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Guidance for Industry

Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Transportation, and Storage Small Entity Compliance Guide

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Office of Food Safety
Division of Plant and Dairy Food Safety, HFS-315
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
(Tel) 301-436-2367
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Table of Contents

- I. Introduction**
- II. Discussion**
 - A. Compliance Dates for the Egg Rule**
 - B. Coverage of the Egg Rule**
 - C. Terms Used in the Egg Rule and In This Document**
 - D. *Salmonella* Enteritidis (SE) Prevention Measures**
 - Pullets
 - Biosecurity
 - Cleaning and Disinfection
 - Rodent, Flies, and Other Pest Control
 - Refrigeration
 - E. Environmental Testing for SE**
 - F. Egg Testing for SE**
 - G. Sampling Methodology for SE**
 - H. Testing Methodology for SE**
 - I. Administration of the SE Prevention Plan**
 - J. Recordkeeping Requirements**
 - K. Registration Requirements**

Guidance for Industry¹

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

Small Entity Compliance Guide

This guidance represents 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

On July 9, 2009, FDA published in the *Federal Register* a final rule that established a regulation part 118 (21 CFR part 118) entitled Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Transportation, and Storage (74 FR 33030). The egg rule in part 118 requires shell egg producers to implement measures to prevent *Salmonella* Enteritidis (SE) from contaminating eggs on the farm and from further growth during storage and transportation, and requires these producers to maintain records concerning their compliance with the rule and to register with FDA.

The egg rule became effective on September 8, 2009.

FDA has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121). This guidance document restates in plain language the legal requirements set forth in part 118 concerning prevention of SE in shell eggs. This regulation is binding and has the full force and effect of law.

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.

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. Discussion

A. Compliance Dates for the Egg Final Rule

We encourage you to comply with the egg rule as soon as possible. However, we are not requiring you to comply with the egg rule right away. As shown in Table 1, the amount of time we are allowing egg producers to comply with the egg rule depends on how many layers you have at a particular farm.

Table 1
Compliance Dates for Egg Producers Based on the Number of Layers at a Particular Farm

If you have ...	The egg rule requires you to comply by ...
50,000 or more layers at one farm	July 9, 2010
At least 3,000, but fewer than 50,000 layers at one farm	July 9, 2012
Fewer than 3,000 layers at one farm	Exempt

Persons who hold or transport eggs for shell egg processing or egg products facilities must comply with the egg rule by July 9, 2010.

(74 FR 33030 at 33034; July 9, 2009)

B. Persons Covered by the Requirements of the Egg Rule (21 CFR 118.1)

1. Who is subject to the egg 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. You are also subject to the refrigeration requirements of the egg rule if you transport or hold shell eggs for shell egg processing or egg products facilities in instances where those eggs come from farms with 3,000 or more laying hens.

(21 CFR 118.1)

2. Who is exempt from the egg rule?

You are exempt from the egg rule if you fall into any of the following categories:

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- Persons who do not produce eggs for the table egg market and who do not hold or transport shell eggs for shell egg processing or egg products facilities;
- Egg producers with fewer than 3,000 laying hens at a particular farm;
- Egg producers who sell all of their eggs directly to consumers; and
- Persons who hold or transport shell eggs for shell egg processing or egg products facilities in instances where the eggs originate from a farm with fewer than 3,000 laying hens.

(21 CFR 118.1)

3. Must I comply with all the requirements of the egg rule if all eggs from my farm are treated in a manner that achieves at least a 5-log destruction of SE for shell eggs or, for egg products, processed in accordance with the Egg Products Inspection Act?

No. You must comply only with the refrigeration requirements in § 118.4(e) for production of eggs on that farm and with the registration requirements in § 118.11.

(21 CFR 118.1(a) (2))

4. Am I covered by the egg rule if my eggs are sold only within my state or I transport eggs only within the same state or I hold eggs for sale only within the same state?

Yes. The egg rule applies regardless of whether the eggs are produced and sold within the same state or sold in interstate commerce.

(74 FR 33030 at 33050; July 9, 2009)

5. Are eggs produced in foreign countries and imported into the United States covered under the egg rule?

Yes. Eggs imported into the United States must comply with the same requirements as those produced domestically.

(74 FR 33030 at 33047; July 9, 2009))

C. Definitions (21 CFR 118.3)

Are the terms "biosecurity," "egg products facility," "farm," "flock," "group," "induced molting," "laying cycle," "molting," "pest," "positive flock," "positive poultry house," "poultry house," "producer," "shell egg (or egg)," "shell egg processing facility," and "treatment (or treated)" defined in the egg rule? If so, where can I find them?

