Guidance for Industry

Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation

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Office of Food Safety
Division of Plant and Dairy Food Safety, HFS-316
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
(Tel) 240-402-2385
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U.S. Department of Health and Human Services
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I. Introduction

The purpose of this document is to provide guidance to egg producers on certain provisions contained in FDA's July 9, 2009, final rule "Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation" (74 FR 33030), including how to implement *Salmonella* Enteritidis (SE) prevention measures, how to sample for SE, and how to maintain records documenting compliance with the final rule.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

FDA issued a final rule on July 9, 2009, requiring shell egg producers to implement measures to prevent SE from contaminating eggs on the farm and from further growth during storage and transportation (21 CFR part 118). The egg rule was effective September 8, 2009. The compliance date for the egg rule is July 9, 2010, for producers with 50,000 or more laying hens, and July 9, 2012, for producers with fewer than 50,000 but at least 3,000 laying hens. Producers with fewer than 3,000 laying hens and those that sell all of their eggs directly to consumers are exempt from the egg rule.

[1] This guidance has been prepared by the Division of Plant and Dairy Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

In the preamble in its July 9, 2009, final rule, FDA announced that it intended to provide guidance on recordkeeping and other provisions of the rule, including further specific recommendations for (1) biosecurity steps and options for achieving these steps, (2) monitoring for flies and on the level of fly activity considered acceptable, and (3) acceptable manure removal. This guidance document is a follow-up to that commitment.

This guidance provides recommendations on the following provisions: *Salmonella* Enteritidis (SE) prevention measures (§ 118.4), environmental testing for *Salmonella* Enteritidis (SE) (§ 118.5), egg testing for *Salmonella* Enteritidis (SE) (§ 118.6), sampling methodology for *Salmonella* Enteritidis (SE) (§ 118.7), and recordkeeping requirements for the *Salmonella* Enteritidis (SE) prevention plan (§ 118.10). These provisions list the measures producers must take to comply with the rule. This guidance offers more specific recommendations and options for several of the measures. While each producer is required to comply with all applicable measures listed in §§ 118.4, 118.5, 118.6, 118.7, and 118.10, producers should select and implement only those recommendations and options from this guidance that are most appropriate and will be most effective for their particular farm and situation.

III. Discussion

A. *Salmonella* Enteritidis Prevention Measures (§ 118.4)

1. Biosecurity (§ 118.4(b))

FDA's egg rule defines biosecurity (see § 118.3) as "a program, including the limiting of visitors on the farm and in poultry houses, maintaining personnel and equipment practices that will protect against cross contamination from one poultry house to another, preventing stray poultry, wild birds, cats, and other animals from entering poultry houses, and not allowing employees to keep birds at home, to ensure that there is no introduction or transfer of [SE] onto a farm or among poultry houses." Biosecurity practices should be designed to prevent SE from coming in contact with resident birds on the farm; the goal of biosecurity is to keep SE away from the birds and the birds away from SE.

The egg rule requires, at a minimum, the following biosecurity measures:

- Limiting visitors on the farm and in the poultry houses (§ 118.4(b)(1));
- Maintaining practices that will protect against cross contamination when equipment is moved among poultry houses (§ 118.4(b)(2));
- Maintaining practices that will protect against cross contamination when persons move between poultry houses (§ 118.4(b)(3));
- Preventing stray poultry, wild birds, cats, and other animals from entering poultry houses (§ 118.4(b)(4)); and
- Not allowing employees to keep birds at home (§ 118.4(b)(5)).

Further specific recommendations for biosecurity steps and options for achieving these steps are outlined below.

Biosecurity can be broken down into three components: isolation, traffic control, and sanitation. Isolation refers to time, distance, and physical barriers that reduce or prevent entry onto the farm and/or into the poultry houses. Traffic control includes restricting human, equipment, and animal movement onto the farm, and movement patterns while on the farm. Sanitation refers to the cleaning and disinfection of poultry houses, people, materials, and equipment.

Isolation

Isolation can be considered in terms of distance between farms or houses on a farm, physical barriers (cages, boot dipping stations), and time (the amount of time between depopulating and repopulating a house), all of which limit the spread of SE.

Distance between farms or houses on a farm. Layout and placement of houses within the farm is very important for minimizing the spread of SE. For new farms or additional houses, egg producers should consider the distance that will be created from other farms, houses, and birds, such as pullets, other hens, and wild birds. For existing houses and farms, egg producers should consider the actual distance from other farms, houses, and birds when determining appropriate prevention measures. Wild birds, waterfowl, exotic pet birds, and domestic poultry can be important sources of Salmonella because closely related species are likely to carry agents that can also infect commercial chickens. In addition, egg producers should give careful consideration to preventing airborne transmission of SE. For example, air intakes of one poultry house that are located away from the outflow vents of other houses reduce the likelihood of airborne transmission of SE.

Physical barriers. Physical barriers are very effective at limiting the spread of SE. Cages limit the fecal-to-oral mode of transmission between chickens because they reduce the amount of fecal material that accumulates where other chickens are exposed to it. Although most fecal contamination of feed occurs from rodents defecating in the feed troughs, properly maintained feed storage silos help limit fecal contamination of feed by pests, which limits fecal-to-oral transmission of SE from pests to birds. Securing buildings and removing feed and harborage for pests (including free-standing water and tall grasses) are effective at creating a barrier around the flock, thereby limiting the spread of SE. Houses should be carefully inspected for possible routes of entry; if any are found, they should be repaired immediately.

Human traffic also should be limited and controlled by the use of physical barriers. SE can be carried on clothing, hair, exposed skin, and footwear. Employees should wear freshly laundered clothing daily, and visitors should be provided with clean protective clothing. Once a poultry house has tested positive for SE, it is especially important to consider physical barriers that will reduce the risk of cross-contamination among houses. A properly maintained boot dipping station that includes a brush for the removal of organic material and a dip with a disinfecting agent can help prevent the exit of SE from the positive house on boots. However, to be effective, all organic material should be removed from the surface of the boot before the boot is dipped into the disinfecting solution. Disinfectants should be properly diluted and changed at least daily (or more often if baths collect a lot of dirt and manure) to be effective. Dry foot baths utilizing dry and/or aerosol disinfectants may be used in lieu of boot dipping stations. Other physical

barriers that producers should consider in the case of an SE-positive house are changing outer clothing upon exiting the positive house and, where practical, having dedicated equipment for the positive house. These barriers reduce the risk of cross-contamination among houses when one or more houses on a farm has tested positive for SE. If having dedicated equipment is not possible, shared equipment should be completely cleaned and disinfected upon removal from the positive house. Although the common egg belt may be impractical to clean and disinfect, once a house has tested positive for SE, the egg belts in that house should be turned off to avoid commingling eggs from the positive house with eggs from other houses on the common egg belt.

