Prevention of Salmonella Enteritidis in Shell Eggs During Production---

Recordkeeping and Registration Provisions

Supporting Statement

A. Justification

1. Circumstances Making the Collection of Information Necessary

Shell eggs contaminated with Salmonella Enteritidis (SE) are responsible for more than 140,000 illnesses per year. The Food and Drug Administration (FDA) is requiring each farm site with 3,000 or more egg laying hens that sells raw shell eggs to the table egg market, other than directly to the consumer, and does not have all of the shell eggs treated, to design and monitor an SE prevention plan. The Public Health Service Act (PHS Act) authorizes the Secretary to make and enforce such regulations as "are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States * * * or from one State * * * into any other State" (section 361(a) of the PHS Act). This authority has been delegated to the Commissioner of Food and Drugs. Under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 342(a)(4)), a food is adulterated if it is prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. Under section 701(a) of the act (21 U.S.C. 371(a)), FDA is authorized to issue regulations for the efficient enforcement of the act.

This prevention plan includes all measures the farm is taking to prevent SE in its flock. Records are required for each of the provisions included in the plan and for plan review and modifications if corrective actions are taken. Since many existing farms participate in voluntary egg quality assurance programs, those respondents may not have to collect any additional information. In addition, all farms covered by any part of the rule are required to register with FDA. We have concluded that recordkeeping and registration are necessary for the success of the SE prevention measures. Written SE prevention plans and records of actions taken due to each provision are essential for farms to implement SE prevention plans effectively. Further, they are essential for FDA to be able to determine compliance.

We request OMB approval for the following collection of information requirements and forms:

21 CFR Part 118.10 -- Reporting

Requires a facility to register with FDA and sets forth the information that the registration submission is required to contain, as well as items of information that registrants are encouraged, but are not required, to submit and the method of submitting the registration.

21 CFR Part 118.11 -- Recordkeeping

Requires a facility to prepare to design and monitor an SE prevention plan that includes all mandatory SE prevention measures, to keep records for each of the provisions included in the plan, including records of chick and pullet procurement, rodent and other pest control, biosecurity, cleaning and disinfection, refrigeration, and testing, diversion, and treatment, and to keep records of plan review and modifications if corrective actions are taken.

Form FDA 3733

The term "Form FDA 3733" refers to both the paper version of the form and the electronic system known as the Shell Egg Producer Facility Registration Module, which is available at http://www.access.fda.gov.

2. Purpose and Use of the Information Collection

We are requiring recordkeeping and registration for each farm site with 3,000 or more egg laying hens that sells raw shell eggs to the table egg market, other than directly to the consumer, and does not have all of the shell eggs treated. Shell egg producers will collect the information for per farm site and per layer house as necessary. FDA will not "collect" these records as a routine matter. Records will be maintained on file at each farm site and will be examined there periodically by the FDA.

Farms will register with FDA either electronically or via mail. Information provided to FDA under these regulations will help the agency to notify quickly the facilities that might be affected by a deliberate or accidental contamination of the food supply. In addition, data collected through registration will be used to support FDA enforcement activities.

3. Use of Improved Information Technology and Burden Reduction

Companies are free to use whatever forms of information technology may best assist them in retaining the appropriate records. We encourage, but do not mandate, the use of electronic recordkeeping.

As noted above, the term "Form FDA 3733" refers to both the paper version of the form and the electronic system known as the Shell Egg Producer Facility Registration Module, which is available at http://www.access.fda.gov. The agency strongly encourages electronic registration because it is faster and more convenient for both FDA and the registrant. In addition, registration updates and cancellations may be accomplished electronically. The system the agency has developed can accept electronic registrations 24 hours a day, 7 days a week, 365 days a year. The individual registering a facility will receive confirmation of electronic registration and the facility's registration number

instantaneously once all the required fields on the registration screen are completed. However, FDA will accept paper registrations. Form FDA 3733 is available for download for registration by mail, fax, or CD-ROM. Registration by mail may take several weeks to several months, depending on the speed of the mail system and the number of paper registrations that FDA will have to enter manually.

4. Efforts to Identify Duplication and Use of Similar Information

There is no duplication of recordkeeping requirements as a result of FDA's regulation and regulations issued by the U.S. Department of Agriculture (USDA). USDA requires records on some of the egg products that they regulate, but these will not overlap in information with the records required by FDA's regulation of shell egg production.

