

lists of biological agents and toxins in both 7 CFR 331.3 and 9 CFR 121.3.

The Act requires that the lists of biological agents and toxins be reviewed and republished biennially, or more often as needed, and revised as necessary. In addition, the Act requires that, when determining whether to include an agent or toxin, the Secretary shall consult with appropriate Federal departments and agencies and with scientific experts representing appropriate professional groups.

In preparation for the biennial review of the list required by the Agricultural Bioterrorism Protection Act of 2002, APHIS' Plant Protection and Quarantine program intends to reevaluate and further develop the criteria used to determine whether an agent has the potential to pose a severe threat to plant health or products. Accordingly, we are holding a series of public meetings to provide a forum for discussion of the criteria that should be used.

The meetings will be held on August 12, 2003, from 5:30 to 8:30 p.m. in Charlotte, NC; on August 19, 2003, from 9 a.m. to 3 p.m. in Riverdale, MD; and on August 21, 2003, from 9 a.m. to 3 p.m. in Sacramento, CA. Information regarding the meetings may be obtained from the person listed under **FOR FURTHER INFORMATION CONTACT**.

Written Comments

If you cannot attend the meeting, you may submit written comments on the topics outlined in this notice. To submit written comments, please follow the instructions listed under the heading **ADDRESSES** near the beginning of this document.

Done in Washington, DC, this 21st day of July, 2003.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 130

[Docket No. 00-024-1]

Veterinary Diagnostic Services User Fees

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to increase the user fees for veterinary diagnostic

services to reflect changes in our operating costs and changes in calculating our costs. We are also proposing to set rates for multiple fiscal years. These proposed actions are necessary to ensure that we recover the actual costs of providing these services. We are also proposing to provide for a reasonable balance, or reserve, in the veterinary diagnostics user fee account. The Food, Agriculture, Conservation, and Trade Act of 1990, as amended, authorizes us to set and collect these user fees.

DATES: We will consider all comments that we receive on or before September 22, 2003.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 00-024-1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. 00-024-1. If you use e-mail, address your comment to regulations@aphis.usda.gov. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 00-024-1" on the subject line.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

FOR FURTHER INFORMATION CONTACT: For information concerning program operations, contact Dr. Randall Levings, Director, National Veterinary Services Laboratories, 1800 Dayton Road, P.O. Box 844, Ames, IA 50010; (515) 663-7357.

For information concerning rate development for the proposed user fees, contact Mrs. Kris Caraher, Accountant, User Fees Section, MRPBS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737-1231; (301) 734-8351.

SUPPLEMENTARY INFORMATION:

Background

User fees to reimburse the Animal and Plant Health Inspection Service (APHIS) for the costs of providing veterinary diagnostic services and import and export related services for live animals and birds and animal products are contained in 9 CFR part 130 (referred to below as the regulations). These user fees are authorized by section 2509(c) of the Food, Agriculture, Conservation and Trade Act of 1990, as amended (21 U.S.C. 136a), which provides that the Secretary of Agriculture may, among other things, prescribe regulations and collect fees to recover the costs of veterinary diagnostics relating to the control and eradication of communicable diseases of livestock or poultry within the United States.

In this document, we are proposing to amend the regulations by increasing the user fees for certain veterinary diagnostic services, including certain diagnostic tests, reagents, and other veterinary diagnostic materials and services. Operating costs have increased since these user fees were established in a final rule published in the **Federal Register** on October 7, 1998 (63 FR 53783-53798, Docket No. 94-115-2). Therefore, the user fees need to be updated to reflect those increases. However, the main reason for the increase in the fees is due to new cost-finding techniques employed by APHIS. The Statement of Federal Financial Accounting Standards (SFFAS) No. 4, "Managerial Cost Accounting Standards and Concepts," issued by the Office of Management and Budget, mandated that APHIS capture cost accounting data in its program costs. We were required to accumulate and report the costs of veterinary diagnostic activities on a regular basis through the use of cost accounting systems and cost finding techniques. In order to comply with SFFAS No. 4, APHIS conducted an Activity Based Costing (ABC) project at the National Veterinary Services Laboratories (NVSL) in Ames, IA, which identified the sources of all costs for veterinary diagnostic services. As a result of that project, we determined that costs for user fee-related services were not adequately being recovered through user fee collections. Based on this determination, we are proposing new fees to recover these newly identified costs. Each of the updated user fees contains a proportionate share of the costs identified in the ABC study. The user fees that we are proposing for veterinary diagnostic goods and services would cover multiple fiscal years (2004 through 2007 and beyond). Establishing annual user fee changes in

advance would allow users to incorporate the fees into their budget planning.

Veterinary diagnostics is the work performed in a laboratory to determine if a disease-causing organism or chemical agent is present in body tissues or cells and, if so, to identify those organisms or agents. Services in this category include: (1) Performing laboratory tests and providing diagnostic reagents and other veterinary diagnostic materials and services at the NVSL Foreign Animal Disease Diagnostic Laboratory (NVSL FADDL) in Greenport, NY; and (2) performing identification, serology, and pathobiology tests and providing diagnostic reagents and other veterinary diagnostic materials and services at NVSL in Ames, IA.

APHIS veterinary diagnostic user fees fall into six categories:

- (1) Laboratory tests, reagents, and other veterinary diagnostic services performed at NVSL FADDL;
- (2) Laboratory tests performed as part of isolation and identification testing at NVSL in Ames;
- (3) Laboratory tests performed as part of serology testing at NVSL in Ames;
- (4) Laboratory tests performed at the pathobiology laboratory at NVSL in Ames;
- (5) Diagnostic reagents produced at NVSL in Ames or other authorized sites; and
- (6) Other veterinary diagnostic services or materials provided at NVSL in Ames.

Need for Regulation

User fees recover the cost of operating a public system by charging those members of the public who use the system, rather than the public as a whole, for its operation. Financing veterinary diagnostic services and products by charging for the right to use the incremental service internalizes those costs to those who require the service and benefit from it.

Veterinary diagnostic services and products enhance livestock production, trade, and research. The socially optimal prices for such commodities, of which veterinary diagnostics are inputs, are those price levels that induce the output level where the marginal benefit (what people are willing to pay for the good) is exactly equal to the marginal social cost (all costs associated with the production of the final output, including veterinary diagnostics). As it stands now, veterinary diagnostic services and products are provided at levels below their full cost to APHIS. These costs are, therefore, only partly incorporated into producers' costs of

production. Our proposed revisions of the fee-for-service charges to recover the costs incurred by APHIS would move the private costs of individuals closer to the true cost of producing their outputs. The proposed annual increases, which would span fiscal years 2004 through 2007, would help ensure that the fees accurately reflect the cost of providing the service.

Development of Fee Structure

User fee components. The user fees proposed in this document are based on average laboratory employee salaries and benefits in each of the fiscal years 2004 through 2007, and estimates of the number of direct labor hours required to provide each service. The proposed user fees have been calculated to recover the full costs for tests, diagnostic reagents, and other veterinary diagnostic services. These costs include direct labor costs, administrative support costs, premium costs (if any), agency overhead costs, and departmental charges. These components are described below; the user fee calculation for the proposed virus isolation fee for fiscal year (FY) 2004 is used throughout as an example.

We are proposing to charge a specific dollar amount for each service we provide (*i.e.*, for each test we perform or each diagnostic reagent or other veterinary diagnostic service we provide). We have attempted to minimize the costs of our services, thereby keeping APHIS user fees at the lowest possible level. If, in the future, a user requests a test, diagnostic reagent, or other veterinary diagnostic material or service that is not specifically listed in our regulations, we would charge the proposed hourly user fee set forth in proposed § 130.19 for the amount of time required to perform the service, calculated to the nearest quarter of an hour.

