SUPPORTING STATEMENT 0579-0234
IMPORTATION PROHIBITIONS BECAUSE OF BOVINE SPONGIFORM ENCEPHALOPATHY

February 2008

Introduction

This collection, 0579-0234, will now be consolidated with two other collections:

0579-0277, Bovine Spongiform Encephalopathy: Minimal Risk Regions
0579-0183, Bovine Spongiform Encephalopathy-Certificate of Origin

These collections include the same regulations and the same forms, and therefore it will be more efficient to have them consolidated into one collection.

A. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

Title 7, U.S.C. 8301, Animal Health Protection Act, authorizes the Secretary of Agriculture to promulgate regulations and take measures to prevent the introduction into the United States and the interstate dissemination within the United States of communicable diseases of livestock and poultry, and to pay claims growing out of the destruction of animals.

Disease prevention is the most effective method for maintaining a healthy animal population and enhancing Animal and Plant Health Inspection Service (APHIS) ability to compete in the world market of animal and animal product trade.

In connection with this disease prevention mission, the Veterinary Services (VS) program of APHIS enforces regulations that pertain to the importation of animals and animal products into the United States and the prevention of foreign animal disease incursions into the United States. The regulations under which APHIS conducts these disease prevention activities are contained in title 9, chapter I, subchapter D, parts 91 through 99 of the *Code of Federal Regulations*. Parts 91, 93, 94, 95, and 96 deal specifically with the importation of certain animals, birds, poultry, meat, other animal products and byproducts, hay, and straw into the United States in order to prevent the introduction of various animal diseases, including BSE.

In an effort to remove unnecessary trade restrictions while continuing to protect the United States against a BSE incursion, VS has recognized a category of regions that present a minimal risk of introducing BSE into the United States via live ruminants and ruminant products, and added Canada to this category.

APHIS is asking OMB to approve, for an additional 3 years, its use of the above information collection activities associated with its efforts to prevent a BSE incursion into the United States.

2. Indicate how, by whom, how frequently, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

Certificate of Processing for BSE-Affected Regions

Each shipment of processed animal protein and other regulated materials and products that originate from a BSE-affected region must be accompanied by an original certificate of processing that is completed and signed by a full-time, salaried veterinarian of the government agency responsible for animal health in the exporting region. The certificate must state that the material or product was derived from a single species other than a mammalian species; that all steps of processing and storing the material or product were carried out in a facility that has been used for the processing and storage of materials derived from only one non-mammalian species; that the foreign facility has never received mammalian protein from any BSE-affected regions; and that the non-mammalian materials intended for export to the United States were transported to and from the facility in a manner that would prevent commingling with prohibited products.

Import Permit Application (VS Form 16-3)

Anyone who imports these animal-derived or cell culture-derived materials or products into the United States must apply for and obtain from APHIS a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors. This permit is obtained by completing a permit application (VS 16-3). On this form the applicant provides such information as the applicant's name and address, the name and address of the individual who is exporting the material or product, the type and amount of material or product being shipped, the intended use of the material or product, and the origin and destination points of the material or product being shipped. Information contained in the VS 16-3 enables APHIS to determine whether the shipment qualifies for import into the United States.

Certificate for Certain Materials and Products from BSE-Free Regions

Each shipment of processed animal protein and other regulated materials or products that originate from a BSE-free region must be accompanied by an original certificate completed and signed by a full-time, salaried veterinarian of the government agency responsible for animal health in the exporting region. This certificate must state the species of animal from which the material or product was derived, as well as the region or regions in which any facility where the material or product was processed is located. Additionally, the certificate must state that the material or product was derived only from animals that have never resided in a BSE-affected region, and that the material or product did not originate in (and was never stored, rendered, or otherwise processed in) a BSE-affected region.

Cooperative Agreement (Signature Only)

APHIS also requires that foreign facilities that process and store regulated materials or products destined for import into the United States must enter into a cooperative agreement with APHIS that provides for annual APHIS inspections of the facility. This agreement, executed by the operator of the facility, is a signature-only document

Seals

Any animals from BSE Minimal Risk Regions entering the United States must be moved, as a group, from the exporting region to the U.S. port of entry in conveyances that have been sealed by veterinary authorities of the exporting region. These seals may only be broken by previously identified personnel once the shipment has arrived at an approved feedlot or slaughtering establishment in the United States. The use of seals ensures that these animals are moved directly to an approved feedlot or to slaughter, and are not inadvertently (or intentionally) diverted to any other destination.