Time. Ample time should be allowed between flocks in a house to prevent the transmission of SE. Under normal conditions, two weeks is adequate for complete cleaning and disinfection of the poultry house. However, the risk of infection from previous flocks should be considered when determining how much time needs to elapse between flocks. Producers should consider longer down times if the environment or eggs of the previous flock in the house were found SE positive. They may also wish to consider swabbing a cleaned and disinfected house to verify that it is SE negative prior to repopulating, if the environment or eggs of the previous flock in the house were positive for SE.

Traffic Control

People and equipment that come onto a farm can introduce SE. One of the most effective ways to control human traffic is with the use of signs, fences, and gates (including locking gates). Buildings should remain locked to the extent possible to ensure that the biosecurity plan is followed by all visitors and nonfarm employees.

Clothing should be provided for visitors, including maintenance and pest control personnel, as they come onto the farm. These can be either disposable or reusable clothing that stays on the farm. Coveralls that cover all street clothing including collars, cuffs, and wristwatches, and plastic or rubber boots or shoe covers that completely cover visitors' shoes should be worn. Hair should be covered with bouffant caps, beards covered with disposable beard covers, and hands washed or sanitized prior to entry into the house.

Extra precautions should be taken for personnel or visitors arriving from other farms or from places considered potentially hazardous (e.g., laboratories, auctions). All visitors should report to a central location and sign a log book before coming on the farm. The log book should record the date, time, person's name, reason for visit, and types of places visited that day. Farm personnel visiting laboratories, other farms, meetings, or restaurants where other producers, service personnel or backyard flock owners visit are at an increased risk of cross-contaminating the farm at which they are employed.

Multiple farms should not share equipment, but if they do, it should be thoroughly cleaned and disinfected between farms. Only clean and disinfected crates, egg cartons, pallets, and other equipment should be brought onto a farm, and business should only be conducted with other companies that also have high biosecurity standards.

Activities at each farm can be divided into "dirty" and "clean" ones. Manure handling, dead bird disposal, disposal of trapped pests, and removal of breeding areas for pests are examples of dirty activities. Examples of clean activities are egg handling, chick handling, movement of birds, and other activities involving contact with live birds. When working with or in the presence of live birds, workers should always move from the youngest birds to the oldest. Personnel and equipment used in dirty activities should be cleaned and disinfected before coming into contact with personnel and equipment involved in clean activities. If equipment or personnel must be shared between the two types of activities, then they should always go from clean activities to dirty ones and not the reverse.

Sanitation

The goal of farm sanitation is to maintain a clean environment for the birds. Sanitation reduces the likelihood of SE coming in contact with the birds, and is, therefore, an important component of biosecurity. Daily attention should be paid to the proper management and disposal of dead birds, loose birds, spilled feed, manure, and refuse. Dead birds should be removed and disposed of as quickly as possible. Daily collection of mortality and disposal will reduce contact with insects, rodents, or other animals that could act as SE vectors. New birds should always be placed in a cleaned and disinfected house.

Spilled feed should not be allowed to amass in or around poultry houses, as it will attract insects, rodents, and wild birds, all of which can bring SE onto the farm and into the houses. Poultry manure and litter should be managed properly so it does not attract flies and other insects or serve as a habitat for rodents that carry SE into the houses. Manure should be kept as dry as possible to make it less attractive to flies and other insects. Special attention should be given to preventing water system leaks and promptly repairing leaks when found. Disposal of cracked eggs into the manure should be avoided since they are an attractive food source for both insects and rodents. Poultry houses should be properly ventilated, as weather permits, since proper ventilation dilutes microbe populations and reduces disease buildup.

Proper disposal of manure and all refuse on the farm is important in eliminating rodent harborage sites. Trash and manure piles are also attractive to wild birds that may carry SE.

(Refs. 3, 4, 10, and 15)

2. Rodents, Flies, and Other Pest Control (§ 118.4(c))

As part of a producer's pest control program, the egg rule requires the following:

- Monitoring for rodents by visual inspection and mechanical traps or glueboards or another appropriate monitoring method and, when monitoring indicates unacceptable rodent activity within a poultry house, using appropriate methods to achieve satisfactory rodent control (§ 118.4(c)(1));
- Monitoring for flies by spot cards, Scudder grills, or sticky traps or another appropriate monitoring method and, when monitoring indicates unacceptable fly activity within a poultry house, using appropriate methods to achieve satisfactory fly control (§ 118.4(c)(2)); and

- Removing debris within a poultry house and vegetation and debris outside a poultry house that may provide harborage for pests (§ 118.4(c)(3)).

Monitoring for Rodents

Some FDA recommended rodent monitoring methods, as well as characterizations of levels of rodent activity, are discussed below.

Visual inspection: Visual inspection is conducted by walking through all areas of a poultry house. Observation of any of the following is likely to indicate unacceptable rodent activity: live rodents, excessive dead rodents, rodent feces, gnaw holes, baited traps without bait, or nests in traps.

Rodent indexing: The Rodent Index (RI) is based on the total number of rodents caught in a house in 7 days using 12 live catch traps and is used to estimate the rodent population. FDA recommends the following procedure for obtaining the RI:

- Bait each of 12 live catch rodent traps with 0.5 oz. of chicken feed.
- Place the traps in areas where recent signs of rodent activity are observed or in areas most likely to catch rodents, e.g., along cage walkways and against walls. Use a minimum of 15 feet distance between traps.
- Check the traps after 2 to 4 days. Remove, count, and record the number of rodents caught.
- Move the traps that did not catch any rodents to a different location, a minimum of 15 feet away. Traps that caught a rodent are placed back in the same location.
- Check the traps again 7 days after they were first placed.
- Record the total number of rodents caught for the week.

The following formula standardizes all rodent catches to a 1-week period using 12 live catch traps by adjusting for periods of time longer or shorter than 7 days and using more or fewer traps.

$$\text{Number of rodents for RI} = \frac{(\text{total number of rodents in traps} \div \text{working traps set}) \times 12}{\text{number of days traps are set}} \times 7$$

The rodent population is then estimated by applying the number of rodents as determined using the formula above to the RI table below. An RI of 1 or less is likely to indicate satisfactory rodent control. If an RI greater than 1 is obtained, the producer should investigate to find out where rodents are entering the house. Section 118.4(c)(1) requires that appropriate methods be taken to achieve satisfactory rodent control when monitoring indicates unacceptable rodent activity within a poultry house.