Each user fee varies based on the direct labor hours required to perform the test or provide the diagnostic reagent or other veterinary diagnostic material or service. For example, the time spent by laboratory personnel to prepare a sample, conduct the test, and read the test would be part of the direct labor hours for testing a tissue sample for disease-causing organisms. In cases where a test is performed for more than one disease, it may take different amounts of time for each disease. Those times have been averaged to calculate the user fee for the test. We have carefully calculated all of our proposed user fees to correctly reflect the direct labor hours required for each test, reagent, or service. We took into account variations in the time needed to provide a service by determining the average

time necessary to provide the service; similar user fee components are used for other agency user fees throughout the regulations.

Direct labor costs. Direct labor costs are the average salary and benefit costs of the laboratory employees performing the service multiplied by the estimated direct labor hours required. Average laboratory costs were used to calculate direct labor costs because we have determined that it is more accurate to use the average salary for laboratory employees to calculate the user fee. For example, the estimated average laboratory salary at the Diagnostic Virology Lab for FY 2004 is \$28.85 per hour. On average, it takes 0.295 hours per virus isolation test, leading to direct labor costs of \$8.51.

Administrative support costs. Administrative support costs are incurred at the laboratories. They include clerical and administrative activities; direct materials; indirect labor hours; rent; billing and collection costs; travel and transportation for personnel, supplies, equipment, and other necessary items; training; legal counsel; capital equipment costs; general supplies for offices, washrooms, and cleaning; contractual services; grounds maintenance; and utilities. Direct materials include the cost of any materials needed to conduct the test or to provide the diagnostic reagent, slide set, tissue set, or service. For example, direct materials for conducting a laboratory test include, but are not limited to, glassware, chemicals, and other supplies necessary to perform the test. Indirect labor hours include supervision of personnel and time spent doing necessary work, such as repairing equipment, that is not directly connected with a specific test, diagnostic reagent, or other veterinary diagnostic material or service. Contractual services may include, but are not limited to, guard service, trash pickup, and maintenance. Utilities include water, telephone, electricity, natural and propane gas, and heating and diesel oil.

The costs of administrative support are applied as a percentage of the base direct labor amount; at NVSL in Ames, administrative support is 296 percent of direct labor, and at NVSL FADDL, administrative support is 1,638 percent of direct labor. For example, the administrative support costs for the virus isolation test are calculated at 296 percent of its direct labor costs of \$8.51 to be \$25.19. The total direct labor and administrative support costs for one virus isolation test are \$33.70.

NVSL FADDL administrative support costs compared to NVSL in Ames costs.

Readers may note that our proposed user fees for tests performed at NVSL FADDL are higher than our proposed user fees for the same tests performed at NVSL in Ames. Both NVSL FADDL and NVSL in Ames work with infectious and contagious disease agents. However, NVSL FADDL, which is isolated from the U.S. mainland, is designed to work specifically with highly infectious diseases exotic to the United States. Because of this, special biosecurity measures are required at NVSL FADDL that are not required at NVSL in Ames. As a result, NVSL FADDL operating costs are higher than NVSL in Ames' operating costs. The user fees we are proposing reflect this difference in costs.

Premium costs. Premium costs are expenses that are incurred solely for a specific test or service. For example, certain tests require expensive reagents in addition to the direct labor time and laboratory materials included in administrative support costs. Premium costs for the proposed flat rate user fees have been included in the proposed calculated fees. For example, each sterilization by gamma radiation at NVSL FADDL requires special radioactive materials, irradiation costs, and travel costs for an APHIS employee to hand-carry the material. Based on the high amount of costs involved, these premium costs have been added to the proposed specific fee involved rather than included as an administrative support cost that is spread among all fees for tests, reagents, and other services.

Agency overhead. Agency overhead is the pro rata share, attributable to a particular diagnostic reagent, material, or veterinary diagnostic service, of the management and support costs for all Agency activities at the regional level and above. Included are the costs of providing budget and accounting services, management support at the headquarters and regional levels, including the Administrator's office, and personnel services, public information services, and liaison with Congress. Agency overhead is calculated at 16.15 percent of total direct labor and support costs. For example, the agency overhead for one virus isolation test is \$5.44, which is the product of virus isolation direct labor and administrative support costs of \$33.70 multiplied by 16.15 percent.

Departmental charges. Departmental charges are APHIS's share, expressed as a percentage of the total cost, of services provided centrally by the U.S. Department of Agriculture. Services the Department provides centrally include the Federal telephone service; mail;

National Finance Center processing of payroll, billing, collections, and other money management; unemployment compensation; Office of Workers Compensation Programs; and central supply for storing and issuing commonly used supplies and departmental forms. The Department notifies APHIS how much the agency owes for these services.

We have included a pro rata share of these departmental charges, as attributed to a particular test, diagnostic reagent, or other veterinary diagnostic material or service, in our user fee calculations at the rate of 5.23 percent. For example, departmental charges to perform one virus isolation test are \$2.05. This amount equals 5.23 percent of total direct labor costs, administrative support costs, and Agency overhead costs of \$39.14 described above.

Reserve. We are proposing to add an amount that would provide for a reasonable balance, or reserve, in the veterinary diagnostics user fee account. All user fees would contribute to the reserve proportionately. The reserve would ensure that we have sufficient operating funds in cases of fluctuations in activity volumes, bad debt, program shutdown, or customer insolvency. We intend to monitor the reserve balance closely and propose adjustments in our fees as necessary to ensure a reasonable balance. For example, the reserve amount included in the calculation for one virus isolation test is \$2.06 per test. The total costs in this example thus far equal \$43.25.

Calculation of proposed user fees. The basic steps in the calculation for each particular service are: (1) Calculate direct labor costs by determining the average amount of direct labor required to perform the service and multiply the average direct labor hours by the average salary and benefit costs for laboratory employees; (2) calculate the pro rata share of administrative support costs; (3) determine the premium costs (if any); (4) calculate the pro rata share of agency overhead and departmental charges, respectively; (5) add all costs; and (6) round up to the next \$0.25 for all fees less than \$10 or round up or down to the nearest dollar for all fees greater than \$10. For example, the total virus isolation cost per test for FY 2004 of \$43.25 is rounded down to \$43 per test. The result of these calculations is a user fee that covers the total cost to perform a particular test or provide a particular veterinary diagnostic material or service one time. As is the case with all APHIS user fees, we intend to review, at least annually, the user fees proposed in this document. We will

publish any necessary adjustments in the **Federal Register**.

In addition, we would remove the following tests because they are either obsolete, no longer being performed at NVSL in Ames or NVSL FADDL, or are being performed but being incorporated into another published rate:

Avian origin bacterial antisera, mycoplasma
Equine origin glanders antiserum
Leptospira culturing
Leptospira serotyping
Mycobacterium avium serotyping
Mycology culture identification
Mycology/fungus culture or isolation
Mycoplasma isolation
Mycoplasma identification
Plasmid typing
Warburg
Virus isolation for Newcastle disease virus
Brucella milk ELISA
Mercaptoethanol
Mycology/fungus serology
Check tests, anaplasma complement fixation
Manual, Brucellosis complement fixation
Manual, Anaplasmosis, Johnes's disease

We would also remove a footnote that appears in the tables in §§ 130.15(a) and 130.16(a) and (b). The footnote describes a discount that applies to all diagnostic, non-import-related complement fixation, hemagglutination inhibition, fluorescent antibody, indirect fluorescent antibody virus neutralization, and peroxidase linked antibody tests. The discount applies to the 11th and subsequent tests on the same submission by the same submitter for the same test and antigen. We have reevaluated the time it takes to conduct these additional tests and have determined that it is no longer cost effective to perform the tests at a discount. Therefore, we would remove the footnote from those tables.

