Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation (Layers with Access to Areas Outside the Poultry House): Questions and Answers Regarding the Final Rule:
Guidance for Industry

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U.S. Department of Health and Human Services
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Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation (Layers with Access to Areas Outside the Poultry House): Questions and Answers Regarding the Final Rule: Guidance for Industry[1]

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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, codified at 21 CFR part 118), that reference the "poultry house." Specifically, this document provides guidance to shell egg producers whose production systems provide laying hens with access to areas outside of a "poultry house" as that term is defined in 21 CFR 118.3.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

Under 21 CFR Part 118 (Part 118), which is a regulation that was promulgated by FDA and is administered by FDA, certain requirements apply only to the "poultry house" as that term is defined in 21 CFR 118.3. As discussed above, this document provides guidance to shell egg producers regarding compliance with Part 118, specifically in the context of production

[1] This guidance has been prepared by the Office of Food Safety's Division of Dairy, Egg and Meat Products in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

systems that provide laying hens with access to areas outside of a "poultry house." As part of this guidance, FDA has identified which areas FDA considers to be outside the "poultry house," as that term is defined in 21 CFR 118.3. This document does not address the requirements of the United States Department of Agriculture (USDA) National Organic Program (NOP). FDA is aware that certified organic egg production systems must comply with the relevant legal requirements associated with the NOP, including requirements relating to "outdoor access." However, FDA does not play any role in interpreting or enforcing such provisions. Nothing in this document should be read as interpreting any of the NOP's requirements. For example, when FDA interprets 21 CFR 118.3 to mean that a certain type of housing style is "outside the poultry house" for the purposes of Part 118, that interpretation does not have any bearing on whether this type of housing style meets the requirements for "outdoor access" under the NOP. To avoid confusion, FDA has changed the terminology used in this guidance from "outdoor access" to "access to areas outside the poultry house."

II. Background

FDA issued a final rule ("the egg rule") on July 9, 2009, requiring shell egg producers and certain other persons to implement measures to prevent *Salmonella* Enteritidis (SE) from contaminating eggs on the farm and from further growth during storage and transportation (21 CFR part 118). The egg rule became effective September 8, 2009. The compliance date for the egg rule was 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.

The egg rule defines the term "poultry house" at 21 CFR 118.3. Several provisions within the egg rule use the term "poultry house." However, some shell egg production systems include areas that are outside of the poultry house. In these production systems, laying hens are, at least sometimes, allowed to go to areas outside of the poultry house.

Four common housing styles are used for laying hens with access to areas outside of the poultry house. The four common housing styles are described and illustrated below in Figure 1.

Indoor Area with Porch: A porch is adjacent 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 can be dirt or grass. Access holes connect the indoor area to the porch.

