

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

**March 2011**

**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.**

The Animal Health Protection Act (AHPA) of 2002 is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The Secretary may also prohibit or restrict import or export of any animal or related material if necessary to prevent the spread of any livestock or poultry pest or disease.

The AHPA is contained in Title X, Subtitle E, Sections 10401-18 of P.L. 107-171, May 13, 2002, the Farm Security and Rural Investment Act of 2002.

Disease prevention is the most effective method for maintaining a healthy animal population and for enhancing the United States' ability to compete in the world market of animal and animal product trade.

The Animal and Plant Health Inspection Service (APHIS) regulates the importation of animals and animal products into the United States to guard against the introduction of animal diseases. The regulations in Title 9, *Code of Federal Regulations* (9 CFR) parts 91, 93, 94, 95, and 96 govern the importation of certain animals, birds, poultry, meat, other animal products and byproducts, hay, and straw into the United States to prevent the introduction of diseases such as bovine spongiform encephalopathy (BSE), a chronic degenerative disease that affects the central nervous system of cattle.

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 has added Canada to this category.

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

1. Import Permit Application (VS Form 16-3)
2. Certificate for Inedible Processed Animal Origin Materials and Products from BSE-Free Regions
3. Cooperative agreements with foreign facilities that process and store regulated materials and products destined for import into the United States (signature only)

4. Certification Statement for Products from BSE Minimal Risk Regions and Japan, and Inedible Processed Animal Proteins of Non-Ruminant Origin from BSE-Affected Regions (signature only)
5. Seals
6. Notification of designation of persons authorized to break seals
7. Agreements with slaughter facilities concerning the use of seals on conveyances transporting animals from BSE Minimal Risk Regions
8. Form for animals imported for immediate slaughter (VS Form 17-33)
9. Certification statement for ruminants (signature only)

**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.**

**Import Permit Application (VS Form 16-3) (Business)**

Under 9 CFR 95.4, the following are allowed into the United States under certain conditions to prevent the introduction of BSE:

- Inedible processed animal proteins, offal, tankage, fat, glands, certain tallow other than certain tallow derivatives, and serum derived from ovines or caprines (9 CFR 95.4(h)(2))
- Serum albumin, serocolostrum, amniotic liquids or extracts, and placental liquids derived from ovines or caprines (9 CFR 95.4(e))
- Bone-derived collagen and collagen products derived from bovines, ovines, or caprines (9 CFR 95.4(d))
- Insulin (9 CFR 95.4(f))
- Bovine-derived tallow (9 CFR 95.4(g))
- Tallow derivatives from bovines (oleochemicals; fatty acids, fatty alcohols, and glycerol)
- Processed animal protein, offal, tankage, processed fats and oils, unprocessed fat, glands, blood, and blood products derived from animals other than ruminants from BSE-affected regions (9 CFR 95.4(c))
- Blood and blood products derived from ruminants that have never been in a BSE-affected region (9 CFR 95.4(c))
- Transit shipment of articles listed in 9 CFR 95.4(i)

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 U.S. Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors. This permit is obtained by completing a VS Form 16-3. The form is available online and can be submitted manually or online via ePermits if the user chooses to register for eAuthentication. The form contains the applicant's name and address, the name and address of the exporter (shipper or manufacturer), the material or product type (including a list of ingredients of animal origin), the approximate amount of material or product being shipped, any treatment the material has undergone before export, and the intended use of the material or product. Information contained in the VS Form 16-3 enables APHIS to determine whether the shipment qualifies for import into the United States.

### **Certificate for Inedible Processed Animal Origin Materials and Products from BSE-Free Regions (Foreign Government)**

Under 9 CFR 95.29, each shipment to the United States of inedible processed animal protein or inedible products containing processed animal proteins that originates 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 processing the material or product 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; these regions must be listed specifically. The original signed certificate must also be presented to Customs and Border Protection agricultural inspectors when the shipment arrives in the United States.

