Guidance for Industry

Questions and Answers Regarding the Final Rule, Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation (Layers with Outdoor Access)

Draft Guidance

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-2367.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

[July 2013]

Table of Contents

Guidance for Industry[1]

Questions and Answers Regarding the Final Rule, Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation

(Layers with Outdoor Access)

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

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), concerning the management of production systems that provide laying hens with access to the outdoors. Laying hens are provided outdoor access in some production systems, including certified organic production systems governed by the United States Department of Agriculture's (USDA) National Organic Program regulations (7 CFR Part 205).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe FDA'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 FDA guidances means that something is suggested or recommended, but not required.

[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.

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 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.

The USDA National Organic Program regulations require that organic poultry have year-round access to the outdoors. Birds must have access to the outdoors, shade, shelter, exercise areas, fresh air, clean water for drinking, and direct sunlight (7 CFR 205.239(a)(1)). Poultry are allowed to be temporarily confined in some circumstances, such as inclement weather or conditions under which the birds' health, safety, or well-being could be jeopardized (7 CFR 205.239(b)). However, continuous total confinement indoors is prohibited by USDA's regulations (7 CFR 205.239(a)(1)).

Four housing styles are most often used for organic egg production. The majority of houses in use for organic egg production are either one of these four styles or some variation. The four housing styles are described and illustrated below.

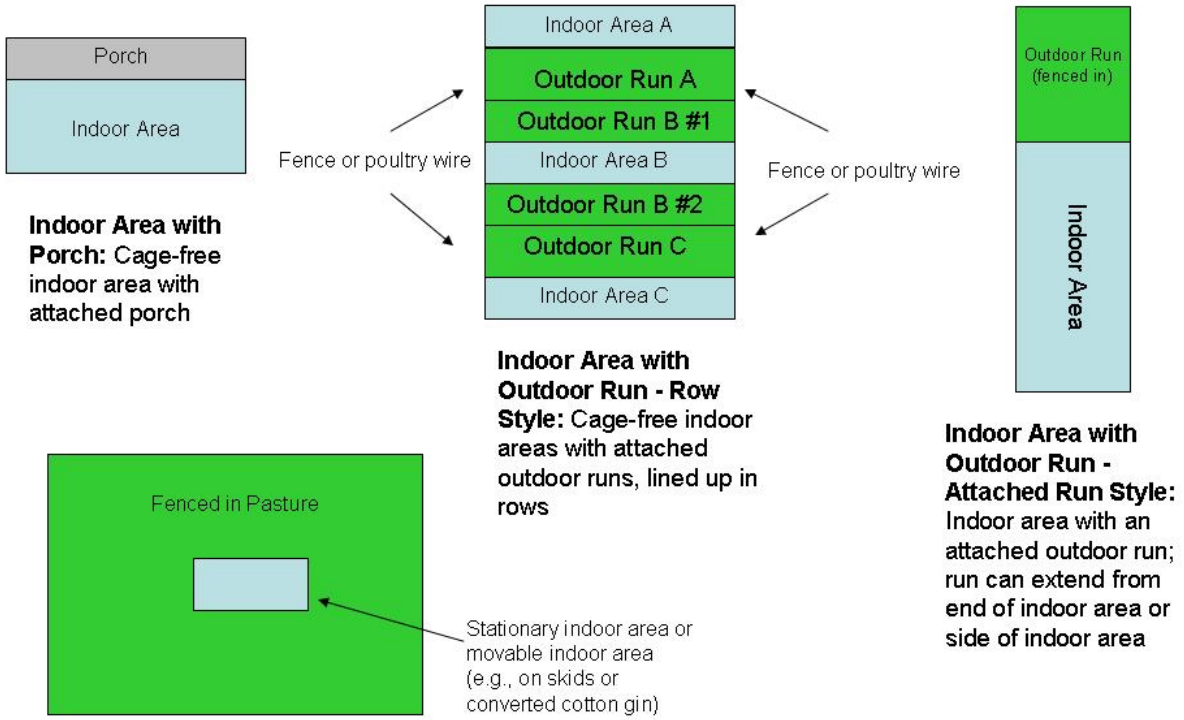
Indoor Area with Porch: A porch is attached to one side of an indoor area. The porch is enclosed with fence material, such as poultry wire; the porch's roof can be solid or made of wire or netting. The porch's floor is often concrete, but can be dirt or grass. Access holes connect the indoor area to 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 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 (as depicted in the drawing) 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.



