AUDIT STANDARDS COMPARISON TO THE FDA SHELL EGGS SAFETY REGULATIONS

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PART 115 — SHELL EGGS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
§115.50 Refrigeration of shell eggs held for retail distribution.				
(b) Except as provided in 21 CFR §115.50(c), all shell eggs, whether in intrastate or interstate commerce, held for retail distribution:				
(1) Shall promptly be placed under refrigeration as specified in 21 CFR §115.50(b)(2) upon receipt at a retail establishment, except that, when short delays are unavoidable, the eggs shall be placed under refrigeration, as soon as reasonably possible; and				
(2) Shall be stored and displayed under refrigeration at an ambient temperature not greater than 7.2 °C (45 °F) while held at a retail establishment.				
(c) Shell eggs that have been specifically processed to destroy all viable *Salmonella* shall be exempt from the requirements of paragraph (b) of this section.				

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PART 118 – PRODUCTION, STORAGE, AND TRANSPORTATION OF SHELL EGGS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
§118.1 Persons covered by the requirements in this part.				
(a) 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 covered by some or all of the requirements in this part, as follows:				
(1) If any of your eggs that are produced at a particular farm do not receive a treatment as defined in §118.3, you must comply with all of the requirements of this part for egg production on that farm.				
(2) If all of your eggs that are produced at the particular farm receive a treatment as defined in §118.3, 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.				
(b) If you transport or hold shell eggs for shell egg processing or egg products facilities, you must comply with the refrigeration requirements in §118.4(e). This section applies only to eggs from farms with 3,000 or more laying hens.				
§118.4 Salmonella Enteritidis (SE) prevention measures.				
You must follow the SE prevention measures set forth in 21 CFR §118.4. In addition, you must have and implement a written SE prevention plan that is specific to each farm where you produce eggs and that includes, at a minimum, the following SE prevention measures:				
(a) *Pullets.* You must procure pullets that are SE monitored or raise pullets under SE monitored conditions. "SE monitored" means the pullets are raised under SE control conditions that prevent SE, including:				

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PART 118 – PRODUCTION, STORAGE, AND TRANSPORTATION OF SHELL EGGS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(1) *Procurement of chicks.* 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;				
(2) *Environmental testing.* (i) The pullet environment is tested for SE when pullets are 14 to 16 weeks of age;				
(ii) If the environmental test required in 21 CFR §118.4(a)(2)(i) 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				
(iii) If the environmental test required in 21 CFR §118.4(a)(2)(i) is positive, you must begin egg testing, as specified in §118.6, within 2 weeks of the start of egg laying.				
(3) *Cleaning and disinfection.* If the environmental test required in 21 CFR §118.4(a)(2) is positive, the pullet environment is cleaned and disinfected, to include:				
(i) Removal of all visible manure;				
(ii) Dry cleaning the positive pullet house to remove dust, feathers, and old feed; and				
(iii) Following cleaning, disinfection of the positive pullet house with spray, aerosol, fumigation, or another appropriate disinfection method.				
(b) *Biosecurity.* As part of this program, you must take steps to ensure that there is no introduction or transfer of SE into or among poultry houses. Among such biosecurity measures you must, at a minimum:				
(1) Limit visitors on the farm and in the poultry houses;				
(2) Maintain practices that will protect against cross contamination when equipment is moved among poultry houses;				

AUDIT STANDARDS COMPARISON TO THE FDA SHELL EGGS SAFETY REGULATIONS

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PART 118 – PRODUCTION, STORAGE, AND TRANSPORTATION OF SHELL EGGS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(3) Maintain practices that will protect against cross contamination when persons move between poultry houses;				
(4) Prevent stray poultry, wild birds, cats, and other animals from entering poultry houses; and				
(5) Not allow employees to keep birds at home.				
(c) *Rodents, flies, and other pest control.* As part of this program, you must:				
(1) 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;				
(2) Monitor for flies by spot cards, Scudder grills, 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.				
(3) Remove debris within a poultry house and vegetation and debris outside a poultry house that may provide harborage for pests.				
(d) *Cleaning and disinfection.* You must clean and disinfect the poultry house according to these procedures 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. As part of the cleaning and disinfection procedures, you must:				
(1) Remove all visible manure;				
(2) Dry clean the positive poultry house to remove dust, feathers, and old feed; and				

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PART 118 – PRODUCTION, STORAGE, AND TRANSPORTATION OF SHELL EGGS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(3) Following cleaning, disinfect the positive poultry house with spray, aerosol, fumigation, or another appropriate disinfection method.				
(e) *Refrigeration.* You must hold and transport eggs at or below 45 °F ambient temperature beginning 36 hours after time of lay. If the eggs are to be processed as table eggs and are not processed for the ultimate consumer within 36 hours from the time of lay and, therefore, are held and transported as required at or below 45 °F ambient temperature, then you may then hold them at room temperature for no more than 36 hours just prior to processing to allow an equilibration step to temper the eggs.				
§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				

AUDIT STANDARDS COMPARISON TO THE FDA SHELL EGGS SAFETY REGULATIONS

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PART 118 – PRODUCTION, STORAGE, AND TRANSPORTATION OF SHELL EGGS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(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				

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PART 118 – PRODUCTION, STORAGE, AND TRANSPORTATION OF SHELL EGGS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(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 21 CFR §118.6(b) through (e).				
(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 21 CFR §118.6(b) through (e).				
(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 21 CFR §118.4(c) 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 21 CFR §118.6(c) 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 21 CFR §118.6(e) are negative for SE, you may continue to supply eggs to the table market.				

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PART 118 – PRODUCTION, STORAGE, AND TRANSPORTATION OF SHELL EGGS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(2) If any of the monthly egg tests in 21 CFR §118.6(e) 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 21 CFR §118.6(c) 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				

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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. FDA will request approval to incorporate by reference any updates to this Web site. 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, 5001 Campus Dr., College Park, MD 20740, 301-436-2364, or you may examine a copy at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, 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*.				

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(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. 552(a) and 1 CFR part 51. FDA will request approval to incorporate by reference any updates to this Web site. 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, 5001 Campus Dr., College Park, MD 20740, 301-436-2364, or you may examine a copy at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, 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				

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PART 118 – PRODUCTION, STORAGE, AND TRANSPORTATION OF SHELL EGGS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
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;				

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PART 118 – PRODUCTION, STORAGE, AND TRANSPORTATION OF SHELL EGGS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(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 who sends all their eggs from a particular farm to treatment, 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.				

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PART 118 – PRODUCTION, STORAGE, AND TRANSPORTATION OF SHELL EGGS	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(d) *Offsite storage of records.* You may store the records required by this part, 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 21 CFR Part 20.				
§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.				