CHAPTER 03: FOODBORNE MICROBIOLOGICAL HAZARDS

SUBJECT	INSPECTION OF EGG FARMS FOR MONITORING COMPLIANCE WITH EGG SAFETY RULE
IMPLEMENTATION DATE	09/30/2024
PRODUCT CODES	Product Code: 15A—01 USE APPROPRIATE PRODUCT CODES
PRODUCT/ASSIGNMENT CODES (PAC)	REPORT PROGRAM ACTIVITIES UNDER THE FOLLOWING PAC CODES: **03836T** (TARGETED EGG FARM INSPECTIONS) **03S836T** (STATE CONTRACT TARGETED EGG FARM INSPECTIONS) **03836C** (COMPREHENSIVE EGG FARM INSPECTIONS/ENVIRONMENTAL SAMPLING) **03S836C** (STATE CONTRACT COMPREHENSIVE EGG FARM INSPECTIONS/ENVIRONMENTAL SAMPLING)

FIELD REPORTING REQUIREMENTS:

Investigators must use eNSpect to complete the Establishment Inspection Report (EIR) and Inspection Protocol (IP) for an Egg Safety Rule inspection (OP12) or for an investigation (OP13). See Investigations Operations Manual (IOM) subchapter *5.11 - Reporting* and subchapter *8.1.9 - General Investigation Reporting* for additional reporting instructions. An exception for creating an EIR or a related document (e.g., Form FDA 483) or an investigation memorandum in eNSpect must be endorsed by the investigator's supervisor. IOM subchapter *5.11.2.1 – Reporting Verified Corrective Actions* directs Office of Inspections and Investigations (OII) field staff to document corrective actions taken during an inspection in the Corrective Action Reporting (CAR) system within eNSpect.

Contents

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)."
(https://www.govinfo.gov/content/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) implement measures to prevent 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 3) 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 farms in order to evaluate 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 evaluating compliance with the Egg Rule, poultry house environmental sampling will be conducted on comprehensive inspections.
- To gather data about the farms to determine their future inspectional priority based on risk assessment using the Egg Inspection Protocol (Egg IP)
- 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 producer responds in accordance with the Egg Rule

2. Program Management Instructions

A. Inspection Priorities

Human Foods Program (HFP)/Office of Compliance Enforcement (OCE)/Office of Compliance Operations and Implementation (OCOI) will identify the domestic farms to be inspected in a separate memorandum issued as early as possible in each fiscal year. The memorandum will indicate the size of the farm and the type of inspection the farm will receive (targeted or comprehensive). Divisions should schedule inspections and collect samples, as applicable, to meet the goals of the program.

The number of inspections and approximate number of sample collections will be entered into eNSpect and FACTS respectively, by HFP/OCE/OCOI.

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

Refer to the Egg Resource SharePoint page on InsideFDA for current resources for egg farm inspections and sampling.

B. Involvement of State Regulatory Partners

If a state program has received a contract to conduct egg farm inspections, a separate list of identified farms for targeted or comprehensive contract inspections will be provided as part of the memorandum. Please contact Office of Integrated Food Safety System Partnerships (OIFSSP), Office of Domestic Partnerships (ODP) for any questions regarding the contract. State contract inspections will be entered into eSAF and migrated over to FACTS.

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

Divisions 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 compliance program and the IOM 5.11.4, Chapter 5 – 'Biosecurity Procedures for Inspections at Poultry Facilities and Farms', and Exhibit 5-19, page 5 – 196 'Standard Operating Biosecurity Procedures for Egg Farm Inspections/ commercial Poultry Operations'. However, State personnel may follow their state agency guidelines for selecting proper respiratory protection. At a minimum, an N95 (or equivalent) type respirator is strongly advised. State inspectors should ask the Division if they have questions about obtaining the required PPE.

C. When to Contact Other Offices within the FDA

If an inspection is in-progress and an answer is required as soon as possible, email OII Egg CAG Inquires. Field inspection staff should indicate that an inspection is 'In-Progress' in the e-mail subject heading. This will ensure that SMEs are available to answer questions or respond to concerns during an inspection. If field inspection staff want to reach out to several SMEs, please send one email and include all HFP and OII Program Contacts to minimize duplication of effort and to ensure consistency of guidance.

PART III - INSPECTIONAL

1. Operations

A. Inspections

Under this program, inspections shall occur at shell egg producers with 3,000 or more laying hens (at a particular farm) that produce shell eggs for the table market and do not sell all eggs directly to consumers. These farms are required to register with the FDA as a shell egg producer and comply with some, or all, of the requirements within FDA's Egg Rule depending on the operations they perform. Each inspection (targeted or comprehensive) will evaluate compliance with the Egg Rule.

Inspectional Frequency

Egg farms will be inspected routinely at an appropriate frequency across the country by FDA and/or State officials or "Contractor" under contract with the FDA. FDA will prioritize these inspections based on the greatest health impact and as deemed appropriate will perform inspections accordingly.

Training

The lead Investigator, and/or State representative, conducting the inspection must have attended, and passed, the OTED FD107: Egg Safety Inspections training course. The course training manual provides specific instructions for how to conduct these inspections. Any State representative(s) participating in the inspection will count towards the minimum number required for egg farm inspection safety measures (2 for targeted inspections, 3 for comprehensive inspections).

Pre-Inspection Notification to the Farm

For several reasons, including personal safety, this program recommends pre-announcement of inspections. Pre-announcement calls placed approximately 24-48 hours before initiating inspections allow for familiarization with the farm's biosecurity practices, and farm operations; however, this decision is left to Division discretion (refer to IOM 5.2.1.1). A sample pre-announcement call script is posted on the Egg Resource SharePoint page.

If the Division has made attempts to contact the farm to pre-announce the inspection but encountered difficulties in doing so (e.g., 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.

Coordination with State Veterinarian

Prior to conducting an inspection, the Division must contact the State Veterinarian or appropriate state animal health official 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.

