

expenditures (about \$60,000) during November.

The Committee believed that assessment billings at the lower \$0.11 per 7/10-bushel carton rate would not be sufficient to cover all of its expenses. Assessing at the higher \$0.14 rate sooner would enable the Committee to maintain its reserves at a satisfactory level and ensure that all of its obligations are met. Funds in the reserve (currently \$23,000) will be kept within the maximum of one fiscal period's expenses permitted by the order (§ 906.35).

The assessment rate recommended by the Committee was derived by dividing anticipated expenses by expected shipments of Texas oranges and grapefruit. Texas orange and grapefruit shipments for the fiscal period are estimated at 9 million 7/10-bushel cartons or equivalents, which should provide \$1,260,000 in assessment income. Income derived from handler assessments, along with interest income and funds from the Committee's authorized reserve, will be adequate to cover budgeted expenses.

In arriving at this budget, the Committee considered information from various sources, including the Committee's Executive Committee. Alternative expenditure levels were discussed based upon the relative need of the Mexican Fruit Fly program to the Texas citrus industry.

The proposed assessment rate of \$0.14 per 7/10-bushel carton of assessable oranges and grapefruit was then determined by dividing the total recommended budget by the 9 million 7/10-bushel cartons of oranges and grapefruit estimated for the 2003–04 fiscal period. The \$0.14 rate will provide \$1,260,000 in assessment income. The additional \$62,506 to fund the Committee's estimated expenses will come from the Committee's reserve and interest income.

A review of historical information (October 1999 through May 2003) and preliminary information pertaining to the upcoming fiscal period indicates that the packinghouse door price for the 2003–04 fiscal period could range monthly, from \$0.26 to \$6.41 per 7/10-bushel carton of Texas oranges and from \$1.30 to \$7.30 for Texas grapefruit, depending upon the fruit variety, size, and quality. Therefore, the estimated assessment revenue for the 2003–04 fiscal period as a percentage of total grower (packinghouse door) revenue could range between 2.2 and 53.8 percent for oranges and 1.9 to 10.8 percent for grapefruit.

This action continues to increase the assessment obligation imposed on

handlers. While assessments impose some additional costs on handlers, the costs are minimal and uniform on all handlers. Some of the additional costs may be passed on to producers. However, these costs are offset by the benefits derived by the operation of the marketing order. In addition, the Committee's meetings were widely publicized throughout the Texas orange and grapefruit industry and all interested persons were invited to attend the meetings and participate in Committee deliberations on all issues. Like all Committee meetings, the May 29 and October 8, 2003, meetings were public meetings and all entities, both large and small, were able to express views on this issue.

This action imposes no additional reporting or recordkeeping requirements on either small or large Texas orange and grapefruit handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

An interim final rule concerning this action was published in the **Federal Register** on November 25, 2003 (68 FR 66001). Copies of that rule were also mailed or sent via facsimile to all orange and grapefruit handlers. Finally, the interim final rule was made available through the Internet by USDA and the Office of the Federal Register. A 60-day comment period was provided for interested persons to respond to the interim final rule. The comment period ended on January 26, 2004, and one comment opposing the assessment increase was received.

The commenter, a Texas citrus producer, stated that he opposes the increased assessment rate because he has lost money growing grapefruit. The commenter does not want to pay an assessment for grapefruit to the Committee.

Under the marketing order, assessments are collected from handlers of Texas citrus to cover order expenses. As stated previously in the regulatory flexibility analysis, some of the assessment costs may be passed on to producers by their handlers. However, USDA concluded that such costs are offset by the benefits derived by the operation of the marketing order.

The commenter went on to ask what could be done to remove themselves from this situation. USDA established the Texas citrus order at the request of producers to help the producers work together to solve marketing problems

that they could not solve individually. However, procedures are available to modify, suspend, or terminate an order. Further, the Committee manager is available to discuss the operation of the marketing order with industry members.

Based on the foregoing, no changes are being made to the assessment rate established by the interim final rule.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: <http://www.ams.usda.gov/fv/moab.html>. Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendation submitted by the Committee and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

#### List of Subjects in 7 CFR Part 906

Grapefruit, Marketing agreements, Oranges, Reporting and recordkeeping requirements.

#### PART 906—ORANGES AND GRAPEFRUIT GROWN IN LOWER RIO GRANDE VALLEY IN TEXAS

■ Accordingly, the interim final rule amending 7 CFR part 906 which was published at 68 FR 66001 on November 25, 2003, is adopted as a final rule without change.

Dated: February 27, 2004.

**A.J. Yates,**

*Administrator, Agricultural Marketing Service.*

[FR Doc. 04–4860 Filed 3–3–04; 8:45 am]

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#### DEPARTMENT OF AGRICULTURE

##### Animal and Plant Health Inspection Service

#### 9 CFR Part 71

[Docket No. 99–017–3]

RIN 0579–AB13

#### Blood and Tissue Collection at Slaughtering and Rendering Establishments

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** We are amending the regulations governing interstate

transportation of animals to establish requirements for the collection of blood and tissue samples from livestock (horses, cattle, bison, captive cervids, sheep and goats, swine, and other farm-raised animals) and poultry at slaughtering and rendering establishments when it is necessary for disease surveillance. Any person who moves livestock or poultry interstate for slaughter or rendering may only move the animals to a slaughtering or rendering establishment listed by the Administrator. The Administrator may list an establishment after determining either that the establishment provides the type of space and facilities specified by the regulations to safely collect blood and tissue samples for disease testing; or that it is not currently necessary to conduct testing at the establishment because the data collected through such testing would not significantly assist the Agency's disease surveillance programs and the facility has agreed to allow testing and provide access to facilities upon future APHIS notification that testing is required. This change will affect persons moving livestock or poultry interstate for slaughter or rendering, slaughtering and rendering plants that receive animals in interstate commerce, and, in cases where test-positive animals are successfully traced back to their herd or flock of origin, the owners of such herds or flocks. The long-term effects of this change will be to improve surveillance programs for animal diseases, to contribute to the eventual control or eradication of such diseases, and to assist in certifying the status of the United States or its regions with regard to freedom from specific animal diseases.

**EFFECTIVE DATE:** March 4, 2004.

**FOR FURTHER INFORMATION CONTACT:** Dr. Adam Grow, National Center for Animal Health Programs, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737-1231; (301) 734-6954.

**SUPPLEMENTARY INFORMATION:**

**Background**

The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA), has many programs to protect the health of livestock and poultry in the United States. These include programs to prevent endemic diseases and pests from spreading within the United States and programs to prevent the introduction of foreign animal diseases, as well as programs to control or eradicate certain animal diseases from the United States.

Regulations governing the interstate movement of animals for the purpose of

preventing the dissemination of animal diseases within the United States are contained in 9 CFR subchapter C, "Interstate Transportation of Animals (Including Poultry) and Animal Products."

The legal authority for USDA to conduct testing was recently restated in the Animal Health Protection Act (7 U.S.C. 8301 through 8317). Section 10409 of that Act (7 U.S.C. 8308) states that the Secretary of Agriculture "may carry out operations and measures to detect, control, or eradicate any pest or disease of livestock (including the drawing of blood and diagnostic testing of animals), including animals at a slaughterhouse, stockyard, or other point of concentration."

On November 27, 2002, we published in the **Federal Register** a proposed rule (67 FR 70864-70875, Docket No. 99-017-1) to amend the regulations in subchapter C, part 71, "General Provisions," to provide for the collection of blood and tissue samples from livestock (horses, cattle, bison, captive cervids, sheep and goats, swine, and other farm-raised animals) and poultry at slaughter. We proposed to require that persons moving livestock and poultry interstate for slaughter only move the animals to slaughtering establishments, including rendering establishments, that have been listed by the Administrator of APHIS. We did not propose to collect samples from all livestock or poultry at slaughter, but to collect samples whenever we believe it is necessary for effective surveillance.

We solicited comments concerning the proposed rule for 60 days ending January 27, 2003. On January 27, 2003, we published in the **Federal Register** a notice (68 FR 3826, Docket No. 99-017-2) in which we extended the comment period for a period of 60 days ending March 28, 2003. We received a total of 19 comments by the close of the extended comment period. The comments were submitted by livestock industry and trade associations, individual producers, and other members of the public. Ten commenters were generally supportive of the proposed rule, although most suggested that APHIS make some changes or provide some more explanation in the final rule. The other commenters expressed concern about the effects of the proposed rule and about some of the specific provisions of the proposal, or suggested that the rule should not apply to particular levels of livestock industries. These comments are discussed by subject below.

*Comments on Listing of Establishments and Selection of Establishments for Testing*

One commenter stated that it is unclear how the list of establishments in proposed § 71.21(a) would be used. As proposed, the list would include both plants that have agreed to sampling and plants where APHIS has determined sampling is unneeded. What would happen when someday APHIS decides it needs to collect samples at one of the "sampling is unneeded" plants? The commenter suggested that the list should include only plants that have agreed to sampling, even if a subset of plants on the list have been told there are no immediate plans to sample there and they do not need to provide facilities at this time.

We agree with the commenter's concern. In preparing the proposed rule, APHIS sought to minimize effects on plants where we did not plan to conduct testing in the near future. We thought the best way to do this was to simply add such plants to the list, allowing them to continue operations without the need for any correspondence with APHIS regarding testing. If it later became necessary to conduct testing at one of these plants, we could contact the plant and inform them that they needed to provide access and facilities for testing at some future date, or they would be delisted and unable to receive livestock moved interstate.

Further study of this issue has convinced us that the list would be more useful, and better understood by industry, if all the plants listed have agreed to provide access and facilities for testing, when needed. APHIS is now prepared to contact all plants engaged in the receipt of livestock moved interstate. We will inform some plants that we wish to conduct testing in the near future, and will add these plants to the list if they agree to provide the access and facilities required for our testing schedule. We will inform the remainder of the plants that we have no immediate plans to conduct testing at them, but that it may become necessary to do so in the future, and we will add these plants to the list if they agree to provide the required access and facilities if and when they are needed.

