

**SUPPORTING STATEMENT 0579-XXXX
BOVINE SPONGIFORM ENCEPHALOPATHY; IMPORTATION OF BOVINE
AND BOVINE PRODUCTS**

March 2012

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 our ability to compete in the world market of animal and animal product trade.

In order to guard against the introduction of animal diseases, the Animal and Plant Health Inspection Service (APHIS) regulates the importation of animals and animal products into the United States. The regulations in 9 CFR parts 92, 93, 94, 95, 96, and 98 govern 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 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, APHIS is proposing to base its classification of the BSE risk status of a region on the results of an evaluation of BSE risk posed by that region. For a country that has been evaluated and classified for BSE risk by the OIE (translated in English as the World Organization for Animal Health), APHIS would consider that risk evaluation and classification as a basis for APHIS' categorization of the country. For a country that is not yet classified by the OIE as to BSE risk, APHIS would, upon request by the country, conduct a risk evaluation of the country, using criteria equivalent to that used by the OIE.

APHIS is asking OMB to approve, for 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.

APHIS proposes to use the following information collection activities to prevent the incursion of BSE into the United States.

Blood and Blood Products Certification

Each shipment of blood and blood products to the United States must be accompanied by certification that the applicable requirements have been met. The shipment must be accompanied 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, representing that the veterinarian issuing the certificate was authorized to do so.

Official Identification

Before the animal's arrival at the port of entry into the United States, each bovine must be officially identified with unique individual identification that is traceable to the premises of origin of the animal. No person may alter, deface, remove, or otherwise tamper with the official identification while the animal is in the United States or moving into or through the United States, except that the identification may be removed at slaughter; and bovines must also be identified using one of the approved methods.

Request for Classification as Negligible or Controlled Risk

A region that has not received classification by OIE as either negligible risk or controlled risk and that wishes to be classified by APHIS as negligible risk or controlled risk must submit to the Administrator a request for such classification, along with documentation sufficient to allow APHIS to conduct an evaluation of whether the country or other region meets the criteria for the classification.

Retention of Classification as Either Negligible Risk or Controlled Risk

To retain such classification beyond 1 year, a region that was classified by APHIS as negligible or controlled risk after being so classified by the OIE must submit to the OIE a written request. A region that was classified as negligible risk or controlled risk by APHIS, but not by the OIE, must submit such information to APHIS.

Recordkeeping: Enforcement of a Ruminant-to-Ruminant Feed Ban

In order for APHIS to determine the eligibility of live bovines for importation from a region classified as BSE negligible risk or BSE controlled risk, it is necessary for APHIS to determine the date from which a ban on the feeding of ruminant material to ruminants has been effectively enforced. To enable APHIS to make such a determination, a BSE negligible risk or controlled risk region must maintain documentation for 3 years and must make the documentation available to APHIS.

Declaration of Importation (VS 17-29)

Upon arrival at the port, the importer completes the 17-29. 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.

Written Notification for Transit of Articles

Shippers moving the articles must notify, in writing, the inspector at both the place in the United States where the articles will arrive and the port of export before such transit.

Export Certificate from Canada

Exporters must complete a certificate that serves as the official identification for the bovines. The original hardcopy must accompany the shipment. The certificate must identify the destination of the animals, and requires signatures of the Canadian accredited veterinarian and the Canadian Food and Inspection Agency veterinarian.

Bovine Imports from Mexico

In addition to meeting all other applicable requirements for export, bovines from Mexico may only be imported in accordance with §93.436.

Bovine Export Health Certificate: Risk Classification

The bovines are accompanied 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, representing that the veterinarian issuing the certificate was authorized to do so, and the certificate states that the region of export of the bovines is classified by APHIS as a negligible risk or controlled risk region for BSE.

Commodities Export Health Certificate: Risk Classification

Commodities must be accompanied by an original certificate stating that the region of export is a BSE negligible risk, controlled risk, or undetermined risk region. The certificate must be issued by a full-time salaried veterinary officer of the national government of the region of export, or issued by a veterinarian designated by the national government of the region of export and endorsed by a full-time salaried veterinary officer of the region of export, representing that the veterinarian issuing the certificate was authorized to do so.

Export Health Certificate: Gelatin

Imported gelatin derived from bovines, ovines, caprines, horses, or swine, or from ovines or caprines from APHIS-approved regions must be accompanied by a certificate that indicates the BSE risk classification of the region of export. The certificate must be issued by a full-time salaried veterinary officer of the national government of the region

of export, or issued by a veterinarian designated by the national government of the region of export and endorsed by a full-time salaried veterinary officer of the region of export, representing that the veterinarian issuing the certificate was authorized to do so.

United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors (VS 16-3)

The following are allowed into the United States under certain conditions to prevent the introduction of BSE if the importer completes and obtains a VS form 16-3:

- Gelatin
- Meat, meat products, and other edible products derived from bovines, ovines, or caprines
- Processed animal protein, offal, tankage, fat, glands, certain tallow other than certain tallow derivatives, and serum derived from ovines or caprines
- Serum albumin, serocolostrum, amniotic liquids or extracts, and placental liquids derived from ovines or caprines
- Collagen and collagen products derived from bovines, ovines, or caprines.
- Insulin
- Bovine-derived tallow
- Tallow derivatives from bovines
- Specified risk materials
- Processed animal protein derived from animals other than ruminants from BSE negligible risk or controlled risk regions
- Transit shipment of articles

Recordkeeping: Proof of Legally Harvested Meat or Dressed Carcass

Legally harvested meat or dressed carcass must be derived from an animal that has been legally harvested in the wild, as verified by proof such as a hunting license, tag, or the equivalent that the hunter or hobbyist must show to the United States Customs and Border Protection officials. Records must be kept for 3 years.

