis- Confirmation/Speciation and Shipment of Confirmed Isolates:

Servicing laboratories are to send *Salmonella* isolates for serotyping within 24 hrs after completion of the analytical portion of the sample analysis. All bacterial cultures should be prepared and submitted according to the directions specified in the Bacteriological Analytical Manual (BAM), Chapter 5, E.11, Submission of cultures for serotyping.

The serotyping laboratories will submit confirmed *Salmonella* Enteritidis isolates to CFSAN for whole-genome sequencing to the address below:

US Food and Drug Administration, CFSAN
Attn: Dwayne Roberson
5100 Paint Branch Parkway
College Park, MD 20740

In addition, the serotyping laboratories will submit confirmed *Salmonella* Enteritidis isolates for Pulse Field Gel Electrophoresis (PFGE) assay to respective servicing laboratories. The servicing laboratory will determine the pulse-field gel electrophoresis (PFGE) pattern of each *Salmonella* Enteritidis isolate. The servicing lab will electronically send the image(s) of the PFGE patterns to CFSAN.

An electronic mail should be sent to the recipient before the shipment. All cultures should be shipped by FedEx overnight and should conform to the rules and regulations regarding the shipment of infectious agents.

Laboratory Classification of Environmental Samples:

The servicing laboratory can classify findings of *Salmonella* spp. that display Group D₁ activity in environmental samples as Lab Class 2 pending serology/speciation and close out FACTS so timeframes will not be affected by serology testing timeframes. If the environmental sample is confirmed as *Salmonella* Enteritidis, the serotyping laboratory will classify the finding as Lab

Class 3 and the servicing laboratory can go back and reclassify their findings to reflect a Lab Class 3.

BIOSECURITY/PERSONAL PROTECTION REQUIREMENTS

These instructions should be followed during every inspection where investigators go into the poultry houses, regardless of whether environmental sampling is conducted.

Egg farm inspections require unique action by Investigators to assure that we do not contaminate or cross-contaminate the environment. Additionally, our investigators must take steps for their personal safety. The following are requirements:

- The Investigator must be enrolled in a Respiratory Protection Program. Prior to using a respirator and entering a poultry facility, the Investigator must be medically cleared, fit tested and trained in the proper use and limitations of the issued respirator. FDA Investigators will be issued permanent respirators. Cartridges/filters do not have to be changed between houses but must be wiped off with a decontaminant. Cartridges/filters can continue to be reused until they become difficult to breathe through or when a wearer tastes/smells a chemical. If a risk assessment determines that a chemical hazard is not present in the poultry house, properly fitted disposable N95 respirators may be worn. If disposable N95 respirators are used, they must be disposed after each entry to a poultry house. Respiratory training will also need to be provided for individuals wearing N95 respirators.
- The Investigator must not be a bird and/or reptile owner in their own home and/or must not have been in any other poultry/reptile facility up to 72 hours before an inspection, including visits to aviaries, tending backyard feeders, etc.
- Disposable personal protective clothing (e.g., Tyvek[®] suits, booties, gloves) must be changed between poultry houses on the farm to avoid any potential for cross-contamination of not just SE but other infectious bird diseases such as avian influenza (AI) and exotic Newcastle disease (END).
- Vehicles to be used for transport to egg farms are required to be cleaned and the tires disinfected prior to arrival at the farm. After leaving the farm location the vehicle must be cleaned, including the car, tires and wheel wells, at a car wash. Tires must again be disinfected with a product that has effective activity in the presence of organic matter. 70% ethanol has limited disinfectant properties and may not be effective against all organisms. For a list of suitable disinfectants, please contact **Michelle Markley, 301-796-8178**.
- Photographs should be obtained, if possible. Use separate disposable cameras for each house. Digital cameras can also be placed in sealable plastic bags, which will be changed out between poultry houses. **NO FLASH should be used at any time, so as not to frighten the birds.**
- Unless mandated otherwise by the farm's Biosecurity procedures, Investigators must take and properly dispose of any waste generated during egg farm inspections. To avoid cross contamination of the interior of vehicles, supplies must be sanitized and waste double bagged before touching the interior of the vehicle.
- Because the nature of the work and the wearing of Tyvek[®] suits and respirators can be tiring and warm, the team should dress appropriately and bring a supply of water, energy drinks, and snacks. Coolers for this use should be clearly identified to ensure that there is no cross contamination with sample coolers.
- Before conducting the inspection, a member of the team should be designated as the team safety officer and be familiar with Biosecurity and Personal Protective Equipment (PPE)

requirements to help support the safety of all team members. However, all team members should be looking after one another and themselves.