To accomplish this change, we would change one sentence in § 71.21(a). In the proposed rule, the sentence read "The Administrator may list a slaughtering establishment after determining that collecting samples for testing from the establishment is not necessary for the purposes of APHIS disease surveillance programs." In this final rule, we are changing that sentence to read "The

Administrator may list a slaughtering establishment or a rendering establishment after determining that collecting samples for testing from the establishment is not currently necessary for the purposes of APHIS disease surveillance programs and the establishment has agreed to allow testing and to provide the access and facilities required by this section upon future APHIS notification that testing is required at the establishment.”

Several commenters were concerned that APHIS would be unaware of some small establishments and fail to list them, possibly causing severe economic harm to plants that are thereby prohibited from accepting animals in interstate commerce. These commenters were concerned that the APHIS list may deal with large establishments, but may miss some plants because they are very small or because APHIS has no interest in sampling there. How will APHIS ensure completeness of the list?

This is a valid concern, but we do not believe any change to the rule is needed to resolve it. Since the proposed rule was published, APHIS has been collecting and verifying the contact information for all plants that would be affected by the regulations, to ensure that we are able to contact them all. If we still fail to contact a plant eligible for listing and leave it off the first list, we are prepared to add the plant to the list after being informed of the omission.<sup>1</sup> A plant in this situation will still be able to accept animals moved interstate while APHIS is in the process of adding it to the list, because APHIS is the agency that would be responsible for denying such movement, and we do not intend to do so when the plant's eligibility to receive such animals is in doubt because of a mistake APHIS made in not contacting the plant about its listing status.

One commenter stated that when APHIS selects plants for sampling, the decision should be based on sound epidemiology, and should consider that surveillance at slaughter at any point in time is not a true random sample of the population. Producers generally only send healthy animals to slaughter. Plant selection would be different depending on whether APHIS was trying to prove freedom from a disease, or delimit a known or suspected disease.

We agree, and intend to follow these principles in determining when and where to collect samples.

#### *Comments on Applicability of Rule to Rendering Plants*

Two commenters suggested that to achieve its purpose, the rule should apply not only to slaughtering establishments producing meat for human food, but also to businesses such as rendering plants that accept livestock to produce other products.

The proposed rule applied to all establishments that slaughter livestock, regardless of the intended use of the products produced at the establishment. The proposal covered meat and poultry slaughter establishments operating under federal inspection, state inspection, and slaughter establishments operating under voluntary inspection pursuant to the Agricultural Marketing Act of 1946, 7 U.S.C. 1621 *et seq.* The provisions of the Federal Meat Inspection Act (FMIA, 21 U.S.C. 601 *et seq.*) and Poultry Products Inspection Act (PPIA, 21 U.S.C. 451 *et seq.*) cover both establishments that slaughter specified animals for human consumption as well as establishments which slaughter specified animals for other than human consumption. The FMIA and PPIA merely exempt certain establishments, such as those which slaughter specified animals which are not intended for human consumption, from the inspection requirements of the Acts. Therefore, we believe that the proposed rule clearly applied to establishments slaughtering livestock or poultry for human consumption, rendering establishments that slaughter livestock or poultry for processing into products intended for human food, and rendering establishments that slaughter livestock or poultry for processing into products other than human food. However, to make this clear, we have added the phrases “slaughtering establishments, including rendering establishments” and “slaughtering or rendering establishments” in the regulation.

There are about 130 packer/renderer operations in the United States, where a rendering establishment operates on the same premises as a slaughtering establishment and processes primarily waste from that slaughtering establishment. The proposed rule as written would allow APHIS to conduct necessary sampling at such establishments by granting access to the slaughtering establishment. However, there are about 150 “independent renderer” establishments in the United States that do not operate on the premises of a slaughtering establishment or process mainly waste from a single establishment. Some of these independent renderers directly accept

livestock for rendering, and these are the types of establishments where APHIS may need to conduct sampling.

In fact, in some circumstances animals received by rendering plants may have a high incidence of disease and provide particularly useful opportunities for sampling, due to the debilitated nature of many animals sent to such plants. Such plants also provide an opportunity to collect a large volume of brain and tissue samples needed for surveillance of bovine spongiform encephalopathy (BSE) and other transmissible spongiform encephalopathy (TSE) diseases, with less disruption to plant operations than would occur in slaughtering establishments.

Recent events have made APHIS testing of cattle at rendering plants even more important. Following the December, 2003, diagnosis of BSE in a single cow in Washington State, the Food Safety Inspection Service (FSIS) implemented a new policy regarding Federally approved slaughtering plants. In an interim rule published in the **Federal Register** on January 12, 2004 (69 FR 1861–1874, Docket No. 03–0251F), FSIS added language to their regulations excluding all non-ambulatory disabled cattle from the human food supply, and requiring that any such cattle that arrive at a slaughter establishment must be condemned and disposed of through approved means. One approved means for disposing of non-ambulatory disabled cattle is through rendering the cattle for use in products that are inedible for human food. Therefore, APHIS expects a substantial increase in the number of non-ambulatory disabled cattle that are sent to rendering plants.

APHIS has also taken action in response to the diagnosis of BSE in a cow in Washington State. Among other actions, APHIS plans to increase its level of BSE testing in domestic cattle. In each of the past several years, APHIS has tested about 20,000 cattle for BSE. Because non-ambulatory cattle have been identified as a high risk group for BSE, three-fourths, or 15,000, of the cattle tested each year have been non-ambulatory cattle. APHIS selected most of these cattle from the non-ambulatory cattle processed at slaughter plants.

In 2004, APHIS plans to increase substantially the number of cattle it tests for BSE. We expect to select many of these cattle from those sent to rendering plants.

Therefore, to emphasize the rule's coverage of rendering plants that accept livestock moved interstate, we are slightly amending the text of § 71.21(a). We are also removing the definition of

<sup>1</sup> Plants may request to be added to the list by writing to National Center for Animal Health Programs, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737–1231.

recognized slaughtering establishment from § 71.1 because the term no longer appears in the revised text.

In the proposed rule, the introductory text of proposed § 71.21(a) read “Any person moving livestock or poultry interstate for slaughter may only move the animals to a slaughtering establishment that has been listed by the Administrator for the purposes of this part. A slaughtering establishment may receive livestock or poultry in interstate commerce only if the slaughtering establishment has been listed by the Administrator. The Administrator may list a slaughtering establishment after determining that collecting samples for testing from the establishment is not necessary for the purposes of APHIS disease surveillance programs. Otherwise, the Administrator will list a slaughtering establishment after determining that it is a recognized slaughtering establishment or a slaughtering establishment that undergoes voluntary inspection under the provisions of the Agricultural Marketing Act (12 U.S.C. 1141 *et seq.*), and that it: \* \* \*.” The section then went on to describe facility space, equipment, and access requirements.

In this final rule, we have amended that text to read as follows: “Any person moving livestock or poultry interstate for slaughter or rendering may only move the animals to a slaughtering establishment or a rendering establishment that has been listed by the Administrator for the purposes of this part.

**Note:** A list of these slaughtering establishments, including rendering establishments, may be obtained by writing to National Center for Animal Health Programs, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737–1231.

Livestock or poultry may not be removed from the premises of a slaughtering establishment or a rendering establishment listed by the Administrator except under a permit issued by APHIS, and in accordance with applicable FSIS regulations in this title. A slaughtering establishment or rendering establishment may receive livestock or poultry in interstate commerce only if the establishment has been listed by the Administrator. The Administrator may list a slaughtering establishment or a rendering establishment after determining that collecting samples for testing from the establishment is not currently necessary for the purposes of APHIS disease surveillance programs and the establishment has agreed to allow testing and to provide the access and facilities required by this section upon

future APHIS notification that testing is required at the establishment. The Administrator will list a slaughtering or rendering establishment after determining that it meets the following facility and access requirements:  
\* \* \*.”

#### *Comments on Poultry Industry Issues*

Four commenters stated that poultry slaughter plants should be exempted from the rule because poultry disease issues are significantly different from disease issues faced by red meat industries, testing for TSE diseases is an important goal of the rule and there are no TSE diseases known to affect poultry, and existing disease monitoring programs (*e.g.*, the National Poultry Improvement Plan and existing Food Safety and Inspection Service [FSIS] sampling programs) are sufficient to monitor for poultry diseases.

We believe that basic disease management issues are similar enough in poultry and red meat industries to support a role for slaughter testing in both. We do not maintain that slaughter testing will ever be the primary means of dealing with poultry disease issues. However, data collected from poultry slaughter testing can be very valuable in dealing with certain disease issues, particularly identifying and characterizing emerging poultry diseases. Slaughter testing at poultry plants has not been needed on as large a scale as it is needed in red meat plants, due to several reasons, including the large amount of poultry testing data already generated under the National Poultry Improvement Plan at the producer level. However, APHIS must have access to collect samples at poultry plants when disease outbreak situations occur that require more surveillance.

One commenter stated that the major differences between poultry and red meat slaughter industries (animal size, layout and construction of plants, diseases and diagnostic methods) mean that a single set of regulatory requirements cannot realistically cover both.

We agree that no single sampling protocol or diagnostic approach would apply to both red meat and poultry industries, due to the different types of diseases involved. However, the rule does not specify this type of detail. It only deals with gaining access to plants to collect samples; it does not include detailed requirements for how to collect samples, how many samples to collect, or how to process them. APHIS will determine the number and type of samples that must be collected from different plants at different times based on current needs for sound

epidemiological surveillance of diseases of current concern. Details regarding how samples will be collected—*e.g.*, on which days, at what time of day, at what point in the production line—will be worked out between APHIS and individual plants, taking into account the nature of the facility in each case. We believe the basic requirements for access and workspace to collect samples apply equally well to poultry and red meat facilities.

