October 2020

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

TERMS OF CLEARANCE: "Before this ICR is renewed, USDA should consider converting forms VS 1-27, VS 16-3, VS 17-29, and VS Form 17-130 to common forms." APHIS has made little progress in converting its multi-ICR agency forms to common forms. It has many forms eligible for conversion but has lacked the expertise and time to develop a process for converting and managing them effectively. The Agency anticipates making material progress on this project in 2021. VS Form 17-130 is currently used only in this active information collection request.

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* (9 CFR) parts 92 through 98, govern the importation of certain animals, birds, poultry, meat, other animal products and byproducts, hay, and straw. The regulations also contain measures for preventing the introduction of various animal diseases into the United States.

Bovine spongiform encephalopathy (BSE) is a chronic degenerative disease affecting the central nervous system of cattle, bison, and closely related bovid species. 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 animal or product information to 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:

9 CFR 95.12(c) - Blood and Blood Products Certification (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 certificate must be issued by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated 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.

9 CFR 93.401(c), 9 CFR 93.419(c), 9 CFR 93.420(b)(2), 9 CFR 93.427(c, d, e) - Official Identification; (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 traceable to the animal's 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. 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.

9 CFR 93.401(c), 9 CFR 93.419, 9 CFR 93.420(b)(2), 9 CFR 93.427(c, d, e) - Recordkeeping: Official Identification (Business and Foreign Government)
Records of identification must be kept for 5 years to facilitate the tracing of disease outbreaks and the movement of sick animals.

9 CFR 92.5(a, b) - Request for Classification as Negligible or Controlled Risk (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 here on the APHIS website.

9 CFR 92.5(c) - Retention of Classification as Either Negligible Risk or Controlled Risk (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.

9 CFR 92.6 - Recordkeeping: Enforcement of a Ruminant-to-Ruminant Feed Ban (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.

9 CFR 93.418(d), 9 CFR 93.422, 9 CFR 93.427(e) - Declaration of Importation (VS 17-29) (Business)

The importer, or importer's designated agent, completes an original copy of the VS Form 17-29 to be presented to Customs and Border Protection at a port of arrival for appropriate distribution. The applicant must provide his or her 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.

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

Shippers moving the articles (i.e., meat, meat products, and other edible products derived from bovines, ovines, or caprines moving in accordance with 9 CFR part 94) 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.

9 CFR 93.405; 9 CFR 93.418, 9 CFR 93.420 - Export Certificate from Canada (Business)

Exporters must complete a certificate confirming that the animals meet all the requirements for import set forth in 9 CFR 93.418 and 9 CFR 93.420. 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.

9 CFR 93.427 - Bovine Imports from Mexico (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.

9 CFR 93.405, 9 CFR 93.406, 9 CFR 93.407, 9 CFR 93.420, 9 CFR 93.436 - Bovine Export Health Certificate: Risk Classification (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.

9 CFR 94.19; 9 CFR 94.20; 9 CFR 94.21 - Commodities Export Health Certificate: Risk Classification (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.

9 CFR 94.23(e), 9 CFR 94.26 - Export Health Certificate: Gelatin (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 and that gelatin from bovines is processed in accordance with the requirements of 9 CFR 94.23. If the gelatin is derived from ovines or caprines, the certificate must state that the gelatin is not derived from ovines or caprines that have been in any region listed in 9 CFR 94.24(a).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.

9 CFR 95.4 - Application for United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors (VS Form 16-3) (Business)

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 94.18-25); (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).

With some exceptions (e.g, if importing under a veterinary certificate), stakeholders who import 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 (VS Form 16-6a). 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 shipper, the material or product type (including a list of ingredients of animal origin), the source animal species and the countries from which the source animals originated, 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.

9 CFR 94.22 - Recordkeeping: Proof of Legally Harvested Meat or Dressed Carcass (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.

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

The importation of serum from ovines or caprines that have been in any region identified by APHIS as affected by 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).

9 CFR 95.4 - Original Certificate for Processed Animal Protein, Offal, Tankage, Fat, Glands, Certain Tallow Other Than Certain Tallow Derivatives, and Serum (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.

9 CFR 95.5 - Certificate to Import Ruminant-Derived Processed Animal Protein (Foreign Government)

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 issue the certificate. The certificate must state the exporting region and that the requirements of 9 CFR 95.5 have been met.