Notification of Official Designee

APHIS has indicated in its regulations that, in order to designate an employee to break official seals, the accredited veterinarian must first supply the name of the designated individual to the APHIS AVIC in the State where the seals will be broken. This designation can take the form of a letter, a memorandum, an e-mail, or whatever means of communication the accredited veterinarian finds most effective. The information is only used to verify that the person who broke the seal had the proper authority to do so. The information is collected as often as new designees are deemed necessary.

Agreement with Slaughter Facilities

The management of the facility agrees that only designated individuals will break the seals, that the facility will contact an APHIS representative or USDA Food Safety and Inspection Service (FSIS) inspector immediately if the seals are not intact when the means of conveyance arrives or if the animals being transported appear to be sick or injured due to transport conditions, and that the facility will cooperate with APHIS representatives and FSIS inspectors by notifying them when sealed shipments are received.

Identification - Eartag

Bovines, sheep, and goats from BSE Minimal Risk Regions that are not destined for direct slaughter in the United States, but are instead destined for an approved feedlot prior to slaughter, must be identified with a brand as well as an ear-tag indicating that the animal has entered the United States from a recognized BSE Minimal Risk Region. This work is the responsibility of the animal owner in Canada. APHIS' regulations already require that these animals be accompanied by a health certificate, since they are moving to a feedlot in the United States and not directly to slaughter.

Ruminants Imported to Approved Feedlots (VS 17-130)

In certain instances, ruminants imported into the United States from BSE Minimal Risk Regions will be moved from the U.S. port of entry directly to an approved feedlot. These animals must be accompanied from the U.S. port of entry to the approved feedlot by VS 17-130, Ruminants Imported to Designated/Approved Feedlots.

The VS 17-130 is used exclusively to ensure that regulated animals are moved directly to an approved feedlot—and then immediately to slaughter—after entering the United States, and not to any other destination. At the time animals are loaded and ready for transport, information is obtained from the animal owner (or the owner's representative) by the port veterinarian, who completes certain sections of the VS 17-130. This information includes the name and address of the consignor and consignee, the name and address of the feedlot to which to animals are being transported, and the number and species of animals being moved.

When the animals arrive at the approved feedlot, an accredited veterinarian or other responsible individual completes the second section of the VS 17-130, certifying that all the animals have been received at the feedlot, the date they were received, and that the seals on the transporting vehicles were present and intact.

A copy of the completed VS 17-130 is returned to the port veterinarian within 14 days after the animals arrive at the feedlot. Use of the VS 17-130 ensures that regulated animals are moved directly to an approved U.S. feedlot, and are not inadvertently (or intentionally) diverted to any other destination.

Permit for the Movement of Restricted Animals (VS 1-27)

APHIS allows certain animals to be imported into the United States from BSE Minimal Risk Regions if they are moved directly from the U.S. port of entry to an approved feedlot, and then directly to a slaughtering establishment. Such animals moving from an approved feedlot to slaughter must be accompanied by a VS 1-27, Permit for Movement of Restricted Animals. These animals include bovines less than 30 months of age, and sheep or goats less than 12 months of age.

At the time animals are loaded and ready for transport, information is obtained from the animal owner (or the owner's representative) by appropriate Federal personnel, who complete certain sections of the VS 1-27. This information includes the owner's name and address, the points of origin and destination of the animals, the number of animals being moved, the purpose of the movement, and various pieces of animal identification data so that each animal in the shipment can be identified. A copy of this form then accompanies the shipment.

Upon arrival at the slaughtering establishment, appropriate slaughter plant personnel or a FSIS representative, such as a meat inspector, must verify on the VS 1-27 that all the animals arrived at their final destination and have been slaughtered. The meat inspector also uses this form to report the slaughter of the animals to VS. An accredited veterinarian or Federal official responsible for overseeing the cleaning and disinfection of the vehicles, also must complete another section to the form certifying that the vehicles have been properly cleaned and disinfected.

The use of the VS 1-27 ensures that regulated animals are moved directly to a designated feedlot and then to slaughter, and are not inadvertently (or intentionally) diverted to any other destination.

Animals Imported for Immediate Slaughter (VS 17-33)

APHIS allows certain animals to be imported into the United States from BSE Minimal Risk Regions if they are moved from the U.S. port of entry directly to a slaughtering establishment. These animals must be accompanied from the U.S. port of entry by form VS 17-33, Animals Imported for Immediate Slaughter. These animals include bovines less than 30 months of age, and sheep or goats less than 12 months of age.

