

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 391, 590, and 592

[Docket No.01-019F]

RIN 0583-AC89

Increases in Fees for Meat, Poultry, and Egg Products Inspection Services—Fiscal Year (FY) 2002

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is increasing the fees that it charges meat and poultry establishments, egg products plants, importers, and exporters for providing voluntary inspection services, overtime and holiday inspection services, identification services, certification services, and laboratory services. These increases in fees reflect the national and locality pay raise for Federal employees (the increase of 3.6 percent anticipated at the time of the proposal to be effective January 2002) and inflation. At this time, FSIS is not changing the fee for the Accredited Laboratory Program. To raise the fees for voluntary egg products inspection (base time) and overtime and holiday voluntary inspection activities, done on other than a continuous resident basis, the Agency is adding Part 592 to the CFR. At this time, FSIS is only including the voluntary egg products inspection fees in this new part. The Agency is also amending the heading of Subchapter I of Chapter III of the CFR by deleting the word "Act" so the heading reads "Egg Products Inspection" because voluntary inspection of egg products is performed under the Agricultural Marketing Act (AMA).

DATES: The final rule is effective January 27, 2002.

FOR FURTHER INFORMATION CONTACT: For information concerning policy issues, contact Daniel Engeljohn, Ph.D., Director, Regulations and Directive Development Staff, Office of Policy, Program Development and Evaluation, FSIS, U.S. Department of Agriculture, Room 112, Cotton Annex, 300 12th Street, SW., Washington, DC 20250-3700, (202) 720-5627, fax number (202) 690-0486.

For information concerning fees, contact Michael B. Zimmerer, Director, Financial Management Division, Office of Management, FSIS, U.S. Department of Agriculture, 5601 Sunnyside Avenue, Mail Drop 5262 Beltsville, MD 20705, (301) 504-5885.

SUPPLEMENTARY INFORMATION:

Background

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*) provide for mandatory Federal inspection of livestock and poultry slaughtered at official establishments, meat and poultry processed at official establishments and egg products processed at official plants. FSIS bears the cost of mandatory inspection. Establishments and plants pay for inspection services performed on holidays or on an overtime basis.

Under the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621 *et seq.*)(AMA), FSIS provides a range of voluntary inspection, certification, and identification services to assist in the orderly marketing of various animal products and byproducts. These services include the certification of technical animal fats and the inspection of exotic animal products, such as antelope and elk. FSIS is required to recover the costs of voluntary inspection, certification, and identification services.

Under the AMA, FSIS also provides certain voluntary laboratory services that establishments and others may request the Agency to perform. Laboratory services are provided for four types of analytic testing: microbiological testing, residue chemistry tests, food composition tests, and pathology testing. FSIS must recover these costs.

Every year FSIS reviews the fees that it charges for providing overtime and holiday inspection services; voluntary inspection, identification, and certification services; and laboratory services. The Agency performs a cost analysis to determine whether the fees that it has established are adequate to recover the costs that it incurs in providing these services. In the Agency's analysis of projected costs for October 1, 2001 to September 30, 2002, the Agency has identified increases in the costs of these inspection services due specifically to the national and locality pay raise for Federal employees (the increase of 3.6 percent anticipated at the time of the proposal to be effective January 2002) and inflation.

FSIS calculated the new fees by adding the projected increase in salaries and inflation for FY 2001 and FY 2002 to the actual cost of the services in FY 2000. The Agency calculated inflation to be 2.0% for FY 2001 and 2.0% for FY 2002. The Agency considered the costs

that it will incur because of the pay raise in January 2002 and averaged its pay costs out over the entire FY 2002.

FSIS did not use the fees currently charged as a base for calculating the new fees for FY 2002 because the current fees are based on estimates of costs to the Agency for FY 2001 and FY 2002. The Agency now knows the actual cost of inspection services for FY 2000 and used the actual costs in calculating the new fees.

The current and new fees are listed by type of service in Table 1.

TABLE 1.—CURRENT AND NEW FEES—PER HOUR PER EMPLOYEE—BY TYPE OF SERVICE

[Except for voluntary inspection of egg products]

Service	Current rate	New rate
Base time	\$38.44	\$42.64
Overtime & holiday	41.00	44.40
Laboratory	60.44	68.32

The differing new fee increase for each type of service is the result of the different amount that it costs FSIS to provide these three types of services. The differences in costs stem from various factors, including different salary levels of the program employees who perform the services. See Table 2.