Farms that have packing facilities integrated on the farm will already be registered by USDA under the Egg Product Inspection Act (EPIA) and by FDA under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which added section 415 of the act (21 U.S.C. 350d), and §§ 1.230 - 1.235 of FDA's regulations (21 CFR 1.230 - 1.235). However, these two registration programs are not a good substitute for the Shell Eggs Registration information collection because there is information required by this rule, namely the size of operation, including the number of houses on the farm and the number of layers per house, which would not have been provided under EPIA or the Bioterrorism Act. Farms already registered under EPIA or the Bioterrorism Act will need to fully reregister for this rule.

5. Impact on Small Businesses or Other Small Entities

FDA is assisting small businesses by exempting very small farms (defined as farms with fewer than 3,000 layers) from the recordkeeping and registration provisions of the rule. In addition, farms with between 3,000 and 50,000 laying hens will have up to three years to comply with the recordkeeping and registration provisions of the rule. However, 99 percent of the farms with more than 3,000 layers are considered small by Small Business Administration (SBA) standards. The SBA defines chicken and egg producers to be small if their total revenues are less than $11.5 million. A producer that receives $0.45 per dozen eggs and has layers that produce 265 eggs per year would have to have over 1,100,000 layers in production to earn revenues of over $11.5 million. Because only about 400 farms fall into the category of 100,000 or more layers, more than 99 percent of the farms with more than 3,000 layers are considered small by SBA standards, and account for roughly 60 percent of all production.

FDA also will assist small businesses to comply with the registration requirements through the CFSAN small business office. In addition, the FDA Industry Systems Help Desk can answer computer system and technical questions, as well as general questions about registration and will attempt to assist small businesses to register. The Help Desk is available Monday through Friday from 7:00 a.m. to 11:00 p.m. Eastern Time. FDA

strongly encourages electronic registration, but provides registration through postal mail, which can reduce the burden on small entities.

6. Consequences of Collecting the Information Less Frequently

If a farm is not registered or the registration for a farm is not updated when necessary, FDA may not be able to contact the farm in case of a known or potential threat to the food supply or other food-related emergency. Written SE prevention plans and records of actions taken due to each provision are essential for farms to implement SE prevention plans effectively. Without written plans and records of actions taken due to each provision, the SE prevention plan would not be effective. Further, recordkeeping and registration are essential for FDA to be able to determine compliance.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this information collection.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA provided an opportunity for public comment on the information collection provisions of the proposed rule, which published in the Federal Register of September 22, 2004 (69 FR 42275). FDA also published a 30-day notice for public comment on the information collection provisions of the final rule, which published in the Federal Register of July 9, 2009 (74 FR 33030). The notice requested that comments be submitted directly to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB). In response to the request for comments in the proposed rule, FDA received many letters containing one or more comments on the information collection provisions of the proposed rule. A summary of the comments received and FDA's responses follows.

(Comment) In the proposed rule, FDA proposed certain recordkeeping requirements and solicited comments on whether additional recordkeeping measures should be required for a comprehensive SE prevention plan, and whether a written SE prevention plan should be required. Several comments supported the proposed recordkeeping requirements but did not comment on expanding them; one comment stated that there is no need for FDA to expand its recordkeeping requirements beyond those proposed. In addition, several comments supported expanding the proposed recordkeeping requirements to include a written SE prevention plan and records for compliance with SE prevention measures. Several comments noted that such records have been very useful in conducting inspections of facilities to determine compliance with the egg quality assurance program requirements and for identifying problems in the producer's SE prevention plan when a test is positive. Another comment stated that records documenting compliance with all aspects of the SE prevention plan will be essential for a producer to determine if their plan is effective and in making adjustments to improve their plan. One comment opposed the requirement of a written SE prevention plan, stating that while a written plan would undoubtedly be an important management tool, and indeed many operations have

such a plan, it is not necessary for FDA to mandate such a document. The comment stated FDA should not place undue emphasis on paperwork, as opposed to actual results. The comment suggested that FDA work with interested parties to develop a model SE prevention plan that could be provided to egg producers for their use.

(Response) FDA agrees with the comments that the final rule should require a written SE prevention plan as well as records to document the effective implementation of that plan. This written SE prevention plan will set forth a producer's plan to implement the regulation's prevention, testing, and diversion measures. A written plan is necessary for producers to ensure that they have effectively and consistently implemented SE prevention measures. Further, a written plan greatly facilitates FDA inspection. SE prevention measures may be quite different among farms, given different facility design and size, and yet be equally effective in preventing SE contamination. Knowledge of the specific prevention measures taken on a farm, as discussed in an SE prevention plan, will assist FDA to assess compliance with the prevention measures.