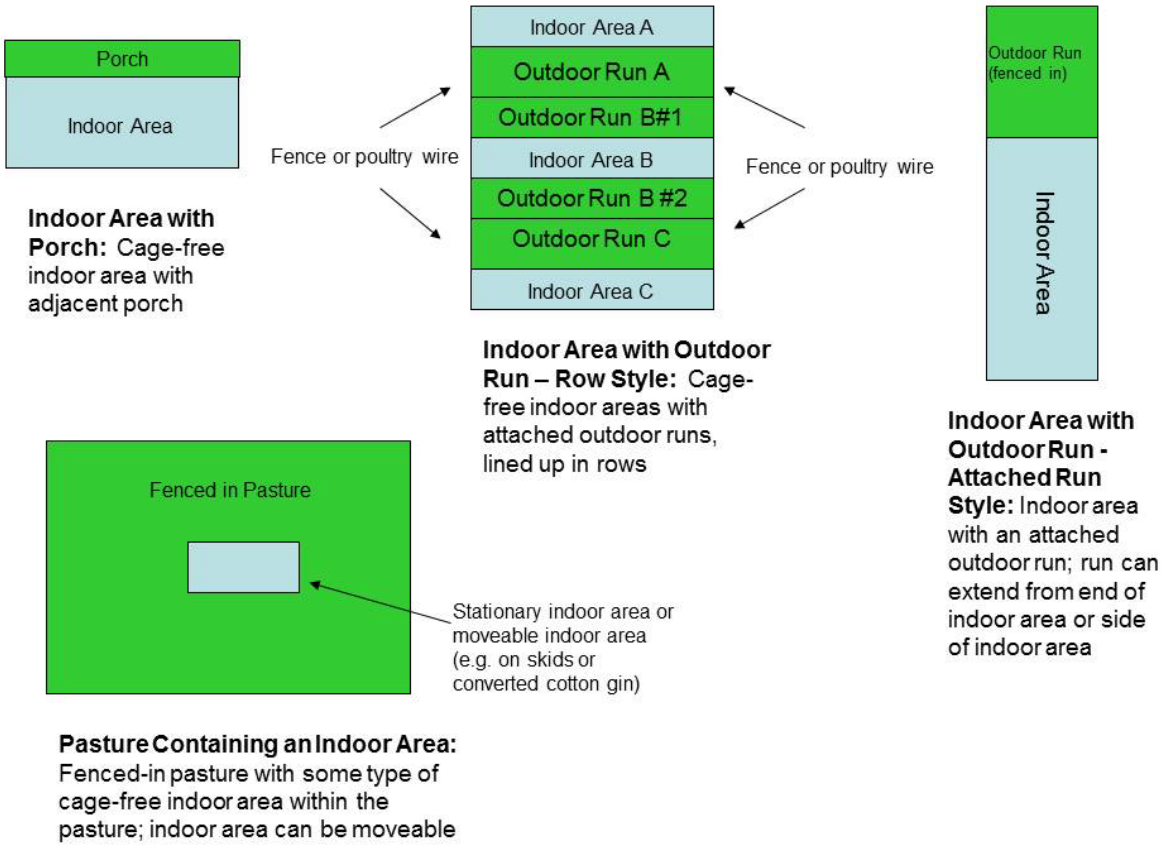
Indoor Area with Outdoor Run – Row Style: Multiple flocks are segregated from one another by a series of adjacent structures that are lined up in a row, very similar to how houses at an in-line farm are arranged. Each indoor area connects to at least one (often two) outdoor runs. The outdoor runs are fenced, usually with poultry wire. The fencing prevents poultry from straying beyond the entire structure and from moving between houses. The outdoor run 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 (see Figure 1) 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.

Figure 1: Illustration of common housing styles used for laying hens with access to areas outside of the poultry house.



In the *Federal Register* of July 24, 2013 (78 FR 44483), FDA made available a draft version of this guidance. In the draft guidance, we proposed to consider porches to be part of the poultry house because we considered them to be part of a structure used to house poultry. However, after

considering additional information provided in the response to the draft guidance, we have concluded that our initial interpretation did not fully consider how the term "structure" is used within the context of 21 CFR 118.3, particularly with respect to the goal of housing poultry and considering factors such as protection from the elements and from predation and control of temperature, humidity, and lighting.

III. Questions and Answers

A. Coverage of the Egg Rule

1. Does the egg rule apply to me if the laying hens on my farm have access to areas outside of the poultry house?

Yes, assuming you meet the criteria for being subject to the rule. You are subject to the egg rule if you are a shell egg producer with 3,000 or more laying hens at a particular farm that does not sell all of your eggs directly to consumers and that produces shell eggs for the table market (21 CFR 118.1(a)).

2. Has FDA issued other guidance that I should consider with respect to my farm?

Yes. This guidance provides information specific to egg production systems that provide laying hens with access to areas that are outside of a poultry house. You should also be aware of the recommendations in the April 2010 Small Entity Compliance Guide, "Prevention of Salmonella Enteritidis in Shell Eggs During Production, Transportation, and Storage," the December 2011 "Guidance for Industry: Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation" (referred to as "the December 2011 Guidance"), and the July 2015 "Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation."

B. Definitions

1. What is the definition of a "poultry house"?

The egg rule defines a "poultry house" as "a building, other structure, or separate section within a structure used to house poultry. For structures comprising more than one section containing poultry, each section that is separated from the other sections is considered a separate house" (21 CFR 118.3).

2. For the purposes of this guidance document, how is FDA using the phrase "area outside the poultry house"?

For the purpose of this guidance document, FDA is using the phrase "area outside the poultry house" to refer to areas to which laying hens have access, but that are not part of the poultry house as that term is defined in 21 CFR 118.3. For example, such areas include porches, outdoor runs, and pastures to which laying hens have access. In the context of this guidance document, the phrase "area outside the poultry house" does not refer to any parts of your farm to which your laying hens do not have access.