TABLE 2.—CALCULATIONS FOR THE DIFFERENT TYPES OF SERVICES IN TABLE 1

Base Time:	
Actual FY 2000 cost	\$39.67
Inflation and salary increases	2.95
Adjustment for divisibility by quarter hours02
Total	\$42.64
Overtime and Holiday Inspection Services:	
Actual FY 2000 cost	\$41.32
Inflation and salary increases	3.07
Adjustment for divisibility by quarter hours01
Total	\$44.40
Laboratory Services:	
Actual FY 2000 cost	\$63.59
Inflation and salary increases	4.73
Total	\$68.32

FSIS is also raising the fees for its voluntary inspection of egg products for base time, which are currently set forth in § 55.510 (b) of Title 7 of the Code of Federal Regulations (CFR), from \$33.64

to \$42.64 per hour per program employee and for overtime and holiday inspection which is currently set forth in § 55.510 (c) of Title 7 of the CFR from \$35.52 to \$44.40 per hour per program employee. The differing proposed fees for basetime services and for holiday and overtime services is due to the different amount that it costs FSIS to provide those services. These differences in cost stem from various factors, which include the differing salary levels of the program employees who perform the services. These fees have not been changed in six years. Additionally, in conjunction with the new fee increase for the voluntary inspection of egg products, FSIS is adding provisions that delineate the types of services that would be considered to be overtime or holiday work.

When the regulations governing the mandatory inspection of egg products were transferred to Title 9 of the Code of Federal Regulations (CFR) on December 31, 1998 (63 FR 72352), the regulations governing the voluntary inspection of egg products were not also transferred. FSIS, however, does perform voluntary inspection of egg products, and certain other products, under the AMA. The Agency is now adding part 592 to Title 9 of the CFR which contains the fees for basetime and overtime and holiday voluntary inspection of egg products, as well as an explanation of what services are considered to be overtime and holiday work. Further, the Agency is amending the heading of Subchapter I of Chapter III of the CFR by deleting the word "Act" so the heading will be "Egg Products Inspection."

At this time, FSIS is only including in part 592 of Title 9 of the CFR the base time fee scheme and the overtime and holiday fee scheme for the voluntary inspection of egg products that is done on other than a continuous resident basis. In a separate rulemaking, the Agency will propose to include in Title 9 of the CFR other provisions of the voluntary inspection of egg products regulations. FSIS will coordinate this effort with AMS.

The Agency must recover the actual cost of voluntary inspection services covered by this rule. These fee increases are essential for the continued sound financial management of the Agency's costs.

Proposed Rule and Comments

On October 16, 2001, FSIS published a proposed rule (66 FR 52548) to increase the fees it charges for meat, poultry, and egg products voluntary, overtime, and holiday inspection

services. The Agency provided 30 days for public comment, ending on November 11, 2001. FSIS received no comments on the proposed rule. The Agency believes that adequate notice has been given to affected parties. The Administrator has determined that these amendments should be effective less than 30 days after publication in the **Federal Register** in order for FSIS to recover the costs of the services provided and reduce the possibility of monetary losses for the Agency. Therefore, the increases in fees will be effective January 27, 2002.

Summary of the Final Rule

FSIS is amending 9 CFR 391.2 to increase the base time fee for providing meat and poultry voluntary inspection, identification, and certification services from \$38.44 to \$42.64 per hour per program employee. The Agency is also amending §§ 391.3, 590.126, and 590.128(a) to increase the rate for providing meat, poultry, and egg products overtime and holiday inspection services from \$41.00 per hour per employee to \$44.40 per hour per employee. Additionally, FSIS is amending § 391.4 to increase the rate for laboratory services from \$60.44 per hour per employee to \$68.32 per hour per employee. Further, the Agency is adding part 592 to the CFR to increase the rate for the voluntary inspection of egg products for base time from \$33.64 to \$42.64 per hour per employee and for overtime and holiday inspection from \$35.52 to \$44.40 per hour per program employee. FSIS is also amending the heading of Subchapter I of Chapter III of the CFR by deleting the word "Act" so the heading reads "Egg Products Inspection" because voluntary inspection of egg products is performed under the AMA.

Executive Order 12866 and Regulatory Flexibility Act

Because this final rule has been determined to be not significant, the Office of Management and Budget (OMB) did not review it under Executive Order 12866.

The Administrator, FSIS, has determined that this final rule will not have a significant economic impact, as defined by the Regulatory Flexibility Act (5 U.S.C. 601), on a substantial number of small entities.

Small establishments and plants should not be affected adversely by the increases in fees because the new fee increases provided for, in general, reflect only a small increase in the costs currently borne by those entities that choose to use the inspection services for which fees are being raised. Moreover,

smaller establishments and plants are unlikely to use a significant amount of overtime and holiday inspection services. The inspection services that the fee increases effect are generally used by larger establishments and plants because of their larger production volume, the greater complexity and diversity of the products that they produce, and the need of their clients (large commercial or institutional establishments) for on-time delivery of large volumes of product.

Establishments and plants that seek the Agency's services are likely to have calculated that the incremental costs of overtime and holiday inspection services will be less than the incremental expected benefits of additional revenues that they would realize from additional production.

