

**CHAPTER 03- FOODBORNE BIOLOGICAL HAZARDS**

<b>SUBJECT:</b> <b>INSPECTION OF EGG FARMS FOR MONITORING COMPLIANCE WITH EGG SAFETY RULE</b>		<b>IMPLEMENTATION DATE:</b> 04/28/2017
<b>DATA REPORTING</b>		
<b>PRODUCT CODES</b>	<b>PRODUCT/ASSIGNMENT CODES</b>	
<b>PRODUCT CODE: 15A--01</b> <b>USE APPROPRIATE PRODUCT CODES</b>	<b>Report program activities under the following PACS:</b>  03836 (Egg Farm Inspection/Environmental Sampling)  03S836 (State Contract Egg Farm Assignment Inspections)	

**FIELD REPORTING REQUIREMENTS:**

**A. Inspectional:**

- Egg Inspection IQ must be used to collect information on the inspection in order to shorten the total inspectional and reporting time burden to complete an inspection. When completed, The Egg Inspection IQ must be inserted into the EIR under the Additional Information section. Note: A CSO must have attended the egg safety inspection class in order to act as a lead for the inspection.
- Changes to the assigned schedule should be arranged in advance with CFSAN/OC/DFPG contact at [Ann.Westerman@fda.hhs.gov](mailto:Ann.Westerman@fda.hhs.gov) or 240-402-1878 and ORS scheduling contacts identified in Part VI.

**B. FACTS Reporting:**

- FACTS Inspection Reporting (Operation 12):

When FDA has the jurisdiction to conduct an inspection and the firm falls under a work-load obligation for the Egg Rule, enter an Operation 12 in FACTS using the Egg Inspection PAC. A list of firms for *Comprehensive* and *Targeted* inspections along with a comprehensive inspection schedule will be sent out by CFSAN/Office of Compliance/Division of Field Programs & Guidance prior to the start of the scheduled fiscal year for inspections.

If a Comprehensive inspection is assigned, but there is an inability to conduct sampling due to firm’s operations and the firm still falls under all of the requirements of the Egg

Rule, then conduct a Targeted Inspection as an Operation 12. Contact the ORA/OFFO contact to discuss why samples were not able to be collected.

- FACTS Investigation Reporting (Operation 13):

When the firm is not required to comply with any portion of the Egg Rule (NOE) or, if a producer sends all their eggs to breakers, then they must comply with registration and refrigeration and if any egg goes to the table egg market then they must comply with all the requirements of the Egg Rule.

If the firm is OOB, then enter an Operation 13 in FACTS. The Operation 13 should reference the program instructions of Comprehensive or Targeted.

*Comprehensive OP 12 -> Targeted OP 12 (see above) or Comprehensive OP 13  
Targeted OP 12 -> Targeted OP 13*

Please follow the IOM SUBCHAPTER 8.10 - GENERAL INVESTIGATION REPORTING

<http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM123515.pdf>

See Breeders/Broilers section (Part III/G) for additional situations in which an OP 13 should be entered and NOT an Operation 12.

- FACTS Sample Reporting:

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

**Sample Collections/Analysis:**

PAC: 03836, 03S836 - Prevention of S. Enteritidis in shell eggs, State Contract Egg Farm Assignment Inspections

PAF: 'MIC'

Sample Basis on CR: Surveillance

Product Code: 52YYY07

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

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**Safety Alert Coding**

Egg farms in all Egg Rule - related work 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 among poultry houses. If you find an egg laying farm identified in FACTS without the "Safety Alert" indication, please speak with your supervisor or District OEI Coordinator to ensure this is completed. Please refer to IOM Chapter 5, Establishment Inspection: <http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM150576.pdf>

for more information on the "Safety Alert" notification.

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## PART I – 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 a final rule entitled “Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation (74 FR 33030).”

(<http://www.gpo.gov/fdsys/pkg/FR-2009-07-09/pdf/E9-16119.pdf>) (hereinafter referred to as the Egg Rule). The Egg Rule requires that shell egg producers 1) to implement measures to prevent *Salmonella* Enteritidis (SE) from contaminating eggs on the farm and from further growth during storage and transportation, 2) maintain records concerning their compliance with the rule, and register with the FDA. The rule became effective in July 2010 for producers with 50,000 or more laying hens at one farm, and in July 2012 for producers with at least 3,000 but fewer than 50,000 laying hens. Farms with fewer than 3,000 laying hens are not subject to the rule.

USDA/AMS, a federal partner in shell egg oversight, has been advised of FDA’s inspectional approach from a national perspective. During FDA inspections, Investigators will alert any on-site USDA/AMS inspectors of their presence.

## PART II - IMPLEMENTATION

### 1. Objectives

- To conduct comprehensive or targeted inspections at egg firms in order to evaluate the firms' compliance with the requirements of 21 CFR 118: Prevention of Salmonella Enteritidis (SE) in Shell Eggs During Production, Storage and Transportation Rule (the Egg Rule)
  - In addition to evaluation of compliance with the Egg Rule, a comprehensive inspection will also include environmental sampling.
- To gather data about the firms to determine their future inspectional priority based on risk assessment using the Egg Inspection IQ
- To document inspectional findings and initiate compliance action as warranted
- To analyze samples for presence of SE, and if SE is found, ensure that the firm responds in accordance with the Egg Rule.

### 2. Program Management Instructions

#### A. Inspection priorities

CFSAN/Office of Compliance/Division of Field Programs & Guidance, in conjunction with CFAN/Office of Food Safety/Division of Dairy, Egg and Meat Products will identify the domestic firms to be inspected in a separate memorandum prior to the start of each fiscal year. The memorandum will indicate the size of the farm and the type of inspection the farm will receive (targeted or comprehensive). The memorandum will include a master tracking schedule indicating the week of comprehensive inspections for districts and identified laboratories for samples. Districts should schedule the targeted inspections and collect samples to meet the goals of the program.

In situations where a change in the comprehensive schedule is needed, the district should coordinate with CFSAN to identify an alternative inspectional date.

The number of inspections and approximate number of sample collections will be entered into FACTS by CFSAN. Individual Districts are to update FACTS with the appropriate number of samples collected.

When an inspection is classified OAI (Official Action Indicated), Districts must conduct compliance follow-up inspections within appropriate timeframes. Refer to FMD-86 for further information.

#### B. Involvement of State Regulatory Partners

If the state program has received a contract to conduct egg firm inspections, during workplanning, the district and the State or "Contractor" partner shall coordinate which of the

targeted inspections shall be conducted by the state under contract. Please contact the Office of Partnerships for any questions regarding the contract.

States may have contracts with FDA to conduct egg farm inspections. The District and the State shall coordinate which of the targeted inspections will be conducted by the State under contract during the workplanning meeting. State contract inspections will be entered into eSAF and migrated over to FACTS. Please contact the Office of Partnerships for any questions regarding the contract.

**Prior to conducting an inspection, the District must contact the State Program 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 Establishment Inspection Report (EIR) for all inspections.**

If a State requests to accompany an inspection, the District should do its best to accommodate this request, regardless of whether or not the State is participating under State contract to conduct egg inspections.

Districts should provide the State inspectors with a copy of this program and refer to the Biosecurity/PPE requirements. The State inspectors participating in the inspection must comply with the Biosecurity and Personal Protection requirements as outlined in this program. However, State personnel may follow their state agency guidelines for selecting proper respiratory protection. At a minimum, an N95 (or equivalent) type mask is strongly advised. State inspectors should ask the District if they have questions about obtaining the required PPE.

After the inspections are concluded, the District shall keep participating State officials informed of any possible compliance actions.

**All regulatory follow-up inspections resulting from OAI classifications, including inspections performed under State contract, shall be conducted by FDA.**

## PART III - INSPECTIONAL

### 1. Operations

#### A. Inspections

##### a. Inspectional Frequency

An egg producer with 3,000 or more laying hens that produces shell eggs for table market is required to register with the FDA as a shell egg producer and comply with FDA's Egg Safety Rule.

Inspections of egg producing establishments are treated the same as all other food manufacturing establishments. Food manufacturers are required to register with the FDA as a food producing establishment. Egg farms will be inspected routinely at an appropriate frequency across the country and by state or "contractor" officials under contract with the FDA. FDA will prioritize these inspections based on the greatest health impact and as deemed appropriate will perform inspections accordingly.

##### b. Egg firms that should not be inspected

- Houses with birds known to have diseases, including SE-positive Pullet houses
- SE- positive houses
- A packing firm, actively enrolled in the USDA/AMS voluntary egg grading program with USDA/AMS with a resident inspector on site, unless as directed as part of trace back in follow up to an outbreak
- An egg-breaking firm on-site that is under USDA/FSIS jurisdiction.
- Under state veterinary recommendations for reasons such as in states that have an active HPAI outbreak.

##### c. Biosecurity/ personal protection requirements

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

In addition to the requirements listed below, prior to inspection, investigators must read and follow all updated biosecurity requirements in Chapter 5 of the IOM: <http://inside.fda.gov:9003/downloads/PolicyProcedures/GuidanceRegulations/FieldInvestigations/UCM504168.pdf>

The team lead should become familiar with the field bulletin prior to the inspection to become familiar with pre, during, and post-inspectional requirements.

Egg farm inspections require unique action by Investigators to assure that we do not contaminate or cross-contaminate the environment. Additionally, 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 firm, the Investigator must be medically cleared, fit tested and trained in the proper use and limitations of the issued respirator. All efforts should be made to wear disposable respirators such as N95 respirators. In the event that one cannot be fitted for a disposable respirator, permanent respirators should be cleaned in accordance with manufacturers' recommendations between houses. For further guidance on respirators refer to Field Bulletin #59. The Investigator needs to determine if a chemical hazard is present in the poultry house, typically done by working with farms management where ammonia levels are regularly monitored. If no chemical hazard is determined, properly fitted disposable N95 respirators may be worn. If disposable N95 respirators are used, they must be disposed of after each entry into a poultry house. Respiratory training and fit test will also need to be provided for individuals wearing N95 respirators. Investigators should have their respirator with cartridges with them in the event a chemical hazard does arise.
- The Investigator must not be a bird owner in their own home and/must not have been in any other poultry firm, or exposed to other poultry or birds up to 72 hours before an inspection, including visits to aviaries, tending backyard feeder. This 72 hour limit may be increased depending on the firm's personal biosecurity program. In situations where outdoor access is provided to hens, the wait time between farms should be increased to 1 week. For a detailed explanation of appropriate wait times for various situations please refer to chapter 5 in the IOM.
- Disposable personal protective clothing (e.g., Tyvek® suits, booties, gloves, hair nets, and respirators) 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 used during egg farm inspections are required to be cleaned before and after every inspection. Refer to Chapter 5 in the IOM for appropriate vehicle cleaning and disinfection procedures.