Number of rodents caught in 7 days with 12 traps	RI	Description of RI
0-10	1	Low
11-25	2	Moderate
26 or more	3	High

Monitoring for Flies

Some FDA recommended fly monitoring methods, as well as characterizations of levels of fly activity, are discussed below. Section 118.4(c)(2) requires that appropriate methods to achieve satisfactory fly control be taken when monitoring indicates unacceptable fly activity within a poultry house.

Spot Card Method: Ordinary (3 inches x 5 inches) white index cards are attached to obvious fly resting surfaces. These are areas with large numbers of fly fecal and regurgitation spots. The number of spot cards will vary depending on the size of the house. At a minimum there should be five equidistant locations per house. After 7 days, the cards are collected, and the number of spots presumably made by flies is counted. The average per card is calculated, giving a spot card index of the fly population. A spot card index of 50 or fewer per card is likely to indicate satisfactory fly control.

Fixed Sticky Tape Method: An ordinary sticky fly tape is hung above the cages in the front, center, and rear of the poultry house. After 7 days, the tapes are removed and the number of flies trapped on the tapes is counted. A weekly count of 50 or fewer flies per tape is likely to indicate satisfactory fly control.

Moving Tape Method: In this method, an ordinary sticky fly tape is unrolled and extended full length. The operator grasps the top of the tape by the string loop and suspends the tape by his side so that the bottom cardboard cylinder is about 2.5 to 5.0 cm from the floor while walking at a normal pace on an inside walkway between the cages. After walking a 1,000-foot route that covers a representative sample of the house population of flies (approximately 5 minutes or two full rows), the operator counts and records the number of flies stuck on the tape. A count of 75 or fewer flies per tape is likely to indicate satisfactory fly control.

Baited Traps: These may be gallon plastic milk jugs hung from the rafters on 18-24 inch wires. The jugs have 2-inch round openings cut in the upper part of the sides to allow flies attracted to bait placed on the inside bottom of the jug to enter. A fly count of 250 or fewer flies per week is likely to indicate satisfactory fly control.

Scudder Grill: A grill, often referred to as a Scudder grill, consists of 16 to 24 wooden slats, fastened at equal intervals to cover an area of approximately 0.8 square meters. The grill is placed where there are natural fly concentrations and the number of flies landing on the grill in a given period of time (usually 30 seconds or l minute) is counted. In each locality, counts are made on 3 to 5 or more of the highest fly concentrations found and the results averaged. A count of less than 20 on a Scudder grill is likely to indicate satisfactory fly control.

Removing Debris

A 3 foot area around a poultry house of gravel or other non-grass substance discourages rodents, as does maintaining grass at a short height (maximum of 6 inches) beyond the 3 foot area. Old equipment, used boards, and discarded debris are rodent harborage areas and should be kept at

least 300 feet away from the house to discourage harborage of rodents. In situations where poultry houses are located less than 300 feet from property lines, producers should practice additional vigilance to secure their property from rodent infestation.

(Refs. 1, 2, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, and 15)

3. Cleaning and Disinfection (§ 118.4(d))

FDA's egg rule requires that a poultry house be cleaned and disinfected according to the following procedures before new laying hens are placed in the house, if that house has had an environmental test or an egg test that was positive for SE at any point during the life of a flock that was housed in the poultry house prior to depopulation:

- Remove all visible manure (§ 118.4(d)(1));
- Dry clean the positive poultry house to remove dust, feathers, and old feed (§ 118.4(d)(2)); and
- Following cleaning, disinfect the positive poultry house with spray, aerosol, fumigation, or another appropriate disinfection method (§ 118.4(d)(3)).

It is important that, once a poultry house has had an SE-positive environmental or egg test, a producer make every effort to rid the environment of SE before new laying hens are placed into that house to prevent the SE problem from being perpetuated in the replacement flock. Although cleaning and disinfection is only required when a house has had an SE-positive test, FDA recommends that producers clean and disinfect every house between flocks.

FDA recommends the following procedures for cleaning and disinfecting poultry houses between flocks:

- Removal of all dead and live chickens, eggs, and other animals
- Removal of all moveable equipment from the house to allow for thorough cleaning
- Placement of fresh rodent bait; this is removed just prior to cleaning
- Physical repair of rodent entry sites
- Application of appropriate insecticides
- Removal of all feed from troughs, hoppers, and feed bins; this is very important for rodent control; feed caked on troughs should be removed by scraping
- Dry cleaning (by scraping, scooping, sweeping, compressed air, or other appropriate methods) of the upper part of the house, starting with the air inlets (inside and outside) and working downward; organic material should be moved into the pit for eventual removal
- Physical removal of manure from dropping boards, cage curtains, cage cross members/bars, and floor joints such that no large, visible clumps of manure remain
- Thorough dry cleaning of fans, housing, brush blades, and louvers
- Removal of all manure and organic material from the pit
- Follow-up of gross cleaning with scraping, scooping, and sweeping
- Inspection of all areas for cleanliness and re-cleaning if necessary

Because manure is a reservoir for SE that has been shed by infected laying hens, once a poultry house has had an SE-positive environmental or egg test, it is important that all visible manure be removed (§ 118.4(d)(1)). Removing all visible manure before new laying hens are placed into a house will help prevent SE from infecting the replacement flock via the manure and rodents. Although the floor in a concrete-floored house could appear light grey after manure removal, there should not be any accumulation of manure in a house that has had the manure removed.

Sanitation of water lines, 2 to 3 days prior to placement of new layers, is recommended as part of dry cleaning, as follows:

- Water lines are filled with an 1870 ppm citric acid solution (2 pounds per gallon of stock metered at 1 ounce per gallon of water).
- After 2 hours, lines are flushed thoroughly.
- Next, lines are filled with a 20 ppm chlorine solution (13 ounces of chlorine bleach (5.25% sodium hypochlorite) per gallon of stock metered at 1 ounce per gallon of water).
- After 2 hours, lines are flushed thoroughly until no smell of chlorine remains.

Wet washing of the house is not required, but may be conducted following dry cleaning, if desired. If wet washing, allow the house to dry thoroughly before disinfecting.

Following cleaning, the house should be disinfected using spray, aerosol, fumigation, or another appropriate disinfection method. Producers should choose a disinfectant that has action against Salmonellae and apply the disinfectant to all surfaces in an effort to kill any remaining SE that may be present on these surfaces. To the extent that it is permitted under applicable local, State, and/or Federal environmental laws, FDA recommends that the disinfectant solution be applied to a 10-foot perimeter area outside the house as well.

If a house tests positive for SE for two successive flocks, the producer should review the cleaning and disinfection procedures and should consider environmental testing of the house before restocking with new layers. Producers should also consider a longer downtime between flocks in that house.

(Refs. 4 and 10)

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

For the purposes of this section:

- *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.