Permit for the Import of Serum

The importation of serum from ovines or caprines that have been in any region identified by APHIS is prohibited, except that serum from ovines or caprines may be imported for scientific, educational, or research purposes if the Administrator determines that the importation can be made under conditions that will prevent the introduction of BSE into the United States. Serum from ovines and caprines imported must be accompanied by a permit issued by APHIS.

Original Certificate for Processed Animal Protein, Offal, Tankage, Fat, Glands, Certain Tallow Other Than Certain Tallow Derivatives, and Serum

Processed animal protein, offal, tankage, fat, glands, certain tallow other than tallow derivatives, and serum derived from ovines or caprines may be imported if, among other requirements, each shipment to the United States is accompanied by an original certificate signed by a full-time, salaried veterinarian of the government agency responsible for animal health in the region of export certifying that the required conditions have been met; except that, for shipments of animal feed from Canada, the

certificate may be signed by a person authorized to issue such certificates by the veterinary services of the national government of the region of origin.

Certificate to Import Meat-and-Bone Meal and Greaves Derived From Bovines

The importation of bovine-derived meat-and-bone meal, or any commodities containing such products, is prohibited unless, among other requirements, each shipment to the United States is accompanied by an original certificate signed by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated 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, representing that the veterinarian issuing the certificate was authorized to do so.

Certificate to Import Collagen Derived From Bovines

The importation of collagen derived from bovines is prohibited because of BSE, unless, among other requirements, each shipment is accompanied to the United States by a certificate that indicates the BSE risk classification of the region of export and that the conditions of this section have been met. The certificate must be issued by a full-time salaried veterinary officer of the national government of the region of export, or issued by a veterinarian designated by the national government of the region of export and endorsed by a full-time salaried veterinary officer of the region of export, representing that the veterinarian issuing the certificate was authorized to do so.

Certificate to Import Derivatives of Tallow Derived From Bovines

The importation of tallow derived from bovines is prohibited, unless, among other requirements, each shipment to the United States is accompanied by an original certificate signed by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated 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, representing that the veterinarian issuing the certificate was authorized to do so.

Certificate to Import Dicalcium Phosphate Derived From Bovines

The importation of dicalcium phosphate derived from bovines is prohibited, unless, among other requirements, each shipment to the United States is accompanied by an original certificate signed by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated 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, representing that the veterinarian issuing the certificate was authorized to do so.

Certificate to Import Processed Animal Protein Derived From Animals Other Than Ruminants From BSE Negligible Risk or Controlled Risk Regions

The importation of processed animal protein derived from animals other than ruminants from BSE negligible risk or controlled risk regions is prohibited, unless, among other requirements, each shipment to the United States is accompanied by an original certificate signed by a full-time salaried veterinary officer of the national government of the region of

origin, or issued by a veterinarian designated 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, representing that the veterinarian issuing the certificate was authorized to do so.

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. The certificates required by this program are provided by foreign regions, not by APHIS. Moreover, these documents require original signatures to be valid and must physically accompany shipments.

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 is collecting in connection with this program is the minimum needed to ensure that BSE is not introduced into the United States via the importation of certain animals or animal products. Any impact of the rule on those entities, most of which are believed to be small in size, is expected to be minimal. The majority (75% of the businesses) of these entities are small in size under the standards of the U.S. Small Business Administration.

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 animals and 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.**

There are no special circumstances associated with this information collection. 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 2012, APHIS engaged in productive consultations with the following individuals concerning the information collection activities associated with this program:

Laurie I. Bryant
Meat Importers Council of America, Inc
1901 Fort Meyer Drive
Suite 110
Arlington, VA 22209
703-522-1910

Kim Holzner
JBS Swift and Co.
1770 Promontory Circle
Greeley, Colorado 80634
970-506-7791

Steve Sanger
Orleans International
30600 Northwestern Highway
Suite 300
Farmington Hills, Michigan 48334
248-855-5556

APHIS' **proposed** rule (APHIS-2008-0010) will describe its information gathering requirements, and also provide a 60-day comment period. During this time, interested members of the public will have the opportunity to provide APHIS with their input concerning the usefulness, legitimacy, and merit of the information collection activities APHIS is proposing.

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 shippers, hunters, U.S. importers of regulated animal products, hobby farms, salaried veterinarians of foreign nations, foreign exporters of processed animal protein and other regulated materials and products, accredited veterinarians, 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.

The annualized cost to the public is estimated to be \$386,280. APHIS arrived at this figure by multiplying the hours of estimated response time (12,876 hours) by the estimated average hourly wage (\$30). The hourly wage was derived using an average of the hourly wage of U.S. importers of regulated animal products; full-time, salaried veterinary officials of exporting regions; and foreign exporters of processed animal protein and other regulated materials and products. APHIS determined the estimated hourly wage via the USDA's International Services personnel in foreign regions and from the U.S. Department of Labor, Bureau of Labor Statistics Report - May 2008 - Occupational Employment and Wages in the United States. See <http://www.bls.gov/news.release/ocwage.t03.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 \$485,694.
(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.

This is a new collection.

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.

These two forms are used in multiple information collections; therefore, it is not practical to include an OMB expiration date because of the various expiration dates for each information collection. APHIS is seeking approval to not display the OMB expiration date on these two forms.

18. Explain each exception to the certification statement identified in Item 19 "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.