Two commenters stated that slaughter testing of poultry will not prevent productivity losses, because flock monitoring by company veterinarians and diagnostic labs provide earlier, more useful awareness of manifestations of disease. One commenter stated that in commercial poultry, velogenic viscerotropic Newcastle disease (VVND) and similar diseases are detected by an extreme surge in mortality, not by slaughter surveillance.

Existing flock monitoring programs produce excellent results in identifying problems with well-known diseases in poultry industries. However, these programs are not designed to focus on new, emerging, or unknown diseases, some of which may not cause immediate large-scale losses to the flock. Slaughter sampling can help APHIS to characterize such diseases and develop useful data about emerging diseases on a national level.

One commenter suggested that alternate sample collection methods should be used for poultry plants that lack space and layout for dedicated inspector facilities. Birds could be bled in the unloading/hanging area before they actually enter the plant. Existing FSIS inspectors on the line could bag and label viscera from birds and place them in a cooler for later, offsite examination.

APHIS will consider using all of these methods if they work well at a particular plant. Procedures for sample collection will be devised in cooperation with the management of each plant to ensure that the needed samples are collected with minimum disruption to plant operations. Certainly, it will be possible to collect needed samples at some poultry plants without adding new inspectors to the production line.

One commenter asked how the rule would enhance VVND detection, and whether there was a blood test suitable for slaughter testing that is specific for VVND.

VVND is not a primary disease target for our plans for slaughter testing, since other effective means of surveillance for it are currently in place. There is no approved blood test for VVND. If it

becomes necessary to test for VVND at slaughter, tissue samples would be sent to a laboratory for diagnosis—as with other diseases for which there is no blood test.

Three commenters stated that the rule should apply to all State and federally inspected poultry slaughtering establishments.

Limits to APHIS authority require that our primary focus must be on establishments that receive livestock or poultry moved interstate. However, APHIS always has worked with States cooperatively when States exercise their authority to conduct sampling at plants conducting business intrastate. APHIS and States share testing data from tests conducted under their respective areas of authority.

One commenter stated that the rule would eliminate the need for the National Avian Influenza Program (NAIP) developed with the United States Animal Health Association (USAHA), but would be more intrusive and costly, and not nearly as effective.

This rule would only affect NAIP testing to the extent that we implement sample collection for avian influenza testing under the rule. We will discuss any perceived need for additional avian influenza testing with NAIP participants, and would only implement additional testing at slaughter if it would clearly contribute valuable additional data about the disease.

Three commenters stated that with regard to poultry, the rule should be limited to control of “program” diseases only, *i.e.*, diseases for which a Federal control or emergency program exists.

Such an approach would not be practical or proactive. One purpose of the sampling conducted under the rule will be to identify and characterize new and emerging disease problems for which Federal or State programs do not exist. Another purpose is to document freedom from exotic diseases that do not exist in the United States, and therefore may not have Federal or State control programs, but which might be introduced at any time. It is important to recognize that our surveillance programs are intended to both characterize known disease problems and to identify emerging disease problems.

Two commenters stated that the proposed rule erroneously stated that the National Poultry Improvement Plan “includes slaughter testing to control certain poultry diseases, particularly those caused by various species of *Salmonella*, *Mycoplasma gallisepticum*, *M. synoviae*, *M. meleagridis*, and avian influenza viruses.”

The commenter is correct, and we apologize for the error in the preamble to the proposed rule that described slaughter testing as part of the National Poultry Improvement Plan procedures.

Three commenters suggested that the rule should include ways to use the data collected from testing to facilitate poultry exports by providing the basis for addressing the export requirements of trading partners.

We agree that data from slaughter testing authorized by this rule may be used to support statements regarding national or regional freedom from specified diseases on export certificates. However, no change to the rule is needed to make this possible. The currently established procedures for export certification described by APHIS regulations in 9 CFR part 91, by the Office International des Epizooties, and by the World Trade Organization allow national governments to use such data in support of certificate statements. APHIS intends to do so when slaughter testing produces data relevant to export certification.

#### *Comments on Economic Impacts*

Five commenters stated that the rule should provide for remuneration by APHIS to plants when inspections disrupt operations, slow movement of the processing line, or cause other financial losses. One additional commenter stated that the rule should provide for remuneration by APHIS when sampling destroys a whole carcass or renders it unusable.

We do not intend to establish a program to compensate plant owners for costs incidental to the process of collecting and testing samples. Many Federal agencies, including APHIS, FSIS, and the U.S. Food and Drug Administration, and others, are authorized to collect product samples for testing purposes and are not required by law to provide compensation for such samples. Such testing is in the public interest and addresses public health concerns. In cases where a plant owner believes the testing program has caused destruction of animals or other articles, the affected party could file a claim under 7 U.S.C. 8308(b)(1), which states that the Secretary “may pay a claim arising out of the destruction of any animal, article, or means of conveyance consistent with the purposes of this subtitle.”

One commenter suggested that the rule should be amended to include only those species and classes of livestock that are currently routinely sampled at slaughter.

As discussed above, our surveillance programs are intended to both

characterize known disease problems and to identify emerging disease problems. Strictly limiting testing to species that have been tested in the past would not accomplish that. Certainly, the vast majority of samples will be collected from classes of livestock that are currently routinely sampled at slaughter, but when APHIS sees a reason to test other species of livestock (defined by the Animal Health Protection Act as “all farm raised animals”) we will do so.

Three commenters stated that the rule would impose substantial burdens on establishments that do not have the necessary size or facilities to accommodate the sampling.

As discussed below in the section “Executive Order 12866 and Regulatory Flexibility Act,” we do not believe this will be the case. Based on discussions with livestock industry groups and slaughter industry groups, and the fact that most slaughtering plants accepting animals in interstate commerce already cooperate with voluntary testing programs, we expect there will be minimal effects on most slaughtering plants in complying with the standards.

One commenter stated that excessive facility adaption costs required by the rule may be passed on to producers, particularly harming those (typically small) producers without long-term marketing contracts.

As discussed above, and in the section “Executive Order 12866 and Regulatory Flexibility Act,” we do not believe many facilities will face large adaption costs. The costs they do face may be passed on to producers, or to buyers of the establishment’s products, or to both, depending on the business situation of the particular establishment.

The same commenters suggested that some slaughter plants may use the rule’s requirements to break existing contracts to buy animals at a certain price and renegotiate the contracts on terms advantageous to the slaughter plants. The example cited was that some pork slaughter plants are buying pigs under long-term contracts at prices that may be higher than current market prices. These plants may choose to become temporarily “unlisted,” effectively breaking the contract, then become listed and resume buying at lower prices, harming producers.

This scenario seems unlikely, because the plant would be undertaking great risks in exchange for questionable gains. First, the plant might be hurt by adverse publicity and possibly lose desired business on a permanent basis during the time it is unlisted. Second, the plant could not make certain business plans based on an expectation that it would be

“delisted” on a particular date and “relisted” on another particular date, because APHIS, not the plant, controls the dates of these actions.

One commenter stated that the proposed rule’s estimate that affected plants would spend “a few thousand dollars” to comply is highly questionable. Even minor modifications to plants often cost tens of thousands of dollars, and the APHIS estimate would not even cover preliminary engineering and design fees.

Based on experience to date collecting samples at plants, the estimate did not assume that plants would have to build actual additions to plant buildings or engage in significant construction. APHIS is already collecting samples at most of the larger plants in the country where sampling is desired, so access and facilities for sampling are already in place at many large plants. APHIS will work with individual plants to minimize the need for expensive modifications. In view of this, we continue to believe that our estimated average cost to comply is accurate.

One commenter asked whether products from carcasses APHIS samples would be withheld from commerce pending test results. If so, plants face significant costs with respect to sanitary segregation, product and offal storage, and possible adverse publicity.

Typically, APHIS does not order carcasses held pending test results for animal diseases. If plants choose to hold carcasses voluntarily pending test results, that is their business decision, not a result of the rule. In accordance with longstanding practice, APHIS, in cooperation with FSIS, may order a carcass held if it is believed to be infected with an agent that poses a human health risk, *e.g.*, tuberculosis, or possibly some emerging diseases. Also, in a recent policy notice published in the **Federal Register** on January 12, 2004 (69 FR 1892, Docket No. 03–048N), FSIS announced that its inspectors will not mark ambulatory cattle that have been targeted for any BSE surveillance testing as “inspected and passed,” until negative test results are obtained. While the APHIS BSE testing program primarily tests non-ambulatory cattle that would not be at slaughter plants, we do intend to test some cattle from slaughter lines, so this policy may result in FSIS holds on several hundred to a few thousand cattle at slaughter plants each year.

#### *Comments on Records, Reports, and Animal Traceback*

Two commenters stated that the rule should require plants to collect information on the premises of origin of

animals slaughtered there, and provide this information to APHIS upon request for traceback purposes. Establishment of a national premises identification program would allow more efficient slaughter surveillance.

The issues of animal identification and traceback procedures are outside the scope of this rulemaking. APHIS is continually examining options to improve animal identification and traceback, and will consider these comments in relation to those issues, but will not make any change to this rule based on the comments.

Five commenters stated that records generated under the rule should keep the identity of individual slaughter plants confidential and not subject to Freedom of Information Act (FOIA) requests.

In general, testing results for surveillance purposes are combined and summarized in reports that do not contain information identifying the particular establishments where tests were conducted. APHIS will handle confidential business information from establishments in accordance with statutory and regulatory requirements established to protect it. With regard to FOIA, APHIS cannot make an advance determination to withhold all identifying information; each FOIA request must be evaluated according to current judicial decisions interpreting applicability of the FOIA statute. Exemption 4 of FOIA does protect “trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential,” but court cases frequently affect how this exemption is applied. The Department of Justice maintains a “FOIA Updates” Web site that discusses how court cases and new interpretations have affected FOIA over time, at <http://www.usdoj.gov/oip/foi-upd.htm>.

