

**SUPPORTING STATEMENT
BOVINE SPONGIFORM ENCEPHALOPATHY (BSE);
IMPORTATION OF ANIMALS AND ANIMAL PRODUCTS
OMB NO. 0579-0393**

NOTE: This information collection merges two currently approved information collections, OMB control number 0579-0393, “Bovine Spongiform Encephalopathy; Importation of Bovines and Bovine Products”, and 0579-0234, “Bovine Spongiform Encephalopathy; Importation of Animals and Animal Products”. After OMB approves this combined information collection package, APHIS will retire OMB control number 0579-0234, and rename OMB control number 0579-0393 as “Bovine Spongiform Encephalopathy; Importation of Animals and Animal Products”.

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, of 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. 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 Title 9, Code of Federal Regulations, Parts 92 through 98, govern the importation of certain animals, birds, poultry, meat, other animal products and byproducts, hay, and straw. It also contains measures for preventing the introduction of various animal diseases into the United States.

Bovine spongiform encephalopathy (BSE) is a chronic degenerative disease that affects the central nervous system of cattle. Authority for preventing incursion of this disease into the United States is contained within 9 CFR 92 through 95. APHIS bases its classification of the BSE risk status of a region on the results of an evaluation of BSE risk posed by that region. It bases its classification of the BSE risk status of a country using the risk evaluation and classification provided by the OIE (World Organization for Animal Health). If an evaluation and classification is not available, APHIS will conduct the evaluation upon request using criteria equivalent to that of the OIE. The risk assessments are based on information collected using various forms and certificates generated during the international movement of cattle.

Importers wishing to bring animals and animal products into the United States must provide shipment information to the USDA APHIS for approval. The information collected is used to prevent the introduction of diseases such as BSE into the United States.

APHIS is asking OMB to approve, for an additional 3 years, its use of these information collection activities in connection with its program to identify and prevent diseases such as BSE from being imported into the United States by animals and animal products.

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 the incursion of BSE into the United States.

Blood and Blood Products Certification; (9 CFR 95.12(c)) (Business and Foreign Government)

Each shipment of blood and blood products to the United States must be accompanied by certification that the requirements in 9 CFR 95.12 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 by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the exporting region, representing that the veterinarian issuing the certificate was authorized to do so.

Official Identification; (9 CFR 93.401(c), 93.419, 93.420(b)(2), 93.427(c, d)) (Business and Foreign Government)

Before an animal's arrival at the port of entry into the United States, it must be officially identified with approved, unique individual identification that is traceable to the premises of origin of the animal, including, but not limited to, official tags, tattoos, and registered brands when accompanied by a certificate of inspection from a recognized brand inspection authority. 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.

Recordkeeping: Official Identification; (9 CFR 93.401(c), 93.419, 93.420(b)(2), 93.427(c, d)) (Business and Foreign Government) (New, PRA violation)

Records of identification must be kept for 5 years to facilitate the tracing of disease outbreaks and the movement of sick animals.

Request for Classification as Negligible or Controlled Risk; (9 CFR 92.5(a, b)) (Foreign Government)

A region that has not received classification by the OIE as either negligible risk or controlled risk, and 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 evaluate whether the country or other region meets the criteria for the classification. A list of the documentation required can be accessed on the APHIS website https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/import-live-animals/ct_import_live_animals.

Retention of Classification as Either Negligible Risk or Controlled Risk; (9 CFR 92.5(c)) (Foreign Government)

A region classified by APHIS as negligible or controlled risk after being so classified by the OIE must submit to the OIE a written request to retain such classification beyond 1 year. A region that was classified as negligible risk or controlled risk by APHIS but not by the OIE must submit such information to APHIS. The required information includes documentation of the following: (1) relevant changes in BSE legislation, compared to the previous year; (2) the importation into the region during the year of cattle, processed animal protein, and products containing processed animal protein; (3) audit findings in rendering plants and feed mills that process ruminant materials or material from mixed species that contains ruminant material, and related to the prohibition of the feeding to ruminants of processed animal protein; (4) audit findings in rendering plants and feed mills that process non-ruminant material, and related to the prohibition of the feeding to ruminants of processed animal protein; (5) infractions at the types of facilities listed above; (6) if and why, in light of the audit findings, there has been no significant

exposure of cattle to the BSE agent through consumption of processed animal protein of bovine origin; (7) surveillance efforts; (8) all clinical BSE suspects; and (9) any new cases of BSE.

