(E) A copy of all certifications required under paragraph (p) of this section.

(v) Access to records required to be maintained under paragraph (p) of this section must be restricted to officials of the national government of the region of origin, representatives of the United States Government, and persons maintaining the records.

(vi) The operator of the slicing/packaging facility must have signed a cooperative service agreement with APHIS prior to receipt of the whole dry-cured hams, pork shoulders, or pork loins for slicing and packaging, stating that all hams, pork shoulders, or pork loins sliced and packaged at the facility for importation into the United States will be sliced and packaged only in accordance with this section.

(vii) The operator of the slicing/packaging facility must be current, in accordance with the terms of the cooperative service agreement signed with APHIS, in paying all costs for an APHIS representative to inspect the establishment, including travel, salary, subsistence, administrative overhead, and other incidental expenses.

(viii) The slicing/packaging facility must allow the unannounced entry into the establishment of APHIS representatives, or other persons authorized by the Administrator, for the purpose of inspecting the establishment and records of the establishment.

(ix) Workers at the slicing/packaging facility who handle pork or pork products in the facility must shower and put on a full set of clean clothes, or wait 24 hours after handling pork or pork products that are not eligible for importation into the United States, before handling dry-cured hams, pork shoulders, or pork loins in the slicing/packaging facility that are intended for importation into the United States.

(x) Pork products intended for importation into the United States may not be in the slicing/packaging facility at the same time as pork products not intended for exportation to the United States.

(2) *Slicing and packaging and labeling procedures.* (i) A full-time salaried veterinarian employed by the national government of the region of origin must inspect each lot of whole dry-cured hams, pork shoulders, and pork loins at the slicing/packaging facility, before slicing is begun, and must certify in English that it is eligible for importation into the United States in accordance with this section; and

(ii) Either a full-time salaried veterinarian employed by the national government of the region of origin, or, if the national government of the region of origin recognizes a local consortium as responsible for product quality, a representative of that local consortium, must certify in English that he or she personally supervised the entire process of slicing and packaging each lot of dry-cured hams, pork shoulders, and pork loins at the slicing/packaging facility; that each lot of dry-cured hams, pork shoulders, and pork loins was sliced and packaged in accordance with the requirements of this paragraph; and that the sliced and packaged pork ham, shoulder, or loin is the same dry-cured ham, pork shoulder, or pork loin certified under paragraph (p)(2)(i).

(iii) The sliced and packaged dry-cured pork ham, pork shoulder, or pork loin must be labeled with the date that processing of the meat under paragraph (i) of this section began, and with the date the meat was sliced and packaged.

(Approved by the Office of Management and Budget under control number 0579–0015)

Done in Washington, DC, this 7th day of November 1997.

Charles Schwalbe,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 97–29989 Filed 11–13–97; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 130

[Docket No. 96–089–1]

Import/Export User Fees; Exemptions

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the user fee regulations to provide that user fees are not charged for veterinary diagnostic services in the following cases: When veterinary diagnostic services are provided in connection with Federal programs to control or eradicate diseases or pests of livestock or poultry in the United States (program diseases) or in support of zoonotic disease surveillance when there is a significant risk to human health; and when veterinary diagnostic reagents are distributed within the United States for testing for foreign animal diseases. In addition, we are eliminating the user fee for export health certificates that are requested and reviewed, but not endorsed. We are making these changes to eliminate confusion, clarify when certain user fees apply, and eliminate an unnecessary user fee.

DATES: Interim rule effective November 7, 1997. Consideration will be given only to comments received on or before January 13, 1998.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 96–089–1, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 96–089–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690–2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Ms. Donna Ford, Section Head, Financial Systems and Services Branch, Budget and Accounting Division, M&B, APHIS, 4700 River Road Unit 54, Riverdale, MD 20737–1232, (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-related and export-related services for live animals and birds and animal products are contained in 9 CFR part 130. Sections 130.14 through 130.18 list the various veterinary diagnostic services for which user fees are charged and the associated user fees.

We are proposing to amend 9 CFR part 130 (the regulations) to provide that user fees will not be charged for veterinary diagnostic services listed in §§ 130.14 through 130.18 in the following cases: (1) When veterinary diagnostic services are provided in connection with Federal programs to control or eradicate diseases or pests of animals in the United States (program diseases) or in support of zoonotic disease surveillance when there is a significant risk to human health; and (2) when veterinary diagnostic reagents are distributed within the United States for testing for foreign animal diseases. In addition, we are eliminating the user fee listed in § 130.20(d) for export health certificates that are requested and reviewed, but not endorsed.