**Additional Disinfectants**

<b><u>Name</u></b> *	<b><u>Manufacturer</u></b>
Tek-Trol® Disinfectant	ABC Compounding Co.
Biophene®	BioSentry
Pine Sol® (original containing Pine oil)	Clorox

Lysol <sup>®</sup> (containing 2-phenylphenol)	Reckitt Benkiser
Lph <sup>®</sup>	Steris Corporation
Phenocide 256 <sup>®</sup>	Lonza, Inc
Phenocide 128 <sup>®</sup>	Lonza, Inc
Phenolic <sup>®</sup> Disinfectant	Johnson Diversey
Vesphene <sup>®</sup>	Steris Corporation
Pheno-Tek II <sup>®</sup>	Bio-Tek industries

\*This list is not all inclusive. Please view the EPA List of Registered Disinfectants for the entire list of registered disinfectants that are classified as phenolics. For any additional questions, please contact **Michelle Markley** at [Michelle.Markley@fda.hhs.gov](mailto:Michelle.Markley@fda.hhs.gov), or **301-796-8178**.

- When taking photographs, use separate disposable cameras for each house. Digital cameras can also be placed in sealable plastic bags, which shall be changed out between poultry houses. **ONLY use flash where appropriate, but be aware of any potentially dangerous situations** (e.g., dust/particulate, ammonia levels, etc.).
- Unless prohibited by the farm's Biosecurity procedures, Investigators must take with them at the end of each day, and properly dispose of off site, 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<sup>®</sup> suits and respirators can be tiring and warm, the team should dress appropriately and take necessary breaks. However, do not use the sample coolers to carry your lunch or break refreshments which will ensure there is no potential for cross contamination with official samples.
- Before conducting the inspection, a member of the team shall 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 from youngest to oldest birds. Houses and birds known to have diseases, including SE, must NOT be visited.**

Any additional questions or concerns regarding PPE should be directed to CDR Michelle Markley, at [Michelle.Markley@fda.hhs.gov](mailto:Michelle.Markley@fda.hhs.gov) or 301-796-8178. Any questions regarding Biosecurity should be directed to Martha Myrick at [Martha.Myrick@fda.hhs.gov](mailto:Martha.Myrick@fda.hhs.gov) or 240-402-5840.

**d. Pre-inspection notification to the firm**

For several reasons, including personal safety, familiarization with the farm's biosecurity practices, and farm operations, pre-announcement (e.g. 24-48 hrs) of surveillance inspections under this program is recommended; however, the decision is left to district discretion (refer to IOM 5.2.1.1). If the District pre-announces the call, the discussion should include the scope of the inspection, the firm's Biosecurity policies to include determining lag time between individual farm site visits (e.g., length of time between visiting a different company's farm and the down time between visiting internal laying sites, which may be multiple locations), waste disposal facilities, types of houses, layout of the houses and bird flock health (including SE positive environments).

If the District has made attempts to contact the farm to pre-announce the inspection but encountered difficulties in doing so (i.e., the farm does not have a phone number, made many attempts to contact and no return phone calls were received, etc.) please document this in the establishment inspection report (EIR). Lack of pre-announcement should not be a reason to not conduct the inspection.

**e. Comprehensive and Targeted Inspections**

- Targeted and comprehensive inspections are to be conducted with teams that include a minimum of 2 and 3 Investigators, respectively. Lead Investigators must have completed and passed DHRD course FD107 Egg Safety Inspection Training. The course training manual provides specific instructions for how to conduct these inspections. **All members of the inspection team must have a current respirator clearance.**
- For comprehensive inspections, a minimum of 3 Investigators are needed per team; 5 are preferable, especially for larger facilities.
- The Lead Investigator must assure that all equipment necessary to conduct environmental sampling is available during each inspection.
- Complete the Egg inspection IQ during both comprehensive and targeted inspections. The IQ is an inspectional tool to help guide the Investigator through the inspection. It provides useful citations under Part 118 of the regulation, covers questions and areas of significance, industry information for trending and will help the Investigator identify inspectional observations for the FDA-483, Inspectional Observations, as appropriate.
- Comprehensive and targeted inspections under this program shall minimally include the following components:
  - Evaluate the SE prevention plan to ensure it minimally includes the following:
    - Procurement of pullets that are SE monitored
    - Biosecurity

- Rodent/Pest control
- Cleaning and disinfecting
- Sampling and testing methodologies for SE
- SE plan administration
- Adequate refrigeration of shell eggs

NOTE: If there is no written plan, determine if SE prevention measures are in place. Lack of a written SE prevention plan is a significant deviation from the Egg Rule. (See Regulatory Follow-up for other significant deviations.)

- Determine if the farm conducted environmental testing at required time periods and if positive samples were found, whether or not appropriate actions were taken in accordance with the Egg Rule.
- Review records required to be maintained by the Egg Rule related to the current flock.
- After review of the SE prevention plan, determine if the SE prevention measures are being implemented by walking through a subset of the houses (\*See below for determining the number of houses to walk through).
- For firms identified as requiring a comprehensive inspection, environmental samples must be collected. For targeted inspections, if serious deviations are encountered during house walk-throughs, environmental samples will need to be collected. In the latter situations, contact Martha Myrick at [Martha.Myrick@fda.hhs.gov](mailto:Martha.Myrick@fda.hhs.gov) or 240-402-5840 to coordinate locating an analyzing laboratory prior to collection of samples.
- Verify the firm's registration:  
All egg farms subject to the Egg Rule are required to register as shell egg producers under 21 CFR 118.11 (this is separate from Food Facility Registration).
- Walk-throughs are to be conducted during ALL inspections. Collection of environmental samples is to be conducted during comprehensive inspections. Note: With exceptions as noted above. The information below outlines the number of houses to walk-through and sample as well.
- Per the current contract statement of work, **state agencies conducting targeted inspections for FDA under contract must conduct a walk-through of a minimum of four (4) houses during the inspection unless the number of houses is less than 4, in which case they must conduct a walk-through of all houses.**

Determining the number of houses to walk through and sample for an inspection:

$$\sqrt{\text{(Total \# of Houses)}} + 1$$

When the square root ( $\sqrt{\quad}$ ) is greater than a whole number, round up to the next highest number; for example, if the square root is 2.1 then round up to  $3 + 1 = 4$  houses to inspect.

Note: Unless otherwise necessary, houses that are depopulated or have known disease issues should not be walked through.

- Investigators are to report bird capacity in sampled houses and sampled house number in sample collection report.

**f. On-site Packing Facilities**

If the farm has an on-site packing operation, determine if eggs are received from any other farms and document the current inspected farm's sanitation practices and procedures for the packing facility. Some farms with egg packing facilities are enrolled in a voluntary egg grading program in which they pay USDA/AMS for shielded egg grading services. The farms that pay for this service have a resident inspector on site and in that situation are continuously evaluated by USDA/AMS for sanitation. A packing operation, actively enrolled in the USDA/AMS voluntary egg grading program with USDA/AMS with a resident inspector on site, shall not be covered under this program. **If the farm is NOT participating in the voluntary egg grading program OR a USDA/AMS inspector is only temporarily onsite (therefore not conducting routine sanitation inspections), then the packing operation shall be inspected under this program. During inspections, FDA investigators, and state regulatory partners accompanying FDA, should inform USDA personnel onsite to let them know of the inspection. This shall be documented in the EIR.**

On-site packing houses are not subject to 21 CFR Part 110 or 117; therefore any observations of insanitation shall be cited on the FDA-483 under section 402(a)(4) of the Act, and any violations of the Egg Rule's refrigeration requirements shall be cited under 21 CFR Part 118. Do not use industry code M-15 when covering these facilities as they will end up on the FSMA high risk inspectional list. Use only G-15 for all egg farms that include a packing house.

If a farm also has an egg-breaking operation on-site, that aspect of their operation is under USDA/FSIS jurisdiction and will NOT be inspected by FDA.

**g. Breeders/Broilers**

In order to improve data for targeting inventory and work planning, firms that fall under the category of Breeder/Broiler shall be identified by the district with the District Use Code (DUC) "BB". District OEI Coordinators were provided with a list of facilities inspected during FY 12 and FY 13, in which inspection results indicate the firm was a breeder/broiler. Moving forward, districts should continue to update the DUC code of any newly identified Breeder/ Broiler firms.

Breeder Hatcheries are used for both Broilers and for Egg Layer birds. The majority of eggs produced at Breeders/Broiler Farms typically do not fall under the Egg Rule. These eggs are hatched and the chicks raised to gain mass quickly in order to be used and sold as meat. “Surplus” eggs (double yolk, dirty, small etc.) that are sent to the table market for human consumption, fall under all the requirements of the Egg Rule, even though that may not have been the original intent. If these eggs are going to the breaker market and will receive further treatment, the firm is only responsible for the refrigeration and registration requirements of Part 118.

- (OP 13) Surplus Eggs which are disposed of or not used for human consumption:
  - No Egg Rule requirements
- (OP 13) Surplus eggs going to the Breaker Market and receive further treatment:
  - Refrigeration and registration requirements
  - Document any agreements
  - Document any knowledge of eggs to table market
- (OP 12) Surplus eggs going to the table market for human consumption:
  - All requirements of the Egg Rule apply; conduct comprehensive or targeted inspection as per the initial assignment.

## B. Sample Collections

Environmental sampling in the poultry houses shall be conducted during all comprehensive inspections 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 poultry houses. Each site with a different address shall receive a separate FDA-482, Notice of Inspection.

**Do not enter any house for environmental sampling or walk through if the house is determined to be SE positive based on the FDA or the firm’s environmental testing or information from the State.**

**Water, feed, and egg samples are NOT to be collected as part of this compliance program.**

### a. Sampling Technique

Drag swabbing manure is the preferred environmental sample. Detailed instructions are available at the following two websites:

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm285101.htm>

<http://www.fda.gov/food/foodscienceresearch/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.