3. Is a porch for layers considered part of a poultry house?

No. FDA does not consider a porch, as described in section II, to be within the definition of a poultry house. A porch consists of an area enclosed with fence material; a roof or other covering (solid or made of wire or netting); and a floor of concrete, dirt, or grass. Hens use access holes to move between the poultry house and the porch. Unlike the poultry house, the porch does not provide substantial protection from the elements or predation, nor does it allow for control of temperature, humidity, and lighting. FDA does not consider the porch to be a building, structure, or part of a structure used to house poultry, and it therefore does not consider the porch to be part of a poultry house.

4. Is an outdoor run considered part of a poultry house?

No. FDA does not consider an outdoor run to be within the definition of a poultry house. Row-style and attached run-style housing consists of a fenced-in outdoor area adjacent to a poultry house. The outdoor run area may have no coverage overhead or it may be covered with netting, and the floors are grass or dirt. Hens use access holes to move between the poultry house and the outdoor run. Unlike the poultry house, the outdoor run does not provide substantial protection from the elements or predation, nor does it allow for control of temperature, humidity, and lighting. FDA does not consider the outdoor run to be a building, structure, or part of a structure used to house poultry, and it therefore does not consider the outdoor run to be part of a poultry house.

5. Is a pasture surrounding an indoor area considered part of a poultry house?

No. FDA does not consider pastured areas to be part of a poultry house. Pastured housing consists of a poultry house (either permanent or moveable) located within a fenced-in pasture. FDA does not consider the pasture to be a building, structure, or part of a structure used to house poultry, and it therefore does not consider the pasture to be part of a poultry house.

6. For other styles, how will FDA determine whether an area outside of a poultry house is part of a poultry house?

The analysis of whether an area is part of a poultry house begins with the definition of "poultry house" in 21 CFR 118.3. (See question III.B.1.) To determine whether or not an area fits into this definition, FDA will consider factors such as the extent to which the area provides protection from the elements and from predation and allows control of temperature, humidity, and lighting, and therefore provides an environment that is conducive to egg production.

C. SE Prevention Measures

1. Must I prevent stray poultry, wild birds, cats, and other animals from entering the poultry house?

Yes. You must prevent stray poultry, wild birds, cats, and other animals from entering poultry houses (21 CFR 118.4(b)(4)).

2. Should I prevent stray poultry, wild birds, cats, and other animals from entering an area outside the poultry house?

You must take steps to ensure that there is no introduction or transfer of SE into or among poultry houses (21 CFR 118.4(b)). Wild birds are common vectors of SE (Andres-Barranco et al., 2014; Awadallah et al., 2013; Cizek et al., 1994; Craven et al., 2000; Davies and Breslin, 2003; Lawson et al., 2014; Liebana et al., 2003; Macdonald and Brown, 1974; Mancini et al., 2014; Obukhovaska, 2013; Tizard, 2004; Troxler, 2009).[2] Cats and other animals also can be vectors of SE (Dewaele et al., 2012).

When there is movement of hens between the poultry house and an area outside the poultry house, this movement can lead to the transfer of SE between the two areas. In this situation, to ensure that there is no introduction or transfer of SE into the poultry house, you should take appropriate steps to prevent stray poultry, wild birds, cats, and other animals from entering the area outside the poultry house.

3. How can I prevent stray poultry, wild birds, cats and other animals from entering an area outside the poultry house?

Examples of steps you can take to prevent stray poultry, wild birds, cats and other animals from entering an area outside the poultry house include limiting layers' access to areas outside the poultry house to hours when wild birds or other animals are not likely to be present, maintaining attractions, such as feed and water, in areas where they do not attract these animals, and temporarily confining layers during periods of wild fowl migration. In some cases, additional steps may be needed to control stray animals in the area outside of the poultry house.

The presence of stray poultry, wild birds, cats or other animals in an area outside the poultry house indicates that this route of exposure of the flock to SE is not adequately controlled. Therefore, FDA recommends that the presence of these animals within an area outside the poultry house should prompt implementation of further facility-specific biosecurity steps, such as those described above, in addition to any steps of this type that your farm already has in place.

4. Must I monitor for rodents and flies and, when monitoring indicates unacceptable rodent or fly activity within a poultry house, use appropriate methods to achieve satisfactory rodent and fly control?

