

SUPPORTING STATEMENT
Restricted, Prohibited, and Controlled Importation of Animal and
Poultry Products and Byproducts Into the United States
OMB No. 0579-0015

NOTE: This information collection combines OMB control number 0579-0213 (Agriculture Organisms and Vectors; Import and Transport Permits), and 0579-0015 (Restricted, Prohibited, and Controlled Importation of Animal and Poultry Products and Byproducts Into the United States). Upon approval, OMB control number 0579-0213 will be retired.

A. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The Animal Health Protection Act (AHPA) of 2002 is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The Secretary may also prohibit or restrict import or export of any animal or related material if necessary to prevent the spread of any livestock or poultry pest or disease. The AHPA is contained in Title X, Subtitle E, Sections 10401-18 of P.L. 107-171, May 13, 2002, the Farm Security and Rural Investment Act of 2002 [7 U.S.C. 8301 et seq.].

Disease prevention is the most effective method for maintaining a healthy animal population and for enhancing the Animal and Plant Health Inspection Service's (APHIS') ability to bolster the United States' capability to compete globally in animal and animal product trade. In connection with this mission, APHIS enforces regulations regarding both the importation of controlled materials and the prevention of foreign animal disease incursions into the United States. These regulations can be found at title 9, chapter I, subchapter D, parts 94, 95, 96, and 122 of the *Code of Federal Regulations* (CFR). APHIS engages in several information collection activities to prevent or control the spread of livestock diseases via the importation of restricted and controlled animal products into the United States.

APHIS is asking the Office of Management and Budget (OMB) to approve, for 3 years, its use of these information collection activities in connection with APHIS' efforts to prevent or control the spread of livestock diseases via the importation of restricted and controlled animal products into the United States.

2. Indicate how, by whom, how frequently, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

APHIS uses the following information activities to enforce regulations regarding both the importation of controlled materials and the prevention of animal disease incursions into the United States:

Certificate from Inspector Stating Conveyance Has Been Cleaned; (9 CFR 94.5(c)(2)(ii); (Foreign Government)

During pre-clearance at foreign ports of exit, garbage on or removed from a vehicle is considered regulated garbage if the vehicle has been in any port outside the United States and Canada within the previous 2 years. However, garbage on or removed from a vehicle (other than an aircraft) is exempt from APHIS restrictions if the vehicle is accompanied by a certificate from an inspector of the foreign government stating that the vehicle was cleared of all garbage, cleaned, and disinfected in the presence of said inspector. This is performed to provide USDA assurances that there will be no introduction of exotic animal and plant pests. The certificate must physically accompany the shipment.

Approved Warehouse Request and Agreement to Handle Restricted Animal Byproducts (Hunting Trophies & Museum Specimens) (VS 16-28); (9 CFR 94.6(b)(2), 9 CFR 95.17); (Business/Not For Profit)

Restricted animal products, byproducts, and controlled materials, including carcasses or parts or products of carcasses of poultry, game birds, and other birds (for both nonprofit and business uses) may be imported for consignment to any museum, educational institution, or other establishment if, among other requirements, the establishment is inspected and approved by USDA using the VS Form 16-28. The VS 16-28 serves as an inspection report to help ensure that USDA-approved establishments are handling restricted and controlled imports in compliance with APHIS regulations. The VS 16-28 is completed by a U.S. Federal animal health official who acquires this information from U.S. establishment operators.

Approved Establishment Request and Agreement to Handle Restricted Animal Byproducts (Hunting Trophies & Museum Specimens) (VS 16-29); (9 CFR 94.6(b)(2), 9 CFR 95.17); (Business)

Restricted animal products, byproducts, and controlled materials, including carcasses or parts or products of carcasses of poultry, game birds, and other birds, may be imported for consignment to any not-for-profit museum, educational institution, or other establishment if, among other requirements, the establishment officer signs the VS 16-29. The VS 16-29 gives APHIS evidence that the establishment officer has the equipment, facilities, and capabilities to store, handle, process, or disinfect such articles to prevent the introduction or dissemination of Newcastle disease (ND), foot-and-mouth disease (FMD), African swine fever (ASF), highly pathogenic avian influenza (HPAI), classical swine fever (CSF), and rinderpest into the United States. The form also shows, by completion and endorsement of the form by APHIS officials, that APHIS has approved the establishment.