Two commenters stated that APHIS should generate an annual report of testing activities and results.

APHIS intends to generate regular reports on the findings of surveillance testing done under this rule, as it does for its other surveillance programs. Among other reports, APHIS submits an annual report to the USAHA documenting the findings of APHIS disease surveillance activities.

One commenter stated that while the proposed rule said APHIS and State representatives would provide a copy of the list of approved establishments upon request, APHIS should also consider easier means (*e.g.*, a Web site) for producers to obtain the information.

We agree with the commenter, and intend to establish a Web site that will contain the list of approved

establishments, provide a procedure for establishments to request their addition to the list, and include links to other information and reports about slaughter surveillance testing.

One commenter stated that plants should be promptly informed by APHIS as to what products are being tested and when results are expected, so plants can determine the manner in which they may wish to voluntarily hold and store products pending results.

Section 71.21(c) provides that APHIS will notify establishments, with “as much advance notice as possible,” as to when APHIS will begin and end sampling at the establishment. This notice would also include the type and approximate number of samples APHIS will collect. Test results will be provided to establishments as soon as they are available to APHIS.

#### *Comments on APHIS–FSIS Coordination*

Three commenters stated that the rule should provide that APHIS will fully use existing FSIS sampling activities and the plant facilities established for them before requesting additional facilities. A commenter also stated that the proposed rule is too vague regarding when APHIS would make plants provide space or facilities and when APHIS would make do with existing FSIS facilities. Terms like “when convenient,” “adequate,” and “at the Administrator’s discretion” do not help readers understand who will be affected or the degree of impact.

APHIS intends to fully utilize existing FSIS sampling activities whenever possible, to avoid adding additional inspectors and increasing the burden on establishments. When APHIS can do so and when we must ask for additional access or facilities is a question that really must be worked out in discussions between APHIS and individual establishments after APHIS decides it must sample at an establishment. It is true that the rule does not let readers deduce which establishments will be sampled and which will not, because the establishments sampled will depend upon ongoing and continually evolving APHIS assessments of disease risk and epidemiology at a national level.

Three commenters stated that APHIS and FSIS should establish a single set of harmonized sampling requirements to facilitate activities and minimize burdens.

While APHIS and FSIS cooperate on sampling, the agencies’ different areas of concern and the possibility of sudden external changes affecting disease risk make it unlikely that a single, enduring

set of sampling requirements is possible. FSIS continually adjusts its sampling levels to adapt to risk indicators or outbreak reports related to human food borne disease, and APHIS does the same with regard to animal diseases. The two agencies will coordinate their activities as much as possible to minimize burden on establishments.

#### Other Comments

One commenter asked whether APHIS inspectors have the expertise to make a certain diagnosis in the field, or will they rely exclusively on preliminary tests such as PCR reactions?

While the nature of individual tests and diagnostic procedures is outside the scope of this rule, it is safe to say that some samples will be subjected to rapid field tests, with positive results confirmed later by laboratory analysis. Other tests may only be performed at a laboratory.

One commenter stated that sample collection by truly independent inspectors is needed to stop the plants from selling dirty, disease-causing meat to American consumers.

Since this comment seems to address human disease risks, rather than animal disease risks, it is outside the scope of the rule.

One commenter suggested that massive levels of BSE and TSE testing (at least 1 million rapid tests a year for 5 years) are needed.

APHIS intends to continue its surveillance for BSE and other TSE diseases, and will seek to increase the number of tests to an optimal level. As noted above, we initially expect to double the number of domestic cattle tested from BSE each year, from 20,000 to 40,000. Since the commenter did not provide a basis for suggesting 1 million tests a year for 5 years, we cannot evaluate this specific suggestion.

One commenter stated that the goal of the proposal, which he summarized as providing a valid national profile of diseased animals going to slaughter, should be restated. In surveillance, negative results (healthy animals) can be as important as positive results (diseased animals) with regard to demonstrating freedom from disease to trading partners.

We agree that both obtaining an accurate profile of animal disease on a national level and demonstrating freedom from particular diseases are important goals of the rule.

One commenter noted that the proposal refers to cull sows and boars as the preferred population for pseudorabies testing. The commenter stated that in reality, two- and three-tier pork production systems with pigs

moving between epidemiologically distinct sites mean that the health status of culls will not necessarily reflect the health status of market pigs. The Meat Juice Pilot Project was cited as an example of a better approach to test market swine at slaughter.

APHIS has worked closely with the swine industry to ensure that even though swine move between several sites in large-scale production systems, we are still able to do meaningful tracebacks of diseased animals and develop good epidemiological information about production system premises. See, for example, our regulations about interstate movement of swine in production systems in 9 CFR part 71. The Meat Juice Pseudorabies Virus Pilot is an important proof-of-concept project that has tested hundreds of thousands of samples from swine packing plants in Iowa over the past several years. One of the things the pilot demonstrated is that it is possible to collect slaughter samples without unduly disrupting plant operations. APHIS intends to continue working with the pilot project, and to apply its principles as we develop additional testing under this rule.

One commenter asked what the repercussions would be if an animal is unknowingly moved interstate to an unlisted plant. Is the person moving the animal (owner, trucker, manager) liable for not being properly informed?

We are not able to give a blanket answer to this question about enforcement of the rule, because so much depends on the facts of each particular case. In general, persons moving livestock interstate are responsible for knowing the requirements of applicable rules and regulations governing such movement. However, plants will know whether or not they are listed as approved to receive livestock moved interstate, and will also typically know if the livestock they are buying were moved interstate, and an unlisted plant would clearly be in violation if it knowingly received animals moved interstate. During the early implementation of this rule, APHIS enforcement will take into account the need for a learning period while plants, producers, and transporters become familiar with its requirements.

One commenter stated concerns about the risks posed by animals that are delivered to a slaughter plant but are then removed from the premises rather than slaughtered. Such animals might be infected with diseases that would not be discovered because the animals are not available for testing.

APHIS is aware of this problem. Occasionally animals are removed from a slaughter plant premises and moved to either a producer's premises or another slaughter plant. Such uncontrolled movements do present a risk of exposing other animals if the animal being moved is infected, and the movements are inconsistent with the definition of "moved to slaughter" in various APHIS regulations, which presumes that animals moved to slaughter will be slaughtered at the destination.

Therefore, we are adding language in this final rule to prohibit the removal of animals moved interstate to a slaughter or rendering establishment from the premises of that slaughter or rendering establishment unless the animals are moved in accordance with a permit issued by APHIS. While removal of animals would generally not be allowed, APHIS may issue a permit for such movement in exceptional cases, e.g., if a plant accidentally receives a shipment of animals that it is unable to slaughter because the size of the animals does not match the slaughter plant's line capabilities, or the slaughter plant is experiencing mechanical difficulties that bring processing to a halt.

To accomplish this change, we are adding the following sentence to § 71.21(a): "Livestock or poultry may not be removed from the premises of a slaughtering establishment or a rendering establishment except under a permit issued by APHIS, and in accordance with applicable FSIS regulations in this title."

One commenter stated that with regard to bovine tuberculosis testing, the proposed rule did not present statistically valid data or identify specific benefits for increasing testing from 1,200 head per year to 4,000 or more, since the current number of cattle infected does not seem significant enough to warrant increased testing.

Eradication of bovine tuberculosis is a priority for USDA and the cattle industry. It should be remembered that bovine tuberculosis caused more losses among U.S. farm animals in the early part of the 20th century than all other infectious diseases combined. Substantial decreases in tuberculosis levels in recent years are partly a result of increased testing for the disease. As levels of tuberculosis decline in a large national cattle population, its low incidence requires more testing to locate remaining pockets of the disease.

One commenter stated that one purpose of the rule is stated as allowing APHIS to collect slaughter samples "whenever we believe it is necessary." This commenter said APHIS should

develop standards for when it is "necessary," to avoid being arbitrary and capricious.

Collecting slaughter samples is necessary at different times and under different circumstances to meet a wide variety of surveillance goals. It is not feasible to develop a rule of general applicability that will describe in advance when sampling will be necessary. Sampling may be used when it is suspected that a disease is in an area, to determine its presence or absence, and to estimate the incidence or prevalence if the disease is present. Sampling may be needed to provide data for new or updated risk analyses produced in support of disease control programs, or required to open international markets for products. Sampling may be increased in an area when a disease outbreak is suspected, then reduced in that area when sufficient tests have been done to prove the suspicion was unfounded. Constantly changing disease outbreak, trade, and livestock industry conditions make it necessary for APHIS surveillance experts to continually revise the mix and degree of sampling activities, based on application of their expert knowledge to current conditions.

Other commenters raised several issues that were outside the scope of this rulemaking that will not be discussed in this final rule.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule with the changes discussed in this document.

#### **Effective Date**

This rule is needed to allow APHIS to conduct effective surveillance programs for dangerous animal diseases, including improved surveillance for BSE in response to the finding of that disease in a cow in Canada, and the December 2003 diagnosis of BSE in a cow in Washington State. Therefore, the Administrator of the Animal and Plant Health Inspection Service has determined, in accordance with the provisions of 5 U.S.C. 553(d)(3), that there is good cause to make this rule effective less than 30 days after publication in the **Federal Register**.

#### **Executive Order 12866 and Regulatory Flexibility Act**

This final rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

The economic analysis prepared for this final rule is set out below. It includes both a cost-benefit analysis as required by Executive Order 12866 and an analysis of the economic effects on small entities as required by the Regulatory Flexibility Act.

APHIS will require persons moving livestock (horses, cattle, bison, captive cervids, sheep and goats, swine, and other farm-raised animals) and poultry interstate to slaughter or rendering to move them only to slaughtering or rendering establishments that have been listed by the Administrator. The Administrator may list an establishment after determining that it is not currently necessary to conduct testing there and that the facility has agreed to grant access and provide facilities if and when needed, or that testing is necessary and that the establishment provides access and facilities for the collection of tissue and blood samples from the animals slaughtered. We are taking this action to increase the effectiveness of our surveillance for livestock diseases. Collection of samples currently occurs on a small, voluntary scale, but it needs to be expanded and to include both large and small slaughtering plants. Samples are currently collected by personnel employed by APHIS, FSIS, or the slaughtering plants themselves.

