DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

21 CFR Part 118
[Docket No. FDA–2000–N–0190]
Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation; Change of Registration Date, Address, and Telephone Number; Technical Amendment

AGENCY: Food and Drug Administration, HHS. ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to correct the date by which producers must register their farm with FDA, reflect a change in the address and telephone number for requesting copies of Form No. 3733, and reflect a change in the address and telephone number for requesting the form by phone at 1–800–523–1733.

DATES: Effective on April 13, 2010.
FOR FURTHER INFORMATION CONTACT: John Sheehan, Center for Food Safety and Applied Nutrition (HFS–315), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1488.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in 21 CFR part 118 to correct the following information: (1) The date by which egg producers must register their farm with FDA, (2) the address and telephone number for requesting copies of Form 3733, and (3) the address to which egg producers must send their CD–ROM. Publication of this document constitutes final action on this change under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedures are unnecessary because FDA is merely updating nonsubstantive content.

List of Subjects in 21 CFR Part 118

Eggs and egg products, Incorporation by reference, Recordkeeping requirements, Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 118 is amended as follows:

PART 118—PRODUCTION, STORAGE, AND TRANSPORTATION OF SHELL EGGS

1. The authority citation for 21 CFR part 118 continues to read as follows:


2. In § 118.11, revise paragraphs (a), (b)(2)(i), and (b)(3)(vi) to read as follows:

§ 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) * * *

(2) * * *

(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.

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(3) * * *

(vi) You must mail the CD–ROM to the U.S. Food and Drug Administration, 5600 Fishers Lane (HFS–681), Rockville, MD 20857.

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Dated: April 7, 2010.
Leslie Kux, Acting Assistant Commissioner for Policy.

[FR Doc. 2010–8358 Filed 4–12–10; 8:45 am]
BILLING CODE 4160–01–S
II. Legal Authority To Collect Fees

The FBI has collected user fees for fingerprint-based CHRI checks since 1982, when the authority to establish and collect fees to process fingerprint-based CHRI checks for noncriminal justice purposes, such as employment and licensing, was set out in Public Law (Pub. L.) 97–257. This statutory authority was renewed annually by subsequent appropriations legislation. Under Public Law 101–162, the FBI was also authorized to establish and collect fees for name-based checks and to set the fees at a level to include an amount to defray expenses for the automation of fingerprint identification and associated costs. Congress, in Public Law 101–515, subsequently authorized the FBI to establish and collect fees for these fees on a continuing basis. This authority was further expanded by Public Law 104–99 with insertion of the term “criminal justice information services” so the FBI was authorized to use the collected fees to “defray expenses for the automation of fingerprint identification and criminal justice information services and associated costs.”

III. Fee Calculation

Standards and Guidelines Used To Calculate the Fees

Public Law 101–515 links the user fees charged for processing fingerprint identification records and name checks to the cost of providing these services. This authority also permits the FBI to establish user fees at a level to include an amount “to defray expenses for the automation of fingerprint identification and criminal justice information services and associated costs.”

In the absence of express statutory authority, Federal agencies are authorized to establish fees by the Independent Offices Appropriation Act of 1952, 31 U.S.C. 9701, which is implemented by specific guidelines in Office of Management and Budget (OMB) Circular A–25. Since the FBI has specific statutory authority to establish and collect fees under Public Law 101–515, the FBI is not required to follow strictly the mandates of OMB Circular A–25. In establishing the fees set out in this rule, the FBI referred to OMB Circular A–25 for guidance in calculating fees based on costs. For example, in calculating the fees, OMB Circular A–25’s definition of full cost “as all direct and indirect costs to any part of the Federal Government of providing a good, resource, or service” was used to include direct and indirect personnel, overhead, and related indirect costs such as material costs, utilities, travel, and equipment. Congress, in the Volunteers for Children Act (VCA), 42 U.S.C. 5119a, limited the fee that can be charged to a volunteer to $18, or the actual cost of providing the service, whichever is less. The statutory term “actual cost” does not appear in OMB Circular A–25, which uses the term full cost, defined as all direct and indirect costs of providing a service. Thus, the FBI defined the actual cost as the full cost of providing this service, when calculating the fee for checks of volunteers under the VCA.