1. Environmental Sampling

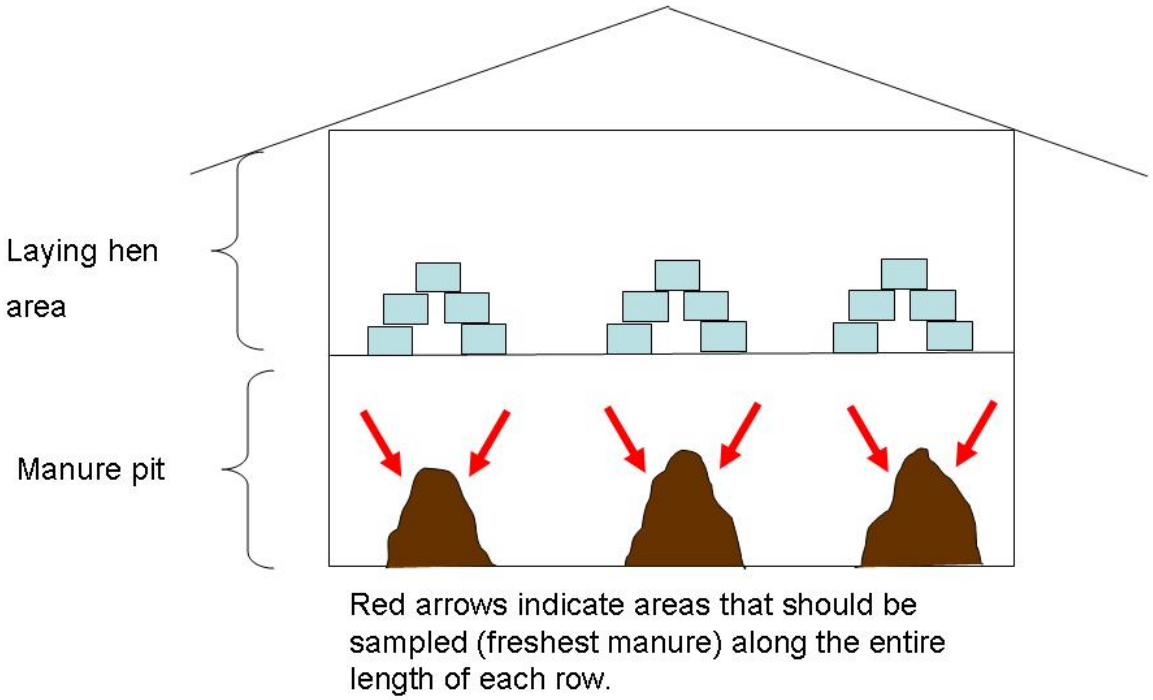
Section 118.7(a) of the egg rule states: "Within each poultry house, you must sample the environment using a sampling plan appropriate to the poultry house layout." FDA's environmental testing method, "Environmental Sampling and Detection of Salmonella in Poultry Houses" (April 2008), which is discussed in the preamble to the final rule and is incorporated by reference into § 118.8(a), describes drag-swabbing the manure pit. FDA understands that variations in poultry house design and/or unsuitable manure pit conditions could require adaptations for collecting representative environmental samples. In those situations, we recommend one of the following alternative environmental sampling methods. Any alternative environmental sampling method that is used must be equivalent to the method set out in "Environmental Sampling and Detection of Salmonella in Poultry Houses" (April 2008) in accuracy, precision, and sensitivity in detecting SE, as required by § 118.8(a).

For all methods described below, the swabs should be sterilized by autoclaving prior to sampling. As an alternative, producers may wish to purchase pre-sterilized swabs. You should moisten the swabs with canned evaporated milk, canned skim (fat-free) evaporated milk, or canned low-fat evaporated milk prior to sampling. FDA recommends wearing sterile gloves when handling and moistening the swabs. Additionally, you should disinfect the top of the can of milk as well as the can opener with 70% ethanol before opening the can. You may place a swab over the opened can of milk to deter flies from contaminating the milk. After sampling, each swab should be placed in its own individual sample bag and approximately 15 ml of the same media used for moistening the swab should be added to the bag to keep the swab moist during transport. One swab equals one sample; samples (swabs) should not be pooled.

<u>High-Rise Poultry House (Pit Style Poultry House)</u>

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.

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



Manure Pits Unsuitable for Drag Swabbing

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.

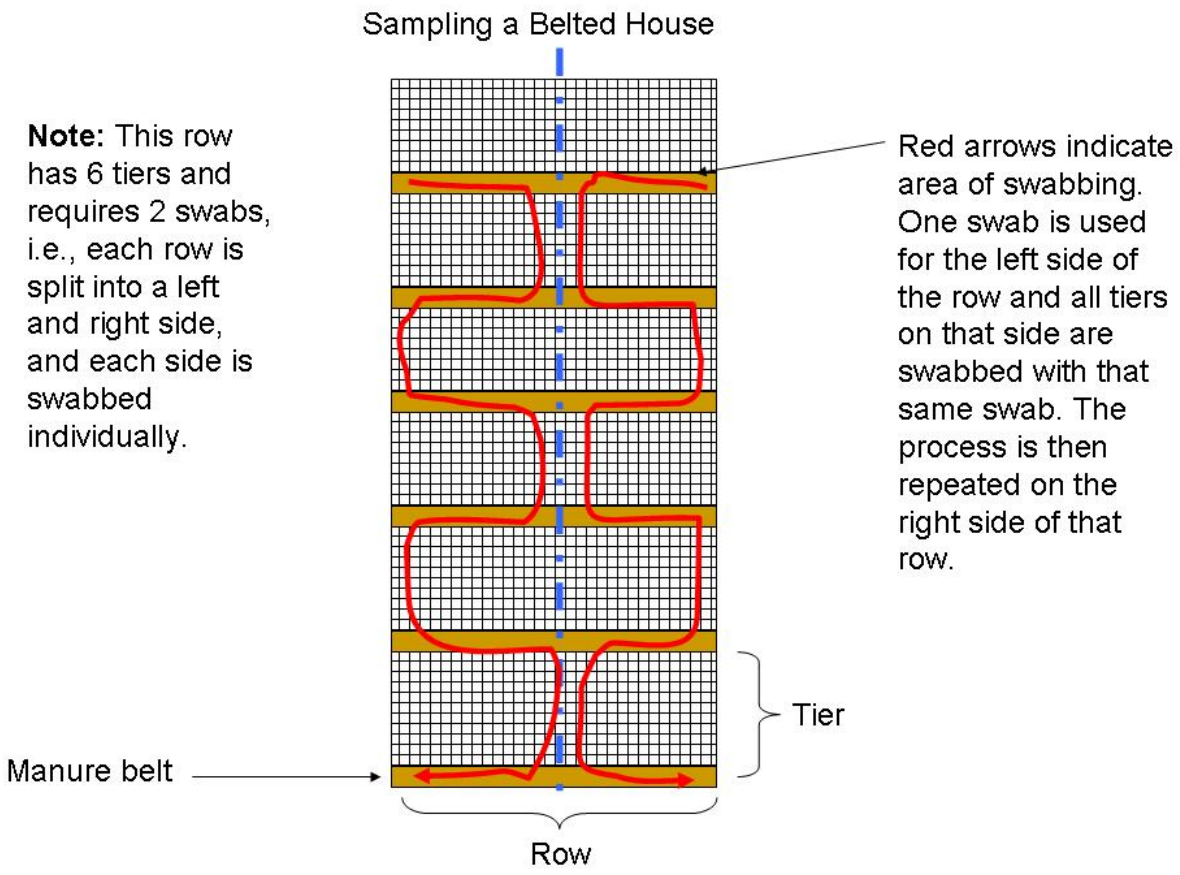
When scraper is running: Attach two drag swabs onto the main manure scraper assembly, so that one drags on the left bank and the other on the right bank of that row, and run the scraper assembly to the opposite end of the house and back. Care should be taken to attach the swabs in such a way that they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

