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[74 FR 33095, July 9, 2009, as amended at 81 FR 5590, Feb. 3, 2016]

§ 118.9 Administration of the Salmonella Enteritidis (SE) prevention plan.

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

(a) Development and implementation of an SE prevention plan that is appropriate for your specific farm and meets the requirements of § 118.4;

(b) Reassessing and modifying the SE prevention plan as necessary to ensure that the requirements in § 118.4 are met; and

(c) Review of records created under § 118.10. This person does not need to have performed the monitoring or created the records.

§ 118.10 Recordkeeping requirements for the Salmonella Enteritidis (SE) prevention plan.

(a) *Records:* You must maintain the following records documenting your SE prevention measures:

(1) A written SE prevention plan required by § 118.4;

(2) Documentation that pullets were ''SE monitored'' or were raised under ''SE monitored'' conditions, including environmental testing records for pullets, as required by § 118.4(a)(2);

(3) Records documenting compliance with the SE prevention measures, as follows:

(i) Biosecurity measures;

(ii) Rodent and other pest control measures;

(iii) Cleaning and disinfection procedures performed at depopulation, when applicable;

(iv) Refrigeration requirements;

(v) Environmental and egg sampling procedures, when applicable, performed under § 118.7;

(vi) Results of SE testing, when applicable, performed under § 118.8 as required in §§ 118.4(a)(2), 118.5, and 118.6;

(vii) Diversion of eggs, if applicable, as required in § 118.6; and

(viii) Eggs at a particular farm being given a treatment as defined in § 118.3, if you are a producer complying with the requirements of this section as described in § 118.1(a)(2).

(4) Records of review and of modifications of the SE prevention plan and corrective actions taken.

(b) *General requirements for records maintained by shell egg producers.* All records required by § 118.10(a) must include:

(1) Your name and the location of your farm,

(2) The date and time of the activity that the record reflects,

(3) The signature or initials of the person performing the operation or creating the record. 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, and

(4) Data and information reflecting compliance activities must be entered on records at the time the activity is performed or observed, and the records must contain the actual values observed, if applicable.

(c) *Length of time records must be retained.* You must retain all records required by this part at your place of business, unless stored offsite under § 118.10(d), for 1 year after the flock to which they pertain has been taken permanently out of production.

(d) *Offsite storage of records.* You may store the records required by this part,

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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.

(e) *Official review of records*. You must have all records required by this part available for official review and copying at reasonable times.

(f) *Public disclosure of records*. Records required by this part are subject to the disclosure requirements under part 20 of this chapter.

§ 118.11 Registration requirements for shell egg producers covered by the requirements of this part.

(a) Shell egg producers covered under § 118.1(a) are required to register their farms with FDA within 30 days of becoming an egg producer or, if already an egg producer, by each farm's applicable compliance date.

(b) Shell egg producers may register their farms by any of the following means:

(1) *Electronic registration*. To register electronically, you must register at *http://www.access.fda.gov*, which will be available for registration 24 hours a day, 7 days a week beginning May 10, 2010. This Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes.

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

(ii) FDA strongly encourages electronic registration for the benefit of both FDA and the registrant.

(iii) Once you complete your electronic registration, FDA will automatically provide you with an electronic confirmation of registration and a permanent registration number.

(iv) You will be considered registered once FDA electronically transmits your confirmation and registration number.

(2) *Registration by mail or by fax*. If, for example, you do not have reasonable access to the Internet through any of the methods described in paragraph (b)(1) of this section, an individual authorized by the owner or operator of a farm, such as an agent in charge, may register by mail or fax.

(i) You must register using FDA Form No. 3733. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration, 5600 Fishers Lane (HFS–681), Rockville, MD 20857, or by requesting the form by phone at 1–800–216–7331 or 301–575–0156.

(ii) When you receive the form, you must fill it out completely and legibly and either mail it to the address in paragraph (b)(2)(i) of this section or fax it to the number on the form.

(iii) If any required information on the form 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).

(iv) FDA will enter complete and legible mailed and faxed registration submissions into its registration system, along with CD–ROM submissions, as soon as practicable, in the order FDA receives them.

(v) 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).

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

(vii) Your facility is considered registered once FDA enters your facility's registration data into the registration system and the system generates a registration number.

(3) *Registration by CD–ROM for multiple submissions*. If, for example, you do not have reasonable access to the Internet through any of the methods

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