- **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 and for manure belts in belted houses) – hand swab

Pre-assembled sterile drag swabs (12 ply 4x4) for the use in comprehensive egg inspection environmental sampling have been purchased and Investigators can obtain these drag swabs through OFFO/FFPOB. Swabs are mailed to districts based on operation requirements. For questions on how to obtain additional drag swabs please contact **Martha Myrick at Martha.Myrick@fda.hhs.gov or 240-402-5840.**

- **Swab Prep**

When the swabs are ready to be used, the Investigator must aseptically moisten them with canned evaporated milk. Multiple cans/vials may be needed with the same lot codes preferred. Sanitize the tops of the milk cans with a 70% ethanol solution prior to opening. Any can openers and/or scissors should also be sanitized in 70% ethanol.

A sterile swab should be placed over the opened can of milk to deter flies from potentially contaminating the milk. After sampling, each swab should be placed in its own individual sample bag and approximately 15 ml of evaporated milk used for moistening the swab should be added to the bag to keep the swab moist during transport. One swab equals one sub sample; sub samples (swabs) should not be pooled. Investigators should wear sterile gloves, use aseptic technique when handling, and moistening the swabs.

Closed control samples for every lot of milk used, each lot of drag swabs, each lot of sterile gloves and each lot of whirlpak bags shall be submitted with the sample.

- **Drag Swab Tools**

In certain situations, use of sampling tools can assist in sample collection. Districts should purchase metal poles, suitable for sanitation (Stainless steel preferred. Use poles that are made of non-porous material and easily disinfected). The moistened drag swab with string shall be aseptically and securely tied to the metal pole. The pole must be thoroughly sanitized between sub samples and between houses.

- **Sampling and Testing for *Salmonella* Enteritidis (§§ 118.5-118.7)**

For interpretation purposes:

- Row* means a group of cages that runs the length of a house; when referring to manure, a row is the pile of manure that collects under one row of cages.
- Bank* means half of a cage row (one side of a row); when referring to manure, a bank is one side of the pile of manure that collects under one row of cages.
- Tier* means a level of cages in each row.

**b. Sample Numbering System**

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

- Manure:  
3L M  
3= Row number  
L = Left side of the bank (use the letter R for the right side of bank)  
M = Manure
- Egg belt:  
1 R 3  
1 = Row number  
R = Right side of the bank (use the letter L for the left side of bank)  
3 = Tier number (if multi-tiered house)
- Walkway:  
  
2 L W  
2 = Walkway/aisle number  
L = Left side of bank (use the letter R for the right side of bank)  
W = Walkway

NOTE: as stated below, do not collect both manure and egg belt/walkway samples. Egg belt and walkway samples shall only be collected when the manure is inaccessible.

### c. Poultry House Styles and Environmental Sampling

*\*Figures illustrated in Attachment B*

- High-Rise Poultry House (Pit Style Poultry House)

This style of house has two stories; the top floor contains rows of cages that house the laying hens, and the bottom floor is the “pit” where the manure collects in a cone shaped pile under each row of cages. Both sides (banks) of each manure cone should be sampled while walking the length of the row twice. For example, walk from the front of the house to the back using one swab and then turn around and walk from the back of the house to the front using the same swab. Use one swab per bank, two swabs per row. The area towards the top of the cone where the freshest manure is accumulated should be the area sampled (Figure 1). Poles that can be easily sanitized may be used if it facilitates sampling. If both sides of the cone are sampled at the same time, care should be taken to ensure that the swabs stay on the same side of the row on the trip to the end of the row and back.

Manure pits unsuitable for drag swabbing:

In a high-rise house, egg belt and walkway samples should ONLY be collected when manure samples cannot be obtained, e.g. when sampling the manure pit presents safety hazards. Do not collect BOTH manure and egg belt/walkway samples.

A combination of egg belt and walkway swabbing should be utilized to obtain representative environmental samples if the manure pit is unsuitable for drag swabbing. Examples of unsuitable conditions include manure that is piled very high or is liquid or semi-liquid. Since this method is an alternative and the optimal sample (i.e., manure) is not able to be collected, a much more thorough sampling scheme should be followed.

Egg belts: Hand-swab every egg belt in the house by swabbing approximately 6-10 inches every 5-10 feet for the entire length of the belt and the de-escalator for the corresponding tier. Use a separate swab for each egg belt/tier (including de-escalators). Continue this process until all egg belts in the house have been sampled.

Walkways: Drag two swabs along the entire 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 back.

- Shallow Pit Poultry House

Most shallow pit poultry houses 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 it may be a dry system where only 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 can take place either while the scraper assembly is running or while it is stationary. Pits should have at least a 24-hour supply of manure before being sampled; therefore, the scrapers should not be operated for at least 24 hours prior to sampling.

When scraper is running: Attach two drag swabs onto the main manure scraper assembly, so that one drags on the left bank and the other on the right bank of that row, and run the scraper assembly to the opposite end of the house and back. Care should be taken to attach the swabs in such a way that they are not buried under manure while the scrapers are being operated; instead, they should drag lightly over the manure. Work with farm management to ensure scheduling of manure scraping to ensure that manure is in the poultry house since they are cleaned out on a more frequent basis.

When scraper is stationary and the firm has locked out the equipment (when applicable): Use hand swabs, i.e., gauze pads without the string attached, to swab the solid manure on all tiers of scraper blades. The scraper blades under each tier should be sampled along with the corresponding side of the main pit scraper using one swab. This swabbing method should be performed for each bank (left and right side) in a row. If the shallow pit has a narrow walkway beneath it, use a drag pole to collect swab samples underneath the row of cages, as described for high rise poultry houses.

- Belted System Poultry House

When sampling a belted system poultry house, each bank 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). If the belted system poultry house has a second story, the process should be repeated on the second floor. In situations where the upper tiers cannot be reached, some type of extension device should be used, such as a solid graphite rod with an alligator clip glued to one end or a metal broom handle that is clapped at both ends. The device should be sanitized between each bank of a row, between rows, and between houses. You should avoid selecting anything with grooves, nooks, or crevices that may make sanitation difficult.

- Colony Style Poultry House

Colony style poultry houses are an open sided type of house that is encountered in parts of the country where year-round weather conditions are favorable (e.g., southern California and Texas). Colony style poultry housing usually consists of two rows of layer cages facing each other with a walkway separating the cage rows and a roof structure over the cages (Figure 3). Usually a board is incorporated into the house structure near ground level at the rear of the cages. This board allows manure to “cone” and stay dry. The top level of this manure cone should be sampled with a drag swab attached to a pole with a short length of sterile string (Figure 4). The entire length of one side of the house should be sampled with one drag swab. This process should be repeated on the opposite side with a new drag swab.

- Single Deck Poultry House

A single deck style poultry house is typically an open-sided style of house usually encountered in the same geographic areas as colony style housing. Like colony style houses, this style of house can only be used where annual weather permits. In single deck style poultry housing, there may be one or multiple tiers of cages and the floor is usually concrete. Manure collects on the floor, creating a row of manure (Figure 5). This “manure row” should be sampled with a drag-swab attached to a pole with a short length of sterile string. The whole length of each row should be sampled by dragging the swab the entire length of the row and back. Individual drag swabs should be used to sample the left and right banks of each row for a total of two samples per row.

- Cage-Free Poultry House

Sampling a cage-free poultry house should be based on 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 visually 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 three 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.

**Extreme care should be taken when using this sampling scheme because hens may pile and suffocate if sudden movements, loud noises, or any behavior that startles the hens is made.**

- Aviary Poultry House

Aviary poultry houses are a type of cage-free poultry house designed to allow more birds per square foot when compared to conventional cage-free operations. Typical aviary systems have rows with “platforms” (Figure 6) that incorporate nest boxes, feeders, waterers, and perches. There is typically a manure belt running under each platform level that conveys manure to the back end of the poultry house. There are floor access areas or “scratch areas” between the platforms rows (See Figure 7). This style of house may be sampled in one of two ways: drag swabbing the scratch areas (i.e., floor areas) or sampling the manure belts.

- Scratch areas: Extreme care should be taken when using this sampling scheme because hens may pile and suffocate if sudden movements, loud noises, or any behavior that startles the hens is made. To sample scratch areas, use two drags swabs per row and drag the swabs the entire length of the row and back, keeping each swab on the respective side of the row (either right or left)(Figure 7). All floor areas in the house should be sampled.
- Manure belts: Manure belts in an aviary poultry house are typically located at the back of the house and are similar to those found in belted system poultry houses except they are wider (Figure 8). When possible, belts should be run one entire revolution to ensure fresh manure has come in contact with the scraper that knocks manure off the belts onto the main belt that leads out of the house. Belts should then be sampled as described in the section for belted system poultry houses (Figure 2).

- Additional poultry house styles that may be encountered during small producer inspections (Figure 9):

Many of the poultry house styles that will be encountered during inspection of small egg producers (i.e. those with at least 3,000 but fewer than 50,000 layers per farm) will be similar to those used in cage-free egg production. In poultry houses where organic eggs are produced, the houses will include an outdoor access area of some type. These houses can usually be categorized into one of four styles. The four housing styles are described and illustrated in Attachment B.

- *Indoor Area with Porch*

A porch is attached to one side of an indoor area. The porch is enclosed with fence material, such as poultry wire. The porch’s roof can be solid or made of wire or netting. The porch’s floor is often concrete, but it can be dirt. Access holes connect the indoor area to the porch.

- *Indoor Area with Outdoor Run – Row Style*  
Multiple flocks are segregated from one another by a series of adjacent structures that are lined up in a row, very similar to how houses at an in-line farm are arranged. Each indoor area connects to at least one (often two) outdoor runs. The outdoor runs are fenced, usually with poultry wire. The fencing prevents poultry from straying beyond the entire structure and from moving between houses. The outdoor access area may have no coverage overhead or it may be covered with netting, and the floors are grass or dirt. Access holes connect the indoor areas to the runs. Runs may be divided into several sections.
  
- *Indoor Area with Outdoor Run – Attached Run Style*  
An outdoor run is attached either to the end of an indoor area or to the side of an indoor area, i.e., where a porch would be located. The outdoor run is a fenced-in area extending from the indoor area; there may be no coverage overhead or it may be covered with netting. The floor of the outdoor run is dirt or grass, and the size of the run can vary greatly. Access holes connect the outdoor run to the side or end of the indoor area, depending on where the run is located.
  