III. Questions and Answers

A. Coverage of the Egg Rule

1. Does the egg rule apply to me if my farm has an outdoor access area for laying hens?
Yes, 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 production systems that provide laying hens with access to the outdoors. You should also be aware of the recommendations in the December 2011 Guidance for Industry: Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation," available at

http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Eggs/ucm285101.htm (referred to as "the December 2011 Guidance").

B. Definitions

1. Is a porch for layers attached to an indoor area considered part of a poultry house?
Yes. A poultry house is "a building, other structure, or separate section within a structure used to house poultry" (21 CFR 118.3). FDA considers the porches used to provide poultry with outdoor access to be part of a "structure…used to house poultry," and therefore part of a poultry house.

2. Is an outdoor run attached to an indoor area considered part of a poultry house?
No. FDA does not consider an outdoor run to be part of a poultry house. Row-style and attached run-style housing consists of a fenced-in outdoor access area attached to a discrete structure used to provide an indoor environment. In such situations, the indoor area is a structure used to house poultry and is therefore a poultry house. FDA does not consider the outdoor access area to be a building, structure, or part of a structure, and it therefore does not consider the outdoor run to be part of a poultry house.

3. 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 large, fenced-in pasture with a discrete structure used to provide an indoor environment. In such situations, the indoor area is a structure used to house poultry and is therefore a poultry house. FDA does not consider the pasture to be a building, structure, or part of a structure, and it therefore does not consider the pasture to be part of a poultry house.

4. For other styles, how will FDA determine whether an outdoor access area is part of a poultry house?
In applying the definition of poultry house, among the factors FDA will consider are the manner and degree to which the outdoor access area is constructed and the extent to which the outdoor access area is integrated with the enclosed structure. For example, in the housing styles described above as indoor areas with outdoor runs and as pasture containing an indoor area, the extent to which the outdoor access area is integrated with the structure is significantly less than in the porch style.

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)). This requirement applies to the entire poultry house, including any outdoor access areas that are part of the poultry house.

2. Should I prevent stray poultry, wild birds, cats, and other animals from entering an outdoor access area that is not part of 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 (Cizek et al., 1994; Craven et al., 2000; Davies and Breslin, 2003; Macdonald and Brown, 1974; Tizard, 2004).

When there is movement of hens between the indoor area and outdoor access area, 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 outdoor access areas that are not part of the poultry house.

3. How can I prevent stray poultry, cats, and other animals from entering an outdoor access area?

A fence, high wall, or similar structure surrounding the outdoor access area can be used to prevent stray poultry, cats, and other animals (other than birds) from entering this area. If used and where feasible, the fencing or other structure should extend below ground level to prevent animals from burrowing under it, be tall enough to prevent animals from leaping over it, and be made of a material such as wire mesh that is resistant to chewing or gnawing by the undesired animals. If fencing is used, the mesh size of the fencing should be appropriate for the animal(s) being excluded.

Fencing may not exclude the smallest of the invasive species, such as mice, rats, and voles. If fencing is used, additional measures like trapping or baiting may be needed to control these pests.

4. How can I prevent wild birds from entering an outdoor access area?

There are several options to prevent wild birds from entering an outdoor access area. For example, the entire outdoor access area can be covered with solid roofing or with netting, such as that used to protect farmed game birds or berry crops. If you choose to use this option, the covering should extend to and connect with the top of any fencing structure. There should not be any gaps between the netting and/or roofing and the fencing, and care should be taken to prevent wild birds from roosting on any pole or structure supporting the netting.

Other options that might prevent wild birds from entering the outdoor access area include temporarily confining layers during periods of wild fowl migration, limiting layers' access to the outdoors to hours when wild birds are not likely to be present, usage of noise cannons to scare wild birds away and maintaining attractions such as feed and water in areas where they do not attract wild birds.