Do not visit a farm when the state veterinary contact recommends to not conduct an inspection due to known avian disease (e.g., Highly Pathogenic Avian Influenza or HPAI).

i. Biosecurity/Personal Protection Requirements

All members of the inspection team must have a current respirator clearance.

Biosecurity measures must be followed during every inspection where Investigators are on-farm and enter 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 IOM 5-19, Chapter 5, page 5-196. The Egg Resource SharePoint page posted on InsideFDA has resources to reference any updated biosecurity measures in regards to cattle implicated poultry house biosecurity requirements.

Egg farm inspections require unique action by Investigators to assure that we do not contaminate or cross-contaminate the environment by following IOM 5.11.4, Chapter 5 – Biosecurity Procedures for Inspections at Poultry Facilities and Farms. Additionally, Investigators must take steps for their personal safety. The following are requirements:

- The Investigator must be enrolled in the Regulatory Operations Respiratory Protection Program (RPP) SOP-000449, ORS Safety Respiratory Protection Resources. Prior to using a respirator and entering a poultry farm, 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 IOM S.9.7. 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.
- The Investigator must not be a bird owner in their own home and must not have been at any other poultry farm or exposed to other poultry or birds up to 72 hours before an inspection, including visits to aviaries or tending backyard feeders. This 72-hour limit may be increased depending on the farm's own 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 IOM 5-19, Chapter 5 - Pre-inspection Measures item #4.

- Disposable personal protective clothing (e.g., coverall, boot covers, gloves, hair nets, safety glasses, 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 IOM 5-19, Chapter 5 - Pre-Inspection Measures item #6 for appropriate vehicle cleaning and disinfection procedures.

Additional Disinfectants Acceptable for Use

Name *	**Manufacturer**
Tek-Trol® Disinfectant	ABC Compounding Co.
Biophene®	BioSentry
Pine Sol® (original containing Pine oil)	Clorox
Lysol® (containing 2-phenylphenol)	Reckitt Benkiser
Lph®	Steris Corporation
Phenocide 256 ®	Lonza, Inc
Phenocide 128®	Lonza, Inc
Phenolic® Disinfectant	Johnson Diversey
Vesphene®	Steris Corporation
Pheno-Tek II®	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 Kenneth Crombie at OC-OCS-OSLA-ROSS-Mgmt@fda.hhs.gov, or (240) 402-5346.

- When taking photographs, digital cameras must be placed in sealable plastic bags, which shall be changed out between poultry houses.
- Investigators must take with them at the end of each day, and properly dispose of offsite, 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 wearing disposable coveralls and respirators can be tiring and warm, the team should dress appropriately and take necessary breaks. Do not use the sample coolers to carry your lunch or break refreshments; this will ensure there is no potential for cross contamination of 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.

ii. Inspection Coverage Requirements:

Both inspection types (comprehensive and targeted) under this program shall, at minimum, include the following components of the Egg Rule:

- Evaluate the SE prevention plan to ensure it minimally includes the following SE prevention measures:
  - Procurement of pullets that are SE-monitored
  - Biosecurity
  - Rodent/Pest control
  - Cleaning and disinfecting
  - Adequate refrigeration of shell eggs

- Collect a copy of the written SE prevention plan and submit with your EIR.
- Determine if the farm has appropriate sampling and testing methodologies for SE and the producer conducted environmental and egg testing at required time periods. If positive environmental samples or egg testing were found, determine whether appropriate actions were taken in accordance with the Egg Rule.
- Review administrative requirements and all associated records required by the Egg Rule for the current flock(s), and if necessary, any prior flocks (where records are required to be kept one year after the life of the flock).
- After review of the SE prevention plan and relevant records, determine if the SE prevention measures are being implemented by walking through a subset of the houses. To determine the number of houses to walk through and sample for an inspection, use the following formula:

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

  When the square root ($\sqrt{}$) is greater than a whole number, round up to the next highest number; for example, if there are 5 houses, and the square root of 5 is 2.2, then round up to 3 + 1 = 4 houses to walk through.
- For farms identified as comprehensive inspection type, poultry house environmental samples must be collected. For targeted inspections, if significant deviations are encountered during house walk-throughs, environmental samples may need to be collected. In the latter situations, contact Martha Myrick, Martha.Myrick@fda.hhs.gov, Lisa Thursam, Lisa.Thursam@fda.hhs.gov, and OII Egg CAG Inquires.
- Verify the farm's registration status:

  All egg farms subject to the Egg Rule are required to register as shell egg producers under 21 CFR 118.11 via the Shell Egg Producers Registration Module in FURLS (this registration is different from Food Facility Registration). Investigators must verify the registration is current, only one is active, and matches the FDA database.

Unless otherwise necessary the following houses should NOT be entered:

- Houses with birds known to have any disease (e.g., Salmonella spp., Newcastle disease, *Mycoplasma gallisepticum*, Egg Drop Syndrome Virus, etc.);
- Positive Poultry Houses as defined in 21 CFR 118.3; poultry houses from which there has been an environmental test that was positive for SE at any time during the life of a group in the poultry house **until that house is cleaned and disinfected** according to 21 CFR 118.4(d);
- Depopulated houses

Note: However, those houses that are depopulated, have known disease issues, or are SE positive **should** be counted and used in this calculation during routine inspections.

When FDA has jurisdiction to conduct an inspection and the farm falls under a workload obligation for the Egg Rule, complete an inspection (OP 12) using the appropriate Egg Inspection PAC. A list of farms for comprehensive and targeted inspections will be sent out by HFP/OCE/OCOI as early as possible in the scheduled fiscal year for inspections.

When possible, changes to the workplan should be arranged in advance with OII/Office of Global and Specialty Human Foods Inspectorate (OGSHFI)/Division of Critical and Specialty Foods (DCSF)/Human Foods Program Expert Branch (HFPEB) program contact Martha.Myrick@fda.hhs.gov, and HFP/OCE/OCOI contact Joshua.Adams@fda.hhs.gov.