Recordkeeping: Enforcement of a Ruminant-to-Ruminant Feed Ban; (9 CFR 92.6) (Foreign Government)

For APHIS to determine the eligibility of live bovines for importation from a region classified as BSE negligible risk or BSE controlled risk, APHIS must 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 8 years (to conform with the time the updated feed ban codified at 21 CFR 589.2000 has been in place) and must make the documentation available to APHIS.

Declaration of Importation, (VS 17-29); (9 CFR 93.418(d), 93.420(b), 93.427 (c, d)) (Business)

The importer, or importer's designated agent, completes an original copy of the VS Form 17-29 to be presented to the Collector of Customs at a port of arrival for appropriate distribution. The applicant provides such information as the applicant's name and address, the name and address of the individual exporting the animal or animals (or embryo/germplasm), the type and number of animals being shipped, the intended use of the animals, and the origin and destination points of the material or product being shipped. The information contained in the VS Form 17-29 enables APHIS to determine if the shipment qualifies for import into the United States.

Written Notification for Transit of Articles; (9 CFR 94.27; 9 CFR 95.15) (Business)

Shippers moving the articles (i.e., meat, meat products, and other edible products derived from bovines, ovines, or caprines moving in accordance with this section) must notify the inspector at both the place in the United States where the articles will arrive and the port of export before such transit. The notification must include the (1) times and dates of arrival in the United States, (2) times and dates of exportation from the United States, (3) mode of transportation, and (4) serial numbers of the sealed containers.

Export Certificate from Canada; (9 CFR 93.418, 93.420) (Business)

Exporters must complete a certificate serving as the official identification for the animals. The original hard copy 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; (9 CFR 93.427) (Business)

In addition to meeting all other applicable requirements for export, bovines from Mexico may only be imported in accordance with 9 CFR 93.436.

Bovine Export Health Certificate: Risk Classification; (9 CFR 93.405, 93.406, 93.407, 93.420, 93.436) (Foreign Government)

Bovines entering the United States 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 exporting region. The certificate must state that the veterinarian issuing the certificate is authorized to do so, and state that the region of export of the bovines is classified by APHIS as a negligible risk where there has been no indigenous case of BSE.

For animals from a region of controlled risk for BSE, the animals must be accompanied by an original certificate issued by a full-time salaried veterinary officer of the national government of the exporting region, representing that the veterinarian issuing the certificate is authorized to do so, and the certificate attests to the BSE risk classification of the exporting region. Further, the certificate must attest that the

animals are identified with unique individual identification traceable to the premises of origin (including, but not limited to, official tags, tattoos, and registered brands when accompanied by a certificate of inspection from a recognized brand inspection authority); the animals are permanently and humanely identified before arrival at the port of entry with a distinct and legible mark identifying the exporting country; and that the animals were born after the date from which the ban on the feeding of ruminants meat-and-bone meal or greaves derived from ruminants has been effectively enforced.

Commodities Export Health Certificate: Risk Classification; (9 CFR 94.19; 94.20; 94.21) (Foreign Government)

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.

The certificates must state for regions of negligible risk: (1) the commodities were exported from a region of negligible risk for BSE; (2) if BSE has been diagnosed in one or more indigenous bovines in the region of negligible risk, the commodities were derived from bovines subject to a ban on the feeding to ruminants of meat-and-bone meal or greaves derived from ruminants; (3) the commodities were derived from bovines that passed ante-mortem and postmortem inspections.

For regions of controlled risk, the certificates must state: (1) the commodities were exported from a region of controlled risk for BSE; (2) the commodities were derived from bovines that passed ante-mortem and postmortem inspections; (3) the commodities were derived from bovines that were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or a pithing process; (4) the commodities were produced and handled in a manner that ensured that such commodities do not contain and are not contaminated with either specified risk materials (SRMs) from regions of controlled risk for BSE, or mechanically separated meat from the skull and vertebral column from bovines 30 months of age or older.