Methodology Used To Calculate the User Fees

The FBI hired a contractor, BearingPoint, Inc., 1676 International Drive, McLean, Virginia 22102 (BearingPoint), to conduct an independent analysis of pertinent costs and to recommend a revised fee schedule for the fingerprint-based and name-based CHRI checks conducted by the CJIS Division. Referencing OMB Circular A–25; the Statement of Federal Financial Accounting Standards (SFAS–4); Managerial Cost Accounting Concepts and Standards for the Federal Government; and other relevant financial management directives, BearingPoint developed a cost accounting methodology and related cost models based upon the concepts and principles of activity-based costing (ABC).

ABC is a business management process that provides information about the relationships between inputs (costs) and outputs (products or services) by quantifying how work is performed (activities). The ABC model used to calculate the user fees was developed using commercially available ABC software and followed generally accepted cost accounting procedures for cost assignment and unit cost calculation. Organizational resources were assigned to activities, and then the activities were assigned to services based upon reported patterns of consumption. BearingPoint identified the total resources associated with the fingerprint-based and name-based CHRI check services and assigned these costs to the services using relevant cost drivers. The cost drivers were selected primarily for their strong cause-effect linkages between the resources and the activities and services that consumed them. BearingPoint worked extensively with FBI staff, including programmatic subject matter experts and statistical experts, to gather the information necessary to devise the cost accounting methodology and to construct a representative ABC model. BearingPoint developed its cost accounting methodology in six steps for the non-automation portion of the fee.

1. Operational labor costs were reviewed and assigned to activities and then to services.

2. Support labor costs were reviewed and assigned to activities and then to services.

3. Nonlabor costs, including unfunded personnel and judgment fund costs, were reviewed and assigned to activities and then to services.

4. Cost estimates were made for FY 2008, when the revised user fees are expected to be implemented.

5. Transaction volumes and trends were analyzed to predict appropriate transaction volumes for FY 2008.

6. Finally, using the projected FY 2008 costs and the projected FY 2008 transaction volumes, the projected unit costs for each service were calculated. The recommended user fees were based on these projected unit costs.

As explained above, under Public Law 101–515, the FBI is also authorized to charge an additional amount for the automation of fingerprint identification and criminal justice information services and associated costs. A similar process was used to develop this portion of the fee. It was determined that the most appropriate basis for the calculation of this portion of the fee was the capital investment and anticipated depreciation costs for automated fingerprint identification and other criminal justice information service capabilities and enhancements to certain automated systems. The costs for these automation efforts were obtained from the FBI’s asset management and financial management systems and records, and program planning documentation. By employing this methodology, users paying the fee will pay for services based on the cost of the automation which is already in place at the time their request is processed. While the funds collected will be used to develop future capabilities, the cost basis of the fee will be the automation in place. The projected FY 2008 volumes were then used to calculate the unit costs for this portion of the fee.

Once the unit costs were calculated, BearingPoint generated the revised fee schedule. The FBI then independently reviewed the BearingPoint recommendations, compared them to current fee calculations and plans for future services, and determined that the revised schedules were both objectively reasonable and in consonance with the underlying legal authorities.
Overview of the Costs Included in the Fee Calculation

The fee calculation was made by gathering the labor and nonlabor costs of those divisions of the FBI that directly or indirectly support the provision of the fingerprint-based and name-based CHRI check services, and then using various drivers to assign those costs to the identified activities. The activities were then assigned to the specific fingerprint-based and name-based CHRI check services or to a general category for all other costs. The ABC model examined in detail only those costs which were related to the fingerprint-based and name-based CHRI check services. These services included both the criminal justice and law enforcement and the noncriminal justice identification services performed by the CJIS Division of the FBI. The discussion below is limited to those costs in the ABC model which were assigned to the fingerprint-based and name-based CHRI check services that are supported by the user fees. In other words, even though the ABC model calculated unit costs for various criminal justice fingerprint-based CHRI check services, these costs will not be discussed in this regulation since they are funded with appropriations and not with user fees.