In addition, Section III.A.1 of the December 2011 Guidance identifies a number of measures that can help keep wild birds away from the areas where laying hens reside, including layout and placement of the poultry house; preventing amassing of spilled feed; and proper disposal of trash and manure.

The presence of wild birds in an outdoor access area indicates that this route of exposure of the flock to SE is not adequately controlled. Therefore, FDA recommends that the presence of wild birds within the outdoor access area prompt implementation of further facility-specific biosecurity measures, such as those described above, in addition to any measures of this type that your farm already has in place.

5. 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 or 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,[2] or sticky 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)). These requirements apply to the entire poultry house, including any outdoor access areas that are part of the poultry house.

6. Should I monitor for rodents and flies in an outdoor access area that is not part of a 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 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)). Rodents and flies are known vectors of SE (Olsen and Hammack, 2000; Meerburg and Kijlstra, 2007). When there is movement of hens between the indoor area and outdoor access area, 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 an outdoor access area that is not part of a 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 these types of outdoor access areas for a variety of reasons. For example, excessive flies in and around pastured laying hens 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 not yet removed from the outdoor access area. Excessive rodent activity can be caused by some of the same factors, or can be caused by other circumstances. For example, when pastured 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 outdoor access area that is not part of 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.

[2] 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.

7. How can I prevent rodents from entering an outdoor access area?

Native field rodents such as voles are adapted to live in natural habitats. In outdoor access areas, it is impossible to exclude rodents in the same way as in poultry houses, but it is possible to reduce their numbers to avoid 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 outdoor access area might not be possible, FDA recommends the following actions to prevent rodents from entering the area:

- Maintain a 6-foot-wide area around the outside periphery of the outdoor access area that is filled with either gravel or other non-grass substance or, if this is not feasible, maintain the grass within this zone to a short height (maximum of 6 inches)
- Remove piles of old material, stacks of straw or hay, trash, weeds, debris, vegetation, and any other material, both inside and immediately outside the outdoor access area, since these can provide harborage for rodents.
- Remove any dead carcasses daily and dispose of them properly.
- Minimize spillage of feed and remove remnants of feed at outdoor feeding sites.
- Minimize access by rodents to feed and water stations.

8. How can I monitor for rodents in an outdoor access area?

Rodents are usually present in fields, but in low numbers, since they are confined to refuge areas where they are not easily detected (Stratford, 2010). Because of the potential for rodent activity in outdoor access areas, FDA recommends monitoring for rodents in the outdoor access area 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 outdoor access areas that are part of the poultry house (e.g., porches), FDA recommends monitoring for rodents in the same manner the agency recommends for other parts of the poultry house. Please refer to Section III.A.2 in the December 2011 Guidance.

For outdoor access areas that are not part of the poultry house (e.g., attached runs or pastures), FDA recommends other 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 outdoor access area 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, 2010). Emphasis should be placed on monitoring outdoor feeding and watering stations as well as shaded roosting areas.

The following levels are likely to indicate satisfactory rodent control:

- 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

9. How can I control rodents in an outdoor access area?

When monitoring indicates unacceptable rodent activity, effective rodent control measures should be applied. Control measures can include both mechanical and physical methods. FDA recommends that you control rodents in an outdoor access area that is part of the poultry house in a manner similar to that used for other parts of the poultry houses. These methods of control include placing rodent traps, bait stations, and/or glueboards across or near paths rodents normally use.

For outdoor access areas that are not part of the poultry house (e.g., attached runs or pastures), FDA recommends that you use a triple line of defense to control rodents. For example, a control plan could include outermost baiting stations at intervals of 30 to 45 feet along the outer edge of the cut perimeter outside of, but within 6 feet of, the outdoor access area. The second line of baiting stations could be placed at intervals of 10 to 15 feet around the perimeter of the outdoor access area in a secured manner that allows access by rodents and prevents access by other animals. Narrow pipes are ideal for this purpose. The third line of defense could be rodent traps scattered about the outdoor access area, protected by caging or fencing made of mesh that allows rodents through but prevents chickens from interfering with the rodent traps. The baiting stations or other control measures should be checked weekly or more frequently if necessary, and fresh bait placed as often as needed.