For regions of unspecified risk, the certificates must state: (1) the commodities were derived from bovines that have never been fed meat-and-bone meal or greaves derived from ruminants; (2) the commodities were derived from bovines that passed ante-mortem and postmortem inspections; (3) the commodities were derived from bovines that were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process; (4) the commodities were produced and handled in a manner that ensured that such commodities do not contain and are not contaminated with any SRMs from regions of undetermined risk for BSE, or mechanically separated meat from the skull and vertebral column from bovines over 12 months of age.

Export Health Certificate: Gelatin; (9 CFR 94.23, 94.26) (Foreign Government)

Imported gelatin derived from bovines, 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 (for bovines) or origin (for other animals), or issued by a veterinarian designated by the national government of the region of export/origin and endorsed by a full-time salaried veterinary officer of the region of export/origin, representing that the veterinarian issuing the certificate was authorized to do so.

Application for United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors (VS Form 16-3); (9 CFR 95.4) (Business) (includes burden merged from 0579-0234)

Under 9 CFR parts 94 and 95, the following are allowed into the United States under certain conditions to prevent the introduction of BSE: (1) processed animal proteins, tankage, offal, and tallow other than tallow derivatives (9 CFR 95.4(b)) (2) processed fats and oils, and derivatives of processed animal protein, tankage, and offal (9 CFR 95.4(b)) (3) glands, unprocessed fat tissue, and blood and blood products (9 CFR 95.4(b)) (4) serum albumin, serocolostrum, amniotic liquids or extracts, and placental liquids and collagen and collagen products derived from ovines or caprines (9 CFR 95.4(e)) (5) insulin (9 CFR 95.4(f)) (6) processed animal protein derived from ruminants (9 CFR 95.5) and animals other than ruminants (9 CFR 95.13 and 14) (7) transit shipment of articles listed in 9 CFR 95.15; (8) gelatin (9 CFR 94.23, 9 CFR 94.26) (10) meat, meat products, and other edible products derived from bovines, ovines, or caprines (9 CFR 18-25) (11) collagen and collagen products derived from bovines (9 CFR 95.7) (12) bovine-derived tallow (9 CFR 95.8) (13) tallow derivatives from bovines (9 CFR 95.9) (14) dicalcium phosphate derived from bovines (9 CFR 95.10); and (15) specified risk materials (9 CFR 95.11).

Anyone who imports these 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, organisms, and vectors. This permit is obtained by completing a VS Form 16-3, Application for Permit To Import or Transport Controlled Material or Organisms or Vectors. 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.

Recordkeeping: Proof of Legally Harvested Meat or Dressed Carcass; (9 CFR 94.22) (Individual)

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 U.S. Customs and Border Protection officials. APHIS asks that records be kept for 3 years.

Permit for the Import of Serum; (9 CFR 95.4(d)) (Business)

The importation of serum from ovines or caprines that have been in any region identified by APHIS as at risk for BSE 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. The permit and application process are the same as that described above for controlled materials, organisms and vectors (i.e., the VS 16-3 application and VS 16-6a permit).

Original Certificate for Processed Animal Protein, Offal, Tankage, Fat, Glands, Certain Tallow Other Than Certain Tallow Derivatives, and Serum; (9 CFR 95.4) (Foreign Government)

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 Ruminant-Derived Processed Animal Protein; (9 CFR 95.5) (Foreign Government)

(Previously titled Certificate to Import Meat-and-Bone Meal and Greaves Derived from Bovines)
The importation of ruminant-derived processed animal protein, 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 exporting region, or issued by a veterinarian designated by the national government of the exporting region and endorsed by a full-time salaried veterinary officer of the national government of the exporting region, representing that the veterinarian issuing the certificate was authorized to do so. The certificate must state the exporting region and that the requirements of 9 CFR 95.5 have been met.

Certificate to Import Collagen Derived From Bovines; (9 CFR 95.7) (Foreign Government)

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 exporting region and that the conditions of 9 CFR 95.7 have been met. The certificate must be issued by a full-time salaried veterinary officer of the national government of the exporting region, or issued by a veterinarian designated by the national government of the exporting region and endorsed by a full-time salaried veterinary officer of the exporting region, representing that the veterinarian issuing the certificate was authorized to do so.