The costs for providing the fee-supported fingerprint-based and name-based CHRI check services include the personnel costs for both direct and indirect support, as well as nonlabor costs such as travel, training, rent, equipment, utilities, printing, contract support, and supplies. In addition, depreciation for existing nonautomation assets was included per OMB Circular A–23 guidance. Finally, portions of the FBI’s costs for workers compensation, unemployment, and the judgment fund, used to pay judgments against the United States where appropriations have not otherwise been provided, were included.

These costs were derived from the FBI’s financial systems and audited financial statements. The FY 2008 predicted costs were obtained by recalculating the depreciation and adding an inflation factor for labor and other nonlabor expenses. The OMB pay raise and inflation factors provided in OMB Circular A–11, Preparation, Submission, and Execution of an Agency Budget, were used. The costs associated with providing the services do not include any of the automation costs which instead were captured in the capital investment and depreciation costs for the automation portion of the fee described below.

The automation costs are divided into those which support fingerprint identification services currently in operation and those which support other criminal justice information services. Both types of automation costs are authorized by Public Law 101–515. The FBI chose to separate these costs to facilitate calculation of the cost of providing fingerprint-based CHRI checks for volunteers, since the VCA limits the fee to the actual cost or $18.00, whichever is less. The FBI is interpreting the actual cost of providing the service to include only the costs for the automation of fingerprint services currently in operation; the actual cost does not include the costs for the automation of other criminal justice information services.

The costs for the automation of the fingerprint identification services include depreciation costs for the fingerprint identification infrastructure and the costs for developing a disaster recovery capability which would allow the FBI’s essential fingerprint identification services to continue in all circumstances as required by OMB Circular A–130, Management of Federal Information Resources (OMB Circular A–130).

The costs for the automation of other criminal justice information services are based on the depreciation of assets already in place and the costs of enhancements which have passed through the approval gates for the planning stages of system development under the FBI’s life cycle management directive. These enhancements include the Next Generation Identification program, which will increase the speed, capacity, and functionality of the FBI’s fingerprint identification process, and the Biometric Interoperability Program which will provide two-way access to information in other major fingerprint databases such as the Department of Homeland Security’s database of nonimmigrant visitors to the United States. The costs also include the automation of certain aspects of the National Crime Information Center (NCIC), the Law Enforcement National Data Exchange (N–DEx) program, and the Uniform Crime Reporting (UCR) program.

There is one additional component of cost which was considered when determining the fees. Federal agencies, certain State agencies, and approved nongovernmental entities that submit fingerprint-based CHRI checks function as de facto centralized billing service providers (CBSPs) by collecting the appropriate (CBSPs) from individuals or subordinate agencies and submitting a consolidated payment. It is more cost-effective for the FBI to bill a CBSP than to process individual direct payments for single fingerprint-based CHRI check submissions.

The FBI employs this centralized billing methodology to collect payment for more than 9.8 million fingerprint-based CHRI checks each year. Under the fee schedule proposed in this rule, the FBI will continue the practice of allowing approved CBSPs to retain a portion (currently $2.00) of the fee for fingerprint-based CHRI checks for performing this centralized billing service. In order to allow the CBSPs to retain this portion of the fee, it is necessary to include this cost when determining the full costs which the fee must cover. At this time, this cost is calculated by multiplying the amount the CBSPs are allowed to retain by the volume of billed transactions. The centralized billing process will be subject to further analysis and, consequently, may be revised in the future.

IV. Proposed Changes to the Fee Schedule

Fingerprint-Based CHRI Checks

The FBI utilized categories or fee classes to set the charges for fingerprint-based CHRI checks. Fee classes are determined by the:

- Type of transaction—manual, electronic, or electronic submission with manual response, or
- Volunteer status under the VCA.

Name-Based CHRI Checks

The name-based CHRI checks are available only to authorized Federal agencies for purposes specifically authorized by statute, e.g., pursuant to the Security Clearance Information Act, 5 U.S.C. 9101. The fee classes for name-based CHRI checks differentiate between manual and electronic submissions.