Application for Permit to Import or Transport Controlled Material or Organisms or Vectors (Controlled Bird Carcasses) (VS 16-3) (previously titled Application for Permit to Import Controlled Bird Carcasses); (9 CFR 94.6(b)(2)); (Business/Not For Profit)

Carcasses or parts or products of carcasses of poultry, game birds, and other birds from regions where ND and HPAI are considered to exist, and that do not otherwise qualify for importation, may be imported (for nonprofit and business uses) only if the importer, using the VS 16-3, applies for and is granted a permit by APHIS authorizing such importation. The products must be moved and

handled as specified on the permit. The applicant must state the mode of transportation; any U.S. ports of entry; the name, organization, complete address, and telephone/fax number of both the shipper and receiver; fully describe the material to be imported and the expected use; the quantity and frequency of importation; any treatment of the material before importation; and proposed disposition. This information enables APHIS to scrutinize the products and determine what, if any, disease threat they may pose to the U.S. poultry population. If APHIS decides to issue an import permit, information on the VS 16-3 also enables APHIS to determine the appropriate safeguard measures. APHIS can then provide port and border personnel with appropriate clearance instructions for the impending shipment.

Certificate of Importation of Eggs, other than Hatching Eggs; (9 CFR 94.6(c)(1)); (Foreign Government)

Eggs, other than hatching eggs, from regions where ND or HPAI is considered to exist, may be imported into the United States only in accordance with 9 CFR 94.6(c). This regulation requires that the eggs be accompanied by a certificate endorsed by the government of the region of origin, or, if from Mexico, by a certificate issued by a veterinarian accredited by the national government of Mexico and endorsed by a full-time salaried veterinary officer of the national government of Mexico. The endorsement indicates that the veterinarian was authorized to issue the certificate.

The salaried veterinary officer of the national government of the region of origin must identify on the certificate the flock of origin, the region of origin, the port of embarkation, the port of arrival, the name and address of the exporter and importer, the total number of eggs (and cases of eggs) shipped with the certificate, and the date the certificate was signed. The eggs qualify for importation in accordance with 9 CFR 94.6(c) if, no more than 90 days before the certificate was signed, a salaried veterinarian accredited by the national government inspected the flock of origin and found no evidence of communicable diseases of poultry; no ND or HPAI occurred on the premises of origin or on adjoining premises during the 90 days before the certificate was signed; there is no evidence that the flock of origin was exposed to ND or HPAI during the 90 days before the certificate was signed; the eggs are from a flock of origin found free of ND; and egg drop syndrome (EDS) is notifiable in the region of origin and there have been no reports of EDS in the flocks of origin of the eggs, or within a 50-kilometer radius of the flock of origin, for the 90 days before issuance of the certificate. The eggs must be washed and sanitized before import and the certificate must so state. The certificate must physically accompany the shipment.

Application for Permit to Import or Transport Controlled Material or Organisms or Vectors (Eggs) (VS 16-3); (9 CFR 94.6(c)(1), (3), (4)); (Business/Not For Profit)

Eggs, other than hatching eggs, from regions where ND or HPAI is considered to exist, may be imported into the United States if they are to be used by not-for-profit entities for scientific, educational, or research purposes, or if they have been cooked or processed, and if APHIS has determined that the eggs can be imported under conditions that will prevent the introduction of ND or HPAI into the United States. Importers must obtain an APHIS-issued import permit before importation by completing the permit application and submitting it to APHIS in writing or electronically. The eggs must be moved and handled as specified on the permit. The applicant must state the mode of transportation; any U.S. ports of entry; the name, organization, complete address, and telephone or fax number of both the shipper and receiver; fully describe the material to be imported and the expected use; the quantity and frequency of importation; any treatment of the material before importation; and proposed disposition.

Marking Requirements (for Eggs from Regions with ND or HPAI); (9 CFR 94.6(c)(1)(i)); (Foreign Government)

Eggs, other than hatching eggs from regions where ND or HPAI is considered to exist, may be imported into the United States only if they are in cases marked by an official of the government of the region of origin with the identity of the flock of origin.

Government Seals; (9 CFR 94.6(c)(1)(1)); (Foreign Government)

Before leaving the premises of origin, the cases in which the eggs are packed must be sealed with the seal of the national government by the accredited veterinarian who signed the certificate. The seal is documented on the Certificate for Importation of Eggs and requires no other paperwork.