Certificate to Import Derivatives of Tallow Derived From Bovines; (9 CFR 95.8, 95.9) (Foreign Government)

The importation of tallow derived from bovines and its derivatives 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 exporting region, or issued by a veterinarian designated by the national government of the exporting region and endorsed by a full-time salaried veterinary officer of the national government of the exporting region, representing that the veterinarian issuing the certificate was authorized to do so.

Certificate to Import Dicalcium Phosphate Derived From Bovines; (9 CFR 95.10) (Foreign Government)

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 exporting region, or issued by a veterinarian designated by the national government of the exporting region and endorsed by a full-time salaried veterinary officer of the national government of the exporting region, representing that the veterinarian issuing the certificate was authorized to do so. The certificate must indicate the BSE risk classification of the exporting region and state that the requirements of 9 CFR 95.10 have been met.

Certificate to Import Processed Animal Protein Derived From Animals Other Than Ruminants From BSE Negligible Risk or Controlled Risk Regions; (9 CFR 95.13, 95.14) (Foreign Government)

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 exporting region, or issued by a veterinarian designated by the national government of the exporting region and endorsed by a full-time salaried veterinary officer of the national government of the exporting region, representing that the veterinarian issuing the certificate was authorized to do so. The certificate must state that the processed animal protein is not of ruminant origin and that conditions of 9 CFR 95.13 and 95.14 have been met.

Certificate for Inedible Processed Ovine/Caprine Origin Materials and Products from a Region Not Listed in 9 CFR 95.4(a)(4); (9 CFR 95.40) (Foreign Government) (merged from 0579-0234)

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); (9 CFR 95.4(c)(5, 6)) (Business) (merged from 0579-0234)

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); (9 CFR 95.4) (Foreign Government) (merged from 0579-0234)

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: (1) ovine/caprine products from regions listed in 9 CFR 95.4(a)(4); (2) 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.

Health Certification and Seals; (9 CFR 93.419(d), 93.420(a)(2)) (Foreign Government) (merged from 0579-0234, previously titled "Seals")

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. Animals for immediate slaughter purposes from Canada entering the United States require an official health certificate issued by a veterinarian designated by Canadian Food Inspection Agency (CFIA) and endorsed by a veterinarian employed by CFIA attesting to the certifications and tests for import.

The official health certificate for bovines must include: (1) name and address of the importer; (2) species, breed, and number of animals to be imported; (3) purpose of the importation; (4) individual identification, which includes the official Canadian eartag number or other approved forms of individual identification, and any other identification present on the animal, including registration number and brands; (5)

description of the bovines, including age in months, sex, breed, and markings (if any), as well as region/country of origin; (6) address or other means of identifying the premises of origin and any other premises where the bovines resided immediately prior to export; (7) specific physical location of the APHIS-approved slaughtering establishment, including the applicable Food Safety and Inspection Service (FSIS) establishment number for bovines for immediate slaughter; (8) name and address of the exporter; and (9) port of embarkation in Canada, the mode of transportation, route of travel (slaughter animals), and port of entry in the United States.

The animals must be inspected and moved as a group directly from the U.S. port of entry to the APHIS-approved slaughtering establishment in conveyances that are sealed with seals of the U.S. government at the port of entry. The route of travel from the port of entry to the approved slaughtering establishment must be listed on the health certificate. The seals may be broken only at the APHIS-approved slaughtering establishment by an authorized USDA representative.

The official health certificate for sheep and goats must include: (1) name and address of the importer; (2) species, breed, number or quantity of ruminants to be imported; (3) purpose of the importation; (4) individual ruminant identification, which includes the official identification required under 9 CFR 93.419(c), and any other identification present on the animal, including registration number, if any; (5) a description of the ruminant, including age, color, and markings, if any; (6) region of origin; (7) address of or other means of identifying the premises of origin and any other premises where the ruminants resided immediately prior to export, including the State or its equivalent, the municipality or nearest city, or an equivalent method, approved by the Administrator, of identifying the location of the premises; (8) specific physical location of the destination where the ruminants are to be moved after importation; (9) name and address of the exporter; (10) port of embarkation in the foreign region; and the mode of transportation; (11) route of travel; and (12) port of entry in the United States.