9 CFR 95.7 - Certificate to Import Collagen Derived From Bovines (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 issue the certificate.

9 CFR 95.8, 9 CFR 95.9 - Certificates to Import Tallow and Derivatives of Tallow Derived From Bovines (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.

9 CFR 95.10 - Certificate to Import Dicalcium Phosphate Derived From Bovines (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.

9 CFR 95.13, 9 CFR 95.14 - Certificate to Import Processed Animal Protein Derived From Animals Other Than Ruminants From BSE Negligible Risk or Controlled Risk Regions (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 9 CFR 95.14 have been met.

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

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.

9 CFR 95.4(c)(5, 6) - 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).

9 CFR 95.4 - 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)

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); and (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.

9 CFR 93.418(d), 9 CFR 93.419(d, e), 9 CFR 93.420(a)(2) - Health Certification and Seals (Foreign Government)

APHIS has specified restrictions on live animals from Canada because of its long land border with the United States, although it is not the only risk-designated import area. Animals for immediate slaughter purposes entering the United States from Canada require an official health certificate issued by a veterinarian designated by the 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) The 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 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 (for 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) The 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.

9 CFR 93.419(e)(3) - Notification of Designation of Persons Authorized to Break Seals (Business)
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 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.

9 CFR 93.420 - 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.

9 CFR 93.420 - 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 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.

9 CFR 93.405, 9 CFR 93.419(d), 9 CFR 93.420(a)(3), 9 CFR 93.436 - Animals Imported for Immediate Slaughter (VS Form 17-33) (Business)

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.

9 CFR 93.419, 9 CFR 93.436 - Certification Statement for Sheep and Goats from Canada (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 requiring specific information (premises 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.

9 CFR 93.419(e)(2), 9 CFR 93.436- Ruminants Imported to Designated/Approved Feedlots (VS Form 17-130) (Business)

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.

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

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

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

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.

9 CFR 94.15(e) - Notice of Transfer - Animal Products (Business)

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 Government-wide use 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://epermits.aphis.usda.gov/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 Statements 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 recordkeepers' discretion. APHIS only requires the information in the records be available if and when requested.

The many certificates required by this program 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.

The information collected for this program is the minimum APHIS requires. APHIS estimates 70 percent of the business respondents are small businesses and the effects of these information collection activities on them 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. They were contacted by email and phone and we discussed how we and they obtain the necessary data and how frequently; how much data is available; the convenience and clarity of reporting formats and other collection instruments; and the clarity of, and necessity for, any recordkeeping requirements. The respondents replied they had no concerns with any of these items and had no further recommendations.

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On Wednesday, June 24, 2020, APHIS published in the Federal Register on pages 37823 and 37824 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.

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

  The total annualized cost to respondents is $14,728,114. This was computed by multiplying the estimated average hourly wage ($35.19) by the total number of burden hours (292,884) needed to complete the work, and then multiplying the result by 1.429 to capture benefit costs.

  The average hourly rates used to calculate the estimate are for herd owners, $38.43; importers, $32.42; veterinarians, $50.59; slaughter plant owners/ managers, $54.51; foreign veterinarians, $32.04; foreign exporters, $18.00; educators and researchers, $22.53; 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..

According to DOL BLS news release USDL-20-0451 released March 19, 2020, employee benefits account for 30 percent of employee costs, and wages account for the remaining 70 percent. Mathematically, total costs can be calculated as a function of wages using a multiplier of 1.429.

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 $16,768,053.

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	532,451	0		3,060	0	529,391
Annual Time Burden (Hours)	292,884	0		17,063	0	275,821

All of the changes in this request are due to estimate adjustments.

The estimated time per response for each of the two activities Request for and Retention of Classification as Either Negative or Controlled Risk were reassessed and increased from .5 hours to 40 and 10 hours respectively. The estimated time per response for the two activities Declaration of Importation and Export Certificate from Canada were also reassesed and increased from .33 hours to .5 hours each. Finally, the estimated responses per respondent for each of these activities, as well as for Animals Imported for Immediate Slaughter, increased slightly for each over the past three years.

Overall, these changes resulted in an increase of 3,060 estimated annual responses and 17,063 hours of estimated burden.

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.