Movement between houses should be inspected from the youngest birds to the oldest birds. Houses and birds known to have diseases, including SE, should NOT be visited.

Any additional questions or concerns regarding PPE should be directed to CDR Michelle Markley, 301-796-8178. Any questions regarding Biosecurity should be directed to DDFI.

INVOLVEMENT OF STATE REGULATORY PARTNERS

The Districts should share this assignment with their commissioned State partners (%) and involve them in the scheduling and planning of all inspections. If the state elects to participate in contract inspections after the contract has been issued, the district should conduct work planning with the State partner to determine which of the targeted inspections will be conducted by the state under contract.

Prior to conducting the inspection, the District must contact the State Program Contact (%) to determine if there is a state quarantine or other prohibition from entering the farm. Investigators are to document that this inquiry was made in the EIR for all inspections.

Prior to planning either type of inspection, consult with the appropriate state regulatory agency contact as identified in (%) regarding the inspections and request that the state accompany FDA on all FDA inspections (even if they have not attended the FDA/DHRD Egg Rule Training Course). Refer to (%) for a list of state officials that currently have responsibility for egg laying operations. The request of the state to accompany FDA on all FDA inspections should be made regardless of whether or not the state is participating in the state contract to conduct egg inspections.

Provide the State Program Contact with a copy of this assignment and refer to the Biosecurity/PPE requirements. The State representative participating in the inspection will need to comply with the Biosecurity and Personal Protection requirements as indicated above, except that State personnel may follow their State requirements for respiratory protection. A minimum of an N-95 type mask is strongly advised. Should the State Agency have questions regarding obtaining the required PPE, they are directed to contact the local FDA District Office.

After the inspections conclude, keep involved state officials informed of any possible compliance actions.

All regulatory follow-up as a result of an OAI, including inspections completed by the State, is to be conducted by FDA.

REGULATORY FOLLOW-UP

FDA's Egg Rule enforcement authority is established under the Public Health Service Act (the PHS Act), as well as the Food, Drug and Cosmetic Act (the Act). As such, the failure to adequately implement the provisions of the Egg Rule is a violation of 42 U.S.C. 264(a) and the regulation in 21 CFR 118 (the Egg Rule). In addition, significant violations of the Egg Rule render the eggs adulterated within the meaning of 402(a)(4) of the Act.

If an inspection results in FDA positive SE environmental samples or uncovers conditions that would warrant additional followup, the district should first inform the State regulatory agency (FDA Commissioned Officer) and USDA: AMS and FSIS of the findings. FDA and the State should jointly contact the firm immediately following the State notification. Per FMD-147, positive results should also be shared with the firm in writing. A copy of the EIR should be provided to the State regulatory agency (FDA Commissioned Officer) upon completion. If the recipient is not commissioned, redaction may be needed.

Districts should recommend Warning Letters to CFSAN for egg producers with significant deviations from the Egg Rule. All violations must be documented on the FDA 483 and discussed with firm management.

Significant deviations from the Egg Rule include:

- Lack of a written SE (SE) prevention plan or significant requirements not included such as:
 - Failure to procure pullets that are SE-monitored
 - Failure to include Biosecurity measures
 - Failure to include Rodent/Pest control measures
 - Failure to include measures for cleaning and disinfecting the poultry house
 - Failure to include measures for adequately refrigerating shell eggs
- Failure to environmentally test for SE during required time periods;
- Failure to divert eggs or begin egg testing after a positive environmental sample (sample must have been taken during required time period);
- Failure to implement the SE prevention plan;
- Failure to maintain required records documenting the implementation of the SE prevention plan; and
- Failure to monitor conditions required for implementation of the SE prevention plan.