10. How can I prevent flies in an outdoor access area?

Preventive measures to keep fly populations at a minimum are based on cleaning and removing areas that support fly larval development. FDA recommends that you prevent excessive fly populations in the outdoor access area with the following actions:

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

11. How can I monitor for flies in an outdoor access area?

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). FDA recommends that you monitor for flies in an outdoor access area as described below.

For outdoor access areas that are part of the poultry house (e.g., porches), FDA recommends monitoring for flies in the same manner the agency recommends for other parts of the poultry house. Please refer to Section III.A.2 in the December 2011 Guidance.

For outdoor access areas that are not part of the poultry house (e.g., attached runs or pastures), 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. USDA's National Organic Program may have requirements regarding the types of attractants and baits that can be used in organic egg production. Monitoring devices should be placed on stakes off the ground or hung from poles strategically placed throughout the outdoor access area. 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:

- 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.

12. How can I control for flies in an outdoor access area?

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

For outdoor access areas that are part of the poultry house (e.g., porches), FDA recommends mechanical and physical control measures with proper use of baits or fly attractant material. These methods should be attempted before considering chemical control because flies have become resistant to many insecticides, making fly populations difficult to control with such chemicals. Properly labeled residual insecticides should be used on areas where flies are seen to rest. USDA's National Organic Program may have requirements regarding the types of pesticides that can be used in organic egg production.

For outdoor access areas that are not part of the poultry house (e.g., attached runs or pastures), FDA recommends control measures that include mechanical and physical methods. Several proprietary 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.

13. Must I remove vegetation and debris in the outdoor access area that may provide harborage for pests?

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)).

14. How should I maintain my vegetation in my outdoor access area so that it does not provide harborage for pests?

If your outdoor access area contains vegetation, it should be kept at a short height (6 inches or less) to ensure it does not provide harborage for rodents. Additionally, vegetation that is outside of but within 6 feet of the outdoor access area also should be kept to a maximum height of 6 inches.

15. Must I clean and disinfect the outdoor access area 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 applies to the entire poultry house, including any outdoor access areas that are part of the poultry house (e.g., porch style).

This requirement does not apply to outdoor access areas that are not part of 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 outdoor access areas that are not part of the poultry house.

16. How can I clean and disinfect an outdoor access area?

For outdoor access areas that are part of the poultry house (e.g., porches), FDA recommends cleaning and disinfecting these areas in the same manner the agency recommends for other parts of the poultry house. Please refer to Section III.A.3 in the December 2011 Guidance. If the floor 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 from the poultry house. With respect to disinfection, food grade disinfectants may be appropriate for use on properly cleaned concrete, wood or other types of floors. USDA's National Organic Program may have requirements regarding the types of disinfectants that can be used in organic egg production. In some situations, it might make sense to rotate the outdoor access area, 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 lay 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.

For outdoor access areas that are not part of the poultry house, many of the cleaning and disinfection methods described in Section III.A.3 of the December 2011 Guidance also might be appropriate and effective, as might tilling the soil, rotating the outdoor access areas and allowing the land to lay dormant between flocks.

D. Environmental Sampling for SE

1. Must I sample an outdoor access area for SE?
You must sample the poultry house environment using a sampling plan appropriate to the poultry house layout (21 CFR 118.7(a)). This requirement applies to the entire poultry house, including any outdoor access areas that are part of the poultry house. This requirement does not apply to outdoor access areas that are not part of the poultry house.

2. How can I sample for SE in an outdoor access area that is part of the poultry house?
For outdoor access areas that are part of the poultry house (e.g., porches), FDA recommends sampling these areas in the same manner the agency recommends for other parts of the poultry house. Please refer to the sampling methodology for "Cage-free Poultry House" in Section III.B.1 in the December 2011 Guidance. The entire outdoor access area should be drag-swabbed; the number of drag swabs is based on the width of the outdoor access area.