### **Cooperative Service Agreement (Signature Only) (Business)**

APHIS requires that foreign facilities that intend to export eligible products to the United States but that also process and store materials ineligible for export (regulated materials from BSE-affected regions) must enter into a cooperative agreement with APHIS that allows APHIS to inspect the facility annually to ensure the facility takes appropriate steps to prevent cross-contamination. This agreement, executed by the operator of the facility, is a signature-only document under 9 CFR 95.4(c)(5) and (6).

### **Certification Statement for Products from BSE Minimal Risk Regions and Japan, and for Inedible Processed Animal Proteins of Non-Ruminant Origin from BSE-Affected Regions (Signature Only) (Foreign Government)**

APHIS allows the entry into the United States of the following products, if they are accompanied by an original signed certification statement that certain conditions were met:

- Ruminant products from BSE Minimal Risk Regions (9 CFR 94.19 and 95.4)
- Whole cuts of boneless beef from Japan (9 CFR 94.27)
- Inedible processed animal proteins, offal, tankage, and other processed fats and oils derived from non-ruminant species (9 CFR 95.4)
- Glands, blood, and blood products derived from ruminants from regions affected by BSE (9 CFR 95.4)

The certification statement—which is a preprinted, signature-only-document—must certify that the commodities meet the requirements stated in 9 CFR 94.5, 94.19, or 94.27. APHIS believes that commodities meeting these conditions are unlikely to contain the BSE agent. The statement must be signed by a full-time salaried veterinary officer of the agency responsible for animal health, or authorized veterinary official, from the national government of the region of origin or export.

### **Seals (Foreign Government)**

Any animal 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 slaughtering establishment in the

United States. The use of seals ensures that these animals are moved directly to slaughter, and are not inadvertently (or intentionally) diverted to any other destination.

#### **Notification of Designation of Persons Authorized to Break Seals (Business)**

APHIS requires that, to designate an employee to break official seals, the local accredited veterinarian first supply the name of the designated individual to the APHIS Area Veterinarian in Charge 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 Concerning the Use of Seals on Conveyances Transporting Animals from BSE Minimal Risk Regions (Business)**

The management of the slaughter facility receiving animals from BSE Minimal Risk Regions must agree in writing that only designated individuals will break the seals. Managers will also agree to certain notifications as set forth below.

#### **Notification Regarding Conditions of Sealed Shipments (Business)**

The management of the slaughter facility will, under the Agreement Concerning the Use of Seals on Conveyances Transporting Animals from BSE Minimal Risk Regions, notify 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.

#### **Animals Imported for Immediate Slaughter (VS Form 17-33) (Business)**

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 VS Form 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.

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. 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 such as port veterinary medical officers, who complete the first section 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 pieces 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, 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 to prevent contact with animals not scheduled for immediate slaughter. This section includes the name and address of the slaughter establishment,

the date the animals were slaughtered, and the signature and title of the slaughter establishment official completing the VS 17-33.

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 postmortem examination—did not show lesions suggestive of tuberculosis, the only reportable disease of interest that can be observed via postmortem lesions.

### **Certification Statement for Ruminants (Signature Only) (Foreign Government)**

All bovines, sheep, and goats entering the United States from BSE Minimal Risk Regions must be accompanied to the 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 preprinted, signature-only document that lists a number of pre-import conditions that must be met, including the following: 1) that the bovines are less than 30 months of age; 2) that the sheep and goats are under 12 months of age, and 3) 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.

### **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 at <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. Thus, they are not candidates for electronic submission. The VS Form 17-33 is a controlled form (which can be completed only by authorized personnel) and is therefore not available to the public online. Moreover, this form also requires an original signature to be valid and must also physically accompany the animal shipment. Thus, it is not a candidate for electronic submission.

**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.**

The information APHIS collects is the minimum needed to ensure that BSE is not introduced into the United States by importing certain animals or animal products. The effect of these information collection activities on small businesses is expected to be minimal; approximately 20 percent of the entities affected by this information collection are small businesses.