According to National Agricultural Statistics Service (NASS) and FSIS statistics for slaughtering establishments that may receive animals in interstate movement, there are approximately 795 plants slaughtering cattle, 757 plants slaughtering swine, 350 plants slaughtering poultry, and 2 plants slaughtering horses. (The horse plants will not be addressed further in this analysis because APHIS currently has no plans to collect samples at them.) Fourteen of the cattle plants and 11 of the swine plants are very large operations that account for 50 percent of the cattle and swine slaughtered each year. Several dozen of the plants are of moderate size; the rest are small businesses. Some of these plants slaughter both cattle and swine, and some slaughter other animals as well (sheep, horses, cervids, etc.). Some degree of sample collection already occurs at virtually all of the cattle plants, e.g., to collect the 12 million blood samples required each year under APHIS's regulations in 9 CFR part 78 for States to maintain their brucellosis classifications. Some sample collection already occurs at about 20 to 25 of the largest swine plants to collect blood samples for pseudorabies testing.

This final rule will allow us to collect samples at plants where sampling does

not now occur, but where sampling is needed to fill information gaps in our animal disease programs. We expect to initiate testing at several large plants, primarily swine plants, where testing has not occurred before, and at approximately 20 small businesses.

As noted above, many slaughtering plants already voluntarily cooperate with APHIS to allow us to collect samples for testing. Because of the relatively small number of additional animals that will be tested and the relatively small number of cases of disease expected to be identified, we do not expect that this rule will have a significant economic effect on any affected entities. Based on discussions with livestock industry groups and slaughter industry groups, and the fact that most slaughtering plants accepting animals in interstate commerce already cooperate with voluntary testing programs, we expect there will be minimal effects on most slaughtering plants in complying with the standards.

The primary economic effects of this rule will be direct costs to those slaughter and rendering plants that will have to provide us with access, workspace, and equipment to collect samples. We believe that some of the 20 to 30 plants that have not already been providing access under voluntary sampling programs may incur some facility adaption costs the first time that we collect samples at them, if they have to create or furnish new office space for inspectors to comply with § 71.21(b), and afterwards may incur some lesser costs if the speed at which the processing line moves is slowed or stopped for samples to be taken.

In the following sections we discuss potential economic effects on the various categories of slaughtering plants, based on the types of animals each processes. We do not specifically address rendering plants in these sections because, excluding the effects of increased BSE testing, the rule is expected to affect only three or four rendering plants, those plants are not small businesses, and we cannot accurately estimate economic effects on rendering plants because we have little economic information concerning these plants. APHIS is currently developing plans to increase BSE testing of cattle at rendering plants, but we are not sure yet how many separate plants must be sampled to provide a representative sample. Preliminary information from the rendering industry suggests that plants that currently render non-ambulatory animals would also process most of any increase in the number of such animals that is rendered. If this is the case, the number of rendering plants

affected by this rule would remain at three or four, or increase only slightly. In recent discussions, renderers have also suggested that allowing APHIS to collect sample would not impose significant costs. The renderers were concerned that later policy developments addressing food safety could significantly affect the costs involved in processing non-ambulatory

animals. For example, renderers stated that if later decisions allow carcasses of non-ambulatory cattle to be rendered for edible products after the cattle have tested negative for BSE, the renderers would have to store the carcasses in refrigerated facilities while awaiting test results.

First, we present two tables summarizing the per-unit costs and the

total industry costs estimated to result from the blood and tissue sampling requirements in this final rule for cattle, swine, and sheep. Bear in mind that the major costs of sample collection are borne by the Federal government, and that the costs to slaughter plants are limited to costs associated with providing access for sample collection.

TABLE 1.—PER-UNIT COST OF BLOOD AND TISSUE SAMPLING—ANNUAL BASIS

Animal	Number slaughtered (millions)	Disease	Samples currently collected	Samples needed	Cost of collection (per unit)	Cost of testing (per unit)
Cattle	35.5	Brucellosis	12 million	12 million	\$0.50–1 <sup>1</sup>	\$0.10–0.50
Cattle	35.5	Tuberculosis	1,200	4,000	22 <sup>2</sup>	20
Swine	101.1	Pseudorabies	750,000	1.2 million	0.45–0.90	1–1.50
Swine	101.1	Brucellosis	750,000	1.2 million	— <sup>3</sup>	1–1.50
Sheep	4.0	Scrapie	12,000	75,000	5–10 <sup>4</sup>	30

<sup>1</sup> Contracts for collecting brucellosis samples are negotiated individually, prices vary widely.

<sup>2</sup> To collect a sample for tuberculosis testing takes a veterinarian about 30 minutes. A 2003 final rule by FSIS revised the hourly user fee FSIS charges for services under its inspection program to \$43.64 per hour; this fee includes \$25 to \$32 per hour of salary (typically a GS–12 level) plus benefits, overhead, and certain travel, operating, and laboratory costs. Additionally, the plant incurs a cost because the speed at which the processing line moves is slowed or stopped for a sample to be taken. Also, FSIS requires that the suspect carcass be held by the plant while the testing is done, which typically takes 3 days. If the test is negative, the carcass is released. If the test is positive, the carcass cannot be sold unless it is done in accordance with FSIS regulations at 9 CFR 311.2, and steps are taken to trace the diseased animal back to its source.

<sup>3</sup> No cost because the same blood sample is used to test for pseudorabies and brucellosis.

<sup>4</sup> Animal health technicians normally collect scrapie test samples. An animal health technician can collect approximately 10 samples for scrapie testing per hour. Adjusting for time spent bagging samples for shipment, collecting identification devices, other administrative duties, and varying levels of efficiency at different facilities based on their layout and slaughter volume, the actual average collection rate will probably be 2 to 3 samples per hour. An approximate hourly wage rate for a technician employed in a slaughtering facility ranges from \$16 per hour to \$21 per hour, based on the GS–7 pay scale plus benefits. Additionally, the plant will incur a cost because the processing line may be slowed or stopped for a sample to be taken.

TABLE 2.—TOTAL COST OF BLOOD AND TISSUE SAMPLING—ANNUAL BASIS

Animal disease	Samples needed	Per-unit cost of collection	Per-unit cost of testing	Estimated total cost (millions) lower bound	Estimated total cost (millions) upper bound
Cattle brucellosis	12 million	\$0.50–1	\$0.10–0.50	\$7.2	\$18
Cattle tuberculosis	4,000	22	20	0.168	0.168
Swine pseudorabies	1.2 million	0.45–0.90	1–1.50	1.74	2.88
Swine brucellosis	1.2 million	.....	1–1.50	1.2	1.8
Sheep scrapie	75,000	5–10	30	2.625	3
Totals	.....	.....	.....	12.933	25.848

**Note:** Only approximately 25 percent of these costs come from increases in sampling resulting from the final rule; the remainder represents sampling already occurring under previous authorizations.

*Profile of Cattle and Swine Slaughtering Plants*

APHIS is trying to increase surveillance for brucellosis, pseudorabies, and tuberculosis at these plants. Collection of samples needs to be expanded to include both large and small slaughtering plants. Under this final rule, samples will be collected by APHIS or FSIS personnel, contractors, or the slaughtering plants themselves.

The meat packing industry is included in the North American Industry Classification System (NAICS)

code of 311611. The Small Business Administration (SBA) definition of small business for NAICS 311611 is a firm with less than 500 employees.

In 2002, the vast majority of meat packing plants were small entities under SBA guidelines. There were 292 large meat packing plants under Federal inspection in 2002. The 50 largest meat companies in the industry had combined sales of \$119.7 billion. Of this total amount, just the 10 largest companies produced \$86.6 billion of the sales. The remaining 40 companies produced \$33.1 billion in sales.

There are 706 federally inspected plants that slaughtered at least one head of cattle in 2002. Fifteen plants account for over 56 percent of the total cattle killed. (Agricultural Statistics Board,

NASS, Livestock Slaughter 2002 Summary, March 2003.) There are 683 plants that slaughter hogs. Nine plants account for 43 percent of the total hogs killed.

*Cost of Testing Additional Tissue Samples for Tuberculosis*

Currently, FSIS collects about 1,200 tissue samples from slaughter cattle each year to be tested for tuberculosis. There are approximately 100 positive test results per year. It is estimated that 0.0002 percent of all U.S. cattle may be infected with tuberculosis. There were 98.5 million head of cattle in the United States as of January 1, 1999. Therefore, it is estimated that fewer than 200 head of cattle are infected with tuberculosis at any one time.

Under this final rule, the direct costs of collecting a tissue sample and testing it for tuberculosis will be borne by APHIS, in either salary or contractor costs. It takes a veterinarian about 30 minutes to collect a sample for tuberculosis testing. An approximate hourly wage rate for a Federal or contractor veterinarian to do these duties is \$22 to \$28 per hour. The cost of laboratory analysis to test for tuberculosis is about \$20.

A slaughtering plant may incur a cost if its processing line must be slowed or stopped for a sample to be taken. Usually, samples can be collected without slowing the line. Currently about 0.003 percent (1,200) of cattle slaughtered are tested for tuberculosis, and we anticipate that after this rule we will initially increase testing to 4,000 head annually. Over time, the annual number of cattle tested for tuberculosis at slaughter may increase to about 5,300, to provide fully adequate surveillance. Because of the small number of additional tests for tuberculosis, this aspect of the final rule will not have a material effect on small business entities.