- *Pasture Containing an Indoor Area*  
An indoor area is located within an outdoor fenced pasture. The indoor area may be a permanent structure or it may be a moveable structure. Moveable structures may be built on skids, or moveable trailers retrofitted with nest boxes may be used. The pasture area may have no coverage overhead or it may be covered with netting, and the size of the pasture varies greatly. If the indoor area is moveable, the housing system usually is designed such that the pastures can be rotated, i.e., the fencing surrounding the pasture can be moved or relocated to fence a fresh patch of pasture, and the indoor area can be moved to the new area with a tractor. In systems with a permanent indoor structure, access holes connect the indoor area to the outdoor pasture. In systems with a moveable structure, access to the outdoor pasture area is through some type of opening in the structure, e.g., an open gate if a retrofitted trailer is used.

NOTE: If any of the above house styles are encountered during an inspection, **ONLY** the indoor areas should be sampled. No samples should be collected from the outdoor access areas or pastures, However, these areas should be included (i.e. walked and evaluated for compliance) when conducting a walk-through of the houses in both targeted and comprehensive inspections. The indoor areas should be sampled in the same manner as cage-free houses are sampled (i.e. based on the width of the house).

#### d. Unique House Designs/Situations

Investigators might encounter variations in poultry house design and/or unsafe manure pit conditions which will require adaptations for collecting representative environmental samples. In situations where the sampling methods listed above cannot be followed or if variations in poultry house design/layout which are not listed below are encountered, Investigators should contact the Gerardo Ramirez at (713) 293-1418 listed in Part VI for further assistance on sampling that environment.

#### e. Sample Shipment

The Districts will arrange sample shipment to the servicing laboratories according to the master tracking schedule included in the memorandum sent out by CFSAN/Office of Compliance/Division of Field Programs & Guidance prior to the start of the fiscal year. Samples must be shipped UPS Next Day Air Early A.M. delivery to guarantee samples are to the laboratory within 24 hours. Please locate the nearest UPS drop location, ensuring that it has overnight delivery services, and their hours of operations.

NOTE: Changes to the assigned schedule should be arranged in advance with CFSAN/OC/DFPG at Ann.Westerman@fda.hhs.gov or 240-402-1878 and ORS scheduling contacts.

## 2. Reporting

- If an inspection results in FDA confirmed positive SE environmental samples, the district shall first inform the State regulatory agency, USDA/AMS and USDA/FSIS of the findings. In addition to contacting the local USDA/AMS office, an interagency report including a summary of objectionable conditions shall be submitted online to USDA/AMS and USDA/FSIS at: <http://www.accessdata.fda.gov/scripts/irf/>
- FDA and the State should jointly contact the firm immediately following the State notification. Please follow field Bulletin #30 for alerting firms of environmental sample positives (<http://inside.fda.gov:9003/downloads/PolicyProcedures/GuidanceRegulations/FieldInvestigations/UCM046269.doc>).  
Per FMD-147 confirmed positive results shall also be shared with the firm in writing. (<http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm103304.htm>)
- EIR: Inspections of these firms may include a headquarters location plus multiple farms at different physical locations. Each of these locations will have an individual registration and FEI numbers. The entire organization may be under one SE Prevention Plan and set of procedures. The Investigator should prepare separate 483s and EIRs regardless of when the inspections are done in close proximity in time. Each location inspected will

need to be reported in FACTS to ensure we have accurate information on last inspection date, products covered and classification.

- Issuing FDA 483s to Contract farms:  
It is common that an egg farm is contracted by a larger company to raise and care for the chickens and oversee egg production. In some instances, the contract farm and larger contracting company share responsibilities for compliance with the Egg Rule. Both the contract farms and the contracting company can fall under the definition of a producer under the Egg Rule in that they own and/or operate a poultry house containing laying hens which produce shell eggs for human consumption. If the contracting company is present during the inspection, FDA 482s should be issued to both the contract farm and to the contracting company for the physical location being inspected. In this situation, two FDA 483s, containing the exact same observations, should be issued to the most responsible person at the contract farm during the time of the inspection and to the contracting company utilizing the physical address where the inspection occurred. If the SE Plan Administrator is the contracting company, a follow- up inspection or investigation with the contracting company may be warranted, especially if the contract farm says they have no authority to change the SE plan. Regardless, the contract farm is responsible for implementing the SE plan and for complying with the Egg Rule. When available, the investigator should collect documentation showing the responsibilities and authorities of each party.

## PART IV - ANALYTICAL

### 1. Analyzing Laboratories

DEN-LAB, PRLNW, PRLSW, and SRL

### 2. Analyses to be Conducted

Environmental samples will be analyzed for *Salmonella* Enteritidis (SE)

### 3. Methodology

*Salmonella* Enteritidis (SE) will be screened according to the following methods:

#### A. *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/FoodScienceResearch/LaboratoryMethods/ucm114716.htm>. Conduct biochemical identification tests to presumptive *Salmonella* isolates.

#### B. *Salmonella* Enteritidis – Confirmation/Speciation and Shipment of Confirmed Isolates

Servicing laboratories are to send *Salmonella* isolates for serotyping as soon as possible 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.

When shipping isolates for further analyses, send an email to the recipient before sending the shipment. All cultures should be shipped by FedEx overnight and should conform to the rules and regulations regarding the shipment of infectious agents.

### **SEROGROUPING OF SALMONELLA SPP**

Proceed to section E.6.b of Bacteriological Analytical Manual (BAM) Online: Chapter 5 <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm070149.htm> and test each of the TSI isolates for *Salmonella* (O) group D<sub>1</sub> activity. If the isolates do not display Group D<sub>1</sub> activity, then the isolates should be considered non-*S. Enteritidis*. All isolates that display Group D<sub>1</sub> activity should proceed to screening by *Salmonella* molecular serotyping (SMS) or traditional serotyping performed by ARL.

**a. Screening by *Salmonella* molecular serotyping**

Proceed to the current version of the “ORA Molecular Serotyping Protocol for Luminex Reagents” at <http://sharepoint.fda.gov/orgs/ORA-ROL-PAR-FDABioPlexTechWrkGrp/SitePages/Home.aspx> and test each isolate to determine if its Enteritidis.

**b. PFGE**

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.

**c. WGS**

The servicing laboratory will determine the whole genome sequence (WGS) of each *Salmonella Enteritidis* isolate. The servicing lab will electronically send the sequence to CFSAN.

Laboratory Classification

The servicing laboratory can classify findings of *Salmonella* spp. that display Group D<sub>1</sub> activity and are *Salmonella Enteritidis* confirmed by SMS and PFGE as Lab Class 3.

**4. Reporting**

- If an inspection results in FDA confirmed positive SE environmental samples, the district should first inform the State regulatory agency, USDA/AMS and USDA/FSIS of the findings. In addition to contacting the [local USDA/AMS office](#), an interagency report including a summary of objectionable conditions should be submitted online to USDA/AMS and USDA/FSIS at: <http://www.accessdata.fda.gov/scripts/irf/>
- FDA and the State should jointly contact the firm immediately following the State notification. Please follow field Bulletin #30 for alerting firms of environmental sample positives (<http://inside.fda.gov:9003/downloads/PolicyProcedures/GuidanceRegulations/FieldInvestigations/UCM046269.doc>).

Per FMD-147 confirmed positive results should also be shared with the firm in writing. (<http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm103304.htm>)

## PART V - REGULATORY/ADMINISTRATIVE STRATEGY

### INSPECTION CLASSIFICATION

ORA and CFSAN have developed a Field Bulletin that addresses the inspectional classifications for these inspections. Please refer to **DDFI Field Bulletin #38: Regulatory Strategy and Inspection Classification for Egg Facility Inspections, 2/1/2011**.

<http://inside.fda.gov:9003/PolicyProcedures/GuidanceRegulations/FieldInvestigations/ucm010365.htm>

**When an inspection is classified OAI (Official Action Indicated), Districts must conduct compliance follow-up inspections within appropriate timeframes. Refer to FMD-86 for further information.**

### REGULATORY FOLLOW-UP

#### Inspections

FDA's Egg Rule enforcement authority is established under the Public Health Service Act (the PHS Act) and 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 section 402(a)(4) of the Act.

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

Alert USDA of any positive environmental positives and significant violations via the online submission form (<http://www.accessdata.fda.gov/scripts/irf/>).

#### **A. Initial Inspection**

Districts should recommend Warning Letters to CFSAN for egg producers with significant deviations from the Egg Rule.

Significant deviations from the Egg Rule include:

- Lack of a written 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 CFSAN 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.

Contact the CFSAN Regulatory Contact before submitting a Warning Letter with only one serious deviation.

#### **B. Warning Letter Follow-Up Inspections**

Districts should consider holding a regulatory meeting with firms when corrective actions are not adequate and/or repeat minor observations are found during a Warning Letter follow-up inspection. Contact CFSAN’s regulatory contact (listed in Part VI) to discuss an enforcement strategy if significant repeat violations are observed (i.e., Order of Diversion or Injunction).

**All regulatory follow-up inspections as a result of an OAI classification, including inspections conducted under State contract, are to be conducted by FDA.**

#### **C. Consideration for Order for Diversion (or equivalent regulatory follow-up)**

If the following scenarios are encountered during an inspection, prior to inspectional closeout, you should notify CFSAN’s regulatory contacts and OFFO/FFPOB to discuss the need for an Order for Diversion:

- If firm records indicate that recent SE-positive eggs were not diverted to treatment.
- If firm records indicate that the pullet environmental samples were SE-positive and the firm failed to conduct egg testing within two weeks of the start of egg laying coupled with poor environmental conditions in the poultry house.
- If firm records indicate that SE-positive environmental samples were obtained and no egg sampling or diversion was conducted coupled with poor environmental conditions in the poultry house.