In addition, reviewing records of implementation of a facility's specific SE prevention measures is the best mechanism for FDA to use to determine whether preventive measures have been implemented over a period of time. These required documents include records of implementation and compliance with all SE prevention measures. Such documents, for example, would include documents that pullets were SE monitored or raised under SE monitored conditions, records of SE environmental and egg testing, and records of activities required by the rule, such as treatment or diversion of eggs, as well as records indicating review of the plan and any changes or modifications made to the plan. Keeping careful written records will help producers ensure that they have effectively and consistently implemented SE prevention measures and will also assist FDA in determining whether the plan is being followed and in identifying problems in the producer’s plan when a test is positive. If changes or modifications need to be made, recording such changes or modifications will help ensure such changes are implemented.

Therefore, under § 118.10, FDA is requiring that egg producers covered by all of the requirements in the rule (§ 118.1(a)(1)) maintain the following records documenting their SE prevention measures: (1) A written SE prevention plan; (2) documentation that pullets were “SE-monitored” or were raised under "SE-monitored" conditions, including environmental testing records for pullets; (3) records documenting compliance with the SE prevention measures; and (4) records of review and of modifications of the SE prevention plan and corrective actions taken. FDA intends to issue guidance regarding the recordkeeping requirement.

(Comment) Two comments stated that FDA should require purchasers of diverted eggs (e.g., egg breaking facilities, shell pasteurization facilities, hard-cooked operations, or other facilities where the eggs could be treated) to maintain records indicating that the diverted eggs have been treated. These comments, submitted by an agricultural department and poultry and livestock commission of two major shell egg producing states, argued that without records there would be no ability to ensure the purchaser would treat the eggs and not simply divert them back to the table egg market.

(Response) FDA agrees with the comments' concern that purchasers of diverted eggs might resell them for the table egg market without treating them and that buyers might not know that the eggs must receive a treatment. To address this concern, FDA has modified this final rule by adding § 118.6(f), which requires that when shell egg producers divert 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. FDA believes this additional requirement will help reduce the likelihood that these eggs will end up on the market without having been treated. We note that USDA-FSIS, not FDA, regulates egg-breaking facilities under the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).

(Comment) One comment commended FDA's statement that "we intend to consider records that come into our possession under this rule as generally meeting the definition of a trade secret or commercial confidential materials" (69 FR 56824 at 56841). However, the comment requested that FDA identify in the final rule what information will be considered confidential commercial information (CCI) or a trade secret, and under what legal authority FDA will defend this designation against any legal challenges.

(Response) FDA's regulations in 21 CFR part 20 govern the disclosure of information under the Freedom of Information Act (FOIA), including the disclosure of CCI and trade section information. The agency's general policies, procedures, and practices relating to the protection of confidential information received from third parties apply to information received under this rule. It is not necessary that FDA designate information upfront as CCI or trade secret because these determinations can be made before releasing any information. If FDA denies a request under FOIA, it will rely on the provisions in that statute which permit the agency to withhold information.

(Comment) One comment encouraged FDA to incorporate an automated recordkeeping requirement into the proposed rule. The comment stated that an automated system would enhance and support the recordkeeping requirements outlined in the proposed rule. The comment argued that such a system could provide farm-specific data, and an efficient, cost-effective way to research compliance. The comment stated that an automated system would greatly reduce the recordkeeping burden placed upon egg producers as well as the time, frequency, and cost associated with FDA inspections.

(Response) FDA believes that the least burdensome way of implementing the recordkeeping requirements is to specify the information that must be contained in the records, but not the format in which the records are kept. Automated technology may not be available or within the means of all producers covered by the rule. We note that egg producers may choose to use automated recordkeeping as long as they maintain all of the required records.

(Comment) In the proposed rule (69 FR 56841 at 56841 through 56842), FDA solicited comments about whether we should require that shell egg producers register with FDA. Several comments supported requiring registrations by egg producers covered by the SE prevention measures. These comments stated that registration of all producers covered by any of the SE prevention measures would be the most efficient method of obtaining the information needed to conduct annual inspections and allocate resources.

Further, several comments stated that such a requirement should be consistent with the program developed under the agency's bioterrorism regulations. The comments further stated that by identifying each farm's location and size, a registration requirement would enable more efficient inspection, as well as better management and oversight of a shell egg recall.

One comment stated that, to create a level playing field across the United States, registering all producers is necessary and that FDA may be able to cooperate with USDA/APHIS, which is presently developing a premises identification program for all animal premises in the United States.

(Response) FDA agrees with the comments and is requiring that egg producers who must comply with all of the SE prevention measures in this rule, and also those producers who must comply only with the refrigeration requirements in this rule, register with FDA and provide information on the name of each farm, its location, layer capacity, and the number of houses. Persons who transport or hold shell eggs for shell egg processing or egg products facilities but who are not egg producers are not required to register with FDA, although they are subject to the refrigeration requirements in § 118.4.