When scraper is stationary: 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 (often referred to as a stacked deck house), 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 capped 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.

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

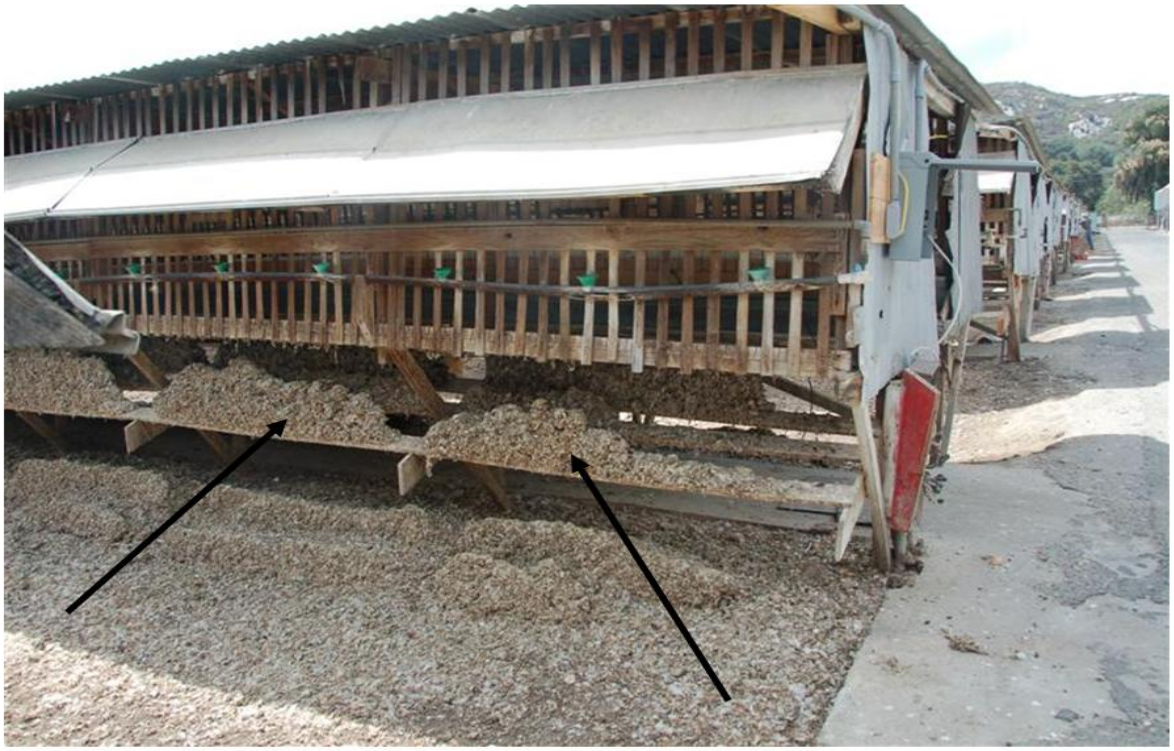


Colony Style Poultry House

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.

Figure 3: Colony style poultry house

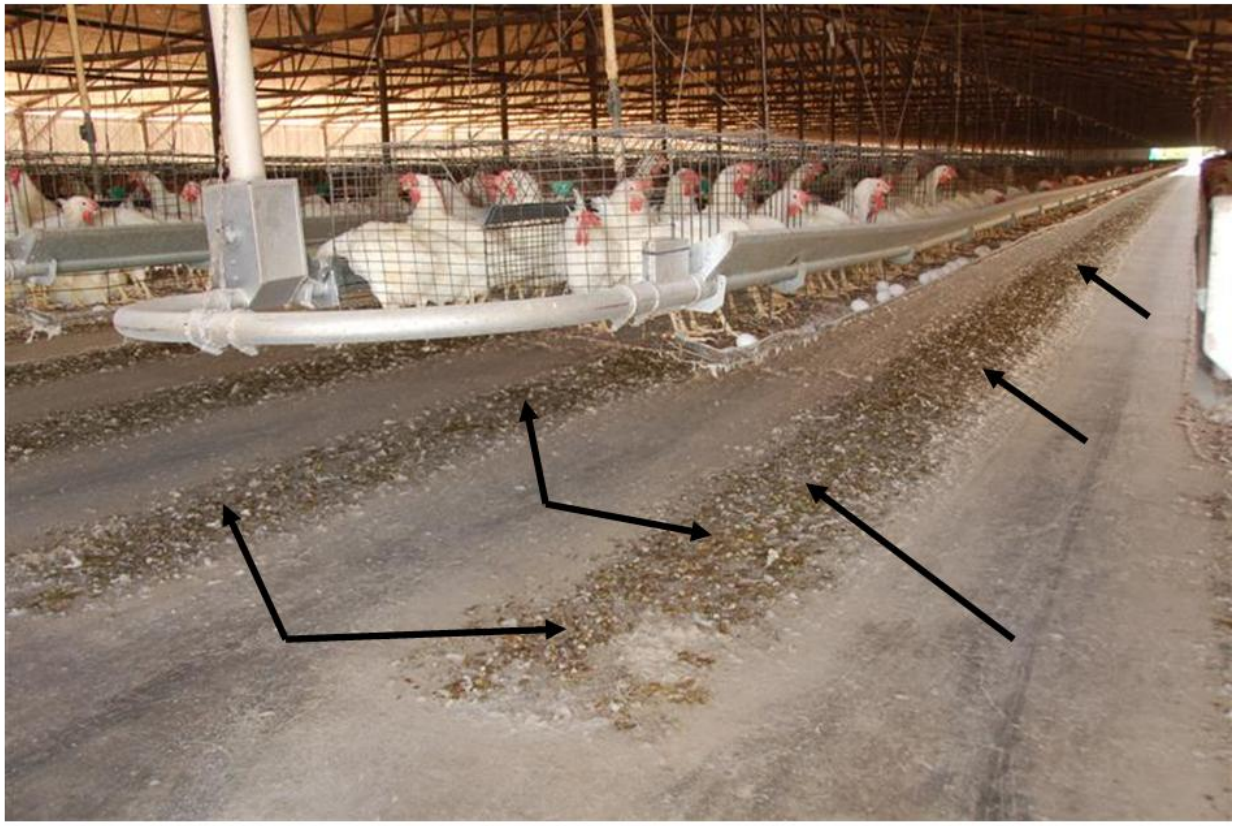
Figure 4: Sampling areas for colony style poultry house



Single Deck Poultry House

Single deck style poultry houses are 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.