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

#### **D. 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.

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**PART VI REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS****1. References**

- a. Investigations Operations Manual, Subchapter 8.10  
<https://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM123515.pdf>
- b. Investigations Operations Manual, Chapter 5.2.1.1  
<https://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM150576.pdf>
- c. Investigations Operations Manual, Chapter 5.2.1.3  
<https://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM150576.pdf>
- d. Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation (74 FR 33030)  
<http://www.gpo.gov/fdsys/pkg/FR-2009-07-09/pdf/E9-16119.pdf>
- e. Code of Federal Regulations, Title 21, Part 118, Prevention of *Salmonella* Enteritidis (SE) in Shell Eggs During Production, Storage and Transportation Rule (the Egg Rule)  
<http://www.gpo.gov/fdsys/pkg/CFR-2010-title21-vol2/pdf/CFR-2010-title21-vol2-part118.pdf>
- f. Field Management Directive No. 86: Establishment Inspection Report Conclusions and Decisions:  
<http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm056246.htm>
- g. EPA List of Registered Disinfectants  
<http://www.epa.gov/oppad001/chemregindex.htm>
- h. Guidance for Industry: Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation  
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm285101.htm>
- i. Environmental Sampling and Detection of *Salmonella* in Poultry Houses  
<http://www.fda.gov/food/foodscienceresearch/laboratorymethods/ucm114716.htm>

**j. Division of Domestic Field Investigations (DDFI) Field Bulletin #30 – Food Program Area Instructions for Environmental Sampling**

<http://inside.fda.gov:9003/downloads/PolicyProcedures/GuidanceRegulations/FieldInvestigations/UCM046269.doc>

**k. Field Management Directive No. 147: Procedure for Release of Analytical Results Pursuant to Section 704(d) and Situations When Dealer is Voluntarily Holding Product**

<http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm103304.htm>

**l. Bacteriological Analytical Manual, Chapter 5, *Salmonella***

<http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm070149.htm#id>

**m. Division of Domestic Field Investigations (DDFI) Field Bulletin No. 38: Regulatory Strategy and Inspection Classification for Egg Facility Inspections, 2/1/2011**

<http://inside.fda.gov:9003/PolicyProcedures/GuidanceRegulations/FieldInvestigations/ucm010365.htm>

**2. Attachments**

Attachment A – Egg Safety Inspection Intelligent Questionnaire

Attachment B – Representative Images of Poultry House Styles

**3. Program Contacts**

**CFSAN:**

General Program Guidance – Ann Westerman, CFSAN/OC/DFPG/PAMB, (240) 402-1878

Regulatory/Compliance Contact – Robyn Jones, CFSAN/OC/DE/FAAB, (240) 402-2575

Egg Rule Contact – Nancy Bufano, OFVM/CFSAN/OFS/DDEMP/EMPB, (240) 402-1493

Scientific Contact - Gerardo Ramirez, OFVM/CFSAN/OFS/DDEMP/EMPB, Office 713-293-1418, BB: 301-529-4187

Laboratory Contact - Thomas Hammack, OFVM/CFSAN/ORS/DM/MMDB, (240) 402-2010

**ORA:**

Scientific Contacts:

- Michael McLaughlin, ORA/ORS, (301) 796-8158

- Peggy Carter, ORA/ORS, (301) 796-6239

ORA/OP Contact – Mei-Ying Li, ORA/OP, (301) 796-5903

Investigational Contact – Martha Myrick, ORA/OFFO/FFPOB, (240) 402-5840

## PART VII - CENTER RESPONSIBILITIES

The Director, Office of Food Safety will evaluate the effectiveness of the program and provide further guidance to the Director, Office of Compliance as appropriate. Working in conjunction with the Program Office, the Program Evaluation Branch (PEB) of the Division of Field Programs and Guidance (DFPG) will prepare a yearly summary report for this compliance program. The summary will outline the Program Office's current objectives, highlight their accomplishment data for the year, and list recommendations for the upcoming year. The report will be made available on the Inside.FDA intranet site under the Programs and Initiatives page:

<http://inside.fda.gov:9003/ProgramsInitiatives/Food/FieldPrograms/ucm013763.htm>

**ATTACHMENT A- Egg Safety Inspection Intelligent Questionnaire**

**Part II: Inspectional Tool**

Note 1: \*NR = No Reference for the observation in Egg Safety Regulation, but information will be useful for risk assessment to determine which firms to subsequently reinspect.

Note 2: Sections 16 (House Design - General) through 34 (House Egg Testing) should be completed for each house.

**1. Business Information and History**

Inspectional Information	Egg Rule Reference	Notes
1.1. Legal status of firm:	* NR	
1.2. Hours of operation:	* NR	
1.3. What is the firm's inspection and compliance history with other regulatory authorities? (Include dates)	* NR	
1.4. Other pertinent compliance or business history (distribution, products, etc.):	* NR	
1.5. Describe the firm's employee training program:	* NR	
1.6. What is the current percentage of shell eggs produced from the farm that are distributed to the table egg market?	* NR	
1.7. Does the egg producer participate in a certification program?	* NR	
1.7.1. No Program	* NR	

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
1.7.2. State EQAP	* NR	
1.7.3. 3rd Party EQAP	* NR	
1.7.4. Company EQAP	* NR	
1.7.5. UEP Certification	* NR	
1.7.6. USDA Organic Certification	* NR	
1.7.7. American Humane Certification	* NR	
1.7.8. Other	* NR	
1.8. Additional information:	* NR	

**2. Recalls**

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
2.1. Has the firm conducted a recall since the last inspection?	* NR	
2.2. Describe the details of any recalls conducted since the last inspection.	* NR	
2.3. Does the firm have recall procedures?	* NR	
2.4. Are the recall procedures written?	* NR	

Inspectional Information	Egg Rule Reference	Notes
2.5. Does the firm practice mock recalls following their procedures?	* NR	
2.6. Additional information regarding recalls:	* NR	

**3. Consumer Complaints**

Inspectional Information	Egg Rule Reference	Notes
3.1. Have there been consumer complaints related to illness or injury?	* NR	
3.2. How many consumer complaints did the firm receive in the last six months?	* NR	
3.3. Who is responsible for consumer complaint review?	* NR	
3.4. Additional information regarding complaints including the response procedure and the results of complaint follow-up:	* NR	

**4. Facility Registration Status**

Inspectional Information	Egg Rule Reference	Notes
4.1. Is the egg facility registered as a shell egg producer?	118.11(a), 118.11(f)	
4.2. When was the egg farm registered?	* NR	
4.3. Reason the egg farm is not registered:	* NR	

Inspectional Information	Egg Rule Reference	Notes
4.4. What is the status of the egg facility's bioterrorism registration?	* NR	
4.5. Additional information:	* NR	

**5. Egg Treatment**

Inspectional Information	Egg Rule Reference	Notes
5.1. If the answer to the following question is yes, then only screens 6 (Five Log Treatment), 7 (Other Business Activities), 35 (Refrigeration), and 36 (Drug Residue) need to be completed. All other screens should be skipped.	* NR	
5.2. Are ALL eggs dedicated to a 5 log treatment (for example, delivered to an egg products plant or treated on site)?	* NR	

***If the answer to 5.2 is Yes (ALL eggs are dedicated to a 5 log treatment), then go directly to 35. Refrigeration.***

**6. Five Log Treatment**

Inspectional Information	Egg Rule Reference	Notes
6.1. Are any eggs subjected to a 5 log treatment?	* NR	
6.2. What is the 5 log treatment?	* NR	

Inspectional Information	Egg Rule Reference	Notes
6.3. If other, describe further:	* NR	

**7. Other Business Activities**

Inspectional Information	Egg Rule Reference	Notes
7.1. Name:	* NR	
7.2. Type:	* NR	
7.2.1. 5 Log Treatment	* NR	
7.2.2. Egg Products Plant	* NR	
7.2.3. Breaking Facility	* NR	
7.2.4. Shell Egg Packer	* NR	
7.2.5. Ownership of Birds	* NR	
7.2.6. Distributor of Eggs (Consignee)	* NR	
7.3. Address:	* NR	
7.4. Address:	* NR	
7.5. City:	* NR	
7.6. State:	* NR	

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
7.7. Zip:	* NR	
7.8. Egg Products USDA Establishment Number:	* NR	
7.9. Additional information:	* NR	

**8. Records Management**

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
8.1. Are all of the firm's records available for review?	118.10( e)	
8.2. Are records retrieved within 24 hours of request?	118.10(d)	
8.3. Are records retained for one year?	118.10(c)	
8.4. Do the firm's records:	* NR	
8.4.1. Contain the name and location of the farm?	118.10(b)(1)	
8.4.2. Contain the date and time of the relevant activity?	118.10(b)(2)	
8.4.3. Contain signatures or initials?	118.10(b)(3)	
8.4.4. Reflect actual values?	118.10(b)(4)	
8.5. Additional Information:	* NR	

**9. Farm and House Structure**

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
9.1. Does the farm have organic flocks, conventional flocks, or both?	* NR	
9.2. Total number of laying hens on farm at the time of inspection:	* NR	
9.3. Total number of eggs produced annually:	* NR	
9.4. Total number of poultry houses on the farm:	* NR	
9.5. Bird strains:	* NR	
9.5.1. Babcock	* NR	
9.5.2. Bovans	* NR	
9.5.3. Dekalb	* NR	
9.5.4. Hy-line Brown	* NR	
9.5.5. Hy-line W-36	* NR	
9.5.6. Hy-line W-98	* NR	
9.5.7. Hy-line Silver-Brown	* NR	
9.5.8. Hy-line Gray	* NR	

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
9.5.9. Isa Brown	* NR	
9.5.10. Lohmann Brown	* NR	
9.5.11. Lohmann White	* NR	
9.5.12. Tegel SB2	* NR	
9.5.13. Tetra Brown	* NR	
9.5.14. Shaver	* NR	
9.5.15. Other	* NR	
9.6. Additional information:	* NR	

**10. Other Animals on Owner's Farm**

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
10.1. Animals maintained on the owner's farm:	* NR	
10.1.1. None	* NR	
10.1.2. Bison	* NR	
10.1.3. Cat	* NR	
10.1.4. Cattle	* NR	

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
10.1.5. Chicken	* NR	
10.1.6. Deer	* NR	
10.1.7. Dog	* NR	
10.1.8. Elk (Wapiti)	* NR	
10.1.9. Fish	* NR	
10.1.10. Game Animals	* NR	
10.1.11. Goat	* NR	
10.1.12. Horse	* NR	
10.1.13. Llama/Alpaca	* NR	
10.1.14. Moose	* NR	
10.1.15. Rabbit	* NR	
10.1.16. Sheep	* NR	
10.1.17. Swine	* NR	
10.1.18. Wild Ducks	* NR	

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
10.1.19. Wild Geese	* NR	
10.1.20. Wild Turkey	* NR	
10.1.21. Exotic/Zoo Animals	* NR	
10.1.22. Other	* NR	
10.2. Additional information:	* NR	