Economic Effects

As a result of the new fees, the Agency expects to collect an estimated \$101 million in revenues for FY 2002, compared to \$94 million under the current fee structure. The costs that industry will experience by the raise in fees are similar to other increases that the industry faces because of inflation and wage increases.

The total volume of meat and poultry slaughtered under Federal inspection in 2000 was about 82 billion pounds (Livestock, Dairy, Meat, and Poultry Outlook Report, Economic Research Service, USDA, March 28, 2001). The total volume of U.S. egg product production in 2000 was about 2.3 billion pounds (2001 Agriculture Statistics, USDA). The increase in cost per pound of product associated with the proposed fees increases is, in general, \$.00008. Even in competitive industries like meat, poultry, and egg products, this amount of increase in costs would have an insignificant impact on profits and prices.

The industry is likely to pass through a significant portion of the proposed fee increases to consumers because of the inelastic nature of the demand curve facing these firms. Research has shown that consumers are unlikely to reduce demand significantly for meat and poultry products, including egg products, when prices increase. Huang estimates that demand would fall by .36 percent for a one percent increase in price (Huang, Kao S., A Complete System of U.S. Demand for Food. USDA/ERS Technical Bulletin No 1821, 1993, p. 24). Because of the inelastic nature of demand and the competitive nature of the industry, individual firms are not likely to experience any change in market share in response to an increase in inspection fees.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This final rule: (1) Preempts State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule. However, the administrative procedures specified in 9 CFR 306.5, 381.35, and 590.300 through 590.370, respectively, must be exhausted before any judicial challenge of the application of the provisions of this proposed rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA, PPIA, or EPIA.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this final rule, FSIS will announce and provide copies of this **Federal Register** publication in the *FSIS Constituent Update*. FSIS provides a weekly *FSIS Constituent Update* via fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS web page located at <http://www.fsis.usda.gov>. The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience than would be otherwise possible. For more information, or to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720-5704.

List of Subjects*9 CFR Part 391*

Fees and charges, Government employees, Meat inspection, Poultry products.

9 CFR Part 590

Eggs and egg products, Exports, Food labeling, Imports.

9 CFR Part 592

Eggs and egg products, Exports, Food labeling, Imports.

For the reasons set forth in the preamble, FSIS is amending 9 CFR Chapter III as follows:

PART 391—FEES AND CHARGES FOR INSPECTION AND LABORATORY ACCREDITATION

1. The authority citation for part 391 continues to read as follows:

Authority: 7 U.S.C. 138f; 7 U.S.C. 394, 1622 and 1624; 21 U.S.C. 451 *et. seq.*; 21 U.S.C. 601-695; 7 CFR 2.18 and 2.53.

2. Sections 391.2, 391.3, and 391.4 are revised to read as follows:

§ 391.2 Base time rate.

The base time rate for inspection services provided pursuant to §§ 350.7, 351.8, 351.9, 352.5, 354.101, 355.12, and 362.5 is \$42.64 per hour per program employee.

§ 391.3 Overtime and holiday rate.

The overtime and holiday rate for inspection services provided pursuant to §§ 307.5, 350.7, 351.8, 351.9, 352.5, 354.101, 355.12, 362.5 and 381.38 is \$44.40 per hour per program employee.

§ 391.4 Laboratory services rate.

The rate for laboratory services provided pursuant to §§ 350.7, 351.9, 352.5, 354.101, 355.12, and 362.5 is \$68.32 per hour per program employee.

PART 590—INSPECTION OF EGGS AND EGG PRODUCTS (EGG PRODUCTS INSPECTION ACT)

3. The authority citation for Part 590 continues to read as follows:

Authority: 21 U.S.C. 1031-1056.

4. Section 590.126 is revised to read as follows:

§ 590.126 Overtime inspection service.

When operations in an official plant require the services of inspection personnel beyond their regularly assigned tour of duty on any day or on a day outside the established schedule, such services are considered as overtime work. The official plant must give reasonable advance notice to the inspector of any overtime service necessary and must pay the Agency for such overtime at an hourly rate of \$44.40.

5. In § 590.128, paragraph (a) is revised to read as follows:

§ 590.128 Holiday inspection service.

(a) When an official plant requires inspection service on a holiday or a day designated in lieu of a holiday, such

service is considered holiday work. The official plant must, in advance of such holiday work, request the inspector in charge to furnish inspection service during such period and must pay the Agency for such holiday work at an hourly rate of \$44.40.

* * * * *

6. Revise the heading of Subchapter I to read as follows:

SUBCHAPTER I—EGG PRODUCTS INSPECTION

7. Add part 592 to Subchapter I to read as follows:

PART 592—VOLUNTARY INSPECTION OF EGG PRODUCTS

Sec.