Inspections of these farms may include a headquarters location plus multiple farms at different physical locations. Each of these locations should have an individual Shell Egg Producer Registration (SEPR), and FEI number. The Investigator should prepare separate FDA 483s and EIRs for each FEI, regardless of when inspections are completed within close proximity in time. Each location inspected will need to be reported in eNSpect to ensure accurate information on last inspection date, products covered, and inspection classification.

Issuing FDA 483s to Contract Farms:

An egg farm may be 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 may 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 Prevention Plan Administrator works for 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 prevention plan. Regardless, the contract farm is responsible for implementing the SE prevention plan and for complying with the Egg Rule. When available, the investigator should collect documentation showing the responsibilities and authorities of each party.

iii. Targeted Inspections

Walkthroughs are to be conducted during all inspections, with the exceptions as noted in this compliance program. Use the formula, √ (Total # of Houses) + 1, to determine the number of houses to walk through. As noted in this program, **do not enter any poultry house for walk through (or environmental sampling) if the house has a known disease or is determined to be a Positive Poultry House as defined in 21 CFR 118.3, through FDA, State, or the farm's environmental testing.**

State agencies should refer to the current statement of work for any changes to current processes. Currently, **State agencies conducting targeted inspections for FDA under contract must conduct a walk-through of a minimum of four houses during the inspection. If the number of houses is fewer than four, state personnel must conduct a walk-through of all houses.** If the number of houses is greater than four, use the formula referenced above.

When inspection findings during a targeted inspection are significant to warrant collection of environmental samples from poultry houses, the inspection should switch to comprehensive and the appropriate PAC should be utilized. All changes from targeted to comprehensive should be first approved by OII/OGSHFI/DCSF through program contact Martha.Myrick@fda.hhs.gov, or OII Egg CAG Inquires, and also coordinated through HFP/OCE/OE/DCFE contact Lisa Thursam at Lisa.Thursam@fda.hhs.gov.

iv. Comprehensive Inspections

If a comprehensive inspection is assigned, but there is an inability to conduct environmental sampling due to the farm's operations (e.g., all houses are positive poultry houses, all houses have avian disease, no houses are currently populated, etc.), then contact the OII/OGSHFI/DCSF program contact at Martha.Myrick@fda.hhs.gov.

For comprehensive inspections, a minimum of 3 Investigators are needed per team.

The Lead Investigator must assure that all equipment necessary to conduct environmental sampling is available during each inspection.

Environmental samples are to be collected during comprehensive inspections, except for reasons noted within this compliance program). Use the formula, √ (Total # of Houses) + 1, explained above to determine the number of houses to sample.

- In each sample collection report, Investigators should identify poultry house capacity, number of layers per house, sampled house identification details (e.g., house #, house structure if multiple floors, etc.) and house style (e.g., aviary, belted, cage-free with outdoor access, etc.)

v. **For Cause Activities**

CORE Outbreaks: Communicate with CORE, or any associated Incident Command System (ICS) Incident Commander, or Incident Management Team (IMT), to determine the objectives of the inspection/investigation.

Follow-up Inspection/Investigation:

- Consumer Complaints or Recalls: When a consumer complaint or recall is received that has an impact on public health or safety, a follow-up operation will be created in eNSpect by Division personnel. All other complaints or recalls received will be addressed by the annual workplan process.
- OAI follow-up inspections/investigations: To be conducted by Divisions to determine compliance within appropriate FMD-86 timeframes. These operations are to be created in eNSpect by Division personnel to account for available resources while ensuring that timeframes are met.

vi. **Coverage of On-farm Shell Egg Processing** (e.g., eggs are washed, graded, packed) for the table egg market **FDA and USDA/AMS may share jurisdiction in on-farm shell egg processing areas. Inspections of shell egg processing areas will vary based on USDA/AMS coverage:**

- If a farm is actively enrolled in the USDA/AMS voluntary egg grading program and is continuously evaluated for sanitation by USDA/AMS resident inspector on site, then the processing area should NOT routinely be inspected under this program. However, there may be for-cause reasons for FDA and State agencies to inspect shell egg processing areas (i.e., Interagency Referral Reports (IRRs), outbreak or traceback investigation, etc.) **Prior to any for-cause follow up inspections of the processing area, please contact the OII and HFP contacts within 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 processing operation should be inspected under this program.**

FDA investigators and/or state regulatory partners should identify themselves to any USDA personnel onsite and explain the purpose of the inspection. All relevant information including USDA/AMS coverage shall be included in the EIR.

Please note: Shell egg processing facilities (as defined per 21 CFR Part 118.3) that are located on an egg farm are not subject to 21 CFR Part 117; therefore, any observations of insanitary conditions shall be cited on the FDA-483 under section 402(a)(4) of the Act. Please refer to PART V - REGULATORY/ADMINISTRATIVE STRATEGY.

Other processing areas:
If a farm has an egg products processing plant on site (e.g., egg breaking, in-shell pasteurization or hard cooking operations), these operations are under USDA/FSIS jurisdiction and shall not be covered by FDA, this should be noted accordingly in the EIR.

B. Investigations

An Investigation could be conducted when the farm is not covered by some, or all, requirements of the Egg Rule. For example:

- Not an Official Establishment (NOE): If a producer sends all shell eggs to treatment (i.e., 5-log destruction of SE, or processed in accordance with Egg Products Inspection Act), then they must comply with registration and refrigeration requirements in the Egg Rule. Note: if any shell egg is sent to the table egg market, then the producer must comply with all the requirements of the Egg Rule.
- Out of Business (OOB): If a farm is no longer in business and all operations are ended, then complete an Investigation and reference the program instructions of Comprehensive or Targeted (Comprehensive Inspection (OP 12) → Comprehensive Investigation (OP 13); Targeted Inspection (OP 12) → Targeted Investigation (OP 13)).
- Verification of state contract removal from inspection: If the state notifies FDA of a firm on the contract list is OOB or Not Operational and a site visit was not made, the FDA must verify this information with a site visit. Some operations are deemed OOB by the state but do not fall under that definition for the FDA.
- The farm has fewer than 3,000 laying hens. Please note: There are certain for-cause situations (i.e., outbreak investigations) where an egg farm with fewer than 3,000 layers may be inspected or investigated. This follow up would generally be initiated under the FFDCA. However, prior to initiating an inspection or investigation of a farm with fewer than 3,000 layers, the Division shall notify and coordinate any follow up with the OII and HFP contacts identified in this program.
- Individuals engaged in the transportation or storage of eggs for shell egg processing or egg products facilities must comply with the refrigeration requirements of the egg safety rule, provided the eggs originate from farms with 3,000 or more laying hens.