Figure 5: 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 physically 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.

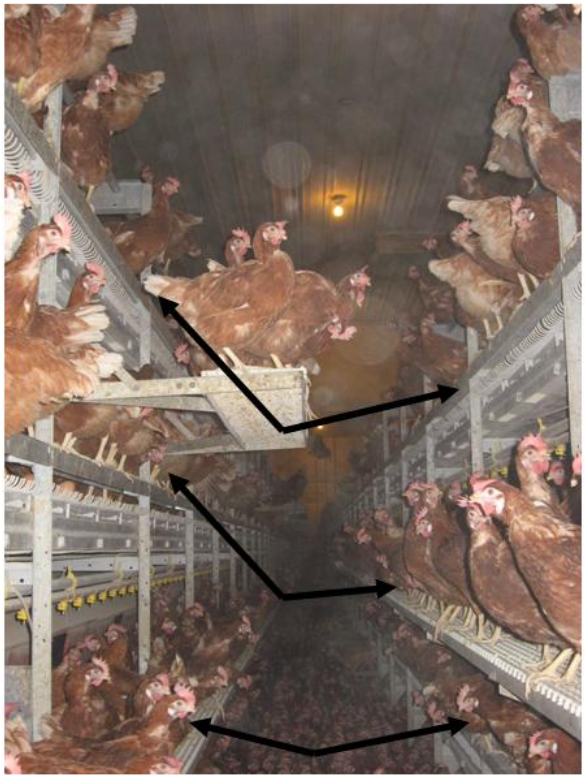
If a house has multiple floors, divide the number of swabs evenly to cover each floor equally.

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.

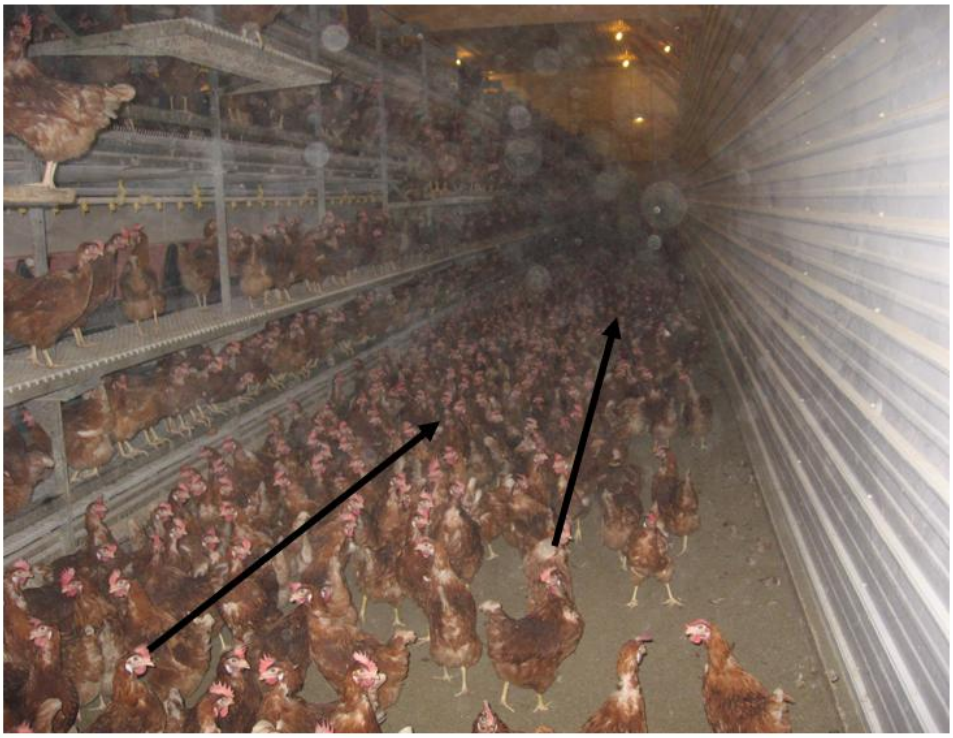
There is typically a manure belt running under each platform level that conveys manure to the back end of the poultry house. There are floor access areas or "scratch areas" between the platforms rows (See Figure 7). This style of house may be sampled in one of two ways: drag swabbing the scratch areas (i.e., floor areas) or sampling the manure belts.

Figure 6: Aviary poultry house platforms



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, two drags swabs per row should be dragged 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.

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



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 this sampling scheme is used, the belts should not be operated for 24 hours prior to sampling to ensure fresh manure is sampled. After the 24-hour wait, 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).