Unlike the VS 17-130 or VS 1-27, the VS 17-33 is used exclusively to ensure that regulated animals are moved directly to slaughter after entering the United States, and not to any other destination (such as a designated feedlot). At the time animals are loaded and ready for transport, information is obtained from the animal owner (or the owner's representative) by appropriate Federal personnel, who complete certain sections of the VS 17-33. This information includes the owner's name and address, the points of origin and destination of the animals, the number of animals being moved, the purpose of the movement, and various piece of animal identification data so that each animal in the shipment can be identified. This form then accompanies the shipment to its destination.

When the animals arrive at the slaughtering facility, appropriate slaughter plant personnel complete the second section of the VS 17-33, certifying that all the animals have been received at the facility, and that the animals were held in pens until slaughter so as to prevent contact with animals not scheduled for immediate slaughter. This section includes the name and address of the establishment, the date the animals were slaughtered, and the signature and title of the establishment official completing the VS 17-33.

The use of the VS 17-33 ensures that regulated animals are moved directly to slaughter, and are not inadvertently (or intentionally) diverted to any other destination.

A third section of the VS 17-33 is completed by a Federal veterinarian at the slaughtering facility who signs and dates the form. In this section, the veterinarian certifies that the slaughtered animals —following a post mortem examination—did not show lesions suggestive of tuberculosis.

Certification Statement for Ruminants (Signature Only)

All bovines, sheep, and goats, entering the United States from BSE Minimal Risk Regions must be accompanied to their destination (a designated feedlot or slaughtering establishment) by a certificate, issued by a full-time salaried veterinary officer of the national government of the region of origin (or issued by a veterinarian designated or accredited by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin) certifying that certain conditions were met before the animals arrived at the U.S. port of entry.

This certificate is a pre-printed, signature-only document that lists a number of pre-import conditions that must be met, including the following: that the bovines are less than 30 months of age, that the sheep and goats are under 12 months of age, and that the bovines, sheep, and goats are not known to have been fed prohibited products during their lifetime.

This certification requirement helps to ensure that animals entering the United States from certain regions pose the most negligible risk possible of introducing BSE into the United States.

Certification Statement for Products from BSE Minimal Risk Regions (Signature Only)

APHIS allows for the entry of a variety of ruminant products from BSE Minimal Risk Regions, provided they are accompanied by a certification statement attesting to the fact that certain conditions were met prior to the entry of these products into the United States. APHIS believes that commodities meeting these conditions are unlikely to contain the BSE agent. The certification statement—which is a pre-printed, signature-only-document—must be issued by a full-time salaried veterinary officer of the national government of the region of origin (or issued by a veterinarian designated or accredited by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin).

The pre-import conditions specified on the certification statement would vary depending upon the particular commodity being imported. The commodities that may be imported under the final rule include fresh (chilled or frozen) boneless meat from bovines less than 30 months of age, fresh bovine liver, fresh bovine tongues, fresh meat of sheep or goats or other ovine or caprines, fresh carcasses of ovine and caprines, sheep casings, certain hunter-harvested wild ruminant products, and certain gelatin, tallow, and offal.

In general, the certification accompanying these commodities into the United States must state that the commodities were derived from animals that, in the case of bovines, were less than 30 months of age and, in the case of sheep or goats, less than 12 months of age; that the commodities were derived from animals not known to have been fed prohibited products during their lifetime, or that were born after the implementation of an effective feed ban, or that were members of a herd not known to be infected with or exposed to BSE; and that the commodities were derived from a slaughtering establishment that complies with a segregation process designed to prevent contamination or commingling of the product with products not eligible for import into the United States.

Designated Feedlot Agreement (Signature Only)

Feedlot owners in the United States who wish to have their feedlots designated to receive sheep and goats from Canada must sign an agreement with APHIS in which they consent to adhere to various requirements concerning the handling, confinement, and feeding of these animals. These requirements are designed to ensure that sheep and goats from Canada are handled in a manner that adequately protects the United States against a disease incursion event. This agreement is a pre-printed document that simply requires the feedlot owner’s signature.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

The import permit application (VS 16-3) may be completed and sent to APHIS electronically. http://www.aphis.usda.gov/forms/vs16-3.pdf
The certificates required by this program are provided by foreign regions, not by USDA. These certificates require an original signature from the issuing officer and must physically accompany the shipment to the United States. The VS Forms 17-130, 1-27, and 17-33 are controlled forms (forms that can be completed only by authorized personnel) and are therefore not available to the public online. Moreover, these documents require original signatures to be valid and must physically accompany the animal shipment.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purpose described in item 2 above.