Sheep and goats imported from Canada for immediate slaughter must be imported through a U.S. port of entry listed in 9 CFR 93.403(b) or as provided for in 9 CFR 93.403(f) in a means of conveyance sealed in Canada with seals of the Canadian Government, and must be moved directly as a group from the port of entry to a recognized slaughtering establishment for slaughter as a group. The sheep and goats are inspected at the port of entry and otherwise handled in accordance with 9 CFR 93.408. The seals on the means of conveyance must be broken only at the port of entry by the APHIS port veterinarian or at the recognized slaughtering establishment by an authorized USDA representative. If the seals are broken by the APHIS port veterinarian at the port of entry, the means of conveyance must be resealed with seals of the U.S. Government before being moved to the recognized slaughtering establishment. 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; (9 CFR 93.419) (Business) (merged from 0579-0234)

To designate an employee to break official seals, APHIS requires 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; (9 CFR 93.420) (Business) (merged from 0579-0234)

The management of the slaughter facility receiving animals from Canada must agree in writing that only designated individuals will break the seals.

Notification Regarding Conditions of Sealed Shipments; (9 CFR 93.420) (Business) (merged from 0579-0234)

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 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); (9 CFR 93.405, 93.419(d), 93.420(a)(3), 93.436) (Business) (merged from 0579-0234)

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 bovines or sheep and/or goats less than 12 months of age.

The VS Form 17-33 is used exclusively to ensure 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 form. 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. The 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 Form 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 form.

A third section of the VS Form 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 Sheep and Goats from Canada (Signature Only); (9 CFR 93.419, 93.436) (Foreign Government) (merged from 0579-0234 and previously titled "Certification Statement for Ruminants (Signature Only)")

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 requiring specific information (premise of origin, name and address of the importer; species, breed, number or quantity of ruminants to be imported; the purpose of the importation; and individual ruminant identification) per 9 CFR 93.405 (a)(4)). The certificate must also list a number of pre-import conditions that must be met, including: (1) the sheep and goats must not be pregnant, (2) the sheep and goats are under 12 months of age, and (3) the sheep and

goats are not known to have been fed prohibited products during their lifetime equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000.

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 Form 17-130); (9 CFR 93.419(e)(2), 93.436) (Business) (merged from 0579-0234)

VS Form 17-130 must be prepared when sheep or goats are imported from Canada for feeding at a designated feedlot. The VS Form 17-130 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.

Recordkeeping: Ruminants Imported to Designated/Approved Feedlots (VS Form 17-130); (9 CFR 93.419(e)(2), 93.436) (Business) (New, PRA violation)

VS Form 17-130 records must be kept for 5 years to facilitate the tracing of disease outbreaks and the movement of sick animals.

Permit for Movement of Restricted Animals (VS Form 1-27); (9 CFR 93.419(e)(5), 93.436) (Business) (merged from 0579-0234)

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. The form is prepared by VS personnel using information provided by importers. Copies of the forms must be kept for 5 years.

Notice of Transfer - Animal Products; (9 CFR 94.15(e)) (Business) (New, PRA violation)

APHIS generally does not require notice of arrival for animal products. However, 9 CFR 94.15(e) specifies that any meat or other animal product not otherwise eligible for entry into the United States may transit the United States for immediate export if the importer notifies the APHIS officer at the U.S. port of arrival of the transiting of such meat or other animal product prior to such transiting; such transit is limited to the maritime or airport port of arrival only, with no overland movement outside the airport terminal area or dock area of the maritime port; and the meat or other animal product is not held or stored for more than 72 hours at the maritime or airport port of arrival.

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.

VS Form 17-29, Declaration of Importation, is available in fillable PDF format at the APHIS website https://www.aphis.usda.gov/library/forms/pdf/vs17_29.pdf. The form can also be processed via the VS

Process Streamlining (VSPS) data entry system at <https://vsapps.aphis.usda.gov/vsps/public/Login.do>. Completed forms can then be submitted by fax, mail, or email, or resaved in PDF and uploaded into the U.S. Customs and Border Protection's (CBPs) Automated Commercial Environment (ACE) Secure Data Portal. APHIS is involved with the Government-wide utilization of the International Trade Data System (ITDS) via ACE to improve business operations and further Agency missions. This allows respondents to submit the data required by CBP and its Partner Government Agencies (PGAs), such as APHIS, through a Single Window concept.