Breeders/Broilers

To improve data for targeting inventory and work planning, farms that fall under the category of Breeder/Broiler shall be identified by the Division with the District Use Code (DUC) “BB”.

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 farm is only responsible for the refrigeration and registration requirements of 21 CFR Part 118. In summary:

- (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

C. Sample Collections

NOTE: Water, feed, egg, and dust samples should NOT be collected as part of routine work conducted under this compliance program. Please refer to IOM 4-21, Chapter 4, Sampling, Sample Schedule Chart 1 for additional *Salmonella* sampling information.

Environmental Sampling

Environmental sampling of the poultry houses shall be conducted during all comprehensive inspections.

Do not enter any poultry house for environmental sampling if the house is determined to be a known SE positive through the FDA, State, or the farm's environmental testing.

Contact the OII Egg CAG Inquires email prior to performing environmental sampling of any processing areas.

i. Sampling Techniques

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

Guidance for Industry: Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation

Environmental Sampling and Detection of Salmonella in Poultry Houses

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

- **Swab Type**
  Drag Swab – 4"x4", 12 ply sterile gauze pad with string (for manure samples), pre-moistened or dry.

Hand Swab – 4"x4", 12 ply sterile gauze pad without string (for egg belt samples and for manure belts in belted houses).

Pre-assembled sterile drag swabs (12 ply 4"x4") for use in comprehensive egg inspection environmental sampling are to be purchased by each division. For questions on how to obtain drag swabs see 'Supply Lists & Equipment Resources' on the Egg Resource SharePoint page, or contact Martha Myrick at Martha.Myrick@fda.hhs.gov.

- **Swab Prep**
  There is the potential for two types of packaged swabs, pre-moistened or dry. When swabs are packaged pre-moistened, these do not need any additional milk prior to sampling.

  If the swabs are dry swabs, the Investigator must aseptically moisten them with canned evaporated milk. Multiple cans/vials may be needed, preferably with the same lot codes. 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.

  After sampling, each swab should be placed in its own individual sample bag with no more than a tablespoon, or approximately 15mL, of canned evaporated milk should be added to the bag to keep the swab moist during transport. Keep samples refrigerated after collection. 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. A sterile swab should be placed over the opened can of milk to deter flies from potentially contaminating the milk during the sampling.

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

ii. Sample Numbering System

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.

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:

3 L 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: Do not collect both manure and egg belt/walkway samples. Egg belt and walkway samples shall only be collected when the manure is inaccessible.

iii. Poultry House Styles for Environmental Sampling

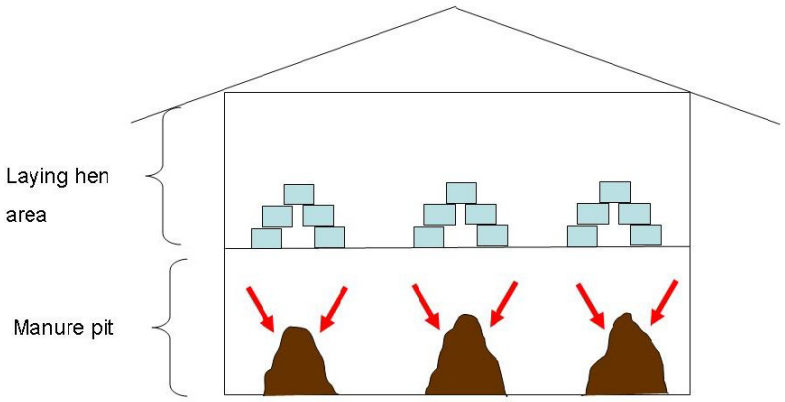
- High-Rise Poultry House (Pit Style Poultry House)
  This style of house has two stories; the top floor contains rows of cages that house the laying hens, and the bottom floor is the "pit" where the manure collects in a cone shaped pile under each row of cages. Both sides (banks) of each manure cone 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). 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.



Red arrows indicate areas that should be sampled (freshest manure) along the entire length of each row.

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

- 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 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 farm 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.

- 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.