The information that APHIS collects is not available from any other source. APHIS is the only Federal Agency responsible for preventing the incursion of exotic animal diseases into the United States.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

This information collection impacts mostly small businesses or other small entities.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

Collecting this information less frequently or failing to collect it would make it impossible for APHIS to effectively prevent BSE-contaminated animal products from entering the United States. A BSE outbreak in the United States could have serious economic consequences for the U.S. beef industry.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.

This information collection is conducted in a manner consistent with the guidelines established in 5 CFR 1320.5.

8. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting form, and on the data elements to be recorded, disclosed, or reported. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, soliciting comments on the information collection prior to submission to OMB.

In 2007, APHIS engaged in productive consultations with the following individuals concerning the information collection activities associated with this program:

Dr. Don Franco
National Renderers Association
801 North Fairfax Street, Suite 207
Alexandria, VA 22314
(561) 968-1575

Stephen Erica
Kissing Fresh Meats
140 East Richmond Street
Philadelphia, PA 19125
(215) 739-4242
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Shlomo Pollak
Pollak Food Distributors
1615 Collamer Avenue
East Cleveland, OH 44110
(216) 851-9911

On Thursday, September 27, 2007, pages 54890–54891, APHIS published in the Federal Register, a 60-day notice seeking public comments on APHIS' plans to request a 3-year renewal of this collection of information. No comments from the public were received.

9. Explain any decision to provide any payment or gift to respondents, other than reenumeration of contractors or grantees.

This information collection activity involves no payments or gifts to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

No additional assurance of confidentiality is provided with this information collection. However, the confidentiality of information is protected under 5 U.S.C. 552a.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

This information collection activity will ask no questions of a personal or sensitive nature.

12. Provide estimates of the hour burden of the collection of information. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.

•Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.

See APHIS Form 71. Burden estimates were developed from discussions with herd owners, U.S. importers of regulated animal products, salaried veterinarians in BSE-free regions and BSE-affected regions, foreign exporters of processed animal protein and other regulated materials and products, accredited veterinarians, feedlot managers, and slaughter facility managers.

•Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.

APHIS estimates the total annualized cost to respondents to be $5,728,500. APHIS arrived at this figure by multiplying the hours of estimated response time (229,140 hours) by the estimated average hourly wage of the above respondents ($25).

$25.03 is the hourly rate derived from the U.S. Department of Labor, Bureau of Labor Statistics May 2006 Report - National Compensation Survey: Occupational Wages in the United States, May 2006. See http://www.bls.gov/oes/current/oes_nat.htm

13. Provide estimates of the total annual cost burden to respondents or recordkeepers resulting from the collection of information (do not include the cost of any hour burden shown in items 12 and 14). The cost estimates should be split into two components: (a) a total capital and start-up cost component annualized over its expected useful life; and (b) a total operation and maintenance and purchase of services component.

There is zero annual cost burden associated with capital and start-up costs, operation and maintenance expenditures, and purchase of services.

14. Provide estimates of annualized cost to the Federal government. Provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information.

The annualized cost to the Federal Government is estimated at $10,471,455.96.
See APHIS Form 79.)

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-1.

There is an adjustment in numbers due to the consolidation of three information collections (see APHIS Forms 71 and 79) listed below:

0579-0277, Bovine Spongiform Encephalopathy: Minimal Risk Regions
0579-0183, Bovine Spongiform Encephalopathy-Certificate of Origin

The combination of the 3 BSE-related collections initially resulted in an increase in burden; however, an error on the previous 0234 collection identified 1,500 respondents with a total of 30,000 responses for a signature only burden. Consequently, this combined collection reflects the corrected figures.

16. For collections of information whose results are planned to be published, outline plans for tabulation and publication.

APHIS has no plans to publish information it collects in connection with this program.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

If forms were to be discarded because of an outdated OMB expiration date, but otherwise usable, higher printing costs would be incurred by the Federal Government. Therefore, APHIS is seeking approval to not display the OMB expiration date on its form.

18. Explain each exception to the certification statement identified in the "Certification for Paperwork Reduction Act."

APHIS can certify compliance with all provisions of the Act.

B. Collections of Information Employing Statistical Methods

There are no statistical methods associated with the information collection activities used in this program.