**11. Administrator for SE Plan**

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
11.1. Is there an administrator for the SE prevention plan?	118.9	
11.2. What is the name and title of the administrator for the SE prevention plan?	* NR	
11.3. Is the administrator trained and/or qualified?	118.9	
11.4. Does the administrator perform all designated tasks?	118.9	
11.5. Is there an SE plan administrator for each farm complex?	118.9	
11.6. Additional information:	* NR	

**12. SE Plan**

Inspectional Information	Egg Rule Reference	Notes
12.1. Does the firm have a written SE prevention plan?	118.10(a)(1)	
12.2. Is the written SE prevention plan site specific?	118.4	
12.3. Is the written SE prevention plan available on site?	118.10(d)	
12.4. Does the written SE prevention plan have a date and the signature (not initials) of the person(s) who administer the plan? (Please enter names and dates)	118.10(b)(3)	
12.5. Does the SE prevention plan adequately address the following areas?	* NR	
12.5.1. Biosecurity	118.4	
12.5.2. Chick suppliers	118.4	
12.5.3. Pullet rearing as SE monitored	118.4	
12.5.4. Pest control programs for flies, rodents, and others	118.4	
12.5.5. Cleaning and disinfection (C and D) procedures	118.4	

Inspectional Information	Egg Rule Reference	Notes
12.5.6. Environmental sampling and testing procedures	118.4	
12.5.7. Environmental testing intervals	118.4	
12.5.8. Diversion of egg procedures	118.4	
12.5.9. Sampling and testing of eggs procedures	118.4	
12.5.10. Refrigeration	118.4	
12.6. Additional information:	* NR	

**13. Implementation of SE Plan**

Inspectional Information	Egg Rule Reference	Notes
13.1. Is the written SE prevention plan fully implemented?	118.4	
13.2. Are SE prevention methods fully followed?	118.4	
13.3. Additional information:	* NR	

**14. Records**

Inspectional Information	Egg Rule Reference	Notes
14.1. Are there records documenting the following:	* NR	
14.1.1. Pullets reared as SE monitored	118.10(a)(2)	

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
14.1.2. Compliance with environmental and egg sampling procedures	118.10(a)(3)(v)	
14.1.3. SE testing results for environmental and egg sampling	118.10(a)(3)(vi)	
14.1.4. Diversion of eggs	118.10(a)(3)(vii)	
14.1.5. Treatment of eggs	118.10(a)(3)(viii)	
14.1.6. Cleaning and disinfecting results	118.10(a)(3)(iii)	
14.1.7. Compliance with biosecurity	118.10(a)(3)(1)	
14.1.8. Compliance with rodent and other pest control	118.10(a)(3)(ii)	
14.1.9. Compliance with refrigeration requirements	118.10(a)(3)(iv)	
14.1.10. Review of the SE plan and all changes or corrective actions taken	118.10(a)(4)	
14.2. Additional information:	* NR	

**15. Houses to be Inspected**

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
15.1. House identification name or number:	* NR	

**16. House Design - General**

Inspectional Information	Egg Rule Reference	Notes
16.1. Age of birds (in weeks) at the time of inspection:	* NR	
16.2. Number of birds per cage:	* NR	
16.3. Number of birds per house:	* NR	
16.4. Is the bird stocking procedure All In / All Out?	* NR	
16.5. Type of house:	* NR	
16.6. Number of rows:	* NR	
16.7. Number of tiers:	* NR	
16.8. Type of caging:	* NR	
16.8.1. Caging	* NR	
16.8.2. Nesting	* NR	
16.8.3. Boxes	* NR	
16.8.4. Open Housing	* NR	
16.9. Number of prior flocks?	* NR	
16.10. Additional information:	* NR	

**17. House Perimeter**

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
17.1. What is the distance to the nearest poultry house?	* NR	
17.2. Have potential harborage for pests in and around the poultry house been removed?	118.4(c)(3)	
17.3. Is there debris inside or around the house perimeter?	118.4(c)(3)	
17.4. Additional information:	* NR	

**18. House Feed and Water System**

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
18.1. What is the feed system type for the house?	* NR	
18.2. What is the water system type for the house?	* NR	
18.3. Water source:	* NR	
18.4. Is the water chlorinated?	* NR	
18.5. Is microorganism testing conducted on the water system for the house?	* NR	
18.6. How often was microorganism testing conducted?	* NR	
18.7. Additional information:	* NR	

**19. House Feed Source**

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
19.1. Name and address of the finished laying hen feed source establishment:	* NR	
19.2. Name:	* NR	
19.3. Address:	* NR	
19.4. Address:	* NR	
19.5. City:	* NR	
19.6. State:	* NR	
19.7. Zip:	* NR	
19.8. Country:	* NR	
19.9. Additional information:	* NR	

**20. House Feed Ingredients**

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
20.1. Feed ingredients include:	* NR	
20.1.1. Animal protein	* NR	
20.1.2. Corn	* NR	

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
20.1.3. Discarded bakery products	* NR	
20.1.4. Mineral	* NR	
20.1.5. Soybean	* NR	
20.1.6. Vitamins	* NR	
20.1.7. Other ingredients	* NR	
20.2. List all types of animal protein:	* NR	
20.3. Calcium supplement source:	* NR	
20.4. List other types of ingredients:	* NR	
20.5. Additional information:	* NR	

**21. House Supplier of Chicks**

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
21.1. Are chicks procured from appropriate sources?	118.4(a)(1)	
21.2. Name and address of the chick supplier:	* NR	
21.3. Name:	* NR	
21.4. Address:	* NR	

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
21.5. Address:	* NR	
21.6. City:	* NR	
21.7. State:	* NR	
21.8. Zip:	* NR	
21.9. Country:	* NR	
21.10. Additional information:	* NR	

**22. House Pullet Rearing Facility**

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
22.1. Name and address of the pullet rearing facility:	* NR	
22.2. Name:	* NR	
22.3. Address:	* NR	
22.4. Address:	* NR	
22.5. City:	* NR	
22.6. State:	* NR	
22.7. Zip:	* NR	

Inspectional Information	Egg Rule Reference	Notes
22.8. Additional information:	* NR	

**23. House Flock Health**

Inspectional Information	Egg Rule Reference	Notes
23.1. Have the birds been SE vaccinated?	* NR	
23.2. Has the flock been molted or is there a planned molt? (If Yes, enter age in weeks)	* NR	
23.3. Additional information:	* NR	

**24. House Flock History**

Inspectional Information	Egg Rule Reference	Notes
24.1. History of vaccination and use of drugs for the birds:	* NR	
24.2. Additional information:	* NR	

**25. House Other Animals Observed**

Inspectional Information	Egg Rule Reference	Notes
25.1. Select any live animals other than hens observed in and around the house:	* NR	
25.1.1. None	* NR	

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
25.1.2. Stray poultry	118.4(b)(4)	
25.1.3. Wild birds	118.4(b)(4)	
25.1.4. Cats	118.4(b)(4)	
25.1.5. Other	118.4(b)(4)	
25.2. Select any indication of birds other than hens observed in the house:	* NR	
25.2.1. Feathers	118.4(b)(4)	
25.2.2. Other	118.4(b)(4)	
25.3. If other, describe further:	* NR	
25.4. Select any indication of rodents observed in the house:	* NR	
25.4.1. Feces	118.4(b)(4)	
25.4.2. Gnaw holes	118.4(b)(4)	
25.4.3. Dead/Skeletons	118.4(b)(4)	
25.4.4. Other	118.4(b)(4)	
25.5. If other, describe further:	* NR	

Inspectional Information	Egg Rule Reference	Notes
25.6. Additional Information:	* NR	

**26. House Biosecurity**

Inspectional Information	Egg Rule Reference	Notes
26.1. Select any biosecurity measures observed:	* NR	
26.1.1. Perimeter fencing	118.4(b), 118.4(b)(3)	
26.1.2. Gates	118.4(b), 118.4(b)(3)	
26.1.3. Footbaths or equivalent measures	118.4(b), 118.4(b)(3)	
26.1.4. Special or limited clothing or shoes	118.4(b), 118.4(b)(3)	
26.1.5. Limitation of equipment sharing between houses	118.4(b), 118.4(b)(3)	
26.2. Are employees allowed to keep birds at home?	118.4(b), 118.4(b)(5)	
26.3. If footbaths are used, how often are they changed?	* NR	
26.4. Select any equipment shared between houses:	* NR	
26.5.1. Brooms	118.4(b), 118.4(b)(2)	
26.5.2. Blowers	118.4(b), 118.4(b)(2)	

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
26.5.3. Manure removal equipment	118.4(b), 118.4(b)(2)	
26.5.4. Dead animal containers	118.4(b), 118.4(b)(2)	
26.5.5. Other equipment	118.4(b), 118.4(b)(2)	
26.6. Are there other issues regarding biosecurity measures that are not reported elsewhere?	118.4(b)	
26.7. Additional information:	* NR	

**27. House Visitor Procedures**

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
27.1. Are visitors limited on the farm and in poultry houses?	* NR	
27.1.1. On the farm	118.4(b), 118.4(b)(1)	
27.1.2. In poultry houses	118.4(b), 118.4(b)(1)	
27.2. Are visitors escorted with limited access on the farm and in the poultry houses?	118.4(b), 118.4(b)(1)	
27.3. Additional information:	* NR	

**28. House Pest Control Measures - Exterior**

Inspectional Information	Egg Rule Reference	Notes
28.1. Are exterior traps/bait stations for rodents present?	118.4(c)(1)	
28.2. Are exterior traps/bait stations in working condition?	118.4(c)(1)	
28.3. Are exterior traps/bait stations accessible to rodents?	118.4(c)(1)	
28.4. Is there bait present in the exterior traps?	118.4(c)(1)	
28.5. Is the firm maintaining exterior traps properly?	118.4(c)(1)	
28.6. Evidence of improper maintenance of exterior traps:	* NR	
28.6.1. Decaying bodies	* NR	
28.6.2. Nesting material	* NR	
28.6.3. Skeletons	* NR	
28.6.4. Other	* NR	
28.7. Additional evidence or comments regarding improper maintenance of exterior traps:	* NR	
28.8. Were loose bait or bait blocks observed on the exterior?	118.4(c)(1)	