New Services

If the FBI offers a new service or otherwise requires a new fee class in the future, the charge for this new fee class will be based upon the closest existing fee class until such time as a new fee class can be established. Authorized users will be advised of the new service or new fee class by CJIS Information Letter or other CJIS communication. The FBI will calculate a fee for the new fee class using the methodology discussed in the NPRM and will publish a revised fee schedule as a notice in the Federal Register. See 73 FR 34906–07 (2008).
V. Discussion of Comments

Comments on the proposed rule were received from two individuals and one professional association.

The comments from the professional association and an individual were fully supportive of the proposed rule. The letter from the professional association stated, “We appreciate the importance of maintaining rigorous personnel security practices, and believe the FBI’s support of non-criminal CHRI checks, whether fingerprint or name-based, is necessary to the success of these programs.” The final comment, from an individual, concerned the need for increased regulation of hazardous materials transportation, rather than the NPRM. After reviewing the comments, the FBI has determined that no changes to the proposed rule are necessary.

VI. Regulatory Certifications

Regulatory Flexibility Act

When an agency issues a rulemaking proposal, the Regulatory Flexibility Act (RFA) requires the agency to “prepare and make available for public comment an initial regulatory flexibility analysis” which will “describe the impact of the proposed rule on small entities.” (5 U.S.C. 603(a)). Section 605 of the RFA allows an agency to certify, in lieu of preparing an analysis, that the proposed rulemaking is not expected to have significant economic impact on a substantial number of small entities. Small entities are defined by the RFA to include small businesses, small organizations, and small governmental jurisdictions.

The fees for providing fingerprint-based and name-based CHRI background checks for noncriminal justice purposes normally are imposed upon the individual subject of the background check, rather than upon small entities. In addition, under the new fee schedule that became effective October 1, 2007, the fee imposed on nonfederal users submitting electronic fingerprint-based CHRI dropped nearly 20 percent per request. This lower fee is applicable to more than 90 percent of the total nonfederal fingerprint-based checks. However, the fee for manual searches was increased, reflecting comparatively higher processing costs for those services. As a result of these different fees, the FBI expects that users will seek the lower costs associated with providing electronic fingerprint submissions.

State and Federal agencies and certain private entities serve as CBSPs, or entities that collect and submit an individual’s fingerprints to the FBI and remit the fee charged to the individual. There are no small businesses, organizations or governmental jurisdictions currently providing billing services as CBSPs.

With regard to name-based CHRI checks, there is no direct or indirect impact on small entities, as only Federal agencies are authorized to request name-based CHRI background checks, and Federal agencies do not fall within the definition of a “small entity.” Accordingly, the Director of the FBI hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Executive Order 12866 (Regulatory Planning and Review)

This regulation has been drafted and reviewed in accordance with Executive Order 12866, Regulatory Planning and Review, section 1(b), Principles of Regulation. The FBI has determined that this rule is a significant regulatory action under Executive Order 12866, Regulatory Planning and Review, section 3(f) and accordingly this rule has been reviewed by the OMB.

Executive Order 12988 (Civil Justice Reform)

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

Executive Order 13132 (Federalism)

This rule will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. The fees for providing fingerprint-based and name-based CHRI background checks for noncriminal justice purposes are imposed upon the individual subject of the background check, rather than on the State. Some States serve as CBSPs by collecting and submitting an individual’s fingerprints to the FBI and remitting the fee charged to the individual. The proposed rule does not alter the amount the FBI allows CBSPs to retain for providing these services, but merely makes small adjustments to the fee schedule already in place. The proposed rule does not alter any of the policy set out at 28 CFR part 20, or 28 CFR parts 901–906. Therefore, in accordance with Executive Order 13132, it is determined that this rule does not have significant federalism implications to warrant the preparation of a Federalism Assessment.

Unfunded Mandates Reform Act of 1995

This rule does not contain a mandate that will result in the expenditure by State, local, and Tribal governments (in the aggregate) or by the private sector of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. While CBSPs may need to adjust their internal automated systems and processes, the change in fee amount is a foreseeable and expected eventuality and therefore, it is expected that these internal systems and processes were created with the capability of adjusting to changed fees without great cost or effort. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This final rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This final rule will not result in an annual effect on the U.S. economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based companies to compete with foreign-based companies in domestic and export markets.