VS Form 16-3, Application for Permit To Import or Transport Controlled Material or Organisms, is available in fillable PDF format at https://www.aphis.usda.gov/library/forms/pdf/VS_16_3.pdf. Users may also use ePermits (https://www.aphis.usda.gov/aphis/resources/permits/ct_learn_epermits).

VS Form 17-33, Animals Imported for Immediate Slaughter, is a controlled form and not available to the public. Authorized personnel (accredited veterinarians) may complete the form online via the Veterinary Services Process Streamlining (VSPS) IT system at <https://vsapps.aphis.usda.gov/vsps/public/Login.do>.

VS Form 17-130, Ruminants Imported to Designated/Approved Feedlots, and VS Form 1-27, Permit for Movement of Restricted Animals, are available electronically through the APHIS VSPS application at <https://vsapps.aphis.usda.gov/vsps/public/Login.do>.

The following activities may be prepared and submitted to APHIS via email: Request for Classification as Negligible Risk or Controlled Risk, Written Notification for Transit of Articles, Notification of Designation of Persons Authorized to Break Seals, Notification Regarding Conditions of Sealed Shipments, and Notice of Transfer - Animal Products.

Five burdens are prepared as memoranda and mailed to APHIS. They are Agreement with Slaughter Facilities Concerning the Use of Seals on Conveyances Transporting Animals from Canada, Certification Statement for Ovine/Caprine Products...and for Inedible Processed Animal Proteins Derived from Ovines/Caprines, Cooperative Service Agreement, Permit for the Import of Serum, and Retention of Classification as Either Negligible or Controlled Risk. Each of these burdens require original signatures on the documents.

For the recordkeeping burdens, methods for storing records are at the discretion of record keepers. The requirement is for information in the records to be available to APHIS if and when requested. The many certificates required by this program that are provided by foreign governments are unique to the region of origin and cannot be managed by APHIS. Moreover, these documents require original signatures and seals to be valid.

Animal identifications such as tattoos and tags are permanent and become part of the animals to which they are attached.

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.

About 70 percent of the business respondents are small businesses. The information collected for this program is the minimum required by the USDA, and the effects of these information collection activities on a substantial amount of the small businesses and other respondents is expected to be minimal.

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, and to track movement of any imported BSE-contaminated animals or products within the United States post-arrival. A BSE outbreak in the United States could have serious economic consequences for the U.S. livestock industry if not identified and mitigated early.

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)

Prepared 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 report the animals' 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 3 years;

Recordkeeping: Official Identification, Recordkeeping: Ruminants Imported to Designated/Approved Feedlots (VS 17-130), and Permits for Movement of Restricted Animals (VS 1-27)

The BSE disease may incubate for up to 5 years. Animal identification records must be kept for this long to facilitate the tracing of disease outbreaks and the movement of sick animals.

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

The request to keep records for enforcement of the feed ban is set at 8 years to correspond with the length of the ban.

- 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 information 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 consulted with the following individuals concerning this information collection:

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

Jamie Cayo
c/o Georgina Steves, CRV USA Holdings Inc.
2423 American Lane
Madison, WI 53704
jamie.cayo@crv4all.us
608-441-3202

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

On Friday, April 28, 2017, APHIS published in the Federal Register on pages 19652 and 19653 a 60-day notice seeking public comments on its 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 remuneration 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, herd owners (including 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 \$8,611,131.60. APHIS arrived at this figure by multiplying the hours of estimated response time (275,821 hours) by the estimated average hourly wage (\$31.22).

The estimated average hourly wage was derived using an average of the hourly wage of herd owners, \$33.60; importers, \$32.11; veterinarians, \$47.59; slaughter plant owners/ managers, \$28.81; foreign veterinarians, \$32.04; foreign exporters, \$18.00; educators and researchers, \$24.58; and foreign processors of restricted animal materials, \$33.00. APHIS determined the estimated hourly wages using information from the USDA's International Services personnel in foreign regions, the U.S. Department of Labor website https://www.bls.gov/oes/current/oes_stru.htm, foreign veterinarian information found at www.healthassistancepartnership.org/veterinarian-salary/, and Salary.com.