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
28.9. Were any rodents observed on the exterior?	118.4(c)(1)	
28.10. What is the number of rodents observed on the exterior?	* NR	
28.11. Are methods for monitoring rodents observed on the exterior?	118.4(c)(1)	
28.12. How are rodents monitored on the exterior?	* NR	
28.12.1. Glueboards	* NR	
28.12.2. Other	* NR	
28.12.3. Describe if other:	* NR	
28.13. Additional information:	* NR	

**29. House Pest Control Measures - Interior**

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
29.1. Are there water leaks?	* NR	
29.2. Are interior traps/bait stations for rodents present?	118.4(c)(1)	
29.3. Are interior traps/bait stations in working condition?	118.4(c)(1)	
29.4. Are interior traps/bait stations accessible to rodents?	118.4(c)(1)	

Inspectional Information	Egg Rule Reference	Notes
29.5. Is there bait present in the interior traps?	118.4(c)(1)	
29.6. Is the firm maintaining interior traps properly?	118.4(c)(1)	
29.7. Evidence of improper maintenance of interior traps:	* NR	
29.7.1. Decaying bodies	* NR	
29.7.2. Nesting material	* NR	
29.7.3. Skeletons	* NR	
29.7.4. Other	* NR	
29.8. Additional evidence or comments regarding improper maintenance of interior traps:	* NR	
29.9. Were loose bait or bait blocks observed in the interior?	118.4(c)(1)	
29.10. Were any rodents observed in the interior?	118.4(c)(1)	
29.11. What is the number of rodents observed in the interior?	* NR	
29.12. Are methods for monitoring rodents observed in the interior?	118.4(c)(1)	

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
29.13. How are rodents monitored in the interior?	* NR	
29.13.1. Glueboards	* NR	
29.13.2. Other	* NR	
29.13.3. Describe if other:	* NR	
29.14. Additional information:	* NR	

**30. House Pest Control Measures - Fly**

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
30.1. Are methods for monitoring flies observed in the interior?	118.4(c)(2)	
30.2. How are flies monitored in the interior?	* NR	
30.2.1. Spot card	* NR	
30.2.2. Scudder grills	* NR	
30.2.3. Sticky traps	* NR	
30.2.4. Other	* NR	
30.2.5. Describe if other:	* NR	

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
30.3. Has a fly control measure been observed?	118.4(c)(2)	
30.4. Where is the fly control measure being applied?	* NR	
30.4.1. Hen level	* NR	
30.4.2. Outside	* NR	
30.4.3. Pit	* NR	
30.5. What fly control measures are being used?	* NR	
30.5.1. Chemical	* NR	
30.5.2. Mechanical	* NR	
30.5.3. Electrical	* NR	
30.5.4. Other	* NR	
30.6. Type of chemical control?	* NR	
30.6.1. Bait	* NR	
30.6.2. Spray	* NR	
30.7. Compound(s):	* NR	

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
30.8. Schedule/frequency of chemical fly control:	* NR	
30.9. Type of mechanical control?	* NR	
30.9.1. Spot card	* NR	
30.9.2. Scudder grills	* NR	
30.9.3. Sticky traps	* NR	
30.9.4. Other	* NR	
30.10. If other, indicate type of mechanical fly control measure:	* NR	
30.11. Type of electrical control?	* NR	
30.11.1. Fly zapper	* NR	
30.11.2. Other	* NR	
30.12. If other, indicate type of electrical fly control measure:	* NR	
30.13. If another type of fly control measure is being used, describe:	* NR	
30.14. Additional information:	* NR	

**31. House Manure Management**

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
31.1. Type of manure system: (If Other, describe in comments)	* NR	
31.2. Frequency of manure removal: (If Other, describe in comments)	* NR	
31.3. Quantity of removal: (If Other, describe in comments)	* NR	
31.4. Condition of manure:	* NR	
31.5. Are rodent burrows present in the manure pit?	* NR	
31.6. Additional information:	* NR	

**32. House Pullet House**

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
32.1. Was there a positive environmental test in the pullet house?	* NR	
32.2. Following a positive environmental test for SE, was the pullet environment cleaned and disinfected?	118.4(a)(3)	
32.3. Was all visible manure removed from the pullet house(s) during cleaning and disinfecting?	118.4(a)(3)(i)	
32.4. Was the pullet house(s) that tested positive for SE dry cleaned?	118.4(a)(3)(ii)	

Inspectional Information	Egg Rule Reference	Notes
32.5. Was the pullet house(s) that tested positive for SE disinfected using appropriate disinfection methods?	118.4(a)(3)(iii)	
32.6. Were any cleaning and disinfection procedures observed while inspecting?	* NR	
32.7. Additional information:	* NR	

**33. House Environmental Verification Testing (Poultry House)**

Inspectional Information	Egg Rule Reference	Notes
33.1. Are environmental tests for SE done at this poultry house?	118.7(a)	
33.1.1. Result of most recent test:	* NR	
33.1.2. Date of most recent test:	* NR	
33.2. Are environmental tests for SE done when pullets are 14 to 16 weeks of age?	118.4(a)(2)(i)	
33.2.1. Result of most recent test:	* NR	
33.2.2. Date of most recent test:	* NR	
33.3. Are environmental tests for SE done when hens are 40 to 45 weeks in age?	118.5(a)	

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
33.3.1. Result of most recent test:	* NR	
33.3.2. Date of most recent test:	* NR	
33.4. Did any of the houses contain groups of hens of different ages?	* NR	
33.5. If yes, were the environmental tests for SE done using appropriate methods when each group of laying hens were 40 to 45 weeks in age?	118.5(a)(1)	
33.6. Are environmental tests for SE done at 4 to 6 weeks after the molting process?	118.5(b), 118.5(b)(1)	
33.6.1. Result of most recent test:	* NR	
33.6.2. Date of most recent test:	* NR	
33.7. Did environmental tests show positive results?	* NR	
33.8. Were the poultry house(s) that tested positive for SE cleaned and disinfected by appropriate procedures before new laying hens were added?	118.4(d)	
33.9. Was all visible manure removed from the poultry house(s) during cleaning and disinfecting?	118.4(d)(1)	

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
33.10. Was the poultry house(s) that tested positive for SE dry cleaned?	118.4(d)(2)	
33.11. Was the poultry house(s) that tested positive for SE disinfected using appropriate disinfection methods?	118.4(d)(3)	
33.12. Did the firm review and make necessary adjustments to the SE prevention plan in response to positive results?	118.5(a)(2)(i), 118.5(b)(2)(i)	
33.13. Did the firm divert eggs for the treatment for the life of the flock in response to positive environmental result?	118.6(a)(1), 118.6(a)(2)	
33.14. Did the firm conduct egg testing in response to a positive result?	118.4(a)(2)(iii), 118.5(a)(2)(ii), 118.5(b)(2)(ii)	
33.14.1. Result of the first 1,000 egg test:	* NR	
33.14.2. Date of the first 1,000 egg test:	* NR	
33.14.3. Result of the second 1,000 egg test:	* NR	
33.14.4. Date of the second 1,000 egg test:	* NR	
33.14.5. Result of the third 1,000 egg test:	* NR	
33.14.6. Date of the third 1,000 egg test:	* NR	

Inspectional Information	Egg Rule Reference	Notes
33.14.7. Result of the fourth 1,000 egg test:	* NR	
33.14.8. Date of the fourth 1,000 egg test:	* NR	
33.15. Did the firm respond in other ways to positive results?	* NR	
33.16. Is the sampling plan appropriate for the house layout?	118.7(a)	
33.17. Is testing conducted by the method entitled "Environmental Sampling and Detection of Salmonella in Poultry Houses" (most current edition) or an equivalent method?	118.8(a)	
33.18. Were any cleaning and disinfection procedures observed while inspecting?	* NR	
33.19. Additional information:	* NR	

**34. House Egg Testing**

Inspectional Information	Egg Rule Reference	Notes
34.1. Is any additional egg testing conducted after meeting the initial testing requirements?	118.6( e)	
34.1.1. Result of most recent test:	* NR	

<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
34.1.2. Date of most recent test:	* NR	
34.2. Is the firm meeting requirements for the four egg tests on flocks in positive poultry houses at two week intervals?	118.6( c), 118.7(b)(1)	
34.3. Is the firm meeting requirements for egg testing after a flock is returned to production?	118.7(b)(2)	
34.4. Were there any positive egg test results since the last inspection?	* NR	
34.5. When one or more of four egg tests are positive, is the firm diverting eggs?	118.6(d)	
34.6. When a monthly egg test from a flock that had been returned to table egg production is positive, is the firm diverting eggs?	118.6(e)(2)	
34.7. Are labeling requirements met for eggs being diverted to treatment?	118.6(f)	
34.8. If test results are positive, does the firm have documentation of diversion?	118.6(a)(1), 118.6(a)(2)	
34.9. Does the firm depopulate birds if tests results are positive?	* NR	
34.10. Does the firm use appropriate testing and sampling methodologies?	118.6(b), 118.8(b)	

Inspectional Information	Egg Rule Reference	Notes
34.11. Additional information:	* NR	

**35. Refrigeration**

Inspectional Information	Egg Rule Reference	Notes
35.1. Are eggs processed and held for more than 36 hours after lay?	118.4( e)	
35.2. If yes, at what temperature are the eggs maintained?	118.4( e)	
35.3. If yes, what monitoring method was observed?	* NR	
35.4. Does transportation occur more than 36 hours after lay?	* NR	
35.5. If yes, at what temperature are the eggs transported?	118.4( e)	
35.6. If yes, how is the transportation temperature monitored?	* NR	
35.7. Additional information:	* NR	