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Yes. The definitions for these terms can be found in § 118.3 of the egg rule. "Biosecurity" and "pest" are also defined in Section II. D. below.

(21 CFR 118.3)

D. *Salmonella* Enteritidis (SE) Prevention Measures (21 CFR 118.4)

- **Pullets**

1. What requirements must I follow when procuring or raising pullets that will become layers on my farm?

You must procure pullets that are SE monitored or raise pullets under SE monitored conditions.

(21 CFR 118.4 (a))

2. What does "SE monitored" mean?

"SE monitored" means the pullets are raised under SE control conditions that prevent SE, including the following:

- Chicks are procured from SE-monitored breeder flocks that meet the National Poultry Improvement Plan's standards for "U.S. S. Enteritidis Clean" status (9 CFR 145.23(d)) or equivalent standard;
- The pullet environment is tested for SE when pullets are 14 to 16 weeks of age;
- If the environmental test is negative, you do not need to perform any additional testing of those birds or their environment until the environmental test at 40 to 45 weeks of age specified in § 118.5(a); and
- If the environmental test is positive, you must begin egg testing, as specified in § 118.6, within 2 weeks of the start of egg laying and you must clean and disinfect the pullet environment to include (1) removing all visible manure; (2) dry cleaning the house to remove dust, feathers, and old feed; and (3) following cleaning, disinfecting the house with spray, aerosol, fumigation, or another appropriate disinfection method.

(21 CFR 118.4(a)(1), (a)(2), and (a)(3))

- **Biosecurity**

1. What is biosecurity?

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Biosecurity is 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.

(21 CFR 118.3)

2. What must I do to ensure I am in compliance with the biosecurity requirements of the egg rule?

The minimum biosecurity measures you must follow are:

- You must limit visitors on your farm and in your poultry houses;
- You must maintain practices that will protect against cross contamination when equipment is moved among your poultry houses;
- You must maintain practices that will protect against cross contamination when persons move between your poultry houses;
- You must prevent stray poultry, wild birds, cats, and other animals from entering your poultry houses; and
- You must not allow your employees to keep birds at home.

(21 CFR 118.4 (b)(1), (b)(2), (b)(3), (b)(4), and (b)(5))

3. May I employ additional biosecurity procedures?

Yes. You may follow additional biosecurity procedures to ensure that there is no introduction or transfer of SE into or among poultry houses on your farm; the list above includes only the minimum procedures you must follow.

(21 CFR 118.4(b))

• Rodents, Flies, and Other Pest Control

1. What is a pest?

A pest is any objectionable animal including, but not limited to, rodents, flies, and larvae.

(21 CFR 118.3)

2. What must I do to ensure I am in compliance with the pest control requirements of the egg rule?

The minimum pest control measures you must follow are:

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- You must monitor for rodents by visual inspection and mechanical traps or glueboards or another appropriate monitoring method;
- When monitoring indicates unacceptable rodent activity within your poultry houses, you must use appropriate methods to achieve satisfactory rodent control;
- You must monitor for flies by spot cards, Scudder grills, or sticky traps or another appropriate monitoring method;
- When monitoring indicates unacceptable fly activity within your poultry houses, you must use appropriate methods to achieve satisfactory fly control; and
- You must remove debris within your poultry houses and vegetation and debris outside your poultry houses that may provide harborage for pests.

(21 CFR 118.4(c)(1), (c)(2) and (c) (3))

3. May I employ additional pest control procedures?

Yes. You may follow additional pest control procedures to control pests on your farm and in your poultry houses; the list above includes only the minimum requirements.

(21 CFR 118.4(c))

• Cleaning and Disinfection

1. When am I required to clean and disinfect my poultry houses?

You must clean and disinfect your poultry houses before new laying hens are added to the houses 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 houses prior to depopulation.

(21 CFR 118.4(d))

2. What procedures must I follow when cleaning and disinfecting my poultry houses?

When cleaning and disinfecting your poultry houses, you must follow these procedures:

- You must remove all visible manure;
- You must dry clean your positive poultry houses to remove dust, feathers, and old feed; and
- Following cleaning, you must disinfect your positive poultry houses with spray, aerosol, fumigation, or another appropriate disinfection method.

(21 CFR 118.4(d)(1), (d)(2), and (d)(3))

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• **Refrigeration**

1. When must I refrigerate my eggs?

You are required to refrigerate eggs from farms with 3,000 or more laying hens beginning 36 hours after they are laid.