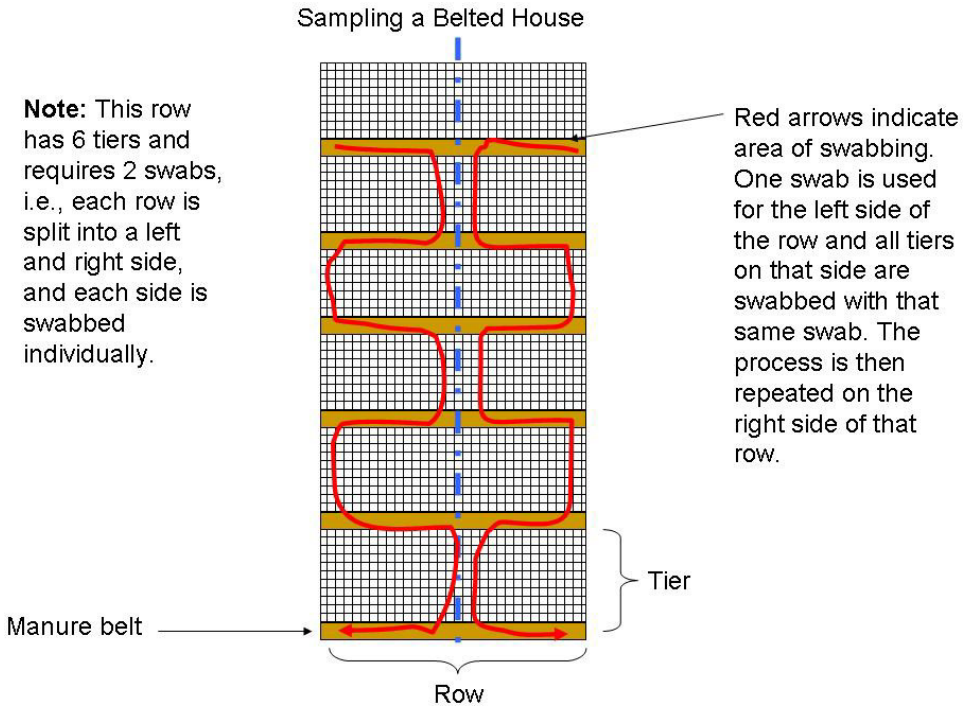


FIGURE 2: Sampling scheme for a belted system poultry house (sample from top to bottom)

- Single Deck Poultry House

  This style of house can only be used where annual weather conditions permit. 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 3). This "manure row" should be sampled with a drag-swab. 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.

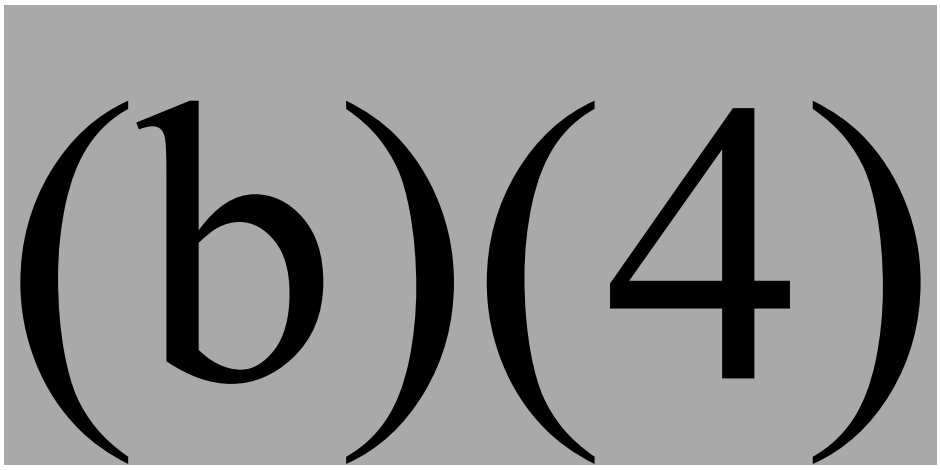


FIGURE 3: Sampling areas for single deck poultry house

- 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. 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 4) 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 platform's rows. This style of house is sampled by swabbing the manure belts. If a house has multiple floors, divide the number of swabs evenly to cover each floor equally.

  - 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 5). 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).

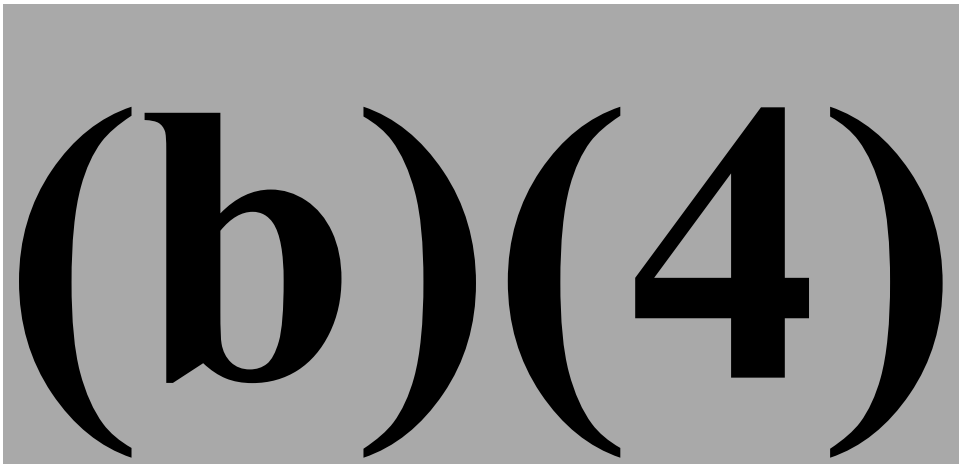


FIGURE 4: Sampling Areas for Aviary poultry house platforms

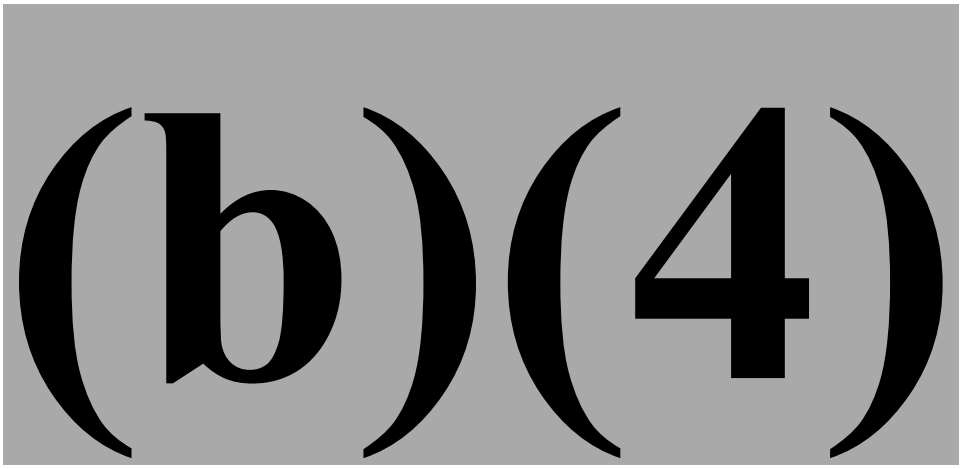


FIGURE 5: Sampling Areas for Aviary poultry house manure belts

- House styles where layers have access to areas outside the poultry house (Refer to Figure 6)
  - *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).