Veterinary Diagnostic Services

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 to identify those organisms or agents. Services in this category include performing laboratory tests at the National Veterinary Services Laboratories (NVSL) and providing diagnostic reagents and other veterinary diagnostic materials and services. Diagnostic reagents are biological materials used in diagnostic tests to detect disease agents or antibodies by causing an identifiable reaction. NVSL also collects data and compiles statistics on the incidence of various livestock diseases based on the results of the veterinary diagnostic tests.

We do not charge user fees for veterinary diagnostic services provided in connection with Federal programs to control or eradicate diseases or pests (program diseases). Examples of program diseases are tuberculosis, brucellosis, and pseudorabies. These activities are covered by appropriated funding. Our policy not to charge for these services was specified in the background portion in previously published proposed and final rules concerning user fees for veterinary diagnostic services (58 FR 15292–15301, Docket No. 91–021–4, March 22, 1993, and 58 FR 38954–38961, Docket No. 91–021–5, July 21, 1993). In this document, we are amending the regulations to specify that user fees are not charged for these services.

While not specified in earlier user fee rules, there are other activities which we cover by appropriated funding instead of user fees. We routinely distribute veterinary diagnostic reagents free of charge to laboratories throughout the United States for testing for foreign animal diseases. This allows these laboratories to immediately test animals suspected of being infected with a foreign animal disease. The distribution of these diagnostic reagents is covered by appropriated funding to ensure that we are able to identify foreign animal diseases as quickly as possible. In this document, we are clarifying the regulations by specifying that this service is exempt from user fees.

In addition, we provide veterinary diagnostic services in support of zoonotic disease surveillance. Zoonotic diseases are those that affect both animals and humans and are communicable from animals to humans. Examples of zoonotic diseases are anthrax, brucellosis, leptospirosis, rabies, salmonellosis, tuberculosis, and vesicular stomatitis. Some of these are program diseases and, therefore, user fees are not charged, as stated above. Occasionally, there are zoonotic diseases that pose a significant threat to human health, and a thorough knowledge of the prevalence of the disease in animals will directly benefit control of the disease in humans. In these cases, we believe that the cost of the testing related to the zoonotic disease surveillance should be covered by appropriated funds. At this time, salmonellosis is the only zoonotic disease that falls into this second category, and user fees are not charged for the salmonella testing that will provide direct benefit to control of disease in humans. User fees are charged for other salmonellosis testing. Therefore, we are amending our regulations to state that user fees are not charged for veterinary diagnostic services provided in relation to zoonotic diseases when the Administrator has determined that there is a significant threat to human health.

We are adding a new § 130.49 to the regulations that lists the circumstances under which we do not charge user fees for veterinary diagnostic services. The exemptions will be specified as follows: User fees for veterinary diagnostic services, including, but not limited to, tests and diagnostic reagents specified in §§ 130.14 through 130.18, are not charged under the following conditions:

(1) When veterinary diagnostic services are provided in connection with Federal programs to control or eradicate diseases or pests of animals in the United States (program diseases);

(2) When veterinary diagnostic services are provided in support of zoonotic disease surveillance when the Administrator has determined that there is a significant risk to human health; and

(3) When veterinary diagnostic reagents are distributed within the United States for testing for foreign animal diseases.

Nonendorsed Export Health Certificates

We established a user fee for nonendorsed export health certificates in a final rule published in the **Federal Register** on May 7, 1996 (61 FR 20421–20437, Docket No. 92–174–2). These are certificates that are requested from the Animal and Plant Health Inspection Service (APHIS) and then are reviewed by APHIS, but either withdrawn or returned without being endorsed. The user fee was intended to cover the costs of the APHIS review. We have reviewed this user fee and have determined that we do not need to charge for these services because these services are comparable to those consultation services that we provide via the telephone to customers requesting information about animal or animal product exportation requirements. Most export health certificates that are returned by the APHIS veterinarian for corrective action are later resubmitted and endorsed. The user fee for the endorsement of these export health certificates recovers the costs for the full review including any consultations. Therefore, we are removing § 130.20(d) from the regulations and will not charge a user fee for export health certificates that are reviewed but not endorsed.

Immediate Action

The Administrator of the Animal and Plant Health Inspection Service has determined that there is good cause for publishing this interim rule without prior opportunity for public comment. Immediate action is warranted to encourage participation in programs to control and eradicate disease and pests of livestock or poultry, eliminate confusion about when user fees are charged, and to eliminate an unnecessary user fee. These changes will benefit users and help ensure that veterinary diagnostic services will continue to be requested for testing in connection with program diseases and zoonotic disease surveillance when there is a significant risk to human health.

Because prior notice and other public procedures with respect to this action are impracticable and contrary to the public interest under these conditions, we find good cause under 5 U.S.C. 553 to make it effective upon signature. We will consider comments that are received within 60 days of publication of this rule in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register**. It will include a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12866 and Regulatory Flexibility Act

This 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.