Finally, in §§ 130.15(a), 130.16(a), and 130.18, we would amend the tables by updating several of the entries to reflect the designations currently used by NVSL to refer to the particular test or service. There would be no change in the services or tests themselves; the names would simply be changed to be consistent with the terminology used by NVSL.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

We are proposing to increase the user fees for veterinary diagnostic services to reflect changes in operating costs and changes in calculating our costs. These

proposed actions are necessary to ensure that we recover the actual costs of providing these services. We are also proposing to provide for a reasonable balance, or reserve, in the veterinary diagnostics user fee account. The reserve would ensure that we have sufficient operating funds in cases of fluctuations in activity volumes, bad debt, program shutdown, or customer insolvency. The Food, Agriculture, Conservation, and Trade Act of 1990, as amended, authorizes us to set and collect these user fees.

Estimated Impact of Changes in Veterinary Diagnostic User Fees

The calculation of impacts of the revision of veterinary diagnostic user fees is hindered by the difficulty in determining the elasticities of demand for the covered services and products. Therefore, Government savings are

assumed equivalent to the total additional user fee collections for each category addressed in this proposed rule. Projections of changes in collections are based on estimates of the annual volume of the affected services and products. Estimates of the annual volumes were made by the Financial Management Division of APHIS using actual volumes from prior years and input from the laboratories.

Change in Collections

Table 1 summarizes the estimated changes in user fee collections for FY 2004 through FY 2007 that are necessary to recover fully the costs of performing these services. These proposed changes would result in a total increase in annual user fee collections of about \$2.9 million over the period discussed in the proposed rule (from \$2.7 million at current fee levels to \$5.6 million in FY

2007). There would be increases in each year from FY 2004 to FY 2007. There would be an increase of about \$2.4 million in FY 2004, about an additional increase of \$101,200 increase in FY 2005, about a \$231,500 increase in FY 2006, and about a \$98,100 increase in FY 2007. If APHIS were to continue to collect user fees at the current rates over this time period, total collections would be approximately \$10.8 million. At the proposed rates, the total would be about \$21.4 million. Because the proposed changes in user fees are intended to cover cost changes that have already occurred and that are projected to occur over the period covered in the proposed rule, this difference of about \$10.6 million demonstrates the shortfall in cost recovery that would occur absent the changes, and, conversely, the savings to taxpayers associated with this proposal.

TABLE 1.—SUMMARY OF CURRENT AND PROJECTED COLLECTIONS OF APHIS VETERINARY DIAGNOSTIC USER FEES

User fee categories	Collections under current fee levels	Estimated additional annual collections from user fee changes				
		FY 2004	FY 2005	FY 2006	FY 2007	Total
FADDL, all	\$164,754	\$140,959	\$9,990	\$10,533	\$10,975	\$172,457
Identification Testing, NVSL	431,920	304,900	26,497	22,913	26,067	380,377
Serology Testing, NVSL	1,076,474	948,408	7,027	134,273	2,210	1,091,918
Pathobiology Testing, NVSL	89,249	29,495	4,050	4,806	4,802	43,153
Diagnostic Reagents, NVSL	480,692	591,526	34,045	38,130	32,866	696,587
Other Veterinary Diagnostic Services, NVSL	461,153	408,962	19,571	20,851	21,184	470,568
Total	2,704,242	2,424,299	101,180	231,506	98,124	2,855,059

The largest increase in collections would occur in FY 2004. The fee increases in FY 2004 cover cost increases that have occurred since the last revision of these fees, in addition to cost increases expected to occur in FY 2004. The increase of about \$2.4 million in veterinary diagnostic user fee collections in FY 2004 would be accounted for in the following manner. Collections from laboratory tests, reagents, and other veterinary services performed at NVSL FADDL would increase by about \$141,000; user fee collections for veterinary diagnostic isolation and identification tests performed at NVSL in Ames would increase by about \$305,000; user fee collections for serology tests performed at NVSL in Ames would increase by about \$948,000; user fee collections for veterinary diagnostic tests performed at the pathobiology laboratory at NVSL in Ames would increase by about \$29,000; user fee collections for reagents produced at NVSL in Ames would increase by about \$592,000; and user fee collections for other veterinary diagnostic services performed at NVSL

in Ames would increase by about \$409,000.

Impact on Users

Veterinary diagnostic services and products are provided to animal importers and exporters, veterinarians, State and Federal agencies and laboratories, commercial laboratories, educational institutions, and foreign governments. To the extent that the proposed changes in user fees would impact operational costs, any entity that utilizes APHIS veterinary diagnostic products or services subject to user fees could be affected by the proposed fee increases. The degree to which any entity could be affected depends on its market power (the extent to which costs can be either absorbed or passed on to its buyers). While the lack of information on profit margins and operational expenses of the affected entities, or the supply responsiveness of the affected industry, prevents the precise prediction of the scale of impacts, some conclusions on overall impacts to domestic and international commerce can be drawn.

The increases in user fees in this proposal represent significant percentages, primarily in the first year covered by this proposed rule. In all six categories, the average proposed fee change exceeds 80 percent in the first year and 100 percent in total over the period covered in the proposed rule. If the user fees cannot be passed on to their customers, the profit margins of some entities may decline as user fees are increased. However, new techniques now allow APHIS to better identify the true costs of providing the veterinary diagnostic services and products covered by user fees. These techniques have shown that there are considerable differences between those true costs and the user fees APHIS has been charging. Operating costs have increased since the last time these fees were adjusted. In addition, it has been shown that the direct labor portion of the fee calculations was vastly underestimated for many of the fees in previous calculations. When a user fee does not cover all associated costs, those costs are shifted away from those receiving and benefitting from the service and

onto APHIS, and thus ultimately to the taxpayer.

There is also reason to believe that the economic effects of the proposed changes on most users would be small. The majority of the user fees would increase by \$50 or less. The majority of the proposed fees should also make only a small contribution to the total additional collections and, therefore, would have a minor impact on the users of those services. This is either because the proposed change is small or the projected volume associated with the user fee is small, or both. In addition, user fees are not charged when tests are provided in the United States in association with a Federal or cooperative disease control program. Also, in addition to the role they play in protecting American agriculture, the veterinary diagnostic services and products we provide facilitate international trade and thereby enhance the business interests of many of those requesting these services.

Nearly 59 percent of the total projected change in collections would come from changes in only 9 of the 190 fees, and more than 93 percent of the change would come from changes in just 43 of the fees covered in this proposed rule. These 43 proposed fee changes are projected to generate \$10,000 or more each in additional annual collections by the end of the period covered by the proposed rule. Several factors suggest, however, that these fee increases should not have a significant impact on users. These fees include small fees applied to a large annual volume of users, large fees applied to a very small volume of users, fees that represent a small percentage of the overall costs associated with a user's output, single fees for reagents with numerous final users, and fees that enhance the marketability of the users' final outputs.

Small Change in Collections

The majority of the individual user fee changes in this proposal would

make only small contributions to the total additional collections, and, therefore, would have a minor effect on the users of those services. This is either because the change in the fee is small or the projected volume associated with the user fee is small, or both (see Table 2).

1. More than 60 percent of the user fees would change by less than \$50, and nearly 16 percent by less than \$10.

2. Nearly 50 percent of the user fees are projected to have an annual volume of 10 or fewer users, and about 65 percent fewer than 90.

3. More than 31 percent of the user fees would change by \$50 or less and have a projected annual volume of 50 or fewer users.

4. More than 62 percent of the fees with more than 100 annual users would change by \$25 or less, and about 62 percent of the fees that would change by more than \$50 have an estimated annual volume of 10 or fewer users.

TABLE 2.—INCREASES AND VOLUMES ASSOCIATED WITH VETERINARY DIAGNOSTIC USER FEES

Total increase in user fee:	Number of fees with estimated annual volume of:				
	10 or fewer	11 to 20	20 to 50	51 to 100	More than 100
\$10 or less	10	1	1	2	15
\$10.01 to \$25	16	3	3	1	26
\$25.01 to \$50	21	2	2	0	10
\$50.01 to \$100	29	1	4	1	9
More than \$100	16	2	4	1	6

Program Diseases

When considering the proposed user fee changes, it is important to realize that user fees are not charged for tests and diagnostic reagents provided in the United States required in connection with current Federal or cooperative programs to control or eradicate various domestic diseases or pests, known as "program diseases." Examples of program diseases are tuberculosis, brucellosis, and pseudorabies. In those situations, no user fee would be charged for veterinary diagnostics.