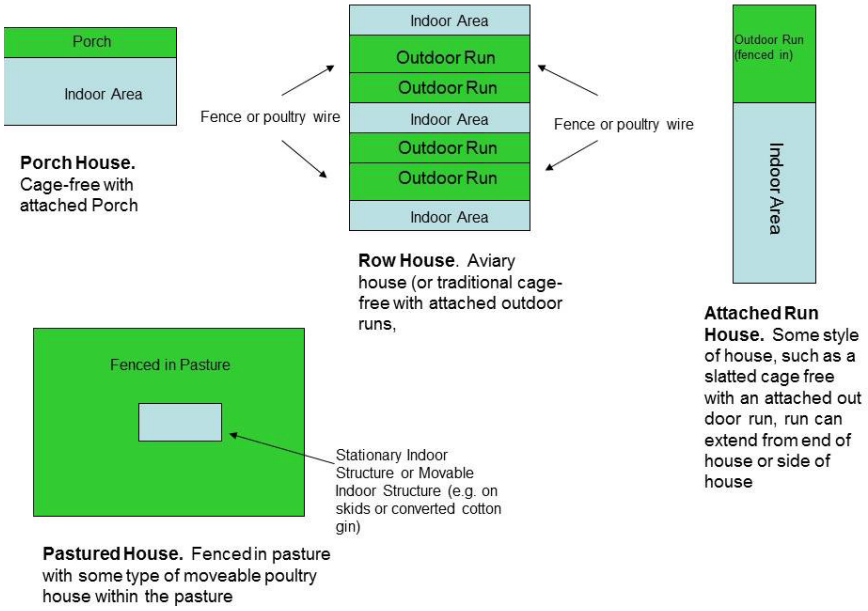


FIGURE 6: Poultry house where layers have access to areas outside the poultry house.

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 Gerardo Ramirez at, Gerardo.Ramirez@fda.hhs.gov, or (713) 293-1418, for further assistance on sampling that environment.

iv. Sample Shipment

The Divisions will arrange sample shipment to the servicing laboratories according to the Laboratory Servicing Table (LST) for farms scheduled for comprehensive inspections in the memorandum sent out by HFP/OCE/OCOI at the start of the fiscal year. Samples must be shipped under refrigeration conditions via UPS Next Day Air Early A.M. delivery to guarantee samples are to the laboratory within 24 hours. Email the laboratory POC at least 1 week prior to sample collection so that the laboratory can be prepared to process the sample when it is received.

Please locate the nearest UPS drop location, ensuring that it has overnight delivery services, and their hours of operation. Upon arrival at laboratory, samples shall be stored under refrigeration conditions before microbiological analysis.

2. Reporting

i. Inspection Reporting (OP 12)

Egg Inspection Protocol (IP) must be used to collect information during an inspection to shorten the total inspectional and reporting time burden to complete an inspection. When an inspection is completed outside of eNSpect, the Egg IP hardcopy (Attachment A) information must be entered into the eNSpect Egg IP.

Establishment inspection reports (EIRs) must be completed in eNSpect per IOM 5.11, Reporting. EIRs must be comprehensive for all initial inspections performed under this compliance program regardless of inspection history. eNSpect IPs must be completed for all egg safety inspections.

Do not use industry code M-15 when covering farms under this program as they will end up on the FSMA high risk inspectional list. Use only G-15 for all egg farms that include a processing area.

When FDA has the jurisdiction to conduct an inspection and the farm falls under a workload obligation for the Egg Rule, complete an inspection (OP 12) using the appropriate Egg Inspection PAC. A list of farms for comprehensive and targeted inspections will be sent out by HFP/OCE/OCOI as early as possible in the scheduled fiscal year for inspections.

If a comprehensive inspection is assigned, but there is an inability to conduct environmental sampling due to farm's operations (e.g., all houses are positive poultry houses, all houses have avian disease, no houses are currently populated, etc.), then contact OII/OGSHFI/DCSF to discuss why houses could not be entered for sampling or walk-throughs.

All discussion items and corrective actions taken by producers in response to inspectional observations must be documented in the Corrective Action Reporting (CAR) system, accessible via eNSpect and CMS. Voluntary corrections should be encouraged for all observations and, when possible, verified prior to the close of the inspection. Use eNSpect to report corrective actions observed during inspections and those received after inspections but before the inspection report is finalized in eNSpect. Use CMS to report and assess any corrective actions received after the EIR has been finalized in eNSpect.

The Office of Inspections and Investigations (OII) field division completes the EIR, including an inspection classification consistent with Field Management Directive (FMD) 86 and FDA policies including this compliance program, within OII established timeframes. The OII division files the inspection documents electronically using the appropriate module (eNSpect, or CMS) accessible to both OII and HFP, refer to FMD-86 for further information on timeframes based on inspection classification.

Inspections of these farms 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 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 eNSpect to ensure we have accurate information on last inspection date, products covered and classification.

State contract inspections will document the information identified in the Egg Inspection Protocols (Attachment A) which will be entered into eSAF and migrated over to FACTS.

Safety Alert Coding:

Egg farms covered by the Egg Rule - related work must have the "Safety Alert" indication in Firm Management Services (FMS) set to "yes" to indicate that personal protective equipment (PPE) is required to be used to prevent introduction or transfer of SE into or among poultry houses. If you find an egg laying farm identified in FMS without the “Safety Alert” indication, please speak with your supervisor or Division OEI Coordinator to ensure this is completed. Please refer to IOM 5.3 Chapter 5, Inspections – Safety During Inspections, or SOP-001378, ORA Field Safety (Personal Safety) Alerts Procedure for more information on the “Safety Alert” notification.

ii. Investigation Reporting (OP 13)

Please follow the IOM 8.1.9, Investigations, GENERAL INVESTIGATION REPORTING

iii. FACTS Sample Reporting (OP 31)

When environmental samples of poultry houses are collected, create a new sample number/CR for each individual poultry house sampled.

Contact OII Egg CAG Inquires prior to performing environmental sampling of any processing areas.