(21 CFR 118.4(e))

2. What is the maximum temperature required for holding and transporting eggs that are at least 36 hours old?

The maximum temperature requirement for holding and transporting eggs that are at least 36 hours old is 45 degrees F ambient (air) temperature.

(21 CFR 118.4(e))

E. Environmental Testing for SE (21 CFR 118.5)

1. Why must I test my poultry house environment for SE?

Environmental testing for SE is one indicator of the effectiveness of your SE prevention plan.

(21 CFR 118.5(a))

2. When must I test my poultry house environment for SE?

In addition to the required environmental test of the pullet environment when pullets are 14 to 16 weeks of age (§118.4(a)(2)(i)), you must perform environmental testing for SE (as described in §§118.7 and 118.8) in each poultry house when any group of laying hens constituting the flock within the poultry house is 40 to 45 weeks of age (§118.5(a)). If you induce a molt in a flock or a group in a flock, you must perform additional environmental testing for SE in the poultry house at 4 to 6 weeks after the end of each molting process. Each time a flock or group within the flock is molted, you must perform environmental testing in the poultry house at 4 to 6 weeks after the end of the molting process.

(21 CFR 118.5(b))

3. What am I required to do if my environmental test is negative?

If your environmental test at 40 to 45 weeks is negative and your laying hens do not undergo induced molting, you do not need to perform any additional environmental

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testing within that poultry house, unless the poultry house contains more than one group of laying hens. If the poultry house contains more than one group of laying hens, you must perform environmental testing on the poultry house when each group of laying hens is 40 to 45 weeks of age.

(21 CFR 118.5(a)(1))

If your environmental test at 4 to 6 weeks after the end of the molting process is negative and none of your laying hens in that poultry house is molted again, then you do not need to perform any additional environmental testing in that poultry house.

(21 CFR 118.5(b)(1))

4. What am I required to do if my environmental test is positive?

If your environmental test at 40 to 45 weeks is positive, then you must:

- Review and make any necessary adjustments to your SE prevention plan to ensure that all measures are being properly implemented;
- AND either
- Begin egg testing, as described in § 118.6;
- OR
- Divert eggs to treatment for the life of the flock in that poultry house.

(21 CFR 118.5(a)(2))

If your environmental test at 4 to 6 weeks after the end of a molting process is positive, then you must:

- Review and make any necessary adjustments to your SE prevention plan to ensure that all measures are being properly implemented;
- AND either
- Begin egg testing, as described in § 118.6;
- OR
- Divert eggs to treatment for the life of the flock in that poultry house.

(21 CFR 118.5(b)(2))

5. When must I have the results from egg testing?

You must have results of egg testing within 10-calendar days of receiving notification of the positive environmental test.

(21 CFR 118.5(a)(2)(ii))

F. Egg Testing for SE (21 CFR 118.6)

1. When must I test eggs for SE?

You must test eggs for SE whenever you have an environmental test positive for SE and you choose not to divert eggs from the flock in the positive house to a treatment for the life of that flock.

If the environmental test for pullets at 14 to 16 weeks of age is positive, you must either divert eggs to treatment for the life of that flock or conduct egg testing within 2 weeks of the start of egg laying.

(21 CFR 118.6 (a)(1))

2. How do I test eggs for SE?

You must conduct four egg tests on the flock in the positive poultry house at 2-week intervals.

(21 CFR 118.6 (c))

3. If all four egg tests are negative for SE, am I required to do any further egg testing?

No. If all four egg tests are negative for SE, you do not need to test any more eggs from that flock.

(21 CFR 118.6 (c))

4. What do I do if any of the four egg tests is positive?

If any of the four egg tests is positive for SE, you must divert, upon receiving notification of an SE-positive egg test, all eggs from that flock to treatment for the life of the flock or until four egg tests at 2-week intervals are negative for SE.

(21 CFR 118.6 (c) and (d))

What if one of my four egg tests is positive, and I divert to treatment and then later achieve negative results for four egg tests at 2-week intervals?

In this situation, you may return to table egg production, upon receiving notification of a negative result for the fourth egg test. However, you must conduct one egg test per month on that flock for the life of the flock.

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(21 CFR 118.6 (e))

5. If all my monthly egg tests are negative for SE, may I continue to supply eggs to the table egg market?

Yes. As long as all of your monthly egg tests are negative for SE, you may continue to supply eggs to the table egg market.

