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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 391

[Docket No. FSIS-2013-0022]

RIN [0583-AD]

Change in Accredited Laboratory Fees

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to amend its regulations to change the fees it charges for the accreditation and the maintenance of accreditation of non-Federal laboratories for the FSIS Accredited Lab Program (ALP). Currently, the Agency charges a flat annual fee of \$5,000 for each accreditation or maintenance of accreditation. Laboratories that participate in FSIS' ALP can receive accreditation in one to six analyte classes. FSIS is proposing to charge laboratories \$5,000 per year for the first analyte class accreditation or maintenance (as it currently does), but to reduce the charges to \$2,900 per year for the second, and \$2,100 per year for each additional analyte class accreditation or maintenance of accreditation.

DATES: Submit comments on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: FSIS invites interested persons to submit comments on this proposed rule. Comments may be submitted by one of the following methods:

- Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- Mail, including CD-ROMs, etc.: Send to Docket Room Manager, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, Room 8-163B, Washington, DC 20250-3700.

- Hand- or courier-delivered submittals: Deliver to Docket Room Manager, Patriots Plaza 3, 355 E. Street SW, Room 8-163B, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2013-0022. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

DOCKET: For access to background documents or comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E. Street SW, Room 8-164, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Charles Williams, Room 6065, South Building, 1400 Independence Avenue SW, Washington, DC 20250; Phone: (202) 720-5627, Email: charles.williams@fsis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

FSIS has been delegated the authority to exercise the functions of the Secretary of Agriculture (7 CFR 2.18, 2.53) as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, et seq.) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, et seq.). FSIS protects the public by verifying that meat and poultry products are wholesome, not adulterated, and properly marked, labeled, and packaged.

In addition, under the Food, Agriculture, Conservation, and Trade Act of 1990, as amended (7 U.S.C. 138-138i), FSIS has authority to accredit non-Federal laboratories. The accreditation allows non-Federal laboratories to conduct analyses of official regulatory meat and poultry samples. One provision (7 U.S.C. 138f) requires that a laboratory seeking accreditation under the 1990 Act or under the FMIA or PPIA pay a

non-refundable accreditation fee to cover the costs of the Accredited Laboratory Program.

Laboratory Accreditation Fees

FSIS is proposing to amend 9 CFR 391.5(a) to change the fee structure for the accreditation and the maintenance of the accreditation of laboratories for the FSIS Accredited Laboratory Program (ALP).

Currently, FSIS charges each laboratory a flat annual fee of \$5,000 per accreditation or maintenance of accreditation. A laboratory may apply for FSIS accreditation and maintenance of accreditation in one to six analyte classes: Food Chemistry, chlorinated hydrocarbons (CHCs), polychlorinated biphenyls (PCBs), arsenic, nitrosamines, and sulfonamides. FSIS charges laboratories the flat rate of \$5,000 for each accreditation obtained regardless of the type or the number of accreditations. A laboratory accredited for all six analyte classes is charged a total fee of \$30,000. FSIS bills annually for the services it provides the laboratories, which includes the cost of FSIS auditing non-Federal laboratories, conducting periodic proficiency test sample studies, on-site review, maintenance of accreditation (includes analyzing proficiency test results and documentation) and other additional costs.

The Agency has determined that the costs to the Accredited Laboratory Program can be reduced when laboratories apply for

multiple accreditations. Most of the cost to the Agency in conducting the ALP is in travel and administering sample studies to determine laboratory proficiency.

FSIS is proposing a sliding scale for accreditations and the maintenance of accreditations after payment of the base fee of \$5,000 for the first accreditation that a laboratory receives. Under the proposal, the Agency would charge laboratories \$5,000 per year for the first analyte class accreditation or maintenance of accreditation, \$2,900 per year for the second, and \$2,100 per year for each additional analyte class accreditation or maintenance of accreditation.

The Agency is proposing a fee of \$2,900¹ for the second accreditation because FSIS staff can review multiple accreditations (different analyte classes) for the same laboratory in one trip. FSIS is proposing \$2,100² for the third, fourth, fifth, and sixth accreditations because, when a laboratory has three or more accreditations, some of the instrument types and chemical processes are similar. This fact means that the review will be less labor intensive. FSIS has determined that the proposed costs to participants in the accredited laboratory program will cover the cost to the Agency for the administration of the program. The proposed costs are

1 Source: FSIS, OPHS, LQAS, Accredited Laboratory Program.

2 Ibid.

included below in Table 1 and are based on available FSIS laboratory and personnel cost data.

Table 1. Proposed ALP Fee Schedule

	Accreditations		
Item	1	2	3-6
Auditing of non-Federal Laboratories	\$ 2,546	\$ 816	\$ 408
Proficiency Tests	\$ 1,237	\$ 1,237	\$ 1,237
Maintenance of Accreditation	\$ 918	\$ 536	\$ 153
Additional Costs	\$ 347	\$ 347	\$ 347
Total	\$ 5,048	\$ 2,936	\$ 2,145
Rounded Total	\$ 5,000	\$ 2,900	\$ 2,100

Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated a "non-significant" regulatory action under section 3(f) of Executive Order (E.O.) 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget under E.O. 12866.