FDA intends to conduct inspections of egg farms to ensure that shell eggs are being produced under controls that will prevent SE contamination and reduce the likelihood that SE-contaminated eggs will cause foodborne illness. We will use the producer registration information to create a database used to efficiently conduct inspections and allocate inspection resources. Covered egg producers must register within 30 days of becoming an egg producer or, if already an egg producer, by the applicable effective date of the rule. Additionally, registered egg producers are required to notify FDA within 120 days of ceasing egg production (excluding seasonal egg producers or those who temporarily cease operation due to labor disputes, fire, natural disasters, or other temporary conditions).

Producers can register online via the Internet, by completing a paper form and mailing or faxing it to FDA, or by sending a CD-ROM containing the relevant registration information to FDA. If ceasing egg production, producers can notify FDA either online via the Internet or by completing a paper form and mailing or faxing it to FDA.

(Comment) One comment objected to requiring producers who pack eggs to register, stating that every producer with packing facilities is registered with the FDA under the registration rule and should not be required to register a second time. The comment agreed that producers that do not pack eggs, but sell eggs that will ultimately go into the

table egg market, should be registered so that FDA can ensure these firms are following the on-farm production and testing requirements of the SE rule.

(Response) Farms are not required to register under FDA's Registration of Food Facilities regulation (21 CFR 1.226(b)). If a farm also has a packing or processing facility, then only the packing or processing facility is required to register under the registration rule if those packing and processing activities do not qualify under the farm exemption (see "farm" definition for activities that are covered in the farm exclusion under 21 CFR 1.227(b)(3)). Because the packing/processing facility registration information may not fully identify the farm location, FDA is requiring that information in this regulation. If the information that would be provided by an egg producer during registration has already been provided under the registration regulation, the producer may submit its registration number rather than registering again.

(Comment) One comment objected to the proposed registration requirement as an unnecessary burden and an unreasonable invasion of privacy. The comment argued that FDA only should check for compliance. The comment further argued that "unexpected visits are not appropriate as a respect for other people and the reality is that no one can hide what you want to see in 24 hours." The comment further argued that registration will result in a loss of privacy for the producer and is unnecessary for the success of the program.

(Response) FDA disagrees with this comment. As stated above, registration will aid in the identification of egg producers for inspection and compliance purposes. We will use the producer registration information to create a database that we will use to efficiently conduct inspections and allocate inspection resources. With regard to "unexpected visits," section 704 of the FFDCA (21 U.S.C. 374) authorizes FDA inspections without advance notice and FDA's practice of making such inspections precedes this rule and is independent of whether registration is required.

(Comment) One comment expressed concern that information submitted to register facilities would be subject to the Federal Freedom of Information Act (5 U.S.C. 552), and that public release of this information could result in a decrease of security at the producer sites. The comment stated that FDA has other means at its disposal to learn the site information needed to administer this program and still respect the need for security at the producer sites.

(Response) FDA recognizes that this information may be subject to disclosure under FOIA, unless there is statutory authority there or elsewhere that protects it. However, we disagree that the risk of such disclosure outweighs the public health benefits of collecting this information. As stated previously, registration will facilitate FDA's identification of egg producers for inspection and compliance purposes. We will use the producer registration information to create a database that we will use to efficiently conduct inspections and allocate inspection resources.

(Comment) Several comments suggested that FDA revise the proposed rule to make the environmental sampling plan flexible. In support of this suggestion, some comments stated that because the rule would cover very diverse egg laying facilities in the United States (e.g., free-range farms and confinement operations using cages or nesting boxes), one single sampling plan would not be effective. One comment recommended a different sampling plan requirement for each operation type. The comment suggested that all confinement "barns" could be sampled under the same plan, and recommended that for such operations FDA require that a minimum of one manure drag sample be obtained from each bank of cages. The comment stated that more research is needed to determine the most appropriate sample sites for operations that are cage-free, pasture-raised, or free-range. Another comment noted that the sampling plan should also be flexible because of variations in operations within geographic areas and across geographic regions, for example, difference in manure collection/disposal systems.

(Response) FDA agrees that because the final rule covers very diverse egg laying facilities, the same sampling plan may not be practical for all operations and that the sampling plan requirement should be flexible to accommodate variations in housing styles. The proposed rule did not specify a particular plan; rather it provided at § 118.7(a) that "[w]ithin each poultry house, you must sample the environment using a scientifically valid sampling procedure." In the final rule, to make more clear that the appropriateness of a sampling plan depends on the house being sampled, we have modified the language in § 118.7(a) to require "a sampling plan appropriate to the poultry house layout." Specific sampling instructions have been incorporated into the environmental testing method, "Environmental Sampling and Detection of Salmonella in Poultry Houses."