(21 CFR 118.6 (e) (1))

6. What am I required to do if any of my monthly egg tests is positive for SE?

If any of the monthly egg tests is positive for SE, you must divert eggs from the positive flock to treatment for the life of the flock or until four egg tests at 2-week intervals are negative for SE.

(21 CFR 118.6 (e) (2))

7. Am I required to label or otherwise identify eggs I am diverting to treatment?

Yes. If you are diverting eggs, the pallet, case, or other shipping container must be labeled and all documents accompanying the shipment must contain the following statement:

“Federal law requires that these eggs must be treated to achieve at least a 5-log destruction of *Salmonella* Enteritidis or processed as egg products in accordance with the Egg Products Inspection Act, 21 CFR 118.6(f).”

This statement must be legible and conspicuous.

(21 CFR 118.6 (f))

G. Sampling Methodology for SE (21 CFR 118.7)

1. How must I sample the poultry house environment for SE?

You must sample the environment within each poultry house using a sampling plan appropriate to the poultry house layout.

(21 CFR 118.7(a))

2. How must I sample eggs for SE?

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To meet the egg testing requirements of § 118.6 (c), you must collect and deliver for testing a minimum of 1,000 intact eggs representative of a day's production from each positive poultry house. You must collect and test four 1,000-egg samples at 2-week intervals for a total of 4,000 eggs.

To meet the monthly egg testing requirement in § 118.6 (e), you must collect and deliver for testing a minimum of 1,000 intact eggs representative of a day's production from each poultry house (that has had an egg test positive for SE) per month for the life of the flock.

(21 CFR 118.7(b) (1) and (b) (2))

H. Testing Methodology for SE (21 CFR 118.8)

1. What method must be used to test environmental samples for SE?

Testing to detect SE in environmental samples must be conducted by the method entitled "Environmental Sampling and Detection of Salmonella in Poultry Houses," April 2008, or an equivalent method in accuracy, precision, and sensitivity in detecting SE.

(21 CFR 118.8(a))

2. Where can I obtain a copy of this testing method for environmental samples?

You may obtain an electronic copy of the April 2008 Environmental Sampling and Detection of Salmonella from FDA's Web site.

You may also obtain a copy from Division of Microbiology (HFS-710), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2364, or you may examine a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD, 301-436-2163, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or you may obtain an electronic copy of this information from NARA's Web site.

(21 CFR 118.8(a))

3. What method must be used to test egg samples for SE?

Testing to detect SE in egg samples must be conducted according to Chapter 5 of FDA's Bacteriological Analytical Manual (BAM), December 2007 Edition, or an equivalent method in accuracy, precision, and sensitivity in detecting SE.

(21 CFR 118.8(b))

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4. Where can I obtain a copy of this testing method for egg samples?

You may obtain an electronic copy of the testing method for egg samples from FDA's BAM.

You may also obtain a copy from Division of Microbiology (HFS-710), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2364, or you may examine a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD, 301-436-2163, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or you may obtain an electronic copy of the testing method for egg samples from NARA's Web site.

(21 CFR 118.8(b))

I. Administration of the SE Prevention Plan (21 CFR 118.9)

1. How must I administer my SE prevention plan on my farm?

You must have one or more supervisory personnel, who do not have to be on-site employees, to be responsible for ensuring compliance with your farm's SE prevention plan.

(21 CFR 118.9 introduction paragraph)

2. What are the qualifications for these supervisory personnel?

This person (or persons) must have successfully completed training on SE prevention measures for egg production that is equivalent to that received under a standardized curriculum recognized by the Food and Drug Administration or must be otherwise qualified through job experience to administer the SE prevention measures. Job experience will qualify this person to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum.

(21 CFR 118.9 introduction paragraph)

3. What are this person's responsibilities?

This person is responsible for:

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- Developing and implementing an SE prevention plan that is appropriate for your specific farm and meets the requirements of §118.4;
- Reassessing and modifying the SE prevention plan as necessary to ensure that the requirements in § 118.4 are met; and
- Reviewing records created under §118.10. (This person does not need to have performed the monitoring or created the records.)

(21 CFR 118.9 (a), (b), and(c))

J. Recordkeeping Requirements for the SE Prevention Plan (21 CFR 118.10)

1. What records am I required to make and keep?

You are required to make and keep the records shown in Table 2.

