

§ 118.5

21 CFR Ch. I (4–1–10 Edition)

§ 118.5 Environmental testing for *Salmonella Enteritidis* (SE).

(a) *Environmental testing when laying hens are 40 to 45 weeks of age.* As one indicator of the effectiveness of your SE prevention plan, you must perform environmental testing for SE (as described in §§ 118.7 and 118.8) in a poultry house when any group of laying hens constituting the flock within the poultry house is 40 to 45 weeks of age.

(1) If an environmental test at 40 to 45 weeks is negative and your laying hens do not undergo induced molting, then you do not need to perform any additional environmental 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, then you must perform environmental testing on the poultry house when each group of laying hens is 40 to 45 weeks of age.

(2) If the environmental test at 40 to 45 weeks is positive, then you must:

(i) Review and make any necessary adjustments to your SE prevention plan to ensure that all measures are being properly implemented and

(ii) Begin egg testing (described in § 118.6), unless you divert eggs to treatment as defined in § 118.3 for the life of the flock in that poultry house. Results of egg testing must be obtained within 10-calendar days of receiving notification of the positive environmental test.

(b) *Environmental testing after an induced molting period.* If you induce a molt in a flock or a group in a flock, you must perform environmental testing for SE in the poultry house at 4 to 6 weeks after the end of any molting process.

(1) If an 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. 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.

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

(i) Review and make any necessary adjustments to your SE prevention plan to ensure that all measures are being properly implemented; and

(ii) Begin egg testing (described in § 118.6), unless you divert eggs to treatment as defined in § 118.3 for the life of the flock in that poultry house. Results of egg testing, when conducted, must be available within 10-calendar days of receiving notification of the positive environmental test.

§ 118.6 Egg testing for *Salmonella Enteritidis* (SE).

(a)(1) If the environmental test for pullets at 14 to 16 weeks of age required by § 118.4(a) is positive, you must divert eggs to treatment (defined in § 118.3) for the life of any flock or conduct egg testing within 2 weeks of the start of egg laying, as specified in paragraphs (b) through (e) of this section.

(2) If you have an SE-positive environmental test at any time during the life of a flock, you must divert eggs to treatment (defined in § 118.3) for the life of the flock in that positive poultry house or conduct egg testing as specified in paragraphs (b) through (e) of this section.

(b) Eggs must be sampled as described in § 118.7 and tested using methodology as described in § 118.8.

(c) You must conduct four egg tests, using sampling and methodology in §§ 118.7 and 118.8, on the flock in the positive poultry house at 2-week intervals. If all four tests are negative for SE, you are not required to do further egg testing.

(d) 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 (defined in § 118.3) until the conditions of paragraph (c) of this section are met.

(e) If you have a positive egg test in a flock and divert eggs from that flock and later meet the negative test result requirements described in paragraph (c) of this section and return to table egg production, you must conduct one egg test per month on that flock, using

sampling and methodology in §§118.7 and 118.8, for the life of the flock.

(1) If all the monthly egg tests in paragraph (e) of this section are negative for SE, you may continue to supply eggs to the table market.

(2) If any of the monthly egg tests in paragraph (e) of this section is positive for SE, you must divert eggs from the positive flock to treatment for the life of the flock or until the conditions of paragraph (c) of this section are met.

(f) 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)." The statement must be legible and conspicuous.

§ 118.7 Sampling methodology for *Salmonella* Enteritidis (SE).

(a) *Environmental sampling.* An environmental test must be done for each poultry house in accordance with §118.5 (a) and (b). Within each poultry house, you must sample the environment using a sampling plan appropriate to the poultry house layout.

(b) *Egg sampling.* When you conduct an egg test required under §118.6, you must collect and test the following number of eggs from the positive poultry house:

(1) 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. The 1,000-egg sample must be tested according to §118.8. You must collect and test four 1,000-egg samples at 2-week intervals for a total of 4,000 eggs.

(2) To meet the monthly egg testing requirement of §118.6(e), you must collect and deliver for testing a minimum of 1,000 intact eggs representative of a day's production per month for the life of the flock. Eggs must be tested according to §118.8.

§ 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.

(b) *Testing of 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. Chapter 5 of FDA's Bacteriological Analytical Manual, December 2007 Edition, is located at <http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/ucm070149.htm>, current as of June 26, 2009. The method is incorporated by reference in accordance with 5 U.S.C.