(Comment) One comment agreed with the sampling protocol established in § 118.6(c) for egg testing for SE, but stated that 24 hours is not a practical timeline to begin egg testing after a positive environment is found. The comment suggested that § 118.6(c) require egg producers to immediately notify the appropriate state agency of the positive environmental findings and that egg sampling commence within 2 weeks after the environmental test results are received. Another comment suggested that FDA revise the time period allowed between receiving a positive environmental sample and conducting the required egg testing from 24 to 72 hours to allow for weekends or holidays when laboratory facilities would most likely not be available to complete the tests. Several comments further argued that the 24-hour requirement for initiating egg testing is impossible, as even collecting the eggs within 24 hours might be difficult at times. In addition, the comments argued that to arrange testing for 1,000 eggs requires scheduling of several items, including people, labs, and media, and cannot be done in 24 hours.

(Response) For the reasons identified in the comments, FDA agrees that 24 hours may not be practical to begin egg testing. Therefore, we have modified § 118.5(a)(2)(ii) and (b)(2)(ii) in the final rule. Rather than setting a time when egg testing must begin, the rule establishes a deadline for conducting and completing such testing and receiving the results. The final rule requires that the results of egg testing for the first 1000 eggs must be obtained within 10 calendar days of receiving notification of the positive

environmental test. This time period allows for the farm to obtain a laboratory to do the work and collect the eggs and for the laboratory to perform and complete the tests.

(Comment) One comment argued that a testing regulatory scheme would not be effective in preventing illnesses from SE. This comment stated that environmental and egg testing only indicates the status of the house at the time of the test.

(Response) Environmental and egg testing alone do not prevent SE, but instead serve as an indicator and verification step that the SE prevention plan is working properly. Further, a positive egg test can prevent contaminated eggs from reaching consumers and thereby protect the public health.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The regulation does not specify confidentiality. However, records that may be consulted during FDA farm inspections are subject to FDA's regulations on the release of information, 21 CFR part 20. Confidential commercial information is protected from disclosure under FOIA under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20). To the extent 21 CFR 20.64 applies, the FDA will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

11. Justification for Sensitive Questions

This information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

Description of Respondents: Respondents to this information collection include farm sites with 3,000 or more egg laying hens that sell raw eggs to the table egg market, other than directly to the consumer, and do not have all of the eggs treated to prevent SE.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1,6]

Description and 21 CFR Section	No. of Recordkeepers[2]	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Prevention Plan Design	867	1	867	20	17,340

118.10(a)(1)[5]					
Chick and Pullet Procurement Records 118.10(a)(2)	4,731	1	4,731	0.5	2,366
Rodent and Other Pest Control 118.10(a)(3)(ii)	4,731	52	246,012	0.5	123,006
Biosecurity Records 118.10(a)(3)(i)	4,731	52	246,012	0.5	123,006
Cleaning and Disinfection Records 118.10(a)(3)(iii)	331	1	331	0.5	166
Refrigeration Records 118.10(a)(3)(iv)	2,600	52	135,200	0.5	67,600
Testing, Diversion, and Treatment	343	52	17,836	0.5	8,918
Records 118.10(a)(3)(v - viii)[3,4]	5,965	1	5,965	0.5	2,983
Environmental Testing[4]	6308	23	145,084	0.25	36,271
Egg Testing	331	7	2317	8.3	19,231
Prevention Plan Review and Modifications 118.10(a)(4)	331	1	331	10	3,310
				Total hours for first year	404,197
				Total recurring hours	386,857

1. There are no capital costs associated with this collection of information.

2. Some records are kept on a by-farm basis and others are kept on a by-house basis. See section V.F (74 FR 33030 at 33078 to 33080) of this document for a detailed description of the breakdown.

3. The annual frequency of records kept for this provision depends on whether the house actually tests positive for SE.

4. Calculations include requirements for pullet and layer houses

5. Actual first year burden hours have been divided by 3 to avoid double counting in the ROCIS system.

6. Calculations include the burden on foreign firms. FDA identified a single farm with more than 3,000 layers in New Zealand that exports shell eggs to the U.S.

FDA estimates the recordkeeping burden of this final rule to be 438,877 hours in the first year (the analogous number in Table 1, 404,197, is a result of dividing by three the burdens that occur only in the first year, to avoid double counting in the ROCIS system), and 386,857 each year thereafter, as shown in Table 1.