**Table 2
Records the Egg Rule Requires You to Make and Keep**

Required Records	Documenting Compliance With...
Written SE prevention plan	21 CFR 118.4
Documentation that pullets were “SE monitored” or were raised under “SE monitored” conditions, including environmental testing records for pullets	21 CFR 118.4(a)
Records documenting compliance with biosecurity measures	21 CFR 118.4 (b)
Records documenting compliance with rodent and other pest control measures	21 CFR 118.4 (c)
Records documenting compliance with cleaning and disinfection procedures performed at depopulation, when applicable	21 CFR 118.4(d)
Records documenting compliance with refrigeration requirements	21 CFR 118.4(e)
Records documenting compliance with environmental and egg sampling procedures, when applicable	21 CFR 118.7
Results of SE testing, when applicable, performed under § 118.8	21 CFR 118.4(a)(2) 21 CFR 118.5 21 CFR 118.6
Diversion of eggs, if applicable	21 CFR 118.6
All eggs at a particular farm being given a treatment	21 CFR 118.1(a)(2)
Records of review and of modifications of the SE prevention plan and corrective actions taken	21 CFR 118.9

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(21 CFR 118.10(a))

2. What information must I include on my records?

You must include the following information on all records required under § 118.10:

- Your name and the location of your farm,
- The date and time of the activity that the record reflects,
- The signature or initials of the person performing the operation or creating the record, and
- The actual values observed, if applicable.

The written SE prevention plan must be dated and carry the signature(s) (not initials) of the person(s) who administers the plan as described in § 118.9.

(21 CFR 118.10 (b)(1), (b)(2) and (b)(3))

3. Can I enter information on required records at the end of the day or the end of the week?

No. Data and information reflecting compliance activities must be entered on records at the time the activity is performed or observed.

(21 CFR 118.10 (b)(4))

4. How long must I retain required records?

You must retain all records required by § 118.10 at your place of business, unless stored offsite (see below), for 1 year after the flock to which they pertain has been taken permanently out of production.

(21 CFR 118.10 (c))

5. May I store required records offsite?

You may store the records required by § 118.10, except for the written SE prevention plan, offsite. You must be able to retrieve and provide the records at your place of business within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

(21 CFR 118.10 (d))

6. Do I have to make required records available to FDA officials?

Yes. You must have all records required by § 118.10 available for official review and copying at reasonable times.

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(21 CFR 118.10 (e))

7. Will information on my records be released to the public?

Records required by § 118.10 are subject to the disclosure requirements under part 20 of this chapter.

(21 CFR 118.10 (f))

K. Registration Requirements

1. Who must register?

Shell egg producers with 3000 or more laying hens at a particular farm that does not sell all their eggs directly to consumers and that produces shell eggs for the table market are required to register their farms with FDA.

(21 CFR 118.11 (a))

2. When must I register?

You must register within 30 days of becoming an egg producer or, if already an egg producer, by your farm's applicable compliance date.

(21 CFR 118.11 (a))

Additionally, if any information you previously submitted was incorrect at the time of submission, you must immediately update your farm's registration. If any information you previously submitted that was correct at the time of submission subsequently changes, you must update your farm's registration within 60 calendar days.

(21 CFR 118.11 (b) (2)(vi) and (b)(3)(x))

3. How do I register?

You may register your farm(s) electronically, by mail or fax, or by CD-ROM.

(21 CFR 118.11 (b)(1), (b)(2), and (b)(3))

4. Which method of registration does FDA prefer?

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FDA strongly encourages electronic registration for the benefit of both FDA and you.

(21 CFR 118.11 (b)(1)(ii))

5. Can another individual register my farm for me?

Yes. An individual authorized by the owner or operator of a farm, such as an agent in charge, may also register a farm.

(21 CFR 118.11 (b)(1)(i))

6. How do I register my farm with FDA electronically?

You can register your farm electronically by accessing the Shell Egg Producer Registration Module from FDA's Web site. The Web site will be available for registration 24 hours a day, 7 days a week, beginning May 10, 2010.

(21 CFR 118.11 (b)(1))

7. Will FDA notify me when my electronic registration is complete?

Yes. FDA will automatically provide you with an electronic confirmation of registration and a permanent registration number.

(21 CFR 118.11 (b)(1)(iii))

8. How do I register my farm with FDA by mail or fax?

You must use FDA Form No. 3733. When you receive the form, you must fill it out completely and legibly and either mail it to the address on the form or fax it to the number on the form.

(21 CFR 118.11 (b)(2) (i) and (b)(2)(ii))

9. Where can I get FDA Form No. 3733?

You may obtain a copy of FDA Form 3733 by writing to the U.S. Food and Drug Administration, HFS-681, 5600 Fishers Lane, Rockville, MD 20857, or by requesting the form by phone at 800-216-7331 or 301-575-0156.