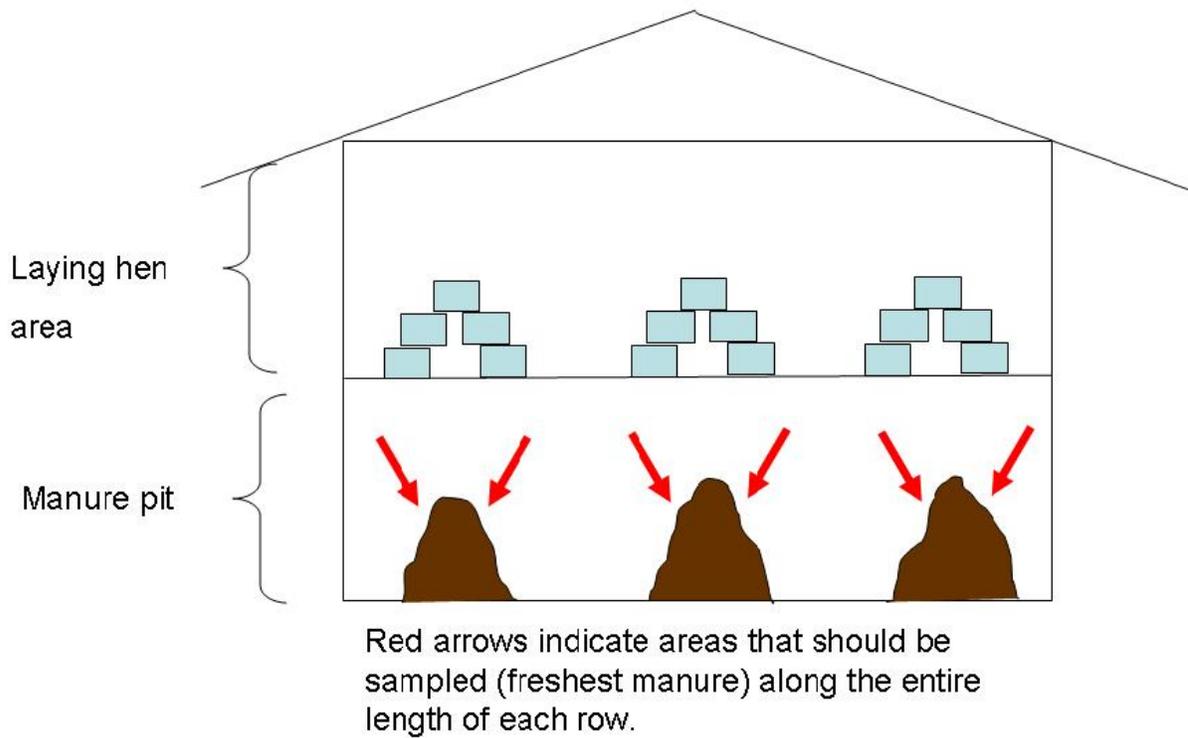
**36. Drug Residue**

Inspectional Information	Egg Rule Reference	Notes
36.1. Do you give any type of medication to your layers?	* NR	

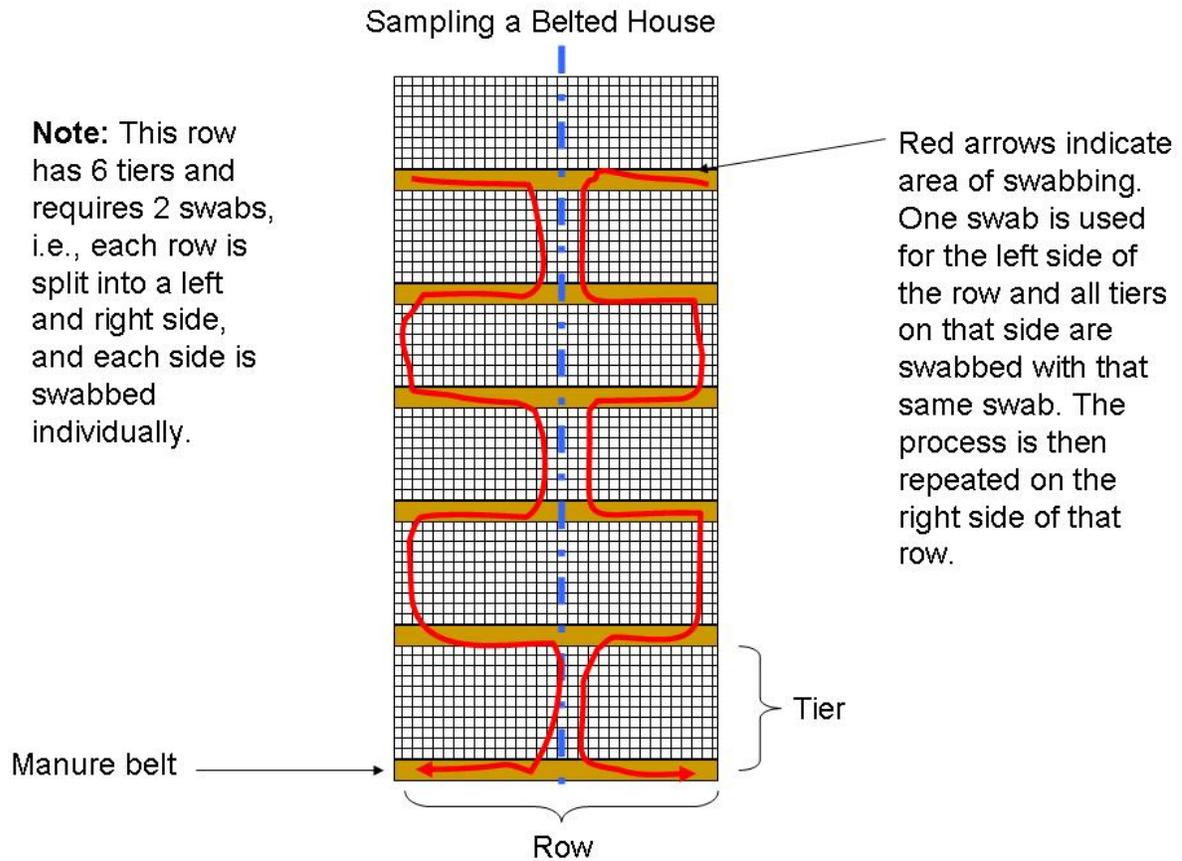
<b>Inspectional Information</b>	<b>Egg Rule Reference</b>	<b>Notes</b>
36.2. What is the route of medication (if other, please describe in comments)?	* NR	
36.3. What is the frequency at which medications are given (if other, please describe in comments)?	* NR	
36.4. What specific types of medications do you include?	* NR	
36.5. What are the concentrations of the drugs used in the layer rations or water supply or other route of application?	* NR	
36.6. Do you practice withdrawal types if drugs are used?	* NR	
36.6.1. If so, what are they?	* NR	
36.7. Do you test your eggs for drug and/or chemical residues?	* NR	
36.7.1. If so, how often are these tests conducted?	* NR	
36.8. Additional information:	* NR	

**ATTACHMENT B: POULTRY HOUSE STYLES**

**FIGURE 1: Sampling a high-rise poultry house (pit style poultry house)**



**FIGURE 2:** Sampling scheme for a belted system poultry house (sample from top to bottom)



**FIGURE 3:** Colony style poultry house



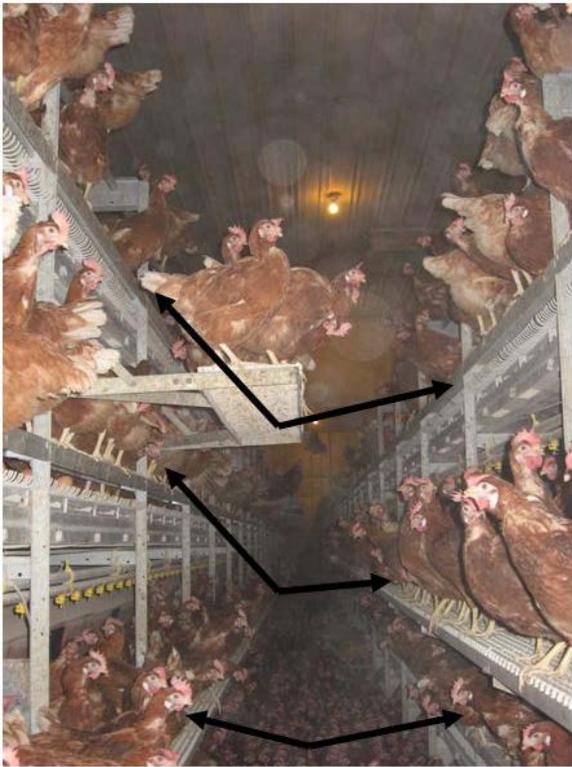
**FIGURE 4:** Sampling areas for colony style poultry house



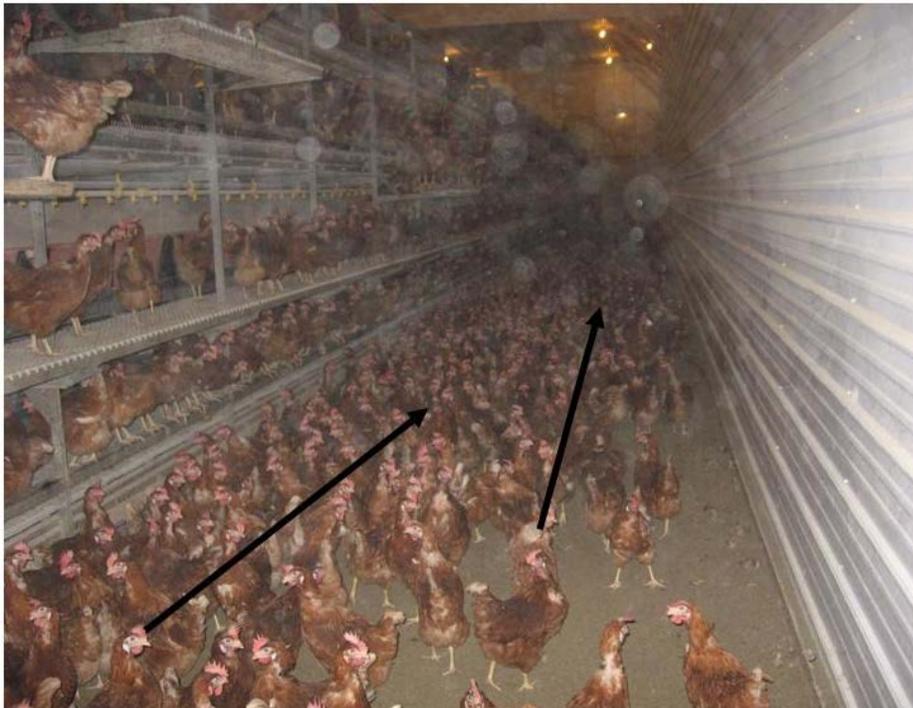
**FIGURE 5:** Sampling areas for single deck poultry house



**FIGURE 6:** Sampling Areas for Aviary poultry house platforms



**FIGURE 7:** Aviary poultry house scratch areas (i.e., floor areas)



**FIGURE 8:** Sampling Areas for Aviary poultry house manure belts



**FIGURE 9:** Poultry house styles that may be encountered during the inspection