Application for Permit to Import or Transport Controlled Material or Organisms or Vectors (Milk) (VS 16-3); (9 CFR 94.16(b)(4)); (Business/Not For Profit)

Small amounts of milk and milk products from regions where FMD has been determined to exist may under certain circumstances be imported for examination, testing, or analysis. The business or not for profit importer must be granted a permit through the VS 16-3 application after which APHIS will authorize such importation. The applicant must state the mode of transportation; any U.S. ports of entry; the name, organization, complete address, and telephone/fax number of both the shipper and receiver; fully describe the material to be imported and the expected use; the quantity and frequency of importation; any treatment of the material before importation; and proposed disposition.

Certificate of Origin for Milk and Milk Products from Regions Free of FMD (previously titled Certificate of Origin for Milk and Milk Products from Regions Free of FMD and Rinderpest); (9 CFR 94.16(d)); (Foreign Government)

Except for milk and milk products imported from Canada, milk or milk products imported from a region listed as free of FMD must be accompanied by a certificate endorsed by a full-time salaried veterinarian employed by the region of export. The certificate, which is completed by the foreign government, must state that the milk was produced and processed in a region recognized as free of FMD or that the milk product was processed in an FMD-free region from milk produced in an FMD-free region. The certificate must name the region where the milk was produced and the region where it was processed. Further, the certificate must state—except for movement that occurs under seal—that the milk or milk product has never been in any region where FMD exists.

Place Placards on Vehicles and Statements on Manifest, Bills of Lading, or Waybills; (9 CFR 95.36(a)); (Business)

Transportation companies or operators of cars, trucks, or other vehicles carrying import products or materials moving under restriction, other than those in tight cases or casks, must affix to and maintain on both sides of all such vehicles durable placards not less than 5 ½ by 6 inches in size, on which must be printed with permanent black ink and in boldface letters not less than 1 ½ inch in height, the words: “Restricted Import Product, Clean and Disinfect Car or Truck.” Each of the waybills, conductors’ manifests, memoranda, and bills of lading for such shipments must have the words: “Restricted import product, clean and disinfect car or truck,” plainly written or stamped on its face.

Certification of a National Government for Gelatin Derived from Horses, Swine, or Non-bovine Ruminants (previously titled Certification of a National Government for Gelatin from Non-Bovine Spongiform Encephalopathy (BSE) Countries or from Non-bovine Species); (9 CFR 94.26); (Foreign Government)

Gelatin derived from horses or swine, or from non-bovine ruminants, must, at the time of entry into the United States, be accompanied by an official certificate issued by the government of the region of origin. The certificate must state the species of animal from which the gelatin is derived.

Certificate Issued by a National Government for Importation of Hides and Skins; (9 CFR 95.16(a)(3)(ii)); (Foreign Government)

Governments of the regions of origin must complete a certificate bearing the seal of the proper department. The certificate ensures that abattoir hides, or skins taken from animals slaughtered under government supervision were taken from animals slaughtered in the specified abattoir and found free from anthrax and FMD. The certificate must physically accompany the shipment.

Certificate of a National Government for Import of Wool, Hair, Bristles; (9 CFR 95.18(c)); (Foreign Government)

Governments of the regions of origin must complete a certificate bearing the seal of the proper department. The certificate ensures that the described wool, hair, or bristles were taken from animals slaughtered in the specified abattoir and found free from anthrax and FMD. The certificate must physically accompany the shipment.

Certificate of a National Government for Import of Glue Stock; (9 CFR 95.20(c)); (Foreign Government)

Glue stock originating in and shipped directly from a region recognized by APHIS as free of FMD may be imported into the United States without other restrictions, if, in addition to compliance with other APHIS regulations, the government of the region of origin provides a certificate bearing the seal of the proper department and signed by an official veterinary inspector. The certificate must show that the glue stock was taken from animals slaughtered in the specified abattoir and found free from anthrax and FMD. The certificate must physically accompany the shipment.

Application for Permit to Import or Transport Controlled Material or Organisms or Vectors (Stomachs of Ruminants or Swine) (VS 16-3); (9 CFR 95.30); (Business/Not For Profit)

Importers, both nonprofits and businesses, must submit a written VS import permit application to APHIS to receive stomachs or portions of the stomachs of ruminants or swine, other than those imported for food purposes under USDA meat inspection regulations. The import permit application asks for the exporter, a description of the permitted material, the proposed use of the imported material, final disposition of the permitted material, and any treatments to the imported material that may inactivate diseases of APHIS concern. Permitted imports will be subject to any restrictions that APHIS deems necessary.

