SUPPORTING STATEMENT 0579-0234
BOVINE SPONGIFORM ENCEPHALOPATHY; IMPORTATION OF ANIMAL AND ANIMAL PRODUCTS

2015

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.

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.

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 uses the following information collection activities to prevent a BSE incursion in the United States.

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

Under 9 CFR 95, 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(b))
- Processed fats and oils, and derivatives of processed animal protein, tankage, and offal (95.4(b))
- Glands, unprocessed fat tissue, and blood and blood products (95.4(b))
- Derivatives of glands and blood and blood products (95.4(b))
- Serum albumin, serocolostrum, amniotic liquids or extracts, and placental liquids derived from ovines or caprines (9 CFR 95.4(e))
- Serum (9 CFR 95.4 (d))
- Insulin (9 CFR 95.4(f))
- Processed animal protein derived from ruminants (9 CFR 95.5)
- Transit shipment of articles listed in 9 CFR 95.15

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 (VS 16-6a). This permit is obtained by completing a VS Form16-3. 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 Ovine/Caprine Origin Materials and Products from a Region Not Listed in 9 CFR 95.4(a)(4) (Foreign Government)

Note: Previously called: Certificate for Inedible Processed Animal Origin Materials and Products from BSE-Free Regions

Under 9 CFR 95.40, each shipment to the United States of inedible processed animal protein or inedible products containing processed animal proteins derived from ovines and caprines that originates from a region not listed in 9 CFR 95.4(a)(4) 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 region listed in 9 CFR 95.4(a)(4), and that the material or product did not originate in or was never associated with materials originating in a region listed in 9 CFR 95.4(a)(4), and was never stored, rendered, or otherwise processed in a region listed in 9 CFR 95.4(a)(4); these regions must be listed specifically. The certificate must clearly correspond to the shipment by means of an invoice number, shipping marks, lot number, or other method of identification. 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 regions listed in 9 CFR 95.4(a)(4)) 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 Ovine/Caprine Products from Regions Listed in 9 CFR 95.4(a)(4), and for Inedible Processed Animal Proteins Derived from Ovines/Caprines(Signature Only) (Foreign Government)

Note: Previously called: 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

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:

- Ovine/Caprine products from regions listed in 9 CFR 95.4(a)(4) (9 CFR 95.4)
- Processed animal protein derived from ovines/caprines (9 CFR 95.5)

The certification statement—which is a preprinted, signature-only-document—must certify that the commodities meet the requirements stated in 9 CFR 95.4. 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)
Animals for immediate slaughter purposes from Canada (owing to its long land border with the United States, Canada is specified in the regulations relating to live animals, although it is not the only risk-designated import area) 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 pertinent APHIS Veterinary Services District official in the State where the seals will be broken. This designation can take the form of a letter, a memorandum, an email, 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 Canada (Business)
The management of the slaughter facility receiving animals from Canada 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 Canada, 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) (animal owner and slaughtering facility)
APHIS allows certain animals to be imported into the United States from Canada 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 are generally 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 sheep and goats entering the United States from Canada 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 sheep and goats must not be pregnant 2) that the sheep and goats are under 12 months of age, and 3) that the 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 Canada pose the most negligible risk possible of introducing BSE into the United States.

Ruminants Imported to Designated/Approved Feedlots (VS 17-130) (Business) (new to this information collection)
This form must be completed at the feedlot by an accredited veterinarian or other designated individual. The form must include the name, address, phone number, and ZIP code of that individual; the number of animals consigned to the feedlot; the species of animals consigned to the feedlot; the license number of the truck or trailer carrying the animals to the feedlot; the seal numbers on the truck; the names and addresses of the consignor and the consignee (including ZIP code and phone number); the name and address of the feedlot; and the name and address of the port veterinarian to whom the form is returned. The form must be returned to the port veterinarian within 14 days of consignment.

Permit for Movement of Restricted Animals (VS Form 1-27) (Business) (new to this information collection)
This permit identifies restricted animals moved for quarantine or slaughter purposes. The information is needed to identify infected or exposed animals moved to specific locations to control and prevent spread of disease. The form must include the name, address, and ZIP code of the owner or shipper and of the destination; an indication whether the animals are moved for quarantine or slaughter; the animals' disease status and the status of their area of origin; the number, species, and identification information of the animals moved; the license number of the transport vehicle; the seal number; and signatures and dates from the inspector, owner or shipper, and the recipient of the animals.

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/library/forms/pdf/VS_16_3.pdf. In addition, this form may be completed via the ePermits IT system.
http://www.aphis.usda.gov/wps/portal/aphis/resources/permits

The VS Form 17-33 is a controlled form (which can only be completed by authorized personnel) and is therefore not available to the public online. Moreover, this form must also physically accompany the animal shipment. However, authorized personnel (accredited veterinarians) may complete the form via the Veterinary Services Process Streamlining (VSPS) IT system. https://vsapps.aphis.usda.gov/vsps/public/Login.do

The VS 17-130 and VS 1-27 are electronic forms and are available through the VSPS IT system. https://vsapps.aphis.usda.gov/vsps/public/Login.do

The certificates required by this program are provided by foreign regions, not by APHS and must physically accompany the shipment to the United States. Thus, they are not candidates for electronic submission.