Large Contributions to Collections

The following factors suggest that even those proposed user fee changes that would generate more than \$10,000 in additional annual collections may have a minimal impact on users.

Thirty-six of the 43 proposed user fees that we expect would generate more than \$10,000 each in additional annual collections would change by less than \$75 each, and 14 would change by less than \$25 each. In addition, most of the user fees covered in this proposal are

collected in association with imports or exports. While those user fees would increase under this proposed rule, the fees continue to represent only a small fraction of the typical costs of purchasing and importing breeding grade registered animals into the United States, which can be between \$1,500 and \$5,000 per head. Purchase and import costs for feeder and slaughter animals are often significantly lower per animal but can easily exceed \$1,500 per shipment depending on the number and type of animals in the shipment. About 18 percent of the total change in collections would come from a single user fee, that for complement fixation (CF) tests. About 90 percent of the CF test user fees are collected for import and export. The \$5 change in the first year under the proposed fees and the \$7 total change in the user fee for CF tests in \$ 130.16 would be very small in relation to the value of the animals involved and to the costs associated with importing and exporting animals. By providing the tests, this movement is facilitated.

A number of the proposed reagent user fees should generate considerable additional annual collections under this proposal. However, while these proposed changes represent considerable percentage increases in those fees, each purchasing laboratory can use the reagents to perform several hundred tests. Therefore, the purchasing laboratory can spread its costs across those several hundred tests for its customers. In addition, provision of the reagents enhances the purchasing laboratory's business, for without the reagents the tests would not be possible.

Along this same line, the fact that check tests would generate considerable additional collections under this proposal should have only a small impact. By passing (getting the correct results on a check test kit), the laboratory is certified to conduct the particular test on samples that are received by the laboratory. Being certified by APHIS to conduct a test enhances a laboratory's ability to attract customers.

Laboratory Tests, Reagents, and other Veterinary Services Performed at NVSL FADDL

The proposed user fee changes for NVSL FADDL veterinary diagnostic services and products could generate additional annual collections of about \$141,000 in the first year and about \$172,000 after all increases covered in this proposal have been implemented. These user fees cover veterinary diagnostic services and products associated with foreign animal diseases, including the diagnosis of foreign animal diseases, training in foreign animal disease recognition, reagent production, and vaccine testing. It should be noted that the NVSL FADDL laboratory is isolated from the mainland United States. Because the laboratory works with diseases exotic to the United States, special biosecurity measures are required at NVSL FADDL that are not required at NVSL in Ames, IA. The proposed user fees reflect the higher operating costs at NVSL FADDL.

Most of the user fees in this category would increase substantially under this proposed rule. The average increase in the first year would be about 89 percent. However, the total impact of the proposed changes should be small. Of the 35 fees in this category, only 4 are associated with increased annual collections of more than \$10,000 each over the entire time period covered in the proposal. These four fees would account for more than 86 percent of the additional collections in this category. By the end of FY 2007, collections from hourly fees would have increased by about \$64,000 annually, collections for virus neutralization tests would have increased by about \$55,000 annually, collections for enzyme linked immunosorbent assay tests would have increased by about \$17,000, and collections for indirect fluorescent antibody tests would have increased by about \$12,000. In addition, the nature of the work at NVSL FADDL should limit the impact of the proposed changes in the user fees. The user fee work at NVSL FADDL is restricted to work associated with foreign animal diseases, and this limits the volume of user fee work at the laboratory. The majority of the user fee work is associated with imports. For example, the virus neutralization test is often used as a prescreening test for foot-and-mouth disease prior to an animal leaving its country of origin to ensure that the animal will not be refused entry into the United States and reexported. Also, a good deal of the user fee work at NVSL FADDL is performed in conjunction with the import of master seeds/cells for vaccines. The

overall cost of developing and importing these vaccines is very high. Because of this, the user fees and the proposed increases in those fees represent a very small portion of an importer's costs.

Veterinary Diagnostic Isolation and Identification Tests Performed at NVSL in Ames

The proposed user fee changes for veterinary diagnostic isolation and identification tests performed at NVSL in Ames could generate additional annual collections of about \$305,000 in FY 2004 and about \$380,000 by the end of FY 2007. The average proposed increase in the fees in this category is more than 100 percent in the first year. However, the total impact of the changes should be small. The average increase in the first year would be less than \$36, and 12 of the 20 fees in this category would change in total by less than \$30 each. Only six of these fees should generate \$10,000 or more in additional annual collections. Two of these fees are primarily associated with required testing at poultry slaughtering facilities, and are paid for by the Food Safety and Inspection Service (FSIS): Bacterial serotyping (Salmonella), which is projected to generate a total of about \$119,000 in additional annual collections, and phage typing (all other), which is projected to generate a total of about \$14,000 in additional annual collections. User fees for these tests are only charged for research and for confirming the FSIS tests. The proposed changes in the user fee for virus isolation tests are projected to generate total additional collections of \$75,000. However, the change in this fee would be only \$11.50 in the first year and \$16.50 in total for virus isolations other than for Newcastle disease.

Veterinary Diagnostic Serology Tests Performed at NVSL in Ames

The proposed user fee changes for veterinary diagnostic serology tests performed at NVSL in Ames could generate additional annual collections of about \$948,000 in FY 2004 and about \$1.1 million by the end of FY 2007. The average total increase in the fees in this category would be more than 100 percent. However, the total impact of these proposed changes should be small. The average increase in the first year would be less than \$9 and would increase by less than \$10 in total. Only three of the fees in this category would increase in total by more than \$20, and 16 would increase by less than \$10. The proposed user fee for CF tests should generate about \$509,000 in total additional annual collections, but the increase in this fee would be only \$6 in

the first year and \$7 in total. About 90 percent of the CF test user fees are collected for import and export. The increases in this user fee would be very small in relation to the value of the animals involved and the costs associated with importing and exporting animals. For example, moving horses into or out of the United States generally requires four CF tests. Breeding stallions move between the northern and southern hemispheres to double the number of annual breeding seasons. These stallions, valued on average at approximately \$400,000 and reaching \$2 to \$4 million, can command breeding fees of at minimum \$10,000 per mare covered. Moving horses by air can cost between \$6,000 and \$9,000 per horse. The user fees represent a tiny portion of the total cost of moving these animals into the country, and by providing the tests, this movement is facilitated.

Veterinary Diagnostic Tests Performed at the Pathobiology Laboratory at NVSL in Ames

The proposed changes in the user fees for veterinary diagnostic tests performed at the pathobiology laboratory at NVSL in Ames could generate additional annual collections of about \$29,000 in FY 2004 and about \$43,000 by the end of FY 2007. The average increase in the fees in this category would be less than \$30 in the first year and \$35 in total. Only two of the proposed fees in this category are projected to generate more than \$10,000 each in additional total annual collections, and the rest less than \$1,000 each. Both of these two fees would change by less than \$10 each in the first year, and by less than \$15 each in total.

Veterinary Diagnostic Reagents Produced at NVSL in Ames

The proposed changes in user fees for veterinary diagnostic reagents produced at NVSL in Ames could generate additional annual collections of about \$592,000 in FY 2004 and about \$697,000 by the end of the FY 2007. The proposed changes to 16 of these fees should generate a total of more than \$10,000 each in additional annual collections. The average increase in this category is less than \$60 in the first year and \$70 in total. Thirty-one of the fees increase by less than \$50 each in total, and 20 by \$25 or less each. While these proposed changes represent considerable percentage increases in those fees, the reagents are the basis for doing tests. The purchasing laboratory can use the reagent to perform several hundred tests. Therefore, the purchasing laboratory can spread its costs across those several hundred tests for its

customers. In addition, the ability to obtain these reagents from APHIS enhances the purchasing laboratory's business, for without the reagents the tests would not be possible.