The number of recordkeepers estimated in column 2 of Table 1 and all other estimates discussed in this section are drawn from estimates of the total number of layer and pullet houses affected by this final rule (74 FR 33030 at 33078 to 33080). We assume that those farms that are currently operating according to recognized industry or State quality assurance plans are already largely in compliance with the plan design and recordkeeping provisions discussed in this section, and therefore would not experience additional costs to comply with recordkeeping provisions. We find that 59 percent of farms with more than 50,000 layers are currently members of State or industry quality assurance plans. Fewer than 8 percent of farms with fewer than 50,000 layers are currently members of quality assurance plans. The estimated number of layer farms incurring a new recordkeeping burden because of this rule is 2,600, and the number of houses affected is 4,731. A detailed breakdown of this estimation is shown in Table 29 (74 FR 33030 at 33078).

Plan design (118.10(a)(1)) and refrigeration records (118.10(a)(3)(iv)) will be kept on a per farm basis, so the number of record keepers for these provisions is 2,600 (the analogous number in Table 1, 867, is a result of dividing the first year burden by three). Plan design is a first year burden only.

Records of chick and pullet procurement (118.10(a)(2)), rodent and other pest control(118.10(a)(3)(ii)), and biosecurity (118.10(a)(3)(i)) will be kept on a per house basis, so the number of record keepers for these provisions is 4,731.

Records of cleaning and disinfection (118.10(a)(3)(iii)) will also be kept on a per house basis, but will only need to be kept in the event that a layer house tests environmentally positive. Prevention plan review and modifications (118.10(a)(4)) will also need to be performed every time a house tests positive. As discussed in Section V.F. (74 FR 33030 at 33078 to 33080), FDA estimates that 7.0 percent will test positive after the provisions of this rule have taken effect. Therefore, the number of record keepers for these provisions is estimated to be 331 (4,731 houses x 0.070) annually.

Records of testing, diversion, and treatment (118.10(a)(3)(v - viii)) will be kept on a per house basis and will include records on flocks from pullet houses. From data provided by comments to the proposed rule, FDA estimates that there are one third as many pullet houses as there are layer houses. Therefore the total number of record keepers for these provisions is 6,308 (4,731 + (4,731/3)). The number of annual records kept depends on whether houses test positive for SE or not. This is further discussed in the paragraphs below.

Because information on the costs of designing the SE prevention plan for eggs is not available, we base these costs on assumptions used to analyze the design of HACCP programs (63 FR 24253 at 24275 to 24285). In particular, we estimate that each plan component will take approximately 20 hours to design. In the event of an environmental positive, the farm must review and modify as necessary its plan design. FDA estimates this will take roughly half the time (10 hours per provision) that it took to originally draft the plan.

We assume that the time required for recordkeeping is roughly equivalent to the time necessary to monitor and document the food safety provisions of a HACCP plan (63 FR 24253 at 24275 to 24286). Because the HACCP time estimate upon which we are basing our estimate involves multiple control points and monitoring, this assumption tends to overstate the cost of recordkeeping for a provision of this final rule. In particular, we expect that, for each house affected, recordkeeping will take one half hour per week per provision that would require weekly or daily monitoring. Records kept for biosecurity measures, rodent and pest control and refrigeration are assumed to be recorded on a weekly basis.

Records for chick and pullet procurement and cleaning and disinfection will only have to be collected roughly once per year and are estimated, as above, to require one half hour to produce each record.

Environmental and egg sampling and testing, diversion and treatment records together have daily, weekly, and monthly aspects, in the event of an environmental positive. In the case of an environmental positive, the record's annual burden is similar to the burden estimated for the weekly records discussed above. If a house tests environmentally negative, the burden is similar to the yearly burden estimated above. Annually, 343 layer and pullet houses ((4,731 layer houses x 0.070) + ((4731/3 pullet houses) x 0.0075))[1] are expected to test positive and 5,965 are expected to test negative ((4,731 layer houses x 0.930) + ((4731/3 pullet houses) x 0.9925)).

The time burden of actually testing is estimated on a per swab sample basis. We estimate that it will take approximately 15 minutes to collect and pack each sample. The time it takes to sample an entire house depends on the number of samples taken. The number of samples depends on whether a farm employs the row based method (an average of 12 samples per house) or the random sampling method (32 samples per house). FDA does not have information to know how many farms will employ either method. For the purposes of this analysis we estimate that roughly 50 percent of the houses affected will employ a row based method and 50 percent will employ a random sampling method, implying an average of 23 samples per house. FDA estimates that all 1,577 pullet and 4,731 layer houses not currently testing will incur the burden of a single test annually.[2]