Yes. You must monitor for rodents by visual inspection and mechanical traps, glueboards, or another appropriate monitoring method and, when monitoring indicates unacceptable rodent activity within a poultry house, use appropriate methods to achieve satisfactory rodent control (21 CFR 118.4(c)(1)). Similarly, you must monitor for flies by spot cards, Scudder grills,[3] sticky

[2] FDA promulgated the egg rule to prevent SE from contaminating eggs. However, we note that some of the requirements of the egg rule also can help prevent the spread of other diseases. For example, wild birds can be a vector for Highly Pathogenic Avian Influenza (HPAI). Many of the same steps that can prevent the introduction of SE into a flock can also help prevent the introduction of HPAI and other diseases.

[3] 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

traps, or another appropriate monitoring method and, when monitoring indicates unacceptable fly activity within a poultry house, use appropriate methods to achieve satisfactory fly control (21 CFR 118.4(c)(2)).

5. Should I monitor for rodents and flies in an area outside the poultry house and, when monitoring indicates unacceptable rodent or fly activity in that area, use appropriate methods to achieve satisfactory rodent and fly control?

As discussed in the answer to question C.2., you must take steps to ensure that there is no introduction or transfer of SE into or among poultry houses (21 CFR 118.4(b)). Rodents and flies are known vectors of SE (Olsen and Hammack, 2000; Meerburg and Kijlstra, 2007). When there is movement of hens between the poultry house and an area outside the poultry house, this movement can lead to the transfer of SE between the two areas. In this situation, to ensure that there is no introduction or transfer of SE into the poultry house, you should take appropriate steps to monitor for and control rodents and flies in the area outside the poultry house. Integrated management of rodents and flies includes a multilevel approach (prevention, monitoring, and control) to ensure the effectiveness of the pest control program.

Unacceptable fly and rodent activity can occur in areas outside the poultry house for a variety of reasons. For example, excessive flies in and around laying hens that are outside the poultry house can be caused by, among other things, excessive manure in areas of entry to portable housing units, excessive manure near feeding areas, or dead animals that have not yet been removed. Excessive rodent activity can be caused by some of the same factors or can be caused by other circumstances. For example, when laying hens have access to a river or pond, producers might find that they need to take steps to control the rodent population at and near that water source, since rivers and ponds can attract rodents. In any situation where monitoring indicates unacceptable fly or rodent activity in an area outside the poultry house, producers should use appropriate methods to achieve satisfactory fly or rodent control to prevent SE from being introduced into the poultry house.

6. How can I prevent rodents from entering an area outside the poultry house?

Native field rodents, such as voles, are adapted to live in natural habitats. In areas outside the poultry house it is impossible to exclude rodents in the same way as within the poultry house, but it is possible to reduce their numbers to minimize the possibility of contact with laying hens (Meerburg et al., 2004). One important component of a rodent management program is to adopt a preventive approach, using a variety of strategies (DEFRA, 2001). While recognizing that exclusion of all rodents from an area outside the poultry house might not be possible, FDA recommends the following actions to prevent rodents from entering the area:

- Maintaining a 6-foot-wide area around the outside periphery of the area that is filled with either gravel or other non-grass substance or, if this is not feasible, maintaining the grass within this zone to a short height (maximum of 6 inches). This would not include the removal of trees or shrubs that do not provide harborage for rodents.
- Removing piles of old material, stacks of straw or hay, trash, weeds, debris, vegetation, and any other material, both inside and immediately outside the area, since these can

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.

provide harborage for rodents.
- Removing any dead carcasses daily and disposing of them properly.
- Minimizing spillage of feed and removing remnants of feed if feeding sites are located in areas outside the poultry house.
- Minimizing access by rodents to feed and water stations.

7. How can I monitor for rodents in an area outside the poultry house?

Rodents are usually present in fields, but in low numbers, since they are confined to refuge areas where they are not easily detected (Stratford, 2012). Because of the potential for rodent activity in areas outside the poultry house, FDA recommends monitoring for rodents in these areas as described below. Observation of any of the following is likely to indicate unacceptable rodent activity: live rodents, excessive dead rodents, rodent feces (especially in feed or grass), gnaw holes, baited traps without bait, nests in traps, presence of native field rodent colonies (such as voles or deer mice), surface runways in the grass leading to underground entrance holes, or characteristic grass clippings on the floor of runways. Additional knowledge of the rodent species is helpful, as the behavior and preferred habitat of each species can differ, and preventive and control measures may need to vary accordingly.