592.1 Scope and purpose.
592.2 Base time rate.
593.3 Overtime rate.
593.4 Holiday rate.

Authority: 7 U.S.C. 1621-1627.

§ 592.1 Scope and purpose.

The fees that shall be charged for, and collected by the Food Safety and Inspection Service for the voluntary base time, overtime, and holiday time inspection services of egg products as provided by FSIS on other than a continuous resident basis shall be at the applicable rates, and on the basis set forth in §§ 592.2 through 592.4 below, in lieu of that for such services set forth in 7 CFR part 55. The fees and charges for such services shall be paid by check, draft, or money order to the Food Safety and Inspection Service.

§ 592.2 Base time rate.

The base time rate for voluntary inspection services of egg products is \$42.64 per hour per program employee.

§ 592.3 Overtime rate.

When operations in an official plant require the services of inspection personnel beyond their regularly assigned tour of duty on any day or on a day outside the established schedule, such services are considered as overtime work. The official plant must give reasonable advance notice to the inspector of any overtime service necessary and must pay the Agency for such overtime at an hourly rate of \$44.40.

§ 592.4 Holiday rate.

When an official plant requires voluntary inspection service on a holiday or a day designated in lieu of a holiday, such service is considered holiday work. The official plant must, in advance of such holiday work, request the inspector in charge to furnish inspection service during such period

and must pay the Agency for such holiday work at an hourly rate of \$44.40.

Done at Washington, DC, on January 17, 2002.

Margaret O'K. Glavin,

Acting Administrator.

[FR Doc. 02-1751 Filed 1-23-02; 8:45 am]

BILLING CODE 3410-DM-P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

RIN 3150-AG87

List of Approved Spent Fuel Storage Casks: FuelSolutions™ Cask System Revision; Confirmation of Effective Date

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Nuclear Regulatory Commission (NRC) is confirming the effective date of January 28, 2002, for the direct final rule that appeared in the *Federal Register* of November 14, 2001 (66 FR 56982). This direct final rule amended the NRC's regulations by revising the BNFL Fuel Solutions (FuelSolutions™) cask system listing within the "List of Approved Spent Fuel Storage Casks" to include Amendment No. 2 to Certificate of Compliance (CoC) Number 1026. Amendment No. 2 modified the Technical Specifications (TS) to allow the W74 canister to be placed in the transfer cask instead of the spent fuel pool until the affected storage cask is repaired or replaced. The TS was also modified to clarify the description of the other non-fissile material permitted to be stored in the W74 canister and to revise the temperatures to correspond to the liner thermocouples. This document confirms the effective date.

DATES: The effective date of January 28, 2002, is confirmed for this direct final rule.

ADDRESSES: Documents related to this rulemaking, including comments received, may be examined at the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD. These same documents may also be viewed and downloaded electronically via the rulemaking website (<http://ruleforum.llnl.gov>). For information about the interactive rulemaking website, contact Ms. Carol Gallagher (301) 415-5905; e-mail CAG@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Merri Horn, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone (301) 415-8126 (e-mail: mlh1@nrc.gov).

SUPPLEMENTARY INFORMATION: On November 14, 2001 (66 FR 56982), the NRC published in the *Federal Register* a direct final rule amending its regulations in 10 CFR 72 to revise the BNFL Fuel Solutions (FuelSolutions™) cask system listing within the "List of Approved Spent Fuel Storage Casks" to include Amendment No. 2 to Certificate of Compliance (CoC) Number 1026. Amendment No. 2 modified the Technical Specifications (TS) to allow the W74 canister to be placed in the transfer cask instead of the spent fuel pool until the affected storage cask is repaired or replaced. The TS were also modified to clarify the description of the other non-fissile material permitted to be stored in the W74 canister and to revise the temperatures to correspond to the liner thermocouples. In the direct final rule, NRC stated that if no significant adverse comments were received, the direct final rule would become final on the date noted above. The NRC did not receive any comments that warranted withdrawal of the direct final rule. Therefore, this rule will become effective as scheduled.

Dated at Rockville, Maryland, this 17th day of January, 2002.

For the Nuclear Regulatory Commission.

Michael T. Lesar,

Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration.

[FR Doc. 02-1719 Filed 1-23-02; 8:45 am]

BILLING CODE 7590-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. 01P-0304]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Ingestible Telemetric Gastrointestinal Capsule Imaging System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the ingestible telemetric gastrointestinal capsule imaging system device into class II (special controls). The special

controls that will apply to this device are set forth below. The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976 (the amendments), the Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997 (FDAMA). The agency is classifying this device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This rule is effective February 25, 2002.

FOR FURTHER INFORMATION CONTACT: Carolyn Neuland, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1220.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the amendments, generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the FDA regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the *Federal Register* announcing such classification.