The time burden of egg testing is calculated per 1,000 eggs (50 samples x 20 eggs per sample). We estimate that it will take the typical farmhand approximately one-half minute per egg to select eggs for testing, so the burden of egg testing is 8.3 hours per 1,000 eggs tested (0.0083 hours per egg x 1,000 eggs). Follow-up egg testing would occur if an environmental test is positive for SE. If egg testing is triggered, the farmer must submit 1,000 eggs to a lab both initially and subsequently every 2 weeks for a total of 4,000 eggs. Furthermore, a farm that has had a positive egg test must continue to test 1,000 eggs each month for the life of the flock. The total burden of egg testing depends on how many houses test positive and the percentage of flocks that are molted (62 percent, or 2,933 out of the 4,731 houses affected). Molted flocks that have a positive egg test initially will have additional egg tests to perform after the flock is molted. Given a positive environmental test, the weighted average number of egg tests per house is 7.

The reporting burden due to the registration requirement is shown in Table 2.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN[1,4]

Description and 21 CFR Section	FDA Form No.	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Registration 118.11[3]	FDA 3733[2]	1,110	1	1,110	2.3	2,553

1. There are no capital costs or operating and maintenance costs associated with this collection of information.

[1] As discussed in Section 1.i (see 74 FR 33030 at 33075), the pullet houses are estimated to test positive at only a rate of 0.75 percent of the time.

[2] Even molted flocks will only test once per year.

2. The term "Form FDA 3733" refers to both the paper version of the form and the electronic system known as the Shell Egg Producer Registration Module, which will be available at http://www.access.fda.gov per §118.11(b)(1).
3. First year burden

4. Calculations include the burden on foreign firms. FDA identified a single farm with more than 3,000 layers in New Zealand that exports shell eggs to the United States.

The registration requirement will be a new, one time reporting burden for all farms with more than 3,000 layers. FDA estimates that there are 3,329 such farms (74 FR 33030 at 33080) (the analogous number in Table 2, 1,110, is a result of dividing the first year burden by three). Using experience gained from implementing section 415 of the FFDCA, FDA estimates that listing the information required by the final rule and presenting it in a format that will meet the agency's registration regulations will require a burden of approximately 2.3 hours per average facility registration. As detailed in section V.F. (see 74 FR 33030 at 33080), FDA expects that it will take farms with access to the Internet 2 hours to register and for farms without easy access to the Internet it will take 3 hours to register. FDA assumes the number of farms with easy access to the Internet is similar to the number used in the BT Registration Rule (68 FR 5378 at 5392 to 5403), that is, 71 percent of farms. The average facility burden hour estimate of 2.3 hours takes into account that some respondents completing the registration may not have readily available Internet access (29 percent).

Estimated Cost to Respondents for the Burden Hours.
FDA estimates the cost to respondents for the burden hours associated with this collection of information to be approximately $11.00 million in the first year and $10.53 million each year thereafter. We estimated total recordkeeping, testing, and registration costs by multiplying the burden in hours (404,197 in the first year and 386,857 annually thereafter) by the recordkeeping labor cost of $18.14 per hour, plus 50 percent to reflect overhead costs.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are capital costs and maintenance costs associated with this collection.

The total annual operating cost of this record collection associated with environmental and egg testing is $10.40.

The operating cost of environmental testing is composed of the following: (1) the cost of shipping the eggs to a qualified laboratory, and (2) the lab costs of testing the eggs.

The cost of shipping samples will vary by the weight of the shipment. We assume that a swab, with its packing material, weighs approximately 1 pound. To calculate the cost of shipping, we estimate the average number of swabs sent per shipment and use rate tables

to determine the cost of shipment.[3,4] We estimate the laboratory cost of testing for SE that has been collected from the environment to be approximately $36.00 per sample.

For row based testing, because each row has two sides, each of which we assume will have to be swabbed, the total number of swabs required is estimated to be approximately 42,650. On average, 12.2 swabs will be used for each house with more than 3,000 layers. The total cost of testing the average large house is $488 (12.2 swabs x ($3.98 shipping + $36.00 lab culture)) when two swabs are used per row.

The random swabbing plan requires that 32 samples be taken per house. The total cost of one round of testing under the random swabbing plan is calculated to be $1,229 per house, regardless of size (32 swabs x (2.42 shipping + $36.00 lab culture)).

Without better information on the method farms will adopt, we estimate that 50 percent of houses will be tested using the random swab method and 50 percent will be tested using the row based method. The average operating cost per test is therefore $895 (($488 + $1,229)/2). Roughly one environmental test per each of the 6,308 pullet and layer houses will be performed each year. Therefore the total annual operating costs will be $5.65 million.