(21 CFR 118.11 (b)(2) (i))

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10. What happens if the information I submit on Form 3733 is incomplete or illegible when FDA receives it?

FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a registration form for revision, FDA will use the means by which the form was received by the agency (i.e., by mail or fax).

(21 CFR 118.11 (b)(2)(iii))

11. What happens when FDA accepts my submitted Form 3733 as complete and legible?

FDA will enter complete and legible mailed and faxed registration submissions into its registration system as soon as practicable in the order FDA receives them. FDA will then mail to the address or fax to the fax number on the registration form a copy of the registration as entered, confirmation of registration, and your registration number. When responding to a registration submission, FDA will use the means by which the registration was received by the agency (i.e., by mail or fax).

(21 CFR 118.11 (b)(2)(iv) and (b)(2) (v))

12. How do I register my farm with FDA by CD-ROM?

If you have multiple submissions, you may submit your registrations by mail via CD-ROM. You must use ISO 9660 (CD-R or CD-RW) data format. These files must be submitted on a portable document format (PDF) rendition of the registration form (FDA Form No. 3733) and be accompanied by one signed copy of the certification statement that appears on the registration form.

(21 CFR 118.11 (b)(3)(i) and (b)(3)(ii))

13. What must I include in my submissions on the CD-ROM?

Each submission on the CD-ROM must contain the same preferred mailing address in the appropriate block on FDA Form No. 3733. A CD-ROM may contain registrations for as many farms as needed, up to the CD-ROM's capacity. The registration on the CD-ROM for each separate farm must have a unique file name up to 32 characters long, the first part of which may be used to identify the parent company.

(21 CFR 118.11 (b)(3)(iii), (b)(3)(iv), and (b)(3)(v))

14. Where do I mail my CD-ROM?

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You must mail the CD-ROM to the U.S. Food and Drug Administration, 5600 Fishers Lane, HFS-681, Rockville, MD 20857.

(21 CFR 118.11 (b)(3)(vi))

15. What happens if the information submitted on my CD-ROM does not comply with FDA's requirements?

FDA will return the CD-ROM to the submitter unprocessed.

(21 CFR 118.11 (b)(3)(vii))

16. What happens when FDA accepts as complete the information I submitted on my CD-ROM?

FDA will enter CD-ROM submissions that comply with its requirements into its registration system as soon as practicable in the order FDA receives them.

(21 CFR 118.11 (b)(3) (viii))

17. Will I be notified when the farms identified on my CD ROM are registered?

Yes. For each farm on the CD-ROM, FDA will mail to the preferred mailing address a copy of the registration(s) as entered, confirmation of registration, and each farm's assigned registration number.

(21 CFR 118.11 (b)(3) (ix))

18. What information must I submit electronically, by mail or by fax, or by CD-ROM when I register my farm with FDA?

You must include the following information:

- The name, full address, and phone number of your farm;
- The average or usual number of layers of each house and number of poultry houses on your farm;
- A statement in which you certify that the information submitted is true and accurate; and
- The name of the individual submitting the registration and the individual's signature (for paper and CD-ROM options).
- If another person submits the form for you, the registration must also include a statement in which the individual certifies that the information submitted is true and accurate, certifies that he/she is authorized to submit the registration, and

Contains Nonbinding Recommendations

identifies by name, address, and telephone number, the individual who authorized submission of the registration.

(21 CFR 118.11 (e)(1), (e)(2), and (e)(3))

19. Must my registration information be in English only?

Yes. You must submit all registration information in the English language using the Latin (Roman) alphabet.

(21 CFR 118.11 (d))

20. Is there a registration fee?

No. No fee is required to register under the egg rule.

(21 CFR 118.11 (c))

21. When is my farm considered registered?

If you register electronically, you will be considered registered once FDA electronically transmits your confirmation and registration number. If you register by mail, fax, or CD-ROM, your farm is considered registered once FDA enters your farm's registration data into the registration system and the system generates a registration number.

(21 CFR 118.11 (b)(1)(iv), (b)(2)(vii), and (b)(3)(xi))

22. Am I required to notify FDA if I cease operations?

Yes. If you are a registered egg producer, you must notify FDA within 120 days of ceasing egg production by completing sections 1b, 1c, and 2 of Form 3733. This notification is not required if you are a seasonal egg producer or you temporarily cease operations due to labor disputes, fire, natural disasters, or other temporary conditions.

(21 CFR 118.11 (g))