If a tuberculosis test is negative, the carcass is processed and sold. If the test is positive, the carcass cannot be sold unless it is done in accordance with FSIS regulations at 9 CFR 311.2, and steps are taken to trace the diseased animal back to its source. If this traceback is successful, the herd has to be quarantined while it is tested and may be depopulated if found positive. However, economic effects related to herd quarantine and depopulation are not reasonably linked to this rule, since herds are already quarantined and depopulated under other APHIS regulations.

#### *Cost of Testing Additional Blood Samples for Cattle Brucellosis*

This final rule will not change the number of brucellosis test samples collected from cattle or the way in which they are processed. This final rule will have no significant economic effect with regard to cattle tested for brucellosis.

Currently there are approximately 12 million blood samples collected each year to test for brucellosis. Under part 78, States must collect these samples in order to maintain their brucellosis status.

There are 795 federally inspected plants that slaughtered at least one head of cattle in 1998. Fourteen plants account for over 50 percent of the total cattle killed. (Agricultural Statistics Board, NASS, Livestock Slaughter 1998 Summary, March 1999.) All

slaughtering plants that ship products across State lines are subject to Federal inspection.

In 1998, there were 35.5 million head of cattle slaughtered; 98.1 percent were subject to Federal inspection. Only cattle that are 2 years old or older are tested for brucellosis.

Most of the blood sample collection is done by plant personnel or by FSIS. APHIS personnel collect only a small percentage of the total samples, approximately 50,000 samples per year, or 0.4 percent of the total.

Testing of the samples for brucellosis costs between \$0.10 and \$0.50 per sample. The high range of costs will cover followup tests from a positive result.

#### *Cost of Testing Additional Blood Samples for Swine Pseudorabies*

Currently there are about 750,000 samples collected per year. An estimated 1.2 million samples are needed for more complete testing. We estimate that less than 1 percent of swine herds are infected with pseudorabies.

At a large plant, two people will be needed to do the collection of blood samples on a full-time basis, at a cost to the government of \$25,000 to \$30,000 per year.

At smaller plants, where not enough swine are slaughtered to warrant having an employee collect blood samples full time, APHIS pays for each sample collected. Rates range from \$0.45 to \$0.90 cents per sample.

The sample is sent to a lab for testing. It costs approximately \$1 per sample for testing. APHIS has some contracts and cooperative agreements with universities to do some testing. The cost is negotiated with each laboratory separately. The rate can be up to \$1.50 per sample.

There are 757 plants that slaughter swine. Eleven plants account for 48 percent of the total swine killed. In 1998, 101.1 million swine were slaughtered; 98.3 percent of all swine slaughtered are slaughtered under Federal inspection. (Agricultural Statistics Board, NASS, Livestock Slaughter 1998 Summary, March 1999.) All slaughtering plants that ship products across State lines are subject to Federal inspection. Some 96 percent of the federally inspected swine at slaughter were barrows and gilts (younger pigs, with less fat, that are used for higher quality cuts of pork). There were about 4 million sows and boars slaughtered in 1998. For testing for pseudorabies, these are the swine that we are concerned about. There is

about a 40 percent turnover in sows per year.

If a herd tests positive, it is then quarantined. The swine can be sold for slaughter but cannot be sold for breeding stock. Swine sold for breeding stock are typically twice as expensive as swine sold for slaughter.

#### *Costs of Testing for Scrapie at Sheep Slaughtering Plants*

As noted previously, the slaughtering plant industry is included in NAICS code 311611. The SBA's definition of small business for NAICS 311611 is a firm with less than 500 employees. Only firms with more than \$100 million in sales average more than 500 employees. Two slaughtering plants that process sheep had sales of more than \$100 million in 1998. (SBA Office of Advocacy, [http://www.sba.gov/advo/stats/int\\_data.html](http://www.sba.gov/advo/stats/int_data.html).)

There are 556 federally inspected plants that slaughtered at least one sheep in 1998. Two plants account for over 40 percent of the total sheep slaughtered. (Agricultural Statistics Board, NASS, Livestock Slaughter 1998 Summary, March 1999.) In 1998, 4.429 million sheep were slaughtered, of which 94.8 percent were subject to Federal inspection. Only about 212,000 of these were mature sheep suitable for scrapie testing.

It is estimated that roughly 1.2 percent of all U.S. sheep flocks are infected with scrapie. In 1998, there were only 63 cases of scrapie reported. Given this incidence, approximately 15,000 animals should be sampled at slaughter each year for optimal monitoring for scrapie. Five distinct tissue samples are collected from each animal's head, resulting in about 75,000 samples to be collected. This level of sampling will detect the incidence and distribution of scrapie with a confidence of over 95 percent.

This final rule is not expected to have a significant adverse economic effect on small businesses. Blood and tissue samples will be collected by APHIS or FSIS personnel or by a contractor paid for by USDA. Firms may incur secondary costs for collecting tissue samples for testing as a result of production lines that may have to be slowed down or stopped temporarily. Firms will also incur costs for providing the space, furnishings, and equipment required for the personnel collecting samples, although we believe many firms will be able to minimize these costs by utilizing some of the space and equipment already provided for Federal and State inspectors and firms' quality assurance personnel.

The primary direct costs will be the cost of collecting samples and the cost of testing samples, both of which will be borne by USDA. Over the long term, samples will cost about \$5 to \$10 each to collect and \$30 each to test. Additionally, the plant may incur a cost because the speed at which the processing line moves may be slowed or stopped for a sample to be taken, similar to the effects already caused by FSIS inspections. The sheep or goat carcass would not have to be held by the plant while the testing is done, so it may continue along on the processing line,

and the processor will not incur the cost of having to hold the carcass. Additional testing for scrapie will provide a better record of diseases and enhance our ability to limit the infection of additional flocks with scrapie. While the costs of additional testing are visible, the benefits often are not. The true economic benefit of additional testing is that it will contribute to control and eventual eradication of scrapie, resulting in better overall flock productivity, a reduction in flocks depopulated due to scrapie, and expanded market opportunities for

animals that can be marketed as scrapie-free. Production of agricultural commodities varies for many reasons, and it is difficult to determine the change in production due to additional testing. Because the percentage of animals currently infected with scrapie is small, we expect that slaughter testing will result in the identification and quarantine of very few additional infected flocks. Quarantining the animals in these flocks is not likely to have a statistically significant effect on current or future production.

TABLE 3.—PER-UNIT COST OF COLLECTING AND TESTING SHEEP AND GOAT SAMPLES FOR SCRAPIE

Animals slaughtered (1998)	Samples to be collected (2000)	Samples needed	Cost of collection <sup>1</sup> (per unit)	Cost of testing (per sample)
4.03 million .....	12,000	75,000	\$5–10	\$30

<sup>1</sup> See footnote 4 to table 1.

TABLE 4.—TOTAL ANNUAL COST OF COLLECTING AND TESTING SHEEP AND GOAT SAMPLES FOR SCRAPIE

Samples needed	Cost of collection (per sample)	Cost of testing (per sample)	Total cost (millions)
75,000 .....	\$5–10	\$30	\$2.625 to 3

*Costs of Testing Captive Cervids at Slaughter*

Captive cervids might be tested at slaughter for tuberculosis and for chronic wasting disease (CWD). The cost per animal of testing cervids for tuberculosis is similar to the cost per animal of testing cattle for this disease. The cost per animal of testing cervids for CWD is similar to the cost per animal of testing sheep for scrapie.

The number of cervids farmed is small compared to cattle, swine, or sheep. Because it is a small industry, NASS does not collect data about cervid production or slaughter. According to the North American Elk Breeders Association, there are 150,000 to 160,000 elk being raised on farms in North America. This number includes elk raised in Canada and Mexico. The number of deer raised on farms is uncertain, but it is also a very small industry compared to cattle, swine, or sheep.

As stated earlier, the meat packing industry is included in NAICS code 311611. The SBA's definition of small business for NAICS 311611 is a firm with less than 500 employees.

In 1996, 91 percent (1,260) of the total number of firms (1,341) in the meat packing business qualified as small businesses. Only firms with more than \$100 million in sales average more than

500 employees. Eighty-one firms had sales of more than \$100 million in 1996. (SBA Office of Advocacy, [http://www.sba.gov/advo/stats/int\\_data.html](http://www.sba.gov/advo/stats/int_data.html).)

Plants that slaughter captive cervids qualify as small businesses. It seems that, currently, there are not enough cervids slaughtered per year to motivate large meat packing businesses to devote production lines to the slaughter of cervids.

This final rule will not have an adverse effect on small businesses that slaughter cervids. Blood samples will be collected either by APHIS, by FSIS, by contractors, or by the firms themselves. Firms will be compensated on a per unit basis for collecting the samples. The costs of testing captive cervids will be similar to the costs of testing cattle. Because of the small number of tests that are expected to be done, this final rule will not have a material effect on small business entities.

*Costs of Testing Poultry at Slaughter*

In 1997, there were 315 poultry processing firms (NAICS code 311615) according to SBA statistics. To qualify as a small business, firms engaged in meat processing must have less than \$500,000 in annual receipts. Even the smallest classification of poultry processing firms, those with fewer than 20 employees, averaged over \$1 million

in annual receipts in 1999. While this does not exclude the possibility that there may be poultry processing firms that qualify as small businesses, we have been unable to locate any such firms. This final rule will not have a significant adverse effect on small businesses.

It is estimated that this final rule may result in the collection of a maximum of 300 samples per quarter, collected from about 100 different poultry plants, to conduct adequate testing for exotic Newcastle disease, avian influenza, or other diseases that APHIS may wish to monitor. Blood samples will be collected either by APHIS, by FSIS, by contractors, or by the firms themselves. Firms will be compensated on a per unit basis for collecting the samples.

We expect that additional testing conducted after this final rule takes effect will be an insignificant amount compared to the testing and inspection already performed at poultry plants. The NASS Agricultural Statistics Board report entitled "Poultry Slaughter," dated February 4, 2000, gives representative figures for the amount of poultry that is inspected or tested at processing plants, and the fraction that is condemned for failing inspection. In December 1999, the preliminary total live weight of poultry inspected was 3.95 billion pounds, up fractionally

from the previous year. Ante-mortem condemnations during December 1999 totaled 15.3 million pounds. Condemnations were 0.39 percent of the live weight inspected. Post-mortem condemnations, at 62 million pounds (N.Y. dressed weight), were 1.75 percent of quantities inspected.