Application for Permit to Import or Transport Controlled Material or Organisms or Vectors (Animal Manure) (VS 16-3); (9 CFR 95.31); (Business/Not For Profit)

Importers, both nonprofits and businesses, must submit a written VS import permit application to APHIS to receive manure of horses, cattle, sheep, other ruminants, and swine. The import permit application asks for the exporter, a description of the permitted material, the proposed use of the imported material, final disposition of the permitted material, and any treatments to the imported material that may inactivate diseases of APHIS concern. Permitted imports will be subject to any

restrictions that APHIS deems necessary. Manure produced by animals transiting to the United States will be subject only to the USDA regulations governing the import of domestic livestock and other animals.

Report of Emergency Unloading of Restricted Import Products (previously titled Report of Telegraph Emergency Unloading of Restricted Import Products); (9 CFR 95.36(b)); (Business)

If it is necessary to unload, en route, any restricted material or products transported in a placarded car, truck, or other vehicle, the carrier must then clean and disinfect the vehicle and any part of a premises that may have had contact with the material or product during unloading or reloading. The carrier must report the unloading incident to the VS Deputy Administrator. This report must include such information as the nature of the emergency, the place where the material was unloaded, the original points of shipment and destination, the number and materials of the original vehicle, and the number and initials of the vehicle into which the material was reloaded in case the original vehicle was not used.

Certificate from a National Government for Importation of Foreign Animal Casings; (9 CFR 96.3); (Foreign Government)

No animal casings can be imported into the United States from any foreign region unless they are accompanied by a certificate completed and signed by the government of the region where the animals were slaughtered and the casings collected, or by a non-government veterinarian authorized by the national government stating that the casings meet the criteria described in the Foreign Official Certificate for Animal Casings. A certificate issued by a non-government veterinarian is valid only if the certificate is endorsed by a veterinarian salaried by the national government of the region in which the animals were slaughtered and the casings were collected. This document certifies that the animals from which casings were derived were healthy and underwent veterinary inspection. It also certifies that the casings were clean, sound, and handled in a sanitary manner, and describes the kind of casings, their weight, and their packaging. The certificate must physically accompany the shipment.

Compliance Agreement (Handling/Disposing of Regulated Garbage) (PPQ Form 519); (9 CFR 94.5(e)); (Business)

Any business engaged in handling or disposing of regulated garbage must first enter into a compliance agreement stating that the person agrees to comply with all APHIS regulations regarding this activity. Specifically, the business agrees to:

- Allow inspectors access to all records maintained by the person regarding handling or disposal of garbage, and to all areas where handling or disposal of garbage occurs.
- If the garbage is regulated under 9 CFR 94.5(c) (garbage generated onboard a conveyance), remove garbage from a means of conveyance only in tight, covered, leakproof receptacles.
- If the garbage is regulated under 9 CFR 94.5(d) (garbage generated in Hawaii), transport garbage interstate in sealed, leakproof packaging approved by the Administrator.
- Move the garbage only to a facility approved by the Administrator.
- At the approved facility, dispose of the garbage in a manner approved by the Administrator and described in the compliance agreement.

The compliance agreement helps APHIS ensure that regulated garbage is handled and disposed of in such a way as to prevent the dissemination of livestock or poultry diseases into or within the

United States. Although APHIS requires the compliance agreement to be completed, the Agency does not complete, review, or receive these documents; Department of Homeland Security's Customs and Border Patrol receives them.

Appeal of Denial or Cancellation of Compliance Agreement or Request for a Hearing;
(9 CFR 94.5(e)(4)); (Business)

APHIS may initiate denial or cancellation of a compliance agreement at any time if APHIS determines the requirements set forth in the agreement are not being met. The owner or operator of the facility whose agreement has been canceled may appeal APHIS' decision, in writing, within 10 days of receiving written notification of the cancellation. The appeal must state all the facts and reasons on which the person relies to show that the compliance agreement was wrongfully canceled.

Application for Permit to Import or Transport Controlled Material or Organisms or Vectors
(Organisms and Vectors) (VS 16-3); (9 CFR part 122); (Business)

United States importers, both nonprofits and businesses, must apply in writing to APHIS for permission to import organisms or vectors into the United States, or transport organisms or vectors from one State, Territory, or the District of Columbia to another State, Territory, or the District of Columbia. The application contains the importer's name, address, telephone number, fax number, a description of the products to be imported, the quantity and frequency of importation, the proposed use of the material, a description of the applicant's facilities for handling the material, the qualifications of the technical personnel who will be working with the material, and a description of any processing the material may have undergone before entering the United States. This information enables APHIS to scrutinize the products and determine what, if any, disease threat they may pose to the U.S. livestock population. If APHIS decides to issue an import permit, information on the VS 16-3 enables officials to determine the appropriate safeguarding measures for the importation. APHIS can then provide port and border personnel with appropriate clearance instructions.