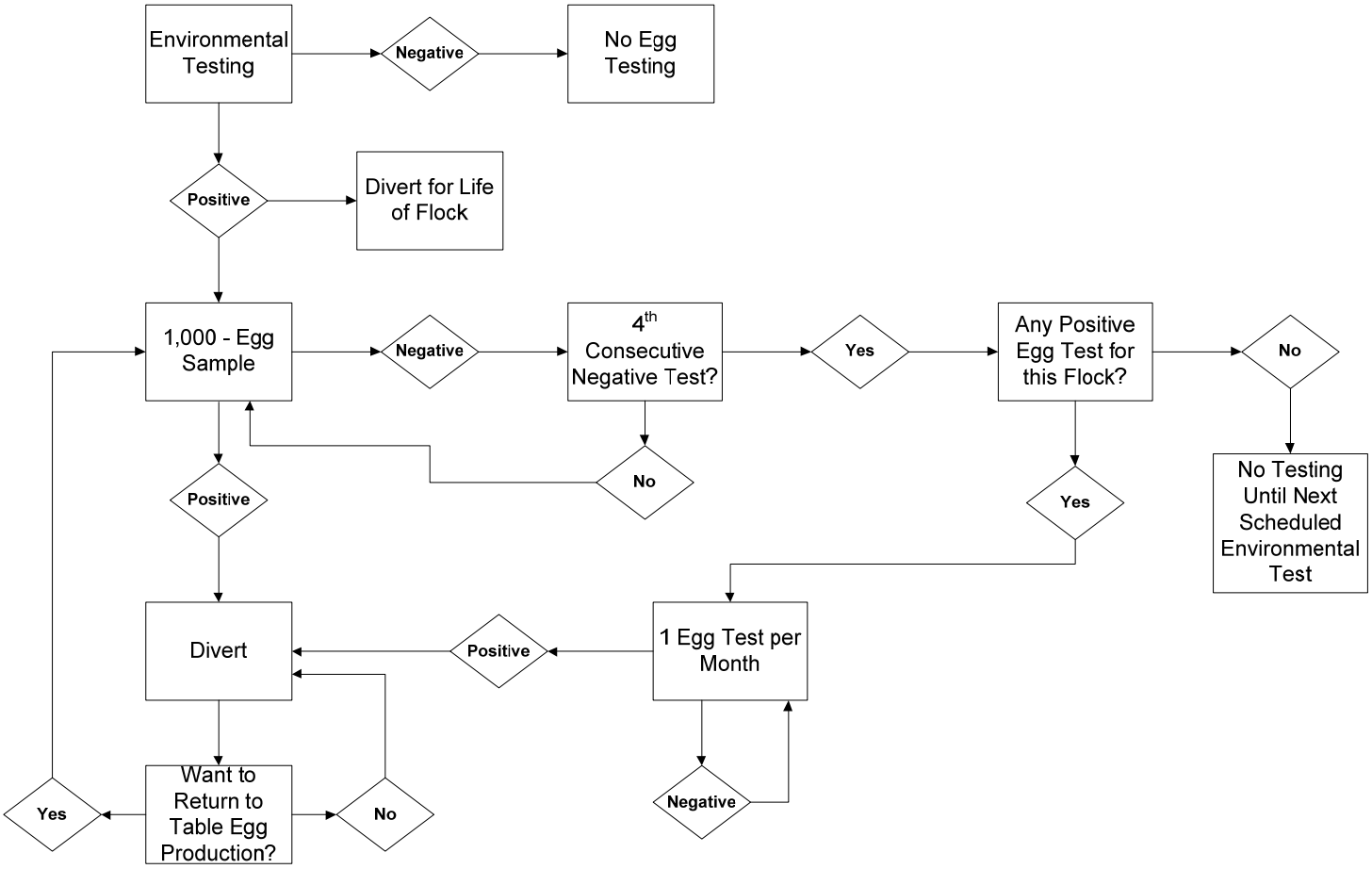
Figure 8: Aviary poultry house manure belts

(Refs. 4 and 10)

2. Egg Sampling

When an environmental test is positive for SE, the egg rule (§ 118.6(a)) requires either egg testing or diverting eggs to a treatment resulting in at least a 5-log reduction in SE. Under the egg testing alternative, four 1,000-egg samples must be tested at two-week intervals (§ 118.7(b)(1)). If all four tests are negative, no further testing is required (§ 118.6(c)). If any of the tests is positive, eggs must be diverted to a treatment that results in a 5-log reduction of SE (e.g., pasteurization) until four consecutive negative egg tests at two-week intervals are obtained (§ 118.6(d)). Following a positive egg test, if a producer is later able to obtain four consecutive negative egg tests and return to table egg production, they must collect and deliver a 1,000-egg sample for testing to a laboratory once a month for the life of the flock (§ 118.6(e)). See Figure 9.

Figure 9: Egg testing flowchart



For each egg test, the producer must collect and deliver for testing a minimum of 1,000 intact eggs representative of a day's production from the positive house (§ 118.7(b)). Since sample size is a minimum of 1,000 intact eggs, FDA recommends that several extra dozen eggs be collected to account for breakage during transport/shipping to the laboratory. The sample should be collected from all areas of the positive house, including all banks, rows and tiers and should be obtained prior to egg belts being turned on or prior to the first collection in operations where hand collection is used. FDA also recommends dividing the house into equal sections and using a systemic sampling approach to obtain a representative sample. There are essentially two types of production systems, caged and cage-free systems with variability existing in house layout within each system. FDA has developed the following guidance to assist producers in collecting an appropriate egg sample when required.

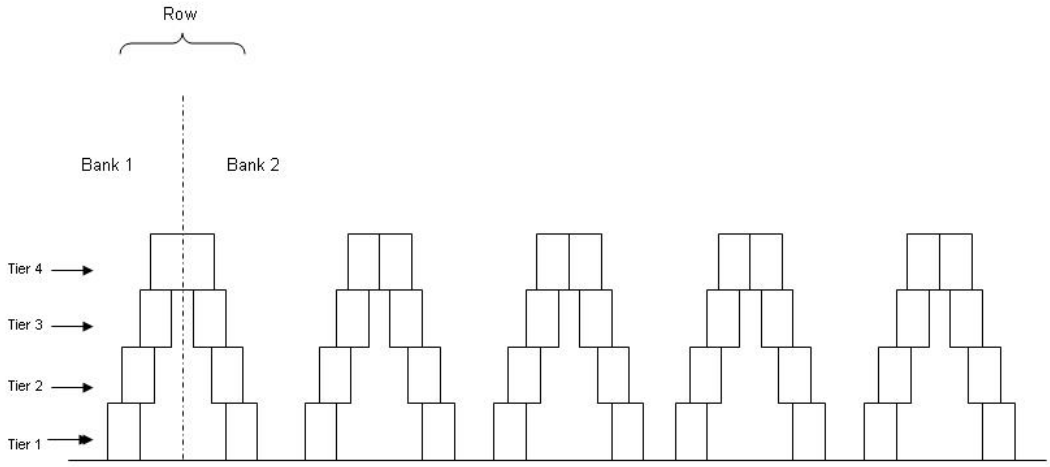
Cage System

Cage systems are the predominant system currently used in the U.S. egg industry. In this system, cages can be configured in a variety of ways and are usually stacked several tiers high. One of

the more common arrangements is in an inverted "V" configuration, referred to as an "A frame configuration," with multiple rows, and several tiers. The following is an example of how to collect a representative sample in this type of system.

Example: This example is for a 5-row wide house with cages stacked 4 tiers high (see Figure 10). In this configuration, there are 10 banks, 5 rows, and 4 tiers.

Figure 10: A five-row wide house with cages stacked four tiers high; cages arranged in an "A" configuration



A 1,080-egg sample is collected (extra eggs account for breakage or eggs that are unsuitable for testing). In this scenario, 216 eggs should be collected from each row (1,080 total eggs divided by 5 rows); this can be further divided into 108 eggs per bank (216 eggs per row divided by 2 banks per row), and, ultimately, 27 eggs per tier on each bank (108 eggs per bank divided by 4 tiers per bank).