In contrast, even if APHIS tested poultry plants at the maximum level that might be necessary under disease surveillance scenarios, and if such testing always resulted in destruction of the poultry tested rather than just collection of a test sample, the total effects would be collection of under 120,000 samples per year, and the loss of under 600,000 pounds of poultry per year.

#### *Liability Costs for All Slaughter Industries*

Some firms expressed concern that sample collection in plants could result in accidents or injury that increase their liability costs. Collection is often done in potentially hazardous conditions; for example, the floors may be wet, the quarters may be cramped, and there are sharp knives and equipment present.

It is difficult to estimate the average cost incurred because of liability issues. The relevant issue here is the marginal increase in liability costs due to this regulation, which is very small. Slaughtering plants are already involved in a potentially hazardous activity. Adding the requirement to collect blood and tissue samples will not add significantly to the liability incurred by a plant, but a small increase in liability costs may be expected.

#### *Benefits of Additional Testing*

Additional testing will provide a better record of diseases and enhance our ability to prevent potential outbreaks of diseases. While the costs of additional testing are visible, the benefits often are not. The true economic benefit of additional testing will be the amount by which production is increased or the amount by which production is not lost due to herds being depopulated because of disease. The benefits of this program include better animal disease control, greater productivity in flocks and herds, fewer animals lost to disease, and greater opportunity to develop export markets for animals and products that can have their disease status backed up by an effective slaughter testing program. Increased testing of slaughter samples will allow us to more quickly identify and isolate herds or flocks affected by disease, reducing the number of animals lost to disease. Production of agricultural commodities varies for

many reasons, and it is difficult to determine the change in production due to additional testing. Because the percentages of animals currently infected with diseases such as pseudorabies and tuberculosis are very small, additional testing for these diseases resulting in the quarantine of some additional herds may not have a statistically significant effect on current or future swine and cattle production, but effective surveillance for these diseases can dramatically increase export markets, increasing the value of herds. Another benefit of additional testing will be that it will contribute to lowering the overall costs of animal disease control programs by generating epidemiological data to make these programs more effective. APHIS alone has spent hundreds of millions of dollars in the past decade on these programs, and more hundreds of millions of dollars on indemnity programs to buy and destroy diseased animals. Over time, a more effective slaughter testing program could reduce these costs. However, in the short-term, a more effective slaughter testing program may detect a higher incidence of diseases, and so may generate greater costs. Gains will accrue in the long-term from improved herd and flock health, reduced disease costs, reduced prophylactic costs, and expanded export opportunities.

#### *Cattle Industry Benefits*

This final rule will not affect the number of samples from cattle collected to test for brucellosis or the way in which the testing is conducted. There will be no economic effect due to this final rule with respect to collecting blood samples for cattle brucellosis. With regard to cattle tuberculosis, on average one herd per year has to be eradicated because of a positive tuberculosis test. The value of the average size herd in 1996 and 1997 ranged from \$46,200 to \$52,976. The value of a herd that has to be eradicated can vary widely depending on the size of the herd and market prices. If one cow is found to be tuberculosis positive, the entire herd is quarantined and may be depopulated. Eliminating the cost of depopulating a herd will represent only a small part of the benefit of additional testing. One benefit of this final rule will be the value of the herds that do not have to be depopulated. As discussed above, another benefit to both the cattle industry and the general public will result from improved disease control and resultant increased productivity.

#### *Swine Industry Benefits*

Elimination of pseudorabies directly impacts producer income. Producers who are able to eliminate this disease from their herds are able to earn up to \$4 more per hog. In addition, pseudorabies kills numerous young piglets and causes reproductive problems in sows. Historically, each year pseudorabies has cost several billion dollars in lost producer revenues and the cost of control measures. To the extent that collecting blood samples and testing contributes to faster elimination of pseudorabies, this rule will have a positive economic impact on producer incomes. APHIS hopes to eliminate pseudorabies within the next year. Additional slaughter testing should allow pseudorabies to be eliminated from U.S. swine herds, or reduced to an insignificant level, several months earlier than would otherwise be possible. The additional slaughter testing that will be allowed will also help establish baseline data that could be used to develop disease control programs to reduce the impact on industry of other swine diseases such as porcine reproductive and respiratory syndrome.

#### *Sheep Industry Benefits*

Improved surveillance will aid eradication of scrapie, which will directly affect producer income. Producers who are able to eliminate this disease from their flocks lose fewer animals to disease and can, therefore, maintain more animals at a lower production cost per animal. They can also sell their animals at a higher price and with fewer regulatory costs and may be able to sell to additional foreign markets. To the extent that collecting samples and testing contributes to elimination of scrapie, this final rule will have a positive economic effect on producer incomes. The additional slaughter testing that will be conducted will also help establish baseline data that could be used to develop disease control programs to reduce the economic effect on industry of other sheep diseases.

#### *Poultry Industry Benefits*

As noted above, the additional testing that will be conducted under this final rule will serve as a minor but valuable supplement to the poultry testing already conducted in accordance with the National Poultry Improvement Plan.

The poultry industry, like other animal industries, will benefit in the form of increased productivity and possible expansion of overseas markets. More effective disease surveillance is

particularly important in the poultry industry because outbreaks of severe avian disease frequently must be controlled by destroying a number of poultry houses in a flock or the entire flock. This often means the loss of tens of thousands of poultry to control a single outbreak. More effective surveillance can also help reopen poultry export markets more quickly following an avian disease outbreak, by documenting containment of a problem.

*Cervid Industry Benefits*

In addition to the benefits cited above for other industries, the cervid industry at present faces the possibility that its major export markets will be cut off unless there is an effective slaughter testing surveillance program for CWD. The Republic of Korea recently banned importation of elk antlers from the United States due to concerns about this disease, and other countries may follow. The elk industry depends on foreign markets for a large part of its revenue, and these markets have indicated that they may not import U.S. elk products unless there is a reasonably effective testing program to ensure the products are not from CWD-positive elk.

*Overall Summary*

The total direct cost of the testing this final rule envisions for cattle, swine, and sheep is between \$12.933 million and \$25.848 million, borne by APHIS. However, as noted above, APHIS already conducts some of this testing on a voluntary basis, although we collect

only a fraction of the samples we believe are needed for an effective testing program. If we subtract the cost of testing APHIS is already conducting, the new total direct costs are between about \$3.4 million and \$4.6 million. In addition to these direct costs for cattle, swine, and sheep, there will be direct testing costs for slaughter testing of horses, cervids, and poultry. The extent of testing to be done in this area is still uncertain, but it will be much smaller than the program for cattle, sheep, and swine, and should not amount to more than a few million dollars in annual direct costs. In addition to direct testing costs borne by APHIS, slaughtering plants will bear certain direct costs related to providing space and access for sample collection, and possible losses if production lines must be slowed for sample collection. We requested comments providing data on costs that slaughter plants might incur, including costs due to slowing the production line as well as office space, equipment, and other costs, but we did not receive any specific data on these subjects.

The benefits of this program include better animal disease control, greater productivity in flocks and herds, fewer animals lost to disease, and greater opportunity to develop export markets for animals and products that can have their disease status backed up by an effective slaughter testing program.

The overall costs of this program that are borne by industry are expected to be relatively minor, though further

information is needed to assess costs for those plants that need to make adjustments to their operations to comply. In most cases, small businesses will have to do little more than to allow sample collectors to have access to their production lines.

In the following table, costs are compared for the level of slaughter sampling and testing APHIS currently conducts and the increase in such activities we expect under this final rule. This table does not include the benefits achieved by current and proposed sampling activity levels, because data are not available to quantify the benefits. As discussed above, the benefits result from avoiding animal disease outbreaks, and there are too many possible outbreak scenarios to allow a meaningful calculation of a benefits range. The expected benefits result from the expectation that sampling and testing helps APHIS avoid some additional animal disease outbreaks, thereby avoiding: (1) The direct cost of dealing with an outbreak (cleaning and disinfection, compensation to producers, quarantine enforcement, etc.), (2) production losses, (3) induced price changes, and (4) the effect of the outbreak on other sectors of the economy. In view of the fact that the economic output of U.S. livestock industries exceeds \$100 billion, an avoided impact of even a fraction of 1 percent on this sector will substantially exceed the total sampling costs estimated in table 5.

TABLE 5.—COSTS OF SAMPLING FOR CATTLE BRUCELLOSIS AND TUBERCULOSIS, SWINE PSEUDORABIES AND BRUCELLOSIS, AND SHEEP SCRAPIE

	Low range	High range
Current sampling costs .....	\$9,494,700	\$21,224,800
Additional sampling costs .....	3,394,300	4,591,200

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 final rule has been reviewed under Executive Order 12988, Civil

Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict 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**

The information collection burden in this final rule includes 120 hours that were not included in the proposed rule. Specifically, the additional hours are for compliance by rendering plants, which were added to the coverage of the final rule. In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping

requirements included in this rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0579-0212.

**Government Paperwork Elimination Act Compliance**

The Animal and Plant Health Inspection Service is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. For information pertinent to GPEA compliance related to this rule, please contact Mrs. Celeste

Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

### List of Subjects in 9 CFR Part 71

Animal diseases, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements, Transportation.

■ Accordingly, we are amending 9 CFR part 71 as follows:

### PART 71—GENERAL PROVISIONS

■ 1. The authority citation for part 71 continues to read as follows:

**Authority:** 7 U.S.C. 8301-8317; 7 CFR 2.22, 2.80, and 371.4.

■ 2. In § 71.1, the definitions of *livestock* and *moved (movement) in interstate commerce* are revised and a definition of *Food Safety and Inspection Service (FSIS)* is added in alphabetical order to read as follows:

#### § 71.1 Definitions.

\* \* \* \* \*

*Food Safety and Inspection Service (FSIS).* The Food Safety and Inspection Service, United States Department of Agriculture.