Inspection of Facilities; (9 CFR 121.18); (Business; Not-for-Profit; State)

Merged from 0579-0213.

APHIS must be allowed to inspect any site at which activities regulated under the pertinent regulations are conducted and must be allowed to inspect and copy any records relating to the activities covered by APHIS' organism and vector regulations.

Additional Information for Cell Cultures and their Products (VS Form 16-7 or equivalent);
(9 CFR 121.6; 9 CFR 112.2; 9 CFR 122.3); (Business)

Merged from 0579-0213.

This is a supplemental form to VS Form 16-3. It requests additional information concerning specific material that requires the use of cell cultures, including monoclonal antibodies, recombinant products, extracts, and viruses. This form asks for the cell line or reference number, the cell line's country of origin, the cell line's passage history or recombinant status, the type of culture media used for the cell line, the names of any animal pathogens studied in the laboratory where the cell line originated, the address of the laboratory where the material originated, and the potential use of the imported cells or products.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

The VS Form 16-3, Import Permit Application, and VS Form 16-7, Additional Information for Cell Cultures and their Products, are automated as fillable PDFs and can be downloaded from the APHIS Electronic Forms Library at https://www.aphis.usda.gov/aphis/resources/forms/ct_vs_forms. These forms can be submitted electronically to APHIS via e-File and the VS Permitting Assistant, <https://efile.aphis.usda.gov/s/vs-permitting-assistant>. E-File, which automates and reduces burden, is currently being phased in, with some applicants submitting all the VS Form 16-3 information electronically.

The VS 16-28 and VS 16-29 are associated with a VS onsite facility inspection. The facility representative and VS inspector sign the form on site at the time of the inspection. The form is subsequently submitted electronically via the Veterinary Services Processes Streamlining (VSPS) system to approving officials within VS, who may electronically sign/approve the form.

The Compliance Agreement PPQ Form 519 is available electronically on the APHIS Electronic Forms Library at https://www.aphis.usda.gov/aphis/resources/forms/ct_ppq_forms.

The Report of Emergency Unloading of Restricted Import Products could be submitted by email or fax. However, at this time, restricted commodities typically move from the port in leakproof containers, so such reporting is not anticipated.

The Certificate from Inspector Stating Conveyance is Clean must physically accompany the conveyance; therefore, it is not a candidate for electronic submission.

The other certification statements used in this program must physically accompany the shipment to the United States and must contain an original signature of the foreign government official, owner, or importer to be valid. However, APHIS fully participates in the government-wide use of the International Trade Data System (ITDS) via the Automated Commercial Environment (ACE), which allows respondents to electronically submit data on incoming shipments to U.S. Customs and Border Protection and its partner government agencies (PGAs), such as APHIS, through a single window concept. Respondents may submit owner/importer statements and shipping documents electronically via the Document Image System (DIS) in ACE in lieu of paper documents. In addition, APHIS has permitted respondents to electronically submit copies of government certificates via the DIS during the COVID-19 outbreak, due to logistical difficulties and safety concerns associated with hard copy deliveries. The other certification statements are:

- Certification of a National Government for Gelatin from Non-BSE Countries or from Non-Bovine Species
- Certificate of a National Government for Importation of Hides and Skins
- Certificate of a National Government for Import of Wool, Hair, or Bristles
- Certificate of a National Government for Import of Glue Stock
- Certificate of a National Government for Importation of Foreign Animal Casings
- Certificate of Importation of Eggs, other than Hatching Eggs

The information technology system called Certification, Accreditation, Registration, Permitting, and other Licensing (CARPOL) was not developed and has been removed from this renewal.

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 in connection with this effort is not available from any other source. APHIS is the only Federal Agency responsible for preventing diseases of animal, poultry products, and byproducts from entering the United States.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

APHIS estimates that no business respondents are small entities involved with this information collection. The information APHIS collects is the absolute minimum needed to protect the United States from the introduction and spread of animal diseases by importing foreign animal and poultry byproducts, organisms, and vectors.

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.