For areas outside the poultry house, FDA recommends monitoring measures such as the use of chew cards, also known as bait cards. These cards are 10 cm x 10 cm paper squares, divided into 1-cm^2 cells, and soaked in canola oil. Cards are placed overnight at 10 m intervals across the area outside the poultry house to observe the level of feeding damage. If five percent or more of the card is eaten, this indicates moderate rodent activity (Whisson et al., 2005; Stratford, 2012). Emphasis should be placed on monitoring feeding and watering stations as well as shaded roosting areas.

The following levels are likely to indicate satisfactory rodent control as appropriate:

- Rodent Index (RI): A RI of 1 or less as described in the December 2011 Guidance
- Chew card (bait cards): An eaten area less than 5 percent
- Visual inspection: No unacceptable rodent activity during visual inspections, as described in the first paragraph of this response

8. How can I control rodents in an area outside the poultry house?

When monitoring indicates unacceptable rodent activity, effective rodent control measures should be applied. Control measures can include both mechanical and physical methods.

For areas outside the poultry house, FDA recommends that you use a triple line of defense to control rodents. For example:

An effective first line of defense to control rodents would be to place baiting stations/traps at least six (6) feet beyond the perimeter fencing surrounding the area outside of the poultry house where hens have access and approximately 30-45 feet apart. The goal is to control the rodents before they approach the area outside the poultry house where hens have access.

An effective second line of defense would be to place baiting stations/traps approximately every 10-15 feet along the outside of the perimeter fence surrounding the area outside of the poultry

house where hens have access. The goal is to control the rodents from entering the area and minimize contacts between rodents and hens.

An effective third line of defense would be to place baiting stations/traps approximately every eight (8) feet along the outside of the exterior wall of the poultry house and scattered in the area outside of the poultry house where hens have access. The goal is to control the rodents that have eluded the previous 2 lines of defenses. These baiting stations/traps would be protected by caging or fencing made of mesh that allows rodents to enter but prevents the hens interfering with them.

The baiting stations or other control measures should be checked regularly (we recommend at least once a week) and, if necessary, the number of baiting stations/traps should be increased and fresh bait added as often as needed.

9. How can I prevent flies in an area outside the poultry house?

Preventive measures to keep fly populations at a minimum are based on cleaning and removing areas that support fly larval development. FDA recommends the following options to prevent excessive fly populations in the area outside the poultry house:

- Decreasing the amount of fresh manure.
- Removing any dead carcasses daily and disposing of them properly.
- Minimizing accumulations of spilled feed and broken eggs.
- Keeping grass and weeds mowed to eliminate resting areas for adult flies and to allow for adequate air movement.
- Removing dead or decaying plants (Williams, 2010; Stafford, 2008).

10. How can I monitor for flies in an area outside the poultry house?

Indoor and outdoor fly populations are seasonal and vary year-to-year. Outdoor fly populations usually increase during spring and summer months; indoor fly populations usually increase during fall and winter months (Albarrak, 2009; Rutz, 2000).

For areas outside the poultry house, FDA recommends the same monitoring methods recommended for poultry houses, such as spot cards, fixed sticky tape, moving sticky tape, Scudder grills, or baited traps. These methods are described in Section III.A.2 in the December 2011 Guidance. Monitoring devices should be placed on stakes off the ground or hung from poles strategically placed throughout the area outside of the poultry house. Some of the baits or fly attractants used in these products can be affected by sunlight; thus, to the extent possible, the device chosen should be placed under some type of cover, e.g., a plywood or tin metal square of sufficient size to keep the monitoring device out of direct sunlight.

The following levels are likely to indicate satisfactory fly control as appropriate:

- Spot Card Method: A spot card index of 50 or fewer per card
- Fixed Sticky Tape Method: A weekly count of 50 or fewer flies per tape
- Moving Sticky Tape Method: A count of 75 or fewer flies per tape
- Scudder Grill: A count of less than 20 on a Scudder grill (see footnote 2)

- Baited Traps: A fly count of 250 or fewer flies per week.

11. How can I control for flies in an area outside the poultry house?

When monitoring indicates unacceptable fly activity, effective fly control measures should be applied. FDA recommends that you control for flies in the area outside the poultry house in a manner similar to that used within the poultry house, including sticky traps and/or baited traps.