Baseline

The FSIS Accredited Laboratory Program, (ALP) is voluntary and charges a non-refundable accreditation fee. Currently, the annual fee is \$5,000 per accreditation (Table 2). As discussed above, FSIS is proposing to reduce fees after the first accreditation. Table 2 below compares current fees to proposed fees.

Table 2: Current and Proposed Accreditation Fee Schedule		
Accreditation	Current Accreditation Lab Fee	Proposed Accreditation Lab Fee
First	\$5,000	\$5,000
Second	\$5,000	\$2,900
Third - Sixth	\$5,000	\$2,100

Currently, there are 53 laboratories accredited for 60 activities.³ Most (42 out of 53) laboratories are accredited for food chemistry. There are 13 laboratories accredited for CHCs and five laboratories for PCBs. Only five of the 53 laboratories are accredited for more than one analyte. These laboratories are accredited for 2-3 analytes. The analysis below assumes laboratories will keep the same number of accreditations under the new fee structure.

³ FSIS, OPHS, LQAS, Accredited Laboratory Program

Expected cost of the Proposed Rule

For the purposes of this analysis, FSIS considers the pre- and post-rule cost to the industry. They are shown in table 3 below. The cost to the industry will fall from \$300,000 per year to \$283,700 per year.

Table 3. Expected Annual Costs Pre- and Post-Rule

# of Analyte Classes	Pre Rule		Post Rule	
	# Labs	Industry Cost	# Labs	Industry Cost
1	48	\$240,000	48	\$240,000
2	3	\$30,000 ⁴	3	\$23,700 ⁵
3	2	\$30,000	2	\$20,000
	53	\$300,000	53	\$283,700

Expected Benefits of the Proposed Rule

The benefit accrued to the industry is equivalent to current accreditation costs minus the proposed accreditation costs which incorporate the proposed efficiencies outlined in the preamble.

The proposed rule will benefit the lab industry by offering a sliding accreditation fee schedule. The lower cost is a result of leveraging efficiencies in the current accreditation process that will allow the industry to realize cost savings if

4 Calculation - Total Cost = (Accreditation 1 Cost * Number of Laboratories) + (Accreditation 2 Cost * Number of Laboratories) = (\$5,000 * 3) + (\$5,000 * 3)

5 Calculation - Total Cost = (Accreditation 1 Cost * Number of Laboratories) + (Accreditation 2 Cost * Number of Laboratories) = (\$5,000 * 3) + (\$2,900 * 3)

they increase the number of accreditations. Under the current accreditation fee schedule, the total industry cost is estimated as \$300,000 ($\$300,000 = 60 \text{ Accreditations} \times \$5,000$) (Table 3). Should the proposed rule be finalized, the total industry cost would be \$283,700, a net benefit of \$16,300 ($\$300,000 - \$283,700 = \$16,300$). If the total number of accreditations remains unchanged, the present value of total industry net benefit due to the proposed rule (Table 4), adjusted with 3% inflation rate for 10 years is \$139,000, resulting in an annualized expected benefit of \$16,295.

Table 4. Summary of Costs and Benefits

Current Costs (FY13)	Proposed Costs (FY14)	Proposed Benefits	Net Benefits (10 years, 3%)
\$ 300,000	\$ 283,700	\$ 16,300	\$ 139,000

Regulatory Flexibility Analysis

The FSIS Administrator has made a preliminary determination that this proposed rule would not have a significant economic impact on a substantial number of small entities in the United States, as defined by the Regulatory Flexibility Act (5 U.S.C. 601 et seq.).

Paperwork Reduction Act

FSIS has reviewed this rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) and has determined that there is no information collection related to this proposed rule.

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, et seq.) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this proposed rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted, (2) no retroactive effect will be given to this rule, and (3) no retroactive proceedings will be required before parties may file suit in court challenging this rule.

Executive Order 13175

This proposed rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this proposed regulation will not have substantial and

direct effects on Tribal governments and will not have significant Tribal implications.

USDA Nondiscrimination Statement

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (Not all prohibited bases apply to all programs.)

Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's Target Center at (202) 720-2600 (voice and TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250-9410 or call (202) 720-5964 (voice and TTY).

Additional Public Notification

FSIS will announce this proposed rule online through the FSIS Web page located at <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register>.

FSIS will also make copies of this Federal Register publication available through the FSIS Constituent Update, which

is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

List of Subjects in 9 CFR Part 391

Fees and charges

For the reasons discussed in the preamble, FSIS is proposing to amend 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. 1622, 1627, and 2219a; 21 U.S.C. 451 et seq.; 21 U.S.C. 601-695; 7 CFR 2.18 and 2.53..

2. In §391.5 revise paragraph (a) to read as follows:
§391.5 Laboratory accreditation fee.

(a) The annual fee for the accreditation and maintenance of accreditation provided pursuant to §439.5 of this chapter shall be \$5,000 for the first analyte class, \$2,900 for the second analyte class, and \$2,100 for each additional analyte class.

* * * * *

Done at Washington, DC on: March 24, 2014.

Alfred V. Almanza,
Administrator.

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