If this information were collected less frequently or not collected, the United States would be at increased risk for the introduction of FMD, ASF, CSF, swine vesicular disease (SVD), ND, or HPAI. This would cause serious economic consequences to several United States livestock industries and potentially serious health consequences for United States livestock.

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;**

Appeal of Denial or Cancellation of Compliance Agreement or Request for a Hearing:
The owner or operator of the facility whose agreement has been canceled may appeal APHIS' decision, in writing, within 10 days of receiving written notification of the cancellation.

- **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;**

- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

No other special circumstances exist that would require this collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.

8. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting form, and on the data elements to be recorded, disclosed, or reported. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, soliciting comments on the information collection prior to submission to OMB.

APHIS engaged in productive consultations with the following individuals concerning the information collection activities associated with this program. We discussed with them 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. The respondents stated via email or phone that they had no concerns with any of these items and had no further recommendations.

Laura Bies
 Executive Director
 The Ornithological Council
 5107 Sentinel Drive
 Bethesda, MD 20816
 Phone: (202) 905-9141
 Email: laurabiesoc@gmail.com

Michael Dugandzic
 Europa Market Co. Inc.
 8100 Water Street
 Saint Louis, MO 63111
 Phone: (314) 631-7288
 Fax: (314) 631-7149
 Email: mdugandzic@europa-market.com

Michelle Singer
Lotus Bakeries North America Inc.
1000 Sansome Street, Suite 220
San Francisco, CA 94111
Phone: (415) 956-8956
Fax: (415) 956-4922
Email: apNAM@lotusbakeries.com

On Friday, April 29, 2022, APHIS published in the Federal Register (87 FR 25440), a 60-day notice seeking public comments on its plans to request a 3-year approval of this collection of information. One general comment was received regarding use of plant-based diets versus animal material and was beyond the scope of the information collection.

9. Explain any decision to provide any payment or gift to respondents, other than reenumeration of contractors or grantees.

This information collection activity involves no payments or gifts to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

No additional assurance of confidentiality is provided with this information collection. Any and all information obtained in this collection shall not be disclosed except in accordance with 5 U.S.C. 552a.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

This information collection activity will ask no questions of a personal or sensitive nature.

12. Provide estimates of the hour burden of the collection of information. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.**

See APHIS Form 71.

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

APHIS estimates the total annualized cost to the respondents for this collection to be \$4,475,811. APHIS arrived at this figure by multiplying the estimated total burden hours (113,354 hours) by the estimated average hourly wage of the below respondents (\$27.25) and then multiplying the result by 1.449 to capture benefit costs.

The average hourly rates used to calculate the estimates include the following:

SOCC Code	Average Salary	Occupation Description
None	\$14.82	Mexican government officials estimate the average hourly wage for foreign government officials, animal health officials, and inspectors.
None	\$25.86	This figure was arrived at by the average of the following contacts: The Canadian Food Inspection Agency (\$57.86); the APHIS contact in South Africa (\$4.38); and the Mexican government (\$12.39).
None	\$64.45	Industry contacts provided the hourly wage of managers of foreign facilities that process restricted animal materials.
45-1011	\$26.18	Importers and individuals transiting various commodities not eligible for importation into the United States (first-line supervisors of farming, fishing, and forestry workers occupations).
None	\$12.30	Laborsta International Web site indicates the average hourly wage for exporters for agriculture, meat, and foods, adjusted for inflation.
53-0000	\$19.88	Transportation companies, carriers, or operators of cars, trucks, or other vehicles (transportation and material moving occupations)
	\$27.24	Average Hourly Salary

The hourly rates for respondents of foreign countries were derived from Laborsta International Web site and consultations with foreign industry contacts. The rates for U.S. respondents were obtained from the U.S. Bureau of Labor Statistics website https://www.bls.gov/oes/current/oes_stru.htm and the average salary was calculated using specific occupations identified by their SOCC codes. In the 2019 reinstatement, the fringe benefit amount was added to the hourly wage (\$21.49) before multiplying it by the total numbers. Since then, APHIS has standardized this calculation and now applies a benefit cost factor to the total wages after it is calculated.

According to DOL BLS news release USDL-22-0469 dated March 18, 2022 (see <https://www.bls.gov/news.release/pdf/ecec.pdf>), benefits account for 31 percent of employee costs, and wages account for the remaining 69 percent. Mathematically, total costs can be calculated as a function of wages, resulting in a multiplier of 1.449.