Environmental Sample Collections/Analysis:
PAC: 03836C, 03S836C (state)

PAF: 'MIC'
Sample Basis on CR: Surveillance or Compliance
Product Code: 52YYY07

When environmental sampling is being conducted during a For-Cause operation utilize the For-Cause PAC for reporting the samples collected.

Please remember to report all related sample numbers from related collection reports in ‘Collection Remarks’ field on Page 1 of the FACTS Maintain Sample Collection screen and record the lead Collection Report in the ‘Related Sample’ field. Additional PAC(s) may be utilized depending on the scope of the assignment/operation.

PART IV - ANALYTICAL

1. Analyzing Laboratories

Divisions are required to coordinate with their servicing lab prior to sample collection. Please refer to the Laboratory Servicing Table (LST) for additional guidance. Send to the lab that has the lowest capacity (%) utilized at the time of shipping.

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* Detection, Isolation and Identification

Use method entitled "Environmental Sampling and Detection of *Salmonella* in Poultry Houses," October 2008. This method is available at the following website: https://www.fda.gov/food/laboratory-methods-food/environmental-sampling-and-detection-salmonella-poultry-houses. Conduct biochemical identification tests to presumptive *Salmonella* isolates.

Proceed to section F.3.b of Bacteriological Analytical Manual (BAM) Online: Chapter 5 https://www.fda.gov/food/laboratory-methods-food/bam-chapter-5-salmonella and test each of the TSI isolates for *Salmonella* (O) group D_1 activity. If the isolates do not display Group D_1 activity, then the isolates should not move forward to confirmation. All isolates that display Group D_1 activity should proceed to subsection B as follows.

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

Servicing laboratories are to analyze *Salmonella* isolates for Whole Genome Sequencing (WGS) and serotyping (SeqSero) 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, F.11, Submission of cultures for serotyping.

C. Whole Genome Sequencing (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 HFP.

D. Laboratory Classification

Laboratory Classification will be assigned after WGS and SeqSero analysis.

Lab Class 1 – only non-D*1* (non-Enteritidis) isolate(s) are recovered and analysis was terminated. (i.e., before confirmation, speciation, and WGS as in subsections B and C).

Lab Class 2 – isolate(s) confirmed as non-*Salmonella* Enteritidis by SeqSero analysis (only isolates screened as D1 and moved forward through confirmation).

Lab Class 3 – isolate(s) confirmed as *Salmonella* Enteritidis by SeqSero analysis.

Note: for certain follow-up investigations, testing for other non-*Salmonella* Enteritidis serotypes may be requested. Analytical methodology and laboratory classification guidance will be provided for these exceptions.

4. Reporting

For confirmed FDA SE positive environmental samples, report results to the producer per FDA procedures.

Pursuant with current MOUs, the sample findings shall be relayed to the applicable State regulatory agency, USDA/AMS and/ or USDA/FSIS. Findings should be submitted http://apps.ams.usda.gov/plantbook/grbr_states2.htm through an interagency report including a summary of objectionable conditions online to USDA/AMS and/or USDA/FSIS at: http://www.accessdata.fda.gov/scripts/irf/.

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

1. Inspectional Findings

The goal of this regulatory strategy is to obtain industry compliance with the Egg Rule and gain prompt voluntary correction of deficiencies; however, appropriate swift enforcement action will be taken when significant violations present a threat to public health. Divisions should also consider their State partners' ability and willingness to request industry's prompt voluntary correction of deficiencies or pursue state enforcement action.

Refer to the resource library or Egg Resource SharePoint page for FDA staff for the 21 CFR part 118 citations ranking document which provides a starting point for determining regulatory significance based on public health. The public health significance of observations and appropriate follow-up activities must be determined on a case-by-case basis.

If FDA covers an on-farm processing area during an inspection, any observations of insanitary conditions shall be cited on the FDA-483 under section 402(a)(4) of the Act. This processing area is not subject to 21 CFR Part 117 or 21 CFR Part 118. The only exception is for observations related to the Egg Rule's refrigeration requirements, which shall be cited under 21 CFR Part 118.4(e).

2. Charges

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.

Additional charges may apply depending on findings during the inspection.

Compliance Actions

Consideration for enforcement depends on several factors including the farm's compliance history, the significance and severity of inspection observations, possible routes of contamination, and the adequacy and timeliness of the farm's corrective actions.

HFP has not given Direct Reference Authority (DRA) for compliance actions related to violations of 21 CFR Part 118, at this time. However, if the only significant violation is failure to register, as required by 21 CFR 118.11(a), a direct-reference Untitled Letter should be sent to the farm.

Please note that all reasonable steps should be taken to obtain voluntary compliance prior to initiating regulatory action. All possible administrative and legal regulatory actions should be discussed with state regulatory partners before moving forward. Divisions should take into consideration state partner's ability and willingness to request industry's prompt voluntary correction of deficiencies or pursue state enforcement action. Refer to Table 1 to determine recommended actions based on inspection findings. If the farm's response is inadequate to protect public health, all available advisory, administrative, and legal tools should be considered, such as a regulatory meeting, untitled letter, warning letter, seizure, injunction, Order of Diversion/Destruction (21 CFR 118.12(a)(1)(i)), or prosecution.

Please see Table 1 below for examples of potential compliance activities associated with ranking and classification outcomes. This summary is a starting point and should not be the sole basis for evaluating the significance of noncompliance. Findings should be assessed on a case-by-case basis and should consider the totality of the observations.