13. Provide estimates of the total annual cost burden to respondents or record-keepers 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.

See APHIS Form 79. The estimated annualized cost to the Federal Government is \$9,717,521.

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

	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	529,391	0	321,260	175,480	0	32,651
Annual Time Burden (Hours)	275,821	0	225,118	37,827	0	12,876

In this renewal, the number of respondents increased from 784 to 2,225. The number of annual responses increased from 32,651 to 529,391 (for a net change of +496,740 responses), and the total burden hours increased from 12,876 to 275,821 (for a net change of +262,945 hours).

The merger of 0579-0234 into this information collection added the burdens Certificate for Inedible Processed Ovine/Caprine Origin Materials and Products, Cooperative Service Agreement, Certification Statement for Ovine/Caprine Origin Materials and Products, Health Certification and Seals, Notification of Designation of Persons Authorized to Break Seals, Agreement with Slaughter Facilities Concerning the Use of Seals on Conveyances Transporting Animals from Canada, Notification Regarding Conditions of Sealed Shipments, Animals Imported for Immediate Slaughter, Certification Statement for Sheep and Goats from Canada, Ruminants Imported to Designated/Approved Feedlots, Recordkeeping for Ruminants Imported to Designated/Approved Feedlots, and Permit for Movement of Restricted Animal.

Three activities were changed, adjusting the type of respondent and burden estimates. The Blood and Blood Products Certification burden now has foreign government and newly added business respondents, as well as adjusted burden estimates. The respondent for Official Identifications was changed from individual to foreign government and the burden estimates adjusted. The respondent for Recordkeeping for Proof of Legally Harvested Meat or Dressed Carcasses was changed from business to individual and burden estimates adjusted.

Three activities were were inadvertently omitted in the previous submission and were added as violations of the Paperwork Reduction Act. They include recordkeeping requirements related to the Official Identification burdens, and another related to Ruminants Imported to Designated/Approved Feedlots

burden. The third burden is new. Titled “Notice of Transfer - Animal Products”, it is applicable to businesses and adds one response and one hour of burden.

All of these changes are summarized in the tables below. Under the respondent type (RESP) column, FG = foreign government, B = business, I = individual. Under the Type of Change column, PROG - change indicates program change due to agency discretion, PROG - new indicates a new burden, PROG - merger indicates a new burden merged from 0579-0234, and PROG - adjust indicates a program adjustment due to agency discretion. ADJUST - estimate indicates a change due to adjustment in the Agency estimate.

CHANGES IN RESPONSES

<u>REGS</u>	<u>REASON</u>	<u>RESP</u>	<u>PREVIOUS RESPONSES</u>	<u>NEW RESPONSES</u>	<u>DIFFERENCE</u>	<u>TYPE OF CHANGE</u>
95.12c	Blood / Blood Products	B	0	280	280	PROG - change
93.401 et al	Official Identification	FG	0	100	100	PROG - change
93.401 et al	Official Identification	I	20	0	(20)	PROG - change
93.401 et al	Record: Official Identif	B	0	105	105	PROG - new
93.401 et al	Record: Official Identif	FG	0	10	10	PROG - new
95.4	VS 16-3	B	200	800	600	PROG - merger, adjust
94.22	Record: Legally Harvest	B	150	0	(150)	PROG - change
94.22	Record: Legally Harvest	I	0	150	150	PROG - change
95.4	Certificate for Inedible	FG	0	69,350	69,350	PROG - merger, adjust
95.4	Coop Service Agreement	B	0	1	1	PROG - merger
95.4	Cert Statement for Ovine/	FG	0	69,350	69,350	PROG - merger, adjust
93.41	Health Certification / Seals	FG	0	60,000	60,000	PROG - merger
93.419	Notify Designated Persons	B	0	5,400	5,400	PROG - merger
93.420	Agree w/ Slaughter Facili	B	0	1	1	PROG - merger
93.420	Notify Regarding Sealed	B	0	1	1	PROG - merger
93.405 et al	VS 17-33	B	0	7,680	7,680	PROG - merger, adjust
93.419 et al	Cert Statement for Sheep	FG	0	1	1	PROG - merger
93.419 et al	VS 17-130	B	0	107,760	107,760	PROG - merger, adjust
93.419 et al	Record: Ruminant Import	B	0	40	40	PROG - new
93.419 et al	VS 1-27	B	0	600	600	PROG - merger
94.15	Notice of Transfer	B	0	1	1	PROG - new
Sub-Total			370	321,630	321,260	
95.12	Blood / Blood Products	FG	280	250	(30)	ADJUST - estimate
93.418 et al	VS 17-29	B	10,000	69,350	59,350	ADJUST - estimate
94.27 et al	Written Notice for Transfer	B	400	115,440	115,040	ADJUST - estimate
93.418 et al	Export Cert from Canada	B	10,000	20,000	10,000	ADJUST - estimate
93.427	Bovine Imports from Mexic	B	10,000	1,200	(8,800)	ADJUST - estimate
93.405 et al	Bovine Export Health Cert	FG	200	120	(80)	ADJUST - estimate
Sub-Total			30,880	206,360	175,480	
Total Responses			+ 31,250	+ 527,990	+ 496,740	