\* \* \* \* \*

*Livestock.* Horses, cattle, bison, captive cervids, sheep and goats, swine, and other farm-raised animals.

\* \* \* \* \*

*Moved (movement) in interstate commerce.* Shipped, transported, delivered, or otherwise aided, induced, or caused to be moved from the point of origin of the interstate movement to the animals' final destination, such as a slaughtering establishment or a farm for breeding or raising, and including any temporary stops along the way, such as at a stockyard or dealer premises for feed, water, rest, or sale.

\* \* \* \* \*

■ 3. A new § 71.21 is added to read as follows:

#### § 71.21 Tissue and blood testing at slaughter.

(a) Any person moving livestock or poultry interstate for slaughter or rendering may only move the animals to a slaughtering establishment or a rendering establishment that has been listed by the Administrator<sup>8</sup> for the purposes of this part. Livestock or poultry may not be removed from the premises of a slaughtering establishment or a rendering establishment listed by the Administrator except under a permit

issued by APHIS, and in accordance with applicable FSIS regulations in this title. A slaughtering establishment or rendering establishment may receive livestock or poultry in interstate commerce only if the establishment has been listed by the Administrator. The Administrator may list a slaughtering establishment or a rendering establishment after determining that collecting samples for testing from the establishment is not currently necessary for the purposes of APHIS disease surveillance programs and the establishment has agreed to allow testing and to provide the access and facilities required by this section upon future APHIS notification that testing is required at the establishment. The Administrator will list a slaughtering or rendering establishment after determining that it meets the following facility and access requirements:

(1) The establishment provides space and equipment in accordance with paragraph (b) of this section<sup>9</sup> within their facility for blood and tissue sample collection;

(2) The establishment allows APHIS, FSIS, or APHIS contractors to take blood and tissue samples from all livestock or poultry at the facility without cost to the United States, and specifically allows these personnel access to the processing line to collect samples; and

(3) The establishment allows APHIS, FSIS, or APHIS contractors to record the identification of individual animals and retain any external or internal identification devices.

(b) The establishment must provide office and sample collection space, including necessary furnishings, light, heat, and janitor service, rent free, for the use by APHIS, FSIS, or APHIS contractors collecting samples for blood and tissue testing under this section. The Administrator will inform each establishment of the exact amount and type of space required, taking into account whether APHIS will be conducting complete tests at the facility, or only collecting samples and sending them elsewhere for testing. At the discretion of the Administrator, small plants need not furnish facilities as prescribed in this section if adequate facilities exist in a nearby convenient location. In granting or denying listing of an establishment, the Administrator will consider whether the space at the facility:

(1) Is conveniently located, properly ventilated, and provided with lockers

suitable for the protection and storage of supplies;

(2) Has sufficient light to be adequate for proper conduct of sample collection and processing;

(3) Includes racks, receptacles, or other suitable devices for retaining such parts as the head, glands, and viscera, and all parts and blood to be collected, until after the post-mortem examination is completed;

(4) Includes tables, benches, and other equipment on which sample collection and processing are to be performed, of such design, material, and construction as to enable sample collection and processing in a safe, ready, efficient, and clean manner;

(5) Has adequate arrangements, including liquid soap and cleansers, for cleansing and disinfecting hands, dissection tools, floors, and other articles and places that may be contaminated by diseased carcasses or otherwise; and

(6) Has adequate facilities, including denaturing materials, for the proper disposal in accordance with this chapter of tissue, blood, and other waste generated during test sample collection.

(c) The Administrator will give the operator of the establishment actual notice that APHIS, FSIS, or an APHIS contractor will be taking blood and/or tissue samples at the establishment. The Administrator may give the operator of the establishment notice in any form or by any means that the Administrator reasonably believes will reach the operator of the establishment prior to the start of sample collection.

(1) The notice will include the anticipated date and time sample collection will begin. The notice will also include the anticipated ending date and time.

(2) The Administrator will give the operator of the establishment as much advance notice as possible. However, the actual amount of notice will depend on the specific situation.

(d) *Denial and withdrawal of listing.* The Administrator may deny or withdraw the listing of an establishment upon a determination that the establishment is not in compliance with the requirements of this section.

(1) In the case of a denial, the operator of the establishment will be informed of the reasons for the denial and may appeal the decision in writing to the Administrator within 10 days after receiving notification of the denial. The appeal must include all of the facts and reasons upon which the person relies to show that the establishment was wrongfully denied listing. The Administrator will grant or deny the appeal in writing as promptly as

<sup>8</sup> A list of these slaughtering or rendering establishments may be obtained by writing to National Center for Animal Health Programs, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737-1231.

<sup>9</sup> FSIS also has equipment and space requirements for official establishments at § 307.2(c) of this title.

circumstances permit, stating the reason for his or her decision. If there is a conflict as to any material fact, a hearing will be held to resolve the conflict. Rules of practice concerning the hearing will be adopted by the Administrator.

(2) In the case of withdrawal, before such action is taken, the operator of the establishment will be informed of the reasons for the proposed withdrawal. The operator of the establishment may appeal the proposed withdrawal in writing to the Administrator within 10 days after being informed of the reasons for the proposed withdrawal. The appeal must include all of the facts and reasons upon which the person relies to show that the reasons for the proposed withdrawal are incorrect or do not support the withdrawal of the listing. The Administrator will grant or deny the appeal in writing as promptly as circumstances permit, stating the reason for his or her decision. If there is a conflict as to any material fact, a hearing will be held to resolve the conflict. Rules of practice concerning the hearing will be adopted by the Administrator. However, withdrawal shall become effective pending final determination in the proceeding when the Administrator determines that such action is necessary to protect the public health, interest, or safety. Such withdrawal shall be effective upon oral or written notification, whichever is earlier, to the operator of the establishment. In the event of oral notification, written confirmation shall be given as promptly as circumstances allow. This withdrawal shall continue in effect pending the completion of the proceeding, and any judicial review thereof, unless otherwise ordered by the Administrator.

(Approved by the Office of Management and Budget under control number 0579-0212.)

Done in Washington, DC, this 1st day of March 2004.

**Bill Hawks,**

*Under Secretary for Marketing and Regulatory Programs.*

[FR Doc. 04-4810 Filed 3-3-04; 8:45 am]

**BILLING CODE 3410-34-P**

**DEPARTMENT OF HOMELAND SECURITY**

**Bureau of Customs and Border Protection**

**19 CFR Part 122**

**Required Advance Electronic Presentation of Cargo Information: Revised Compliance Dates for Air Cargo Information**

**AGENCY:** Customs and Border Protection, Department of Homeland Security.

**ACTION:** Announcement of revised compliance dates.

**SUMMARY:** This document advises the public of the revised implementation schedule set forth by the Bureau of Customs and Border Protection requiring the advance electronic transmission of information for cargo brought into the United States by air. The original date set for compliance was March 4, 2004. There will be staggered starting dates for compliance, with the earliest compliance date set for August 13, 2004.

**DATES:** The compliance date for the advance electronic transmission of inbound air cargo information published December 5, 2003 (68 FR 68140) is modified pursuant to § 122.48a(e)(2). The implementation schedule set forth in the **SUPPLEMENTARY INFORMATION** discussion establishes three different compliance dates when CBP will require electronic transmission of inbound air cargo manifest data, depending on the location of the airport where cargo arrives in the United States.

**FOR FURTHER INFORMATION CONTACT:** David M. King, Manifest and Conveyance Branch, (202) 927-1133.

**SUPPLEMENTARY INFORMATION:**

**Background**

Section 343(a) of the Trade Act of 2002, as amended (the Act; 19 U.S.C. 2071 note), required that the Bureau of Customs and Border Protection (CBP) promulgate regulations providing for the mandatory collection of electronic cargo information, by way of a CBP-approved electronic data interchange system, before the cargo is either brought into or sent from the United States by any mode of commercial transportation (sea, air, rail or truck). The cargo information required is that which is reasonably necessary to enable high-risk shipments

to be identified for purposes of ensuring cargo safety and security and preventing smuggling pursuant to the laws enforced and administered by CBP.

On December 5, 2003, CBP published in the **Federal Register** (68 FR 68140) a final rule specifically intended to effectuate the provisions of the Act. In particular, a new § 122.48a was added to the CBP Regulations (19 CFR 122.48a) to implement the Act's provisions relating to inbound air commerce. Section 122.48a(a) describes the general requirement that for inbound aircraft with commercial cargo aboard, CBP must electronically receive information concerning the incoming cargo in advance of its arrival. Section 122.48a(e)(1) set a general compliance date of March 4, 2004 for those air carriers required to participate, and other parties electing to participate, in advance automated cargo information filing. However, pursuant to § 122.48a(e)(2) CBP has set forth a revised implementation schedule in order to complete necessary modifications to the approved electronic data interchange system, train CBP personnel at affected ports and complete certification testing of new participants.

The CBP-approved electronic data interchange system, through which the affected parties will be required to transmit and receive information pursuant to these regulatory provisions, is known as the Air Automated Manifest System (Air AMS). Although CBP and certain trade members presently participate in Air AMS on a voluntary basis, the final rule established procedures not currently supported by the existing system edits in Air AMS. Therefore, CBP has undertaken to modify certain critical aspects of Air AMS. CBP will introduce these changes by May 13, 2004, when a 90-day certification testing period begins for all parties who develop Air AMS communications.

Accordingly, it is necessary for CBP to revise the compliance dates for the advance electronic transmission of air cargo information as specified in the following implementation schedule. Compliance dates are staggered because they will allow CBP to deploy training resources for its personnel on a regional basis and prevent CBP from having to conduct certification testing for all new participants at one time.