Other Veterinary Diagnostic Services or Materials Provided at NVSL in Ames

The proposed changes in user fees for other veterinary diagnostic services or materials provided at NVSL in Ames could generate additional annual collections of about \$409,000 in FY 2004, and about \$471,000 by the end of FY 2007. Providing check tests could account for about 47 percent of the total additional collections in this category, about \$221,000. NVSL in Ames certifies laboratories to conduct certain tests, employing "check test kits" to perform the certification. The kits consist of about 20 sera (or live organisms if it is for culture), and the laboratory conducts the test it wants to be certified to perform using the sera in the check test kit. The laboratory must get a predetermined number of the sera right (positive or negative) in order to pass and be certified to run the tests. The proposed user fees for this service should not have a significant impact on the laboratories because being certified by APHIS to conduct a test enhances their ability to attract customers who pay the laboratory to conduct tests. Another large portion of the additional annual collections would be from the proposed fee for fetal bovine serum safety test. The proposed changes to this fee are projected to generate total additional annual collections of about \$131,000 by the end of FY 2007. This fee is for testing fetal bovine serum to be sure it is free of foreign viruses. This serum is needed to grow viruses and is used by biologics manufacturers and diagnostic laboratories. Its value is high even relative to the large fee for the test.

Small Entities

The Regulatory Flexibility Act requires that agencies specifically consider the economic impact associated with their rules on small entities. The Small Business Administration (SBA) has set size criteria according to the categories of the North American Industrial Classification System (NAICS), which is used as a guide in determining which economic entities meet the definition of a small business.

The veterinary diagnostic services provided by APHIS at NVSL FADDL and NVSL in Ames are provided to determine if a disease-causing organism or chemical agent is present in body tissues or cells and to identify those organisms or agents. As such, the users

of these services and products include importers, exporters, non-APHIS veterinarians, commercial laboratories and pharmaceutical manufacturers, State laboratories, universities, and foreign governments. These users may be affected by the proposed changes to user fees for veterinary diagnostic services and products.

The SBA's criterion for a small entity engaged in importing and exporting live animals, poultry, and birds is 100 or fewer employees. The criterion for a small veterinary testing laboratory is \$6 million or less in annual sales. The criterion for a small pharmaceutical manufacturing company is 750 or fewer employees.

The number of entities specifically using the veterinary diagnostic products and services covered in this proposal that would qualify as a small entity under SBA criteria cannot be determined at this time. However, more than 99 percent¹ of the entities in livestock wholesale, poultry wholesale, and other farm product raw material wholesale (including horses and mules) can be considered small. Under NAICS, import and export merchants, agents, and brokers are included in the wholesale trade sector. According to the latest available information,² 94 percent of all testing laboratories, including veterinary testing laboratories, can be considered small. According to the 1997 Economic Census, at least 97.9 percent³ of all chemical manufacturers can be considered small. Pharmaceutical manufacturing is included in this category under NAICS. It is, therefore, likely that the majority of users affected can be considered small. However, because the overall impacts of the proposal are expected to be limited, the impacts on small entities should be limited as well.

Costs and Benefits of User Fees

User fees for veterinary diagnostic services and products are intended to meet broad economic objectives. User fees promote the internalization of the real cost of providing veterinary diagnostic services and products in consumer transaction decisions. User fees also achieve savings in Government expenditures, and, therefore, reduce the tax support necessary for the system to operate at a given level. These tax funds can then be used in other programs or to reduce taxes overall and, thus, diminish the efficiency losses associated

with the generation of taxes (deadweight loss plus collection costs).

Cost of Services

User fees reduce Government expenditures for fee-based services by shifting the burden of financing Federal services from general taxpayers to users and by curtailing the amount demanded for veterinary diagnostic service-related products. The consumer response to user fees is a movement toward a more socially optimal level of demand where users incorporate the cost of veterinary diagnostic services and products into their private costs.

As circumstances affecting the cost of providing services and products change, the amount of the user fees must be reevaluated to ensure that the user fee accurately reflects the cost of providing the services at that point in time. The socially optimal level of output, where the true cost is more fully incorporated into the transaction, is therefore maintained.

Benefits of Services

The net gain associated with the adjustment in consumer demand is quantified by subtracting the consumer welfare losses from the savings in Government expenditures. The magnitude of this gain depends on the elasticities of demand for each particular service or product (consumer responsiveness to changes in user fees). These elasticities are unknown. The demand for veterinary diagnostic services and products is intertwined with the demand for the commodities of which the products and services are inputs. However, there is no evidence to suggest that a significant change in demand for veterinary diagnostics has occurred due to the imposition or alteration of user fees in the past. When consumer adjustment is small, there is a correspondingly low net social gain.

Additional social gain can be expected from the reduction in losses associated with collecting and apportioning taxes to finance the veterinary diagnostic products and services. This reduction in losses arises from the internalization by consumers of the social cost of obtaining veterinary diagnostic products and services, and from the reduction in deadweight losses due to taxation.

Comparison of Benefits and Costs

To evaluate the overall costs and benefits of the user fee program, the two types of net benefits must be compared with the cost of the user fees. Because the demand elasticities for the veterinary diagnostic service-related products are unknown, the only

¹ U.S. Census Bureau, 1997 Economic Census.

² U.S. Census Bureau, 1992 Economic Census.

³ In 1997, 13,187 of 13,474 chemical manufacturing establishments had fewer than 500 employees.

measures are the savings in Government expenditures and the administrative cost involved in obtaining these savings. APHIS already has a user fee program and a mechanism for collecting these fees in place. This proposal would update existing fees. Therefore, increases in administrative costs would be very small. Differences between the level of the user fees and actual cost of performing the services have become considerable. Therefore, the Government savings associated with this proposal should be substantial. It is likely that the net gain in reducing the burden on taxpayers as a whole would outweigh the cost of administering the revisions of the user fees.

The proposed user fee increases are needed to move toward economic efficiency. From the point of view of society, the optimal level of output is where the marginal benefit to society equals the marginal cost to society. User fees help to internalize the cost of performing the veterinary diagnostic services into the private transaction, and their revision helps ensure that the user fees adequately reflect the cost of performing the services over time.

Summary

The impacts of the proposed increases in veterinary diagnostic user fees in this proposal are expected to be muted. The majority of the proposed changes to the user fees are either small, associated with few users, or both. Over the period covered by the proposed rule, more than 60 percent of the individual increases are less than \$50, nearly 16 percent increase by less than \$10, and about 65 percent are associated with 100 or fewer

users. The majority of the proposed fees should also make only small contributions to the total additional collections and, therefore, would have a minor impact on the users of those services. This is either because the proposed change is small or the projected volume associated with the user fee is small, or both. Even in those instances in which the change in a user fee would generate a larger total increase in collections, the impact should not be significant because they are small fees applied to a large annual volume of users, large fees applied to a very small volume of users, fees that represent a small percentage of the overall costs associated with a user's output, single fees for reagents with numerous final users, or fees that enhance the marketability of the user's final outputs. Therefore, the increases are not generally expected to substantially reduce profits or impede exports or imports. Indeed, the full burden of the proposed user fee changes is not likely to be borne entirely by the purchasers of products and services.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (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) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 130

Animals, Birds, Diagnostic reagents, Exports, Imports, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements, Tests.

Accordingly, we propose to amend 9 CFR part 130 as follows:

PART 130—USER FEES

1. The authority citation for part 130 would continue to read as follows:

Authority: 5 U.S.C. 5542; 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 3701, 3716, 3717, 3719, and 3720A; 7 CFR 2.22, 2.80, and 371.4.