Table 1: Compliance Activity Examples

Regulatory Significance	Example Deficiency	Inspection Classification and Possible FDA Response/Action
Critical	• No written *Salmonella* Enteritidis (SE) Prevention Plan or significant lack of implementation of an SE Prevention Plan; • AND lack of control observed • AND eggs are associated with illness, recall, and/or pose a SAHCODHA risk	**OAI** Contact OCE/OE; request voluntary diversion of eggs to a treatment, submission of corrective action plan, and/or voluntary recall, if warranted. • Order of Diversion/Destruction • Administrative Detention • Injunction (Preliminary or Permanent) • Seizure • Warning Letter • Regulatory Meeting

Major	• No written SE Prevention Plan
	• Inadequate procedures or lack of implementation of an SE Prevention Plan
	  ○ Not procuring pullets that are SE monitored or raising pullets under SE monitored conditions
	  ○ Inadequate biosecurity measures
	  ○ Inadequate pest control program
	  ○ Inadequate cleaning and disinfection of an SE positive poultry house
	  ○ Inadequate refrigeration controls
	• Not conducting environmental monitoring for SE at required time periods
	• Not diverting eggs or beginning egg testing after an SE positive environmental test
	• Inadequate testing methodology for environmental or egg testing
		OAI
		
		• Warning Letter
		• Regulatory Meeting
		• Administrative Detention
		• Injunction (Permanent)
		• Seizure
		
		OR
		
		VAI
		If public health significance is remote
		
		• Warning Letter (if there are uncorrected/repeat items that may lead to food safety risk)
		• Regulatory Meeting (if corrective actions are not adequate and/or repeat minor observations are found during a Warning Letter follow-up inspection)

Regulatory Significance	Example Deficiency	Inspection Classification and Possible FDA Response/Action
Minor	• Inadequate record keeping requirements • No SE plan administrator, but controls appear adequate	**NAI** Generally, minor observations are not significant to public health. Items should be discussed, and producers should be urged to correct observations during the inspection. Corrections should be verified and documented. Do not print on 483 OR **VAI** **Issue FDA 483**, if repeat condition or pattern of observations

3. Additional Information

Voluntary correction is often the most effective and expedient means by which to protect public health and obtain compliance. Divisions should take steps to obtain voluntary correction prior to initiating regulatory action. When voluntary correction is not forthcoming, the Agency should pursue routine regulatory procedures to address significant observations. Refer to *FMD-86 Establishment Inspection Report Conclusions and Decisions* for further guidance.

If the farm inspected under this program has significant inspectional findings, positive SE environmental samples, and/or conditions are observed that present a public health concern, a conference call between the OII/OHFI Division , and HFP/OCE/OE program contacts identified in part VI of this program should be scheduled before closing the inspection to discuss possible enforcement strategies. If this information is known prior to beginning the inspection, a call should be scheduled prior to the start of the inspection.

The Division should submit any recommendation for enforcement actions following procedures with Office of Compliance Implementation and Consultation, Division of Compliance Consultation (OCIC/DCC)

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

PART VI REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS

1. References

Major guidance and reference materials pertaining to this program are listed below. Additional guidance may be found in the resource library.

A. **Investigations Operations Manual, Subchapter 8.1.9, General Investigation Reporting**

B. **Investigations Operations Manual, Chapter 5.2.6, Pre-Announcements**

C. **Investigations Operations Manual, Chapter 5.3.1.2, Personal Safety Plan**

D. **Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation (74 FR 33030)**

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)**

F. **Field Management Directive No. 86: Establishment Inspection Report Conclusions and Decisions**

G. **EPA List of Registered Disinfectants**

H. **Guidance for Industry: Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation**

I. **Environmental Sampling and Detection of *Salmonella* in Poultry Houses**

2. Attachments

A. Egg Safety Inspection Protocols (IP) Hard Copy

3. Program Contacts

HFP Program Contacts:

Program Contact	Email	Phone	Office
Joshua Adams	joshua.adams@fda.hhs.gov	(312) 596-4166	HFP/OCE/DCI/OCOI/CPAB
Lisa Thursam	lisa.thursam@fda.hhs.gov	(313) 393-8193	HFP/OCE/OE/DCFE
Nancy Bufano	nancy.bufano@fda.hhs.gov	(240) 402-1493	HFP/OMFS/ODSS/DDS
Gerardo Ramirez	gerardo.ramirez@fda.hhs.gov	(713) 293-1418 (office) (301) 529-4187 (cell)	HFP/OMFS/ODSS/DDS

Guodong Zhang	guodong.zhang@fda.hhs.gov	(240) 402-2943	HFP/OLOAS/OAMT/DFES/MMDB
Evelyn Ladines	evelyn.ladines@fda.hhs.gov	(949) 608-4450	HFP/OLOAS/ORTS/DSPC
Teresa Bills	teresa.bills@fda.hhs.gov	(615) 854-0019	HFP/OIFSSP/ODP/DDPI/HAB

OII Program Contacts:

Program Contact	Email	Phone	Office
Kenneth Crombie	kenneth.crombie@fda.hhs.gov	(240) 402-5346	OCS/OSLA/ROSS
Martha Myrick	martha.myrick@fda.hhs.gov	(240) 402-5840	OII/OHFI/OGSHFI/DCSF/HFPEB
Margaret Klug	margaret.klug@fda.hhs.gov	(313) 409-3329	OII/OHFI/OGSHFI/HFNES

PART VII - CENTER RESPONSIBILITIES

The Director, Office of Microbiological Food Safety will evaluate the effectiveness of the program and provide further guidance to the Director, Office of Compliance and Enforcement as appropriate. Working in conjunction with the Program Office, the Compliance Program and Assignment Branch (CPAB) of the Division of Compliance Implementation (DCI) 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: Compliance Program Summaries

Change History

Item	Change	Date
1	Created PACs for comprehensive and targeted inspections	8/28/2024
2	Added Inspection Protocol (IP) reporting requirement and attachment	8/28/2024
3	Added references to new Egg Resource SharePoint page	8/28/2024
4	Created Compliance Activity Examples table	8/28/2024
5	Updated analytical methodology	8/28/2024
6	Updated POCs and hyperlinks	8/28/2024
7	Updated POCs and CFSAN/ORA references to HFP/OII	12/12/2024
8	Removed ORA Division Compliance references	12/12/2024

ATTACHMENT A – Egg Inspection Protocols (Hard Copy)

Egg Farm IP House v2.8.pdf

Egg Farm IP House v2.8

Egg Farm IP v2.8.pdf

Egg Farm IP v2.8