Some of the items in this information collection have been included in the International Trade Data System (ITDS) Automated Commercial Environment (ACE) project with Customs and Border Protection.

APHIS is also building a new IT system called eFile which will include some of the items in this information collection.

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, such BSE, 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 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. livestock 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;**

Ruminants Imported to Designated/Approved Feedlots (VS 17-130)
This form must be completed at the feedlot by an accredited veterinarian or other designated individual. This form must be returned to the port veterinarian within 14 days of consignment to notify the port veterinarian of its arrival at the feedlot.

- **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 other 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.

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

Laurie Bryant

Meat Importers Council of America
1707 L. Street, Suite 200
Washington, DC 20036
703-522-1910

Gina Tumbarello
American Feed Industry Association
2101 Wilson Blvd., Suite 916
Arlington, VA 22011
703-558-3561

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

On Tuesday, December 30, 2014, pages 78385-78396, APHIS published in the Federal Register a 60-day notice seeking public comment on this information collection. During that 60-day comment period, APHIS received two comments from interested members of the public. Both comments were rants against the U.S. government, one stated a distrust in the Mexican government, and one didn't believe BSE is a real risk to United States.

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 $7,508,225. APHIS arrived at this figure by multiplying the hours of estimated response time (231,307 hours) by the estimated average hourly wage of the above respondents ($32.46).

Herd owners: $35.20
Importers: $29.07
Veterinarians: $46.22
Slaughter plant owners/managers: $27.96

The average hourly rate for the above respondents is derived from the U.S. Department of Labor; Bureau of Labor Statistics May 2014 Report – National Occupational Employment and Wage Estimates United States. See http://www.bls.gov/oes/#tables.]

Foreign veterinarians: $24.49
Foreign exporters: $18.00
Foreign processors of restricted animal materials: $55.00

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, Salary.com indicates an average hourly wage of $23.77 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 $5,442,883. (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:

N

	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	235,752 235752	0 0	700 700	109,763 109763	0 0	125,289 125289
Annual Time Burden (Hr)	231,307 231307	0 0	134,233 134233	26,750 26750	0 0	70,324 70324
Annual Cost Burden ($)	0 0	0 0	0 0	0 0	0 0	0

Overall, the number of responses increased from 125,289 to 235,752 resulting in a total increase of 110,463 responses (program change: 700 responses and adjustment: 109,763 responses) and the burden hours increased from 70,324 to 231,307 resulting in a total increase of 160,983 hours (program change: 134,233 hours and adjustment: 26,750 hours). The program and adjustment changes are described below in more detail.

The following program changes occurred and the justifications are described below:

- The Certification Statement for Ovine/Caprine Products from Regions Listed in 9 CFR 95.4 and for Inedible Processed Animal Proteins Derived from Ovines/Caprines has both a program change and an adjustment. For the program change, APHIS increased the hours per response from .02 to 1 hour to better account for the time needed to ensure that all of the conditions listed in 9 CFR 95.4 have been met before signing any

documentation/certification. This program change didn't change the number of responses, but it is responsible for increasing the burden hours by +134,064 hours. The adjustment in burden is described below with the other adjustments for this information collection.

- APHIS is adding VS 1-27 to this information collection (program change: +600 responses and +150 burden hours). This form is already approved for use by other APHIS VS programs.

- APHIS is also adding VS 17-130 back to this information collection (program change/violation: +100 responses and +19 burden hours). APHIS discontinued OMB approval in a past submission of this information collection, because it was thought that it would no longer be used with the changing disease statuses and regulations; however, APHIS continued to use the form without OMB approval. Since ROCIS doesn't allow for individual item violations, this violation is listed as a program change, but will be reported in the ICB as a violation.

The following adjustments occurred in burden mainly because of a rise in imports from Canada and other general business/disease status fluctuations:

- Certification Statement for Ovine/Caprine Products from Regions Listed in 9 CFR 95.4 and for Inedible Processed Animal Proteins Derived from Ovines/Caprines (+81,282 responses and +1,626 burden hours).

- VS 16-3 (+154 responses and +77 burden hours).

- Certificate for Inedible Processed Ovine/Caprine Origin Materials and Products from a Region Not Listed in 9 CFR 95.4 (+31,607 responses and +31,607 burden hours).

- VS 17-33 (-3,280 responses and -6,560 burden hours).

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 expiration date will appear on VS 17-33 and VS 17-130.

VS 1-27 and VS 16-3 are used in multiple information collections; therefore, it is not practical to include an OMB expiration date because of the various expirations 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 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.