2. In § 130.14, paragraphs (a), (b), and (c), the tables would be revised to read as follows:

§ 130.14 User fees for FADDL veterinary diagnostics.

(a) * * *

Reagent	Unit	User fee			
		Oct. 1, 2003– Sept. 30, 2004	Oct. 1, 2004– Sept. 30, 2005	Oct. 1, 2005– Sept. 30, 2006	Beginning Oct. 1, 2006
Bovine antiserum, any agent	1 mL	\$150.00	\$155.00	\$160.00	\$165.00
Caprine antiserum, any agent	1 mL	184.00	189.00	195.00	202.00
Cell culture antigen/microorganism	1 mL	103.00	106.00	109.00	111.00
Equine antiserum, any agent	1 mL	186.00	192.00	198.00	204.00
Fluorescent antibody conjugate	1 mL	169.00	172.00	176.00	179.00
Guinea pig antiserum, any agent	1 mL	184.00	189.00	194.00	200.00
Monoclonal antibody	1 mL	222.00	229.00	235.00	243.00
Ovine antiserum, any agent	1 mL	176.00	181.00	187.00	193.00
Porcine antiserum, any agent	1 mL	152.00	157.00	162.00	167.00
Rabbit antiserum, any agent	1 mL	179.00	185.00	190.00	196.00

(b) * * *

Test	Unit	User fee			
		Oct. 1, 2003– Sept. 30, 2004	Oct. 1, 2004– Sept. 30, 2005	Oct. 1, 2005– Sept. 30, 2006	Beginning Oct. 1, 2006
Agar gel immunodiffusion	Test	\$30.00	\$31.00	\$32.00	\$33.00
Card	Test	17.00	17.00	18.00	18.00
Complement fixation	Test	36.00	37.00	38.00	40.00

Test	Unit	User fee			
		Oct. 1, 2003– Sept. 30, 2004	Oct. 1, 2004– Sept. 30, 2005	Oct. 1, 2005– Sept. 30, 2006	Beginning Oct. 1, 2006
Direct immunofluorescent antibody	Test	22.00	23.00	24.00	25.00
Enzyme linked immunosorbent assay	Test	26.00	27.00	28.00	29.00
Fluorescent antibody neutralization (classical swine fever)	Test	194.00	201.00	208.00	215.00
Hemagglutination inhibition	Test	57.00	59.00	61.00	63.00
Immunoperoxidase	Test	29.00	30.00	31.00	32.00
Indirect fluorescent antibody	Test	35.00	36.00	37.00	39.00
In-vitro safety	Test	570.00	589.00	609.00	630.00
In-vivo safety	Test	5,329.00	5,387.00	5,447.00	5,509.00
Latex agglutination	Test	23.00	24.00	25.00	26.00
Tube agglutination	Test	28.00	28.00	29.00	30.00
Virus isolation (oesophageal/pharyngeal)	Test	180.00	186.00	192.00	199.00
Virus isolation in embryonated eggs	Test	346.00	358.00	370.00	383.00
Virus isolation, other	Test	155.00	160.00	166.00	171.00
Virus neutralization	Test	52.00	54.00	56.00	58.00

(c) * * *

Veterinary diagnostic service	Unit	User fee			
		Oct. 1, 2003– Sept. 30, 2004	Oct. 1, 2004– Sept. 30, 2005	Oct. 1, 2005– Sept. 30, 2006	Beginning Oct. 1, 2006
Bacterial isolation	Test	\$112.00	\$115.00	\$119.00	\$123.00
Hourly user fee services ¹	Hour	445.00	460.00	476.00	492.00
Hourly user fee services—Quarter hour	Quarter hour	111.00	115.00	119.00	123.00
Infected cells on chamber slides or plates	Slide	49.00	50.00	51.00	53.00
Reference animal tissues for immunohistochemistry	Set	171.00	177.00	182.00	187.00
Sterilization by gamma radiation	Can	1,740.00	1,799.00	1,860.00	1,923.00
Training (school or technical assistance)	Per person per day	910.00	941.00	973.00	1,006.00
Virus titration	Test	112.00	115.00	110.00	123.00

¹ For all veterinary diagnostic services for which there is no flat rate user fee, the hourly rate user fee will be calculated for the actual time required to provide the service.

* * * * *

3. In § 130.15, paragraphs (a) and (b), the tables would be revised to read as follows:

§ 130.15 User fees for veterinary diagnostic isolation and identification tests performed at NVSL(excluding FADDL) or other authorized site.

(a) * * *

Test	Unit	User fee			
		Oct. 1, 2003– Sept. 30, 2004	Oct. 1, 2004– Sept. 30, 2005	Oct. 1, 2005– Sept. 30, 2006	Beginning Oct. 1, 2006
Bacterial identification, automated	Isolate	\$48.00	\$50.00	\$51.00	\$53.00
Bacterial identification, non-automated	Isolate	81.00	84.00	87.00	90.00
Bacterial isolation	Sample	33.00	34.00	35.00	36.00
Bacterial serotyping, all other	Isolate	51.00	52.00	53.00	55.00
Bacterial serotyping, Pasteurella multocida	Isolate	16.00	17.00	18.00	18.00
Bacterial serotyping, Salmonella	Isolate	33.00	34.00	35.00	36.00
Bacterial toxin typing	Isolate	109.00	112.00	116.00	120.00
Bacteriology requiring special characterization ...	Test	83.00	86.00	89.00	92.00
DNA fingerprinting	Test	54.00	56.00	58.00	59.00
DNA/RNA probe	Test	77.00	79.00	81.00	83.00
Fluorescent antibody	Test	17.00	17.00	18.00	19.00
Mycobacterium identification (biochemical)	Isolate	104.00	107.00	111.00	114.00
Mycobacterium identification (gas chromatography)	Procedure	87.00	90.00	93.00	96.00
Mycobacterium isolation, animal inoculations	Submission	770.00	791.00	814.00	837.00
Mycobacterium isolation, all other	Submission	136.00	141.00	146.00	151.00
Mycobacterium paratuberculosis isolation	Submission	65.00	67.00	70.00	72.00
Phage typing, all other	Isolate	38.00	39.00	41.00	42.00
Phage typing, Salmonella enteritidis	Isolate	21.00	22.00	23.00	24.00

(b) * * *

Test	Unit	User fee			
		Oct. 1, 2003– Sept. 30, 2004	Oct. 1, 2004– Sept. 30, 2005	Oct. 1, 2005– Sept. 30, 2006	Beginning Oct. 1, 2006
Fluorescent antibody tissue section	Test	\$27.00	\$27.00	\$28.00	\$29.00
Virus isolation	Test	43.00	45.00	46.00	48.00

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4. In § 130.16, paragraphs (a) and (b), the tables would be revised to read as follows:

§ 130.16 User fees for veterinary diagnostic serology tests performed at NVSL (excluding FADDL) or at authorized sites.