The operating cost of follow-up egg testing is composed of the following: (1) the value of the eggs being tested, (2) the cost of shipping the eggs to a qualified laboratory, and (3) the lab costs of testing the eggs.

The lost value of the eggs used for testing is the number of eggs tested times the producer price of an egg.[5] To avoid double counting of the cost of diversion (for those eggs being tested), we modify this value to account for the fact that as many as 26 percent of eggs being tested may be required to be diverted at the time of testing. The price that the typical producer receives for table eggs is about $0.43 per dozen, while the price a producer receives for diverted eggs is about $0.26 per dozen eggs expected value of a tested egg is the weighted average of the value of a table egg and a diverted egg, or about $0.03 per egg.[6] The value of the eggs tested is the value per egg times the number of eggs tested. The value of every 1,000 eggs tested is $32.15.

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[3] The cost of shipping 12 swabs (12 pounds) overnight is estimated to be between $25.58 and $70.73, including pickup charges (Ref. 98). We divide the average cost of shipping by 12 to obtain the cost per swab ($3.98).

[4] The cost of shipping 32 swabs (32 pounds) overnight is estimated to be between $42.10 and $114.65, including pickup charges. We divide the average cost of shipping ($77.44) by 32 to obtain the cost per swab ($2.42).

[5] Using the producer price of the egg may slightly underestimate the value of the lost egg. Although much of the price increase between producer and consumer includes transfers, there is real value added during some processing.

[6] The following calculation is used to reach this figure. [(74 percent of eggs not diverted x $0.43 per dozen table eggs) + (26 percent of eggs diverted x $0.26 per dozen diverted eggs)] ÷ 12 eggs in a dozen = $0.03215 per egg.

Eggs that are collected will have to be shipped to a laboratory for analysis. The cost of shipping these eggs depends on the weight of the eggs being shipped. We estimate that 1,000 large eggs weigh approximately 111 pounds. The cost of shipping these eggs in two 60-pound packages (including packing) to the laboratory is approximately $260.[7]

The largest cost of egg testing is the laboratory; we estimate the average lab cost for 1 batch of 20 eggs to be $35.16.[8] Hence, for 50 tests the laboratory cost of eggs testing is $1,758 per 1,000 eggs tested (50 batches x $35.16 per test).

The total operating cost of egg testing is the sum of each of the previously stated costs. Therefore, the cost of egg testing is $2,049 per 1,000 eggs tested ($32.37 lost income from egg sales + $259.05 shipping costs + $1,758 lab costs). As shown in Table 1, there will be approximately 2,317 tests performed annually.[9] Therefore the annual operating cost of egg testing is $4.75 million.

14. Annualized Cost to the Federal Government

FDA's review of the registration documents would generally occur as part of the registration process. FDA would devote approximately 2 hours per registration to the inspection of the documents. FDA estimates the annualized cost to the Federal Government for the review of records retained by a firm to be $105.09 per review. In this calculation of cost, FDA estimates the hourly cost for review and evaluation at a base GS-12, step 1 salary of $35.03 per hour for the locality pay area of Washington-Baltimore-Northern Virginia for 2009. Two hours multiplied by $35.03 per hour equals $70.06. To account for overhead, this cost is increased by 50 percent, making the cost to the Federal Government $105.09 per review. FDA estimates that there are 3,329 farms with more than 3,000 layers. If all 3,329 farms register, then the cost to the government to review the registrations is estimated to be $349,845 (3,329 registrations x $105.09 per review). Over a three year period, the reviews will cost the Federal Government, on average, $116,615 per year.

15. Explanation for Program Changes or Adjustments

This is a new collection requirement. The increase in reporting and recordkeeping burdens reflect our estimate of the number of registrations that would be required by the final rule and the amount of recordkeeping associated with the SE prevention plans required by the final rule.

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[7] The cost of shipping a 60-pound package overnight is between $67.35 and $191.70, including pickup charges. We multiply the average cost of shipping ($129.52) by 2 to obtain the total cost of $259.05.

[8] For the testing method FDA prescribes, the lab cost per 20 egg pool is $35 initially and an additional $30 for confirmation if the pool tests positive. Upon an environmental positive, eggs will test positive at a rate of 2.75 per 10,000. Therefore the probability of a pool of 20 eggs testing negative is 99.45 percent ((1 – (2.75/10,000))^20). Conversely the probability of a pool testing positive is 0.55 percent. So the expected cost of a test is $35.16 (($35 x 0.9945) + ($65 x 0.0055)).

[9] This is an overestimate, as we're only considering the static model here, which does not allow farms to opt out of egg testing by diverting eggs for the remaining life of the flock.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans to publish data from this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are not seeking approval to not display the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

N/A