CHANGES IN HOURS

<u>REGS</u>	<u>REASON</u>	<u>RESP</u>	<u>PREVIOUS BURDEN</u>	<u>NEW BURDEN</u>	<u>DIFFERENCE</u>	<u>TYPE OF CHANGE</u>
95.12c	Blood / Blood Products	B	0	140	140	PROG - change
93.401 et al	Official Identification	FG	0	200	200	PROG - change

93.401 et al	Official Identification	I	40	0	(40)	PROG - change
93.401 et al	Record: Official Identif	B	0	53	53	PROG - new
93.401 et al	Record: Official Identif	FG	0	5	5	PROG - new
95.4	VS 16-3	B	600	800	200	PROG - merger, adjust
94.22	Record: Legally Harvest	B	3	0	(3)	PROG - change
94.22	Record: Legally Harvest	I	0	24	24	PROG - change
95.4	Certificate for Inedible	FG	0	69,350	69,350	PROG - merger, adjust
95.4	Coop Service Agreement	B	0	1	1	PROG - merger
95.4	Cert Statement for Ovine/	FG	0	69,350	69,350	PROG - merger, adjust
93.41	Health Certification / Seals	FG	0	60,000	60,000	PROG - merger
93.419	Notify Designated Persons	B	0	1,350	1,350	PROG - merger
93.420	Agree w/ Slaughter Facili	B	0	1	1	PROG - merger
93.420	Notify Regarding Sealed	B	0	1	1	PROG - merger
93.405 et al	VS 17-33	B	0	3,840	3,840	PROG - merger, adjust
93.419 et al	Cert Statement for Sheep	FG	0	1	1	PROG - merger
93.419 et al	VS 17-130	B	0	20,474	20,474	PROG - merger, adjust
93.419 et al	Record: Ruminant Import	B	0	20	20	PROG - new
93.419 et al	VS 1-27	B	0	150	150	PROG - merger
94.15	Notice of Transfer	B	0	1	1	PROG - new
Sub-Total			643	225,761	225,118	
95.12	Blood / Blood Products	FG	140	125	(15)	ADJUST - estimate
93.418 et al	VS 17-29	B	3,300	22,886	19,556	ADJUST - estimate
94.27 et al	Written Notice for Transfer	B	200	18,470	18,270	ADJUST - estimate
93.418 et al	Export Cert from Canada	B	3,330	6,600	3,270	ADJUST - estimate
93.427	Bovine Imports from Mexic	B	3,330	396	(2,934)	ADJUST - estimate
93.405 et al	Bovine Export Health Cert	FG	800	480	(320)	ADJUST - estimate
Sub-Total			11,100	48,957	37,827	
Total Burden Hours			+ 11,743	+ 274,718	+ 262,945	

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 collected 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.

APHIS is seeking approval not to display the expiration date on VS Forms 1-27, 16-3, and 17-29. The three forms are used in multiple OMB-approved information collections, each with different expiration dates. It is impractical to assign a common date under these circumstances.

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.