3. Is the sampling methodology used for the indoor areas of poultry houses applicable to outdoor access areas that are part of the poultry house?
Yes. Drag swabs[3] may be used to sample the environment of an outdoor access area. The number of drag swabs is based on the width of the outdoor access area. Please refer to the sampling methodology for "Cage-free Poultry House" in Section III.B.1 in the December 2011 Guidance.

E. Other

1. If I vaccinate my hens that have access to the outdoor access area, am I still required to follow all of the SE prevention measures in the egg rule?
Yes. FDA concluded in the final 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 sampling requirements. 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. Regardless of whether you provide your laying hens with outdoor access, if you have identified a vaccination program that is effective for your particular farms, FDA encourages the use of the program as an additional SE prevention measure.

2. If I vaccinate my hens that have access to the outdoor access area, must I still sample the outdoor access area for SE at the required timeframes?
Vaccination is not a substitute for any requirements of the egg rule, for the reasons discussed above in the answer to question E.1. For more information regarding sampling outdoor access areas, see the answer to question D.1.

---

[3] A drag swab is a gauze pad attached to a length of twine or string; the pad is moistened with a medium prior to being dragged over the surface being sampled.

IV. References

Albarrak, A. S. Comparative studies on housefly, *Musca domestica* L., population in different animal farms in relation to attractants and control at Hail Province, Saudi Arabia. Pak. Entomol. 31(2):142-148, 2009.

Arzey, G., E. Macarthur and I. Littleton. "NSW biosecurity guidelines for free range poultry farms," 2007.

BC Poultry Association. "BC Poultry Biosecurity Reference Guide," 2010. Available at: http://www.prwatson.co.uk/aiproject/English/Compartmentalisation/07BiosecurityManuals/BCManualReferenceGuideChaptersAll.pdf. Accessed 6 November 2011.

Berry, J. G. Fly Control in the Poultry House. ANSI-82-06. Oklahoma Cooperative Extension Service. Oklahoma State University, 2009. Available at: http://pods.dasnr.okstate.edu/docushare/dsweb/Get/Document-2115/ANSI-8206web.pdf

Cizek, A., I. Literak, K. Hejlicek, F. Treml, and J. Smola. *Salmonella* contamination of the environment and its incidence in wild birds. Zantralbl. Veterinarmed B. 41:320-327, 1994.

Cox, B. BC Poultry Biosecurity Reference guide. BC Poultry Association, Canada. 79 p., 2007. Available at: http://www.prwatson.co.uk/aiproject/English/Compartmentalisation/07BiosecurityManuals/BCManualReferenceGuideChaptersAll.pdf

Cozens, M. "*Salmonella enteritidis* monitoring and certification program, Queensland," 2008. Available at: http://www.dpi.qld.gov.au/documents/Biosecurity_GeneralAnimalHealthPestsAndDiseases/Salmonella-enteritidis-program.pdf.

Craven, S., N. J. Stern, E. Line, J. S. Bailey, N. A. Cox, and P. Fedorka-Cray. Determination of the incidence of *Salmonella* spp., *Campylobacter jejuni*, and *Clostridium perfringens* in wild birds near broiler chicken houses by sampling intestinal droppings. Avian Dis. 44:715-720, 2000.

Davies, R. H. and M. Breslin. Observations on *Salmonella* contamination of commercial laying farms before and after cleaning and disinfection. Vet. Rec.152:283-287, 2003.

DEFRA, Department for Environment, Food and Rural Affairs. The welfare of hens in free range systems. London, U.K., 2001. Available at: http://www.defra.gov.uk/publications/files/pb6490-hens-020130.pdf

Despins, J. L., J. A. Vaughan, and E. C. Turner. Role of the lesser mealworm, *Alphitobius diaperinus* (Panzer) (Coleoptera: Tenebrionidae), as a predator of the house fly, *Musca domestica* L. (Diptera: Muscidae), in poultry houses. The Coleopterists Bulletin (42) 3:211-216, 1988.

Geden, C. J. Methods for monitoring outdoor populations of house flies, *Musca domestica* L. (Diptera: muscidae). Journal of Vector Ecology. 30(2):244-250, 2005.