The 27-eggs-per-tier sample should include the entire length of the tier. A random starting point can be selected, provided that the sample is representative of all areas in that tier. Eggs should be collected in new egg flats to prevent cross contamination that could result from previously

used flats. This sampling scheme would ensure collection of an appropriate sample representative of a day's production.

Cage-Free Systems

Cage-free systems are utilized for production of specialty eggs such as organic or free-range eggs. In this type of production system, eggs can be either hand-gathered or gathered via an egg belt. If the eggs are completely hand-gathered (i.e., no egg belts), the producer should determine how many flats of eggs are produced in a day (an average number), then divide the average number of flats produced daily by the number of flats needed. The answer will serve as a guide for which flats to collect for sampling. For example, if a producer needs 1,080 eggs (36 flats) and his average production is 360 flats per day, he will collect every 10^{th} flat for sampling.

If eggs are collected via an egg belt, the producer should collect the egg sample from the first or second collection. The producer should divide the number of eggs needed for the sample by three and also determine the length of time required per collection. One-third of the eggs needed should be collected at the beginning of the collection, one-third from the middle of the collection, and one-third at the end of that egg collection. For example, if 1,080 eggs are needed for the sample, 360 eggs would be collected at the beginning of the collection, another 360 eggs from the middle of the collection, and the remaining 360 eggs at the end of that collection. The producer should collect eggs evenly from all collection tables, if more than one table is used.

Unique Production Systems

FDA recognizes the vast diversity in production systems and the need to develop sampling protocols for unique production systems. In such situations, producers should follow these four basic principles of egg sampling:

- 1,000 minimum eggs sample (intact eggs);
- Representative of day's production;
- Collected only from the house that tested positive; and
- Collected from all potential egg laying areas of the positive house.

(Refs. 4 and 10)

C. Recordkeeping (§ 118.10)

The egg rule requires producers to maintain a written SE prevention plan as well as records to document the effective implementation of that plan (§118.10). This written SE prevention plan should set forth a producer's plan to implement the regulation's prevention, testing, and diversion measures. A written plan is necessary for producers to ensure that they have effectively and consistently implemented SE prevention measures. Further, a written plan greatly facilitates FDA inspection. SE prevention measures may be quite different among farms, given different facility design and size, and yet be equally effective in preventing SE contamination. Knowledge of the specific prevention measures taken on a farm, as discussed in an SE prevention plan, will assist FDA in assessing compliance with the prevention measures.

In addition, reviewing records of implementation of a facility's specific SE prevention measures is the best mechanism for FDA to use to determine whether preventive measures have been implemented over a period of time. These required documents include records of implementation and compliance with all SE prevention measures (§ 118.10(a)). Keeping careful written records will help producers ensure that they have effectively and consistently implemented SE prevention measures and will also assist FDA in determining whether the plan is being followed and in identifying problems in the producer's plan when a test is positive. If changes or modifications need to be made, recording such changes or modifications will help ensure such changes are implemented.

FDA's egg rule requires producers to maintain the following records to document the SE prevention measures:

- A written SE prevention plan, dated and signed (not initialed) by the administrator(s) of the plan (§ 118.10(a)(1) and (b)(3));
- Documentation that pullets were SE-monitored or raised under SE-monitored conditions, including environmental testing records for pullets (§ 118.10(a)(2));
- Records documenting compliance with the following (examples of each type of record are shown in parentheses):
    - Biosecurity measures (examples: log-in sheets, inspection reports of boot-dipping stations, and cleaning and disinfection logs for equipment shared among houses) (§ 118.10(a)(3)(i));
    - Rodent and other pest control measures (examples: records showing dates of inspection, inspection findings, and steps taken to eliminate problems) (§ 118.10(a)(3)(ii));
    - Cleaning and disinfection procedures performed at depopulation, when applicable (examples: records showing names and concentrations of cleaning and sanitizing agents used) (§ 118.10(a)(3)(iii));
    - Refrigeration requirements (examples: temperature logs or temperature recorder charts and times that allow for the calculation of 36 hours from time of lay) (§ 118.10(a)(3)(iv));
    - Environmental and egg sampling procedures, when applicable (examples: records showing dates and sampling procedures used) (§118.10(a)(3)(v));
    - Results of SE testing, when applicable (§ 118.10(a)(3)(vi));
    - Diversion of eggs, when applicable (example: records of where eggs were sent and dates sent) (§ 118.10(a)(3)(vii));
    - Eggs at a particular farm being treated, when applicable (example: records of where eggs were sent and dates sent) (§ 118.10(a)(3)(viii));
- Records of review and of modifications of the SE prevention plan and corrective actions taken (§ 118.10(a)(4)).

All records must include the following information:

- Name of the producer and location of the farm (§ 118.10(b)(1));
- Date and time of activity that the record reflects (§ 118.10(b)(2)); and
- Signature or initials of the person performing the operation or creating the record (§ 118.10(b)(3)).

General recordkeeping requirements:

- Data and information reflecting compliance activities must be entered on records at the time the activity is performed or observed, and the records must contain the actual values observed (if applicable) (§ 118.10(b)(4)).
- Records must be retained for at least 1 year after the flock to which they pertain has been taken permanently out of production (§ 118.10(c)).
- These records, with the exception of the written SE prevention plan, may be stored offsite, provided they can be retrieved and provided at the producer's place of business within 24 hours of request for official review (§ 118.10(d)).
- Electronic records are considered to be onsite if they are accessible from an onsite location (§ 118.10(d)).

IV. References

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday.

1. Axtell, R.C. "Integrated Fly-control Program for Caged-poultry Houses." *Journal of Economic Entomology*. 63(2):400-405, 1970.

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12. Scott, H.G. and K.S. Littig, "Flies of Public Health Importance and Their Control, Training Guide-Insect Control Series," U.S. Department of Health, Education, and Welfare, Public Health Service, Communicable Disease Center, Atlanta, GA 30333.

13. Stafford, K.C., C.H. Collison, and J.G. Burg. "House Fly (Diptera: Muscidae) Monitoring Method Comparisons and Seasonal Trends in Environmentally Controlled High-rise, Caged-layer Poultry Houses." *Journal of Economic Entomology*. 81(5):1426-1430, 1988.

14. Turner, E.C. and P.L. Ruszler. "Research Note: A Quick and Simple Quantitative Method to Monitor House Fly Populations in Caged Layer Houses." *Poultry Science*. 68:833-835, 1989.

15. United Egg Producers/United Egg Association. "Recommended Security Measures: Farms, Production, and Processing Facilities."