(a) * * *

Test	Unit	User fee			
		Oct. 1, 2003– Sept. 30, 2004	Oct. 1, 2004– Sept. 30, 2005	Oct. 1, 2005– Sept. 30, 2006	Beginning Oct. 1, 2006
Brucella ring (BRT)	Test	\$33.00	\$34.00	\$35.00	\$36.00
Brucella ring, heat inactivated (HIRT)	Test	33.00	34.00	35.00	36.00
Brucella ring, serial (Serial BRT)	Test	49.00	51.00	53.00	54.00
Buffered acidified plate antigen presumptive	Test	6.00	7.00	7.00	7.00
Card	Test	4.00	4.00	4.00	4.00
Complement fixation	Test	15.00	15.00	16.00	16.00
Enzyme linked immunosorbent assay	Test	15.00	15.00	16.00	16.00
Indirect fluorescent antibody	Test	13.00	13.00	14.00	14.00
Microscopic agglutination-includes up to 5 serovars.	Sample	21.00	22.00	23.00	24.00
Microscopic agglutination-each serovar in excess of 5 serovars.	Sample	4.00	4.00	4.00	4.00
Particle concentration fluorescent immunoassay (PCFIA).	Test	33.00	34.00	35.00	36.00
Plate	Test	6.00	7.00	7.00	7.00
Rapid automated presumptive	Test	6.00	6.00	6.00	7.00
Rivanol	Test	6.00	7.00	7.00	7.00
Tube agglutination	Test	6.00	7.00	7.00	7.00

(b) * * *

Test	Unit	User fee			
		Oct. 1, 2003– Sept. 30, 2004	Oct. 1, 2004– Sept. 30, 2005	Oct. 1, 2005– Sept. 30, 2006	Beginning Oct. 1, 2006
Agar gel immunodiffusion	Test	\$15.00	\$15.00	\$16.00	\$16.00
Complement fixation	Test	15.00	15.00	16.00	16.00
Enzyme linked immunosorbent assay	Test	15.00	15.00	16.00	16.00
Hemagglutination inhibition	Test	13.00	13.00	14.00	14.00
Indirect fluorescent antibody	Test	13.00	13.00	14.00	14.00
Latex agglutination	Test	15.00	15.00	16.00	16.00
Peroxidase linked antibody	Test	14.00	14.00	15.00	15.00
Plaque reduction neutralization	Test	16.00	17.00	17.00	18.00
Rabies fluorescent antibody neutralization	Test	41.00	42.00	44.00	45.00
Virus neutralization	Test	12.00	12.00	13.00	13.00

* * * * *

5. In § 130.17, paragraph (a), the table would be revised to read as follows:

§ 130.17 User fees for other veterinary diagnostic laboratory tests performed at NVSL (excluding FADDL) or at authorized sites.

(a) * * *

Test	Unit	User fee			
		Oct. 1, 2003– Sept. 30, 2004	Oct. 1, 2004– Sept. 30, 2005	Oct. 1, 2005– Sept. 30, 2006	Beginning Oct. 1, 2006
Aflatoxin quantitation	Test	\$27.00	\$28.00	\$29.00	\$30.00
Aflatoxin screen	Test	26.00	27.00	28.00	29.00

Test	Unit	User fee			
		Oct. 1, 2003– Sept. 30, 2004	Oct. 1, 2004– Sept. 30, 2005	Oct. 1, 2005– Sept. 30, 2006	Beginning Oct. 1, 2006
Agar gel immunodiffusion spp. identification	Test	11.00	12.00	12.00	13.00
Antibiotic (bioautography) quantitation	Test	59.00	61.00	63.00	65.00
Antibiotic (bioautography) screen	Test	108.00	112.00	115.00	119.00
Antibiotic inhibition	Test	59.00	61.00	63.00	65.00
Arsenic	Test	16.00	16.00	17.00	17.00
Ergot alkaloid screen	Test	59.00	61.00	63.00	65.00
Ergot alkaloid confirmation	Test	77.00	80.00	83.00	86.00
Feed microscopy	Test	59.00	61.00	63.00	65.00
Fumonisin only	Test	33.00	35.00	36.00	37.00
Gossypol	Test	89.00	92.00	95.00	98.00
Mercury	Test	131.00	135.00	140.00	145.00
Metals screen	Test	40.00	41.00	43.00	44.00
Metals single element confirmation	Test	11.00	12.00	12.00	13.00
Mycotoxin: aflatoxin-liver	Test	108.00	112.00	115.00	119.00
Mycotoxin screen	Test	43.00	44.00	46.00	48.00
Nitrate/nitrite	Test	59.00	61.00	63.00	65.00
Organic compound confirmation	Test	79.00	82.00	85.00	88.00
Organic compound screen	Test	137.00	141.00	146.00	151.00
Parasitology	Test	26.00	27.00	28.00	29.00
Pesticide quantitation	Test	119.00	123.00	128.00	132.00
Pesticide screen	Test	54.00	56.00	58.00	60.00
pH	Test	24.00	25.00	26.00	26.00
Plate cylinder	Test	89.00	92.00	95.00	98.00
Selenium	Test	40.00	41.00	43.00	44.00
Silicate/carbonate disinfectant	Test	59.00	61.00	63.00	65.00
Temperature disks	Test	118.00	122.00	126.00	130.00
Toxicant quantitation, other	Test	99.00	103.00	106.00	110.00
Toxicant screen, other	Test	30.00	31.00	32.00	33.00
Vomitoxin only	Test	48.00	49.00	51.00	53.00
Water activity	Test	30.00	31.00	32.00	33.00
Zearaleone quantitation	Test	48.00	49.00	51.00	53.00
Zearaleone screen	Test	26.00	27.00	28.00	29.00

* * * * *

6. In § 130.18, paragraphs (a) and (b), the tables would be revised to read as follows:

§ 130.18 User fees for veterinary diagnostic reagents produced at NVSL or other authorized site (excluding FADDL).

(a) * * *

Reagent	Unit	User fee			
		Oct. 1, 2003– Sept. 30, 2004	Oct. 1, 2004– Sept. 30, 2005	Oct. 1, 2005– Sept. 30, 2006	Beginning Oct. 1, 2004
Anaplasma card test antigen	2 mL	\$87.00	\$89.00	\$92.00	\$95.00
Anaplasma card test kit without antigen	Kit	115.00	119.00	123.00	127.00
Anaplasma CF antigen	2 mL	46.00	46.00	46.00	46.00
Anaplasma stabilate	4.5 mL	160.00	165.00	170.00	175.00
Avian origin bacterial antisera	1 mL	43.00	44.00	46.00	47.00
Bacterial agglutinating antigens other than brucella and salmonella pullorum.	5 mL	49.00	51.00	52.00	54.00
Bacterial conjugates	1 mL	87.00	90.00	93.00	96.00
Bacterial disease CF antigens, all other	1 mL	26.00	27.00	28.00	29.00
Bacterial ELISA antigens	1 mL	27.00	27.00	28.00	29.00
Bacterial or protozoal, antisera, all other	1 mL	54.00	56.00	58.00	60.00
Bacterial reagent culture ¹	Culture	66.00	68.00	70.00	73.00
Bacterial reference culture ²	Culture	206.00	213.00	221.00	228.00
Bacteriophage reference culture	Culture	155.00	161.00	166.00	172.00
Bovine serum factor	1 mL	16.00	17.00	17.00	18.00
Brucella abortus CF antigen	60 mL	136.00	141.00	146.00	151.00
Brucella agglutination antigens, all other	60 mL	136.00	141.00	146.00	151.00
Brucella buffered plate antigen	60 mL	155.00	161.00	166.00	172.00
Brucella canis tube antigen	25 mL	102.00	105.00	107.00	109.00
Brucella card test antigen (packaged)	Package	81.00	84.00	87.00	90.00
Brucella card test kit without antigen	Kit	106.00	109.00	111.00	113.00
Brucella cells	Gram	17.00	17.00	18.00	18.00
Brucella cells, dried	Pellet	5.00	5.00	5.00	6.00
Brucella ring test antigen	60 mL	218.00	225.00	233.00	241.00
Brucella rivanol solution	60 mL	27.00	27.00	28.00	29.00
Dourine CF antigen	1 mL	81.00	84.00	86.00	89.00

Reagent	Unit	User fee			
		Oct. 1, 2003– Sept. 30, 2004	Oct. 1, 2004– Sept. 30, 2005	Oct. 1, 2005– Sept. 30, 2006	Beginning Oct. 1, 2004
Dourine stabilate	4.5 mL	102.00	105.00	107.00	109.00
Equine and bovine origin babesia species antiserums.	1 mL	115.00	119.00	123.00	127.00
Equine negative control CF antigen	1 mL	267.00	272.00	276.00	281.00
Flazo-orange	3 mL	11.00	12.00	12.00	13.00
Glanders CF antigen	1 mL	70.00	73.00	75.00	77.00
Hemoparasitic disease CF antigens, all other	1 mL	489.00	505.00	522.00	540.00
Leptospira transport medium	10 mL	4.00	4.00	4.00	4.00
Monoclonal antibody	1 mL	88.00	90.00	93.00	95.00
Mycobacterium spp. old tuberculin	1 mL	21.00	22.00	23.00	24.00
Mycobacterium spp. PPD	1 mL	16.00	17.00	18.00	18.00
Mycoplasma hemagglutination antigens	5 mL	163.00	168.00	174.00	180.00
Negative control serums	1 mL	16.00	17.00	18.00	18.00
Rabbit origin bacterial antiserum	1 mL	47.00	48.00	50.00	52.00
Salmonella pullorum microagglutination antigen	5 mL	14.00	14.00	15.00	15.00
Stabilates, all other	4.5 mL	623.00	640.00	659.00	678.00

¹ A reagent culture is a bacterial culture that has been subcultured one or more times after being tested for purity and identity. It is intended for use as a reagent with a diagnostic test such as the leptospiral microagglutination test.