Regulatory recommendations regarding a firm with any of the above deviations must be submitted to the Division of Enforcement via electronic copy (e.g., doc, pdf files, etc.) via the "Mission Accomplishment and Regulatory Compliance Services-Compliance Management Services" (MARCS-CMS) link located on Inside FDA's IT Application Page under ORA Applications.

If the following scenarios are encountered during an inspection, prior to inspectional closeout, you should notify CFSAN's regulatory contacts to discuss the need for an Order of Diversion:

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If the only significant violation noted is failure to register as required by 21 CFR 118.11(a), districts should send a direct-reference untitled letter to the firm.

Specimen charge:

The article is in violation of Public Health Services Act, Title 42 U.S.C. Section 264(a), and the regulation codified in 21 CFR 118.

The article is adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 342(a)(4)] because it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

All regulatory follow-up as a result of an OAI, including inspections completed by the State, is to be conducted by FDA.

Regulatory Strategy for Egg Facility Inspections

ORA and CFSAN have developed an instructional Field Bulletin that addresses the violations which will support an OAI or VAI inspectional classifications as well as appropriate regulatory followup. (%)

TIMEFRAMES

This assignment is **High Priority** and should begin upon receipt under the aforementioned schedule of inspections (%). The end date of the assignment should be upon completion of all egg farm inspections. Please contact Jennifer Beal, DDFI, if there are any needed deviations from the schedule of inspections. If a regulatory action is indicated based on the investigational and analytical findings, the district should adhere to established timeframes for submitting reports and recommending action to CFSAN.

RESOURCES AND DATA REPORTING

Data Reporting:

Inspections:

FDA PAC: 03F836 - FY10/FY11 Egg Farm Inspection / Environmental Sampling Assignment

State Contract PAC: 03S836 – State Contract Egg Farm Assignment Inspections

Product Code: 15A--01 (Egg, Chicken, In Shell)

IMPORTANT: Please remember to report all sample numbers from related collection reports on Page 2 of the FACTS Maintain Inspection Results Screen.

Egg Farm Inspections conducted under this Assignment by both FDA and the States **will count** towards the FY11 High Risk Foods Performance Goal. **In order to receive credit towards the Performance Goals these inspected firms will need to be flagged with the 'A1' - CFSAN Additional Firm Program Risk Identifier Code in FMS.** They should only be flagged 'A1' if they were not previously identified as 'F1'. They should not be flagged both 'F1' and 'A1'.

An inspectional tool (Attachment A (targeted inspections) or B (comprehensive inspections)) should be used to collect information on the inspection as a different method of data collection in order to shorten the total inspectional and reporting time burden to complete an inspection.

Sample Collections/Analysis:

PAC: 03F836 - FY10/FY11 Egg Farm Inspections / Environmental Sampling Assignment
PAF: 'MIC'
Sample Basis on CR: 'Environ-Survl'
Product Code: 52YYY99

NOTE: When environmental samples are collected over more than one day, create a new sample number/CR each day.

General Notes:

- (1) Egg laying farms in all Egg Rule related assignments must have the "Safety Alert" indication in FACTS/Firm Manager set to "yes" to indicate that personal protective equipment is required to be used to prevent introduction, transfer and cross contamination of *Salmonella* Enteritidis among poultry houses.
- (2) The TURBO EIR sites are available now. **Deviations from Part 118 only** are to be noted on the 483.21 CFR 110 does not apply to egg production houses.

EIR:

Inspections of these establishments will likely include a headquarters location plus multiple farms. Each of these locations may have individual registrations and FEI numbers. The entire establishment may be under one SE Prevention Plan and set of procedures. The investigator may prepare one EIR for these situations, which includes each farm location, rather than multiple EIRs. However, each separate location will need to have an inspection reported in FACTS to ensure we have accurate information on last inspection date, products covered and classification. Each of those FACTS entries should refer to the location of the EIR (Factory File/FEI #) covering the overall inspection. Additionally, observations related to specific locations and not all locations should be clearly identified and delineated in the EIR.

FACTS:

CFSAN has entered the assignment into FACTS with an approximate number of inspections and sample collections for each district.

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ATTACHMENTS

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