IX. Conclusion

After careful consideration, the Department does not believe that any change to the rule is necessary based on these comments. Accordingly, pursuant to the authority set forth in Public Law 101–515, as amended by Public Law 104–99, set out in the notes to 28 U.S.C. 534, part 20 of chapter I of Title 28 of the CFR is amended as follows:

List of Subjects in 28 CFR Part 20

Classified information, Crime, Intergovernmental relations, Investigations, Law enforcement, Privacy.

Accordingly, pursuant to the authority set forth in Public Law 101–515, as amended by Public Law 104–99, set out in the notes to 28 U.S.C. 534, part 20 of chapter 1 of Title 28 of the CFR is amended as follows:

PART 20—CRIMINAL JUSTICE INFORMATION SYSTEMS

1. The authority citation for Part 20 is revised to read as follows:

The Coast Guard is also establishing two additional moving safety zones at shoreline on the Calcasieu River, 2 miles ahead and 1 mile astern of certain designated vessels while in transit on the Calcasieu Channel or Calcasieu River. Meeting, crossing or overtaking situations are not permitted within the security zone unless specifically authorized by the Captain of the Port.

The moving security zone may commence at any point while certain vessels are transiting the Calcasieu Channel or Calcasieu River on U.S. territorial waters (12 nautical miles) in the Captain of the Port (COTP) Port Arthur zone. These security zones are needed to protect vessels, waterfront facilities, the public, and other surrounding areas from destruction, loss, or injury caused by sabotage, subversive acts, accidents, or other actions of a similar nature. Unless exempted under this rule, entry into or movement within these security zones is prohibited without permission from the Captain of the Port or a designated representative.

DATES: This rule is effective May 13, 2010.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2009–0317 and are available online by going to http://www.regulations.gov, inserting USCG–2009–0317 in the “Keyword” box, and then clicking “Search.” This material is also available for inspection or copying at the Docket Management Facility (M–D10), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail Mr. Scott Whalen, Marine Safety Unit Port Arthur, TX, telephone (409) 719–5086, or e-mail scott.k.whalen@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: Regulatory Information

On September 8, 2009, we published a notice of proposed rulemaking (NPRM) entitled “Security Zone: Calcasieu River and Ship Channel, LA” in the Federal Register (74 FR 46040). We received 2 comments on the proposed rule. No public meeting was requested and none was held.

Background and Purpose

Heightened awareness of potential terrorist acts requires enhanced security of our ports, harbors, and vessels. This rule establishes new, distinct security zones on the waters of the Calcasieu River. These zones will protect waterfront facilities, persons, and vessels from subversive or terrorist acts. This rule also eliminates the moving safety zone for non-gas free LNGs transiting the Calcasieu Channel and Calcasieu River and adds a distinct moving security zone that may commence at any point while certain vessels are transiting the Calcasieu Channel or Calcasieu River on U.S. territorial waters in the Captain of the Port, Port Arthur zone. Due to the potential for terrorist attacks, this rule allows the Captain of the Port to create moving security zones around certain vessels as deemed necessary on a case-by-case basis. By limiting access to these areas, the Coast Guard is reducing potential methods of attack on these vessels, and potential use of the vessels to launch attacks on waterfront facilities and adjacent population centers located within the Captain of the Port zone. Vessels having a need to enter these security zones must obtain express permission from the Captain of the Port, Port Arthur or a designated representative prior to entry.

These zones are in an area concentrated with commercial facilities considered critical to national security. This rule does not restrict access to vessels engaged, or assisting in commerce with waterfront facilities within fixed security zones, vessels operated by port authorities, vessels operated by waterfront facilities within the fixed security zones, and vessels operated by federal, state, county or municipal agencies. By limiting access to these areas the Coast Guard is reducing potential methods of attack on vessels, waterfront facilities, and adjacent population centers located within the zones. Vessels not exempted under the provisions of this regulation and desiring to enter these zones are required to obtain permission from the Captain of the Port, Port Arthur or a designated representative prior to entry.

Discussion of Comments and Changes

The Coast Guard received two comments concerning the NPRM. One commenter recommended that the boundaries of the proposed security zones at PPG Industries, Inc. (PPG) be extended to include the transfer dock located at the southern end of PPG...