Food and Drug Administration, HHS

§118.8 Testing methodology for Salmonella Enteritidis (SE).

(a) Testing of 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. The April 2008 Environmental Sampling and Detection of Salmonella Web site is located at http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/ucm114716.htm, current as of June 26, 2009. The Director of the Federal Register approves the incorporation by reference of “Environmental Sampling and Detection of Salmonella in Poultry Houses,” April 2008, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The FDA will request approval to incorporate by reference any updates to this Web site. The FDA will change the date of the Web site in this paragraph with each update. You may 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 go to: http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html.

§ 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 performed at depopulation, when applicable;
   (vi) Results of SE testing, when applicable, performed under §118.7;
   (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).
(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