This rule provides that we do not charge user fees for (1) veterinary diagnostic services related to program diseases, (2) veterinary diagnostic services related to zoonotic disease surveillance when there is a significant risk to human health, (3) the distribution of diagnostic reagents within the United States used in testing for foreign animal diseases, or (4) services provided to review, but not endorse, export health certificates. Our policy, has been not to charge user fees for these services, and we are now

clarifying that policy in the regulations. Therefore, this rule should have no impact on entities whether they are large or small.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will 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 rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all 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.

Paperwork Reduction Act

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

Regulatory Reform

This action is part of the President's Regulatory Reform Initiative, which, among other things, directs agencies to remove obsolete and unnecessary regulations and to find less burdensome ways to achieve regulatory goals.

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, 9 CFR part 130 is amended as follows:

PART 130—USER FEES

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

Authority: 5 U.S.C. 5542; 7 U.S.C. 1622; 19 U.S.C. 1306; 21 U.S.C. 102–105, 111, 114, 114a, 134a, 134b, 134c, 134d, 134f, 135, 136, and 136a; 7 CFR 2.22, 2.80, and 371.2(d).

§ 130.20 [Amended]

2. Section 130.20 is amended by removing paragraph (d) and redesignating paragraph (e) as paragraph (d).

3. A new § 130.49 is added to read as follows.

§ 130.49 Exemptions.

(a) *Veterinary diagnostics.* User fees for veterinary diagnostic services, including, but not limited to, tests and diagnostic reagents specified in §§ 130.14 through 130.18, are not charged under the following conditions:

(1) When veterinary diagnostic services are provided in connection with Federal programs to control or eradicate diseases or pests of livestock or poultry in the United States (program diseases);

(2) When veterinary diagnostic services are provided in support of zoonotic disease surveillance when the Administrator has determined that there is a significant threat to human health; and

(3) When veterinary diagnostic reagents are distributed within the United States for testing for foreign animal diseases.

(b) [Reserved].

Done in Washington, DC, this 7th day of November 1997.

Charles Schwalbe,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 97–29990 Filed 11–13–97; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 310, 381, and 417

[Docket No. 97–056DF]

RIN 0583–AC40

Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems—Sample Collection—Technical Amendments and Corrections: Direct Final Rule

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Direct final rule.

SUMMARY: FSIS is making technical corrections and amendments to the final rule, ''Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems,'' published on July 25, 1996. In response to worker safety concerns, FSIS will permit samples collected for generic *E. coli* testing of turkeys to be collected by sponging two sites. Samples may still be collected by the whole bird rinse procedure (shaking turkeys in a bag containing a buffer solution). FSIS will also permit chickens and turkeys to be taken from the end of the slaughter line if it is impracticable to take a whole bird from the end of the chilling process. Additionally, FSIS is amending the regulations to add the performance standard for *Salmonella* in fresh pork sausage, which was unavailable at the time the rule was published, and correct a minor editorial oversight.

DATES: This rule will be effective on January 13, 1998, unless adverse or critical comments are received on or before December 15, 1997. If adverse or critical comments within the scope of the rulemaking are received, FSIS will issue timely notice in the **Federal Register**.

ADDRESSES: Send an original and two copies of adverse written comments within the scope of the rulemaking to: FSIS Docket Clerk, DOCKET # 97–056DF, Room 102, Cotton Annex, 300 12th Street, SW, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250–3700. Reference materials cited in this docket will be available for public inspection in the FSIS Docket Room from 8:30 to 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Ms. Patricia Stolfa, Assistant Deputy Administrator, Office of Policy, Program Development and Evaluation, (202) 205–0699.

SUPPLEMENTARY INFORMATION:

Background

On July 25, 1996, FSIS published a final rule ''Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems,'' (61 FR 38806). The final rule required all slaughter establishments to test for generic *E. coli* at a frequency based on production volume to verify that plants are meeting the established performance criteria. In the preamble to the final rule, FSIS solicited comments and information on a number of technical issues concerning the protocols for generic *E. coli* testing and announced that conferences would be held to discuss these issues.

The first conference was held on September 12 and 13, 1996. Participants discussed issues such as testing frequency, sampling procedures, and revision of the testing protocol to better account for differing establishment characteristics. In light of these comments, FSIS published the May 13, 1997, final rule ''Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems—Technical Amendments and Corrections'' (62 FR 26211). The final rule made some changes to the *E. coli* testing requirements.

On May 8, 1997, FSIS held a follow-up conference ''Technical Conference: Review of *E. coli* Testing.'' A panel of