**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.**

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**

- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

No special circumstances exist that would require this collection to be conducted in a manner inconsistent with the general information collection guidelines 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 2011, APHIS engaged in productive consultations with the following individuals concerning the information collection activities associated with this program:

Dr. Sergio Nates  
National Renderers Association  
801 North Fairfax Street, Suite 207  
Alexandria, VA 22314  
703-683-2914

Stephen Erica  
Kissing Fresh Meats  
140 East Richmond Street  
Philadelphia, PA 19125  
215-739-4242  
kissenfrest@rcn.com

Shlomo Pollak  
Pollak Food Distributors  
1615 Collamer Avenue  
East Cleveland, OH 44110  
216-851-9911

The Agency's notice of information collection activity was announced in the Federal Register on Tuesday, June 16, 2011, pages 35185-35186. One comment was received from a concerned citizen about her perception of the general maltreatment of animals. It had no relevance to the purpose of the collection.

**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. Any and all information obtained in this collection shall not be disclosed except in accordance with 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 \$2,126,598. APHIS arrived at this figure by multiplying the hours of estimated response time (70,324 hours) by the estimated average hourly wage of the above respondents (\$30.24).

Herd owners - \$31.13

Importers: \$10.22

Veterinarians - \$43.32

Slaughter plant owners/managers: \$48.67

The average hourly rate for the above respondents is derived from the U.S. Department of Labor; Bureau of Labor Statistics May 2009 Report – National Occupational Employment and Wage Estimates United States. See <http://www.bls.gov/oes/#tables>.]



Foreign veterinarians: \$21.63  
 Foreign exporters: \$10.29  
 Foreign processors of restricted animal materials: \$53.89

The average hourly rate for the above respondents is derived from contacts at the Canadian Food Inspection Agency, government contacts in South Africa and Mexico, Laborsta International, and foreign industry contacts.

Further, Michigan State University, Iowa State University, and Johns Hopkins University's (which are common importers with APHIS) Web sites indicate the average hourly wage of \$22.75 for officials at museums, educational institutions, or other establishments importing restricted animal byproducts and controlled materials these are not-for-profit importers (i.e. researchers).

**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.**

No annual cost burden is associated with capital and startup 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 \$1,815,669. (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.**

ICR Summary of Burden:

|                            | Requested | Program Change Due to New Statute | Program Change Due to Agency Discretion | Change Due to Adjustment in Agency Estimate | Change Due to Potential Violation of the PRA | Previously Approved |
|----------------------------|-----------|-----------------------------------|---|---|--|---------------------|
| Annual Number of Responses | 125,289   | 0                                 | -40,170                                 | -4,341                                      | 0  | 169,800             |
| Annual Time Burden (Hr)    | 70,324    | 0                                 | -150,982                                | -7,834                                      | 0  | 229,140             |
| Annual Cost Burden (\$)    | 0         | 0                                 | 0                                       | 0   | 0  |                     |
| N                          |           |                                   |   |   |  |                     |

The number of respondents decreased from 9,800 to 5,949, the number of responses decreased from 169,800 to 125,289, and the total burden hours decreased from 229,140 to 70,324 - a drop of 158,816 hours. These decreases are due to the elimination of two forms and the designated feedlot agreement resulting in program changes of -40,170 responses and -150,982 burden hours. The adjusted decreases of -4,341 annual responses and -7,834 burden hours are because of the decreased number of respondents completing information activities for this collection in the following areas:

|  | <u>2008 Respondents</u> | <u>2011 Respondents</u> |
|--|-------------------------|-------------------------|
| Import Permit Application (VS 16-3)                        | 1,000                   | 574                     |
| Certificate for processing materials from BSE-free regions | 1,000                   | 13                      |
| VS 17-33   | 1,000                   | 35                      |

**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.**

The certificates used in this information collection are provided by foreign governments so there is no concern about expiration dates for those forms.

The VS 16-3 form is used in eight collections; therefore, it is not practical to include an OMB expiration date because of the various expiration dates for each collection. APHIS is seeking approval to not display the OMB expiration date on this form.

The expiration date will appear on the VS 17-33.

**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.