Gray, J. P., C. W. Maddox, P. C. Tobin, J. D. Gummo, and C. W. Pitts. Reservoir competence of *Carcinops pumilio* for *Salmonella enteritidis* (Eubacteriales: Enterobacteriaceae), J. Med. Entomol. 36(6): 888-891, 1999.

Kuney, D. R. Poultry Fact Sheet – Guidelines For risk reduction of microbial introduction into poultry flocks and Products. U.C. Cooperative Extension, 1999.

MacDonald, J. W. and D. D. Brown. Salmonella infection in wild birds in Britain. Vet. Rec. 94(14):321-322, 1974.

Meerburg, B. G., M. Bonde, F. W. A. Brom, S. Endepols, A. N. Jensen, H. Leirs, J. Lodal, G. R. Singleton, H. J. Pelz, T. B. Rodenburg, and A. Kijlstra. Towards sustainable management of rodents in organic animal husbandry. Njas-Wageningen Journal of Life Sciences 52, 195-205, 2004.

Meerburg, B. G. and A. Kijlstra. Role of rodents in transmission of *Salmonella* and *Campylobacter*. Journal of the Science of Food and Agriculture 87:2774–2781, 2007.

OIE Terrestrial Animal Health Standards Commission. Terrestrial Animal Health Code, Chapter 6.4. Biosecurity Procedures in Poultry Production. World Organization for Animal Health, 2001.

Olsen, A. R. and T. S. Hammack. Isolation of *Salmonella* spp. from the housefly, *Musca domestica* L., and the dump fly, *Hydrotaea aenescens* (Wiedemann) (Diptera: Muscidae), at caged-layer houses. Journal of Food Protection 63:958-960, 2000.

Roche, A. J., N. A. Cox, L. J. Richardson, R. J. Buhr, J. A. Cason, B. D. Fairchild, and N. C. Hinkle. Transmission of *Salmonella* to broilers by contaminated larval and adult lesser mealworms, *Alphitobius diaperinus* (Coleoptera: Tenebrionidae), Poultry Science 88:44-48, 2009.

Rutz, D. A. Pest Management Recommendations for Poultry. College of Agricultural Sciences, Penn State University, 2000. Available at: http://ento.psu.edu/extension/animals/poultry-pest-mgmt-2/view

Skov, M. N., A. G. Spencer, B. Hald, L. Petersen, B. Nauerby, B. Carstensen, and M. Madsen. The role of litter beetles as potential reservoir for *Salmonella enterica* and thermophilic *Campylobacter* spp. between broiler flocks. Avian diseases 48:9-18, 2004.

Stafford, K. C. III. Integrated Management of Poultry Operations. In: Fly Management Handbook, A Guide to Biology, Dispersal, and Management of the Housefly and Related Flies for Farmers, Municipalities, and Public Health Officials. Bulletin 1013. The Connecticut Agricultural Experimental Station, 2008. Available at http://www.ct.gov/caes/lib/caes/documents/publications/bulletins/b1013.pdf

Stratford, G. Managing Mice in the Field. Department of Primary Industries, Victoria, Australia, 2010. Available at: http://www.dpi.vic.gov.au/agriculture/pests-diseases-and-weeds/pest-animals/ag1414-managing-mice-in-the-field

United States Department of Agriculture/Animal and Plant Health Inspection Service. Further guidance on biosecurity and disease prevention and control for nonconfinement poultry production for poultry production operations. USDA/APHIS/Veterinary services. May 4, 2005.

Tizard, I. Salmonellosis in wild birds. Seminar in Avian and Exotic Pet Medicine. 13(2):50-66, 2004.

United States Animal Health Association. Resolution 53, Amendment of the National Organic Program Section 25.239 to make access to the outdoors optional for poultry. USAHA, Reno, Nevada, Oct 18-24, 2007.

Whisson, D. A., R. M. Engeman, and K. Collins. Developing relative abundance techniques (RATs) for monitoring rodent populations. Wildlife Research 32, 239-244, 2005.

Williams, R. Livestock and Poultry, Control of Poultry Pests. E-2-W. Purdue Extension, Purdue University, 2010. Available at: http://extension.entm.purdue.edu/publications/E-3.pdf