For areas outside the poultry house, FDA recommends control measures that include mechanical and physical methods. Products designed for outdoor use are available for use with the methods requiring some type of bait or fly attractant. Also, you should identify fly breeding sites and alter or eliminate the source that seems to attract the flies and/or allow them to breed. Insecticides should not be used as a substitute for good management and sanitation. If using insecticides, only those products that are approved for poultry farm use should be considered, and these should be carefully applied following directions for use (Berry, 2009). The chickens themselves should not be considered a control mechanism for flies since flies can carry SE (Olsen and Hammack, 2000). Although darkling beetles (*Alphitobius diaperinus*) and hister beetles (*Carcinops pumilio*) are predators of flies, their use to control fly populations is not recommended because they are vectors of SE (Despins et al., 1988; Gray et al., 1999; Skov et al., 2004; Roche et al., 2009). Other biological control agents have been proposed to control flies. However, at this time it is unknown if any of the other proposed biological controls can serve as vectors of SE, so care should be taken when using them.

12. Must I remove vegetation and debris that may provide harborage for pests in the area outside the poultry house?

Yes. You must remove debris within a poultry house and vegetation and debris outside a poultry house that may provide harborage for pests (21 CFR 118.4(c)(3)).

13. How should I maintain my vegetation in the area outside the poultry house so that it does not provide harborage for pests?

If the area outside the poultry house contains vegetation that poses a potential harborage for rodents, FDA recommends that it be kept at a short height (6 inches or less) to ensure it does not provide harborage for rodents. Because most trees do not pose a potential harborage for rodents or other pests, it is generally not necessary to remove trees in order to comply with 21 CFR 118.4(c)(3). In production systems where birds are rotated through pastures, the 6-inch height recommendation only applies to pastures that contain birds.

14. Must I clean and disinfect the area outside the poultry house prior to adding new laying hens if I have had one or more SE positive test results (environmental or egg)?

You must clean and disinfect the poultry house before new laying hens are added to the house, if you have 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 (21 CFR 118.4(d)).

This requirement does not apply to areas outside the poultry house. However, as is discussed in the answer to question C.2., you must take steps to ensure that there is no introduction or transfer of SE into or among poultry houses (21 CFR 118.4(b)). In a situation where a poultry house is

being repopulated following an SE-positive environmental test or egg test, FDA recommends that you take steps to eliminate SE from areas outside the poultry house before adding new laying hens.

15. How can I clean and disinfect an area outside the poultry house?

For areas outside the poultry house with concrete or wood floors, FDA recommends cleaning and disinfecting these areas in the same manner FDA recommends for the poultry house. Please refer to Section III.A.3 in the December 2011 Guidance. If the ground is dirt or grass, tilling the soil may be part of an effective strategy to remove visible manure and potentially-contaminated dust, feathers, and old feed. In some situations, it might make sense to rotate the area outside the poultry house to which laying hens have access, so that the area that was in use at the time of the SE-positive test result is no longer in use. Allowing the potentially-contaminated area to lie dormant between flocks could be part of an effective disinfection strategy. If an area is left dormant in this manner, appropriate biosecurity measures should be put in place to ensure that SE is not transferred out of the dormant area via employees or equipment.

D. Environmental Sampling for SE

1. Must I sample an area outside the poultry house for SE?

No. While you must sample the poultry house environment using a sampling plan appropriate to the poultry house layout (21 CFR 118.7(a)), this requirement does not apply to areas outside the poultry house.

E. Other

1. If I vaccinate my hens that have access to the area outside the poultry house, am I still required to follow all of the SE prevention measures in the egg rule?

Yes. FDA concluded in the egg rule (74 FR 33030 at 33035) that data on the efficacy of vaccines are not sufficient to allow substitution of vaccination for any of the SE prevention measures. Therefore, the rule does not exempt a producer who vaccinates its birds from the SE prevention measures that are required by the rule. Vaccination against SE is most effective when it is one part of a larger SE prevention plan which includes SE-monitored pullets, effective biosecurity measures, effective rodent and fly control, thorough cleaning and disinfection procedures, and a monitoring program for SE in the environment and eggs. If you have identified a vaccination program that is effective for your particular farms, FDA encourages the use of this program as an additional SE prevention measure.

IV. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at https://www.regulations.gov. References without asterisks are not on public display at https://www.regulations.gov because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the

website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

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