² A reference culture is a bacterial culture that has been thoroughly tested for purity and identity. It should be suitable as a master seed for future cultures.

(b) * * *

Reagent	Unit	User fee			
		Oct. 1, 2003– Sept. 30, 2004	Oct. 1, 2004– Sept. 30, 2005	Oct. 1, 2005– Sept. 30, 2006	Beginning Oct. 1, 2006
Antigen, except avian influenza and chlamydia psittaci antigens, any.	2 mL	\$55.00	\$57.00	\$59.00	\$61.00
Avian antiserum except avian influenza anti- serum, any.	2 mL	44.00	45.00	47.00	48.00
Avian influenza antigen, any	2 mL	30.00	31.00	32.00	33.00
Avian influenza antiserum, any	6 mL	93.00	96.00	100.00	103.00
Bovine or ovine serum, any	2 mL	115.00	119.00	123.00	127.00
Cell culture	Flask	136.00	141.00	146.00	151.00
Chlamydia psittaci spp. of origin monoclonal antibody panel.	Panel	88.00	90.00	93.00	95.00
Conjugate, any	1 mL	66.00	68.00	71.00	73.00
Diluted positive control serum, any	2 mL	22.00	23.00	24.00	24.00
Equine antiserum, any	2 mL	41.00	42.00	44.00	45.00
Monoclonal antibody	1 mL	94.00	96.00	99.00	102.00
Other spp. antiserum, any	1 mL	51.00	51.00	52.00	52.00
Porcine antiserum, any	2 mL	95.00	99.00	102.00	105.00
Porcine tissue sets	Tissue set	152.00	153.00	155.00	157.00
Positive control tissues, all	2 cm ² section	55.00	57.00	58.00	60.00
Rabbit origin antiserum	1 mL	47.00	48.00	50.00	52.00
Reference virus, any	0.6 mL	163.00	169.00	174.00	180.00
Viruses (except reference viruses), chlamydia psittaci agent or chlamydia psittaci antigen, any.	0.6 mL	27.00	28.00	29.00	30.00

* * * * *

**§ 130.19 User fees for other veterinary
diagnostic services or materials provided at
NVSL(excluding FADDL).**

7. In § 130.19, paragraph (a), the table
would be revised to read as follows:

(a) * * *

Service	Unit	User fee			
		Oct. 1, 2003– Sept. 30, 2004	Oct. 1, 2004– Sept. 30, 2005	Oct. 1, 2005– Sept. 30, 2006	Beginning Oct. 1, 2006
Antimicrobial susceptibility test	Isolate	\$95.00	\$98.00	\$101.00	\$105.00
Avian safety test	Test	3,774.00	3,871.00	3,972.00	4,075.00
Check tests, culture	Kit ¹	162.00	167.00	171.00	176.00
Check tests, serology, all other	Kit ¹	326.00	337.00	349.00	361.00
Fetal bovine serum safety test	Verification	1,061.00	1,078.00	1,096.00	1,114.00

Service	Unit	User fee			
		Oct. 1, 2003– Sept. 30, 2004	Oct. 1, 2004– Sept. 30, 2005	Oct. 1, 2005– Sept. 30, 2006	Beginning Oct. 1, 2006
Hourly user fee services: ²					
Hour	Hour	84.00	84.00	84.00	84.00
Quarter hour	Quarter hour	21.00	21.00	21.00	21.00
Minimum	25.00	25.00	25.00	25.00
Manual, brucellosis culture	1 copy	104.00	107.00	111.00	114.00
Manual, tuberculosis culture (English or Spanish)	1 copy	155.00	161.00	166.00	172.00
Manual, Veterinary mycology	1 copy	155.00	161.00	166.00	172.00
Manuals or standard operating procedure (SOP), all other	1 copy	31.00	32.00	33.00	34.00
Manuals or SOP, per page	1 page	2.00	2.00	2.00	2.00
Training (school or technical assistance)	Per person per day	300.00	310.00	320.00	331.00

¹ Any reagents required for the check test will be charged separately.

² For veterinary diagnostic services for which there is no flat rate user fee, the hourly rate user fee will be calculated for the actual time required to provide the service.

* * * * *

Done in Washington, DC, this 18th day of July, 2003.

Peter Fernandez,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 03-18849 Filed 7-23-03; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

[7590-01-P]

RIN 3150-AH00

Emergency Planning and Preparedness for Production and Utilization Facilities

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its emergency planning regulations governing the domestic licensing of production and utilization facilities. The proposed rule would amend the current regulations as they relate to NRC approval of licensee changes to Emergency Action Levels (EALs) and exercise requirements for co-located licensees.

DATES: Submit comments October 7, 2003. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any one of the following methods. Please include the following number (RIN 3150-AH00) in the subject line of your comments. Comments on

rulemakings submitted in writing or in electronic form will be made available to the public in their entirety on the NRC rulemaking Web site. Personal information will not be removed from your comments.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attn: Rulemakings and Adjudications Staff.

E-mail comments to: SECY@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at (301) 415-1966. You may also submit comments via the NRC's rulemaking Web site at <http://ruleforum.llnl.gov>. Address questions about our rulemaking Web site to Carol Gallagher (301) 415-5905; e-mail cag@nrc.gov.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm Federal workdays. (Telephone (301) 415-1966).

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at (301) 415-1101.

Publicly available documents related to this rulemaking may be examined and copied for a fee at the NRC's Public Document Room (PDR), Public File Area O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. Selected documents, including comments, can be viewed and downloaded electronically via the NRC rulemaking Web site at <http://ruleforum.llnl.gov>.

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/NRC/ADAMS/index.html>. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's

public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to pdr@nrc.gov.

FOR FURTHER INFORMATION CONTACT:

Michael T. Jamgochian, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.
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SUPPLEMENTARY INFORMATION: The Commission is proposing to make two changes to its emergency preparedness regulations contained in 10 CFR part 50, Appendix E. The first proposed amendment relates to the NRC approval of licensee changes to Emergency Action Levels (EALs), paragraph IV.B and the second proposed amendment relates to exercise requirements for co-located licensees, paragraph IV.F.2. A discussion of each of these proposed revisions follows.

NRC approval of licensee changes to EALs, 10 CFR part 50, Appendix E, Paragraph IV.B.

EALs are part of a licensee's emergency plan. There appears to be an inconsistency in the emergency planning regulations regarding the NRC approval of nuclear power plant licensee changes to EALs. Section 50.54(g) states that licensees may make changes to their emergency plans without Commission approval only if the changes "do not decrease the effectiveness of the plans and the plans, as changed, continue to meet the standards of § 50.47(b) and the requirements of Appendix E" to 10 CFR part 50. By contrast, Appendix E states that "EAL's shall be * * * approved by NRC." However, the current industry practice, in general, has been to make