13. Provide estimates of the total annual cost burden to respondents or recordkeepers resulting from the collection of information (do not include the cost of any hour burden shown in items 12 and 14). The cost estimates should be split into two components: (a) a total capital and start-up cost component annualized over its expected useful life; and (b) a total operation and maintenance and purchase of services component.

No annual cost burden is associated with capital and startup costs, operation and maintenance expenditures, and purchase of services.

14. Provide estimates of annualized cost to the Federal government. Provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information.

See APHIS 79. The annualized cost to the Federal government is estimated at \$8,993,561.

Prior to 2021, the certificates collected were in paper format and were not logged into a system which may have led to an overestimation of the responses for certificates. As of March 2021, the Agency requires importers to input the required import data and certificates into the ACE system which has attributed to a more accurate estimate of certificates, resulting in a decrease in the number of responses to the certificate of origin for milk and milk products from regions free of FMD.

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	64,405	0	5,956	-157,950	0	216,399
Annual Time Burden (Hr)	113,354	0	6,271	-320,651	0	427,734

This request for renewal includes the merger of 0579-0213.

This request for renewal is for 64,405 estimated responses and 113,354 estimated burden hours, reflecting decreases of 151,994 responses and 314,380 burden hours from the previous request. The number of respondents is 30,902, an increase of 27,465 from the previous renewal.

The increase in respondents is largely due to a sharp increase in the number of applicants for the certificate of origin for milk and milk products from regions free of FMD, which rose from 42 to 25,660. The certificate from a national government for importation of foreign animal casings increased from 972 to 17,322. The other changes are attributed to APHIS using an improved system for tracking actions.

The decrease in responses is attributed to the certificate of origin for milk and milk products from regions free of FMD, which changed from 203,952 to 25,660. Prior to 2021, the certificates collected were in paper format and were not logged into a system which may have led to an overestimation of the responses for certificates. As of March 2021, the Agency requires importers to input the required import data and certificates into the ACE system which has attributed to a more accurate estimate of certificates.

A compilation of changes are shown in the tables below.

CHANGES IN RESPONSES

FG = Foreign Government; B = Business; NP = Not for Profit; Trib = Tribal

9 CFR	ACTIVITY	RESPOND. TYPE	CURRENT BURDEN	PREVIOUS BURDEN	CHANGE	TYPE OF CHANGE
94.5(c)(2)(ii)	Cert Stating Conveyance Cleaned	FG	210	309	-99	Estimate
94.6(b)(2); 95.17	Approved Warehouse Request	B	4	318	-314	Estimate
94.6(b)(2); 95.17	Approved Establishment Request	B	67	102	-35	Estimate
94.6(b)(2)	Application to Import Controlled Bird Carcasses	NP	2,126	1,538	+588	Estimate
94.6(c)(1)	Cert Import Eggs (not Hatching)	FG	1,993	2	+1,991	Discretionary
94.6(c)(3)	App Import Eggs Specific Cases for Research	B	0	46	-46	Discontinued
94.6(c)(1), (3), (4)	App Import Eggs (Controlled Materials)	NP	1,993	274	+1,719	Estimate
94.6(c)(1)(i)	Marking Requirements/Eggs	FG	1	1	0	No change
94.6(c)(1)(i)	Seals	FG	1	1	0	No change
94.6(b)(4)	App Import Milk (Controlled Materials)	NP	2,103	68	+2,035	Estimate
94.16(d)	Cert Origin Milk/Milk Products	FG	25,660	203,952	-178,292	Estimate
95.36(a)	Place Placards/Statements	B	1	160	-159	Estimate
94.26	Cert Gelatin Derived from Horses/Swine/Non-Bovines	FG	5,486	1,104	+4,382	Estimate
95.16(a)(3)(ii)	Cert Import Hides/Skins	FG	14	4,862	-4,848	Estimate
95.18(c)	Cert Import Wool/Hair/Bristles	FG	1,054	867	+187	Estimate
95.20	Cert Import Glue Stock	FG	2,355	1,010	+1,345	Estimate
95.30	App Import Stomachs of Ruminants/Swine	B	568	11	+557	Estimate
95.31	App Import Animal Manure	B	62	22	+40	Estimate
95.36(b)	Report Emergency Unloading of Restricted Import Products	B	4	4	0	No change
96.3	Cert Import Casings	FG	17,322	972	+16,350	Estimate
94.5(e)	Compliance Agreement/Garbage	B	84	741	-657	Estimate
94.5(e)(4)	Appeal Denial/Cancellation of Compliance Agreement	B	14	1	+13	Estimate
121.6; 122.2/3	App Import Organisms/Vectors	B	3,075	35	+3,040	Estimate
121.18	Inspection of Facilities	B	60	0	60	Discretionary (merge)
121.18	Inspection of Facilities	Trib.	15	0	15	Discretionary (merge)
121.18	Inspection of Facilities	State	64	0	64	Discretionary (merge)
121.6; 122.2/3	Add Info Cell Cultures/Products	B	69	0	+69	Discretionary (merge)
	Totals		64,405	216,399	-151,994	

CHANGES IN BURDEN HOURS

FG = Foreign Government; B = Business; NP = Not for Profit; Trib = Tribal

9 CFR	ACTIVITY	RESPOND. TYPE	CURRENT BURDEN	PREVIOUS BURDEN	CHANGE	TYPE OF CHANGE
94.5(c)(2)(ii)	Cert Stating Conveyance Cleaned	FG	21	31	-10	Estimate
94.6(b)(2); 95.17	Approved Warehouse Request	B	4	318	-314	Estimate
94.6(b)(2); 95.17	Approved Establishment Request	B	7	10	-3	Estimate
94.6(b)(2)	Application to Import Controlled Bird Carcasses	NP	2,126	1,538	+588	Estimate
94.6(c)(1)	Cert Import Eggs (not Hatching)	FG	1,993	2	+1,991	Estimate
94.6(c)(3)	App Import Eggs Specific Cases	B	0	46	-46	Discontinued
94.6(c)(1), (3), (4)	App Import Eggs (Controlled Materials)	NP	1,993	274	+1,719	Estimate
94.6(c)(1)(i)	Marking Requirements/Eggs	FG	1	1	0	No Change
94.6(c)(1)(i)	Seals	FG	1	1	0	No Change
94.6(b)(4)	App Import Milk (Controlled Materials)	NP	2,103	68	+2,035	Estimate
94.16(d)	Cert Origin Milk/Milk Products	FG	51,320	407,904	-356,584	Estimate
95.36(a)	Place Placards/Statements	B	1	16	-15	Estimate
95.36(a)	Cert Gelatin Derived from Horses/Swine/Non-Bovines	FG	5,486	1,104	+4,382	Estimate
95.16(a)(3)(ii)	Cert Import Hides/Skins	FG	28	9,724	-9,696	Estimate
95.18(c)	Cert Import Wool/Hair/Bristles	FG	2,108	1,734	+374	Estimate
95.20	Cert Import Glue Stock	FG	4,710	2,020	+2,690	Estimate
95.30	App Import Stomachs of Ruminants/Swine	B	568	11	+557	Estimate
95.31	App Import Animal Manure	B	62	22	+40	Estimate
95.36(b)	Report Emergency Unloading of Restricted Import Products	B	4	4	0	No Change
96.3	Cert Import Casings	FG	34,644	1,944	+32,700	Estimate
94.5(e)	Compliance Agreement/Garbage	B	105	926	-821	Estimate
94.5(e)(4)	Appeal Denial/Cancellation of Compliance Agreement	B	14	1	+13	Estimate
121.6; 122.2/3	App Import Organisms/Vectors	B	4,920	35	+4,885	Discretionary
121.18	Inspection of Facilities	B	480	0	480	Discretionary (merge)
121.18	Inspection of Facilities	Trib	120	0	120	Discretionary (merge)
121.18	Inspection of Facilities	State	512	0	512	Discretionary (merge)
121.6; 122.2/3	Add Info Cell Cultures/Products	B	23	0	+23	Discretionary (merge)
	Totals		113,354	427,734	-314,380	

16. For collections of information whose results are planned to be published, outline plans for tabulation and publication.

APHIS has no plans to publish information it collects in connection with this program.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

VS Forms 16-3, VS 16-7, VS 16-28, VS 16-29, and PPQ Form 519 are used in multiple information collections; each with different OMB approval expiration dates. It would not be practical to add an expiration date to the forms at this time. APHIS and OIRA are currently developing procedures for creating and maintaining a consolidated intra-Agency common form ICR. Upon the forms' inclusion in the common form ICR upon its approval, the forms will be updated with the appropriate PRA banners, ICR control numbers, and OMB approval expiration dates.

18. Explain each exception to the certification statement identified in the "Certification for Paperwork Reduction Act."

APHIS can certify compliance with all provisions under the Act.

B. Collections of Information Employing Statistical Methods

There are no statistical methods associated with the information collection activities used in this program.